

Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Environmental and Social Impact Assessment Report

January 2024

Mott MacDonald | Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project Environmental and Social Impact Assessment Report

Mott MacDonald Mesa Koz Sahrayıcedit District Atatürk Street No. 69 / 255 34734 Kadıköy Istanbul Turkey

T +90 (0) 216 766 3118 mottmac.com

Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Environmental and Social Impact Assessment Report

January 2024

Mott MacDonald T Danışmanlık Mühendislik Ltd Şti. is a member of the Mott MacDonald Group registered in England and Wales no 1110949. Registered office: Mott MacDonald House, 8-10 Sydenham Road, Croydon CR0 2EE, United Kingdom

Issue and Revision Record

Revision	Date	Originator	Checker	Approver	Description
A	19.10.2022	Elif Hot Öç Dilan Laçin Ecenur Alper Bianca Barsanoğulları Gökhan Metin Ece Kılıçözlü Sadık Avcı Kerem Ali Boyla Dr. Mecit Vural Dr. Ece Ayşe Berkay İsmail Ulusoy Ersin Ala Erdem Kesen Mahmut Tuncer Çetin Ozan Kaya Abdullah Halim Özatay Yunus Ekim Serkan Akdemir Prof. Dr. Ahmet Carhan Prof. Dr. Tamay Başağaç Gülşen Akgün İnce	P Karakaya	N Ayvaz Ozen	Environmental and Social Impact Assessment Draft Report
В	13.03.2023	B Barsanogullari E Alper	P Karakaya	N Ayvaz Ozen	Revision No. 1
С	23.10.2023	B Barsanogullari E Alper	P Karakaya	N Ayvaz Ozen	Revision No. 2
D	20.12.2023	B Barsanogullari	P Karakaya	N Ayvaz Ozen	Revision No. 3
E	19.01.2024	B Barsanogullari	P Karakaya	N Ayvaz Ozen	Revision No. 4
F	28.02.2024	B Barsanogullari	P Karakaya	N Ayvaz Ozen	Revision No. 5
G	14.06.2024	B Barsanogullari	P Karakaya	N Ayvaz Ozen	Revision No. 6

Document reference: 425836 | 01 | G |

Information class: Standard

This Report has been prepared solely for use by the party which commissioned it (the 'Client') in connection with the captioned project. It should not be used for any other purpose. No person other than the Client or any party who has expressly agreed terms of reliance with us (the 'Recipient(s)') may rely on the content, information or any views expressed in the Report. This Report is confidential and contains proprietary intellectual property and we accept no duty of care, responsibility or liability to any other recipient of this Report. No representation, warranty or undertaking, express or implied, is made and no responsibility or liability is accepted by us to any party other than the Client or any Recipient(s), as to the accuracy or completeness of the information contained in this Report. For the avoidance of doubt this Report does not in any way purport to include any legal, insurance or financial advice or opinion.

We disclaim all and any liability whether arising in tort, contract or otherwise which we might otherwise have to any party other than the Client or the Recipient(s), in respect of this Report, or any information contained in it. We accept no responsibility for any error or omission in the Report which is due to an error or omission in data, information or statements supplied to us by other parties including the Client (the 'Data'). We have not independently verified the Data or otherwise examined it to determine the accuracy, completeness, sufficiency for any purpose or feasibility for any particular outcome including financial.

Forecasts presented in this document were prepared using the Data and the Report is dependent or based on the Data. Inevitably, some of the assumptions used to develop the forecasts will not be realised and unanticipated events and circumstances may occur. Consequently, we do not guarantee or warrant the conclusions contained in the Report as there are likely to be differences between the forecasts and the actual results and those differences may be material. While we consider that the information and opinions given in this Report are sound all parties must rely on their own skill and judgement when making use of it.

Information and opinions are current only as of the date of the Report and we accept no responsibility for updating such information or opinion. It should, therefore, not be assumed that any such information or opinion continues to be accurate subsequent to the date of the Report. Under no circumstances may this Report or any extract or summary thereof be used in connection with any public or private securities offering including any related memorandum or prospectus for any securities offering or stock exchange listing or announcement.

By acceptance of this Report you agree to be bound by this disclaimer. This disclaimer and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by, and construed in accordance with, the laws of England and Wales to the exclusion of all conflict of laws principles and rules. All disputes or claims arising out of or relating to this disclaimer shall be subject to the exclusive jurisdiction of the English and Welsh courts to which the parties irrevocably submit.

Contents

Abb	oreviat	ions and	l Acronyms	27
EX	ECUTI	IVE SUM	IMARY	31
1	INT	RODUCT	ΓΙΟΝ	37
	1.1	Overvie	W	37
	1.2	Purpose	e of this ESIA	38
	1.3	ESIA Pr	rocess	38
	1.4	Structur	e and Content of the ESIA	38
		1.4.1	Executive Summary	39
		1.4.2	The Main Environmental and Social Impact Assessment Report	39
		1.4.3	Environmental and Social Management Plan	40
	1.5	Stakeho	older Engagement	40
	1.6	Limitatio	ons	40
2	PRC	JECT D	ESCRIPTION	41
	2.1	Backgro	bund	41
	2.2	Project	Location	42
	2.3	Project	Overview	44
	2.4	Current	Status of the Planning, Design and Construction	46
	2.5	Analysis	s of Alternatives	46
		2.5.1	No Project Alternative	46
		2.5.2	Alternative Laboratory Project	46
		2.5.3	Alternative Project Location	47
		2.5.4	Project Technology Alternatives	51
	2.6	Project	Components	59
		2.6.1	Overview	59
		2.6.2	Administrative Building	63
		2.6.3	Research and Development (R&D) Building	63
		2.6.4	Experimental Animals Production/Test Building	64
		2.6.5	Vaccine Production and Storage Building	64
		2.6.6	Technical Building	65
		2.6.7	Waste Building	65
		2.6.8	Recreational Area and Kindergarten	66
		2.6.9	Security Building and Observation Towers	66
	2.7	Design	Concept	67
		2.7.1	Applicable Codes and Standards	67
		2.7.2	Facility and Process Design	68
		2.7.3	Animal Testing and Production	74
		2.7.4	Security	76
		2.7.5	Emergency	76
		2.7.6	BSL Certification	77

2.8	Responsibilities and Organizational Structure 84					
2.9	Project C	Construction	85			
	2.9.1	Construction Schedule	85			
	2.9.2	Traffic and Access	85			
	2.9.3	Construction Materials and Equipment	85			
	2.9.4	Employment	86			
INST	ITUTION	IAL AND REGULATORY FRAMEWORK	88			
3.1	National	Institutional Framework	88			
3.2	National	Regulatory Framework	90			
	3.2.1	National Legislative Framework	90			
	3.2.2	Applicable National Environmental, Health, Safety and Social Legis	slation 90			
	3.2.3	International Conventions Ratified by Turkiye that are Relevant to	the Project 97			
3.3	Internatio	onal Requirements	99			
3.4	3.4 Defined Gaps Between National Legislative Framework and Applicable WB ESSs103					

4	SCC		D METHODOLOGY OF THE ESIA	105
	4.1	Introduo	ction	105
	4.2	Catego	rization of the Project	105
	4.3	Scoping	g Stage	105
	4.4	Scoping	g Results	106
	4.5	Applica	ble World Bank ESSs	106
	4.6	ESIA P	rocess	107
		4.6.1	Introduction	107
		4.6.2	Area of Influence	108
		4.6.3	Baseline	108
		4.6.4	Assessment of Impacts	109
		4.6.5	Assessment of Cumulative Impacts	111
		4.6.6	Identification of Mitigation Measures	111
		4.6.7	Stakeholder Engagement	111
		4.6.8	Proposals for Monitoring	112
	4.7	ESIA T	eam	112
5	STA	KEHOLI	DER ENGAGEMENT	113
	5.1	Overvie	2W	113
	5.2	Principl	es of Consultation	113
	5.3	Consult	tation Requirements	113
		5.3.1	Overview	113
		5.3.2	National Consultation Requirements	114
		5.3.3	World Bank Consultation Requirements	114
		5.3.4	Public Consultation Requirements under the EU	115

	0.011		110
5.4	Stakeholder Identification 1		
	5.4.1	Overview	116

	5.4.2	Area of Influence and Selection of Local Districts/Neighbourhoo	ods for
		Consultation	116
	5.4.3	Project Stakeholders	118
5.5	ESIA C	onsultation Activities and Outcomes	123
	5.5.1	Stakeholder Engagement Activities Conducted Prior to ESIA	123
	5.5.2	Scoping Site Visit and Consultation (December 2021)	125
	5.5.3	Stakeholder Engagement Activities during ESIA	126
	5.5.4	Public Consultation during ESIA Disclosure	131
5.6	Consult	ation Planned throughout the Lifetime of the Project	134
5.7	Project	Grievance Mechanism	139
	5.7.1	Overview	139
	5.7.2	Public Grievance Mechanism	140
	5.7.3	Workers' Grievance Mechanism	142
	5.7.4	Project Grievance Resolution Process	143
	5.7.5	World Bank's Grievance Redress Service	145
	5.7.6	Community Liaison Officer	145
	5.7.7	Project Contact Information	145
GEC	DLOGY,	SOILS AND CONTAMINATED LAND	147
6.1	Introduo	ction	147
	6.1.1	Study Area and Area of Influence	147
	6.1.2	Data Limitations	147
3.2	Baselin	e Description	147
	6.2.1	Overview	147
	6.2.2	Geology	148
	6.2.3	Seismic, Liquefaction and Landslide Risks	154
	6.2.4	Soils and Contaminated Land	158
6.3	Assess	ment of Impacts	161
	6.3.1	Methodology	161
	6.3.2	Determining Magnitude, Sensitivity, and Impact Significance	162
	6.3.3	Impacts related to Seismic Risks	163
	634	Impacts on Soils	164
64	Mitigatio	on Measures	165
0.1	6 4 1	Design Phase	165
	642	Construction Phase	165
	643	Operation Phase	166
65	Compli	ance against National and International Requirements	167
0.5	651	Salemic Risks	167
	652	Soils and Contaminated Land	162
66	Docidur		100
6.7	Propose	ed Monitoring and Reporting	170
HYD	KOLOG	JY AND HYDROGEOLOGY	171

7.1	Introduc	tion	171
	7.1.1	Study Area and Area of Influence	171

7.2	Data Limitations		
7.3	Baseline		172
	7.3.1	Overview	172
	7.3.2	Surface Water Resources	173
	7.3.3	Groundwater Resources	180
	7.3.4	Flood Risks	181
7.4	Assessm	nent of Impacts	182
	7.4.1	Methodology	182
	7.4.2	Determining Magnitude, Sensitivity, and Impact Significance	183
	7.4.3	Impacts on Surface Waters and Groundwater	185
	7.4.4	Impacts Related to Floods	187
7.5	Mitigatio	n Measures	188
7.6	Complia	nce with National and International Requirements	191
	7.6.1	National Requirements	191
	7.6.2	International Requirements	192
7.7	Residua	Impacts	193
7.8	Propose	d Monitoring and Reporting	193

8 MATERIAL RESOURCES, WASTE AND WASTEWATER MANAGEMENT194

8.1	Introduction 1		
	8.1.1	Study Area and Area of Influence	194
	8.1.2	Data Limitations	194
8.2	Baseline	Description for Material Resources, Waste and Wastewater Mana	agement
			194
	8.2.1	Material Resources	194
	8.2.2	Waste and Wastewater Management	196
8.3	Assessm	nent of Impacts	206
	8.3.1	Methodology and Assessment Criteria	206
	8.3.2	Determining Magnitude, Sensitivity, and Impact Significance	207
	8.3.3	Construction Phase	208
	8.3.4	Operation Phase	210
8.4	Mitigatio	n Measures	212
	8.4.1	General	212
	8.4.2	Construction Phase	215
	8.4.3	Operation Phase	219
8.5	Residua	I Impacts	227
8.6	Complia	nce with National and International Requirements	229
	8.6.1	National Requirements	229
	8.6.2	International Requirements	236
8.7	Propose	d Monitoring and Reporting	248
	ידו ואו ור		240

AIR QUALITY			249
9.1	Introduc	tion	249
	9.1.1	Study Area and Area of Influence	249
	9.1.2	Data Limitations	250

		9.1.3	Air Quality Standards Specified for the Project	250
	9.2	Baseline	e Description	251
		9.2.1	Climate and Meteorological Conditions	251
		9.2.2	Air Quality Baseline Conditions	254
		9.2.3	Air Quality Baseline Measurements	255
		9.2.4	Greenhouse Gases and Climate Mitigation	258
	9.3	Assessr	nent of Impacts	260
		9.3.1	Methodology	260
		9.3.2	Determining Magnitude, Sensitivity and Impact Significance	261
		9.3.3	Construction Phase	262
		9.3.4	Operation Phase	268
	9.4	Mitigatio	on Measures	284
		9.4.1	Construction Phase	284
		9.4.2	Operation Phase	285
	9.5	Complia	ance with National and International Requirements	286
		9.5.1	National Requirements	286
		9.5.2	International Requirements	289
	9.6	Residua	al Impacts	292
	9.7	Propose	ed Monitoring and Reporting	292
10	NOIS	SE AND	VIBRATION	294
	10 1	Introduc	tion	294
	10.1	10 1 1	Study Area and Area of Influence	294
		10.1.1	Data Limitations	295
		10.1.2	National and International Requirements	296
	10.2	Method	plogy and Assessment Criteria	298
	1012	10.2.1	Definitions	298
		10.2.2	Methodology	300
		1023	Determining Magnitude, Sensitivity, and Impact Significance	301
	10.3	Baseline	e Conditions and Measurements	302
	10.4	Noise M	Iodelling and Mapping	304
		10.4.1	Noise Sources	304
		10.4.2	Results of Noise Modelling	305
	10.5	Calculat	tion of Vibration Levels	310
		10.5.1	Vibration Sources	310
		10.5.2	Results of Vibration Level Calculations	310
	10.6	Assess	nent of Impacts and Regulatory Compliance	311
		10.6.1	Assessment of Noise Impacts	311
				214
		10.6.2	Assessment of vibration impacts	.314

11	SOC	10-ECO	NOMIC BASELINE	318
	11.1	Introduct	ion	318
		11.1.1	Study Area and Area of Influence	318
		11.1.2	Methodology	319
		11.1.3	Data Limitations	321
	11.2	Baseline	Conditions	321
		11.2.1	Overview	321
		11.2.2	Population and Demographics	321
		11.2.3	Economy	331
		11.2.4	Income Distribution	332
		11.2.5	Employment and Livelihood	333
		11.2.6	Vulnerable Groups	334
		11.2.7	Education	336
		11.2.8	Agriculture and Livestock Activities	338
		11.2.9	Gender Equality	341
		11.2.10	Health Services	342
		11.2.11	Vaccine Studies and R&D Laboratories in Turkiye	344
		11.2.12	Governance and Community Organization	345
		11.2.13	Public Infrastructure	346
	11.3	Assessm	ient of Impacts	348
		11.3.1	Determining Magnitude, Sensitivity, and Impact Significance	348
		11.3.2	Impacts on Socio-economy	349
	11.4	Mitigation	ns and Enhancement Measures	352
		11.4.1	Construction Phase	352
		11.4.2	Operation Phase	353
	11.5	Compliar	nce with National and International Requirements	353
		11.5.1	National Requirements	353
		11.5.2	International Requirements	355
	11.6	Residual	Impacts	355
	11.7	Proposed	d Monitoring and Reporting	355
12	LANI	D USE A	ND ZONING	357
	12 1	Introduct	ion	357
		12.1.1	Study Area and Area of Influence	357
		12.1.2	Data Limitations	357
	12.2	National	and International Requirements	357
	12.3	Baseline	Description	358
		12.3.1	Overview	358
		12.3.2	Project Site Location and Features	359
		12.3.3	Previous Land Use Patterns	363
		12.3.4	Surrounding Land Use	364
		12.3.5	Planned and Ongoing Developments on the Surrounding Area	368
		12.3.6	Regional Plans and Zoning	369

		12.4.2	Determining Magnitude, Sensitivity, and Impact Significance	372
		12.4.3	Impacts Related to Land Use	373
	12.5	Mitigatic	on Measures	374
	12.6	Residua	Il Impacts	374
	12.7	Propose	ed Monitoring and Reporting	374
13	TRA	FFIC IM	PACT	375
	13.1	Introduc	tion	375
		13.1.1	Study Area and Area of Influence	375
		13.1.2	Data Limitations	375
	13.2	Baseline	e Description	375
		13.2.1	Transportation Infrastructure in Ankara Province	375
		13.2.2	Transportation Infrastructure in Akyurt District	377
		13.2.3	Use of Existing Road Infrastructure by Nearby Facilities	380
		13.2.4	Future Developments	384
	13.3	Assessr	nent of Impacts	385
		13.3.1	Methodology	385
		13.3.2	Determining Magnitude, Sensitivity, and Impact Significance	386
		13.3.3	Construction Phase	387
		13.3.4	Operation Phase	388
	13.4	Mitigatic	on Measures	390
		13.4.1	Design Phase	390
		13.4.2	Construction Phase	391
		13.4.3	Operation Phase	391
	13.5	Complia	ince with National and International Requirements	392
		13.5.1	National Requirements	392
		13.5.2	International Requirements	393
	13.6	Residua	Il Impacts	394
	13.7	Proposed Monitoring and Reporting		394
14	COM	1MUNIT	Y HEALTH, SAFETY AND SECURITY	396
	14.1	Introduc	tion	396
		14.1.1	Study Area and Area of Influence	396
		14.1.2	Data Limitations	397
	14.2	Baseline	e Description	397
		14.2.1	Background	397
		14.2.2	Biosafety and Biosecurity	400
		14.2.3	Exposure to Disease and Infections	403
		14.2.4	Infrastructure	406
		14.2.5	Life and Fire Safety and Emergency Response	407

14.3.2 Determining Magnitude, Sensitivity and Impact Significance 408

407

408

408

	14.3.3	Construction Phase	410
	14.3.4	Operation Phase	411
14.4	Mitigatio	n during Construction	413
	14.4.1	General	413
	14.4.2	Project Related Labour Influx	413
	14.4.3	Dust and Noise	414
	14.4.4	Traffic and Transportation	415
	14.4.5	Hazardous Materials and Waste Management	415
14.5	Mitigatio	on during Design and Operation	415
	14.5.1	General	415
	14.5.2	Air Quality and Noise	416
	14.5.3	Traffic and Transportation	417
	14.5.4	Hazardous Materials and Waste Management	417
	14.5.5	Decontamination	418
	14.5.6	Biosafety	425
	14.5.7	Biosecurity	429
	14.5.8	Infrastructure Safety	435
	14.5.9	Life and Fire Safety and Emergency Response	436
	14.5.10	Life and Fire Safety at the Kindergarten Facility	439
14.6	Complia	nce with National and International Requirements	443
	14.6.1	National Requirements	443
	14.6.2	International Requirements	447
14.7	Residua	I Impacts	452
14.8	Propose	ed Monitoring and Reporting	452
ANIN	IAL WE	LFARE	453
15 1	Introduc	tion	153
13.1	15 1 1	Study Area and Area of Influence	453
	15.1.1		453
15.2	Raseline	Description	453
10.2	15 2 1	Conceptual Framework for Animal Welfare	453
	15.2.1	Specific Conditions of the Project within the scope of Animal W	elfare458
15 3	Assessn	nent of Imnacts	458
10.0	15.3.1	Methodology	458
	15.3.2	Determining Magnitude, Sensitivity, and Impact Significance	459
	15.3.3	Impacts in Terms of Animal Use Ethics	460

	15.3.2	Determining Magnitude, Sensitivity, and Impact Significance	459
	15.3.3	Impacts in Terms of Animal Use Ethics	460
	15.3.4	Impacts on Quality of Scientific Research	461
	15.3.5	Economic Impacts	461
	15.3.6	Impacts on Education	462
15.4	Mitigatior	n Measures	462
	15.4.1	Design Phase	462
	15.4.2	Operation Phase	463
	15.4.3	Compliance against Applicable Standards and Requirements	463
15.5	Residual	Impacts	468
15.6	National	and International Requirements	468
	15.6.1	National Requirements	468

		15.6.2	International Requirements and Guidelines	469
	15.7	Proposed	d Monitoring and Reporting	470
16	LAB		D WORKING CONDITIONS	471
	16.1	Introducti	ion	471
	16.2	National	and International Requirements	471
		16.2.1	National Requirements	471
		16.2.2	International Requirements	473
		16.2.3	Comparison of International Requirements and National Law in La Working Conditions	abour and 476
	16.3	Baseline	Description	486
		16.3.1	Labour and Working Conditions in Turkiye	486
		16.3.2	Project Employment and Labour Relations	487
		16.3.3	Occupational Health and Safety	491
	16.4	Assessm	ent of Impacts	495
		16.4.1	Methodology	495
		16.4.2	Determining Magnitude, Sensitivity, and Impact Significance	495
		16.4.3	Construction Phase	496
		16.4.4	Operation Phase	497
	16.5	Mitigatior	n Measures	499
		16.5.1	Construction Phase	499
		16.5.2	Operation Phase	500
	16.6	Residual	Impacts	503
	16.7	Proposed	d Monitoring and Reporting	503
17	BIOD	DIVERSI	ΓY	504
	17.1	Introducti	ion	504
		17.1.1	Study Area and Area of Influence	504
	17.2	Methodo	logy and Assessment Criteria	505
		17.2.1	Methodology	505
		17.2.2	Determining Magnitude, Sensitivity, and Impact Significance	506
		17.2.3	Data Limitations	507
	17.3	Overview	of Baseline Conditions: Terrestrial Flora and Fauna	507
		17.3.1	Terrestrial Flora	512
		17.3.2	Terrestrial Fauna	517
		17.3.3	Protected Sites and Other Sites in the Vicinity of the Project Site	518
	17.4	Assessm	ent of Impacts	519
	17.5	Mitigatior	n Measures	520
		17.5.1	Construction Phase	520
		17.5.2	Operation Phase	521
	17.6	Residual	Impacts	522
	17.7	Compliar	nce against National and International Requirements	522
	17.8	Proposed	d Monitoring and Reporting	523
	-		5 1 5	-

18 CULTURAL HERITAGE

	18.1	Introduct	tion	524
		18.1.1	Study Area and Area of Influence	524
		18.1.2	Data Limitations	526
	18.2	Baseline	Description	526
		18.2.1	Site Location	526
		18.2.2	Archaeological and Historical Background	527
		18.2.3	Observations of Archaeological Walkover Surveys at the Project	Site534
	18.3	Assessm	nent of Impacts	536
		18.3.1	Overview	536
		18.3.2	Methodology and Assessment Criteria	537
		18.3.3	Construction Phase	540
		18.3.4	Operation Phase	542
		18.3.5	Summary of Outcomes	542
	18.4	Mitigatio	n Measures	542
		18.4.1	Construction phase	542
		18.4.2	Operation phase	543
	18.5	Complia	nce with National and International Requirements	543
		18.5.1	National Regulatory Framework for Tangible and Intangible Cultu	ral Heritage 543
		18.5.2	International Regulatory Framework for Tangible and Intangible C Heritage	Cultural 544
	18.6	Residua	I Impacts	544
	18.7	Propose	d Monitoring and Reporting	544
19	CUM	ULATIV	E IMPACT ASSESSMENT	546
	19.1	Introduct	tion	546
	19.2	National	and International Guidance and Requirements	546
	19.3	Methodo	blogy	547
		19.3.1	Assumptions and Limitations	547
		19.3.2	Identification of Boundaries and VECs	548
	19.4	Develop	ments in the vicinity of the Project site	548
		19.4.1	Otonomi Outlet Shopping Mall and Wellness Centre Project	549
		19.4.2	Ankara International Exhibition and Convention Centre Project	551
		19.4.3	Ankara Esenboğa Airport Metro Line Project	552
	19.5	Cumulat	ive Impact Analysis of the Developments	553
		19.5.1	Air Quality	553
		19.5.2	Noise	554
		19.5.3	Traffic	554
		19.5.4	Waste	556
		19.5.5	Socio-economy	557
	19.6	Cumulat	ive Impact Mitigation	557
		19.6.1	Air Quality	557
		19.6.2	Noise	558
		19.6.3	Traffic	558
		40.04	Masta	559
		19.6.4	Waste	556

	19.7	Conclus	ion	559
20	ENV	IRONME	ENTAL AND SOCIAL MANAGEMENT	560
	20.1	Introduc	tion	560
		20.1.1	Potential Project Impacts and Risks	560
		20.1.2	Summary of Commitments	561
	20.2	ESMS F	Planning	561
		20.2.1	Scope of the ESMS Planning	561
		20.2.2	Plans, Policies and Procedures	562
		20.2.3	Environmental, Health, Safety and Social Impact and Risk Assessm	nent563
		20.2.4	Legal and Other Requirements	563
		20.2.5	Targets, Objectives and Programs	564
	20.3	Impleme	entation of the ESMS	564
		20.3.1	Responsibilities, Resources and Training	564
		20.3.2	Operational Control	567
		20.3.3	Environmental and Social Emergency Preparedness and Response	e 567
	20.4	ESMS C	Control, Monitoring and Reporting	568
		20.4.1	Monitoring	568
		20.4.2	Reporting	568
		20.4.3	Non-conformities and Corrective, Preventive and Improving Actions	568

21 ENVIRONMENTAL AND SOCIAL AUDIT OF THE CONSTRUCTION WORKS

			569
21.1	Introduct	ion	569
	21.1.1	Background	569
	21.1.2	Overview of the Construction Works	569
	21.1.3	Description of Audit Process	571
	21.1.4	Limitations	571
21.2	Environm	nental and Social Management	571
	21.2.1	General	571
	21.2.2	Occupational Health and Safety (OHS)	576
	21.2.3	Labour and Working Conditions	580
	21.2.4	Community Health and Safety	588
	21.2.5	Stakeholder Engagement and Public Grievance Mechanism	588
	21.2.6	Environment	589
	21.2.7	Environmental and Social Action Plan for Phase 1 Construction	Activities 592

ANNEXES

Figures

Figure 1-1: ESIA process	38
Figure 2-1: Project location	42
Figure 2-2: Project site and its parcel division	43
Figure 2-3: Project location alternatives	47
Figure 2-4: Project Layout	60
Figure 2-5: 3-D visual of the Project components	62
Figure 2-6: 3-D view of the Administrative Building	63
Figure 2-7: 3-D view of the R&D and Experimental Animals Production/Test buildings	64
Figure 2-8: 3-D view of the Vaccine Production and Storage Building	65
Figure 2-9: 3-D view of the Waste Building	66
Figure 2-10: 3-D view of the Kindergarden	66
Figure 2-11: Typical BSL 1, 2 and 3 Laboratories	69
Figure 2-12: A Typical BSL3 Laboratory	70
Figure 2-13: Simplified process flow diagram for production of inactive viral vaccines	73
Figure 4-1: ESIA process	108
Figure 5-1: National legislative requirements for public consultation	114
Figure 5-2: Identification of stakeholders and engagement scheme	116
Figure 5-3: Neighbourhoods within 1, 3 and 5 km distance of the Project site	117
Figure 5-4: Existing land use of the bounded area	118
Figure 5-5: A Photo from the Public Consultation Meeting	132
Figure 5-6: Photos from Engagement Activities at the Settlements (Left: Meeting with Sarac	alar
Mukhtar, Right: Meeting with Balıkhisar Mukhtar, Bottom: Meeting with Local Residents)	133
Figure 5-7: Photos from Engagement Activities at Otonomi (Left) and İşbir Yatak (Right)	134
Figure 5-8: Steps of the Grievance Mechanism of the Project ⁴	144
Figure 6-1: Main geological formations at the Project site	149
Figure 6-2: A section of the general geology of the Project site area, 1/100,000 scaled map	150
Figure 6-3: Locations of the boreholes drilled during the ground survey study	153
Figure 6-4: Earthquake hazard map of Turkiye	155
Figure 6-5: Distribution of natural disasters in Ankara	156
Figure 6-6: Earthquake hazard map (in terms of Peak Ground Acceleration for a 475-year re	currence
period) in the Project site	157
Figure 6-7: Soil sampling location	160
Figure 7-1: Hydrological basins in Turkiye	173
Figure 7-2: Project site within the Sakarya Basin	174
Figure 7-3: Stream Sub-basins of Sakarya Basin	174
Figure 7-4: Surface water resources in the vicinity of the Project site	176
Figure 7-5: Çubuk Stream (Photographs taken near the northern site boundary)	176
Figure 7-6: Çubuk-I and Çubuk-II Dams	1//
Figure 7-7: Sensitive urban areas in the Sakarya Basin	178
Figure 7-8: Surface water sampling location	180
Figure 7-9: water resources around the Project Site	181
Figure 9-1: Impact Area Selected for the Air Quality Modelling Study	250
Figure 9-2: Akyurt wind rose	253

Figure 9-3: Locations of representative air quality monitoring stations in Ankara	254
Figure 9-4: Baseline Ambient Air Quality Measurement Locations (PM_x: Particulate matter	and dust
deposition monitoring locations, PAS_x: Passive gas sampling locations)	256
Figure 9-5: GHG Emissions of Ankara Province in 2019 according to GPC Basic ⁸	259
Figure 9-6: Short Term PM Deposition Emissions for Construction Phase	265
Figure 9-7: Long Term PM Deposition Emissions for Construction Phase	265
Figure 9-8: Maximum Daily Average PM10 Emissions for Construction Phase	266
Figure 9-9: Maximum Annual Average PM10 Emissions for Construction Phase	266
Figure 9-10: Maximum Daily Average PM2.5 Emissions for Construction Phase	267
Figure 9-11: Maximum Annual Average PM2.5 Emissions for Construction Phase	267
Figure 9-12: Maximum Hourly Average VOC Emissions for Operation Phase	273
Figure 9-13: Maximum 8-Hour Average CO Emissions for Operation Phase	273
Figure 9-14: Maximum Hourly Average NO ₂ Emissions for Operation Phase	274
Figure 9-15: Maximum Yearly Average NO ₂ Emissions for Operation Phase	274
Figure 9-16: Maximum Hourly Average SO ₂ Emissions for Operation Phase	275
Figure 9-17: Maximum Yearly Average SO ₂ Emissions for Operation Phase	275
Figure 9-18: Maximum Hourly Average HCI Emissions for Operation Phase	276
Figure 9-19: Maximum Daily Average HCI Emissions for Operation Phase	276
Figure 9-20: Maximum Hourly Average HF Emissions for Operation Phase	277
Figure 9-21: Maximum Daily Average HF Emissions for Operation Phase	277
Figure 9-22: Maximum Hourly Average PM10 Emissions for Operation Phase	278
Figure 9-23: Maximum Annual Average PM10 Emissions for Operation Phase	278
Figure 9-24: Maximum Hourly Average PM2.5 Emissions for Operation Phase	279
Figure 9-25: Maximum Annual Average PM2.5 Emissions for Operation Phase	279
Figure 10-1: Area of influence	295
Figure 10-2: Project site and receptor locations	303
Figure 10-3: Construction Phase Noise Map L _{day}	306
Figure 10-4: Construction Phase Noise Map Lnight	307
Figure 10-5: Operation Phase Noise Map Lday	309
Figure 10-6: Operation Phase Noise Map Lnight	309
Figure 10-7: Construction Vibration Levels and Limit Values	311
Figure 11-1: Population Density of Ankara Districts (Green to red: Least to most populated)	323
Figure 12-1: Location of Ankara Province and Akyurt District (Prepared through ArcMap 10.	8.1)360
Figure 12-2: Project site and its parcel division (Prepared through ArcMap 10.8.1)	361
Figure 12-3: The previous land use patterns of the Project site (Project site boundary is indi-	cated in
Figure 12-4: Existing land use of the bounded area	365
Figure 12-5: The section of Baskent Ankara 1/25 000 Master Zoning Plan - Akvurt for 2023	370
Figure 13-1: Road Network in and around Ankara Province	376
Figure 13-2: Main roads and highways in and around Ankara province (the blue shaded are	2
indicates the Project site)	377
Figure 13-3: State Roads Volume (Daily) Map of Akyurt District in Ankara Province as of 20.	20
(Project site is indicated in the figure)	378
Figure 13-4: Road network in the vicinity of the Project site	379

Figure 13-5: Bus stations in the vicinity of the Project site (the approximate locations of the r	earby
bus stops were taken from google earth pro satellite images)	380
Figure 13-6: Close-up views of the streets/roads in the vicinity of the Project site by using Ge	oogle
Earth street view	382
Figure 13-7: Planned major road and railway systems in the vicinity of the Project site (appro	oximate
locations and routes were taken from 1/25,000 scaled Zoning Plan, 2023)	385
Figure 13-8: Probable route alternatives to be used by construction vehicles	388
Figure 13-9: Layout and Internal traffic flow within the Project site	389
Figure 14-1: Area of Influence	397
Figure 14-2: Guideline for Disinfection and Sterilization	400
Figure 14-3: Biosafety Management System Cycle	401
Figure 14-4: Risk Assessment Framework	402
Figure 14-5: Routes of exposure and causes of LAIs based on literature	404
Figure 14-6: Incidents involved in the infection	405
Figure 14-7: Probable cause of the incidents ¹²	405
Figure 14-8: The types of biological Indicators	423
Figure 17-1: Area of Influence (AoI) for biodiversity assessment	504
Figure 17-2: The approximate location of the strip of trees within the Project site observed in	
December 2021	508
Figure 17-3: The historical changes of the land pattern in the Project site	509
Figure 17-4: Birds encountered during the ecological walkover surveys including a) Magpie	(Pica
Pica), b) Great Tit (Parus major), c) Chaffinch (Fringilla coelebs) and Tree Sparrow (Passer	
montanus) and d) Robin (Erithacus rubecula)	517
Figure 17-5: The Project site and the nearest Key Biodiversity Sites	519
Figure 18-1: Illustration of area of influence for tangible and intangible cultural heritage (Plea	ase refer
to Table 18-1)	526
Figure 18-2: General View from Altinova Historic Stone Bridge	528
Figure 18-3: International Tangible Cultural Heritage Areas	529
Figure 18-4: National Tangible Cultural Heritage Areas	532
Figure 19-1: Rapid Cumulative Impact Assessment (RCIA) approach of the IFC	547
Figure 19-2: The location of Otonomi Outlet Shopping Mall and Wellness Centre project near	r the
Project site	550
Figure 19-3: Otonomi Outlet Shopping Mall and Wellness Centre project site plan	550
Figure 19-4: Ankara International Exhibition and Convention Centre Layout	552
Figure 19-5: The location of Akyurt International Fair Area near the Project site	552
Figure 19-6: The expected route of Ankara Esenboğa Airport Metro Line near the Project site	e553
Figure 21-1: Extent of Phase I Construction Works	570
Figure 21-2: Construction Site Organisational Chart of the EPC Contractor	573

Tables

Table 1-1: Report Structure	39
Table 2-1: SWOT analysis considered for location alternatives of the proposed developmen	t by MoH
	48
Table 2-2: Vaccine production technology alternatives	53
Table 2-3: Bioreactor alternatives: key advantages/disadvantages	57
Table 2-2: Project components and footprint/operational areas	61
Table 2-3: Standards Required for ABSL2 and ABSL3 Laboratories	67
Table 2-4: The summary of risk groups to biosafety levels, practices and equipment	68
Table 2-5: The principles of Three Rs	75
Table 2-6: Basis of BSL-3 Laboratory Certification Checklist (NIH Biosafety Level 3 Laborat	ory
Certification Requirements, 2006)	78
Table 2-7: Construction equipment	86
Table 3-1: Applicable Turkish Legislation	91
Table 3-2: Description of the World Banks ESSs and Their Relevance to the Project	99
Table 3-3: Major Gaps Between WB ESSs and National Legislation	103
Table 4-1: Criteria for Determining Magnitude	110
Table 4-2: Criteria for Determining Sensitivity	110
Table 4-3: Impact Significance Matrix	110
Table 4-4: The ESIA Team	112
Table 5-1: The ESSs of the World Bank that are relevant to the stakeholder engagement	115
Table 5-2: Stakeholder List for Governmental Authorities	118
Table 5-3: Stakeholder List for Non-Governmental Bodies	121
Table 5-4: Stakeholder List for Universities and Research Laboratories	122
Table 5-5: Stakeholder List for Neighbouring/Nearby Facilities	122
Table 5-6: Other Stakeholder Groups	123
Table 5-7: The first stakeholder list for the Project (created by the Environmental and Socia the PMSU)	Team of 123
Table 5-8: Consultation and Survey Methods and Number of Stakeholders Reached	128
Table 5-9: Stakeholder Engagement Approach and Future Stakeholder Engagement	135
Table 6-1: Information about the boreholes	151
Table 6-2: The soil parameters recommended in the Geotechnical Report to be used in sta	tic
calculations	157
Table 6-3: Results of the soil investigation study	159
Table 6-4: Criteria for Determining Sensitivity	162
Table 6-5: Criteria for Determining Magnitude	162
Table 6-6: Impact Significant Matrix	163
Table 6-7: Building Use Classes and Building importance Coefficients	167
Table 6-8: Earthquake Design Classes (EDC)	167
Table 6-9: Parameters defined in Ground Survey Report according to the Turkish Building	
Earthquake Regulation	168

Table 6-10: National Regulations on Soils and Contaminated Land that are Relevant to the	Project
Ŭ	168
Table 7-1: Baseline water quality analysis results	179
Table 7-2: Severe flooding events recorded in Ankara between 1950-2018	182
Table 7-3: Criteria for Determining Sensitivity	183
Table 7-4: Criteria for Determining Magnitude	184
Table 7-5: Impact Significant Matrix	185
Table 7-6: National Regulations on Water Resources and Quality that are Relevant to the P	roject
	191
Table 8-1: Chemical Disinfectants	195
Table 8-2: Treatment and Disposal Methods for Categories of Health Care Waste	199
Table 8-3: Expected Waste Generation During the Construction Phase	202
Table 8-4: Expected Waste Generation During the Operation Phase	203
Table 8-5: Expected Waste Generation by Building During the Operation Phase of the Projection	ect204
Table 8-6: Criteria for Determining Sensitivity	207
Table 8-7: Criteria for Determining Magnitude	207
Table 8-8: Impact Significant Matrix	207
Table 8-9: Impact Assessment of Waste and Wastewater Generation During the Construction	on Phase
	208
Table 8-10: Impact Assessment of Waste and Wastewater Generation During the Operation	n Phase
	210
Table 8-11: Mitigation Measures / Management Options of the Waste and Wastewater Gene	eration
During the Construction Phase	217
Table 8-12: Waste segregation and the collection frequency	224
Table 8-13: Mitigation Measures / Management Options of the Waste and Wastewater Gen	eration
During the Operation Phase	226
Table 8-14: Residual Impacts after the Application of Relevant Mitigation Measures	228
Table 8-15: Nationally Set Requirements and Best Practices	230
Table 8-16: Wastewater Discharge Limits Set by National and Local Legislation	235
Table 8-17: Compliance with WHO Guidelines Related with the Project	237
Table 9-1: Ambient Air Quality Standards	251
Table 9-2: Average temperature and sunshine data for a period of 60 years (1960-2020)	252
Table 9-3: Precipitation data for Ankara for a period of 60 years (1960-2020)	252
Table 9-4: Relative humidity and pressure data for a period of 60 years (1960-2020)	253
Table 9-5: Monthly average wind speed between the years 1960-2020	253
Table 9-6: EU Council Directive 2008/50/EC, Turkish (as per RAMAQ Annex 1) and WBG G	eneral
EHS Guidelines Ambient Air Quality Standards	254
Table 9-7: Baseline Ambient Air Quality (Dust and Dust Deposition) Measurement Results	257
Table 9-8: Baseline Ambient Air Quality (Gas) Measurement Results	257
Table 9-9: Energy Demand by Laboratory Type	259
Table 9-10: Determination of Receptor Sensitivity - Operational Phase	261
Table 9-11: Determination of Impact Magnitude - Operational Phase	261
Table 9-12: Impact Significant Matrix	261
Table 9-13: Emission Factors for Non-residential Construction	262
Table 9-14: Vehicle Emission Factors	262

Table 9-15: Number of Equipment to be Used in the Construction Phase of the Project	263
Table 9-16: Emission Calculations According to the Number of Equipment to be Used in the	Project 263
Table 9-17: Modelling Results for Construction Phase	263
Table 9-18: Daily or Short-Term Cumulative Evaluation of the Construction Phase	264
Table 9-19: Yearly or Long-Term Cumulative Evaluation of the Construction Phase	264
Table 9-20: Cumulative Evaluation of the Construction Phase	268
Table 9-21: Equipment to be Used in the Operation Phase of the Project	268
Table 9-22: Industrial Emission Standards	268
Table 9-23: Steam Boiler Emission Calculations	269
Table 9-24: Pure Steam Generator Emission Calculations	270
Table 9-25: Typical Measurement Results of the Emissions Sources from the Active Pharma Industry Facilities	aceutical 270
Table 9-26: Modelling Results for Operation Phase	271
Table 9-27: Comparison of the Operation Phase Emissions Cumulative Evaluation with Hou Values	rly Limit 272
Table 9-28: Comparison of the Operation Phase Emissions Cumulative Evaluation with Yea Values	rly Limit 272
Table 9-29: Cumulative Evaluation of PM ₁₀ for the Operation Phase	280
Table 9-30: Cumulative Evaluation of PM _{2.5} for the Operation Phase	280
Table 9-31: Cumulative Evaluation of SO ₂ for the Operation Phase	281
Table 9-32: Cumulative Evaluation of NO2 for the Operation Phase	281
Table 9-33: Cumulative Evaluation of VOC for the Operation Phase	282
Table 9-34: Cumulative Evaluation of HCI for the Operation Phase	282
Table 9-35: Cumulative Evaluation of HF ⁻ for the Operation Phase	283
Table 9-36: Operation Phase GHG Emission Sources	284
Table 9-37: National Regulations on Air Quality that are Relevant to the Project	286
Table 9-38: National Regulations on Energy Efficiency that are Relevant to the Project	288
Table 9-39: Limit Values Stipulated in the RCAPOI	289
Table 9-40: Limit Values Stipulated in the International Legislation (WBG and EU)	290
Table 9-41: WBG EHS Guidelines Emission Standards	290
Table 9-42: WBG Emission Standards for Small Combustion Facilities	291
Table 10-1: Environmental Noise Limits (RENC)	296
Table 10-2: Allowable timeframes for outdoor activities in residential areas (RENC)	296
Table 10-3: Vibration Limits for Construction (RENC)	297
Table 10-4: WBG Noise Level Guidelines	297
Table 10-5: Guidance on Effects of Vibration Levels on Humans	298
Table 10-6: Transient Vibration Guide Values for Cosmetic Damage of Buildings	298
Table 10-7: Basic acoustical terms and concepts	298
Table 10-8: Perception of sound	299
Table 10-9: Criteria for Determining Sensitivity	301
Table 10-10: Criteria for Determining Magnitude due to Construction and Operational Noise	301
Table 10-11: Impact Significance Matrix	302
Table 10-12: Summary information on receptors	302

Table 10-13: Baseline Measurement Results for RENC(Lden)	303
Table 10-14: Baseline Measurement Results for Noise Level Guidelines as per WBG Gener	al EHS
Guidelines Standards (Ldn)	303
Table 10-15: Construction Machinery and Equipment	304
Table 10-16: Operation Machinery and Equipment	305
Table 10-17: Construction Noise Model Results (for RENC), Lden	305
Table 10-18: Construction Noise Model Results (for WBG standards), Ldn	306
Table 10-19: Operation Noise Model Results, Lden	307
Table 10-20: Operation Noise Model Results, Ldn	307
Table 10-21: Reference Vibration Levels of Construction Equipment (FTA Document)	310
Table 10-22: Construction Phase Noise Assessment Results (WBG, Ldn) ⁵	313
Table 10-23: Operation Phase Noise Assessment Results (WBG, Ldn)	313
Table 10-24: Summary Results for Construction Vibration	314
Table 11-1: The number of household surveys for each neighbourhood	320
Table 11-2: Gender distribution of PAPs surveyed in June 2022 (by neighbourhoods)	320
Table 11-3: Population of Districts in Ankara (2022)	321
Table 11-4: Characteristics of the neighbourhoods and their districts	325
Table 11-5: The distribution of population and number of households of the Project affected	
neighbourhoods (based on the findings of the mukhtar interviews in June 2022)	326
Table 11-6: Ownership status distribution of houses within the Project affected neighbourho	ods
(based on the findings of the mukhtar interviews in June 2022)	326
Table 11-7: Demographic information of the head of the households within the Project affec	ted
neighbourhoods (based on the findings of the household socio-economic surveys in June 2	022)328
Table 11-8: Household information within the Project affected neighbourhoods (based on th	e findings
Table 11-0: Data on facilities, business enterprises and factories located in the Project affect	tod
neighbourhoods (based on the findings of the business interviews in June 2022)	,.eu 331
Table 11-10: Main economic activities within the Project affected neighbourboods (based or	n the
findings of the mukhtar interviews in June 2022)	332
Table 11-11: Distribution of businesses in within the Project affected neighbourhoods (base	d on the
findings of the mukhtar interviews in June 2022)	333
Table 11-12: Distribution of working status of residents surveyed within the Project affected	
neighbourhoods (based on the findings of the household socio-economic surveys in June 2	022)334
Table 11-13: Distribution of the vulnerable groups within the Project affected neighbourhood	ds (based
on the findings of the mukhtar interviews in June 2022)	336
Table 11-14: Vulnerable groups surveyed within the Project affected neighbourhoods (base	d on the
findings of the household socioeconomic surveys in June 2022)	336
Table 11-15: Data provided by Akyurt and Pursaklar Social Assistance and Solidarity Found	dation
	336
Table 11-16: Education levels on district basis	337
Table 11-17: Distribution of students by level of schools within the Project affected neighbou	urhoods
(based on the findings of the mukhtar interviews in June 2022)	337
Table 11-18: Educational status of the household heads surveyed within the Project affecte	d

neighbourhoods (based on the findings of the household socioeconomic surveys in June 2022)338

Table 11-19: Information on agricultural activities in neighbourhoods in close proximity of the Project				
site (based on the data obtained from Akyurt and Pursaklar District Directorates of Agricultur Forestry)	re and 339			
Table 11-20: Total number of cattle and small ruminants in neighbourhoods in close proximi	ty of the			
Project site (based on the data obtained from Akyurt and Pursaklar District Directorates of A and Forestry)	griculture 340			
Table 11-21: Distribution of total agricultural land within the Project affected neighbourhoods on the findings of the mukhtar interviews in June 2022)	; (based 340			
Table 11-22: Comparison of gender equality in Turkiye based on WEF Global Gender Gap I	ndex 341			
Table 11-23: Comparison of gender equality in Ankara with Turkiye	341			
Table 11-24: Data regarding the health services within the Project affected neighbourhoods on the findings of the mukhtar interviews in June 2022)	(based 344			
Table 11-25: Organizations within the Project affected neighbourhoods (based on the finding mukhtar interviews)	js of the 345			
Table 11-26: Infrastructure quality within the Project affected neighbourhoods (based on the of the mukhtar interviews and household surveys conducted in June 2022)	findings 346			
Table 11-27: Most preferred means of transportation within the Project affected neighbourhor (based on the findings of the mukhtar interviews and household surveys conducted in June	ods 2022) 347			
Table 11-28: Most crucial problems within the Project affected neighbourhoods (based on th	e			
findings of the mukhtar interviews and household surveys conducted in June 2022)	347			
Table 11-29: Criteria for Determining Sensitivity	348			
Table 11-30: Criteria for Determining Magnitude	348			
Table 11-31: Impact Significant Matrix	349			
Table 11-32: Local employment for unskilled people requested by mukhtars of the Project at	fected			
neighbourhoods (based on the findings of the mukhtar interviews in June 2022)	350			
Table 11-33: Related National Legal Framework	353			
Table 12-1: Key National Legislation Related to Land Use	357			
Table 12-2: Approximate land distribution in Akyurt, Pursaklar and Çubuk districts,	365			
Table 12-3: Number of estimated residential houses by neighbourhoods	366			
Table 12-4: Reviewed zoning plans	369			
Table 12-5: 1/1000 Implementation Zoning Plan Amendment Land Use Distributions	371			
Table 12-6: Criteria for Determining Sensitivity	372			
Table 12-7: Criteria for Determining Magnitude of Impacts on Land Use	372			
Table 12-8: Impact Significant Matrix	373			
Table 13-1: The condition of the roads/streets based on visual observation	383			
Table 13-2: Criteria for Determining Sensitivity	386			
Table 13-3: Criteria for Determining Magnitude	386			
Table 13-4: Impact Significant Matrix	387			
Table 13-5: National Regulations on Traffic Safety that are Relevant to the Project	392			
Table 13-6: The World Bank Documents of Traffic and Road Safety	393			
Table 14-1: The summary of risk groups to biosafety levels, practices and equipment 398				
Table 14-2: Infrastructure quality within the Project affected neighbourhoods (based on the findingsof the surveys and mukhtar interviews in June 2022)406				
Table 14-3: Criteria for Determining Sensitivity	409			

Table 14-4: Criteria for Determining Magnitude	409			
Table 14-5: Impact Significant Matrix	410			
Table 14-6: Chemical and Physical Categories for Decontamination	419			
Table 14-7: The main disinfectant classes and their activity levels	421			
Table 14-8: Chemical disinfectants according to their active ingredients and their properties	421			
Table 14-9: The common autoclaving protocols for different type of wastes	423			
Table 14-10: The number of UV-C lamps according to the room dimension	425			
Table 14-11: An Example of Risk Assessment Management at 3 Different Levels of Risk	428			
Table 14-12: Risk Assessment Template	434			
Table 14-13: International Standards to be followed by the Project	448			
Table 14-14: Applicable EU Directives	449			
Table 15-1: The basic and updated definitions of the three Rs*	456			
Table 15-2: Reduction strategies or approaches at three levels	457			
Table 15-3: Criteria for Determining Sensitivity	459			
Table 15-4: Criteria for Determining Magnitude	459			
Table 15-5: Impact Significant Matrix	459			
Table 15-6: Applicable Design/Management Requirements and Corresponding Measures to Compliance of the Project	Ensure 463			
Table 16-1: National Laws and International Conventions Regarding Labour and Working Co and Occupational Health and Safety	onditions 471			
Table 16-2: Applicable International Labour Organization Conventions on Labour and Workir Conditions	ng 476			
Table 16-3: Comparison of International Requirements and National Law in Labour and Work	king 477			
Table 16-4. The distribution of the workforce in the health sector in Turkive by their profession				
Table 16-5: Criteria for Determining Sensitivity	495			
Table 16-6: Criteria for Determining Magnitude	496			
Table 16-7: Impact Significant Matrix	106			
Table 17-1: Criteria for Determining Conservation Value (Sensitivity of the receiving environ	nent)			
Table 17-1. Ontena for Determining Conservation value (Gensitivity of the receiving environi	506			
Table 17-2: Guidelines for Definition of Magnitude in the ESIA	507			
Table 17-3: Impact Significant Matrix	507			
Table 17-4: Identified flora species of the Project site	514			
Table 17-5: Bird species observed within the Project site	517			
Table 18-1: Area of influence for tangible and intangible cultural heritage	525			
Table 18-2: International Tangible Cultural Heritage Areas	529			
Table 18-3: National Tangible Cultural Heritage Areas	530			
Table 18-4: International Intangible Cultural Heritage Elements nd	533			
Table 18-5: National Intangible Cultural Heritage Elements	533			
Table 18-6: Details of face-to-face interviews on Intangible Cultural Heritage Elements	534			
Table 18-7: Intangible Cultural Heritage Elements in the Project Aol	536			
Table 18-8: Guidance for assessing value of heritage assets (Annex 3A of the ICOMOS CHIA				
Guidance)	537			
Table 18-9: Criteria for Determining Magnitude (Annex 3B of the ICOMOS CHIA Guidance)	539			
Table 18-10: Scale and Severity of Change/Impact Matrix	540			

Table 18-11: Potential Construction Activities	540
Table 18-12: Intangible Cultural Heritage Impact Assessment	541
Table 19-1: Details of developments in the vicinity of Project site	549
Table 20-1: The key roles and responsibilities for implementation of the ESMS during constr	uction 565
Table 20-2: The key roles and responsibilities for implementation of the ESMS during operate	ion565
Table 21-1: Phase I construction components and footprint/operational areas	570
Table 21-2: Subcontractor Companies by Their Duties and Approximate Number of Workers	574
Table 21-3: Environmental and Social Action Plan for Construction Activities	593

Abbreviations and Acronyms

ABSL	Animal Biosafety Level	IDEA	Istanbul Experimental Research Centre
ADR	The European Agreement concerning the International Carriage of Dangerous Goods by Road	IHR	International Health Regulations
Aol	Area of Influence	ILO	International Labour Organization
AFAD	Ministry of Interior, Disaster and Emergency Management Presidency	INDC	Intended Nationally Determined Contribution
AIFD	Researcher Pharmaceutical Companies Association	IPCC	Intergovernmental Panel on Climate Change
AMM	Ankara Metropolitan Municipality	ISO	International Standards Organization
ANSI	American National Standards Institute	IUCN	International Union for the Conservation of Nature
ASKI	Ankara Water and Sewerage Administration	KBA	Key Biodiversity Area
AWI	Animal Welfare Institute	KLİMİK	Turkish Clinical Microbiology and Infectious Diseases Association
AWMA	American Veterinary Medical Association	KUTTAM	Koc University Research Centre for Translational Medicine
Вар	Benzo(a)pyrene	KUISCID	Koc University İşbank Centre for Infectious Diseases
BAS	Building automation system	L&FS	Life and Fire Safety
BaU	Business as Usual	LAIs	Laboratory-acquired infections
BERN	Bern Convention	LC	Least Concern
BOD	Biological Oxygen Demand	LRA	Local Risk Assessment
BMBL	Biosafety at Microbiological and Biomedical Laboratories	LRP	Livelihood Restoration Plan
BSATs	Biological Select Agents and Toxins	LTL	Long-term Limit
BSC	Biological safety cabinet	MAD	Mutual Acceptance of Data
BSL	Biosafety Level	MLA	Mutual Lateral Agreement
BSO	Biological Safety Officer	MoAF	Ministry of Agriculture and Forestry
ВТЕХ	Benzene, toluene, ethylbenzene and xylene	МоСТ	Ministry of Culture and Tourism
BUC	Building Use Class	MoEUCC	Ministry of Environment, Urbanization and Climate Change
BUHASDER	Prevention of Communicable Diseases Association	МоН	Ministry of Health
CAB	Community Advisory Board	MoIT	Ministry of Industry and Technology
CAS	Chemical Abstracts Service	MoLSS	Ministry of Labour and Social Security
CBD	Convention on Biological Diversity	ΜοΤΑΤ	Mobile Hazardous Waste Transport Monitoring System
CBRN	Chemical, Biological, Radiological and Nuclear	ΜοΤΙ	Ministry of Transport and Infrastructure
CCTV	Closed-circuit television	MSDS	Material Safety Data Sheet
CDC	U.S. Centres for Disease Control	МТА	General Directorate of Mineral Research and Exploration
CEN	European Committee for Standardization	NAF	North Anatolian Fault
CFCs	Chlorofluorocarbons	NAFZ	North Anatolian Fault Zone

CFR	Code of Federal Regulations	NAQMN	National Air Quality Monitoring Network
CGMP	Current Good Manufacturing Practice	NBC	National Biosafety Committee
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora	NBCP	National Biosafety Contact Point Person
cGMP	Current Good Manufacturing Practice	NFPA	National Fire Protection Association
CHIA	Cultural Heritage Impact Assessment	NGOs	Non-governmental organizations
CIMER	Turkish Presidential Communication Centre	NIH	U.S. National Institute of Health
CIOMS	Council for International Organizations of Medical Sciences	NOx	Nitrogen Oxides
CITES	Convention on Trade in Endangered Species	NSF	U.S. National Science Foundation
СМС	Chemistry, Manufacturing, and Controls	OECD	The Organisation for Economic Co-operation
CMR	Carcinogenic, Mutagenic or Reproductive Toxins	OHSMP	Occupational Health and Safety Management Plan
CoC	Code of Conduct	OIE	World Organisation for Animal Health
COD	Chemical Oxygen Demand	OLAW	Office of Laboratory Animal Welfare
CWA	CEN Workshop Agreement	OPA	ortho-phthalaldehyde
3-D	3-Dimensional	OSHA	Occupational Safety and Health Administration
dB	Decibels	ÖSYM	Student Selection and Placement Centre
DGR	Dangerous Goods Regulations (IATA)	PAPR	Powered Air Purifying Respirator
DIN	German Institute for Standardisation	PAPs	Project Affected Persons
DRM	Design Requirements Manual	PBT	Persistent, Bio-accumulative and Toxic
DSI	General Directorate of State Water Works	PDoEUCC	Provincial Directorate of Environment, Urbanization and Climate Change
Ed	Dynamic Modulus of Elasticity	PGA	Peak Ground Acceleration
EDC	Earthquake Design Class	PID	Project Information Document
EEA	European Environment Agency	PM	Particulate Matter
EEE	Electrical and Electronic Equipment	PMSU	Project Management Support Unit
EGO	Electricity, Gas and Bus Management	PPE	Personal protective equipment
EHD	Infectious Diseases Association	PPP	Public Private Partnership
EHS	Environment, Health and Safety	PTW	Permit to Work
EHSS	Environmental, Health and Safety and Social	PVC	Polyvinyl Chloride
EIA	Environmental Impact Assessment	R&D	Research and Development
EINECS	European Inventory of Existing Commercial Chemical Substances	RAMAQ	Regulation on Assessment and Management of Air Quality
EKMUD	Turkish Infectious Diseases and Clinical Microbiology Specialization Association	RP	Resettlement Plan
EMEP	European Monitoring and Evaluation Programme	RCAPOI	Regulation on the Control of Air Pollution Originating from Industry
EN	European Standard/Norms	RID	European Agreement on the Carriage of Dangerous Goods by Rail
END	EU Environmental Noise Directive	S ₁	1.0 Second Period Spectral Acceleration
ENE	East to Northeast	S _{D1}	1.0 Second Period Design Spectral Acceleration
EPA	U.S. Environmental Protection Agency	S _{DS}	Short Period Design Spectral Acceleration
ERAGEM	Erciyes University Vaccine Research Development Centre	Ss	Short Period Spectral Acceleration

ESCP	Environmental and Social Commitment Plan	SABIM	MoH Communication Centre
ESF	Environmental and Social Framework	SAL	Sterility Assurance Level
ESIA	Environmental and Social Impact Assessment	SBN	Meeting Point at Health
ESMF	Environmental and Social Management Framework	SEA	Strategic Environmental Assessment
ESMP	Environmental and Social Management Plan	SEM/EDXA	Scanning electron microscopy with energy dispersive X-ray analysis
ESMS	Environmental and Social Management System	SEP	Stakeholder Engagement Plan
ESSs	Environmental and Social Standards	SES	Trade Union of Public Employees in Health and Social
EU	European Union	SF	Dilution Factor
EUROVENT	A provider of third-party performance certification programmes for HVAC industry	SEA/SH	Sexual Exploitation and Abuse/Sexual Harassment
F ₁	1.0 Second Period Local Ground Effect Coefficient	SOP	Standard Operational Procedure
Fs	Short Period Local Ground Effect Coefficient	SSI	Social Security Institution
FDA	U.S. Food and Drug Administration	STL	Short-term Limit
FHWA	U.S. Department of Transportation Federal Highway Administration	SWOT	Strengths, weaknesses, opportunities, threats
FRS	U.S. Farmer Registration System	ТВММ	Turkish Grand National Assembly
FTA	Federal Transit Administration	TENMAK	Turkish Energy, Nuclear and Mining Research Authority
G _{max}	Maximum Shear Modulus	TEPAV	Turkish Economic Policy Research Foundation
GBVH	Gender-Based Violence and Harassment	THKD	Turkish Protection of Animals Association
GDP	Gross Domestic Product	Three Rs	Replacement, Reduction, Refinement
GDPH	General Directorate of Public Health	TKN	Total Kjeldahl Nitrogen
GHG	Greenhouse Gas	тмс	Turkish Microbiology Society
GHSA	Global Health Security Agenda	ТММОВ	Union of Chambers of Turkish Engineers and Architects
GIIP	Good International Industry Practices	товв	Union of Chambers and Commodity Exchanges of Turkiye
GLCs	Ground Level Concentrations	ТРН	Total Petroleum Hydrocarbons
GLP	Good Laboratory Practice	ТРНА	Turkish Public Health Agency
GM	Grievance Mechanism	TPMDA	Turkish Pharmaceutical and Medical Devices Agency
GMOs	Genetically Modified Organisms	TRY	Turkish Lira
GMP	Good Manufacturing Practice	TS	Turkish Standards
GMT	Good microbiological techniques	TSKB	Turkish Industrial Development Bank
GPC	Global Protocol for Community-Scale Greenhouse Gas Emissions Inventories	TUBITAK	The Scientific and Technological Research Council of Turkiye
HADMEK	Central Ethics Committee for Animal Experiments	TUÇEV	Environmental Protection Foundation
HADYEK	Local Ethics Committee for Animal Experiments	TURKAK	Turkish Accreditation Institution
HASUDER	Public Health Specialist Association	TUSEB	Health Institutes of Turkiye
ΗΑΥΤΑΡ	Animal Right's Federation	UFAW	Universities Federation for Animal Welfare

HAZOP	Hazard and Operability Studies	UN	United Nations
HCF	Health Care Facility	UNECE	United Nations Economic Commission for Europe
HEPA	High efficiency particulate air [filter]	UNEP-GEF	United Nations Environment Program, the Global Environment Facility
HFCs	Hydrofluorocarbons	UNESCO	United Nations Educational, Scientific, and Cultural Organisation
HIDER	Turkish Hospital Infections and Control Association	UNFCCC	United Nations Framework Convention on Climate Change
HR	Human Resources	UPS	Uninterruptible power supply
HVAC	Heating, ventilation and air conditioning	USDA	United States Department of Agriculture
HSSSP	Health System Strengthening and Support Project	VOC	Volatile Organic Compounds
HWMS	Healthcare Waste Management System	VRV	Variable Refrigerant Volume
IAEA	International Atomic Energy Agency	WB	World Bank
IAS	Invasive Alien Species	YIDEP	Local Climate Change Action Plan
ΙΑΤΑ	International Air Transport Association	WEF	World Economic Forum
ICAO	International Civil Aviation Organisation	WHA	World Health Assembly
ICC	International Code Council	WHO	World Health Organization
ICLAS	International Council for Laboratory Animal Science	WOAH	World Organization for Animal Health (<i>formerly</i> OIE)
ICOMOS	International Council on Monuments and Sites		

EXECUTIVE SUMMARY

Socio-economic inequalities in Turkiye have been restricting the proper access of the population to healthcare services. In the recent years, the Government of Turkiye has taken some significant steps to reduce inequalities on access to health services and to strengthen the health system. The Health System Strengthening and Support Project (HSSSP), which is financed by the World Bank, is one of these steps. The objectives of the HSSSP include improvement of primary and secondary prevention of selected noncommunicable diseases, increasing the efficiency of hospital management, enhancement of the capacity of the Ministry of Health (MoH) for evidence-based policymaking, and strengthening the Government's capacity to respond to COVID-19. The HSSSP consists of four components, of which the fourth component was included in the second restructuring of the Project, due to the need for expansion of the scope to include prevention, detection and response to the threat posed by COVID-19 and to strengthen the national systems in terms of similar public health preparedness issues. The Component 4 of the HSSSP component finances procurement activities for pharmaceuticals and equipment necessary for COVID-19 treatment, as well as procurement and installation of specific equipment for the sub-projects to be undertaken by the Republic of Türkiye Ministry of Health (MoH). These sub-projects are Istanbul Experimental Research Center (IDEA) and Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory.

This ESIA Report is prepared for the Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory Project (the Project), which aims to achieve enhanced national vaccine research and development capacity, strengthened capacity to combat pandemics/epidemics risks at national or international level, and improved infrastructure in Turkiye for experimental animal production to support vaccine-related studies. The Project site is in Balıkhisar neighbourhood of Akyurt district of Ankara province which is in the Central Anatolian region of Turkiye.

The Project will involve Biosafety Level-3 / Animal Biosafety Level-3 activities and will require necessary infrastructure and measures against associated biosafety risks to ensure safe operation of the Project units, proper management of medical/laboratory wastes, safety in animal testing procedures, as well as personnel health and safety. The MoH will ensure that the Project is designed, constructed and operated in compliance with national legislation and the World Health Organization (WHO) guidelines (including the WHO Laboratory Biosafety Manual, 4th edition) which define specific requirements with respect to ventilation, hygiene and clean room standards. The laboratories will be certified in accordance with WHO guidelines by a third party.

The Project is described in Chapter 2, including the Project alternatives, components, detailed design aspects and Project phases. Legal and Institutional Framework for environmental and social aspects is presented in Chapter 3 including National Legislation, international agreements and conventions and the World Bank's Environmental Social Framework (ESF). Scope and methodology of the ESIA study is detailed in Chapter 4, indicating the Project categorization, scoping process, and the studies to be performed under ESIA.

Stakeholder engagement activities are detailed in Chapter 5, focusing on public consultation procedures, stakeholder identification for the Project, the stakeholder consultation activities and outcomes, and the grievance mechanism. The ESIA consultations aimed to gather baseline data, understand the Project-related concerns and requests of Project Affected Persons (PAPs), reflect opinions of key stakeholders and identify vulnerable groups. The minutes of these consultations are provided in Annex C. Consultations during ESIA preparation involved meetings with district and province level governmental institutions, meetings with non-governmental organizations, interviews with the representatives of neighbouring facilities, business enterprises and factories, socio-economic household surveys with PAPs in the area of influence, mukhtar interviews and focus group interviews with women residing in the neighbourhoods directly affected and/or the closest surroundings. Consultations following the completion

and publishing of the draft final ESIA involved a public consultation meeting as well as further meetings with PAPs including representatives of neighbouring facilities, mukhtars of nearby neighbourhoods and residents of nearby neighbourhoods.

Baseline conditions, impact assessment and proposed mitigation measures of the physical environment related with the Project are detailed in Chapters 6 to 10 of this ESIA Report, including geology and soils, hydrology and hydrogeology, material resources, waste and wastewater, air quality, and noise and vibration. Baseline conditions, impact assessment and proposed mitigation measures of the social environment related with the Project are comprehensively detailed in Chapters 11, 12, 13, 14, 16, and 18 of this ESIA Report, including land use and zoning, traffic, community health, safety and security, labour and working conditions, and cultural heritage. Chapter 15 discusses Animal Welfare, Chapter 17 Biodiversity, Chapter 19 Cumulative Impact Assessment and Chapter 20 cover Environmental and Social Management Plans.

Proposed environmental and social impacts of the Project discussed in the abovementioned sections are summarized as follows:

Geology, Soils and Contamination

Geology, soils and contaminated land impact assessment has been conducted through the use of primary data collected for the Project site prior to and during the ESIA, as well as secondary data based on desktop studies.

No change in the seismology risk of the area is expected as a result of the Project, as none of the Project activities are expected to be of such powerful extent to influence the existing tectonic risks. However, major impacts on the integrity of structures and functionality of the Project (e.g. collapse of the buildings) from earthquake loads might occur during both construction and operation phases following an earthquake event of large magnitude if the design did not consider the resulting earthquake loads. The Project structures will be designed to address such impacts.

The construction of the Project involves extensive groundworks for site clearance and topsoil removal, foundations, drainage and infrastructure, which increases the probability of soil compaction and erosion. Additionally, temporary use of land for construction can lead to adverse impacts on soil quality. The introduction of construction materials and processes can increase the risk of pollution and contamination due to the potential release of contaminants and hazardous materials from accidental leaks and spills. The site clearance activities also have the potential to result in increased runoff during heavy rainfall, leading to the transportation of sediments and potential pollution to nearby watercourses. Necessary mitigation measures will be implemented to prevent or minimize surface runoff.

Overall, the magnitude of impacts on geology and soils is defined as "minor" significance for the Project. Necessary mitigation actions are defined in Chapter 6 for design, construction and operation phases.

• Hydrology and Hydrogeology

The nearest water body to the Project site is the Çubuk Stream which is adjacent to the northwest boundary of the Project site. Baseline water quality in the Çubuk stream was evaluated as part of the ESIA study through surface water quality sampling and analysis.

During the construction phase of the Project, potential effects on groundwaters and surface waters could include temporary localised changes in hydrological and hydrogeological conditions, increased risk of pollution events, changes to landform causing increased erosion and sediment release into the nearby streams, and alteration of drainage paths due to loss of vegetation cover. Compaction of soils and habitat degradation resulting from an increase in off-road vehicle movements is also likely to affect drainage paths. Risk of pollution in the construction phase will be mainly due to the use of construction vehicles, generation of construction waste and potential release of contaminants into the groundwaters and adjacent surface waters. Dust creation, excavations and stockpiles of exposed soil may lead to high suspended solid/sediment loads within surface runoffs and impacts to the Çubuk stream especially during

rainfall events. Potential release of contaminants into the groundwaters and the Çubuk stream may also occur via surface runoff and/or infiltration of spillages and leaks resulting from the use of hazardous materials (such as fuel oil, lubricants, paints) as well as construction materials (such as liquid cement, lime), and the refueling and maintenance of the equipment and vehicles used during construction.

During the operational activities of the Project, failure of the pre-treatment of liquid and industrial (including medical) wastewater generated by the Project would be a significant risk to both the operating wastewater treatment facilities of ASKI and threaten the community health and safety. Therefore, impacts related to wastewater discharges are classified as having major magnitude with low receptor sensitivity (i.e. having some capacity to absorb proposed changes or moderate opportunities for mitigation) and therefore considered as moderate.

Necessary mitigation actions are defined in Chapter 7 for construction and operation phases.

• Material Resources, Waste and Wastewater Management

Potential impacts during the construction phase associated with the use of raw materials include the utilization of potentially finite and/or scarce resources such as building materials and water, as well as handling of hazardous materials which may lead to contamination. No adverse impacts from extraction of raw materials or production of finished materials will be generated directly by the Project. It will be a priority for the contractor to minimize the use of material resources and to consider reuse, recycling, regeneration and energy conservation in the supply and disposal of construction materials.

Wastes will be generated during the construction phase of the Project for which appropriate waste management, minimisation and disposal practices will need to be established. Hazardous waste materials are also expected to be generated during construction. Management of these hazardous wastes will require particular consideration, including final treatment or disposal options.

Laboratories are among the most resource-intensive buildings in terms of materials, water, energy and other resources. During the operational phase, it is anticipated that various hazardous and non-hazardous materials/chemicals will be used in the facility and solid and liquid wastes will be generated as non-hazards and hazardous waste. A Waste Building is planned to be constructed which will be used to store the hazardous and non-hazardous waste (including medical waste) before final transportation and disposal facilities. All wastes generated in operation activities will be transferred from the operation buildings to the Waste Building via underground galleries. Types of wastewater to be generated during operations is domestic wastewater which will be directed to the sewerage system of ASKI (Ankara Water and Sewerage Administration); industrial wastewater which will be pre-treated with sand trap and oil separator prior discharge to sewerage system of ASKI; and laboratory wastewater which will be pre-treated prior to being directed to the sewerage system of ASKI.

Considering the nature and scale of the Project, the magnitude of resource utilization impacts during the operation phase can be estimated as moderate. Therefore, integration of sustainability and resource efficiency practices to the Project will be essential.

Necessary mitigation actions are detailly defined in Chapter 8 for construction and operation phases.

• Air Quality

Air quality impacts which arise during the construction of the Project include: (i) dust arising from on-site construction activities of the project area, stripping of vegetative soil, loading and transporting on trucks – dust generated by construction activities can be mechanically transported off site by wind or resuspension by vehicles, and (ii) emissions associated with on-site plant and vehicles – typically Particulate Matter, Sulphur dioxide (SO₂) and Nitrogen oxides (NO_x). Necessary measures will be taken during the construction phase of the Project for dust suppression.

For the operation phase of the Project, potential air emissions that may occur are due to ventilation shafts, pure natural gas fired steam generator and steam boilers. In pharmaceutical manufacturing

facilities, volatile organic carbon (VOC) emissions may originate from reactor vents, filtration systems in the separation process, valves and various unit equipment. Particulate matter may originate from secondary manufacturing. Low levels of HCl and HF emissions are also probable.

Necessary mitigation actions are defined in Chapter 9 for design, construction and operation phases as well as energy efficiency measures which will be taken into consideration.

Noise and Vibration

Main noise sources during construction activities include use of construction machinery and equipment that will be required for earthworks, structural works and finishing. Increased noise levels during construction activities have the potential to result in negative impacts to the background noise levels creating health risks at nearest sensitive receptors.

The main noise sources during operation will be the equipment related to energy generation and heating and cooling systems including pumps, compressors, steam generators, fans, variable refrigerant volume systems, air handling units and cooling towers. Additionally, there will be vehicle movements within the Project site including loading/unloading and car parking areas.

Necessary mitigation actions are defined in Chapter 10 for construction and operation phases.

• Socio-economy

The key potential socioeconomic impacts identified can be summarized as: (i) national benefits of contribution to national vaccine production and skilled workforce during operation, (ii) local benefits during construction and operation related to creation of employment opportunities, (iii) benefits to the local economy through supply of goods and materials, and (iv) potential negative impacts on surrounding receptors (i.e., agricultural lands, neighbouring business facilities) and vulnerable groups (especially women) during construction activities

Necessary mitigation of adverse impacts and enhancement measures on socio-economy, local employment, livelihood conditions, agricultural labourers, public infrastructure, gender and vulnerable/disadvantaged groups/individuals, and local suppliers are provided in Chapter 11 for construction and operation phases.

• Land Use

No land acquisition or restriction on the land use is foreseen by the MoH regarding the Project. No informal settlers/users of land were identified in the Project site during the ESIA study. The Project is not expected to result in physical and economic displacement impacts on local people residing in and using land in the project's immediate area of influence.

Although the proposed Project area is located in a developed urban setting, the site itself is characterised as a vacant land with soil cover and its existing character will be changed to industrial upon construction of the Project. The Project is expected to generate some adverse impacts on the local natural environment, in particular, the natural floodplain and drainage patterns will be altered through the site area. The required flood mitigation measures to protect the site are detailed in Chapter 7. Adverse impacts on flora and fauna due to the change of the land character and corresponding mitigation measures are discussed in Chapter 17.

Since no impact related to land use is expected during the operation phase of the Project, no mitigation is deemed necessary. However, it is recommended to introduce public grievance mechanism for Project-related land use concerns and grievances.

• Traffic

Additional traffic load on the existing road network will be generated by transportation of materials and equipment/consumables, transport of wastes and excavation materials from the site and daily commute of personnel to and from the Project site during construction. There will also be additional traffic load due to daily commute of construction workers to and from the Project site.

The operational phase traffic will be generated from delivery of materials (including consumables and chemicals), outbound transport of products and wastes, visits by maintenance personnel and site visitors, and daily commute of facility personnel to and from the Project site.

Necessary mitigation actions are defined in Chapter 13 for design, construction and operation phases of the Project.

• Community Health and Safety

Several activities in the construction and operation phases which if not mitigated are likely to cause disturbance to local communities include: project related influx, dust and noise, traffic and transportation, hazardous materials and waste management, air quality and noise, biosafety and biosecurity, and infrastructure safety, life and fire safety and emergency response.

During the operation phase of the Project, a specific emergency programme covering biosafety and biosecurity aspects will be devised for the BSL3/ABSL3 laboratories. A protocol for emergency evacuation will be deployed at all Project components as part of emergency response procedures. A specific focus shall be given to the kindergarten as the users of the kindergarten will be children who are considered to be a high risk group.

General mitigation measures include implementation of Project Environmental and Social Management Plan (ESMP) for construction and operation, establishment of Environmental and Social Management System (ESMS), strict adherence to the design codes and standards, keeping ongoing consultation with communities and stakeholders, and monitoring feedbacks and grievances received from workers, communities and stakeholders.

Necessary mitigation actions are defined in Chapter 14 for design, construction and operation phases of the Project.

• Animal Welfare

From a conservative viewpoint, considering the high sensitivity of receptors and moderate magnitude of adverse impacts, without any mitigation, the significance of animal welfare impacts during the operation phase would be assessed as major. However, a detailed evaluation of each scientific research project will be performed by the local ethics committee to be established, compliance will be ensured, and a set of mitigation measures set out in Chapter 15 will be applied to address these impacts.

Labour and Working Conditions

Potential risks and impacts during construction and operation phases related to labour and working conditions are: unfair treatment, discrimination and unequal opportunity of workers and Sexual Exploitation and Abuse and Sexual Harassment/SEA/SH. Mitigation measures include the Project's Labour Management Procedures (LMP), which include workers' grievance mechanism and information disclosure to the workers on terms and conditions of employment; contractor and subcontractor management (including child and forced labour); overtime working without workers' consent and/or compliance with national and international requirements; awareness raising regarding SEA/SH and mandatory Code of Conduct (CoC), guidelines for; construction camp conditions and management; and biosafety risks. The LMP provides the guideline for Contractors' Labor Management Plans.

Necessary mitigation actions are defined in Chapter 16 for construction and operation phases.

• Biodiversity

During the construction phase of the Project, the potential impacts could include: permanent habitat loss within the Project footprint; noise and light disturbance from construction activities affecting fauna species; the use of herbicides and pesticides in the recreational area to maintain landscaping might have negative impact on the birds; disturbance to riverine habitat (the area between the stream and the borders of the recreational area), due to deposition and storage of excess soil material along the stream and construction of walls and other structures to channel the water; introduction or spread of non-native invasive species accidently,

Indirect impacts on biodiversity are expected to include waste disposal, without directly impacting species' populations and habitats, and when mitigated in line with environmental management plans could be avoided.

During operational phase of the Project, the potential adverse impacts on habitat, flora and fauna may include: increased noise and disturbance to fauna due to Project activities and traffic increase; disturbance affecting fauna from light and human presence from operation activities; low pollution risk arising from accidental spills due to mismanagement of materials and wastes.

Necessary mitigation actions are defined in Chapter 17 for construction and operation phases.

Cultural Heritage

Potential activities to be undertaken during the construction phase of the Project that can have adverse impact on tangible and intangible cultural heritage, are: removal of vegetation and/or dismantling of building(s); installation of fencing; topsoil stripping; excavation of foundations; siting of construction sites and other Project/associated facilities; landscaping/ earth-mounding; waste disposal including excess excavated materials; presence of workforce; and leaks and spills.

The Project has no potential to impact tangible or intangibly cultural assets during the operating phase.

A Cultural Heritage Management Plan and its sub-procedure, namely the Chance Find Procedure, are developed for the Project to avoid, minimize and prevent the effects of the construction phase of the Project on cultural assets. Necessary mitigation actions are defined in Chapter 18.

The cumulative impact assessment (CIA) of the Project is presented referring to a methodological tool in Chapter 19. The CIA included assessment of cumulative impacts which may arise due to three other projects within the defined Project AoI regarding air quality, noise, traffic, waste, and socio-economy. It is expected that the cumulative impacts associated with the developments within the close vicinity of Project area together with the Project are not expected to have a major significance level on the surrounding environment and local communities provided that necessary mitigation measures are taken. Effective communication will be sought by the Project with the other development projects in close vicinity to coordinate the mitigation measures and management strategies being applied to minimise and monitor the impacts on air quality, noise, traffic, and waste management.

The scope, roles and responsibilities for environmental and social management, capacity development and training requirements and monitoring methodologies with requirements for successful implementation of environmental and social management practices are given under Chapter 20. Chapter 20 defines the proposed Environmental and Social Management System (ESMS) for the Project.

Lastly, Chapter 21 defines the environmental and social monitoring and audit mechanism defined for the construction works performed under the Project. The audit mechanism involves description of construction phase organizational capacity, subcontractor and supply chain management, construction supervision, environmental management, occupational health and safety measures, labour and working conditions, community health and safety measures, stakeholder engagement activities. Finally, an environmental and social action plan (ESAP), which represents the mitigation measures that will be taken for preventing the impacts defined in relevant chapters of this report, was presented for the Project construction activities.
1 INTRODUCTION

1.1 Overview

An Environmental and Social Impact Assessment (ESIA) study has been conducted for "Vaccine Production Centre, Experimental Animal Production Centre and Animal Biosafety Level 3 Laboratory (ABSL3)" (the Project), which is proposed to be developed in Akyurt district of Ankara province in the Central Anatolian region of Turkiye. The Project will be developed on land with an approximate area of 79,300 m² including a recreational area. The Project site consists of two parts: the main project complex area (i.e. parcel 1555-4) and the recreational area.

The Project comprises of the following main buildings and units: administrative building, research and development (R&D) building, experimental animals production/test building, vaccine production and storage buildings, waste centre, technical building and security building. Further details of the Project are provided in *Chapter 2: Project Description*.

The Project is one of the two sub-projects to be implemented within the scope of Component 4 of the Health System Strengthening and Support Project (HSSSP) which is financed by the World Bank. The Component 4 of the HSSSP will finance procurement activities for pharmaceuticals and equipment necessary for COVID-19 treatment, as well as procurement and installation of specific equipment for the sub-projects to be undertaken by Ministry of Health (MoH), which are:

- Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory (the Project)
- Istanbul Experimental Research Center (IDEA)¹

The construction of the Project will not be covered under the World Bank Loan and will be financed by utilizing the treasury budget. The construction works of the Project have been initiated in the second quarter of 2022, and are planned to be completed at the end of 2023. The Project site is owned by the treasury. An environmental and social audit of the ongoing construction works against the national legislation and international requirements is presented in *Chapter 21: Environmental and Social Audit of Construction Works*.

As noted above, the MoH is seeking finance from the World Bank (WB) to fund the procurement and installation of Project's equipment and machinery. An Environmental and Social Impact Assessment (ESIA) study is required to be undertaken for granting of the Ioan to the Project. The Project Management Support Unit (PMSU) of the MoH is responsible of coordinating the ESIA activities and Mott MacDonald (the Consultant) has been assigned to undertake the ESIA study. The purpose of this ESIA study is i) to identify and assess the potential environmental and social risks and impacts that the Project may have on the environment and communities within its area of influence, ii) to avoid or where avoidance is not possible, minimise, mitigate or compensate for adverse impacts on the environment and communities, iii) to ensure that affected communities are appropriately engaged on issues that could potentially affect them, and iv) to promote improved social and environmental performance through the effective use of management systems.

¹ Istanbul Experimental Research Center (IDEA) is located in Istanbul and currently running its laboratory activities with a BSL2 level laboratory. New experimental animals and equipment will be procured to upgrade current BSL2 laboratory to ABSL2 level and also to equip a new laboratory at ABSL3 level at IDEA for the purpose of studying the efficiency of vaccines in the experimental animals.

1.2 Purpose of this ESIA

This document represents the draft ESIA report which has been prepared in line with the requirements of the Environmental and Social Standards (ESSs) of the World Bank's Environmental and Social Framework (ESF) which became effective in October 2018, as well as national environmental and social legislation. As part of the ESIA, an Environmental and Social Management Plan (ESMP) is also developed (presented in Annex B) which indicates the way the Project risks and impacts will be mitigated, managed, and monitored during both construction and operation phases of the Project.

The construction of the Project is considered as an associated facility in accordance with the World Bank's ESF. Therefore, the ESIA study has been undertaken in compliance with the requirements of the ESF and Turkish legislation. In addition to the World Bank ESSs, the ESIA considers the World Bank Group's applicable Environment, Health and Safety (EHS) guidelines, World Health Organization (WHO) Laboratory Biosafety Manual (2020) and Biorisk Management: Laboratory Biosecurity Guidance (2006), UN Model Regulations on the Transport of Dangerous Goods, and other relevant international guidelines which are detailed in *Chapter 3: Institutional and Regulatory Framework*.

1.3 ESIA Process

ESIA is a process for systematically predicting and assessing likely risks and impacts of a project on natural and social environments. This is followed by the determination of the significance of those impacts and supporting appropriate mitigation measures to avoid, minimise, mitigate or compensate for adverse impacts relevant to the nature and scale of the project, as well as ultimately providing the factual information that's required by decision makers to determine if those are acceptable in terms of its residual impacts. The key steps of the ESIA process are presented in Figure 1-1. Information about the key steps outlined below is described in *Chapter 4: Scope and Methodology of the ESIA*.



Figure 1-1: ESIA process

1.4 Structure and Content of the ESIA

The ESIA consists of the Executive Summary and the Environmental and Social Impact Assessment Report including its Annexes, as detailed below.

1.4.1 Executive Summary

Project Executive Summary provides a description of the ESIA process and describes the Project along with documentation of the potential impacts and mitigation measures in a way that is easily understood by the general public.

1.4.2 The Main Environmental and Social Impact Assessment Report

The main ESIA report includes the technical chapters which describe the scope of assessment, the regulatory framework, the assessment methodology, baseline conditions, predicted risks and impacts, proposed mitigation, residual impacts as well as cumulative impacts. An environmental and social audit of the ongoing construction works against the national legislation and international requirements is presented in the last chapter of the report. Supporting documents which form a part of the ESIA are presented as annexes due to their size. References to these are provided in the main text of the ESIA report. The structure and content of the ESIA report and Annexes are shown in Table 1-1.

Chapter	The
Chapter 1	Introduction
Chapter 2	Project Description
Chapter 3	Institutional and Regulatory Framework
Chapter 4	Scope and Methodology of the ESIA
Chapter 5	Stakeholder Engagement
Chapter 6	Geology, Soils and Contaminated Land
Chapter 7	Hydrology and Hydrogeology
Chapter 8	Material Resources, Waste and Wastewater Management
Chapter 9	Air Quality
Chapter 10	Noise and Vibration
Chapter 11	Socio-economic Baseline
Chapter 12	Land Use and Zoning
Chapter 13	Traffic Impact
Chapter 14	Community Health, Safety and Security
Chapter 15	Animal Welfare
Chapter 16	Labour and Working Conditions
Chapter 17	Biodiversity
Chapter 18	Cultural Heritage
Chapter 19	Cumulative Impact Assessment
Chapter 20	Environmental and Social Management
Chapter 21	Environmental and Social Audit of Construction Works
Annex A	Official Correspondence Letters
Annex B	Environmental and Social Management Plan (ESMP) and sub-management plans
Annex C	Stakeholder Engagement Activities
Annex D	Project Description Supporting Information
Annex E	Technical Supporting Information
Annex F	Template for Biosafety Manual Outline
Annex G	Questionnaires Used During Stakeholder Interviews in June 2022
Annex H	Stakeholder Engagement Plan
Annex I	Title Deed

Table 1-1: Report Structure

Title

Chaptor

Chapter	Title
Annex J	Laboratory/Facility Commissioning

1.4.3 Environmental and Social Management Plan

An Environmental and Social Management Plan (ESMP), together with its sub-management plans, is annexed in this ESIA report and describes the environmental and social mitigation and monitoring measures, the criteria for their successful implementation and the relevant timeframes during the preconstruction, construction and operation of the Project. The ESMP is a living document that needs to be reviewed regularly and updated as required to ensure reflecting any changes in the Project implementation.

1.5 Stakeholder Engagement

Stakeholder engagement activities were undertaken starting from the scoping stage of the ESIA study to ensure that the views and concerns of the Project stakeholders are considered and addressed within the scope of the ESIA. A Stakeholder Engagement Plan (SEP)² was developed to provide a plan for how public disclosure, consultation and communication will be conducted systematically during the ESIA process and throughout the lifetime of the Project. The stakeholder engagement approach and an overview of the consultation activities undertaken and planned for pre-construction, construction and operational phases of the Project are summarized in *Chapter 5: Stakeholder Engagement* of this report.

1.6 Limitations

The available Project information and documentation which has been used by the ESIA team as a basis for assessment were limited during the ESIA studies as the design process for the Project was still evolving. Additionally, a detailed construction timetable for Phase II of the Project has not yet been disclosed and therefore the timing and sequencing of works is as yet unknown and would be determined at later stages. However, it is estimated that the Phase I construction works are to be finalized in March 2024, and the Phase II construction works are expected to be initiated in 2025. It is anticipated that the operation phase will be initiated in year 2027. Any limitations and uncertainties associated with impact prediction or the sensitivity of receptors due to the absence of data are explicitly stated in relevant chapters of this report. Where applicable, the ESIA makes commitments concerning measures that should be put in place with monitoring and/or environmental or social management plans to deal with such uncertainties.

² The SEP of the Project is provided in Annex H of the ESIA report.

2 PROJECT DESCRIPTION

2.1 Background

The World Bank assists governments in formulating a preparedness plan to provide the highest level of medical care, maintain primary healthcare, and minimize risks to both staff and patients. Socio-economic inequalities in Turkiye have been restricting the proper access of the population to healthcare services. In the recent years, the Government of Turkiye has taken some significant steps to reduce unequal access to health services and to strengthen the health system. The Health System Strengthening and Support Project (HSSSP), which is financed by the World Bank, is one of these steps.

The objectives of the HSSSP include improvement of primary and secondary prevention of selected noncommunicable diseases, increasing the efficiency of hospital management, enhancement of the capacity of the Ministry of Health (MoH) for evidence-based policymaking, and strengthening the Government's capacity to respond to COVID-19. The HSSSP consists of four components:

- Component 1: Primary and Secondary Prevention
- Component 2: Increasing the Efficiency of Public Hospital Management and Operations
- Component 3: Improving the Effectiveness of Overall Health Sector Administration
- Component 4: Strengthening the Capacity of MoH to respond to COVID-19

Component 4 was included in the HSSSP in the second restructuring, due to the need for expansion of the scope to include prevention, detection and response to the threat posed by COVID-19 and to strengthen the national systems in terms of similar public health preparedness issues. The Component 4 of the HSSSP component will finance procurement activities for pharmaceuticals and equipment necessary for COVID-19 treatment, as well as procurement and installation of specific equipment for the sub-projects to be undertaken by MoH, which are:

- Ankara Akyurt Vaccine Production Center, Experimental Animal Production Center and ABSL3 Level Laboratory (the Project)
- Istanbul Experimental Research Center (IDEA)³

The Component 4 of the HSSSP will also finance recruitment of individual consultants and Biosafety Level 2, 3 and 4 training activities of the vaccine research and production personnel.

The HSSSP will be complemented by a new construction in Ankara. The construction will not be covered under the World Bank Loan and will be financed by utilizing the treasury budget. Hence, it is considered as an associated facility in accordance with the World Bank's Environmental and Social Framework (ESF). Therefore, the environmental and social risks and impacts of the construction and operation of the Project as per the provisions of the ESF and Turkish legislation are covered in this ESIA report.

The main objectives of the Project include enhancing the national vaccine research and development capacity, strengthening the capacity to combat pandemics/epidemics risks at national or international level, and improving the infrastructure in Turkiye for experimental animal production to support vaccine-related studies.

³ Istanbul Experimental Research Center (IDEA) is located in Istanbul and currently running its laboratory activities with a BSL2 level laboratory. New experimental animals and equipment will be procured to upgrade current BSL2 laboratory to ABSL2 level and also to equip a new laboratory at ABSL3 level at IDEA for the purpose of studying the efficiency of vaccines in the experimental animals.

2.2 Project Location

The Project site is located in Balıkhisar neighbourhood of Akyurt district of Ankara province which is in the Central Anatolian region of Turkiye and has a total surface area of approximately 79,331 sq.m⁴. Total construction footprint area is 21,446.35 sq.m⁵. The Project site consists of two land plots: the main project complex area (i.e. parcel 1555-4) and recreational area. The site located is in an urban setting, surrounded by factories and commercial enterprises as explained in *Chapter 12: Land Use and Zoning* in detail.

The location of the Project site and its parcel division are shown in

Figure **2-1** and Figure 2-2, respectively.



Figure 2-1: Project location

⁴ Total surface area of the Project site is retrieved from the Draft Zoning Plan Amendment Explanation Report for Ankara Akyurt Balıkhisar Neighborhood parcel 1555-4 and its surrounding (2022) by Özok Planlama İmar Mühendislik Ltd. Şti.

⁵ The construction footprint areas are retrieved from the Project document presenting building layouts/details and floor plans prepared by Mesart Mimarlık ve İnşaat A.Ş.



Figure 2-2: Project site and its parcel division

Parcel 1555-4 has the status of registered land and is owned by the treasury since more than five years and allocated to the MoH (please see Annex I for the title deed of this parcel). The parcel where recreational area is planned to be developed is unregistered land. As reported by the representatives of MoH, necessary applications have been made by the Ministry of Environment, Urbanization and Climate Change (MoEUCC) regarding the merge of the two adjacent parcels. The MoH representatives stated in November 2023 that the land allocation process is still ongoing. It is anticipated that the zoning plans will be finalized before the initialization of Phase II construction works. Subsequently, the title deed registration process will begin and the merged parcels, on which the Project is planned to be developed, will be assigned a new name. The process is expected to take approximately two or three months. The works on the parcels will be carried out within the scope of the Phase II construction works. Therefore, no delay is foreseen in the Project schedule.

The parcel adjacent to the Project site to the southeast, which has been allocated to General Directorate of Public Health (GDPH) of MoH, is currently occupied by a vaccine and pharmaceuticals storage warehouse. The warehouse belongs to and is operated by the GDPH of the MoH. The facility also operates a warehouse building that is located on the Project site (i.e. on parcel 1555-4) currently used for storage of vaccines. Neighbouring pharmaceutical facilities (i.e. Türk İlaç ve Serum Sanayi AŞ, TTS Türktıpsan AŞ) as well as the MoH have the opportunity to store vaccines in the warehouse. This structure will be demolished, and the site will be cleared prior to start of the construction of the Project. No infrastructure and/or upper structure is present in the lot where recreational area is planned to be developed within the Project site. No informal users or renters on the land on which the Project will be constructed were identified during either site visit conducted in December 2021 and June 2022. The MoH and mukhtar of Balıkhisar also confirmed that there are no informal users or renters on the Project site. A number of photos of the Project site taken during the site visit in December 2021 are given below.



Photo 2-1: Photos from the Project site (Photos were taken in December 2021)

There is an existing unnamed road, crossing through the Project site boundaries from north to south (between parcel 1555-4 and the recreational area), that will be closed once the Project is operational. A new access road (20m wide) is planned to be built outside the Project site boundaries running parallel to the Çubuk stream and put into service, which will be enable access of the public to the neighbouring facilities and agricultural areas. Although road constructions are usually undertaken by municipalities, this new road will reportedly be constructed by MoH within the scope of the Project to enable continued traffic flow around the Project site. The existing road is mostly used by the people (i.e. workers, clients) who would like to access neighbouring facilities, enterprises and agricultural areas. Also, the road is unofficially utilized for test drives by the enterprises and clients of Otonomi (a highway vehicles sales point near the Project site). The users of the road have medium sensitivity regarding the impacts deriving from road closure. The magnitude of impacts will be minor. There is negligible impact expected from the road closure.

2.3 **Project Overview**

Laboratories are classified based on a biocontainment designation system as biosafety level (BSL) 1, 2, 3 and 4 depending on the risk grade of studied biological agents and have varying design features, containment facilities and operational procedures.

- Biosafety Level-1 (BSL1) represents basic level of containment that relies on standard microbiological practices. In these laboratories, no special primary or secondary barriers are recommended, other than a sink for hand washing.
- Biosafety Level-2 (BSL2) represents clinical, diagnostic, teaching and other laboratories in which work is done with broad spectrum of indigenous moderate risk agents. Primary hazards to personnel working with agents relate to the accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Personal protective equipment should be used as appropriate.

Secondary barriers such as hand washing sinks and waste decontamination facilities must be available to reduce potential environmental contamination.

- Biosafety Level-3 (BSL3) represents clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious and potentially lethal infection. More emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community and the environment from exposure to potentially infectious aerosols.
- Biosafety Level-4 (BSL4) represents practices with dangerous and exotic agents that pose a high
 individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which
 there is no available vaccine or therapy. The facility is generally in a separate building or completely
 isolated zone with complex, specialized ventilation requirements and waste management systems to
 prevent release of viable agents to the environment.

The proposed Project will involve BSL3 / ABSL3 level activities and will require necessary infrastructure and measures against associated biosafety risks to ensure safe operation of the Project units, proper management of medical/laboratory wastes, safety in animal testing procedures, as well as personnel health and safety. The MoH will ensure that the Project is designed, constructed and operated in compliance with national legislation and the WHO guidelines (including the WHO Laboratory Biosafety Manual, 4th edition) which define specific requirements with respect to ventilation, hygiene and clean room standards. The laboratories will be certified in accordance with WHO guidelines by a third party.

In Turkiye, a number of BSL2 and BSL3 laboratories are established under the responsibilities of governmental authorities, as well as several universities (such as Ankara University, Erciyes University and Koc University). The Scientific and Technological Research Council of Turkiye (TUBITAK) Marmara Research Centre Genetic Engineering and Biotechnology Institute also operates BSL3 laboratories. In addition to these, there are different biosafety level laboratories working on human and animal health established by private companies (such as Dollvet Biotechnology Inc., Vetal Animal Health Products Inc.). Most of the governmental laboratories in Turkiye are research-based laboratories, while the laboratories owned by private companies are also used for production purposes.

The proposed Project will accomplish the following:

- Conducting R&D studies and pilot/industrial level production of live, inactivated and recombinant vaccines and monoclonal antibodies,
- Design of clean areas and various biosafety level (BSL1-2-3) conditions in accordance with national and international standards, where process development can be conducted for production,
- Establishing bioreactors and laboratory equipment of different scales required for pilot-scale production, providing basis for phase 1,2,3 vaccine testing studies,
- Establishing an experimental animal unit required for in vivo tests of these studies,
- Establishing a structure for operation according to GLP⁶ and GMP⁷ rules, and
- Establishing a centre suitable in line with latest technology and needs, in order to enable universities and private sector carry out educational and R&D studies.

With the facilities that will be built within the Project scope, the MoH will have sufficient capacity to research and produce a wide range of vaccines (including SARS-CoV 2, diphtheria, botulism, tetanus antitoxin, rabies) and related products (i.e., serum/immunoserum, antibody/antigen products). In the R&D facility, in-house and external scientists will be able to conduct research studies in viral and bacterial vaccine development and successful batch-scale scientific studies will be forwarded into pilot-scale production.

⁶ Good Laboratory Practice

⁷ Good Manufacturing Practice

The Project will employ qualified research and production personnel with specific training in facility procedures, handling of equipment and infected animals, and manipulation of pathogenic agents. Personnel working in BSL3/ABSL3 laboratories should be also trained on sample and waste handling/storage as well as management of biosafety risks.

2.4 Current Status of the Planning, Design and Construction

The following key activities are planned as part of the proposed Project:

- Design processes,
- Mobilization,
- Construction works (including earth and infrastructural works, landscaping works, mechanical and electrical works),
- Installation and testing of equipment,
- Certification and commissioning, and
- Operation.

The architectural design of the Project has been completed by Mesart Mimarlık ve İnşaat A.Ş. contracted by the MoH. The detailed design of the Project components is under responsibility of MoH. The detailed design is currently ongoing and has not been finalized during the drafting of this ESIA report. Therefore, the information presented in this chapter and the associated assessments made in the relevant sections of the ESIA report are limited to the information made available to the ESIA team by MoH. If significant changes occur in the planning and design of the Project in the future, these will be further reviewed by MoH and subsequent assessments will be made and necessary mitigation measures identified as necessary.

Construction of the Project has been initiated in the second quarter of 2022 and includes the basic construction works of the Phase I components (please refer to Section 2.6.1 for description of the Phase I and Phase II planning for the Project). An environmental and social audit was performed in 22 December 2022 for assessing the compliance of ongoing basic construction works against the national legislation and international requirements. Detailed information regarding the environmental and social audit has been presented in *Chapter 21: Environmental and Social Audit of Construction Works*. According to the up-to-date information provided by MoH in November 2023, it is understood that Phase I construction works are ongoing, and expected to be finalized in March 2024. It was noted that almost 80% of the Phase I construction works have been completed as of October 2023. Additionally, it is noted by MoH that Phase II construction works are anticipated to start in 2025 while start date of operation is anticipated to be the year 2027.

2.5 Analysis of Alternatives

2.5.1 No Project Alternative

Considering the fact that Turkiye currently lacks the necessary infrastructure for vaccine research and production, the "No Project Alternative" should only consider the forgone benefits to public in terms of increased strength of the health system and of public health preparedness. Benefits are improved research capability, enhanced capacity to combat pandemics/epidemics, infrastructural development with sufficient capacity laboratories and production units allowing development of a wide range of vaccines and related products, which would be not possible in the event of the Project not going ahead.

2.5.2 Alternative Laboratory Project

The MoH initially planned to construct high safety level laboratories (BSL3, BSL4, ABSL3) in Bilkent locality of Ankara province on a land area of 293,482 m². The MoH proposed the project as Turkish Public Health Agency (TPHA) and Turkish Pharmaceutical and Medical Devices Agency (TPMDA) Campus Project (will be named as TPHA and TPMDA Campus Project hereafter). Although the proposed

development involved biotechnology R&D activities, it did not involve vaccine production. The TPHA and TPMDA Campus Project was canceled for the reasons listed below and instead, the Project was proposed to provide vaccine production activities in addition to biosafety level laboratory services:

- The TPHA and TPMDA Campus Project was planned to be developed with the financing model of public private partnership (PPP) investment with a construction period of 3 years and an operation period of 15 years. However, it was concluded that implementation of the PPP model with private sector involvement would constitute risks for a research center of high biosecurity level (BSL4) and that the project could fail.
- After the onset of the Covid-19 pandemic, other possible epidemic possibilities and in response, the need for domestic vaccine research and production arose, therefore the Project was transformed into a vaccine development center.
- The idea of establishing a BSL4 laboratory with a high biosafety level, which is a globally limited practice, was abandoned and it was decided by the MoH to establish a BSL3 laboratory suitable for vaccine production and animal experiments.

2.5.3 Alternative Project Location

Upon cancellation of the TPHA and TPMDA Campus Project, the proposed Project was initially planned to be developed in Mahmatli, Gölbaşı locality of Ankara. The Project location alternatives, Alternative 1-Mahmatli and Alternative 2 – Akyurt (*selected Project location*) are illustrated in Figure 2-3 below.



Figure 2-3: Project location alternatives

Project location alternatives for the proposed development were assessed by MoH in terms of their strength, weakness, opportunities, and threats based on preliminary baseline studies conducted for the site alternatives. A summary of the Project location alternatives considered for the proposed development are provided in Table 2-1.

Alternative Location	Strengths	Weaknesses	Opportunities	Threats	Final Decision
1-Mahmatlı, Gölbaşı	 The land is close to Ankara-Konya Highway and Ankara-Niğde Highway. Therefore, it has a logistically advantageous location. The land is located remotely from city center and other industrial facilities. The Project site is not located within the borders of any protected area. There is no surface water resource near the Project site. 	 There are hills around the land (on 3 sides) and the land stays in the most hollow point in the region. There are no storm water drainage channels in the region to prevent water accumulation and to enable storm water drainage. The groundwater lies between 2 and 4 meters below the ground level at the Project site. The decontamination facility, where liquid wastes from the BSL3 laboratory are treated, will be constructed at 4.5-5 meters below the ground level. The facility is designed as a single block large production area and this cuts off the flow direction of the storm water. There is no double-line power infrastructure to feed the facility neither within and in the close vicinity of the Project site. There is no natural gas infrastructure to feed the facility neither within and in the close vicinity of the Project site. Therefore, the construction of the infrastructure to feed the facility. It must be connected from the closest region. There is no room for expansion in the existing land proposed for the Project. The Project site is surrounded with agricultural lands. Expropriation will be required for any future expansion. 	 Remoteness of the Project site to the settlement areas and industrial facilities is important in terms of public health safety. Since it is treasury land, there is no need for expropriation for the proposed Project site (in Mahmatlı). The Project site is surrounded with agricultural lands and there is room for future expansion. 	 The Project will be constructed on an area where there is no settlement, and this may lead to opening of the area for settlement. The agricultural characteristic of the area will disappear with the establishment of the facility. Storm water is likely to accumulate below the Project site. Risk of groundwater contamination is high; therefore, this will cause cost and schedule overruns. The flow direction of the storm water will be cut off with the establishment of the Project. The construction of the electricity infrastructure will cause cost and schedule overruns. The construction of the natural gas infrastructure will cause cost and schedule overruns. The construction of the water infrastructure will cause cost and schedule overruns. The construction of the water infrastructure will cause cost and schedule overruns. The construction of the water infrastructure will cause cost and schedule overruns. The construction of the storm schedule overruns. The construction of the storm schedule overruns. The construction of the stort is schedule overruns. The construction of the stort is be made to informal users and individuals will create bureaucratic problems. 	No go

Table 2-1: SWOT⁸ analysis considered for location alternatives of the proposed development by MoH

⁸ SWOT stands for strengths, weaknesses, opportunities, threats.

Alternative Location	Strengths	Weaknesses	Opportunities	Threats	Final Decision
		• The proposed Project site is remotely located from pharmaceuticals and medical device factories in Ankara province. This may create challenges in logistics terms.			
		 There are informal users on the proposed Project site (in Mahmatlı) which is a treasury land. There will also be formal and informal users on the potential areas to accommodate the infrastructure facilities that are required to be constructed. This triggers WB ESF ESS5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement, and requires the preparation and implementation of the Resettlement Plan. 			
2-Balıkhisar, Akyurt	 This land is approximately 10 thousand square meters larger than the land proposed in Gölbaşı. There is room for expansion which is important for the proposed Project. The proposed Project site is on a flat area. There is no slope on the land. There is a "GDPH Vaccine and 	 The land is far from the city center. However, there are industrial facilities and auto galleries around the proposed Project site. Çubuk Stream flows along the northwest boundary of the Project site. The nearest point of the main project complex is at an approximate distance of 90 meters to Cubuk Stream 	 Since it is treasury land, there is no need for expropriation for the proposed current Project site. Since the facility will be built in developed area, the development of a rural area (such as the location of the Gölbaşı facility) to construction will be prevented. 	 Since there are industrial facilities and auto dealers around the Project site, extra measures may be required in terms of public health and safety. It will be required to undertake necessary mitigation measures against potential impacts on aquatic habitats and water quality of Çubuk Stream that may occur during both during construction and 	Selected Location
	 Pharmaceuticals Storage Warehouse" in the adjacent parcel to the Project site. The proposed Project site is located in close proximity to Esenboă a airport Ubuk Stream. The area around the project si surrounded by industrial facilit dealers and there is no addition expansion area. 	 The area around the project site is surrounded by industrial facilities and auto dealers and there is no additional expansion area. 	 Since the proposed Project site have access to the existing infrastructure facilities, there is no need for construction of additional infrastructures. 	operational phases of the Project.	
	 In recent years, biotechnology investments have been proposed/developed in the region. Five different factories processing/producing 	•	 It will not be necessary to execute ESS5 or prepare a Resettlement Plan, as there are no formal or informal users on the land. 		
	pharmaceuticals and medical devices have been established within a distance of 7 km in the region, (Vilsan Veteriner İlaç Sanayi, Türk İlaç ve Serum Sanayi AŞ, TTS Türktıpsan AŞ, Türk Plast Sağlık Ürünleri AŞ).		• With the existing vaccine storage warehouse located in the parcel adjacent to the project site, there will be additional storage and distribution possibilities for the products to be produced at the facility, particularly		
	There is a sufficient infrastructure to feed the facility (i.e. double line		during pandemic periods.		

Alternative Location	Strengths	Weaknesses	Opportunities	Threats	Final Decision
	 electricity, storm water, natural gas, water and wastewater infrastructures). Project site is not located within the border of any protected area. There are no formal or informal users on the current treasury land. Parts of the land are only used by the vaccine storage as a temporary scrap storage area. 		 The airport provides a great advantage in terms of international supply of raw materials, and the logistics of domestic and foreign researchers who will use the facility, which are the most important factors for vaccine production. The products produced in the pharmaceutical and medical device factories which are currently present in the region, or likely to be established, will be easily supplied and raw materials will be provided with ease. Since infrastructure facilities are in place, no additional budget or time will be required. 		

Source: Ministry of Health

Presently, the current location is selected by MoH and no site alternatives are officially considered for the Project other than those described above. The selected Project site is considered to be advantageous since it is allocated to the MoH, does not require expropriation and/or resettlement. Advantages of the selected site location also include its closeness to the existing factories processing/producing pharmaceuticals and medical devices (within a distance of 7 km to the north and northeast) and its remoteness from the densely residential populated parts of the Ankara city. Additionally, the Project site is easily accessible by the existing road infrastructure and air transportation due to its proximity to Esenboğa Airport.

2.5.4 Project Technology Alternatives

As noted by the MoH, specific alternatives for units, equipment and layout of the laboratories and pilot-scale production areas will be considered in optimizing the Project, as the design progresses. Consideration of environmental and social implications of each alternative will be incorporated into the consideration of alternatives as the design advances. Specific units and equipment of the Project will be procured and installed through the 'Design and Supply' model, based on the general technical specifications to be issued by MoH (for example, temperature, pressure, humidity, number of air changes, lighting, steam, water and medical gas requirements, etc. for a production unit). Final quantities, qualifications and capacities of such specific units and equipment will be further assessed by MoH based on the technology reviews to be undertaken during the procurement process and will become available at later stages of the Project.

2.5.4.1 Vaccine Production Technologies

A review of available vaccine production technologies can essentially be considered under the headings listed below. Commentary on a number of technologies is provided in Table 2-2 and considered with key advantages and disadvantages.

- Live attenuated virus vaccines: Live attenuated vaccines are traditionally produced by serial passage of disease producing viruses in cultured cells with selection for a weakened replication capability and thus reduced virulence. The virulence of viruses in live-attenuated vaccines is reduced, but the viruses still retain the ability to replicate.
- Whole inactivated virus vaccines: Inactivated vaccines, also called killed vaccines, are produced by first growing bacteria and the virus in a culture medium and then inactivating it by treatment with chemicals, heat or radiation. The viruses in these vaccines cannot replicate and so have no risk of causing infection, even in immunocompromised patients. Although safer than live attenuated vaccines, the immunogenic epitopes of inactivated viruses may be structurally deformed during the inactivation process, which can undermine the protection they may provide.
- Viral vector vaccines: In contrast to conventional whole virus vaccines and protein-based vaccines that directly introduce antigenic proteins to stimulate host immune responses, vector vaccines use non-pathogenic viral vectors to deliver antigen-coding DNA fragments to host cells for expression of the antigen using cellular protein-making machinery. Recombinant vector vaccines use an attenuated virus or bacterium to introduce microbial DNA to cells of the body.
- **Subunit vaccines**: Protein subunit vaccines use fragments of protein from the virus to trigger protective immunity against it. Rather than injecting a whole pathogen to trigger an immune response, subunit vaccines purified subunits which have been specially selected for their ability to stimulate immune cells.
- Viral-like particle vaccines: Virus-like particles (VLPs) are self-assembled viral structural proteins that mimic the conformation of native viruses but lack the viral genome. VLP vaccines represent an evolution of protein subunit vaccinology and may also be regarded as a specific class of subunit vaccines.
- Nucleic acid (DNA and mRNA) vaccines: Similar to viral vector vaccines, nucleic acid vaccines introduce genetic instructions (DNA or mRNA encoding disease-specific antigens) to host cells and utilize the host cells' protein-making machinery to generate immunogens. The in-situ synthesis of these foreign immunogens within the host cells effectively elicits both antibody production and T-

cell induction, which are important parameters of protection. In addition, nucleic acid vaccines can more easily be manufactured on a large scale.

Table 2-2: Vaccine production technology alternatives

Technology	Characteristics	Advantages	Disadvantages	Clinically approved examples
Whole inactivated virus vaccines	Compared with live-attenuated vaccines, whole inactivated virus vaccines are less effective, mainly eliciting the antibody mediated immune response with minimal cell-mediated immune response, and thus usually require multiple doses to boost immunity. In addition, there is an increased risk of allergic reactions due to the presence of large amounts of unrelated structural antigens of microbes. Inactivated vaccines usually do not require refrigeration, and they can be easily stored and transported in a freeze-dried form, which makes them cheap and easily accessible to people in developing countries. Dedicated production areas should be used for the handling of live cells capable of persistence in the manufacturing environment, for pathogenic organisms of Biosafety Risk Group 3 or 4 and/or for sporeforming organisms until the inactivation process is accomplished and verified. For <i>Bacillus anthracis, Clostridium tetani</i> and <i>Clostridium botulinum</i> strictly dedicated facilities should be utilized for each individual product. Where a spore-forming organisms occurs in a facility or suite of facilities only one product should be processed at any one time.	 Safer than live attenuated virus Broad antigenic profile Stable 	 Potential epitope alteration by inactivation process Reduced immune response, requirement for multiple doses Requirement for biosafety facilities Lower purity 	Typhoid, Cholera, Hepatitis A virus, Plague, Rabies, Influenza, Polio
Live attenuated virus vaccines	Live attenuated virus vaccines usually produce strong and long-lasting antibody-mediated (humoral) and cell-mediated immune responses by mimicking natural infection, but extensive safety evaluation is required. Live attenuated vaccines also carry a higher risk than other types of vaccines, including the possibility of reversion to a virulent state and the danger of persistent infection in immunocompromised patients. There is another possibility of interference by related viruses, as is suspected in the case of oral polio vaccine in developing countries. Therefore, biosafety of live attenuated vaccines needs to be carefully evaluated before proceeding to clinical use. Another limitation is that live, attenuated vaccines usually need the cold chain to stay potent, and skilled healthcare workers to handle them.	 Stronger immune response Preservation of native antigen Mimicking natural infection Broad antigenic profile 	 Risk of residual virulence, especially for immune- compromised people Potential risk of disease Requirement for biosafety facilities 	Measles, Mumps, Polio (Sabin), Rota virus, Yellow Fever, Bacillus Calmette
Viral vector vaccines	"Vector" refers to the virus or bacterium used as the carrier. Viral vectors allow simultaneous expression of multiple antigenic determinants while avoiding the safety risks associated with the use of the whole pathogenic virus. DNA viral vectors that have been used in antigenic delivery systems include poxviruses, herpesvirus, and adenovirus, while RNA viral vectors, such as retrovirus and flavivirus, have been studied as well. Viral vectors have the advantages of being capable of inducing both antibody and T-cell-mediated immunity in the absence of an adjuvant, do not require complex purification development, may be able to generate antigens with native conformation, and may be able to deliver more than one gene (e.g., multiple antigens from different parasite life stages that could induce a broad protective immunity). Viral vector vaccines can be broadly divided into two types: nonreplicating and replicating viral vector vaccines. Because viral vector vaccines result in endogenous antigen production, they are more likely to induce both humoral and cellular immune responses. Viral vector vaccines can be developed and produced quickly on a large scale and do not require very low temperatures for transportation and storage. However, pre-existing immunity to the vector can limit the ability of the vector to deliver genetic material to host cells and thus reduce the effectiveness of the vaccine.	 Less infectious Stronger immune response Preservation of native antigen Mimicking natural infection Fast to produce Lower doses/single dose Reusable platform Both cell- and antibody-mediated immunity 	 More complicated manufacturing process Risk of genomic integration Response dampened by pre-existing immunity against vector 	Ebola virus

Technology	Characteristics	Advantages	Disadvantages	Clinically approved examples
	The manufacturing process for viral vector vaccines is more complicated than other approaches, including the optimization of cellular systems and the exclusion of contaminants, which can greatly affect the efficiency of viral vectors. Moreover, recombinant viruses carry the risk of integrating their genome into the human host, so additional biosafety assessment will be required before entering clinical trials. Finally, if the chosen viral vector can infect the general populations, the pre-existing immunity on the viral vector could dampen the induced immune response, which has been seen in adenovirus and measle virus-based vaccines.			
Subunit vaccines	Recombinant protein vaccines: These are protein-based vaccines that contain a viral protein or its segment as the antigen to elicit immune responses. The antigen molecules can be manufactured from the microbe using recombinant DNA technology. This is a well-developed platform and many approved vaccines are in this category. Because it is inherently safe and uses well-established techniques of protein purification, these vaccines comprise the largest category in COVID-19 vaccine development. Similar to inactivated vaccines, protein subunit vaccines elicit mainly antibody-mediated immunity with a weak induction of T-cell response. Adjuvants are usually needed for this type of vaccine to boost the immune response and enhance vaccine efficacy. Conjugate vaccines: Conjugate subunit vaccines bind a pathogen antigen (polysaccharide chain) with a carrier protein that lends additional immunogenicity to the vaccine. Soon after the introduction of conjugate H. influenzae type b vaccines into vaccination programmes, researchers realised that conjugate vaccines not only provided a direct protective effect for vaccinated individuals but they were able to interrupt circulation of the organism through reduction of colonisation, which resulted in herd immunity with protection of nonvaccinated individuals and near elimination of the pathogen in countries where routine vaccines with remarkable safety profiles.	 Safe and well- tolerated especially immuno- compromised patients Cannot revert to virulence Can withstand conditions (e.g. temperature, light exposure, humidity) 	 Lower immunogenicity Requirement of adjuvant or conjugate to increase immunogenicity Often require multiple doses for long-term immunity 	Hepatitis B, Human Papilloma virus, Pertussis, Influenza, Streptococcus pneumoniae, Haemophilus influenzae type b
Viral-like particle (VLP) vaccines	Viral like particles (VLPs) are composed of viral capsid/coat proteins that, when recombinantly expressed from a host cell, can self-assemble into a capsid-like structure in the absence of the viral genome and other non-structural virus proteins. As such, these noninfective particles provide a scaffold onto which multiple copies of an antigen (or epitope) can be chemically coupled or arrayed. This clustering of antigens/epitopes on the VLP surface allows for enhanced cognate activation of B-cells and antibody responses. In manufacturing, a major VLP vaccine development challenge is that fermentation monitoring requires frequent removal of samples, followed by centrifugation, cell disruption and chromatography to partially purify the VLPs. Overall, purification of VLPs could involve several steps of density gradient ultracentrifugation and chromatography. Therefore, large-scale production of VLP vaccines could be capital intensive, which will consequently give rise to expensive vaccines.	 Non-infectious Safe and well- tolerated for immune- compromised individuals Broad antigenic profile No risk of mutation due to lack of genetic material More stable than subunit vaccines 	 Limited immunogenicity Lower purity Complicated manufacturing process 	Hepatitis B virus, Human Papillomavirus
DNA vaccines	DNA vaccines contain genes encoding viral antigenic components that are expressed by plasmid vectors and delivered into cells through electroporation. The platform can also be easily adapted to produce a new vaccine for another antigen. The manufacturing of DNA vaccines is inexpensive, rapid and scalable. A bacterial culture fermenter is used to provide large-scale plasmid DNA. Initial plasmid construction. cell	Safe and well- toleratedFast to produceScalable	 Lower immunogenicity Difficult administration route 	NA

Technology	Characteristics	Advantages	Disadvantages	Clinically approved examples
	 bank preparation, bacterial fermentation and plasmid purification are completed within 2-4 weeks. DNA vaccines are relatively stable at ambient temperatures. Plasmid DNA is obtained by extraction and purification from bacterial cells containing the desired gene. The purification of DNA plasmids is difficult because supercoiled pDNA (the product) is quite similar in size and structure to the contaminating RNA, genomic DNA and open-circular pDNA that are released upon cellular lysis. There are several well-established protocols for obtaining pDNA at bench scale. Following harvest, cells are lysed, followed by filtration or centrifugation, chromatography and organic solvent precipitation. The final purity is adequate for laboratory experiments, but not suitable for therapeutic purposes. Furthermore, some of the methods used at small scale (e.g., alkaline lysis, isopropanol precipitation) are not readily scalable. GMP production of pDNA at preclinical scale is therefore not a solved problem and requires careful planning to develop optimal and economical commercial processes. 	 Highly adaptable to new pathogens Stable at room temperature Native antigen expression 	 Risk of genomic integration May need special delivery devices 	
mRNA Vaccines	The mRNA vaccines are comprised of mRNA carrying the genetic instruction of the protein antigens with the mRNA encapsulated in lipid nanoparticles (LNPs). Upon vaccination, LNP-mRNA is delivered to the cytosol of the host cells and the mRNA is subsequently used as a template for protein antigen synthesis. mRNA is non-infectious, non-integrating, and is degraded by normal cellular processes shortly after injection, decreasing the risk of toxicity and long-term side effects. Intracellular expression of the antigen by mRNA may lead to strong T cell responses typically seen with viral vector-based and DNA vaccines. mRNA vaccines enable delivery of multiple mRNA to the same cell allowing the generation of multi-protein complexes or protein antigens from different pathogens thus creating a single vaccine against several targets. mRNA vaccines are manufactured using chemically defined, consistent processes, regardless of the antigen encoded by the mRNA, and this has the potential to simplify vaccine production, scale up, quality control, and the overall vaccine development timelines. Additionally, since production is based on an in vitro cell-free transcription reaction, safety concerns regarding the presence of cell derived impurities and viral contaminants commonly found in other platforms are minimised. The simplified manufacturing process, which uses the same reaction materials and vessels for any target, allows GMP facilities to switch to a new protein target within a very short period of time, with minimal adaptation to process and formulation. The manufacturing platform includes the upstream processing, which comprises the enzymatic generation of mRNA, and the downstream processing, which includes the unit operations required to purify the mRNA product. The generation of mRNA by in vitro transcription (IVT) at large scale and under current good manufacturing practice conditions is challenging. However, downstream processing together with fill-tofininh, is still the major bottleneck in the mRNA vaccine productio	 Safe and well-tolerated Highly adaptable to new pathogen Native antigen expression Fast to produce No genome integration risk Stimulates strong T cell response Simple formulations 	 Lower immunogenicity Requirement of low temperature storage and transportation Potential risk of RNA- interferon response May need special delivery systems 	COVID-19

References:

- D'Amore, T. and Yang, Y-P. (2019) Advances and Challenges in Vaccine Development and Manufacture. www.bioprocessingintl.com
- Gerson, D.F., Mukherjee, B. and Banerjee, R. (2007) Vaccine Scale-Up and Manufacturing from "AIDS Vaccine Development: Challenges and Opportunities (Edited by: Wayne Koff, Patricia Kahn and Ian D. Gust)", Caister Academic Press, U.K.
- Gallo–Ramirez, L.E., Nikolay, A., Genzel, Y., Reichl, U. (2015) Bioreactor concepts for cell culture-based viral vaccine production. Expert Rev. Vaccines 14(9): 1181–1195.
- Ghattas, M., Dwivedi, G. Lavertu, M., Alameh, M.G. (2021) Vaccine Technologies and Platforms for Infectious diseases: current progress, challenges, and opportunities. Vaccines 9: 1490-1520.
- Ingolotti, M., Kawalekar, O., Shedlock, D. J., Muthumani, K., Weiner, D. B. (2010) DNA vaccines for targeting bacterial infections. Expert Rev. Vaccines 9: 747–763.
- John, S., Yuzhakov, O., Woods, A., Deterling, J., Hassett, K., Shaw, C.A., and Ciaramella, G. (2018) Multi-antigenic human cytomegalovirus mRNA vaccines that elicit potent humoral and cellmediated immunity. Vaccine 36: 1689–1699.
- Josefsberg, J.O and Buckland, B (2012) Vaccine process technology. Biotechnology and Bioengineering 109 (6): 1443-1460.
- Krammer, F. (2020) SARS-CoV-2 vaccines in development. Nature 586: 516-527.
- Mohsen, M. O., Augusto, G., Bachmann, M. F. (2020) The 3Ds in virus-like particle based-vaccines: Design, Delivery and Dynamics. Immunol. Rev. 296: 155–168.
- Lopes, A.G. (2015) Single-use in the biopharmaceutical industry: A review of current technology impact, challenges and limitations. Food and Bioproducts Processing 93: 98-114.
- Pardi, N., Hogan, M. J., Porter, F. W., Weissman, D. (2018) mRNA vaccines a new era in vaccinology. Nat. Rev. Drug Discovery 2018, 17: 261–279.
- Rappuoli, R. Black, S. and Lambert, P.H. New Decade of Vaccines 2: Vaccine discovery and translation of new vaccine technology. Lancet 2011, 378: 360–68
- Rauch, S, Jasny, E, Schmidt, K, E, Petsch, B. (2018) New vaccine technologies to combat outbreak situations. Front Immunol. 9: 1963.
- Rosa, S.R., Prazeres, D.M.F., Azevedo, A.M., Marques, M.P.C. (2021) mRNA vaccines manufacturing: Challenges and bottlenecks. Vaccine 39: 2190–2200.
- Slack, S.L. (2022) A PhD Thesis on "A high-throughput approach to vaccine bioprocess development", University College London.
- Tariq, H., Batool, S., Asif, S., Ali, M., Abbasi, B.H. (2022) Virus-like particles: revolutionary platforms for developing vaccines against emerging infectious diseases. Frontiers in Microbiology 12.
- Ura, T., Okuda, K., Shimada, M. (2014) Developments in viral vector-based vaccines. Vaccines 2: 624-641.
- Yadav, D.K., Yadav, N., Khurana, S.M.P. (2014) Vaccines: Present Status and Applications, Chapter 26. Animal Biotechnology, 491-508.
- Xenopoulos, A. and Pattnaik, P. (2014) Production and purification of plasmid DNA vaccines: is there scope for further innovation? Expert Rev. Vaccines, 13: 1537–51.

2.5.4.2 Bioreactors

The choices of the vaccine type and the production process, including bioreactor type and operation mode, are crucial for successful manufacturing of human vaccines. These factors have a significant impact on vaccine quality, as well as on manufacturing capacity, production volumes, process times and product costs. Based on the electron acceptor, the bioreactor design may be for aerobic, anaerobic or microaerobic conditions. In aerobic processes, the methods of providing oxygen have resulted in mechanically agitated bioreactors, airlift columns, bubble columns and membrane reactors.

In traditional vaccine manufacturing, bioreactors (including all production vessels, transfer piping and process control instrumentation) are typically made from stainless steel, allowing them to be continually reused. This, however, increases production time, resource consumption (e.g., water, energy) and operational costs due to the necessary cleaning, sterilising and assembly which occurs between each experiment. Advances over the past decades have made it possible to replace many of stainless-steel systems with single use plastic and polymer film systems. Single-use bioreactor bags are used for e.g. cell culture and fermentation, while single-use assemblies consist of plastic components that are used in diverse bioprocessing steps (e.g. tubing). Single-use bioreactors are usually a cheaper investment and are available in lower volumes, enabling manufacturers to test different cell lines and growth conditions quickly and at a lower cost to optimize vaccine production. Importantly, single-use bioreactors can minimize potential cross-contamination.

Choosing between stainless and these single use technologies (SUT) is a crucial decision for a new producer. In general, the number of batches of vaccine that a particular facility produces determines whether stainless steel or SUT is preferable. A small number of annual batches is better suited to SUT, while for large numbers, stainless steel is more cost effective.

Table 2-3 below identifies key advantages and disadvantages of stainless steel and SUT systems in vaccine production.

Bioreactor type	Advantages	Disadvantages
Stainless Steel Systems	 Customized designs Proven technology Less dependence on supplier No bags, no managing stocks Lower leakage risk during culture Good control of pO2 and pH Geometry of vessel and stirrer blades chosen by users Suitable for any bioreactor volume 	 Long delivery times High capital investment More qualification and validation time (cleaning and sterilization in place, CIP/SIP¹⁰) Large footprint Higher energy costs Time-consuming batch turn-over Higher maintenance costs Higher contamination risk Higher direct and indirect man-hours Higher-level bioreactor operators Higher operator risk: e.g., hot pipes, pressure
Single Use Technology (SUT)	 Standardized or Customized designs (standard units are quicker and easier to set up than equivalent stainless-steel facilities) Decreased risk of cross-contamination and increased assurance of sterility Lower capital investment 	 Relatively young technology Total dependence on bag supplier Expensive bags; managing stocks and supply Higher leakage risk during culture Bag geometry and stirrer design may influence the process

Table 2-3: Bioreactor alternatives: key advantages/disadvantages⁹

¹⁰ CIP: Clean-in-Place, SIP: Steam-in-Place

⁹ Compiled from Bou, J.R. and Wilde, D.D. Comparing Multiuse and Single-Use Bioreactors (MUBs vs SUBs). BioProcess International, 2014, 12(4).

Bioreactor type	Advantages	Disadvantages
	Short delivery times	Limited volumes (i.e. 2000 L)
	 Less qualification and validation time 	 Optical sensors, sometimes not fully accurate
	 No CIP/SIP processes needed 	
	 Flexibility (facility capacity can be quickly expanded by adding additional units) 	
	Small footprint	
	Lower energy costs	
	Quick-change, short non-operation stops	
	Lower maintenance costs	
	Lower man-hours	
	 Lower-level bioreactor operators 	
	Lower operator risks	

Presently, it is known that a significant challenge faced by the decision makers in the biopharmaceutical industry is selecting between traditional (stainless-steel) and single-use manufacturing processes. Although there are established decision-support tools used for determining the costs and efficiencies of traditional and single-use manufacturing processes, the environmental burden of these processes remain unclear, and despite some preliminary work, this has not been the subject of significant and precise engineering analysis. The environmental impacts of manufacturing alternatives can be quantified using a life cycle assessment (LCA) methodology which is based upon a comprehensive analysis estimating the cumulative environmental impacts of the process, product or activity.

A detailed life cycle assessment was performed by Pietrzykowski et al. (2013) for comparing the singleuse and conventional stainless-steel modes of operation¹¹. According to Lalor, Fitzpatrick, Sage and Byrne (2019), the result of this analysis indicated reduced environmental burden from the single-use process across a variety of operating scales due to the reduced need for water and steam utilities associated with the elimination of cleaning and sterilisation procedures, which outweighed the increased solid waste disposal requirements associated with the increased use of single-use technologies¹².

Another LCA study¹³ focusing specifically on single-use technologies (SUT) have shown that the largest contribution to the life cycle environmental impact for SUT was found to be the electricity used to operate the facility. Another interesting result within the study is that the contribution to the environmental footprint from end-of-life due to the use of plastic SUT was extremely small when comparing with other impact sources. According to Budzinski et al. (2022), the majority of the electricity use comes from powering the cleanroom infrastructure of the facility. In reducing electricity consumption per kg of product output, it is significant to consider both the cleanroom classifications used, as well as "time in plant". It was also suggested within the study that if fully closed processing technology can be deployed, a reduction in cleanroom classifications can be rationalized, greatly reducing air change rates and their associated energy consumption. Striving for shorter processing times or less time in-plant will not only reduce the process electricity demand but more importantly will reduce the cleanroom infrastructure contribution. The establishment of plant utilization targets and the number of manufacturing shifts are considered as key characteristics to be managed.

Furthermore, the environmental sustainability of the facility does not only depend on the types of processes used during production, there will also be other areas of activity that might reduce its

¹¹ Pietrzykowski, M., Flanagan, W., Pizzi, V., Brown, A., Sinclair, A., Monge, M., 2013. An environmental life cycle assessment comparison of single-use and conventional process technology for the production of monoclonal antibodies. J. Clean. Prod. 41, 150–162. https://doi.org/10.1016/j.jclepro.2012.09.048.

¹² Lalor, F., Fitzpatrick, J., Sage, C., Byrne, E., 2019. Sustainability in the biopharmaceutical industry: Seeking a holistic perspective. Biotechnology Advances, 37, 698-707. <u>https://doi.org/10.1016/j.biotechadv.2019.03.015</u>

¹³ Budzinski, K., Constable, D., D'Aquila, D., Smith, P., Madabhushi, S. D., Whiting, A., Costolloe, T., & Collins, M., 2022. Streamlined life cycle assessment of single use technologies in biopharmaceutical manufacture. New BITECHNOLOGY, 68, 23-86. <u>https://doi.org/10.1016/j.nbt.2022.01.002</u>

environmental burdens. These activities include, but not limited to: facility's structural design, materials, active control, services, and geographical setting; the production format and equipment selection; materials sourcing, packaging, transport; and waste handling.

2.5.4.3 Facility Units and Layouts

In deciding the appropriate standard for the facilities, it is necessary to consider the types of operations to be carried out in each area. Most cell culture processes can be sub-divided into the following phases:

- Preparation of master and working cell banks
- Preparation of inoculants
- Support functions, e.g. preparation of media and reagents
- Incubation/fermentation
- Downstream processing, e.g. harvesting, extraction, purification
- Formulation of the dosage form
- Sterile filtration, filling, freeze drying
- Inspection, labelling and packaging

Preparation of cell banks, inoculants, sterile filtration, filling and freeze drying should be carried out in aseptic facilities with the appropriate level of containment. Fermentation should be carried out in closed systems. Support functions, down-stream processing and formulation of the dosage form should be carried out in clean facilities, with the appropriate level of containment at the harvesting stage.

Types of manufacturing layouts typically include the following:

- Train: A "train" of linear clusters of suites with a common corridor for each specific process operation. This allows processing to start in the lead/upstream suite (e.g., bioreactor) and progress down the train (e.g., chromatography operations). This model is well-suited for several types of larger-scale commercial applications, especially single-product facilities that deal with a non-potent compound.
- Stack: A "stack" of several larger, parallel multiple-purpose suites with a clean supply corridor on one side and a dirty return corridor on the opposite side. This configuration isolates each suite via airlock systems, so any one major process is performed independently and is contained.
- Flexible: As the number of licenced vaccines and technologies has increased, it has become clear that more flexibility and in some cases decentralisation in manufacture is advantageous to reduce cost, increase supply and provide additional capacity to cope with situations such as pandemics. Flexible manufacturing layouts have emerged in recent years which make use of single-use, disposable technologies for greater adaptability. Specific equipment units for the vaccine being manufactured are moved in place as required. When a change of product is required, these units are reconfigured or replaced. This is ideal for efficiency in the use of technicians and scientists as they can monitor several operations.

2.6 **Project Components**

2.6.1 Overview

The Project site consists of two land plots: the main project complex area (i.e. parcel 1555-4) and recreational area (shown in Figure 2-4). The main project complex area consists of the following buildings and units:

- Administrative Building (Depots, security, cafeteria, administrative office, guest house),
- Research and Development (R&D) Building (including a Biobank),
- Experimental Animals Production/Test Building,

- Vaccine Production and Storage Buildings consisting of three blocks (including bacterial and viral pilotscale production areas and quality control laboratories),
- Loading/Unloading Area (located north of the production buildings),
- Waste Centre,
- Technical Building,
- Security Building, and
- Observation Towers.

In addition to the units listed above, a recreational area is planned to be developed within the Project site. The recreational area will establish a buffer zone between Çubuk stream and the main project complex. A kindergarten, which will be used by only operational staff, is planned to be built within the recreational area. Additionally, a totem statue will be positioned within the recreational area close to the entrance. Remaining portions of the recreational area will consist of landscaping and rest areas.

The layout, showing the locations of the units, and 3-D visualisation of the Project site are illustrated in Figure 2-4 and Figure 2-5, respectively.



Figure 2-4: Project Layout

The Project buildings will have a total footprint area of 21,446 m². All buildings within the main project complex area (including the Waste Building and the Technical Building) are designed to be connected to each other through galleries (4x4 m wide) to be built on the basement floor which will ease and provide safe operational management. All buildings to be constructed within the scope of the Project are planned

to be equipped with rooftop solar energy panels for energy production. Project components to be constructed and their footprint/operational areas are presented in Table 2-4.

Table 2-4: Project components and footprint/operational areas¹⁴

Building No	Building Name	Footprint area (m²)	Total operational area (m ²)
1	Administrative Building (Basement + Ground Floor + 3 floors + Attic)	2142.00	10,714.09
2	Glass Cafeteria (Ground floor)	206.92	206.92
3	Research and Development Building (Basement + Ground Floor+ 2 floors + Attic)	1941.95	5968.63
-	Parking Garage (Basement)	171.72	171.72
4	Experimental Animals Production/Test Building (Basement + Ground Floor+ 2 floors + Attic)	1842.98	7231.40
5	Vaccine Production and Storage Buildings (Consisting of three blocks) (Basement + Ground Floor+ 1 floor + Attic)	11,262.53	31,272.97
6	Technical Building (Basement + Ground Floor + Attic)	1676.25	3366.90
7	Waste Building (Basement + Ground Floor + Attic)	617.76	1262.06
8	Kindergarden (Ground floor)	502.83	502.83
9	Security Building (Ground floor)	160.97	160.97
-	Kindergarden Security Building (Ground floor)	8.75	8.75
-	Observation Towers (x5)	138.5	138.5
-	Galleries	980.11	980.11
-	TOTAL	21,446.35	61,985.85

¹⁴ The construction footprint areas are retrieved from Project document presenting layouts, building details, surface areas and floor plans prepared by Mesart Mimarlık ve İnşaat A.Ş.



Figure 2-5: 3-D visual of the Project components

In order to ensure elimination of biosafety risks in case of an earthquake event, the architectural design of the Project requires seismic isolation method to be applied to the three blocks to be built as Vaccine Production and Storage Buildings. The Administrative Building, R&D Building and Experimental Animals Production/Test Building are designed to have raft foundations that will also be protective against seismic risks.

An open visitor parking area for ten cars will be available outside the site entrance near the Security Building. There will also be open car parking areas at the main project complex area (i.e. parcel 1555-4) and recreational area dedicated for both employees and visitors. Open car parking areas dedicated for employees will be available at five locations (with an estimated total capacity of 131 cars) in the main project complex area. A total of 99 cars will be able to park in the recreational area (parking area for ten cars in front of the kindergarten and parking area for 89 cars dedicated for visitors). Additionally, there will be a basement level parking garage with a total footprint of 171.72 m². There will be also a bike path included in the design of the recreational area.

A landscaping study has been undertaken by the MoH including proposed number of trees and shrubs to be planted, amount of vegetative soil to be laid down, as well as the type and details related with plant species. It is proposed that total of 2005 trees (including leaved and coniferous trees), 1510 shrubs, 6950 seasonal plants and 123 volubilate plants will be planted within the Project site (including parcel 1555-4 and recreational area) forming a total planted area of approximately 20,000 m².

The whole Project site will be fenced with security walls fitted with razor wires and closed-circuit television system (CCTV) cameras. The site will consist of two phases (zones) with different security levels; (i) Phase I includes the Administrative, R&D and Experimental Animals Production/Test Buildings and (ii) Phase II includes the Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area. Phase II will be protected at a higher security level and there will be a secondary security control for entrance to Phase II from Phase I by both vehicles and pedestrians.

There will be two different entrance-exit points dedicated for cars/pedestrians and trucks which will provide safe access to the campus. Additionally, different entrance-exit doors in the buildings for services, transfer animals and materials are allocated in the design of Phase I.

2.6.2 Administrative Building

The administrative building will have a basement floor, ground floor and three floors. The basement floor of the administrative building will consist of technical areas, parking garage, laundry rooms and kitchen. The ground floor will have dining hall, cafeteria, meeting rooms, service areas and offices. The 1st and 2nd floors will comprise of offices, meeting rooms and service areas. The 3rd floor will have temporary guest accommodation rooms (approximately 17 rooms) for academic visitors to facilitate them carry out laboratory research 24/7. In the attic, there will be a maintenance room and rooftop solar energy panels for energy production. The 3-D visual of the administrative building is shown in Figure 2-6. Floor plans of the administrative building are presented in Annex D.



Figure 2-6: 3-D view of the Administrative Building

The Project aims to bring teams and people together from both private sector and academies who are developing technologies. As mentioned above, the Administrative Building will have meeting rooms which are dedicated for visitors, facilitated with smooth and easy access to/from social areas, dining halls etc. Necessary plans are considered in the design stage to provide separate access for personnel and visitors.

Moreover, there will be a glass cafeteria positioned between the administrative building and the R&D building. The glass cafeteria can be directly reached from the ground floor of the administrative building.

2.6.3 Research and Development (R&D) Building

The R&D building will have a basement floor, ground floor and two floors. The basement floor will consist of technical areas (UPS room, storage room, maintenance room, etc.) and parking garage, and the entrance in the basement floor will be also used as service entrance. The ground floor will have registration and admissions unit and laboratory area. The 1st and 2nd floors will comprise of offices, laboratory areas, wet and technical volumes. There will also be a biobank unit on the 2nd floor.

Similar to the administrative building, there will be a maintenance room, where technical units will be placed, and rooftop solar energy panels for energy production in the attic. Floor plans of the R&D building are presented in Annex D.

2.6.4 Experimental Animals Production/Test Building

The building will have a basement floor, ground floor and two floors. The basement floor will consist of laboratory and wet volumes as well as transfer and asepsis areas for experimental animals coming to the facility. The ground floor will have laboratory area, wet volumes and offices. The 1st and 2nd floors will comprise of laboratory area, maintenance room and wet volumes. Similar to the administrative and R&D buildings, there will be a maintenance room, where technical units to be placed, and rooftop solar energy panels for energy production in the attic.

Floor plans of the building are presented in Annex D. The 3-D visual of the R&D and Experimental Animals Production/Test building is shown in Figure 2-7.



Figure 2-7: 3-D view of the R&D and Experimental Animals Production/Test buildings

2.6.5 Vaccine Production and Storage Building

The Vaccine Production and Storage Building will contain bacterial and viral pilot-scale production areas and will have a basement floor, ground floor and a first floor. The building will consist of three blocks:

- Raw materials and production warehouse
- Filling and inactive vaccines filling areas
- Pilot production and single-use production area

Seismic isolation method will be applied to the three blocks to be built as production buildings considering earthquake risks. The basement floor of the three blocks will comprise of technical volumes, storage rooms, liquid waste decontamination rooms (300 m²) as well as galleries which connect all blocks to ease and provide safe operational management. Moreover, there will be a shelter in the basement floor of the raw materials and production warehouse with an approximate area of 2500 m². In the ground floors of the blocks, there will be warehouses, filling and production areas including laboratories, chemical rooms, cold storage rooms whereas the 1st floor of the blocks will have offices, laboratories, air-conditioner center and warehouses.

Similar to all other buildings positioned in the main project complex area, there will be a maintenance room, where technical volumes to be placed, and rooftop solar energy panels for energy production in the attic.

Floor plans of the Vaccine Production and Storage Buildings are presented in Annex D. The 3-D visual of the Vaccine Production and Storage Buildings is shown in Figure 2-8.



Figure 2-8: 3-D view of the Vaccine Production and Storage Building

In the Vaccine Production and Storage Building, a sample acceptance unit will be established in the quality control laboratories. Sample flow within the quality control laboratories will be monitored with a specialized software program and the results will be published in the system after the relevant tests on the registered samples are performed.

2.6.6 Technical Building

The Technical building will have a basement floor and a ground floor. On the basement floor, there will be two fire storage depots (300 m³ each) and potable water storage depot (300 m³), fuel tank area, electrical storage room, automation room, preliminary treatment system as well as mechanical area. The heat and energy need of all blocks will be met and fed through the galleries from Technical Building. On the ground floor, there will be compressor room, purified water treatment and steam production room, boiler room, generator room, mechanical and electrical workshops, UPS room, technical office, accumulator room, transformer room. There will be cooling towers on the rooftop. Floor plans of the technical building are presented in Annex D.

2.6.7 Waste Building

The waste building will have a basement floor, ground floor as well as attic. On the basement floor, there will be rainwater storage depot (900 m³) and areas reserved for pumps. On the ground floor, there will be two waste storage rooms (cold rooms) and two reserved storage areas. There will be separate rooms/compartments allocated for domestic and medical wastes.

Similar to all other buildings positioned in the main project complex area, there will be rooftop solar energy panels for energy production in the attic. Floor plans of the waste center are presented in Annex D. The 3-D visual of the waste building is shown in Figure 2-9.



Figure 2-9: 3-D view of the Waste Building

2.6.8 Recreational Area and Kindergarten

A kindergarten (having only ground floor) with open and closed playgrounds is planned to be built within the recreational area. The closed playground is designed with skylight systems to bring the natural light into the building. The 3-D visual of the kindergarten and its close surrounding are illustrated in Figure 2-10.



Figure 2-10: 3-D view of the Kindergarden

2.6.9 Security Building and Observation Towers

The main security building will comprise of ground floor and have two sections; (i) pray room and information desk room and (ii) personnel and security control. There will be rooftop solar energy panels for energy production in the attic of the security building.

Five observation points have been positioned at the Project site (both the Project main complex area and recreational area) to ensure the security of the Project during the operation period (see Figure 2-6). Cross sectional view of security building (front and back) as well as observation towers/locations are presented

in Annex D. Number of observation points may be increased in the final design based on the security needs.

2.7 Design Concept

2.7.1 Applicable Codes and Standards

Design, installation and operation of the Project will be based on national and international laboratory and biosafety standards/guidelines including TS-EN, NIH, WHO and CDC. Please refer to Table 2-5 for a summary of the standards required for ABSL3 laboratories and their scopes. Please refer to Section 14.6.2 for further information.

Table 2-5: Standards Red	quired for ABSL2 and	ABSL3 Laboratories
--------------------------	----------------------	--------------------

Standard	Scope	
WHO Laboratory Biosafety Manual (LBM) and Associated Monographs, 4 th edition, 2010	BSL2/BSL3 facility requirements and certification	
WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006	Biorisk Management, Laboratory biosecurity guidance	
CEN/CWA 15793 Laboratory Bio Risk Management Standard	Biorisk management standard	
DIN 1946 Ventilation and Air Conditioning DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and Refrigeration products) EN 12237:2003 Ventilation for Buildings. Ductwork. Strength	Requirements regarding air conditioning system, ventilation for buildings, heat ventilation, refrigeration strength and leakage of circular sheet metal ducts	
and Leakage of Circular Sheet Metal Duct ISO 35001: 2009 Bio-risk Management for Laboratories	Defines a process to identify, assess, control and monitor the risks associated with hazardous biological materials	
Standards of Accreditation in Health – Laboratory Kit	"SAS Laboratory Kit" which describes "Turkiye Accreditation in Health System". This set was developed for laboratories consists of two parts including standards, assessment criteria and guidelines.	
TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments	Clean room certification: Identification of clean room class, HEPA filter system sealing, air flow, number of air change, room pressure difference, room temperature and humidity, room sound level tests	
TS EN 12128: 2002: Bio-Technology Research- Development and Analysis Laboratories - Safety levels, risk areas, locations and physical safety rules for micro-biology laboratories	This standard is structured on ISO 3864 (Safety colours and signs), ISO 7000 (Graphical symbols for use on equipment), ISO 8995 (Principles of visual ergonomics-The lighting of indoor work systems)	
TS EN 12469 Biotechnology – Performance Criteria regarding Microbiological Safety Cabinets	Certification of biological safety cabinets	
TS EN 12347 Biotechnology - Performance Criteria for Steam Sterilizators and Autoclaves	Autoclave validation	
Prevention of Biologic Factors Exposures Regulation (In compliance with European Union: Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work)	Regulates the minimum provisions regarding the prevention and protection of health and safety risks that may arise or may arise from the exposure of employees to biological factors in the workplace.	
US CDC-NIH "Biosafety at Microbiological and Biomedical Laboratories (BMBL)"	The BMBL is a manual published jointly by the National Institutes for Health (NIH) and the Centres for Disease Control and Prevention (CDC) that lays out the code of practice for biosafety and biocontainment in the U.S. The BMBL is referenced in the Select Agent Regulations and is used in many professional and academic laboratories.	

The biosafety guidelines for laboratories cover facility and laboratory design as well as code of practice, laboratory equipment, health and medical surveillance, training, waste handling, and chemical, fire, electrical and radiation equipment safety. The MoH will ensure that the vaccine research and production centre will be operated in compliance with national legislation and WHO Guidelines (particularly WHO Laboratory Biosafety Manual, 4th edition) for the personnel safety and prevention of spread of any infection. Before putting into operation, and then on an annual basis, laboratory facilities will be independently certified and validated to meet the respective standards as detailed in Section 2.7.6.

2.7.2 **Facility and Process Design**

The Project is a multi-structured project with research facilities as well as bacterial and viral pilot-scale production units, and is planned to have a flexible structure for future adjustments. As noted above, the design options for the proposed Project will strictly follow international codes, references, standards and guidelines. Based on these standards, alternative layouts will be considered during the design phase. The preferred site layout of the proposed Project will consist of services, units/laboratories and areas presented in Section 2.6.

Biosafety levels of the laboratories and units within the Project will be assigned as BSL2 or BSL3 depending on the risk grade of studied biological agents. The laboratories and units will have varying design features, containment facilities and operational procedures in line with the basic requirements set out in Table 2-6 and as shown in Figure 2-11.

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic Biosafety Level 1	Basic teaching research	GMT**	None; open bench
2	Basic Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing biohazard sign	Open bench plus BSC* for potential aerosols
3	Containment Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing-controlled access directional airflow	BSC and/or other primary devices for all activities.
4	Maximum containment Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC and or positive pressure suits in conjunction with Class II BSCs, double ended autoclave (through the wall), filtered air.

Table 2-6: The summary of risk groups to biosafety levels, practices and equipment¹⁵

BSC, biological safety cabinet; **GMT, good microbiological techniques

⁶⁸

¹⁵ Laboratory Biosafety Manual, 3rd Edition, WHO, 2004



Figure 2-11: Typical BSL 1, 2 and 3 Laboratories¹⁶

¹⁶ WHO Laboratory Biosafety Manual (3rd Edition), 2004.

A typical BSL3 laboratory is shown in Figure 2-12 below. An anteroom is located at the entrance to the laboratory to provide space for personnel to wear personal protective gowns, respirators and other PPE. Research activities in the laboratory are typically conducted in a Biological Safety Cabinet (BSC). Air pressure differentials in the building create airflows from the anteroom into the laboratory, then into the BSCs. Locked freezers are used to store organisms when not in use. A pass-through autoclave is typically used to decontaminate all laboratory materials and equipment exiting the facility as waste. An autoclave is a pressure chamber used to carry out high temperature sterilization. Waste containers are marked as appropriate for the level of stored waste. Air exhaust from BSCs, autoclaves and from room spaces passes through double HEPA filtration banks prior to release from the facility stack. Liquid wastes from sinks or floor drains are typically collected in facility collection tanks for treatment.



Figure 2-12: A Typical BSL3 Laboratory

The planning and designing of laboratories are a vast subject that requires input from many professionals working in a wide range of disciplines. Building a new laboratory that needs to remain usable and sustainable for decades requires decisions which are taken with clarity of purpose to realistically address the function required from the Project. Therefore, studies are still ongoing regarding the detailed facility and process design for the Project.

According to the WHO Biosafety Manual, the facility design features listed below are core components for biosafety for all laboratories handling biological agents which will be integrated in the facility design.

- Ample space will be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- Designated hand-washing basins operated by a hands-free mechanism will be provided in each laboratory room, preferably close to the exit door.
- Laboratory entrance doors will have vision panels (to avoid accidents during opening), appropriate fire ratings and they will be self-closing.
- Doors will be appropriately labelled with the international biohazard warning symbols wherever biohazardous materials are handled and stored.
- In the process management, material entry and exit from the relevant areas will be made by authorized personnel, and chemical usage and storage will be monitored.
- Laboratory walls, floors and furniture will be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory.
- Laboratory bench tops will be impervious to water and resistant to disinfectants, acids, alkalis, organic solvents and moderate heat.
- Laboratory furniture will be fit for purpose. Open spaces between and under benches, cabinets and equipment will be accessible for cleaning.

- Laboratory lighting (illumination) will be adequate for all activities. Daylight will be utilized effectively to save energy. Undesirable reflections and glare will be avoided.
- Emergency lighting will be sufficient to permit safe stopping of work as well as safe exit from the laboratory.
- Laboratory ventilation where provided (including heating/cooling systems, especially fans/local cooling split-system air conditioning units) will ensure airflows do not compromise safe working. Consideration will be given to resultant airflow speeds and directions, and turbulent airflows will be avoided; this applies also to natural ventilation.
- Laboratory storage space will be adequate to hold supplies for immediate use to prevent clutter on bench tops and in aisles. Additional long-term storage space, conveniently located outside of the laboratory room/space, will be considered.
- Space and facilities will be provided for the safe handling and storage of chemicals and solvents, radioactive materials, and compressed and liquefied gases if used.
- Facilities for storing food and drink, personal items, jackets and outerwear, facilities for eating and drinking will be provided outside the laboratory, first-aid facilities will be accessible and suitably equipped/stocked.

Specifications on laboratories' risk activities in WHO Laboratory Biosafety Manual have changed from the 3rd edition into the 4th edition of the Manual. Accordingly, topics related to BSL3 level laboratories are covered in the 4th edition of the Manual as "Heightened control measures". Therefore, the Project will need to accommodate additional in-built heightened control measures (engineering controls) and be designed in a way that enables the incorporation of heightened control measures and facilitates their safe operation and associated protocols. Heightened control measures associated with facility design will include the following:

- Laboratory rooms/spaces will be physically separated from areas open to unrestricted traffic flow within the building, thus the risk of exposure to passing individuals not directly involved in the laboratory work will be reduced.
- Windows in a laboratory with heightened control measures should be closed and sealed.
- Where gaseous disinfection is selected as a heightened control measure for decontamination and waste management, laboratory room/space airtightness will need to be enhanced which will be achieved by sealing all surfaces and/or laboratory penetrations to prevent the escape of hazardous gases.
- Laboratory exhaust airstream will be configured to discharge in a way that reduces the likelihood of exposure of any people, animals and/or the outside environment to the exhaust air, for example, discharging exhausts away from air intake vents. Additionally, exhaust air will be filtered before exhausting.
- Space for the onsite treatment of laboratory waste and dedicated secure storage for laboratory waste will be provided until it can be transported off-site for decontamination.

In addition to core requirements and heightened control measures indicated in the WHO Laboratory Biosafety Manual, design considerations which are detailed in the associated monographs¹⁷ will be taken into account in the design of the laboratories. Some of them provide physical separation between the laboratory and the surrounding buildings by use of an anteroom¹⁸, using controlled access systems such

¹⁷ Monographs on Biological safety cabinets and other primary containment devices, on Personal protective equipment. Laboratory design and maintenance, Decontamination and waste management

¹⁸ An anteroom is an intermediary room used to create an additional layer of separation and safety between the heightened control measures laboratory and outside rooms or the general laboratory. Anterooms are commonly used as a changing area, where laboratory coats and other PPE that are to be used inside the laboratory are put on.

as card pass readers to also address biosecurity concerns, safeguards for the equipment being used during the laboratory procedures such as Biological Safety Cabinets¹⁹.

The units/areas of the Project which require specific measures to be applied are being identified and further assessed by the Project design team through risk assessments. Risk assessment is a systematic process of gathering information and evaluating risks to support a risk management strategy that is informed by the likelihood and consequences of an inadvertent release of and/or exposure to a biological agent. Risk assessment is essential to guide the selection of risk control measures and ensure biosafety within the laboratory when working with biological agents. The assessment requires consideration of many factors including: routes of transmission of the biological agents, pathogenicity and infectious dose, availability of prophylactic treatment or a vaccine, disease severity and mortality, contagiousness, endemicity, high-risk laboratory procedures (such as work with aerosols, high titres or volumes of the biological agents being produced/handled, sharps, animals), competency of laboratory personnel, susceptibility of individual personnel and biosecurity (potential for misuse of biological agents/use as a weapon for harm).

The ABSL3 laboratories to be established within the Project will involve practices suitable for work with laboratory animals infected with indigenous or exotic agents, agents that present a potential for aerosol transmission and agents causing serious or potentially lethal disease. Therefore, ABSL3 builds upon the standard practices, procedures, containment equipment and facility requirements and has special engineering and design features which are being assessed in detail by the Project design team.

All samples entering the facility will be recorded in the software system at the sample acceptance unit and the sample acceptance, distribution and archiving processes will be undertaken in accordance with GLP rules. A barcoding system will be used for tracking of the incoming samples.

Protective clothing will be used in BSL laboratories in accordance with the WHO requirements. In accordance with the GLP and GMP, health screenings, periodic health monitoring, and vaccinations of the personnel will be obligatory and followed by the quality assurance unit.

Biosafety and biosecurity aspects of the Project are further assessed and addressed in *Chapter 14: Community Health, Safety and Security* considering community and occupational health and safety conditions based on related designs, documents and specifications.

Although a general framework for process design has been established including active and inactive viral vaccine and bacterial vaccine production units taking into account the maximum WHO requirements that must be present, it is unclear at this stage which specific biological agents will be studied. Detailed process flows will be determined based on the specific agents, as technologies will vary and additional design features may be required for different products. As noted by the MoH, specific alternatives for units, equipment and layout of the laboratories and pilot-scale production areas will be considered in optimizing the Project, as the design progresses. Additionally, a full-scale vaccine production area is allocated within the design to ensure flexibility for future production capacity expansion.

The proposed generalized process flow for inactive viral vaccine production within the scope of the Project indicating sequential steps to be applied is shown in Figure 2-13 below.

¹⁹ Biological Safety Cabinet (BSC) is the most commonly used engineering control for limiting aerosol risks to reducing exposure to aerosols. BSC act to isolate aerosol-generating work or equipment from other areas of the laboratory.


Figure 2-13: Simplified process flow diagram for production of inactive viral vaccines

GMP will comprise both design and operation aspects, including personnel qualifications and training, technical infrastructure (purified water, steam, HVAC/ventilation, decontamination, sterilization, biosafety, fermenter/bioreactor units and similar). Specific units and equipment of the Project will be procured and installed through the 'Design and Supply' model, based on the general technical specifications to be issued by MoH. Final quantities, qualifications and capacities of such specific units and equipment will be further assessed by MoH based on the technology reviews to be undertaken during the procurement process and will become available at later stages of the Project. The design of the Project will include the following main elements:

- Sterilization/decontamination: For sterilization of the equipment, steam (wet) sterilization will be applied at 121-134°C for between 15-45 minutes and dry air sterilization will be applied at 300°C for 3 minutes. On the other hand, gas phase H₂O₂ (hydrogen peroxide) decontamination will be applied for room area decontaminations. In accordance with the relevant protocols, H₂O₂ decontamination will not be applied in areas where live animals are present. All wastes exiting the laboratories and production areas will be regarded as medical waste, which will be subject to decontamination in dedicated autoclaves and then forwarded to the Waste Building. Medical wastes that are classified as pathological waste will then be forwarded to authorized facilities for incineration. Liquid wastes generated will be forwarded to and treated at the liquid waste decontamination unit planned to be installed at basement level of the Vaccine Production Building.
- Water supply: Potable water for the Project will be supplied upon preliminary water treatment at the Technical Building. Purified water for laboratory/production operations will also be produced in the Technical Building. Within the scope of the stormwater project, surface waters will be collected with the rain harvesting principle in in the basement of the Waste Building as reinforced concrete storage tank with a capacity of 900 m³. This tank will be the source of the automatic irrigation system which will be used for the recreational areas and will have the capacity to store irrigational water to be utilized for 6 days.

- Ventilation: Design of planned HVAC systems is in progress and will be carried out in accordance with applicable ventilation codes and standards. Exhaust systems of the production areas will be configured in accordance with filtration and discharge rules of cGMP²⁰ and BSL3, in line with NIH and TS-EN 12128 standards. In general, in HVAC systems, it is planned that blow will be subject to G4+F7+F9+H14²¹ HEPA filtration while exhaust will be subject to G4+H14 HEPA filtration. In BSL3 areas, G4+H14+H14 HEPA filtration will be applied. All areas will be fed with 100% fresh air. Runaround wet heat recovery systems²² will be applied.
- Fire protection: Fire and emergency detection systems is one of the major elements of the equipment to be procured within the scope of the Project. Automatic fire alarm system for the entire facilities will be installed. Fire suppression for the BSL3 laboratories will be provided by a standard wet-pipe fire sprinkler system. In addition, fire extinguishers will be available in accessible areas and all fire-fighting equipment will be regularly maintained and serviced.
- Pest control: With the pest control system to be established, the biological risk factors in the facility will be minimized by the measures to be taken according to the seasonal and environmental population presence. In accordance with GMP, this infrastructure must be established in the facility and a pest control officer must be present.
- Instrumentation control: Electrical and mechanical systems (including HVAC) will be controlled through a building automation system (BAS). Failure tests will be developed consistent with laboratory design parameters to verify correct operations at normal operational conditions vs. emergency power, and to ensure that the BAS maintains operational set points during all scenarios.
- Maintenance and inspections: Procurement of the equipment will be conducted in line with the tender specifications to be developed. The operation of the Project will be carried out entirely by the MoH, however service procurement contracts will be made for maintenance, repair, calibration, validation and certification processes for devices to be utilized in operation phase. Periodical maintenance and inspections of devices to be installed within the Project, such as autoclaves, boilers, compressors, air tanks, LPG tanks, hydraulic fluid circuits, booster (pressurization systems), industrial and medical gas tanks, cooling units, pneumatic fluid circuits, gas cylinders, cryogenic tanks, will be performed according to the specific requirements and instructions of the manufacturer companies and national legislation. Periodical maintenance will be followed within the quality assurance system.

2.7.3 Animal Testing and Production

Animal experiments involving risk grade 3 agents will be conducted in ABSL3 level laboratories, which require specific practices for biosafety and animal welfare management. Experimental animals will be accommodated in the Experimental Animals Production/Test Building which will consist of separate laboratories/rooms for production and in-vivo testing of experimental animals with independent air conditioning and ventilation systems. The building is planned to host around 6000-7000 experimental animals (including scorpion, rat, snake, rabbit, mouse, fish²³).

Animal experiments are important for study of severe infectious diseases to determine their pathogenesis and to develop vaccines and drugs. Laboratory animal welfare is closely related to scientific quality and

- ²¹ G4 class HEPA filters are designed to remove 80-90% of air-borne particles of size more than 10 microns. F7 class HEPA filters are designed to remove 80-90% of air-borne particles of size more than 0.4 micron.
 - F9 class HEPA filters are designed to remove more than 95% of air-borne particles of size more than 0.4 micron.

²⁰ cGMP refers to the Current Good Manufacturing Practice regulations enforced by the FDA

H14 class HEPA filters are considered medical grade filters able to capture significant percentages (99.995%) of particles smaller than 0.3 micron.

²² Run-around heat recovery systems are systems in which the airflows are completely separated from one another. As a result, they are suitable for applications in which no leakages between the supply and extract air are desired or permitted for hygienic reasons.

²³ Zebra fish, axolotl fish, amphibious fish

good animal welfare conditions are beneficial to the reliability of scientific data. Animal welfare requires the animal to maintain physical and psychological well-being by provision of living conditions in accordance with its nature, and alleviating animal stress and pain in experiments as much as possible while also achieving the study objectives. Controlling animal stress and pain can reduce aggression, the benefits being reduced aerosol contamination as well as animal scratches and bites, providing good occupational health and safety conditions for the workers. When physical and psychological well-being of the animals are maintained, the animals minimize their stress response to the environment and manipulations. Therefore, they have more stable physiological and biochemical indicators and the results of studies with animal experiments are more reliable²⁴. Experimental animal production studies and their maintenance and use in vaccine production will require Standard Operational Procedures (SOPs) throughout the operation with respect to biosafety and animal welfare.

Replacement, Reduction and Refinement (the "Three Rs") principle will be followed in animal experiments which is a legal requirement of the Directive 2010/63/EU on the protection of animals used for scientific purposes and the Turkish Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes which is parallel to the European Union (EU) Directive (see Table 2-5). "Three Rs" is the key strategies of a systematic framework aimed at achieving the goal of humane experimental techniques and should always be considered when animals are used for the purposes of basic, translation and applied research, regulatory testing and production as well as for the purposes of education and training. "Three Rs" principle encompasses the components presented in the directive²⁵.

Three Rs	Definition
Replacement	Testing approaches that avoid or replace the use of live animals in an experiment where they would have otherwise been used. Replacement could include the use of established animal and human cell lines, or cells and tissues or mathematical and computer models or physicochemical methods
Reduction	Approaches that minimise the number of animals used per experiment or study, either by enabling researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals, thereby avoiding further animal use. Examples include improved experimental design and statistical analysis, combination of studies, international harmonisation of testing requirements (e.g. (ICH) to avoid duplicate testing and the use of technologies, such as imaging, to enable longitudinal studies in the same animals.
Refinement	Approaches that minimise the pain, suffering, distress or lasting harm that may be experienced by the animals. Refinement applies to all aspects of animal use, from the housing and husbandry used to the scientific procedures performed on them. An example of refinement is the use of appropriate anaesthetics and analgesics

Table 2-7: The principles of Three Rs

As per the EU (Directive 2010/63/EU) and applicable Turkish legislation, the main principles regarding the welfare of the animals to be used for experimental and other scientific purposes and the qualifications of the working personnel are given below:

- Having equipment and tools in accordance with the procedures applied to the animal species being housed,
- Ensuring appropriate environment and environmental control for the care and housing of experimental animals,
- Ensuring the standards on physical structures for the care and shelter of animals,
- Establishing an animal welfare unit,
- Compliance with the plans and procedures specified in the legislation in cases such as the release of animals or their return to families, methods of killing and sharing of organs and tissues,

²⁴ Guo, M., Wang, Y., Liu, J., Huang, Z., Li, X. (2019). Biosafety and data quality considerations for animal experiments with highly infectious agents at ABSL-3 facilities. Journal of Biosafety and Biosecurity, 1(1), 50–55. https://doi.org/10.1016/j.jobb.2018.12.011

²⁵ Official website of the European Union: Animals used for scientific purposes accessed from <u>https://ec.europa.eu/environment/chemicals/lab_animals/3r/alternative_en.htm</u> on 18.02.2022

• Employing personnel with adequate training on animal welfare, animal health and protection of public health.

Detailed structure and management regarding emergency response, principles of internal animal management, animal waste management and rehabilitation of animals are assessed and addressed in the relevant chapters of this ESIA report.

2.7.4 Security

As described above, the site will consist of two phases (zones) with different security levels:

- Phase I includes the Administrative, R&D and Experimental Animals Production/Test Buildings and
- Phase II includes the Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area.

Phase II will be protected at a higher security level and there will be a secondary security control for entrance to Phase II from Phase I by both vehicles and pedestrians. Single-point entry will be facilitated though the main security building. Additionally, five observation points have been positioned at the Project site (both the Project main complex area and recreational area) to ensure the security of the Project during the operation period.

The whole Project site will be fenced with J9 type security block walls of 1.5 m height having 1 m railing profile above and fitted with razor wires. CCTV cameras will also be available. Single point for entrance and exit of the guests, personnel and cargo can slow down the evacuation speed in case of an emergency. Therefore, emergency exit points will be available at various locations along the security walls. The cross-sectional view of J9 type security walls is presented in Annex D.

Employees will be able to enter the Project site with identity cards and will be allowed to enter areas that their access is authorized. After the necessary checks are made at the security point, the visitors and other persons who come to the facility will receive an appointment confirmation and will be accompanied to the relevant area. In the event of a terrorism threat despite all precautions, the security of the units and personnel will be ensured, and the relevant protocols of the Ministry of Internal Affairs will be implemented.

2.7.5 Emergency

Emergencies can include those related to biological outbreaks, chemical incidents, fire, electrical breakdown, radiation incidents, pest infestation, flooding, or personal health issues of personnel. All laboratory facilities must have good safety standards for all such hazards and necessary risk control measures should also be in place. Relevant authorities should be consulted where necessary.

Emergency situations will be considered in the design as indicated in the local risk assessments and will include the geographical and meteorological context. Safety systems will cover fire, electrical emergencies and emergency/incident response facilities based on risk assessment. Emergency equipment will include emergency power generation for critical systems, hands free emergency eyewash, emergency shower, emergency two-way communication system, system provided for electronic transfer of information to outside of containment, emergency lighting, fire alarms and extinguishers, chemical spill kits within containment in addition to fire detection system and equipment. Emergency contact numbers will be displayed in all areas. Directions to exit in case of any incidence will be provided. In the Project, there will be reliable and adequate electricity supply and lighting to permit safe exit during emergencies.

Where corrosive, oxidizing or reactive chemicals are used, handled or stored, qualified first-aid personnel will always be ensured. Appropriately equipped first-aid stations will be easily accessible throughout the facility and emergency eye-wash stations and/or showers will be provided close to all workstations. First-aid kits will be checked routinely to make sure products are within their use-by dates and are in sufficient supply. If eyewash stations with piped water are to be used, these will also be checked regularly for correct functioning.

Spill kits, including disinfectant, must be easily accessible to personnel. Depending on the size, location, concentration and/or volume of the spill, different protocols may be necessary. Written procedures for cleaning and decontaminating spills will be developed and followed by suitably trained personnel.

Introducing additional segregation, separation and access controls to the facility design can also result in barriers and challenges to emergency response to deal with adverse events that may occur. Therefore, controlled access systems will be complemented by procedural controls to ensure that monitoring is effective and emergency responses are initiated when necessary. Emergency escape routes from inner segregated areas will be established.

Emergency systems and associated monitoring and response procedures are particularly important if the laboratory allows personnel to work alone. The medical emergency response team (onsite or external) should be informed about the risks of the biological agents that are handled in the laboratory and the medical equipment that is accessible close to the laboratory.

2.7.6 BSL Certification

The BSL/ABSL laboratories within the scope of the Project will be certified by an independent third-party. The certification process will be performed in accordance with the WHO requirements as specified in the WHO Laboratory Biosafety Manual (3rd edition, 2004) and the WHO Laboratory Biosafety Manual (4th edition, 2020). The certification process will conform to the procedures defined in the Environmental and Social Management Framework (ESMF) of the HSSSP.

According to the WHO Laboratory Biosafety Manual (3rd edition) Chapter 8, laboratory certification is the systematic examination of all safety features and processes within the laboratory. In case of BSL laboratories, biosafety practices and procedures are also examined. Laboratory certification is an ongoing quality and safety assurance activity that should take place on a regular basis. Therefore, laboratory certification differs from laboratory commissioning in several important ways (please refer to *Annex J: Laboratory/Facility Commissioning* for the principles of the commissioning process²⁶).

BSL2 and BSL3 laboratories shall not be operated without certification. Laboratory certification helps to ensure that:

- proper engineering controls are being used and are functioning adequately as designed,
- appropriate standard operating procedures (SOPs) and administrative controls such as documentation and record retention systems are in place,
- personal protective equipment is appropriate for the tasks being performed,
- decontamination of waste and materials has been adequately considered and proper waste management procedures are in place,
- proper procedures for laboratory safety (including physical, electrical, chemical and biological safety) are in place, and
- the laboratory personnel are under medical surveillance and receive immunizations for infectious agents or toxins they work with.

According to the WHO Laboratory Biosafety Manual (3rd edition) Chapter 8, adequately trained professionals may conduct laboratory certification activities. Institutions may employ personnel having the appropriate skillset required for conducting audits, surveys or inspections (these terms are used interchangeably) associated with the certification process. However, institutions may consider engaging or be required to engage a third-party to provide these services.

²⁶ Laboratory/facility commissioning may be defined as the systematic review and documentation process signifying that specified laboratory structural components, systems and/or system components have been installed, inspected, functionally tested and verified to meet national or international standards, as appropriate. The respective building system's design criteria and design function establish these requirements. In other words, laboratories designated as Biosafety Levels 1–4 will have different and increasingly complex commissioning requirements.

Biosafety laboratory facilities may develop audit, survey or inspection tools to help ensure consistency in the certification process. These tools should be flexible enough to allow for the physical and procedural differences between laboratories necessitated by the type of work being conducted, while at the same time providing a consistent approach within the laboratory. Care must be taken to ensure that these tools are used only by appropriately trained personnel, and that they are not used as a substitute for a sound professional biosafety assessment.

Recertification of the facility will be performed on an annual basis, as a minimum. A comparison should be made to the baseline established during initial certification. Detailed records of the certification process and test results must be maintained to provide an accurate operations history of the laboratory. Standardization of an initial and annual certification process for BSL3 facilities will provide accountability that ensures proper and regular maintenance and demonstrates the use of standard operating procedures that protect human and animal occupants, the environment and the research integrity.

The onsite certification audit includes visual inspections and testing of containment equipment (including biosafety cabinets, centrifuges, mechanical systems, autoclaves, wastewater decontamination equipment) as well as mechanical, electrical, plumbing systems. Mechanical ventilation performance test covers a controlled shutdown and restart of its normal operation and single point of failure tests (power failure, failures of ventilation equipment and systems).

The main steps of the certification review are as follows:

- I. Evaluation of administrative controls and ability to facilitate maintenance operations to ensure occupant safety and facility integrity
- II. Validation of engineering controls
- III. Review standard operating procedures (SOPs)

The certifier will be provided with drawings and specifications of all equipment, materials and parts, as well as the results of commissioning and testing carried out by the contractors. Biosafety policies and SOPs will also be provided by the users and laboratory operators.

Upon completion of the audit, the certifier summarizes and presents nonconformities and quality issues in the Findings Observation Report. The necessary steps are identified in the Corrective Action Report. This report provides tracking of nonconformities and corrective solutions until they are closed. A certificate of conformity is issued after all non-compliance items are closed.

Findings of the audit, survey or inspection should be discussed with laboratory personnel and management. Within the laboratory, an individual should be identified and made responsible for ensuring that corrective actions are taken for all deficiencies identified during the audit process. Certification of the laboratory should not be completed, and the laboratory should not be declared functional, until deficiencies have been adequately addressed.

Critical areas to inspect or validate that testing has been completed prior to BSL3 and ABSL3 laboratory operational start-up is provided in Table 2-6 below.

Table 2-8: Basis of BSL-3 Laboratory Certification Checklist (NIH Biosafety Level 3 Laboratory Certification Requirements, 2006)

Ι.	Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity
l.1	 Review Background Materials That Affect Maintenance Operations Obtain and review Commissioning Report Review architectural and mechanical drawings to ensure design intent is being met Review biosafety policies and procedures (SOPs) for the laboratory (facility) Training of occupants and maintenance staff Evaluate administrative and engineering procedures to determine if they meet Review waste management procedures Assess laboratory accident response protocols Evaluate decontamination procedures for appropriateness with respect to the protocols being conducted or anticipated Review integrated pest management program Review SOPs for document retention, maintenance, and lab procedures
1.2	Inspect and Evaluate
	 Finishes, penetrations & caulking integrity for architectural elements such as doors, around the ceilings, lighting fixtures, electrical devices, etc. within containment to meet requirements for: Cleanability of all surfaces including furniture Smoothness of all surfaces Sealed seams and penetrations Monolithic, slip resistant floors Surface impermeability to liquids Resistance of surfaces to chemicals, disinfectants and moderate heat Gas tightness for decontamination Pest management requirements Non-operable windows Bioseals
1.3	Inspect Room Layout, Placement of Equipment and Equipment Condition
	 Evaluate autoclave verification testing procedures; inspect logs Evaluate access control and exit procedures Evaluate availability of; Emergency equipment Emergency two-way communication system System provided for electronic transfer of information to outside of containment Emergency lighting Working fire extinguisher Availability of chemical spill kit within containment Evaluate redundancy requirements for particular facility such as air handling units, exhaust fans, decontamination system components (e.g. pumps & HEPA filters) Assess location of BSL3 labs in relation to BSL2, support labs, offices and break rooms, elevators, loading docks, etc. for effects on laboratory pressurization and airflow. This includes operational condition of doors. Presence of an anteroom w/ or w/o a shower Storage provided for donning clean protective clothing and safety equipment Hands-free sink located near exit of laboratory Office location outside of containment Inspect signage for proper posting Biohazard sign Agents used Names and telephone number for laboratory management

- o Special requirements such as required use of PPEs, personnel access
- Review list of all mechanical controls and their locations
- o Review start up and shut down procedures in case of emergency

l.	Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity	
1.4	Evaluate Maintenance Frequency and Review Maintenance Logs	
	 Autoclaves BSC filters Centrifuges Door/equipment locks HVAC balancing HVAC belts HVAC Motors/Sheaves Lights Plumbing 	
II.	Validation of Engineering Controls	
II.1	Validate that extra capacity is present on both supply and exhaust systems and quantify the estimated spare capacity (must document how extra capacity was calculated or estimated)	
II.2	Ensure single pass air flow	
II.3	Measure directional air flow, pressure relationships, air changes and record data	
II.4	Directional air flow must be established from clean areas into contaminated areas. In the event that multiple containment zones exist within a laboratory or laboratory suite, sequentially more negative pressure differentials must be established so that the more contaminated spaces are maintained at a negative pressure with respect to less contaminated areas. Pressure differentials across doorways must be measured using a device calibrated against a primary standard. Ideally,	

at least -0.05 in WG (-12.5 Pa) should be maintained from clean areas to more contaminated areas. In no case should

Example (only for illustration purpose):



II.5

Develop HVAC system and electrical systems failure tests consistent with laboratory design parameters. Perform tests and record data. To verify correct operations these tests should include at a minimum:

- Normal operations to emergency power
- Emergency power in normal operations
- Loss of supply fans (individual and in combination)

the differential be less than -0.03 in. WG (-7.6 Pa) when the door is closed.

- Loss of exhaust fans (individual and in combination)
- Building automation system (BAS) maintains operational set points during all scenarios and return to normal operations.
- Upon reboot BAS must retain operational set points.
- If an uninterrupted power supply (UPS) is installed, verify operation of relays
- Provide UPS for BAS
- Assess if UPS is operational
- Ensure that laboratories are maintained at negative pressure with respect to less contaminated areas.

I.	Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity		
II.6	Assess HVAC equipment condition		
	 Visually inspect Belts Belt guards Wiring Duct supports and connections Guide wires (if applicable) Dilution air dampers (if applicable) Bearings (high pitched squealing) Ductwork system workmanship, damage, etc. Ensure that motor operating temperatures are maintained within equipment specifications Ensure that interlock between supply and exhaust is operational Verify correct placement of biological safety cabinets with respect to supply and exhaust diffusers, doors and traffic patterns. Use smoke at the face of the cabinet to ensure that the air curtain is not being disrupted by supply or exhaust diffusers placed in proximity of the cabinet(s) or opening and closing doors and traffic patterns. 		
II.7	Perform smoke tests to demonstrate directional airflow		
	 Doors Vents Windows Autoclave Other vented areas 		
II.8	Inspect and challenge door interlock systems and automatic door closers		
	 Door closers are required Ensure that doors automatically close and latch Interlocks required Check operability Open and close doors in all possible sequences Ensure that delay set points are tight enough to preclude inadvertent override of interlock 		
11.9	Test all alarms		
	 HVAC Failure Alarm Availability of air flow alarms showing if the room has gone positive under normal conditions or if door is open for greater than 20 seconds. Availability of a visual indication for personnel to be aware if the room is under positive or negative pressure prior to entering into the lab Review fire alarm annual documentation Review security alarm annual documentation 		
II.10	Discharge exhaust assessment (as a measure of performance)		
	 Inspect rooftop landscape for re-entrainment opportunities Laboratory exhaust stacks- minimum 3m height above highest point on roof Check Exhaust stack locations and discharge velocities Exhaust velocity = 15-20 m/s or 3000-4000 fpm Is all aerosol-producing equipment exhausted by certified HEPA filtration devices? Ensure that continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory Ensure that discharge of local exhaust ventilation (LEV) devices is removed from air intakes to prevent re-entrainment Consider local conditions (e.g., HEPA filters on exhaust, dilution air) 		
II.11	Verification of air change rates (ACR) in containment spaces		
	 ACR is determined during design based on sensible and latent heat loads contaminants and odors that require containment space usage Measure supply and exhaust air volumes using a device calibrated annually Calculate ACR; monitor trends In no case should the ACR be less than 6/hr for labs and 10/hr for animal facilities 		

I.	Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity		
II.12	 Review biological safety cabinet (BSC) validation data BSCs must be on an annual validation schedule Verify that BSCs are located away from doors and vents Verify that installation of BSC is correct for cabinet type. Inspect HEPA filter installations Review validation documentation for all exhaust HVAC HEPA installations Verify that HEPA filters are on portable air vacuum systems at point of use and at the barrier Visually inspect 		
	 Isolation valves for decon Decon and challenge ports Scanning access 		
II.13	 Validate MEP (Mechanical, Electrical, Plumbing) Inspect for adequate illumination Verify that circuit breakers are outside of containment Backflow prevention for lab water system Sinks and drains properly marked Availability of emergency power for critical systems Availability of hands free emergency eyewash Availability of emergency shower Caulking and sealing requirements for electrical devises such as conduits, boxes, lights, etc. Validate provision for dedicated vacuum pump, if present Inspect effluent decontamination system, if present 		
II.14	 Validate autoclave availability, operations and bioseal integrity Test interlocks Confirm cycle –test load Visually inspect bioseal Smoke test bioseal Validate maintenance of sterilization temp. of 121 degrees for 60 minutes. Autoclave-out capability directly from the BSL3 facility in new facilities In older facilities where autoclave-out may not be available, an autoclave must be available near the BSL3 facility so that containment of biohazardous waste is maintained. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) is considered if recommended by the biosafety unit/department 		
Ш.	Review SOPs		
III.1	 Autoclave & Decontamination To decontaminate materials before removing them from the biosafety cabinet If an autoclave is available near but outside the BSL3 facility, ensure adequate decontamination procedures in place for wet and dry biohazardous materials that leave the facility Assess the travel route to nearest autoclave avoids public corridors Assess procedures for use of and disposal of PPEs Assess procedures for decon of equipment that leaves the facility for repair or discontinuation of use Review storage and transport of biohazardous materials Assess type of disinfectant to be used and if it is of adequate strength and type for the biohazardous materials 		

• Validate schedule and frequency of changing HVAC filters on vacuum lines

I.	Evaluation of Administrative Controls and Ability to Facilitate Maintenance Operations to Ensure Occupant Safety and Facility Integrity		
III.2	Safety SOPs		
	 Identification of responsible person for BSL3 facility Use, storage and disposal of Personal Protective Equipment 		
	Documented limited personnel access to facility		
	Procedures for maintenance to enter facility		
	Hand washing procedures are in place		
	Use of mechanical pipetting devices; NO mouth pipetting		
	 Procedures in place to minimize production of aerosols 		
	Decontamination procedures are in place		
	 I raining program is in place and documentation available for training and refresher courses of all personnel allowed in the BSL-3 facility 		
	Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel		
	 A biosafety manual specific to the laboratory has been prepared and adopted 		
	Biosafety precautions are incorporated into standard operating procedures		
	 If animals are housed under ABSL3 conditions, all animal specific regulations and biosafety procedures are followed 		
III.3	Occupational Health Monitoring, if appropriate		
	Blood/ Serum Storage		
	Vaccinations		
	 High-risk (immune suppressed, pregnant, etc.) individuals Health screening 		
	 Annual updates of Exposure Control Plan to include documentation of all locations where BSL3 agents or materials are used or stored 		
III.4	Biohazardous Materials Use Authorization (e.g., Human Pathogen Registration, Recombinant DNA Registration, Select Agent, etc.)		
	Current BUA (Biohazardous Materials Use Authorization)		
	Symptomology page		
	Procedures for how samples are received		
	 Validate that a current Laboratory Animals Ethical Committee approval is on file (if animals are used in the facility. 		

A Facility Certification Specialist as a third-party will be contracted directly by MoH, to undertake the certification of the Project laboratories. Certification process will be conducted in line with the survey forms provided in Tables 5 through 7 of the WHO Laboratory Biosafety Manual (3rd edition). The independent Facility Certification Specialist contracted by MoH will be experienced with the certification of at least three laboratories and will have at least 10 years of experience in certification and operation of a BSL3 level laboratory. The independent Facility Certification Specialist will also be experienced in review/approval of ABSL3/BSL2 facility design, construction and commissioning.

There are different certification procedures in each country. Certification is mandatory in the US and Canada for working with select agents and exotic animal pathogens, respectively. Singapore and Australian governments maintain an official certification scheme for BSL3 laboratories or quarantine facilities, respectively. In the US, any person with experience and expertise can certify laboratories. In Canada certifications are done by government experts. In Singapore and Australia, certifiers are approved or accredited by the competent authority. In all other countries, the certifier is a recognized biosafety professional or biocontainment engineer with extensive experience and expertise in certification of biosafety facilities, including facility-related and organizational risk controls. The WHO or other organizations do not accredit or certify the certifiers.

In Turkiye, there is no comprehensive biosafety legislation in place. With respect to the certification of BSL laboratories, the Project will refer to the international standards, guidelines and regulations including but not limited to:

• WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020,

- CWA 15793:2008 Laboratory Biorisk Management Standard,
- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020,
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019,
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006,
- ISO 14644 series, Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones,
- ANSI/ASSP Z9.14:2020 Testing and Performance-Verification Methodologies for Biosafety Level 3 (BSL-3) and Animal Biosafety Level 3 (ABSL-3) Ventilation Systems,
- Canadian Biosafety Standard, 3rd. Edition, November 2022.

2.8 Responsibilities and Organizational Structure

Phase I construction phase of the Project is undertaken by the General Directorate of Health Investments (GDHI) of the MoH. GDHI carries out the monitoring and supervision of the construction works.

The basic construction works for Phase I construction activities of the Project are presently continued by the Engineering, Procurement and Construction (EPC) Contractor and its subcontractors. YDA Construction (a subsidiary of YDA Group) has become the EPC Contractor of the Phase I construction works through an agreement signed with the MoH in February 2022. Within YDA Construction, an EHS Specialist and a Human Resources Officer in relation to social issues are onsite full-time. In addition, environment, OHS, human resources and public relations officers in the head office support the Project.

The roles and responsibilities regarding Phase II have not yet been fully clarified, however it is anticipated that the GDHI will contract the following:

- Situation and Needs Analysis Consultant: The Situation and Needs Analysis Consultant will take part in preparation of situation and needs analyses which will form the basis for the preliminary design.
- Preliminary Design Consultant: Preliminary design works will be carried out by the preliminary design consultant. Staff will include an environmental expert, a social expert, an OHS expert and a biosafety expert. After the preliminary design studies are completed, the Phase II Contractor will be determined.
- Phase II Contractor: The Phase II Contractor will be selected by the design supply installation method and will undertake the detailed design, construction, equipment supply, and commissioning and certification processes of the Project. The works to be performed by the contractor company will be supervised by GDHI and the Preliminary Design Consultant. The Phase II Contractor's staff will include an environmental expert, a social expert, an OHS expert and a biosecurity expert.

In addition, prior to the Phase II construction phase of the Project, a Project Implementation Unit (PIU) will be established within the General Directorate of Public Health (GDPH) of the MoH, and the environmental and social experts to be included in the PIU will be involved in administrative processes, contractual issues and monitoring/control processes.

The operation of the Project will be undertaken by the General Directorate of Public Health (GDPH) of the MoH. The necessary staff will be assigned for the operation process in accordance with the WHO standards and technical trainings will be provided prior to the operation.

The roles and responsibilities related to the operation phase have not yet been fully clarified, however the Project is expected to employ approximately 200 operational staff, most of whom will be civil servants of the MoH. Studies to determine the operational structure and employment profile of the Project are still ongoing. The technical departments to be established within the Project will include biomedical, quality management, occupational health and safety, and information technology. Competent personnel profiles with respect to the Project's operational activities will be identified and staff will be recruited based on the minimum unit/department requirements. Personnel competences in the relevant units/departments will be approved by the facility management. The personnel will be able to work after receiving and completing

the necessary trainings including GLP, GMP, emergency and CBRN²⁷ incidents, waste management. First aid, fire and emergency response teams of the facility will be formed under the responsibility of the occupational health and safety department.

The MoH is planning to establish a biosafety committee to take part in the operation of the Project and biosafety officers will be assigned for the BSL3 laboratories, production units and waste units. The biosafety committee will be an institutional committee created to act as an independent review group for biosafety issues reporting to senior management, in line with the requirements of the WHO Laboratory Biosafety Manual (4th edition, 2020). The membership structure of the biosafety committee will reflect the different occupational areas of the proposed facility as well as its scientific expertise, and will be defined as the design progresses.

2.9 **Project Construction**

2.9.1 Construction Schedule

The Phase I construction works of the Project has been initiated in the second quarter of 2022 and is planned to be completed in March 2024. Phase I construction includes the basic construction works of the Administrative, Research & Development and Experimental Animals Production/Test Buildings.

No information is currently available regarding the detailed construction schedule for the Phase II construction activities, which include the construction of the remaining Project components (i.e. Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area) as well as overall finishing works such as electrical, mechanical and plumbing, procurement and installation of equipment, and the commissioning/certification processes. However, it is estimated that the Phase II construction works are expected to be initiated in 2025 and the operation phase will be initiated in year 2027.

2.9.2 Traffic and Access

During the construction of the Project, the existing road network is utilised for transportation of materials and equipment/consumables, transport of wastes and excavation materials from the site and daily commute of personnel to and from the Project site. Main and local roads are utilised as required, dependent upon the point of origin of plant/materials etc. The heavy vehicles are transporting ready mix concrete and other construction materials mainly from Pursaklar (in the west) and Çubuk (in the north) districts. The maximum number of daily heavy vehicles operating to and/or from the Project site during the construction phase will be 130. The traffic routes to be used by transport vehicles associated with the construction activities, along with the impacts/risks on the roads nearby the Project area that are used by various local businesses and factories, are discussed in *Chapter 13: Traffic Impact*.

During the construction period, the existing road crossing through the Project site boundaries from north to south (between parcel 1555-4 and the recreational area) will remain open and the entrance and exit to the construction site will be provided from this road. A new access road is planned to be put into service outside the Project site boundaries before the closure of the existing road.

2.9.3 Construction Materials and Equipment

It is anticipated that approximately 4048 m³ of aggregate, 1900 m³ of concrete, 1685 tons of ribbed steel and 308 tons of structural steel will be utilized during construction. Approximately 618 unreinforced C30 type concrete of 7.5m will be used for soil improvement works. No asphalt will be needed for the Project. There will not be any concrete batching plant to be established in either the Project site and/or in its close vicinity. The ready-mixed concrete and aggregate are supplied from sources outside the Project site.

²⁷ CBRN: Chemical, biological, radiological and nuclear

During the later stages of the construction, there will be two onsite temporary laydown areas (25mx12m) for construction materials which will be appropriately managed to avoid potential disturbance and run-off. There will be no requirement for additional land other than the defined Project site. Appropriate management practices for these materials will need to be adopted, as discussed in *Chapter 8: Material Resources, Waste and Wastewater Management*.

The types and quantities of construction equipment with respect to various construction works are detailed in Table 2-9.

Equipment	Number
Bored piling machine	2
Tower crane (8tonnes)	2
Tractor	1
Tractor loader	1
Roller (10t/3t)	1
Mobile crane (35tonnes)	1
Mini loader	1
Compactor	1
Generator (105kW)	2

Table 2-9: Construction equipment

2.9.4 Employment

During the social site visits conducted in June 2022, the Project site was observed from outside and brief information on the Phase I construction activities was obtained from the site chief of the EPC (Engineering, Procurement and Construction) Contractor. Accordingly, construction works were ongoing and there were less than 10 workers in the Project site for current construction works. It was reported by the site chief that there will be 250 workers at most during the peak times of construction.

The next site visit was held on 22 December 2022 in order to specifically assess the construction site and current activities. At the time of the site visit, there were a total of 80 workers on the site. Of these 80 workers, approximately 20 were the technical and management personnel of the EPC Contractor whereas 35 were the workers of the EPC contractor and the rest was subcontracted workers.

The number of all workers vary by the workload and the progress of the construction works each month. The exact number was determined based on the payroll records of November 2022. At peak times, there were 127 workers (including technical, management and construction workers of the EPC Contractor, and subcontracted workers) on the site. The highest number of workers on the construction site was recorded on 15 November 2022.

Approximate number of workers on the construction site for December 2022 was 90; 30 of which were subcontracted workers and the rest was the workers of the EPC Contractor.

There was no labour accommodation on the construction site at the time of the site visit. The EPC Contractor stated that labour accommodation was not required for this phase of the construction activities. There are shuttles for access to the construction site, many workers use the shuttles and few use public transportation or personal cars.

For Phase II construction activities, the MoH has not made a tender announcement yet. Therefore, no certain information is currently available regarding the workforce profile or employment practices for Phase II. However, it is anticipated that the number of workforce will be similar to Phase I. It is expected that the maximum number of workforce will be 150 people during Phase II, but this number will be discussed and decided during the preliminary design studies to be performed. In addition, the

representatives of the EPC Contractor stated that they will consider bidding for the Phase II as long as the requirements are favourable for both sides.

3 INSTITUTIONAL AND REGULATORY FRAMEWORK

3.1 National Institutional Framework

The central government entities in Turkiye are set out below:

- The Presidency, including the presidential administrative offices and policy councils
- Turkish Grand National Assembly (TBMM)
- Ministries that create policies and perform compliance assurance functions. The ministries also contain a number of general directorates and offices, which coordinate and supervise a range of specific activities.

The key national level institutions in Turkiye responsible of managing environmental and social aspects related to the proposed Project include the following:

- Ministry of Health (MoH): The MoH makes policies related to protection of the public health and coordinates, regulates and supervises healthcare services. It consists of several general directorates and institutions including:
 - MoH General Directorate of Health Investments: The general directorate coordinates the engineering services for the infrastructure used by MoH and its subsidiaries, prepares projects for these services, controls construction activities and conducts necessary expropriation works for the immovables.
 - MoH General Directorate of Health Services: The general directorate plans, regulates, and determines the standards for protective, diagnosis, treatment and rehabilitation services, regulates/makes arrangements regarding the patient rights and occupational health issues and inspects the health institutions and organizations based on the relevant legislation and policy of MoH.
 - MoH General Directorate of Emergency Health Services: The general directorate plans, organizes and manages the health services in emergency situations and disasters.
 - MoH General Directorate of Public Health: The general directorate coordinates family physician services, determines the technical and physical features of the family health centres, community health centres and similar, and prepares programs and studies against the contagious diseases and health threats.
 - MoH Project Management Support Unit (PMSU): PMSU coordinates between the national and international parties and the implementing units of MoH for the Health Transformation and Social Security Reform Project implementation. It also monitors and assesses the project implementation and provides technical assistance to the implementing units.
- **Ministry of Environment, Urbanisation and Climate Change (MoEUCC):** The MoEUCC sets principles and policies for protection of environment, monitors and audits implementation, and regulates settlements and environmental protection measures. MoEUCC is also the lead authority for domestic and international climate change policies and the implementation of the relevant strategy and action plan. It is made up of several directorates including the following:
 - MoEUCC General Directorate of EIA, Permit and Inspection: Along with its local governorates, this general directorate is the authority in charge of issuing environmental permits for emissions and discharges, as well as the environmental impact assessment decisions for projects.
 - MoEUCC General Directorate of Spatial Planning: This general directorate identifies the procedures and guidelines related to preparation of all kinds of physical spatial development plans

and environmental management plans at all scales, approving these plans and ensuring that those plans are implemented and monitored.

- MoEUCC General Directorate of Environmental Management: This general directorate is the primary authority in environmental protection and monitoring procedures, holding the authority for assessment, supervision and sanctioning in coordination with governorate structures at the local level.
- Ministry of Agriculture and Forestry (MoAF): The MoAF establishes policies on protection, and maintenance of forest areas as well as management of agricultural investments and acitivities. Duties of the MoAF also include determining policies on conservation and sustainable use of water resources.
 - MoAF General Directorate (DG) of Water Management: This DG ensures protection of water resources with the relevant international conventions and legislation and sets policies for their use. It ensures the coordination of national and international water management, preservation of surface and ground water quality and quantity, determines standards for the receiving environments with the relevant institutions and organisations, and monitors water quality.
 - General Directorate of State Water Works (DSI): DSI is a state agency organised under the MoAF and is responsible for planning, management, development of all the water resources in Turkiye. DSI has a broad administrative capacity in terms of allocation of water resources and investment of infrastructure. It coordinates its functions through its regional directorates.
- **Ministry of Labour and Social Security (MoLSS):** The MoLSS is responsible for labour and social security affairs, including coordination and monitoring of all aspects associated with occupational health and safety.
- **Ministry of Industry and Technology (MoIT):** The MoIT is responsible for industrial and commercial affairs in Turkiye and determines industrial policies and strategies with the principles of ensuring efficiency and cleaner production. It also cooperates with relevant organizations in order to set out science, technology and innovation policies in line with economic development, social development and national security objectives and to ensure their implementation.

Administratively, Turkiye is divided into a total of 81 provinces, which are further subdivided into administrative districts which may cover both rural and urban areas, of which there are 973 in total. The local level government entities include the following:

- **Governorates:** Each of the 81 provinces in Turkiye is administered by a governor appointed by the President. As the chief executive of the province and principal agent of the central government, each governor supervises other government officials assigned to carry out ministerial functions in his/her province. The districts are administered by appointed sub-governors, who report directly to the governor and are responsible for a number of directorates including, amongst others, education, health, population, and security, which in turn are closely linked to the ministries of central government.
- **Municipalities:** All districts have municipalities, headed by an elected mayor, who administers a defined municipality area. The major services for which municipalities are responsible include urban planning and implementation, management of transportation system, construction and maintenance of urban roadways and provision of water, sewerage and utility services, as well as waste collection/disposal.
- **Muhktars:** The lowest level of government is the villages and neighbourhoods, headed by elected mukhtars taking care of specific administrative matters. The mukhtars are elected through local elections for five-year terms.

3.2 National Regulatory Framework

3.2.1 National Legislative Framework

The studies regarding the environmental, health, safety and social issues that are parts of the ESIA have been carried out considering the current relevant laws and regulations applicable in Turkiye for the biotechnology sector, which are defined below.

The Environmental Law No. 2872 is Turkiye's primary framework for environmental legislation is supported by a series of laws, regulations, and communiques. It lays out the main responsibilities and requirements of the institutional authorities and the businesses regarding protection and preservation of the environment. Labor, health and safety issues are collectively ruled by the Labor Law No. 4857, Occupational Health and Safety (OHS) Law No. 6331 and associated regulations. They aim to regulate the employer and the employee's duties, powers, responsibilities, work related rights, working conditions and obligations to provide occupational health and safety at work and improve the current health and safety conditions.

The Turkish Regulation on Environmental Impact Assessment (EIA) dated 2014 is largely in line with the EU Directive on the assessment of the effects of certain public and private projects on the environment (2011/92/EU), including relevant key steps such as monitoring, public consultation, scoping, disclosure and auditing. The EIA Regulation (2014) has been repealed in July 2022 as the new EIA Regulation was published in the Official Gazette dated 29 July 2022 and numbered 31907. As it is also mentioned in Temporary Article 1 of the new EIA Regulation; it must be noted that since the EIA opinion letter for the Project was obtained on 13 August 2020 (before the publication of the new EIA Regulation in 2022), the Project is subject to the former EIA Regulation (2014). The former EIA Regulation divides projects into two categories: (i) Annex-I Projects; projects that have significant potential impacts and require an EIA and (ii) Annex-II Projects, those that are likely to have significant impacts on the environment and subject to screening. In order to assess the national EIA requirements applicable to the proposed Project, the official view of the Ministry of Environment, Urbanization and Climate Change (MoEUCC) was requested by the MoH on 10 August 2020. In their response letter dated 13 August 2020, MoEUCC stated that production of pharmaceutical product active substances is addressed under the Annex-I of the EIA Regulation "Article 35 – facilities where active substances of agricultural pesticides and/or pharmaceutical products are produced", and production of pharmaceutical products/medicines is addressed under the Annex-II of the EIA Regulation "Article 4a - facilities where agricultural pesticides and pharmaceutical products (excluding vaccine and serum production) and plant growth regulators are produced". Since production of active substances of pharmaceutical products will not be undertaken by MoH within the scope of the Project, it does not fall under the Annex-I of the former EIA Regulation. As the Annex-II explicitly excludes vaccine and serum production, the Project does not fall under the Annex-II of the regulation either. Therefore, the Project is "exempted" under the abovementioned regulation and legally no additional EIA exemption letter is required. Note that although the EIA Regulation underwent significant revisions in 2022, the annex classifications of the regulation that are relevant to the Project remain the same.

3.2.2 Applicable National Environmental, Health, Safety and Social Legislation

The key national regulations applicable to the Project are given in Table 3-1. The associated permit and compliance requirements for the Project are indicated along with the applicable provisions in the relevant sections of this report.

January 2024

Table 3-1: Applicable Turkish Legislation

Law/Regulation	Official gazette (OG) date	OG number
Environmental Legislation		
Environmental Law (2872)	11.08.1983	18132
Groundwater Law (167)	23.12.1960	10688
Law on Conversation of Cultural and Natural Assets (2863)	23.07.1983	18113
Regulation on Environmental Impact Assessment	29.07.2022	31907
Regulation on Environmental Permit and License	10.09.2014	29115
Regulation on Environmental Audit	12.06.2021	31509
Workplace Opening and Permit Regulation	10.08.2005	25902
Regulation on Environmental Noise Control	30.11.2022	32029
Regulation on Prevention and Mitigation of Major Industrial Accidents	30.12.2013	2887
Regulation on Soil Pollution Control and Point-Source Contaminated Sites	08.06.2010	27605
Regulation on Classification, Labelling and Packaging of Materials and Mixtures	11.12.2013	28848
Regulation on Safety Data Sheets for Hazardous Substances and Mixtures	13.12.2014	29204
Regulation on Road Transportation of Hazardous Materials	24.04.2019	30754
Regulation on Registration, Evaluation, Permission and Restriction of Chemicals	23.06.2017	30105
Regulation on the Classification, Labelling and Packaging of Substances and Mixtures	11.12.2013	28848
Water Pollution Control Regulation	31.12.2004	25687
Regulation on Wastewater Discharges to Sewage System	19.09.2011	Published by ASKİ ²⁸
Regulation on the Protection of Groundwater against Pollution and Deterioration	07.04.2012	28257
Regulation on Control of Pollution Caused by Hazardous Substances in Aquatic Environment	26.11.2005	26005
Industrial Air Pollution Control Regulation	03.07.2009	27277
Regulation on the Control of Air Pollution caused by Heating	13.01.2005	25699
Regulation on Assessment and Management of Air Quality	06.06.2008	26989
Regulation on Greenhouse Gas Emissions	17.05.2014	29003
Regulation on Ozone Depleting Substances	07.04.2017	30031
Regulation on Fluorinated Greenhouse Gases	04.01.2018	30291
Waste Management Regulation	02.04.2015	29314
Zero Waste Regulation	12.07.2019	30829
Regulation on Landfilling of Waste	26.03.2010	27533
Regulation on Control of Waste Oils	21.12.2019	30985
Regulation on Control of Polychlorinated Biphenyls and Polychlorinated Terphenyls	27.12.2007	26739
Regulation on Control of Packaging Waste	27.12.2017	30283
Regulation on the Control of End-of-life Tires	25.11.2006	26357
Regulation on Control of End-of-Life Vehicles	30.12.2009	27448
Regulation on Control of Medical Waste	25.01.2017	29959
Regulation on Control of Waste Vegetable Oil	06.06.2015	29378
Regulation on Control of the Waste Batteries and Accumulators	31.08.2004	25569

²⁸ Ankara Metropolitan Municipality General Directorate of Water and Sewerage

Law/Regulation	Official gazette (OG) date	OG number
Regulation on Control of Waste Electrical and Electronic Appliances	22.05.2012	28300
Regulation on Control of Excavation, Construction and Demolition Waste	18.03.2004	25406
Regulation on the Waste Generated from the Radioactive Substance Usage	02.09.2004	25571
Regulation on Safe Transportation of Radioactive Substances	08.07.2005	25869
Regulation on Radioactive Waste Management	09.03.2013	28582
Regulation on the Control of Odorous Emissions	26.12.2008	27092
Regulation on Energy Efficiency in Buildings	05.12.2008	27075
Regulation on Increasing Efficiency in the Use of Energy Sources and Energy	27.10.2011	28097
Regulation Concerning Exploitation of Trees and Shrubs on Private-registered Immovables not Regarded as Forest	10.12.2020	31330
Legislation related to Health and Safety, Labour Practices		
Labour Law (4857)	10.06.2003	25134
Law on Trade Union and Collective Bargaining (6356)	18.10.2012	28460
Law on Public Servants (657)	23.07.1965	12056
Regulation on Contractors and Subcontractors	27.09.2008	27010
Regulation on Working Duration Related to Labour Law	06.04.2004	25425
Regulation on Excess Work and Work in Excess Periods related to Labour Law	06.04.2004	25425
Regulation on Special Principles in Works Carried out by Employing Workers in Shifts	07.04.2004	25426
Regulation on Minimum Wage	01.08.2004	25540
Regulation on Suspension of Work in Workplaces	01.08.2004	28603
Law on Metropolitan Municipalities (5126)	23.07.2004	25531
Law on Municipalities (5393)	13.07.2005	25874
Law on Public Tenders (4734)	22.01.2002	24648
Law on Public Tender Agreements (4735)	22.01.2002	24648
Law on Occupational Health and Safety (6331)	30.06.2012	28339
Occupational Health and Safety Services Regulation	29.12.2012	28512
First Aid Regulation	29.07.2015	29429
Regulation on Occupational Health and Safety in Construction Works	05.10.2013	28786
Regulation on the Procedures and Principles of the Employee's Health and Safety Trainings	15.05.2013	28648
Regulation on Occupational Health and Safety Committees	18.01.2013	28532
Regulation on Occupational Health and Safety Risk Assessment	29.12.2012	28512
Regulation on Duties, Authority, Responsibilities and Trainings of Occupational Health and Safety Specialists	29.12.2012	28512
Regulation on Duties, Authority, Responsibilities and Trainings of On-site Doctor and Other Health Personnel	20.07.2013	28713
Regulation on Occupational Health and Safety in Temporary or Fixed Term Employment	23.08.2013	28744
Regulation on Environmental Noise Emission Generated by the Outdoor Equipment Used at Site	30.12.2006	26392
Exhaust Gas Emission Control Regulation	11.03.2017	30004
Turkiye Earthquake Regulation for Buildings	18.03.2018	30364
Road Traffic Regulation	18.07.1997	23053
Law on People with Disabilities (5378)	07.07.2005	25868
Regulation on Accessibility Monitoring and Auditing	20.07.2013	28713

Law/Regulation	Official gazette (OG) date	OG number
Regulation on the Health and Safety Measures to be taken in Workplace Buildings and Additions	17.07.2013	28710
Regulation on Protection of Buildings from Fire	19.12.2007	26735
Regulation on the Protection of the Workers against Risks Relevant to Noise	28.07.2013	28721
Regulation on the Protection of the Workers against Vibration Risks	22.08.2013	28743
Regulation on the Control of Dust Emissions	05.11.2013	28812
Regulation on the Protection of Workers from the Dangers of the Explosive Media	30.04.2013	28633
Regulation on the Emergency Situations in Workplaces	18.6.2013	28681
Regulation on Health and Safety Measures in Working with Chemical Substances	12.08.2013	28733
Regulation on Health and Safety Measures for Working with Carcinogenic and Mutagenic Substances	06.08.2013	28730
Regulation on Use of Personal Protective Equipment in Workplaces	02.07.2013	28695
Regulation on the Works in Which Workers shall Work Maximum Seven and Half Hours or Less in a Day in Terms of Health Rules	16.07.2013	28709
Regulation on Safety and Health Signs	11.09.2013	28762
Regulation on Manual Handling	24.07.2013	28717
Regulation on the Prevention of Exposure Risks from Biological Agents	15.06.2013	28678
Regulation on Radiation Safety	24.03.2000	23999
Regulation on Ion Radiation Resources used in Health Services and Radiation Dose Limits of Working Staff and Work Principles	05.05.2012	28344
Legislations related to Land Acquisition		
Law on Expropriation (2942)	08.11.1983	18215
Zoning Law (3194)	09.05.1985	18749
Legislations related to Stakeholder Engagement and Grievance Mechanism		
Law on Right to Information (4982)	24.10.2003	25269
Law on Preservation of Personal Data (6698)	07.04.2016	29677
Regulation on Environmental Impact Assessment (EIA)	29.07.2022	31907
Regulation on the Principles and Procedures for Enforcement of the Law on the Right to Information	27.04.2004	25445
Law on Use of the Right to Petition (3071)	10.11.1984	18571
Legislations related to Cultural Heritage		
Law on the Conservation of Cultural and Natural Assets (2863)	23.07.1983	18113
Other laws and regulations specific to the Project		
Biosafety Law (5977)	26.03.2010	27533
Regulation on Working Principles and Procedures of the Biosafety Committee and Board	13.08.2010	27671
Public Health Law (1593)	06.05.1930	1489
Regulation on Working Procedures and Principles of Laboratories for Public Health Services	09.03.2019	30709
Regulation on Good Laboratory Implementation Principles, Harmonisation of Test Units, Supervision of Good Laboratory Practice Implementation and Works	09.03.2010	27516
Regulation on Good Laboratory Practice Implementation Compliance Monitoring Program	02.06.2021	31499
Regulation on Duties, Working Procedures and Principles of Service Units of the Ministry of Health	22.12.2017	30278
Animal Protection Law (5199)	01.07.2004	25509
Regulation on Working Procedures and Principles of Animal Testing Ethics Committees	15.02.2014	28914

Law/Regulation	Official gazette (OG) date	OG number
Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes	13.12.2011	28141
Regulation on Improvement and Evaluation of Quality in Health	27.06.2015	29399
Regulation on Chemical, Biological, Radiological, Nuclear Danger and Hazard	01.10.2020	31261
Regulation on Medical Laboratory	09.10.2013	28790
Regulation on Clinical Research of Pharmaceuticals and Biological Products	13.04.2013	28617
Regulation on Research on Clinical Medical Devices	06.09.2014	29111
Regulation on Test, Control and Calibration of Medical Devices	25.06.2015	29397
Communique of Working Procedures and Principles of Tuberculosis Laboratories	25.10.2015	29513
Regulation on Surveillance and Control Principles of Communicable Diseases	30.05.2007	26537
Regulation on Protection of Human Health from Harmful Effects of Volatile Substances	05.08.2010	27663
Veterinary Services, Plant Health, Food and Fodders Law (5996)	13.06.2010	27610
Communiqué on Notification System of Infectious Diseases	06.11.2004	25635
Fight Against Tuberculosis Law (5368)	15.04.1949	7183
Treatment of Malaria Law (7402)	11.01.1960	10402
Regulation on Fight Against and Protection from Rabies	18.01.2012	28177
Regulation on Genetically Modified Organisms and Their Products	29.05.2014	29014
Regulation on Authorizations Regarding Radiation Facilities and Radiation Applications	17.12.2020	31337

3.2.2.1 Details on Some Key National Laws and Regulations Applicable to the Project

Details on the Environmental Legislation

As mentioned in Section 3.2.1, the Environmental Law No. 2872 regulates as an umbrella law and sets the primary framework for performing environmental management practices in Turkiye. The law is supported by series of laws, regulations and communiques that covers various subjects, such as water, wastewater, waste, chemicals and hazardous substances, air quality, soil contamination, licensing, energy efficiency, etc. Each of these laws, regulations and communiques have been taken into consideration in the relevant sections of this ESIA report to put forth the compliance status of the Project activities in regard with the national and regional legislation.

Turkish EIA Regulation and EIA Processes

According to the Environmental Law No.2872, institutions, organizations and businesses that may cause environmental risks as a result of their planned activities are obliged to prepare an Environmental Impact Assessment (EIA) Report or a Project Description Document. Unless the *"EIA positive" decision* or the *"EIA not required" decision* is taken; the relevant approval, permit, incentive, construction or operation licenses cannot be given for these projects.

The Environmental Impact Assessment Regulation of Turkiye determines the administrative and technical procedures and principles to be followed in the EIA process. When an activity (a Project) is planned, the Project developer is responsible for preparing an Environmental Impact Assessment (EIA) Report along with other relevant permits required to carry out for the Project. The EIA Regulation of Turkiye is in line with the EU Directive on the assessment of the effects of certain public and private projects on the environment (2011/92/EU). The regulation covers the following:

• Type of projects of which the Environmental Impact Assessment Application File, Environmental Impact Assessment Report and Project Description Document will be requested and the matters to be discussed within these documents,

- Administrative and technical procedures and principles to be followed within the Environmental Impact Assessment process,
- Application, pre-construction, construction, operation and post-operation monitoring, control and auditing of projects within the scope of Environmental Impact Assessment process, and
- Necessary training activities for the effective and widespread implementation of the Environmental Impact Assessment system of Turkiye and for strengthening the institutional structure.

The Projects/facilities are subject to EIA Report issuance according to the nature of the Project/facility, capacity, or location of the activity. Activities subject to the provisions of the Environmental Impact Assessment Regulation are listed in Annex I and Annex II of the Regulation. A full EIA report is required for Annex I activities and these Projects go through the entire EIA process. On the other hand, a Project Description Document (PDD) is prepared for Annex II activities in accordance with the outlines given in the regulation. If the decision of "EIA is required" is given as a result of the submission of the PDD, a full EIA is prepared. Please refer to Section 3.2.1 for detailed information on position of the Project in regard to the EIA Regulation and EIA processes.

Environment Related Permits and Licenses

Environmental related permitting and licensing activities are performed in accordance with the Environmental Law No:2872 and is regulated with the Environmental Permit and License Regulation of Turkiye. The purpose of the Environmental Permit and License Regulation is to regulate the procedures and principles to be followed for the projects/activities listed in the annexes of the regulation during the environmental permitting and licensing processes. Within the scope of this regulation, facilities are classified based on their environmental impacts as follows: (a) Facilities with a high pollution impact on the environment (Annex-1 list); and (b) Facilities with a pollution impact on the environment (Annex-1 list); and (b) Facilities from PDoEUCC). An environmental permit (Annex-1 facilities from MoEUCC, Annex-2 facilities from PDoEUCC). An environmental permit covers at least one of the following: air emissions, wastewater discharge, noise control, deep-sea discharge or hazardous materials discharge. A Temporary Operation Permit is issued for a period of one year until the requirements of the environmental permit are fulfilled.

Details on the Legislation related to Labour and Working Conditions

The MoH estimates that there will be need for both contracted/subcontracted workers and public servants during the operation phase of the Project. As already known, there are contractors and subcontractors employed for the construction activities. In this regard, the workforce of the Project relies on the Turkish Labour Law No. 4857 and Law on Public Servants No. 657 together with the relevant regulations about labour and working conditions.

The Turkish Labour Law No. 4857 regulates as an umbrella law for labour-related practices at national context. Main objectives of this law include proper management of labour and working conditions, defining the roles, responsibilities and rights of workers as well as employers who reach an agreement about work through a mutual employment contract. Additionally, it embraces certain principles such as working hours, overtime hours, non-discrimination based on gender, race, political opinion, religion etc. And equal opportunity for all, minimum age for employment²⁹, employment of disabled personnel, minimum wage, right to unionization and collective bargaining, termination and compensation benefits, annual leave and other leave opportunities (i.e. maternal leave).

Law on Public Servants No. 657 regulates all personnel affairs of the public servants including the required qualifications, appointments, duties, rights and obligations, salaries and allowances. The Law

²⁹ Minimum age of employment is defined as 15 in the Turkish Labour Law No. 4857. Yet, it is stated in the law that children who have completed the age of fourteen and have completed the compulsory primary education can be employed in soft works as long as the work does not interfere with their physical, mental, social, educational and moral development.

also includes articles on unionization, ways to raise grievance, retirement, annual leave and other leave opportunities (i.e. sickness leave).

Other laws and regulations that are in line with the Turkish Labour Law No. 4857 and Law on Public Servants No. 657 are listed and briefly defined as follows:

- Law on Trade Union and Collective Bargaining (6356): The objective of this Law is to make collective bargaining agreements between workers and employers in order to determine the mutual economic and social conditions and working conditions through decent and proper means.
- Law on People with Disabilities (5378): The purpose of this Law is to ensure that the disabled people benefit from their fundamental rights and freedoms through full and effective participation in social life including employment opportunities in the labour market on an equal basis with other individuals. The Law commits to preventing the discrimination based on disability in any aspect of employment (i.e. recruitment, proposed working hours and conditions, continuity of employment, career development, and healthy and safe working conditions).
- Regulation on Contractors and Subcontractors: The Regulation aims at managing the conditions for the establishment of the employer and subcontractor relationship, the notification and registration of the subcontractor's workplace, and the issues that should be included in the subcontractors' contracts within the scope of the Labour Law No. 4857.
- Regulation on Minimum Wage: The Regulation is based on the principles to be applied during the determination of the minimum wage as well as the duties and obligations of the employer. The provisions of this Regulation cover all workers within the scope of the Labour Law No. 4857 that have an employment contract. The Regulation commits to the principle of equality in wages.

Details on the Legislation related to Occupational Health and Safety

The scope of the Project requires certain occupational health and safety measures to be taken during both construction and operation phases. All measures will be in line with the Law on Occupational Health and Safety No. 6331, which is in place for all regulations related to health and safety of the workforce.

The purpose of the Law on Occupational Health and Safety No. 6331 is to regulate the duties, authorities, responsibilities, rights and obligations of employers and employees in order to ensure occupational health and safety at workplaces and to improve existing health and safety conditions.

In line with this Law, there is a variety of additional laws and regulations depending on the workplace and the scope of the work (i.e. noise, vibration, dust, chemical substances). Majority of these laws and regulations will be applied within the scope of the Project.

The Law also necessitates informing workers about the work-related health and safety risks together with providing them trainings to prevent such risks. The usage of personal protective equipment is one of the most significant requirements for workers in the context of occupational health and safety. Furthermore, the Law requires the employers to carry out regular health controls for their workers and report if any near misses, injuries, incidents or death occur at the workplace.

Details on the Legislation related to Land Acquisition

When any land acquisition or expropriation is required, Law on Expropriation No. 2942 is applied within the scope of the national legislation. The Law defines certain principles and procedures to be followed during compensation of assets or properties that will be expropriated. Additionally, the people affected from the expropriation need to be consulted on compensation value in line with this Law. The scope of the Law does not include informal land users or squatters, only compensations for legal titles are covered within the Law. However, since the ownership of the two parcels that the Project will be constructed on belongs to the MoH, this Law is not required to be applied. The MoH confirmed that the Project will not make any additional land acquisition or expropriation. The Project will not have negative impacts on livelihoods resulting from land acquisition. Additionally, there is no informal user on the Project land and it belongs to the MoH.

Details on the Legislation related to Stakeholder Engagement and Grievance Mechanism

Law on Right to Information No. 4982 regulates the procedure and the basis of the right to information according to the principles of equality, impartiality and openness that are the necessities of a democratic and transparent government.

Citizens of the Turkish Republic are entitled to apply Turkish Grand National Assembly and the public authorities by written petition, in respect to their requests and complaints, in accordance with the Article 3 of the Law on Use of the Right to Petition No. 3071. Foreigners residing in Turkiye are also entitled to enjoy this right on the condition of reciprocity and using Turkish language in their petitions.

Regulation on Environmental Impact Assessment (EIA) was prepared in the context of the Article 10 of the Environmental Law. It aims at preventing the potential destructive environmental impacts of the projects and decrease or alleviate the existing environmental impacts of these projects. The legal obligation to prepare a Stakeholder Engagement Plan and organise a public consultation meeting at the beginning of the national EIA process is defined within this Regulation on EIA. This Regulation refers to informing and consulting the public about the Project, holding the meeting at the Project site, prior approval of the place and date of the meeting by the Governor and announcement in a local and national newspaper at least 10 days before the meeting.

3.2.3 International Conventions Ratified by Turkiye that are Relevant to the Project

Turkiye has ratified several international conventions and agreements with respect to environmental conservation. Those conventions and agreements that could have relevance to the Project are listed below:

- Paris Agreement of the United Nations Framework Convention on Climate Change (2016) (Turkiye made the ratification accession on 6 October 2021)
- Vienna Convention for the Protection of Ozone Layer (1985) and the Montreal Protocol on Substances that Deplete the Ozone Layer (1987)

Relevant international conventions ratified by Turkiye regarding cultural heritage:

- United Nations Educational, Scientific, and Cultural Organisation (UNESCO) Convention on the Protection and Promotion of the Diversity of Cultural Expressions (Turkiye made the ratification accession on 02 November 2017)
- UNESCO Convention for the Safeguarding of the Intangible Cultural Heritage (Turkiye made the ratification accession on 27 March 2006)
- UNESCO Convention on the Protection of World Cultural and Natural Heritage (Turkiye made the ratification accession on 16 March 1983)
- UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (Turkiye made the ratification accession on 21 April 1981)

Additionally, the following should be abided by the Project in regard to biodiversity issues:

- Convention on Biological Diversity (CBD) (1996)
- Bern Convention on Protection of Europe's Wildlife and Living Environment (acceded by the Decision of the Council of Ministers dated 9 January 1984 and published in the Turkish Official Gazette dated 20 February 1984 and no. 18318)
- CITES Convention on Trade in Endangered Species of Wild Flora and Fauna (1975)
- International Union for the Conservation of Nature (IUCN) list of threatened species (the IUCN Red List)

International Labour Organization (ILO) Conventions that Turkiye has ratified are listed below³⁰:

- C 2 Unemployment Convention, 1919
- C 11 Right of Association (Agriculture) Convention, 1921
- C 14 Weekly Rest (Industry) Convention, 1921
- C 15 Minimum Age (Trimmers and Stokers) Convention, 1921
- C 26 Minimum Wage-Fixing Machinery Convention, 1928
- C 29 Forced Labour Convention, 1930
- C 34 Fee-Charging Employment Agencies Convention, 1933
- C 42 Workmen's Compensation (Occupational Diseases) Convention (Revised), 1934
- C 45 Underground Work (Women) Convention, 1935
- C 53 Officers' Competency Certificates Convention, 1936
- C 55 Shipowners' Liability (Sick and Injured Seamen) Convention, 1936
- C 58 Minimum Age (Sea) Convention (Revised), 1936
- C 59 Minimum Age (Industry) Convention (Revised), 1937
- C 68 Food and Catering (Ships' Crews) Convention, 1946
- C 69 Certification of Ships' Cooks Convention, 1946
- C 73 Medical Examination (Seafarers Convention, 1946
- C 77 Medical Examination of Young Persons (Industry) Convention, 1946
- C 80 Final Articles Revision Convention, 1946
- C 81 Labour Inspection Convention, 1947
- C 87 Freedom of Association and Protection of the Right to Organise Convention, 1948
- C 88 Employment Service Convention, 1948
- C 92 Accommodation of Crews Convention (Revised), 1949
- C 94 Labour Clauses (Public Contracts) Convention, 1949
- C 95 Protection of Wages Convention, 1949
- C 96 Fee-Charging Employment Agencies Convention (Revised), 1949
- C 98 Right to Organise and Collective Bargaining Convention, 1949
- C 99 Minimum Wage Fixing Machinery (Agriculture) Convention, 1951
- C100 Equal Remuneration Convention, 1951
- C102 Social Security (Minimum Standards) Convention, 1952
- C105 Abolition of Forced Labour Convention, 1957
- C108 Seafarers' Identity Documents Convention, 1958
- C111 Discrimination (Employment and Occupation) Convention, 1958
- C115 Radiation Protection Convention, 1960
- C116 Final Articles Revision Convention, 1961
- C118 Equality of Treatment (Social Security Convention, 1962)
- C119 Guarding of Machinery Convention, 1963
- C122 Employment Policy Convention, 1964
- C123 Minimum Age (Underground Work) Convention, 1965
- C127 Maximum Weight Convention, 1967
- C133 Accommodation of Crews (Supplementary Provisions) Convention, 1970

³⁰ Accessed from <u>https://www.ilo.org/ankara/conventions-ratified-by-turkey/lang--en/index.htm</u> on 07 January 2023.

- C134 Prevention of Accidents (Seafarers) Convention, 1970
- C135 Workers' Representatives Convention, 1971
- C138 Minimum Age Convention, 1973
- C142 Human Resources Development Convention, 1975
- C144 Tripartite Consultation (International Labour Standards) Convention, 1976
- C146 Seafarers' Annual Leave with Pay Convention, 1976
- C151 Labour Relations (Public Service) Convention, 1978
- C152 Occupational Safety and Health (Dock Work) Convention, 1979
- C153 Hours of Work and Rest Periods (Road Transport) Convention, 1979
- C155 Occupational Safety and Health Convention, 1981
- C158 Termination of Employment Convention, 1982
- C159 Vocational Rehabilitation and Employment (Disabled Persons) Convention, 1983
- C161 Occupational Health Services Convention, 1985
- C164 Health Protection and Medical Care (Seafarers) Convention, 1987
- C166 Repatriation of Seafarers Convention (Revised), 1987
- C167 Safety and Health in Construction Convention, 1988
- C176 Safety and Health in Mines Convention, 1995
- C182 Worst Forms of Child Labour Convention, 1999
- C187 Promotional Framework for Occupational Safety and Health Convention, 2006

Out of 59 Conventions ratified by Turkey, 55 are in force, 3 Conventions have been denounced and one has been abrogated. These are C 15 Minimum Age (Trimmers and Stokers) Convention, C 34 Fee-Charging Employment Agencies Convention, C 58 Minimum Age (Sea) Convention (Revised), C 59 Minimum Age (Industry) Convention (Revised). None of these Conventions listed above have been ratified in the past 12 months.

3.3 International Requirements

This section provides an overview of the international regulatory framework and applicable standards for the Project. The following guidelines and manuals of the World Bank have been primarily taken into account during the ESIA process:

- The World Bank's Environmental and Social Framework (ESF), 2017
- The World Bank Group's Environment, Health and Safety (EHS) General Guidelines, 2007
- The World Bank Group's EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing, 2007
- The World Bank Group's EHS Guidelines for Healthcare Facilities, 2007

The Environmental and Social Standards (ESSs) of the World Bank Environmental and Social Framework (ESF) (effective as of October 2018) are listed below in Table 3-2 together with brief description and their relevance to the Project:

World Bank ESSs	Description	Relevance to the Project
ESS 1: Assessment and Management of Environmental and Social Risks and Impacts	ESS 1 requires the assessment, identification, evaluation and management of the environment and social risks and impacts of the project in a manner consistent with the ESSs. It regulates the adoption of differentiated measures in equal sharing of the development benefits and opportunities resulting from the project.	In line with the ESS 1, the MoH has been embracing the relevant national legislation and international standards for the effective implementation of the Project. Based on the impact assessment outcomes, measures on the environmental and social impacts of the Project are defined.

Table 3-2: Description of the World Banks ESSs and Their Relevance to the Project

World Bank ESSs	Description	Relevance to the Project	
	Other requirements covered under the ESS 1 are the development of an Environmental and Social Commitment Plan (ESCP), implementation of all measures and actions set out in the legal arrangement including the ESCP, and conducting monitoring and reporting on the environmental and social performance of the project against the ESSs. Undertaking stakeholder engagement and disclosing appropriate information in accordance with the ESS 10 is also in the scope of the ESS 1.	The MoH will apply the measures in order to enhance the environmental and social performance and ensure compliance of the Project with the World Bank ESSs, national legislation, and international requirements. Such applications of the measures will be based on the ESIA and environmental and social management plans and procedures prepared specific to the Project.	
	During the application of the ESS 1, national environmental and social institutions, systems, laws, regulations and procedures are required to be utilized in the development and implementation phases of the project.		
	Overall, the ultimate objective is to promote improved environmental and social performance, in ways which recognize and enhance Borrower capacity.		
ESS 2: Labour and Working Conditions	ESS 2 aims at promoting safety and health at work, ensuring fair treatment, non-discrimination and equal opportunity for all project workers, protect project workers, including vulnerable workers such as women, persons with disabilities, children (of working age, in accordance with this ESS) and migrant workers, contracted workers, community workers and primary supply workers.	The MoH will be applying all relevant principles defined under the ESS 2 for the workforce of the Project in both construction and operation phases. The application of the principles will be in accordance with written labour-related procedures and management plans (i.e. occupational health and safety, workers' grievance mechanism, human resources and labour management) specifically	
	The standard commits to the preventing the use of all forms of forced labour and child labour. Certain principles about freedom of association and collective bargaining of project workers as well as provision of accessible means to raise workplace concerns and grievances are also covered within the ESS 2.	prepared for the Project, all of which comply with the ESS 2, national legislation, and applicable international requirements (i.e. ILO).	
ESS 3: Resource Efficiency and Pollution Prevention and Management	The objective of the ESS 3 is to avoid or minimize adverse impacts on human health and the environment by avoiding or minimizing the polluting activities and emissions, managing existing pollution where necessary, avoiding generation of hazardous and non-hazardous wastes, and promoting the use of sustainable	Within the scope of the ESS 3, the Project risks related to the release of pollutants (to air, water, and land) are assessed and identified. For effective implementation and management of the identified actions, Project-specific management plans that are complying with the ESS 3, national legislation, and applicable international standards are	
	resources.	prepared on the subjects such as air quality, pollution prevention, chemicals and hazardous materials, resource efficiency, and waste and wastewater.	
ESS 4: Community Health and Safety	ESS 4 focuses on the ways to anticipate and avoid adverse impacts on the health, safety and security of project-affected communities during the project lifecycle. It requires the Borrower to adopt effective measures to address emergency events. The community exposure to project-related traffic and road safety risks, infrastructural obstacles, diseases and hazardous materials should be avoided or minimized. Similarly, for avoidance or	Within the scope of the Project, a number of management plans related to ensuring community health and safety (i.e. Community Health and Safety Management Plan, Emergency Preparedness and Response Plan, Security Management Plan, Traffic Management Plan) are prepared to be applied during both construction and operation phases. The MoH will apply sufficient security measures (i.e. preparation and implementation of the management	
	minimization the risks to the project-affected communities, safeguarding of personnel and property need to be ensured properly.	plans, employment of the security personnel, fencing the Project area) to avoid or minimize the Project risks on the local communities.	
ESS 5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement	ESS 5 principles requires that physical displacement, economic displacement, and/or involuntary resettlement of communities or persons should be prevented in the projects in which project-related land acquisition and	ESS5 is scoped out of the ESIA since no land acquisition is foreseen for the Project or its components and the Project site has no identified settlers/users.	

World Bank ESSs	Description	Relevance to the Project
	restrictions on land use are practiced. When unavoidable, involuntary resettlement should be minimized by exploring project design alternatives. In such cases, adverse social and economic impacts from land acquisition or restrictions on land use should be mitigated through providing timely compensation for loss of assets at replacement cost, assisting displaced persons in their efforts to improve, or at least restore, their livelihoods and living standards.	No expropriation, resettlement and/or economic displacement have occurred related to the Project.
ESS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources	ESS 6 aims at protection and conservation of biodiversity and habitats. Application of the relevant measures for the design and implementation of projects, which could have an adverse impact on biodiversity, is a requirement defined under this ESS. By this way, sustainable management of living natural resources are ensured and promoted in projects.	The Project commits to the requirements of the ESS 6. In line with the potential impacts of the Project on biodiversity and habitats, a number of mitigation measures are defined. Additionally, a Project-specific Biodiversity Management Plan is prepared for better management and control of the activities that may pose biodiversity-related risks during both construction and operation phases.
ESS 7: Indigenous Peoples/Sub-Saharan African Historically Underserved Traditional Local Communities	This ESS applies to a distinct social and cultural group possessing certain characteristics identified in accordance with the ESS7 (i.e. collective attachment to geographically distinct habitats, ancestral territories, or areas of seasonal use or occupation, as well as to the natural resources in these areas, customary cultural, economic, social, or political institutions that are distinct or separate from those of the mainstream society or culture, a distinct language or dialect, often different from the official language or languages of the country or region in which they reside).	ESS7 has been scoped out as there are no indigenous people in Turkiye.
ESS 8: Cultural Heritage	ESS 8 aims at protecting cultural heritage from the adverse impacts of project activities and support its preservation, addressing cultural heritage as an integral aspect of sustainable development, promoting meaningful consultation with stakeholders regarding cultural heritage, and promoting equitable sharing of benefits from the use of cultural heritage.	The MoH will be applying relevant principles defined under the ESS 8 in both phases of the Project. The applications of the MoH will be in line with the certain plans and procedures prepared within the scope of the Project (i.e. Cultural Heritage Management Plan and Chance Find Procedure).
ESS 9: Financial Intermediaries	Financial Intermediaries (Fis) are required to monitor and manage environmental and social risks and impacts of the projects they finance. The objectives of the ESS 9 are to set out the ways that the FI will assess and manage environmental and social risks and impacts associated with the subprojects it finances, promote good environmental and social management practices in the subprojects the FI finances; and promote good environmental and sound human resources management within the FI.	ESS9 is not applicable to the Project as there will be no financial intermediaries.
ESS 10: Stakeholder Engagement and Information Disclosure	This ESS recognizes the importance of open and transparent engagement between the Borrower and project stakeholders as an essential element of good international practice. Effective stakeholder engagement can improve the environmental and social sustainability of projects, enhance project acceptance, and make a significant contribution to successful project design and implementation.	To ensure the compliance of the MoH in management of grievances, organization of stakeholder engagement and consultation activities, and information disclosure processes in line with the ESS 10, a number of improvements and actions are defined for the Project. As the ESS 10 requires, the successful and effective stakeholder engagement practices will be emphasized throughout the lifecycle of the Project. The list of the Project stakeholders is prepared and

World Bank ESSs	Description	Relevance to the Project
	This ESS ensures that the process of stakeholder engagement will involve the following: stakeholder identification and analysis; planning how the engagement with stakeholders will take place; disclosure of information; consultation with stakeholders; addressing and responding to grievances; and reporting to stakeholders.	ways to engage with each stakeholder group are specified. For the systematic implementation of the ESS 10 standards, a Project-specific Stakeholder Engagement Plan is prepared. Additionally, the Project Grievance Mechanism is in place that the Project stakeholders can raise their concerns and grievances through various channels.

The International Health Regulations (IHR) represents an obligation for all World Health Organization (WHO) Member States to work together for global health security. The IHR has a purpose to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

The World Health Organization (WHO) published Laboratory Biosafety Manual (2020) to encourage countries to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. The Project will ensure that the operation phase will be in compliance with the appropriate practices and procedures observed by the WHO for the assigned biosafety level.

The following standards, guidelines and manuals of the WHO and other relevant institutions are applicable to the Project and have been taken into consideration during the ESIA in terms of biosafety and biosecurity aspects:

- WHO Laboratory Biosafety Manual and Associated Monographs, 4th edition, 2020
- WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006
- UN Model Regulations on the Transport of Dangerous Goods, 2021
- WHO Good Manufacturing Practices for Biological Products, Annex 2, 2016
- WHO White Paper-Establishing Manufacturing Capabilities for Human Vaccines, 2017
- WHO Guidance on regulations for the Transport of Infectious Substances, 2021
- Centres for Disease Control (CDC) and Prevention-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020
- The National Institutes of Health (NIH) Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006
- 21 Code of Federal Regulations (CFR) Food and Drugs
 - 21 CFR Part 200: General (Drugs)
 - 21 CFR Part 210: Current Good Manufacturing Practice in Manufacturing Processing, Packing or Holding of Drugs
 - 21 CFR 600: Biological Products
 - 21 CFR 610: General Biological Products Standards
- U.S. Food and Drug Administration (FDA) Vaccine and Related Biological Product Guidances
- FDA Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) Guidances
- FDA Development and Licensure of Vaccines to Prevent COVID-19, Guidance for Industry, 2020
- World Organisation for Animal Health (OIE) Terrestrial Manual, Chapter 1.1.3: Transport of Biological Materials, 2018
- International Civil Aviation Organisation (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air, 2021-2022 Edition

• Biological Weapon Convention, 1975

The standards and guidelines applicable to the Project in relation to animal welfare are as follows:

- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes
- OIE Terrestrial Animal Health Code, 2021
- OIE Guidelines on Disaster Management and Risk Reduction in Relation to Animal Health and Welfare and Veterinary Public Health
- The Council for International Organizations of Medical Sciences (CIOMS) and International Council for Laboratory Animal Science (ICLAS) International Guiding Principles for Biomedical Research Involving Animals, 2012
- The Universities Federation for Animal Welfare (UFAW), UFAW Handbook on The Care and Management of Laboratory and Other Research Animals 8th ed., 2010
- AWI (Animal Welfare Institute) Comfortable Quarters for laboratory animals 10th ed., 2015
- Office of Laboratory Animal Welfare (OLAW) National Institutes of Health Guide for the Care and Use of Laboratory Animals, 8th ed., 2011
- United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service Animal Welfare Act and Animal Welfare Regulations, 2020

Apart from the national and international directives and legislations, there are several international standards available in the EU applied for containment laboratory planning, construction and operation, mainly:

- European Standard EN 12128:1998 Biotechnology Laboratories for research development and analysis, containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements addresses the physical containment elements of the microbiology laboratory,
- ISO/EN 15189:2003 Medical laboratories Particular requirements for quality and competence,
- European Committee for Standardization (CEN) / CR 12739:1998 Biotechnology Laboratories for research, development and analysis – Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard.

3.4 Defined Gaps Between National Legislative Framework and Applicable WB ESSs

The major gaps determined between the applicable WB Environmental and Social Standards (ESSs) and the national legislative framework of Turkiye are assessed in Table 3-3 provided below.

World Bank ESSs	Identified Gaps	Mitigation of gaps applicable to this project	
ESS 1: Assessment and Management of Environmental and Social Risks and Impacts	The main gaps between the national EIA Regulation and ESS1 are determined as follows:	Project-specific ESIA studies should be performed by including the potential	
	 Social impact assessment is not fully integrated into the national legislation, leading to a lack of appropriate social basis and assessment of project-related social impacts, including impacts on disadvantaged or vulnerable groups and gender-related issues in environmental impact assessments (EIAs). 	social impacts of the Project. Sub- management plans are prepared to address specific risks/impacts in accordance with their level of significance.	
	 Lack of an executive summary and information on the legal and institutional framework in the Turkish EIAs (The level of technical knowledge provided in the non-technical summary -which is a requirement in EIA reports- may not be sufficient to meet World Bank requirements). 		
	 Limited or insufficient reference to the associated facilities. 		

Table 3-3: Major Gaps Between WB ESSs and National Legislation

103

World Bank ESSs	Identified Gaps	Mitigation of gaps applicable to this project
ESS 2: Labour and Working Conditions	In general, national laws and regulations regarding working and working conditions meet the requirements of ESS2. The worker grievance mechanism is the main gap between the national legislative framework and ESS2. There are no specific requirements in the national legislation on working and working conditions regarding a grievance mechanism that allows workers to submit their grievances to the employer.	Prepared Labour Management Procedures provides guidance on relevant management measures (e.g., worker grievance mechanism, code of conduct) envisaged by ESS2.
ESS 3: Resource Efficiency and Pollution Prevention and Management	Majority of the relevant national legislation is in line with EU directives. Therefore, it is assumed that there are no major gaps between ESS3 and related national legal framework.	The risks and impacts associated with the ESS3 are discussed in relevant chapters of this ESIA report. Sub- management plans are prepared to address specific risks/impacts depending on their level of significance.
ESS 4: Community Health and Safety	The general principles of public health and safety are addressed in various laws and regulations. In general, there are no defined major gaps in terms of legal framework. However, impacts from labour flows and risks related to gender-based violence are not explicitly included in national legislation.	The risks and impacts associated with the ESS4 are discussed in Chapter 14 of this ESIA report. It is also addressed through the related sub-management plans prepared for the Project.
ESS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources	No major gaps have been identified in terms of legal framework related with ESS6. In some cases, the level of consideration of sensitive ecological areas that are not legally protected, such as Key Biodiversity Areas in the local EIA Process, does not meet the requirements set by ESS6. In addition, management and monitoring of potential impacts, mitigation measures and residual impacts are generally not detailed in the legislation.	ESS6 requirements are included in the ESMP of the Project.
ESS 8: Cultural Heritage	No major gaps have been identified between the ESS8 and national legislation regarding the scope of project activities.	Chance Finds Procedure have been included in the ESMP of the Project.
ESS 10: Stakeholder Engagement and Information Disclosure	Effective and transparent stakeholder engagement is the key defined gap for ESS10. There is no provision in national legislation for the development of a project specific Stakeholder Engagement Plan for public consultations. Stakeholder engagement is only a requirement in the EIA process and there are no other requirements for the construction or operation phases of projects. Furthermore, the national legislation does not have specific provisions to address the concerns of vulnerable groups in the consultation process. National legislation has provisions that allow citizens to lodge complaints and grievances, however, it does not require a project- specific grievance mechanism.	(SEP) prepared for the Project provides the relevant tools and shall be adopted/used during the implementation of the Project.

4 SCOPE AND METHODOLOGY OF THE ESIA

4.1 Introduction

In accordance with international lending requirements for environmental and social assessment, the scope of works for the ESIA includes:

- Review of environmental and social (including labour, gender, community health and safety) risks and impacts of the Project and related facilities, including planned or unplanned but predictable developments caused by the Project that may occur later or at a different location to the extent possible
- Risks and impacts that may arise for each key stage of the Project cycle, including pre-construction, construction and operation phases
- Role and capacity of the relevant parties including government, contractors and suppliers
- Potential third-party impacts including supply chain considerations

The ESIA has identified adverse and positive, direct and indirect, and cumulative impacts of the Project related to the biological/physical and the socio-economic environment.

The definition of the Project includes all infrastructure and facilities that are directly part of the proposed development or are associated with the development, that exist specifically for or as a result of the Project. Consideration of associated infrastructure is carried out to the extent possible given its level of definition or development at the time of assessment of the primary project facilities.

This chapter presents the key findings of the scoping stage and the general methodology followed to produce the present ESIA.

4.2 Categorization of the Project

The World Bank has identified the risk category of the Project as Substantial. The ESIA study suggests that this categorization is valid and that it is feasible to mitigate and manage the majority of impacts associated with the Project through appropriate environmental and social management together with the monitoring to be specified in the Environmental and Social Management Plan (ESMP) and related plans.

4.3 Scoping Stage

Scoping is a crucial stage in the ESIA process that identifies aspects of the project that are likely to give rise to environmental and impacts. Final Scoping Report (issued in May 2022) was approved by the World Bank in June 2022. The Scoping Report was based on the review of the available project documentation provided by the MoH as well as environmental and social information collected through secondary sources and field surveys, and the review of national legislation and international standards. During the scoping stage, the following aspects have been evaluated in line with the World Bank ESS1:

- Environmental and social issues to be addressed in the ESIA were defined,
- Indicators for the necessary key information regarding the Project and the ways that the information would be obtained were determined,
- The process of understanding relevant legislation, national and international standards and their relevance to the ESIA study was initiated,
- A provisional assessment of the environmental and social risks and impacts for all stages of the Project, including pre-construction (design phase), construction and operation, as well as for accidents and emergencies was described,

- All components of the Project (including facilities, infrastructure and activities related to the Project) were taken into account,
- The impacts and risks of the Project on physical, natural, social, cultural and economic environment, and health and safety of the community and the labour force were considered,
- Preliminary identification of alternatives that need to be investigated within the Project was included in the process,
- Cumulative impacts from planned development of the Project and/or any other existing or planned developments were considered,
- The work schedule and the evaluation methodologies to be used were determined and explained,
- Possible limitations that may affect the progress of the work schedule were identified,
- The assessment covered both adverse impacts and positive/beneficial impacts together with the measures on improvement,
- Initial stakeholder engagement activities and primary consultations with stakeholders, which is a crucial part of the ESIA process, started in the scoping stage.

4.4 Scoping Results

The following issues were determined as the key environmental and social impacts based upon the findings of the Scoping Report:

- Waste management during construction and operation (particularly medical and hazardous waste),
- Wastewater (medical, domestic and stormwater) generation, treatment and discharge during construction and operation phases,
- Air emissions during operation phase,
- Occupational and community health, safety and security during construction and operation, especially:
 - Labour safety during construction
 - Biosafety during operation
 - Life and fire safety during operation
 - Emergency preparedness and response during operation
 - Security and effective communication during operation
- Animal welfare impacts during the operation,
- Increase in road traffic during construction and operation, and nuisance to the nearby settlements (e.g. noise, dust),
- Potential cumulative impacts related to the Project (e.g. traffic load during construction and operation; labor/security related impacts due to the influx of workers to the area; and cumulative production of medical and hazardous wastes).

4.5 Applicable World Bank ESSs

the following World Bank ESS's are applicable to the Project:

- ESS 1: Assessment and Management of Environmental and Social Risks and Impacts
- ESS 2: Labour and Working Conditions
- ESS 3: Resource Efficiency and Pollution Prevention and Management
- ESS 4: Community Health and Safety
- ESS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resources
- ESS 8: Cultural Heritage
- ESS 10: Stakeholder Engagement and Information Disclosure

- Please refer to Table 3-2 for a description of how each of the relevant ESSs will be applicable to the Project.
- ESS5 is scoped out of the ESIA, since no land acquisition is foreseen for the Project or its components and the Project site has no identified settlers/users, therefore no expropriation, resettlement and/or economic displacement have occurred related to the Project. ESS7 has been scoped out as there are no indigenous people in Turkiye. ESS9 is not applicable as there will be no financial intermediaries.

4.6 ESIA Process

4.6.1 Introduction

As defined in the World Bank's Environmental and Social Framework (ESF), ESIA is an instrument and a systematic process to identify and assess the potential environmental and social risks and impacts of a proposed project, evaluate alternatives, and design appropriate mitigation, management and monitoring measures to compensate adverse impacts, provide benefits, and improve decision making. The ESIA process anticipates and evaluates the impact of a project on various aspects of the physical, biological, cultural, and socioeconomic environment. This is followed by the identification of appropriate mitigation measures to prevent, mitigate, correct, offset or compensate for adverse impacts related to the nature and scale of the project.

In the projects targeting to contribute to sustainable development, it is crucial to consider and integrate the environmental and social aspects in the project cycle. The ESIA process is regarded as the most efficient method to fulfil this task of consideration and integration. Within the scope of ESIA, impacts were assessed for key phases of the Project process including pre-construction (design phase), construction and operation.

The first stage of the ESIA process is screening the current conditions to identify whether an ESIA study needs to be conducted for the proposed project. This stage is mostly determined through the lender's categorization patterns in accordance with the project scale and activities. The ESIA study is required to be conducted if the project scale and activities are included in the categorization patterns.

In the ESIA study of the Project, the guidelines and the approach of the World Bank were adopted. The steps of the ESIA process are explained in relevant sections of this chapter.

Following scoping and identification of likely environmental and social risks and impacts, specialist assessments were carried out in order to predict potential impacts associated with the development and propose measures to mitigate the impacts as appropriate. Each assessment follows a systematic approach, with the principal steps being:

- Description of assessment methodology used,
- Identification of the spatial and temporal scope of potential impacts (area of influence),
- Description of baseline conditions,
- Impact assessment,
- Identification of appropriate mitigation measures as required,
- Assessment of residual environmental impacts.



Figure 4-1: ESIA process

4.6.2 Area of Influence

The area of influence (AoI) indicates where proposed works, including related facilities and infrastructure will have a direct or indirect impact on the physical and social environment. This can result from aspects such as the physical land-take or as a result of the extent of the potential impact that extend beyond the development physical boundary such as noise emissions or emissions to air. The area of influence can also vary according to the stage of the Project being assessed such that construction impacts may have a greater area of impact than for operation. For each impact assessment, the spatial and temporal area of influence are defined.

4.6.3 Baseline

As part of the ESIA process, existing environmental and social conditions in the Project's impact area need to be defined in detail. For the significant impacts and key issues determined during the scoping stage, information regarding the existing environmental and social conditions were collected based on field surveys and measurements, secondary data (i.e., existing published documents, reports, plans) and the documents and information provided by the MoH. Baseline field surveys (such as air quality and noise measurements, ecological and archaeological walkover surveys) were started during the scoping phase
of the ESIA study. The need for additional baseline data collection (i.e. soil and surface water quality measurements) were identified during the ESIA process and relevant data were collected to inform the assessment study as necessary.

Relevant baseline information used to support the assessment process is referenced and summarised in each of the impact assessment chapters (i.e. chapters 6 through 19) of this ESIA Report. Supporting baseline information is provided where relevant in annexes.

4.6.4 Assessment of Impacts

This stage is conducted by evaluating and making predictions about the significance of impacts on the basis of the collected data. During the assessment, the relevant social and environmental risks and the impact of the Project on the environment and people are considered. Such phases are followed by designing appropriate mitigation measures for significant impacts and determining whether any residual impacts remain even after the application of mitigation measures.

In the assessment of impacts stage, environmental and social changes, risks and impacts as a consequence of the Project are reviewed starting from the scoping stage. Impact assessment is performed through evaluating each potential impact, identifying the value and sensitivity of affected receptors, predicting the magnitude of impacts and assessing the significance of impacts within the nature and scope of the Project. The assessment of the significance of impacts and identification of residual impacts takes account of any incorporated mitigation measures adopted and is largely dependent on the extent and duration of change, the number of people or size of the resource affected and their sensitivity to the change.

The magnitude of the impacts is estimated through the mathematical modelling for appropriate impact areas (e.g. noise, air quality). For the impacts that cannot be represented through mathematical models (e.g. impacts on ecology), professional judgment is utilized. Generic criteria for defining magnitude and sensitivity are summarised below.

Magnitude

The assessment of magnitude is undertaken in two steps. Firstly, the key issues associated with the Project are categorised as beneficial or adverse. Secondly, the magnitude of potential impacts is categorised as major, moderate, minor or negligible based on consideration of the parameters such as:

- Duration of the impact ranging from beyond decommissioning to temporary with no detectable impact
- Spatial extent of the impact for instance, within the site, boundary to regional, national, and international
- Reversibility ranging from permanent requiring significant intervention to return to baseline to no change
- Likelihood ranging from occurring regularly under typical conditions to unlikely to occur; and
- Compliance with legal standards and established professional criteria ranging from substantially exceeds national standards and limits / international guidance to meets or exceeds minimum standards or international guidance.

Table 4-1 outlines generic criteria for determining magnitude.

Table 4-1: Criteria for Determining Magnitude

Description
Fundamental change to the specific conditions assessed resulting in long term or permanent change, typically widespread in nature, and requiring significant intervention to return to baseline; exceeds national standards and limits.
Detectable change to the specific conditions assessed resulting in non- fundamental temporary or permanent change.
Detectable but minor change to the specific condition assessed
No perceptible change to the specific condition assessed.

Source: Mott MacDonald

Sensitivity

Sensitivity is generally site-specific, and the relevant criteria are developed from baseline information gathered. The sensitivity of a receptor is determined based on review of the population (including proximity / numbers / vulnerability) and presence of features on the site or the surrounding area. Generic criteria for determining sensitivity of receptors are outlined in Table 4-2. Each detailed assessment will define sensitivity in relation to their topic.

Magnitude (Beneficial or Adverse)	Definition (considers duration of the impact, spatial extent, reversibility and ability to comply with legislation)
High	Vulnerable receptor (human or ecological) with little or no capacity to absorb proposed changes or minimal opportunities for mitigation
Medium	Vulnerable receptor (human or ecological) with limited capacity to absorb proposed changes or limited opportunities for mitigation
Low	Vulnerable receptor (human or ecological) with some capacity to absorb proposed changes or moderate opportunities for mitigation
Negligible	Vulnerable receptor (human or ecological) with good capacity to absorb proposed changes or and good opportunities for mitigation

Source: Mott MacDonald

Impact Evaluation and Determination of Significance

Impacts are identified and significance is attributed taking into account the interaction between magnitude criteria and sensitivity criteria as presented in the significance matrix in Table 4-3.

Table 4-3: Impact Significance Matrix

	Sensitivity of Receptors			
Magnitude of Impact	Negligible	Low	Medium	High/Very High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

Source: Mott MacDonald

For each aspect, the significance of impacts will be discussed before and after mitigation (i.e. residual impact). Impacts identified as having major or moderate significance based on the above approach are classified as significant impacts.

Where feasible the following hierarchy of mitigation measures will be applied to reduce, where possible, the significance of impacts to acceptable levels:

- Mitigation / elimination through design,
- Site / technology choice, and
- Application of best practice.

Uncertainties

Any uncertainties associated with impact prediction or the sensitivity of receptors due to the absence of data or other limitation are explicitly stated. Where applicable, the ESIA makes commitments concerning measures that should be put in place with monitoring and/or environmental or social management plans to deal with the uncertainty. This will be summarised in the Project environmental and social management plan (ESMP) that includes the environmental and social monitoring requirements, and which will form part of the ESIA.

4.6.5 Assessment of Cumulative Impacts

Cumulative impacts are those impacts that may result from the combination of past, present or future actions of existing or planned activities in a project's area of influence. While a single activity may itself result in an insignificant impact, it may, when combined with other impacts (significant or insignificant) in the same geographical area and occurring at the same time, result in a cumulative impact that is significant.

Chapter 19: Cumulative Impacts Assessment of this ESIA presents an assessment of the cumulative impact of the Project, taking into account the scheme as a whole as well as with any other known present and planned developments in the area of influence.

4.6.6 Identification of Mitigation Measures

To prevent, minimize or compensate/offset the adverse impacts, it is essential to identify mitigation measures in accordance with the Turkish regulations and laws, international guidelines and best practices and the World Bank's ESSs. By considering disadvantaged and vulnerable groups/individuals, different mitigation measures may be defined in order to protect them from adverse impacts that may affect them disproportionately. Potential environmental and social opportunities and benefits including those that would improve the environmental and social sustainability of the Project are also included in this stage.

An Environmental and Social Management Plan that forms part of the ESIA has been developed for the Project to ensure compliance with the good international practice, including the World Bank Environmental and Social Framework (ESF), general and industry-specific environmental, health, and safety (EHS) guidelines and best practices documents alongside the national legislation.

4.6.7 Stakeholder Engagement

During the ESIA study, stakeholder consultation and engagement activities were undertaken starting from the scoping stage of the Project to ensure that the views and concerns received from project stakeholders (community members, government institutions, non-governmental organizations [NGOs], etc.) are considered and addressed within the scope of the ESIA. A standalone Stakeholder Engagement Plan (SEP)³¹ has been developed for the Project to provide information regarding the way public disclosure and consultation activities, communication and engagement with stakeholders will be systematically conducted throughout the life of the Project.

³¹ The SEP of the Project is provided in Annex H of the ESIA report.

The stakeholder engagement approach and activities for the Project are detailed in *Chapter 5: Stakeholder Engagement* of this report.

4.6.8 **Proposals for Monitoring**

Where appropriate, proposals for future monitoring have been put forward in each of the impact assessment chapters (i.e. chapters 6 through 19) of this ESIA Report. These proposals for monitoring have been designed to evaluate the accuracy of the impact prediction and the success of the implemented mitigation measures. The plans for future monitoring of the ESMP implementation has been committed within the ESMP constituting Annex B of this ESIA Report.

The ESMP aims at avoidance of impacts; however, in the conditions where avoidance is not possible, it offers technically and financially feasible and cost-effective mitigation measures to offset, minimize or reduce the negative environmental and social risk and impacts of the Project to reasonable levels. In addition to the ESMP, sub-management plans have been developed for the construction and operation phases of the Project. The ESMP will provide for indicative costing of the mitigation and monitoring measures as well.

4.7 ESIA Team

The ESIA team for the Project is introduced in Table 4-4 below.

Position/Responsibilities	Experts
Project Manager	Dr. Pelin Karakaya
Senior Environmental Consultant	Neslihan Ayvaz Özen
Senior Environmental Consultant	Elif Hot Öç
Environmental Consultant	Bianca Barsanoğulları
Environmental Consultant	Dilan Laçin
Social Consultant	Ecenur Alper
Senior Social Impact Assessment Expert	Gökhan Metin
Land Acquisition and Resettlement Expert	Ece Kılıçözlü
Stakeholder Engagement Expert	Sadık Avcı
Biodiversity Expert	Kerem Ali Boyla
Biodiversity Expert	Dr. Mecit Vural
Biomedical Waste Management Expert	Dr. Ece Ayşe Berkay
Air Quality Experts	İsmail Ulusoy Ersin Ala
Noise/Acoustic Experts	Erdem Kesen Mahmut Tuncer Çetin Ozan Kaya
Cultural Heritage Experts	Abdullah Halim Özatay Yunus Ekim Serkan Akdemir
Biosafety and Biosecurity Expert	Prof. Dr. Ahmet Carhan
Animal Welfare Expert	Prof. Dr. Tamay Başağaç
Occupational Health and Safety Expert	Gülşen Akgün İnce

Table 4-4: The ESIA Team

5 STAKEHOLDER ENGAGEMENT

5.1 Overview

Open and transparent stakeholder engagement is critical for a project's sustainability, ownership and implementation. The objective of the stakeholder engagement is to provide opportunity for affected and/or interested individuals, groups, communities and organizations to express their opinions and concerns about the Project, so that these opinions/concerns can be considered and addressed during assessment of impacts and identification of mitigation measures. ESIA preparation and disclosure abides by ESS1 and ESS10 and adheres to the principle of effective stakeholder engagement throughout the Project cycle.

This chapter outlines the information disclosure and consultation activities that have been undertaken as part of the ESIA process in accordance with the Stakeholder Engagement Plan (SEP) produced during the ESIA process and updated throughout. The key objective of this chapter is to present a summary of the outcomes of the ESIA stakeholder engagement activities, as well as an overview of the consultation activities planned for pre-construction, construction, and operational phases of the Project.

5.2 Principles of Consultation

The Project follows the World Bank ESSs for consultation and stakeholder engagement. In line with World Bank ESS10, consultation and engagement involve the following aspects:

- Identification and analysis of all potentially affected individuals, groups, communities, organizations, and vulnerable/disadvantaged individuals and groups that will be considered as stakeholders,
- Planning the steps for the way stakeholder engagement, information disclosure and meaningful consultation with stakeholders will be held,
- Identification of the issues that may be risky for the Project or the stakeholders,
- Disclosure of project information to the stakeholders in a timely, understandable, accessible and appropriate manner and format,
- Addressing a grievance system/mechanism for long-term communication between the Project and the stakeholders which provides an accessible and inclusive means to raise issues and concerns,
- Responding to grievances through the grievance mechanism, and
- Reporting to stakeholders.

Initiating the stakeholder engagement in an earlier phase of the Project enables the engagement process to be successful and effective. In line with the World Bank ESS10 and international best practice, stakeholder engagement started during the scoping phase of the Project through engagement with the key project stakeholders. Stakeholder engagement continued throughout the ESIA process.

5.3 Consultation Requirements

5.3.1 Overview

This section provides an overview of the national and international consultation requirements and applicable standards for the Project, which include the following:

- Turkish EIA Regulation,
- International requirements (including the Environmental and Social Framework of the World Bank), and
- Relevant European Union (EU) directives.

5.3.2 National Consultation Requirements

Under the scope of the current Turkish EIA Regulation (published in the Official Gazette dated 29 July 2022 and numbered 31907), several references are made to information disclosure and stakeholder participation. Public participation to EIA process is a legal obligation for the project owner as per the 1st clause of Article 9 of the EIA Regulation.



Figure 5-1: National legislative requirements for public consultation

National applicable legislation related to consultation, information disclosure, stakeholder engagement and grievance mechanism also includes Law on Right to Information (No. 4982), Law on Preservation of Personal Data (No. 6698), Law on Use of the Right to Petition (No. 3071), and Regulation on the Principles and Procedures for the Enforcement of the Law on the Right to Information.

5.3.3 World Bank Consultation Requirements

The World Bank's Environmental and Social Framework (ESF) (effective as of October 2018) has been primarily taken into account during the stakeholder engagement and SEP preparation processes of this ESIA study. In addition, the consultation principles on openness, access to information, accountability, transparency, visibility and accessibility that are defined in the World Bank Group Consultation Guidelines (effective as of June 2019) have been taken into consideration during the stakeholder engagement and SEP preparation processes.

The Environmental and Social Standards (ESSs) of the World Bank ESF that are relevant to the stakeholder engagement are listed in Table 5-1 below.

Table 5-1: The ESSs of the World Bank that are relevant to the stakeholder engagement

ESS	Key Policies and Objectives
ESS 1: Assessment and Management of Environmental and Social Risks and Impacts	ESS1 sets out the Borrower's responsibilities for assessing, managing and monitoring environmental and social risks and impacts associated with each stage of a project supported by the Bank through Investment Project Financing, in order to achieve environmental and social outcomes consistent with the ESSs.
	Accordingly, the Borrower will continue to engage with, and provide sufficient information to stakeholders throughout the life cycle of the project, in a manner appropriate to the nature of their interests and the potential environmental and social risks and impacts of the project. For High Risk and Substantial Risk projects, the Borrower will provide to the Bank and disclose documentation, as agreed with the Bank, relating to the environmental and social risks and impacts of the project prior to project appraisal. The documentation will address, in an adequate manner, the key risks and impacts of the project, and will provide sufficient detail to inform stakeholder engagement and Bank decision making.
ESS 10: Stakeholder Engagement and Information Disclosure	This ESS recognizes the importance of open and transparent engagement between the Borrower and project stakeholders as an essential element of good international practice. Effective stakeholder engagement can improve the environmental and social sustainability of projects, enhance project acceptance, and make a significant contribution to successful project design and implementation. This ESS ensures that the process of stakeholder engagement will involve the following: stakeholder identification and analysis; planning how the engagement with stakeholders will take place; disclosure of information; consultation with stakeholders; addressing and responding to grievances; and reporting to stakeholders.

The requirements of the World Bank ESF specifically refer to the need for and means of achieving community engagement, disclosure of relevant project information, appropriate consultation processes and grievance mechanisms throughout the project lifecycle. The requirements for stakeholder engagement in projects are:

- Start as early as possible in the project cycle,
- Continue throughout the life of the project,
- Be free of external manipulation, interference, coercion, or intimidation,
- Where applicable enable meaningful community participation, and
- Be conducted on the basis of timely, relevant, understandable, and accessible information in a culturally appropriate format.

5.3.4 Public Consultation Requirements under the EU

EU requires certain projects (private or public) that are likely to have significant effects on the environment, to conduct an environmental impact assessment (EIA) in line with the EIA Directive 85/337/EEC which requires public consultation throughout project development, impact assessment and project implementation. Additionally, a range of public plans and programs (i.e., concerning land use, transport, energy, waste or agriculture) are subject to a similar process called a strategic environmental assessment (SEA), where environmental considerations are already integrated at the planning phase, and possible consequences are taken into account before a project is approved or authorized so as to ensure a high level of environmental protection. In both cases, consultation with the public is a central aspect, which goes back to the Aarhus Convention, a multilateral environmental agreement under the auspices of the United Nations Economic Commission for Europe (UNECE), which entered into force in 2001 and to which the EU and all its member states are parties. It guarantees three rights to the public: public participation in environmental decision-making, access to environmental information held by public authorities (i.e., on the state of the environment or of human health where affected by the former), and the right of access to justice where the other two rights have been disregarded.

5.4 Stakeholder Identification

5.4.1 Overview

Stakeholders are persons or groups who are directly or indirectly affected by a project, as well as those who may have interests in a project and/or the ability to influence its outcome, either positively or negatively. The external stakeholders of the Project and the corresponding engagement approach during the ESIA process are summarized in Figure 5-2.



Figure 5-2: Identification of stakeholders and engagement scheme

5.4.2 Area of Influence and Selection of Local Districts/Neighbourhoods for Consultation

The Project is located in Balıkhisar neighbourhood of Akyurt (centre located within 5 km distance to the Project site). The local area of influence has been selected to be the area with a radius of 5 km around the Project site and consultation has been targeted towards eight neighbourhoods located within three districts (i.e. Akyurt District, Pursaklar District and Çubuk District) in this area. Such an approach is considered to have captured all members of the public and stakeholders who could potentially be directly or indirectly affected by the Project and associated infrastructure. The consultation process also included a range of local governmental bodies and local NGOs. Accordingly, the neighbourhoods within the area of influence are as follows (neighbourhood centres shown in Figure 5-3):

Neighbourhoods with settlements in close proximity to the Project site;

- Balıkhisar (Akyurt District), centre located approximately 5 km to the northeast, with a population of 964 people
- Saracalar (Akyurt District), centre located approximately 1 km to the south, with a population of 1148 people
- Saray Gümüşoluk (Pursaklar District), centre located approximately 3 km to the west, with a
 population of 1251 people
- Altınova (Pursaklar District), centre located approximately 2 km to the south, with a population of 3974 people

Neighbourhoods within 5 km radius;

Güzelhisar (Akyurt District)

- Saray Cumhuriyet (Pursaklar District)
- Yenice (Çubuk District)
- Dumlupinar (Çubuk District)



Figure 5-3: Neighbourhoods within 1, 3 and 5 km distance of the Project site

Additionally, neighbouring and nearby facilities, business enterprises and factories (see Figure 5-4 for locations) were consulted during the engagement activities.

Neighbouring/nearby facilities, business enterprises and factories;

- Ministry of Health General Directorate of Public Health (GDPH) Vaccine and Pharmaceuticals Storage Warehouse,
- Otonomi (Road vehicles sales point that includes around 700 independent businesses),
- Otonomi Outlet Shopping Mall and Wellness Centre (to be constructed),
- YDS Yakupoğlu A.Ş. (Safety shoe manufacturer),
- Işbir Yatak Mattress Factory and General Directorate,
- Işbir Sünger Mattress Foam Industry Factory,
- Private parcel owners (Agricultural lands/parcels located to the northwest of the Project site northern side of the Cubuk stream),
- Student Selection and Placement Center (ÖSYM) Exam Centre,
- Halkbank Warehouse and Social Facilities,
- Man Turkiye,
- İşbir Optik,
- Borusan Automotive,
- Vilsan Veterinary and Medicine Industry (Vilsan Veteriner ve İlaç Sanayi),
- Turkish Medicine and Serum Industry,
- TTS Türktıpsan A.Ş,



• TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.).

Figure 5-4: Existing land use of the bounded area

Source: Prepared through ArcMap 10.8.1.

There are also agricultural areas in close proximity to the Project site. As shown in the Figure 5-4 above, the lands used for agricultural purposes are across the Çubuk Stream. Two formal renters and users of these agricultural lands were consulted as a part of the stakeholder engagement.

5.4.3 Project Stakeholders

Identified key stakeholders for the Project are categorized as governmental bodies, non-governmental bodies, universities and research laboratories, neighboring and nearby facilities, and other stakeholder groups (including settlements, vulnerable/disadvantaged groups, community members and media), which are given in Table 5-2 through Table 5-6**Table 5-5** below.

Table 5-2: Stakeholder List for Governmental Authorities

Level Organization Relation to the Project Ministry of Health (MoH) MoH, General Directorate of Health Investments The Project has been proposed MoH, General Directorate of Public Health MoH, General Directorate of Public Hospitals The Project has been proposed MoH, General Directorate of Administrative Services MoH, General Directorate of Health Information The Project has been proposed MoH, General Directorate of Health Information Systems MoH, General Directorate of Health Services

GOVERNMENTAL BODIES

GOVERNMENTAL BODIES

Level	Organization	Relation to the Project
	MoH, General Directorate of Health Improvement	
	MoH. General Directorate of Emergency Health	-
	Services	
	MoH, Office of Press and Public Relations	-
	MoH, Health Institutes of Turkive (TUSEB)	-
	MoH, Turkish Medicine and Medical Devices Agency	-
	Ministry of Agriculture and Forestry (MoAF)	
	MoAF. General Directorate of Food and Control	-
	MoAF. General Directorate of Livestock	-
	MoAF. General Directorate of Fisheries and	-
	Aquaculture	MoAE may have specific views
	MoAF. General Directorate of Nature Conservation and	about the operation of the Project
	National Parks	related to R&D, laboratories and
	MoAF, General Directorate of State Water Works	production units.
	MoAF, General Directorate of Water Management	-
	MoAF. Veterinary Control Central Research Institute	-
	MoAF. Foot and Mouth Disease Institute (SAP	-
	Institute)	
	Ministry of Environment. Urbanization and Climate Change	
	(MoEUCC)	
	MoEUCC. General Directorate of EIA. Permit and	-
	Audit	MoEUCC has regulatory
	MoEUCC. General Directorate of Environmental	functions in relation to the Project
	Management	such as environmental impact
	MoEUCC. General Directorate of Infrastructure and	assessment permits and
	Urban Transformation	environmental permitting.
	MoEUCC. General Directorate of Spatial Planning	-
	MoEUCC. General Directorate of Protection of Natural	-
	Assets	
	Ministry of Transport and Infrastructure (MoTI)	MoTI may have specific views
	MoTI General Directorate of State Airports Authority	regarding evaluation of the
	MoTI Civil Aviation General Directorate	Project, which is approximately
	MoTI General Directorate of Infrastructure Investments	2,000 m away from Esenboğa
	MoTI General Directorate of Highways	 Airport, according to the obstacle plan and other relevant legislation as well as existing and planned structures and legislation in the region.
	Ministry of Labour and Social Security (MoLSS)	Mol SS may have specific views
	MoLSS, General Directorate of Labor	on labour and working conditions.
	MoLSS, General Directorate of Occupational Health	and health and safety of facility
	and Safety	personnel.
	Ministry of Interior, Disaster and Emergency Management Presidency (DEMP- <i>AFAD in Turkish</i>)	AFAD has a function to respond to emergency situations and cooperate with various government agencies.
	Ministry of Industry and Technology (MoIT)	<u> </u>
	MoIT, General Directorate of Research and	MoIT may have views on technology development.
	Development Incentives	
	MoIT, General Directorate for Strategic Research and	
	Productivity	
	Scientific and Technological Research Council of Turkiye	TUBITAK may have specific
	(TUBITAK) Marmara Research Center- Institute of Genetic	views on the Project on R&D
	Engineering and Biotechnology	aspects.
	Ministry of Culture and Tourism (MoCT)	

GOVERNMENTAL BODIES

Level	Organization	Relation to the Project	
	MoCT General Directorate of Cultural Heritage and	MoCT may have views in terms of	
	Museums	legislation.	
	5 th Regional Directorate of DSI (State Water Works)	This organization may have specific views about water courses running close to the Project site.	
	9 th Regional Directorate of Ministry of Agriculture and Forestry	This organization may have specific views on the potential protected areas close to the Project site and the status of the trees in the Project site.	
Regional	4 th Regional Directorate of General Directorate of Highways	The organization may provide opinion regarding road crossing within the Project site.	
	Ankara Regional Board Directorate of Cultural Assets Protection	This organization is an important stakeholder to identify and clarify the archaeological potential of the Project site.	
	The Governorship of Ankara	The governorship representing the national government is the highest authority in the province.	
	Ankara Metropolitan Municipality	_	
	Ankara Metropolitan Municipality, Directorate of		
	Environmental Protection and Control		
	Ankara Metropolitan Municipality, Directorate of Zoning		
	and City Planning	The metropolitan municipality and	
	Ankara Metropolitan Municipality, Directorate of	its relevant departments will have	
		responsibilities in relation to the	
	Ankara Metropolitan Municipality, Ankara Electricity,	Flojeci.	
	Gas and Bus Operations Organization (EGO General Directorate)	-	
	Services		
	Ankara Governorship Provincial Directorate of Health	These organizations are involved	
	Ankara Provincial Directorate of Health, Pharmacy and	in the provision of health services	
	Medical Devices Branch	and healthcare workforce in the	
Provincial	Ankara Provincial Directorate of Public Health	province.	
	Ankara Governorship Provincial Directorate of Social Security Institution	This organization may provide specific views on labour and working conditions, and health and safety of facility personnel.	
	Ankara Governorship Provincial Directorate of Environment, Urbanization and Climate Change (PDoEUCC)	PDoEUCC has regulatory functions related to the Project such as environmental impact assessment permits and environmental permitting.	
	Ankara Provincial Directorate of Agriculture and Forestry	These organizations may provide	
	Esenboğa Airport Veterinary Border Control Directorate (under MoAF)	provincial-specific and/or site- specific views on the Project.	
	Ankara Provincial Directorate of Disaster and Emergency	These organizations have a	
	Management	function to manage and respond	
	Ankara Provincial Command of Gendarmerie	to emergency situations.	
	Ankara water and Sewer Administration (ASKI)	I nese organizations may provide	
	ASKİ Akyurt Regional Directorate	water/wastewater infrastructure of the Project site.	
District	The Local Governorship of Akyurt, The Municipality of Akyurt		

GOVERNMENTAL BODIES

Level	Organization	Relation to the Project
	Directorate of Zoning and Urbanisation	The Project site is located in
	Directorate of Civil Works	Akyurt district and the local
	Directorate of Plan and Project	governorship, the central
	Directorate of Cleaning Works	municipality and their related
	Directorate of Municipal Police	regarding obtaining relevant
	Akyurt District Directorate of Health	permits, approvals during
	The Local Governorship of Pursaklar, The Municipality of	planning, and construction and
	Pursaklar	operation phases of the Project.

Table 5-3: Stakeholder List for Non-Governmental Bodies

NON-GOVERNMENTAL BODIES

Level	Organization	Relation to the Project
	Turkish Medical Association	It is important to engage this association to understand their concerns.
	Turkiye Trade Union of Health Workers (Sağlık-İş)	
	Trade Union of Public Employees in Health and Social Services (SES)	-
	Trade Union of Revolutionary Health Workers (Dev-Sağlık İs)	-
	Trade Union of Employees of Health and Social Services (Sağlık-sen)	-
	Trade Union of Turkish Health (Türk Sağlık-sen)	-
	Independent Trade Union of Public Workers in Health and Social Services (Bağımsız Sağlık-sen)	- Trade unions and associations are
	United Trade Union of Public Workers in Health and Social Services (Genel Sağlık İş)	important stakeholders representing the labour rights of
	Turkish Microbiology Society (TMC)	health sector personnel and
	Turkish Clinical Microbiology and Infectious Diseases Association (KLİMİK)	research and development laboratories.
	Turkish Infectious Diseases and Clinical Microbiology Specialization Association (EKMUD)	-
	Prevention of Communicable Diseases Association (BUHASDER)	-
	Pediatric Infectious Diseases and Immunization Association	-
National	Clinical Research Association	-
	Infectious Diseases Association (EHD)	-
	Turkish Hospital Infections and Control Association (HIDER)	-
	Researcher Pharmaceutical Companies Association (AIFD)	-
	Public Health Specialist Association (HASUDER)	-
	Turkish Thoracic Society	-
	Turkish Red Crescent (Kızılay)	-
	Turkiye Confederation of Disabled	Requesting opinion of this federation is important to understand their expectations.
	Animal Right's Federation (HAYTAP)	These Federation and associations
	Turkish Protection of Animals Association (THKD)	- are important stakeholders representing the animal rights.
	World Health Organization (WHO) - Turkiye	Requesting opinion of this organization is important to understand their views and requirements.
	Chamber of Environmental Engineers	_

NON-GOVERNMENTAL BODIES

Level	Organization	Relation to the Project
	Chamber of Forests Engineers	
	Chamber of City Planners	
	Chamber of Civil Engineers	
	Chamber of Architects	I hese chambers and associations
Provincial and District	Environmental Protection Foundation (TUÇEV)	may provide provincial-specific and
	Ankara City Council	Or site-specific views related to the
	Ankara Chamber of Industry	
	Ankara Chamber of Trade	
	Akyurt Industrial and Business People Association	

Table 5-4: Stakeholder List for Universities and Research Laboratories

UNIVERSITIES AND RESEARCH LABORATORIES

Level	Organization	Relation to the Project
	Ankara University- Faculty of Veterinary	
	Koc University (Istanbul)-Research Centre for Translational	
	Medicine (KUTTAM)	
Universities,	Koc University (Istanbul)-İşbank Centre for Infectious Diseases	
Research	(KUISCID)	Universities and Research Laboratories are key stakeholders having associated research
Laboratories	Erciyes University-Vaccine Research Development Centre	
Contros and	(ERAGEM)	
	Istanbul University- Faculty of Veterinary Medicine	laboratories.
Companies	TUBİTAK Marmara Research Centre (MAM) - Genetic	
	Engineering and Biotechnology Institute	-
	Dollvet Biotechnology Inc.	
	Vetal Animal Health Products Inc.	

Table 5-5: Stakeholder List for Neighbouring/Nearby Facilities

NEIGHBOURING/NEARBY FACILITIES

Level	Organization	Relation to the Project			
	YDS Yakupoğlu A.Ş.	Facilities, centres and lands/parcels, neighbouring to the			
	Işbir Yatak Mattress Factory and General Directorate				
	Otonomi (highway vehicles sales point)				
Neiahbourina	GDPH Vaccine and Pharmaceuticals Storage Warehouse of	Project site, are key stakeholders			
Facilities	МоН	in order to monitor the associated			
	Private parcel owners (agricultural lands/parcels located to the	impacts from both construction			
	northwest of the Project site- northern side of the Cubuk stream)	and operational phases of the			
	Project representatives of Otonomi Outlet Shopping Mall and	Project.			
	Student Selection and Placement Center (OSYM) Exam Centre				
	Halkbank Warehouse and Social Facilities				
	lşbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi	Mattress Foam Industry (İşbir Sünger Sanayi			
	Ticaret A.Ş.)				
	Man Turkiye	Facilities, located in close			
Neerby	İşbir Optik	proximity to the Project site, are			
Facilities	Borusan Automotive	key stakeholders in order to monitor the associated impacts			
1 dointies	Vilsan Veterinary and Medicine Industry (Vilsan Veteriner ve İlaç	from both construction and			
	Sanayi)	operational phases of the Project.			
	Turkish Medicine and Serum Industry (Türk İlaç ve Serum	· · · ·			
	Sanayi)				
	TTS Türktıpsan A.Ş	_			
	TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)				

Table 5-6: Other Stakeholder Groups

STAKEHOLDER GROUPS

Level	Group	Relation to the Project	
Settlements	Neighbourhoods within a radius of approximately 5 km to the Project site include Saracalar, Balıkhisar, Saray Gümüşoluk, Altınova, Yenice, Saray Cumhuriyet and Dumlupınar	Neighbourhoods are key stakeholders considering potential impacts of the Project.	
Vulnerable/	Female workers of the closest businesses near the Project site Elderly, disabled, women headed households in Balıkhisar,	Vulnerable groups are key	
Disadvantaged Groups	Saray Gumuşoluk, Saracalar and Altinova neighbourhoods Women groups in Balıkhisar and Saracalar neighbourhoods People with disabilities	 stakeholders considering potential impacts of the Project. 	
Community Members	Individuals and groups residing in the neighbourhoods within a radius of approximately 5 km to the Project site Workers from the community employed or to be employed for the construction activities (including contractors and subcontractors)	- Community members are key stakeholders considering potential impacts of the Project.	
Media	Vorkers of neighbouring facilities Local, regional and social media (including newspapers, TV stations, social media channels)	It is important to engage with local and regional media organizations for effective public disclosure and consultation.	
Project workers	All Project workers of both construction and operation phases (including MoH employees, contractors, subcontractors and supply chain companies)	Project workers are significant stakeholders for technical, environmental and social excellence of the Project.	

5.5 ESIA Consultation Activities and Outcomes

5.5.1 Stakeholder Engagement Activities Conducted Prior to ESIA

The PMSU of MoH conducted an online disclosure meeting on 20 December 2021 to inform stakeholders about potential environmental and social impacts of the "Component 4: Strengthening Capacity of MoH to respond to COVID-19" of HSSSP (including the Project). The first stakeholder list for the Project, which is shown in the table below, was created by the Environmental and Social Team of the PMSU for the online meeting held on 20 December 2021.

Table 5-7: The first stakeholder list for the Project (created by the Environmental and Social Team of the PMSU)

Key Stakeholder Groups	Stakeholders in the Group
	Ministry of Health
	General Directorate of Public Hospitals
	Turkish Medicines and Medical Devices Agency
	General Directorate of Public Health
	General Directorate of Health Services
	General Directorate of Emergency Health Services
	General Directorate of Health Promotion
Public Institutions at	General Directorate of Health Investments
National Level	General Directorate of Health Information Systems
	General Directorate of Administrative Services
	General Directorate of Press and Public Relations
	Ministry of Environment, Urbanization and Climate Change
	Directorate General of Environmental Impact Assessment, Permit and
	Inspection
	Directorate General of Environmental Management
	Ministry of Energy and Natural Resources

Key Stakeholder Groups	Stakeholders in the Group
	Ministry of Treasury and Finance
	Ministry of Industry and Technology
	Ministry of Agriculture and Forestry
	General Directorate of Nature Conservation and National Parks
	Health Institutes of Turkive (TUSEB) (Vaccination Institute. Health Policies.
	Health Services Quality and Accreditation, Biotechnology institutes)
	TUBITAK Marmara Research Center (MAM) - Genetic Engineering and
	Biotechnology Institute
	Governorates
	Ankara Governorate
	İstanbul Governorate
	Provincial Directorate of Agriculture and Forestry
	Ankara
Public Institutions at	İstanbul
Public Institutions at	Provincial Directorate of Environment and Urbanization
	Ankara
	İstanbul
	Ankara Regional Directorate of Highways
	Provincial Health Directorate
	Ankara
	İstanbul
	District Municipalities
	Küçükçekmece Municipality
	Akyurt Municipality
	District Governorates
	Küçükçekmece District Governorate
	Akyurt District Governorate
Public Institutions at District	Project Beneficiary Hospitals and their related units
Level	Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and
	Research Hospital (MAESH)
	İstanbul Experimental Research Center (İDEA)
	Headman's Offices
	İstasyon Quarter Headman's Office (İstanbul)
	Atakent Quarter Headman's Office (İstanbul)
	Balıkhisar Quarter Headman's Office (Ankara)
	Chambers of Industry
Groups Representing	İstanbul Chamber of Industry
Professional and	Ankara Chamber of Industry
Commercial Stakeholders	Chambers of Commerce
	İstanbul Chamber of Commerce
	Ankara Chamber of Commerce
	Infectious Diseases and Clinical Microbiology Specialty Society of Turkiye
	_(EKMUD)
	Pediatric Intectious Diseases and Immunization Association
Non-governmental	I urkish Society of Microbiology (TSM)
Organizations	Intectious Diseases Association (EHD)
	I urkish Society of Hospital Infection and Control (HIDER)
	Intectious Diseases Prevention Association (BUHASDER)
	Association of Research-Based Pharmaceutical Companies (AIFD)
Universities	Ankara University Faculty of Veterinary Medicine
	Istanbul University Faculty of Veterinary Medicine

The meeting invitation together with the meeting agenda and the website link directing to the Project's draft Environmental and Social Management Framework (ESMF)³² were sent to the identified stakeholders through official channels. NGOs and universities were also contacted by phone. The ESMF

³² ESMF dated November 2021

of the HSSSP was disclosed online prior to the meeting to facilitate consultation with the stakeholders. In the meeting agenda, it was stated that opinions and suggestions could be provided regarding the Project's ESMF document until 29 December 2021.

In addition to health specialists and NGOs, this online meeting was attended by local key stakeholders including Akyurt Municipality, Akyurt District Governorship, Akyurt District Directorate of Health. The institutions and organizations which attended the meeting are listed below:

- The Ministry of Health: General Directorate of Health Promotion, General Directorate of Public Health, Office of Press Counsellor, Project Management and Support Unit,
- Ministry of Energy and Natural Resources,
- Ministry of Industry and Technology: General Directorate of Strategic Research and Efficiency,
- Ministry of Industry and Technology: Ministry of Industry and Technology, General Directorate of Industry, General Directorate of National Technology,
- Ministry of Treasury and Finance: Department of Support Services,
- The World Bank,
- Ankara Provincial Directorate of Health,
- İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery,
- Akyurt Municipality,
- Akyurt District Governorate,
- Akyurt District Directorate of Health,
- ESIA Consultancy Company and Its Experts,
- Turkish Society of Microbiology,
- Infectious Diseases and Clinical Microbiology Specialty Society of Turkiye (EKMUD),
- University of Health Sciences, Institute of Defensive Health Sciences, Department of Chemical, Biological, Radiological and Nuclear Defence (CBRN Defence),
- University of Health Sciences Hamidiye Faculty of Medicine, Department of Medical Microbiology
- Ankara Yıldırım Beyazıt University Faculty of Health Sciences,
- Ankara University Faculty of Veterinary Medicine.

The meeting included a presentation describing the Project as well as providing information about stakeholder relations and the grievance mechanism. In line with the feedback received during the meeting, the ESMF was revised and finalized, and the final version was disclosed in February 2022 on the website of the PMSU³³.

5.5.2 Scoping Site Visit and Consultation (December 2021)

The stakeholder engagement process of the Project has started during the scoping phase through engagement with the key project stakeholders. A scoping field study was conducted on 28 and 29 December 2021 by the social experts (a senior social impact assessment expert, a land acquisition and resettlement expert, a stakeholder engagement expert and a social consultant) of the ESIA team. Scoping consultations were undertaken with key public institutions, to determine potential Project Affected Persons (PAPs)/stakeholders, to gain a deeper understanding of the Project area and potential Project impacts, and to understand their perception of the Project in order to reflect their views and recommendations to Project design and respond to any concerns they may have on the Project. Consultations were also held with neighbouring facilities that may be prone to direct Project construction and operation impacts. The external stakeholders interviewed within the scope of field studies are listed below.

³³ https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html

- Mayor of Akyurt,
- Deputy Mayors of Akyurt,
- District Governor of Akyurt,
- Akyurt District Health Director,
- Mukhtar of Balıkhisar neighbourhood,
- Mukhtar of Saracalar neighbourhood,
- CEO of YDS³⁴,
- Board Member of YDS,
- Business Development Manager of Işbir Yatak Mattress Factory and General Directorate,
- Quality Control Management Director of Işbir Yatak Mattress Factory and General Directorate,
- Operations Manager of Otonomi.

The minutes and notes of these stakeholder consultations are presented in Annex C of this report. The findings of the consultations are summarized below:

- The Mayor's and the District Governor's approach towards the Project was positive and supportive. It was observed that Akyurt Municipality supports the Project and is willing to take part in the Community Advisory Board as an active participant and effective board member. Flood risk and reclamation requirements associated with the Çubuk stream was an issue of concern noted by the Akyurt Municipality to be consulted with the General Directorate of State Water Works (DSI).
- The Project is located in Balıkhisar neighbourhood (centre within 5 km distance to the Project site, with a population of 964) and Saracalar is the closest neighbourhood (centre within 1 km distance, with a population of 1148) to the Project site. Therefore, the mukhtars of these neighbourhoods were interviewed during the scoping phase field study. Mukhtars' information level on the Project was limited to the news shared on media, however they welcomed the Project. The ESIA team informed the mukhtars regarding the planned stakeholder engagement activities to be carried out for the Project.
- During the consultations with neighbouring facilities, dust and odour safety were reported as the main issues of concern requiring measures. Other issues of concern reported by the neighbouring facilities included the infrastructural (i.e., sewerage and waste management) inadequacies in the area and whether the existing infrastructure issues will be elevated as a result of the proposed Project.
- During the meetings, participants from the neighbouring factories were briefly informed that gender equality and violence issues against women would be addressed within the framework of the ESIA. In this context, safety of female employees in the nearby factories and the risk of being exposed to harassment or violence during the Project construction were also addressed in the meetings. Facility representatives stated that employees rarely leave the factory during work hours, and they stay inside the factory for lunch breaks and other breaks. Mitigation measures have been defined within the ESIA study to maintain safety of female workers around the Project site.

5.5.3 Stakeholder Engagement Activities during ESIA

5.5.3.1 Overview

The ESIA consultations aimed to gather baseline data, understand the Project-related concerns and requests of PAPs, reflect opinions of key stakeholders and identify vulnerable groups. The consultations involved meetings with district and province level governmental institutions, meetings with non-governmental organizations, interviews with the representatives of neighbouring facilities, business enterprises and factories, socio-economic household surveys with PAPs in the area of influence, mukhtar interviews and focus group interviews with women residing in the neighbourhoods directly affected and/or

³⁴ Safety shoe manufacturing company

the closest surroundings. The content and sections of the questionnaires for household surveys, mukhtar interviews, business enterprise/factory interviews, and focus group interviews with women were designed by taking into account the scope of the Project and ESIA requirements of World Bank. All questionnaires were approved by the Project Team within the PMSU of the MoH on 30 May 2022. The content and sections of the questionnaires are briefly listed below:

- Household surveys
 - Information about the interviewee (i.e. age, gender, vulnerability category (if applicable)
 - Information about the household (i.e. number of people living in the house, students, elderly, disabled, age and gender distribution within the household, infrastructural conditions of the house)
 - The major problems within the neighbourhood
 - Information about the Project
 - Grievance mechanism
- Business/enterprise interviews
 - Information about the interviewee (i.e. age, gender)
 - Information about the workplace (i.e. name, address, number of male and female workers, working hours, number of workers using shuttles to commute, number of vehicles that the facility has (by type), infrastructural conditions of the neighbourhood)
 - Information about the Project
 - Grievance mechanism
- Mukhtar interviews
 - Information about the mukhtar
 - Information about the neighbourhood and residents (i.e. population, vulnerable groups, educational services, health services, security, infrastructural conditions, transportation, economy, agriculture and livestock, organizations)
 - The major problems within the neighbourhood
 - Information about the Project
 - Grievance mechanism
- Focus group interviews:
 - Daily life of the women in the neighbourhood (i.e. working, farming, childcare, elderly care, cooking)
 - The major problems that women face within the neighbourhood (i.e. access to education, lack of health services, lack of transportation infrastructure, poverty, unemployment)
 - Leisure time activities of women
 - Information about the Project
 - The approach of women in case people move to the neighbourhood to work in the Project activities
 - Discussion about the risks related to SEA/SH
 - Grievance mechanism

For more details, the questionnaires are provided in Annex G of the ESIA report.

Accordingly, 109 socio-economic household surveys (please refer to section 11.1.2 for details of the sampling methodology for surveys) and focus group interviews with 21 women (who were randomly selected) in four neighbourhoods, eight mukhtar interviews (within mukhtars of neighbourhoods within a distance of 5 km to the Project site), nine business interviews, interviews with two users of agricultural lands near the Project site, interviews with 20 representatives of public institutions, local governments and two NGO representatives have been carried out during the ESIA preparation, which are outlined below in Table 5-8. During the consultations and surveys, a Project Information Document (PID) describing the key

elements of the Project, including its rationale, composition, potential benefits and risks, environmental and social aspects, was also shared with the interviewed/surveyed stakeholders.

Consultation/Survey Methods	Number of Stakeholders
Household Surveys	 109 Household Surveys 26 household surveys in Balıkhisar 32 household surveys in Saracalar 37 household surveys in Saray Gümüşoluk 14 household surveys in Altınova
Mukhtar Interviews	8 Mukhtar Interviews Balıkhisar Saracalar Güzelhisar Saray Gümüşoluk Altınova Saray Cumhuriyet Dumlupınar Yenice
Women Focus Group Interviews	 4 Meetings, 21 Participants Balıkhisar (5 participants) Saracalar (5 participants) Saray Gümüşoluk (5 participants) Altınova (6 participants)
Business Interviews	 9 Business Interviews Student Selection and Placement Centre (ÖSYM) E-exam Centre Halkbank Warehouse and Social Facilities Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.) İşbir Optik Otonomi - Özkan Automotive İşbir Yatak Mattress Factory and General Directorate MAN Turkiye Borusan Automotive Turkish Medicine and Serum Industry (Türk İlaç ve Serum Sanayi) & TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)
Interviews with users of agricultural lands	 Two users of Agricultural Lands Users of private lands located to the west of the Çubuk Stream used for agricultural purposes
Meetings	 Regional and Local Authorities, 20 Stakeholders Akyurt District Municipality, Mayor Akyurt District Municipality, Deputy Mayor Akyurt District Municipality, Deputy Mayor Akyurt District Municipality, Chief of the Planning and Projects Directorate Akyurt District Governorship, District Governor Akyurt District Health Directorate, Director Akyurt District Directorate of Agriculture & Forestry, Director Akyurt District Governorship, District Governor Pursaklar District Governorship, District Governor Pursaklar District Governorship, District Governor Pursaklar District Social Assistance and Solidarity Foundation, Civil Servant Pursaklar District Directorate of Agriculture & Forestry, Director Pursaklar District Directorate of Agriculture & Forestry, Director District Directorate of Agriculture & Forestry, Director Pursaklar District Directorate of Agriculture & Forestry, Director District Directorate of Agriculture & Forestry, Director Pursaklar District Directorate of Agriculture & Forestry, Director Pursaklar District Social Assistance and Solidarity Foundation, Director DSI (Directorate General for State Water Works). Regional Director

Table 5-8: Consultation and Survey Methods and Number of Stakeholders Reached

Consultation/Survey Methods	Number of Stakeholders			
	 DSI (Directorate General for State Water Works), Watershed Management, Monitoring and Allocations Branch Manager Directorate of Esenboğa Airport Veterinary Border Control, Director Ankara Metropolitan Municipality Waste Coordination Branch Office, Branch Manager Ankara Metropolitan Municipality Waste Coordination Branch Office, Civil Servant Ankara Metropolitan Municipality Waste Management Branch Office, Branch Manager Ankara Metropolitan Municipality Infrastructure Coordination Centre, Director Ankara Water and Sewerage Administration (ASKI), Deputy General Manager 			

The stakeholders' opinions and views on the Project are presented in the following sections. The minutes and notes of these stakeholder meetings and consultations are presented in Annex C of this report.

5.5.3.2 Surveys and Interviews

Interviews with Mukhtars

The findings of the interviews conducted with eight mukhtars within the scope of the stakeholder engagement activities in June 2022 indicate that the mukhtars do not expect any adverse impacts to arise from the proposed development. The most important positive impact of the Project at the national level is perceived as the improvement of vaccine production and health services, while at local level it is expected that the Project will contribute to local employment opportunities as well as regional growth and development.

The topics that the mukhtars would like to be informed the most are as follows:

- The commencement and the end date of the Project construction,
- The vaccination production process, how the vaccines will be produced and which vaccines will be produced,
- As animal production will be performed within the scope of the proposed activities, will there be generation of odour emissions? What will be the measures to prevent this?
- Local employment

Interviews with Neighbouring Facilities, Business Enterprises and Factories

During the meetings with nine representatives of various neighbouring facilities, business enterprises and factories, two of the representatives expressed that the Project would not negatively affect corporate activities while three stated that they did not have adequate knowledge about the Project and the remaining told that their activities might get impacted. Potential adverse impacts voiced by the representatives are as follows:

- During the construction phase, dust and noise might affect their work-related activities.
- Any kind of changes in the employee shuttle and truck service routes due to Project traffic during the construction phase might increase the travel times. However, representatives stated that the new service route would be two or three kilometres longer when compared to previous route and this would not be a major impact for facilities. Therefore, no request was raised by representatives on this issue. Mitigation measures to be taken on managing traffic impact are provided in Section 13.4.2.
- Possible closure of the section of the unnamed road (between parcel 1555-4 and the recreational area) as a result of the Project might adversely affect the enterprises and clients of Otonomi who

currently unofficially use that road for test drives. Interviewed car dealers stated that Otonomi is placed on a very large land in which alternative roads for test drives could be created in case the existing unnamed road is closed.

- Possibility of labour loss to the Project by local private sector biotechnology facilities during the operation period due to competitive labour market.
- The topics that the workplace representatives would like to be informed the most are as follows:
- The commencement and the end date of the Project construction,
- Dust, noise and traffic impacts,
- Health measures to be taken.

Household Surveys

As mentioned earlier, a total of 109 household surveys were conducted within the scope of the stakeholder engagement activities in June 2022. Based on the results of the surveys, 64% of the participants stated that the Project is likely to cause positive impacts while 8% thought that the impacts of the Project might be adverse. 26% did not have an opinion about the impacts of the Project and 2% thought the Project will create both positive and negative impacts.

The topics that the participants would like to be informed the most are as follows:

- The commencement and end date of the Project construction,
- Local employment,
- Dust, noise and traffic impacts,
- Health measures to be taken.

Female Focus Group Interviews

Focus group interviews were held with women in Balıkhisar, Saracalar, Saray Gümüşoluk and Altınova neighbourhoods.

- They believe the Project will create positive impacts both for Turkiye and for their neighbourhood. They hope the transportation systems around Balıkhisar will be improved together with the Project.
- They expect the Project to increase employment opportunities and improve the neighbourhood.
- Women residing in Balıkhisar, Saray Gümüşoluk and Altınova neighbourhoods did not report any concerns related to the Project and its impacts.
- Women residing in Saracalar neighbourhood have concerns about the waste and pollution related to the Project. Also, they stated that the existence of workers from outside the neighbourhood during construction may make them feel insecure.

5.5.3.3 Consultation with Governmental Authorities

According to the interviews conducted with key governmental stakeholders, the Project is expected to have positive impacts on national and local levels. The interviewed stakeholders believe that the most significant benefits of the Project will be vaccine production, improvements in the health sector, regional development and support for local employment. Even though in general the stakeholders do not believe that the Project would have negative impacts, they would like to be informed further about the Project including the measures to be taken against possible impacts as well as the operation practices.

The important issues raised during of the consultations are summarized below:

According to the consultations held with Akyurt Municipality, when the Project starts operating, locals
of Akyurt should be prioritized for employment. The Project should offer internship opportunities for the
students and graduates of the Health Vocational High School in the district. Akyurt Municipality also
once again noted the flood risk and reclamation requirements associated with the Çubuk stream and
that the issue needs to be consulted with the General Directorate of State Water Works (DSI).

- According to the consultations held with DSI, no rehabilitation works have been performed or are
 planned by DSI on the adjacent section of Çubuk Stream. A flood study and stream rehabilitation
 works (including a flood protection wall) are highly needed for this region. The Watershed
 Management, Monitoring and Allocations Branch Manager of DSI stated that the authority has already
 performed a flood study for the Project area and notified MoH (with their letter dated 28 February
 2022) of their findings including the flood level to be taken into consideration for the design of
 structures.
- According to the consultations held with the Ankara Metropolitan Municipality (AMM) and Ankara Water and Sewerage Administration (ASKI), there are wastewater infrastructure deficiencies in the area where the Project will be developed. It was noted by the ASKI Deputy General Manager that an official letter should be submitted to ASKI to inquire about the infrastructure requirements of the Project. It was also reported that the AMM has facilities in place with the capacity to dispose of all wastes likely to be produced by the Project and operates a waste incineration plant for disposal of the pathogenic wastes. The medical wastes to be produced by the Project will be collected by ITC, which is a licensed medical waste disposal company contracted by AMM.

5.5.4 Public Consultation during ESIA Disclosure

Public disclosure and engagement activities of the Project have been managed by PMSU of the MoH and carried out with the support of the ESIA team through the channels defined in the SEP of the Project. A virtual public consultation meeting was held on 20 May 2024 (at 14:00) following the approval of the draft ESIA report by the WB and the disclosure of the report on the MoH website. The meeting was undertaken virtually to allow for wider participation of public and stakeholders. The public consultation meeting was announced to the Project stakeholders by invitations through e-mail and telephone. Links to the Project documents (including draft final SEP and ESIA) published on the PMSU website (<u>https://pydb.saglik.gov.tr/TR-103390/turkiye-halk-sagligi-acil-durumlarina-hazirlikli-olma-projesi.html</u>) were also delivered to stakeholders.

The MoH invited public institutions via official letters which included the link to the virtual meeting. Mukhtars, being the primary contact persons for reaching out to community members, were specifically contacted by phone. The mukhtars of the Balıkhisar and Saracalar neighbourhoods were invited to the meeting and were requested to announce the meeting to the local communities through appropriate methods. Additionally, nearby industrial facilities (İşbir Yatak, Otonomi, and YDS) were contacted prior to the meeting. An official invitation letter was sent to YDS, whose KEP (registered e-mail) address was available.

The virtual public consultation meeting was conducted with 30 participants representing the Project stakeholders. However, no representatives from the companies, mukhtars, or residents from the neighborhoods attended the meeting. The participants of the meeting are listed below:

- Project Management Support Unit of MoH
- General Directorate of Public Health of MoH
- General Directorate of Health Investments of MoH
- Ankara Provincial Health Directorate
- Ministry of Agriculture and Forestry
- Ministry of Environment, Urbanization, and Climate Change
- Ministry of Industry and Technology
- Ankara Metropolitan Municipality
- General Directorate of State Hydraulic Works
- District Governorship of Akyurt
- Akyurt District Health Directorate
- Mott Macdonald (ESIA Consultant)

The new project of MoH, which will be financed by the WB (Türkiye Preparedness for Public Health Emergencies Project) and includes financing of the Project was presented to the participants by PMSU at the beginning of the meeting. The objective and components of the Project, proposed activities, potential E&S impacts, proposed mitigation measures, and information about the framework E&S plans were presented by PMSU to the participants. Following the PMSU presentation, the ESIA consultant Mott MacDonald's experts provided details about the ESIA Report, which was finalized prior to the meeting and disclosed on the PMSU website. This presentation covered the project description, project significance, its potential environmental and social impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. The presentation was supported with figures, photographs and maps, and the impacts of the construction and operation phases of the project were presented separately.

The minutes of the meeting is provided in Annex C. A photo from the virtual meeting is shown in Figure 5-5 below.



Figure 5-5: A Photo from the Public Consultation Meeting

Participants were invited to ask questions and provide comments after the presentations during the question-and-answer section. However, no positive or negative feedback was received from the stakeholders. The contact information for PMSU environmental and social experts was provided to the participants, allowing project stakeholders to reach out with any potential questions or comments.

Given that no representatives from the companies, mukhtars, or neighborhood residents attended the virtual meeting, PMSU conducted additional on-site engagement activities after the virtual consultation meeting. On 12 June 2024, mukhtars of Balıkhisar and Saracalar neighborhoods were met at their offices. They were informed about the ESIA disclosure process, project schedule, technical details, potential environmental and social impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. Following the introduction to the mukhtars, details about the Project were presented to the local people at the Balıkhisar neighborhood tea house. Approximately 15 local residents attended the meeting, and participants indicated that there were no grievances related to the Project due to the location of the project area. Participants stated that there is no interaction between the settlements and the project area, and that the Ankara-Esenboğa Airport road acts as a natural barrier. The website link to the ESIA report and information on the grievance mechanism were provided to the participants.

In addition, İşbir Yatak and Otonomi representatives were visited as part of the on-site engagement activities, which had been consulted at the beginning of the ESIA studies. YDS representatives were attempted to be reached, however, no response was received and they could not be contacted for a meeting. The Deputy General Director of İşbir Yatak and the operations manager of Otonomi were informed about the ESIA process and technical details of the Project. Information about the stakeholder engagement processes and grievance mechanism tools was presented to the stakeholders. It was learned that no external grievances from the workers of İşbir Yatak and enterprises of Otonomi had been sent to the management, and there were no grievances about the Project activities.

Since the kindergarten will be used by the children of health workers to be employed in the VPC who have not been selected yet, it is not possible to consult with the parents at this stage. However, future consultations regarding the ESIA will include these parents.

Photos from engagement activities undertaken on 12 June 2024 are shown in Figure 5-6 and Figure 5-7 below.



Figure 5-6: Photos from Engagement Activities at the Settlements (Left: Meeting with Saracalar Mukhtar, Right: Meeting with Balıkhisar Mukhtar, Bottom: Meeting with Local Residents)



Figure 5-7: Photos from Engagement Activities at Otonomi (Left) and İşbir Yatak (Right)

5.6 Consultation Planned throughout the Lifetime of the Project

To enlarge the outreach of the needed information to be shared with the Project stakeholders, Project specific communication materials (i.e. brochures, posters, leaflets) will be developed. This documentation will be disclosed through various communication channels (i.e. social media accounts, SMS, WhatsApp, e-mails, website, mails). Also, environmental and social experts of the Project will organize face-to-face meetings with stakeholders to the possible extent. By this way, it will be ensured that all Project stakeholders (including vulnerable/disadvantaged groups identified within the scope of the Project) have equal access to the Project related information.

The SEP needs to be reviewed and updated regularly and should include stakeholder engagement activities carried out during the pre-construction, construction and operation periods of the Project. The SEP will be updated every year and the updated version will be published on the Project website.

The proposed implementation timetable and responsibilities for stakeholder engagement throughout the lifetime of the Project is outlined in Table 5-9 below.

Table 5-9: Stakeholder Engagement Approach and Future Stakeholder Engagement

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
Loca	al Communities					
1	Neighbouring facilities, nearby facilities, factories and businesses Residents in the closest neighbourhoods Users of the closest agricultural lands	- Local	 Consultation about the Project stages, informing on possible effects of the Project and communication mechanism with stakeholders, informing about grievance mechanism of the Project Environmental and social impacts of the Project Mitigation measures defined within the ESIA report Environmental and Social Management Plans ESIA report, SEP, PID and other Project related documents 	 Visit Face-to-face consultation meeting Website Social media Posters, billboards Online meetings 	Construction and Operation	 PMSU Community Advisory Board (CAB)
2	Mukhtars of the Project Impacted Neighbourhoods (Balıkhisar, Saracalar, Saray Gümüşoluk, Altınova) and their neighbour settlements (Güzelhisar, Saray Cumhuriyet, Dumlupınar and Yenice)	Local	 Consultation about Project stages, informing about possible effects of the Project and communication mechanisms with stakeholders, informing about grievance mechanism of the Project Mitigation measures defined within the ESIA report Environmental and social impacts of the Project Environmental and Social Management Plans Local employment ESIA report, SEP, PID and other Project related documents 	 Visit Consultation meeting Web site Social media Posters Online meetings 	Construction	PMSUCAB
3	Vulnerable Groups		Consultation about Project stages, informing about possible	• Visit		
	Elderly	-	effects of the Project and communication mechanisms with stakeholders, informing about grievance mechanism of the Project, provisions to prevent the risks of sexual exploitation	Consultation meetingWeb site		
		Local	and abuse (SEA) and sexual harassment (SEA/SH)	 Social media 	Construction and	PMSU
	Children	- •	 Mitigation measures defined within the ESIA report 	 Posters 	Operation	 CAB
			Environmental and social impacts of the Project	 Accessible platforms with audio devices special 		
	Female workers of the closest businesses and factories		 Environmental and Social Management Plans Local employment 	education coordinators and sign language		

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
			 ESIA report, SEP, PID and other Project related documents 	translators when necessary		
Publ	ic Institutions					
4	Public institutions/ stakeholders at national level	National	 Consultation about Project stages, informing about possible effects of the Project as well as grievance mechanism of the Project, 	VisitCorrespondenceWebsiteOnline meetings	Construction and Operation	PMSUMoH
5	Public institutions/ stakeholders at provincial and district level	Regional	 Permissions, consultation about Project stages; informing about grievance mechanism of the Project Environmental and social impacts of the Project Mitigation measures defined within the ESIA report Environmental and Social Management Plans 	VisitCorrespondence	Construction and Operation	• PMSU
6	District Municipalities	Regional	 Consultation about the Project, informing about grievance mechanism of the Project, interviewing for grievances, receiving opinions and recommendations Environmental and social impacts of the Project Mitigation measures defined within the ESIA report Environmental and Social Management Plans 	VisitCorrespondence	Construction and Operation	• PMSU
Educ	cational Institutions					
7	Universities and Research Laboratories	Regional	 Consultation about Project stages, informing about possible effects of the Project and communication mechanisms with stakeholders, informing about grievance mechanism of the Project ESIA report, SEP, PID and other Project related documents 	VisitConsultation meetingWebsite	Construction and Operation	• PMSU

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
Prima	ary Health Care Institutions					
8	Hospitals, Health Centres and Pharmacies	Regional	 Consultation about Project stages, informing about possible effects of the Project and communication mechanisms with stakeholders, informing about grievance mechanism of the Project ESIA report, SEP, PID and other Project related documents 	 Visit Consultation meeting Website Social media Posters 	Construction and Operation	PMSUMoH
NGO	S					
9	NGOs	National and Regional	 Consultation about general stages of the Project and construction activities Consultation about expected positive and negative effects of the Project, informing about grievance mechanism of the Project Environmental and social impacts of the Project Mitigation measures defined within the ESIA report Environmental and Social Management Plans ESIA report, SEP, PID and other Project related documents 	 Visit Consultation meeting Website Social media Posters 	Construction and Operation	PMSUCAB
Media	a					
10	Media Associations and Agencies	National and Regional	 Sharing information on general stages of the Project and construction activities Consultation about expected positive and negative effects of the Project, informing about grievance mechanism of the Project ESIA report, SEP, PID and other Project related documents 	 Press release Visit Consultation meeting Website Social media 	Construction	PMSUCAB
Inter	nal Stakeholders					
11	MoH Units	National and Regional	 Project updates and changes in operations information on labour rights, contract information, code of conduct including 	Trainings	Construction and Operation	• PMSU

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
			provisions for SEA/SH, workers' grievance mechanism of the Project etc.	Face to face meetings		• МоН
The Project's contractors ar suppliers, construction work	The Project's contractors and		 Workers' grievance mechanism 			
	suppliers, construction workers		 Environmental and Social Management Plans 	 Correspondence 		
			 ESIA report, SEP, PID and other Project related documents 			

5.7 Project Grievance Mechanism

5.7.1 Overview

The main objective of a Grievance Mechanism (GM) is to assist resolve complaints and grievances in a timely, proactively, unbiased, effective and efficient manner that satisfies all parties involved. Specifically, it provides a transparent and credible process for fair, effective and lasting outcomes. It also builds trust and cooperation as an integral component of broader community consultation that facilitates corrective actions. It aims at continuously improving the Project performance through regular assessments of the grievances and identifying structural adjustments by conducting root cause analysis. It is necessary to disclose the grievance mechanism to all stakeholders in a clear and understandable way. As defined in the Environmental and Social Management Framework (ESMF)³⁵ developed by the PMSU, the GM of the Project:

- Provides affected people with avenues for making a complaint or resolving any dispute that may arise during the course of the implementation of projects,
- Ensures that appropriate and mutually acceptable redress actions are identified and implemented to the satisfaction of complainants,
- Supports accessibility, anonymity, confidentiality and transparency in handling complaints and grievances, and
- Avoids the need to resort to judicial proceedings (unless as a last resort).

The Project parties involve the MoH (including PMSU, General Directorate of Health Investments, General Directorate of Public Health together with the Project Implementation Unit to be established), EPC Contractor of the construction activities of the Project, and the consultants employed during the design, construction, and operation phases. To ensure the successful implementation and management of the Project GM, each party will assign community liaison officers for managing grievances as well as implementing stakeholder engagement and disclosure activities in general.

The categorization of grievances will be as follows:

- Complaints
- Suggestions
- Information requests
- Other

Grievances will be classified based on the main concerns raised by the stakeholders during the stakeholder engagement activities within the scope of the ESIA study and the key potential impact areas during the construction and operation phases, which are listed below:

- Air quality
- Dust
- Noise and vibration
- Traffic
- Flood risks
- Negative impacts on infrastructure
- Negative impacts on livelihoods
- Negative impacts on environment (including waste management and protection of surface waters)
- Biosafety risks
- Occupational health and safety

³⁵ Accessed from <u>https://pydb.saglik.gov.tr/Eklenti/42794/0/cevrevesosyalyonetimnihaitrpdf.pdf</u> on 28 January 2023.

- Employment
- Complaints due to the contractors
- Working conditions
- Sexual exploitation and abuse (SEA) and sexual harassment (SH)

This list will be updated according to the content of the grievances to be received.

5.7.2 Public Grievance Mechanism

Public grievance mechanism of the Project is in place in order to ensure that all public stakeholders identified within the scope of the Project can raise their grievances, concerns, suggestions or requests through defined grievance channels.

The public grievance mechanism is established in line with the ESMF prepared for the HSSSP. Accordingly, suggestions and complaints can be directed through the website of the PMSU³⁶. Applications can also be directed by telephone and/or mail of PMSU contact addresses. Annex 10.1 of the SEP shows the Turkish version of the application form that is provided on the website of the PMSU. The public grievance mechanism channel of the PMSU is suitable for raising anonymous grievances.

As the Project concerns the whole country, national mechanisms that are already in use will also be available in accordance with the newly established grievance mechanism. These mechanisms are as follows:

- SABIM (Ministry of Health Communication Centre) receives the grievances, concerns and suggestions from employees, health workers and patients either in person or anonymously. SABIM can be reached via the channels listed below:
 - Hotline by phone "Alo 184" line, which is accessible 24/7,
 - Website via https://sabim.gov.tr/,
 - WhatsApp communication line via 0541 888 0184, or
 - In person from the Patient Communication Unit.

By providing necessary software integrations to the new system, it has been ensured that all Project related grievances submitted through SABIM are directly delivered to the community liaison officer working at the MoH. The MoH personnel will register the grievances to the grievance log, which is provided in the Annex 10.3 of the SEP.

- Another national grievance channel is called "Presidential Communication Centre" (CIMER), which
 operates as the official public system to receive grievances, suggestions, or requests from individuals.
 CIMER has published a guidance manual in Turkish for individuals willing to use the system³⁷. CIMER
 will be available to the Project stakeholders as an alternative channel to raise Project-related
 grievances. The Project-related grievances received through CIMER will be investigated by the
 relevant authority representatives of CIMER at first. Those representatives will send the grievance
 directly to the community liaison officers assigned within the scope of the Project. After, the resolution
 of the grievance, the grievance applicant will be communicated about the resolution and closure
 through CIMER. The channels to access CIMER are listed below:
 - Petition and post to T.C Cumhurbaşkanlığı Külliyesi 06560 Beştepe, Ankara, TURKEY,
 - Website: http://www.cimer.gov.tr,
 - Call Centre: 150, or
 - Phone number: +90 312 525 55 55.

³⁶ <u>https://pydb.saglik.gov.tr/TR-76672/talep-oneri-ve-sikayet-formu.html</u>

³⁷ The guidance manual can be accessed via https://cimer.gov.tr/50sorudacimer.pdf

- The "Foreigners Communication Centre" (YIMER) provides an opportunity for foreigners to convey grievances. YIMER will be available for foreign Project stakeholders to report their Project-related grievances through the following communication channels:
 - Website: http://www.yimer.gov.tr,
 - Call Centre: 157, or
 - Phone number: +90 312 157 11 22.

By integrating national grievance channels to the Project-specific grievance mechanism, all grievances reported by external stakeholders in the scope of the Project will be recorded and addressed. Nevertheless, the Public Grievance Mechanism of the Project will not be limited to communication channels at national or ministerial level. Rather, community grievances will be received and managed at contractor and consultant level. The main contractors of the Project to be employed for both construction and operation phases will establish their own public grievance mechanism specific for the Project and assign a community liaison officer for management of the Project-related grievances. These grievance mechanisms to be established by the contractors will be integrated to the existing system within the Project Grievance Mechanism.

The public grievance mechanisms of the main contractors of the Project will be suitable also for receiving anonymous grievances. The grievance form provided in Annex 10.2 of the SEP will be used throughout the life of the Project by the contractors and anonymous applications will be allowed within the scope of the contractors' public grievance mechanism. After the grievances are successfully closed, the corrective actions taken will be displayed and the grievance applicants will be informed about the resolution by the community liaison officers of the contractors.

If a grievance is received about the construction activities by the national/ministerial level grievance channels, the community liaison officer within the MoH will get in contact with the community liaison officer of the EPC Contractor who will be in charge of managing grievances received from both public and the Project workers (including subcontractors).

The community liaison officers of the contractors are responsible for reporting to the MoH about the closure of the grievances received via national/ministerial channels as well as the grievances received via the grievance channels of the contractors. The MoH will monitor all grievances through the reports provided by the contractors and the central grievance log.

After the grievances are successfully closed and the corrective actions are taken, the results of the grievances including anonymous grievances will be announced on the Project website (https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html).

Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)

The Project will have security measures (i.e. security personnel, surveillance system through security cameras) to minimize the risk of SEA/SH cases. In addition to the security measures, the public grievance mechanism channel of the PMSU is available and accessible by stakeholders to report any grievances, suggestions or requests related to SEA/SH issues. The grievance mechanism allows for anonymous applications, which is especially critical for reporting any SEA/SH related issue. The privacy, health and safety of the grievance applicant will be the key principles in handling SEA/SH cases. The identity of the grievance applicant will be fully maintained to ensure confidentiality and hinder the risks of retaliation.

SEA/SH cases will be recorded and analysed as a part of the current grievance mechanism of Project. However, they will be approached in a more sensitive way and in an immediate timeframe.

The public grievance mechanism of the Project will be disclosed to the Project's external stakeholders through stakeholder engagement activities and consultation meetings as defined in the Section 5.6.

Public grievance mechanism of the Project is explained in more details in the SEP.

5.7.3 Workers' Grievance Mechanism

Workers' grievance mechanism covers all grievances, requests and suggestions reported by the Project employees (including Project Implementation Unit members, contractor and subcontractor workers) and the employees of the supplier companies within the scope of the Project.

A Project-specific Workers' Grievance Mechanism procedure for both construction and operation phases will be prepared in line with the WB ESS2 requirements. The procedure will define the ways to report grievances, ways to address these grievances received from all Project employees, and community liaison officers for management of the workers' grievances.

While the MoH is responsible for the entire grievance mechanism of the Project, the contractors are responsible for establishing their own workers' grievance mechanisms and reporting the outcomes of the mechanism to the MoH throughout the life of the Project. The MoH will monitor the worker grievances through the reports provided by the contractors and the central grievance log.

Similar to the public grievance mechanism, the Project will embrace and integrate relevant national grievance mechanisms to the Workers' Grievance Mechanism. SBN (Health Meeting Point of Ministry of Health) is one of these grievance mechanisms that is in place for health workers. It is possible to raise anonymous grievances through SBN. Grievances can be submitted through the following channels:

- Website <u>https://sbn.saglik.gov.tr/</u>, or
- Hotline by phone "Alo 182", which is accessible 24/7.

The Project employees can also report grievances via CIMER, which is already explained in the previous section. The channels to access CIMER are as follows:

- Website: http://www.cimer.gov.tr,
- Call Centre: 150, or
- Phone number: +90 312 525 55 55.

Apart from national grievance mechanism channels, the Project will establish additional tools (i.e. grievance boxes, raising grievances through reporting to the workers' representatives, separate meetings with female workers) in the Project site and facilities to enable the Project employees report grievances. The tools will be established by the contractors and integrated to the existing system within the Project Grievance Mechanism.

The following will be applied for successful implementation and management of workers' grievance mechanism through grievance boxes:

- There will be at least three grievance boxes at the Project site and facilities; and, there will be available and empty grievance forms as well as pens next to the boxes.
- The grievance boxes will be locked and secured. Only the community liaison officer of the contractors during construction phase and operation phase will have the keys of the boxes. Only these personnel will have the authority to open and check boxes.
- The workers will have the opportunity to apply anonymously.
- The grievance form provided in Annex 10.2 of the SEP will be used within the scope of the workers' grievance mechanisms of the contractors throughout the life of the Project.
- The location of the boxes will be specifically selected as out of sight from bystanders and cameras (i.e. resting areas) in order to preserve the anonymity of the grievance applicant.
- The grievance boxes will be checked daily and grievances will be registered to the grievance log immediately.
- Grievances will be classified depending on their subjects while registering to the grievance log.

There will be workers' representatives who will be assigned by the Project workers. Reporting grievances to the workers' representatives will also be a part of the workers' grievance mechanism. Workers' representatives will be responsible for informing the community liaison officers that manage grievances about all grievances that s/he received either verbally or in written way. The community liaison officers will register those grievances into the grievance log.

The workers (including subcontractors) will be informed about the grievance mechanism as a part of the induction process. The information provided during the induction will involve that the workers will not be retaliated or fired just because they raise grievances.

The agreements/specifications signed with the supplier companies will involve the information about the Project's grievance mechanism. Community liaison officers assigned for managing grievances will investigate the grievances reported by the Project workers together with a workers' representative and personnel from senior management team such as the Human Resources Manager of contractor companies employed for the Project's phases.

After the grievances are successfully closed and the corrective actions are taken, the results of the grievances including anonymous grievances will be displayed on the notice boards within the Project site.

Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)

There will be security measures (i.e. security personnel, surveillance system through security cameras) to minimise the risk of SEA/SH cases in the Project site. In addition to the security measures, workers will have the opportunity to raise grievances related to SEA/SH through grievance boxes with the possibility of anonymous application.

SEA/SH cases will be recorded and analysed as a part of the current grievance mechanism of Project. However, when a SEA/SH grievance is reported, it will be approached in a more sensitive way and in an immediate timeframe in comparison with other grievances.

The privacy, health and safety of the complainant will be the key principles in handling SEA/SH cases. The identity of the grievance applicant will be kept strictly confidential to hinder the risks of retaliation.

As a good practice, the Project parties are recommended to organize separate meetings with workers on a regular basis (i.e. quarterly) to learn if they have any concerns or grievances related to SEA/SH risks and to improve the existing security measures if they are not adequate. Such meetings can be managed by the community liaison officers managing grievances or the Human Resources Manager with active participation of workers who are subject to SEA/SH risks to the extent possible.

5.7.4 Project Grievance Resolution Process

The flow of operation of the Project Grievance Mechanism (both community and workers' grievance mechanisms), which is visualized in Figure 5-8 below, will be in line with the resolution process defined in the ESMF developed by the PMSU.



Figure 5-8: Steps of the Grievance Mechanism of the Project⁴

<u>Receive and Register the Grievance</u>: Grievance/complaint applications are registered by the community liaison officers of the Project parties (MoH including PMSU, General Directorate of Health Investments, General Directorate of Public Health together with the Project Implementation Unit to be established, EPC Contractor of the construction activities, and the consultants employed during the design, construction and operation phases). All applications are registered in a central log.

<u>Acknowledgement of the Grievance by the MoH:</u> Following the registration of the grievance, the complainant is informed by the MoH that the grievance is registered.

<u>Define Related Departments and Actions:</u> The community liaison officers of the MoH will conduct classification and initial assessment in order to define the related department(s) and actions for timely and accurate resolution of the grievance.

<u>Inform Complainant:</u> After the experts in the related department(s) review the grievance and take the relevant action(s) to address the grievance, the response is sent to complainant.

<u>Obtain Information about Action Taken to Avoid/Reduce the Issue:</u> Information regarding the action(s) taken in order to address the issue are forwarded to the MoH by the experts in the related department(s). Where the grievance requires further investigations, root cause analysis or actions, the MoH may request the assistance of outside authorities as appropriate.

<u>Close the Complaint</u>: After all these steps are followed, the grievance/complaint is closed and marked as resolved. Announcements regarding the results and corrective actions taken will be properly displayed through the Project website and notice boards within the Project site.

The grievance mechanism of the Project should respond to the complainant within 15 days after the grievance is received. If the resolution period of the grievances will take longer due to further investigation (i.e. to receive official letters, opinions), then it can expand to 30 days. However, the complainant (if not anonym) should be informed about the prolonged resolution process.

While the MoH is responsible for implementation and managements of the entire grievance mechanism of the Project, other Project parties are also responsible for establishing their own Grievance Mechanism Procedures for both workers and the public, and reporting the grievances and outcomes of the mechanism to the MoH. These grievance mechanisms and procedures developed by other parties will be integrated to the Project Grievance Mechanism. The MoH will monitor the Project grievances through regular reports provided by the Project parties.
5.7.5 World Bank's Grievance Redress Service

Communities and individuals who believe that a World Bank-supported project has or is likely to have adverse effects on them, their community, or their environment have the opportunity to submit their grievances through existing project-level grievance redress mechanisms or the World Bank's Grievance Redress Service (GRS).

GRS ensures the World Bank's responsiveness and accountability to project-affected communities by ensuring that grievances are promptly reviewed and addressed.

All grievances must be in writing and addressed to the GRS through the following ways:

- Online, access the online form
- By email to grievances@worldbank.org
- By letter or by hand delivery to the World Bank Headquarters in Washington D.C., United States or any World Bank Country Office – print and use this form (DOCX)

Grievances must:

- Identify the project subject of the grievance
- Clearly state the project's adverse impact(s)
- Identify the individual(s) submitting the complaint
- Specify if the complaint is submitted by a representative of the person(s) or community affected by the project
- If the complaint is submitted by a representative, include the name, signature, contact details, and written proof of authority of the representative.

Supporting evidence is not necessary but helpful in reviewing and resolving the complaint. The complaint may also include suggestions on how the individuals believe the complaint could be resolved. All complaints will be treated as confidential. The GRS will not disclose any personal data that may reveal the identity of complainants without their consent.

More information on how to raise grievances to the World Bank's GRS is provided in the World Bank website³⁸.

5.7.6 Community Liaison Officer

The Project parties involve the MoH (including PMSU, General Directorate of Health Investments, General Directorate of Public Health together with the Project Implementation Unit to be established), EPC Contractor of the construction activities of the Project, and the consultants during the design, construction and operation phases. To ensure the successful implementation and management of the Project GM, each party will assign a community liaison officer for managing grievances. Resolving the incoming complaints, informing the stakeholders, and communicating with the stakeholders will be carried out by these community liaison officers.

5.7.7 Project Contact Information

All the Project plans, reports and the results of the public grievances together with the corrective actions taken will be published on the Project website (<u>https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html</u>).

Additionally, suggestions and complaints related to the Project can be directed through the following:

³⁸ The website can be accessed through <u>https://www.worldbank.org/en/projects-operations/products-and-services/grievance-redress-service</u>.

Contact Information

Project: Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Main Responsible Party of the Project: The Turkish Republic Ministry of Health Project Management Support Unit

Address: Bilkent Yerleşkesi, Üniversiteler Mahallesi Dumlupınar Bulvarı 6001. Cadde No:9 06800 Çankaya/Ankara-TURKIYE

E-mail: trhealth@saglik.gov.tr

Project website:

https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html

Grievance form: https://pydb.saglik.gov.tr/TR-76672/talep-oneri-ve-sikayet-formu.html

The public grievance mechanism of the Project and grievance channels will be disclosed to the Project's external stakeholders through stakeholder engagement activities and consultation meetings as defined in the Section 5.6.

The Project employees will be informed about the workers' grievance mechanism and channels through induction trainings.

6 GEOLOGY, SOILS AND CONTAMINATED LAND

6.1 Introduction

This chapter considers the potential impacts of the Project regarding geology, soils and contaminated land. The aim of the assessment will be to generally characterize the potential risks regarding geology (i.e. seismic and landslide risks) and soils (i.e. any existing or potential future soil contamination) associated with construction and operational phases of the Project. Please note that impacts on hydrology and hydrogeology are assessed in *Chapter 7: Hydrology and Hydrogeology* of this ESIA report.

Information on the existing environments regarding baseline ground and soil conditions is provided in Section 6.2. The next sections provide the impact assessment, mitigation measures proposed, compliance with the relevant framework of national and international legislation and standards, and any residual impacts following mitigation.

6.1.1 Study Area and Area of Influence

The area of influence with regards to geology and soils considers all locations where ground disturbance and physical works are likely to take place during the construction and operational phases of the Project. It covers the Project site boundaries and areas outside the Project site to be temporarily used during the construction phase such as disposal sites where excavation waste will be taken to. Provided suitable mitigation measures are incorporated, operations associated with the proposed activities are unlikely to significantly affect overall, geology and soils outside of the Project area.

6.1.2 Data Limitations

Some of the assessment in this chapter is based on the information presented in the reports of the sitespecific geotechnical and ground survey studies carried out for the Project site, however, it should be recognised that the investigations in these studies examined only the portion of the Project site which covers the 1555-4 parcel where most of the Project structures will be built. The remaining area is the recreational area which will consist of landscaping and kindergarden. It should be noted that no drilling has been undertaken at the recreational area within the scope of the ground surveys.

The assessment of the potential for soil contamination has been undertaken based on available information on current and historical land use, as well as the soil quality investigation carried out within the scope of the ESIA process. However, it should be recognised that any such investigation can examine only a fraction of the subsurface conditions. As such, unexpected ground and soil conditions may be present that have not been identified at this stage. Uncertainty relating to the soil conditions will be addressed in the design of the Project and suitable mitigation measures will be in place and detailed in the construction management plans to manage unexpected contamination if identified during the construction works.

6.2 Baseline Description

6.2.1 Overview

Data sources for evaluation of baseline conditions on geology (including landslide and seismic risks) and soil contamination included the following:

 Review of historical information on the geology, landslides and seismicity and previous uses of the proposed area,

- A site walkover and review of aerial photography to clarify the environmental setting, current land uses, presence, and location of any significant sources of contamination, hazardous materials, and any visible signs of contamination including stained soil or noticeable odors,
- Review of available ground survey studies, limited to areas directly impacted by construction activities and the Project,
 - Boring logs, "Geotechnical Report"³⁹ and "Ground and Foundation Survey Data Report"⁴⁰ prepared for the Project
 - Seismic hazard report for the Project site⁴¹
- A soil quality investigation carried out within the scope of the ESIA process,
- Desk-based research of published literature on the existing status of the current landslide and seismic activity as well as the soil contamination in the Project site.

6.2.2 Geology

6.2.2.1 Regional Geology

The rock units that characterize the Ankara region and its vicinity can be classified mainly into three units, from oldest to youngest: Karakaya nappe, Anatolian nappe and cover rocks. Karakaya nappe is a tectonic unit, and is subdivided into two units as Lower Karakaya nappe and Upper Karakaya nappe. The Lower Karakaya nappe is represented by a metamorphic rock assemblage (meta-melange) under the greenschist facies conditions of a subduction accretionary prism. In general, the Anatolian Nappe is an undifferentiated coloured ophiolitic mélange or subduction complex accreted at the south-facing northern active margin of the northerly subducting northern Neo-Tethyan ocean floor. Both tectonic units are the product of different orogenic events and are separated from each other by a thick sedimentary sequence in normal stratigraphic position. From bottom to top, the group consisting of molassic conglomerate, sandstone, siltstone, red ammonite facies, platform limestones and turbiditic limestones is the upper Liassic-Lower Cretaceous age. In general, these three units are associated with each other tectonically and all three are unconformably overlain by Late Cretaceous-Quaternary cover rocks⁴².

6.2.2.2 Geology of the Project Site

The Project is planned to be constructed in Balıkhisar neighbourhood, Akyurt district of Ankara province in Turkiye. The Geological Map of Turkiye published by the General Directorate of Mineral Research and Exploration (MTA) indicates that the main geological formations underlying the Project site are undifferentiated quaternary as shown in the Figure 6-1. It consists of thick and medium layered conglomerates, conglomerate-sandstone alternations, medium and thick layered coarse sandstones, pebbly clay and sandy clay, which are composed of sediments of different ages deposited during the Quaternary.

³⁹ Parcel based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkey Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti. (2021)

⁴⁰ Ground and Foundation Survey Data Report for the Phase 1 Project of the Turkey Vaccine and Biotechnological Product Research and Production Centre by Duha Jeoloji & Jeoteknik (2021)

⁴¹ Drawn out from the AFAD (Disaster and Emergency Management Presidency) Turkey Earthquake Hazard Maps Interactive Web Application (https://tdth.afad.gov.tr) in December 2021

⁴² Demirtaş, R., Özdemir, A., Erkoç, H., Kaya, İ. (2017). Geology Report of Mining Licence Area (3333981), Akyurt, Ankara, Central Anatolia, Türkiye (https://doi.org/10.13140/RG.2.2.29884.69767)



Figure 6-1: Main geological formations at the Project site⁴³

A section of the general geology of the region is provided in the Ground and Foundation Survey Data Report prepared for the Project site (as shown in Figure 6-2), which also characterizes the Project site as alluvium deposits of the Quartenary (Qal). The unit is composed of clay, sand, pebbles and gravels that are not consolidated or loosely consolidated in the beds of rivers in the region. The thickness of alluvium generally ranges from 10 to 30 meters.

⁴³ General Directorate of Mineral Research and Exploration (MTA) - Geosciences Map Viewer accessed from http://yerbilimleri.mta.gov.tr on 04.02.2022



Figure 6-2: A section of the general geology of the Project site area, 1/100,000 scaled map⁴⁴

No zoning-based geological or geotechnical studies have previously been conducted for the area where the Project will be situated. Geology/geotechnical investigations were conducted within the scope of

⁴⁴ Ground and Foundation Survey Data Report for the Phase 1 Project of the Turkey Vaccine and Biotechnological Product Research and Production Centre by Duha Jeoloji & Jeoteknik (2021)

tender for the Phase I construction ⁴⁵ of the Project, in order to examine the geological and geotechnical features of the main project complex area (parcel no 1555-4) and obtain the geotechnical parameters to be used by the construction contractor involved during/responsible from the construction phase of the Project. A Geotechnical Report⁴⁶ and a Ground and Foundation Survey Data Report⁴⁷ were prepared.

The studies described above involved field surveys, field studies (drilling), laboratory work and desk studies. According to the Ground and Foundation Survey Data Survey Report prepared by Duha Jeoloji Jeoteknik, 43 boreholes of 22 m depth were installed in the study area. Detailed information about the locations, depths and groundwater conditions for each borehole are presented in Table 6-1; whereas the locations of the boreholes are illustrated in



Figure 6-3. Drilling and sampling were performed according to TS 1901-1 and TS EN ISO 22475-1 standards. Studies were carried out using hydraulic drilling machinery and equipment.

No.	Total Depth (m)	Groundwater Level (m)	Coordinate-X	Coordinate-Y
1	22	6.5	40.084642°	32.968212°
2	22	8.0	40.084946°	32.967702°
3	22	6.5	40.084827°	32.968406°
4	22	7.5	40.085177°	32.967989°
5	22	6.5	40.084708°	32.967873°

Table 6-1: Information about the boreholes

⁴⁵ Please note that the Project will consist of two Phases: i) Phase I includes the Administrative, R&D and Experimental Animals Production/Test Buildings and ii) Phase II includes the Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area.

⁴⁶ Parcel based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkey Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti. (2021)

⁴⁷ Ground and Foundation Survey Data Report for the Phase 1 Project of the Turkey Vaccine and Biotechnological Product Research and Production Centre by Duha Jeoloji & Jeoteknik (2021)

No.	Total Depth (m)	Groundwater Level (m)	Coordinate-X	Coordinate-Y
6	22	6.5	40.084950°	32.968537°
7	22	7.5	40.085282°	32.968085°
8	22	5.5	40.085087°	32.968662°
9	22	6.0	40.085423°	32.968241°
10	22	8.0	40.085175°	32.967359°
11	22	4.5	40.085190°	32.968782°
12	22	4.5	40.085498°	32.968322°
13	22	7.5	40.085525°	32.966932°
14	22	3.2	40.085632°	32.968452°
15	22	7.5	40.085383°	32.967126°
16	22	7.0	40.085692°	32.966684°
17	22	3.5	40.085776°	32.968601°
18	22	3.7	40.085971°	32.969123°
19	22	3.8	40.085965°	32.968758°
20	22	4.0	40.086456°	32.968112°
21	22	7.0	40.085329°	32.967840°
22	22	4.5	40.086078°	32.967018°
23	22	7.0	40.085507°	32.967975°
24	22	5.0	40.085963°	32.966842°
25	22	5.0	40.085666°	32.967568°
26	22	4.5	40.085905°	32.967192°
27	22	5.5	40.085621°	32.968090°
28	22	5.0	40.086221°	32.967167°
29	22	4.0	40.085758°	32.968229°
30	22	4.0	40.086343°	32.967319°
31	22	4.5	40.085894°	32.967797°
32	22	4.0	40.086114°	32.967461°
33	22	4.0	40.085895°	32.968362°
34	22	4.2	40.086463°	32.967477°
35	22	3.5	40.086039°	32.968503°
36	22	4.0	40.086594°	32.967617°
37	22	5.0	40.086140°	32.968058°
38	22	4.0	40.086366°	32.967724°
39	22	4.5	40.086326°	32.966998°
40	22	3.5	40.086484°	32.966742°
41	22	4.0	40.086695°	32.967389°
42	22	3.0	40.086852°	32.967123°
43	22	3.5	40.086611°	32.967059°



Figure 6-3: Locations of the boreholes drilled during the ground survey study

Seismic refraction (7 profile), microtremor (4 locations) and electrical resistivity (4 locations) measurements were carried out during the geological/geotechnical investigation in order to identify dynamic-elastic properties (i.e. the geophysical features) of the Project site. Based on the abovementioned analysis, the details of the area classification and important features which may affect the design are as follows:

- Vs30 velocity⁴⁸ is in the range of 222-266 m/s, and the ground class is ZD (Ground class ZD is defined as medium-firm layers of sand, gravel or clay).
- Groundwater was encountered between 3.0-8.0 meters below ground level and the curves obtained from the electrical resistivity study show low resistivity values. Due to the fact that the region is alluvial, the corrosion degree generally varies from corrosive and medium corrosive.
- When the dynamic elasticity modulus (E_d) values and maximum shear modulus (G_{max}) values are examined, the ground layers are generally classified as "Medium Loose Ground".
- The relative ground amplification factors are 2.6/2.7. Most of the spectral amplification value changes in the study area are in the "B, moderate danger level" class⁴⁹.
- In the study area, the ground dominant vibration period values are 0.57- 0.63 seconds. Accordingly, the relative dominant period changes are classified as "C, high danger level".

Based on the above-mentioned studies, the ground profile in the Project site is summarized as follows:

• 0 - 0.5 m: Vegetative soil

⁴⁸ The average shear wave velocity up to 30 meters depth is referred as Vs30.

⁴⁹ The approach adopted in the assessment involves division of the area into three zones as (A, B, and C). Zone A shows the most favourable (in terms of earthquake hazard) 33% percentile (e.g. higher equivalent shear wave velocities, lower spectral amplifications and lower spectral accelerations), zone B the medium 34% percentile and zone C shows the most unsuitable 33% percentile (e.g. lower equivalent shear wave velocities, higher spectral amplifications and higher spectral accelerations) as defined in A. Ansal, (2004). Recent Advances in Earthquake Geotechnical Engineering and Microzonation, 253–266. Kluwer Academic Publishers.

- 0.5 -12.5 m: High/low plasticity clay
- 12.5 -14.5 m: Sandy gravel
- 14.5 -30 m: High/low plasticity clay

6.2.2.3 Tectonics

The region is located in the Anatolide tectonic belt south of the North Anatolian Fault (NAF). It gained its tectonic structure with the Alpine orogenic phase. In Ankara and its surroundings, magmatic activities in the form of eruptions took place in different periods during the Cenozoic, which formed andesite, trachyte and basalt, and their tuffs and agglomerates. Volcanics, which spread around Hüseyingazi hill and Ovacık village, in Elmadağ in the east and at the plain outlet in the west, are represented by andesite, locally lava, tuff and agglomerates. These units, which are named as Tertiary volcanic series, are interbedded within Miocene units at the plain exit. Although the age of the volcanism is not certain, it has been estimated that it probably started after the Upper Cretaceous and continued until the end of the Miocene. Ankara and its surroundings were exposed to uplift by the Hercynian tectonic movements and underwent erosion and deformation. In the Permian, the area was invaded by marine environment which continued until the end of the Upper Cretaceous. Finally, limestone overlain the conglomerates at the base of Jurrasic and flysches on top of it. These levels were affected by the Alpine oronegenesis, resulting in many micro- and macro-sized folding and local fractures. Volcanism continued until Miocene. At the end of the Miocene, the region completely transitioned to the terrestrial environment. The small and shallow lakes were moved and filled by rivers and similar movements because of the erosion and deterioration of the units around the Pliocene⁵⁰.

6.2.3 Seismic, Liquefaction⁵¹ and Landslide Risks

According to the Turkiye earthquake hazard map shown in Figure 6-4, Peak Ground Acceleration 475 (PGA 475) (recurrence period of 475 years) in Ankara province is up to 0.3 PGA.

⁵⁰ Ground and Foundation Survey Data Report for the Phase 1 Project of the Turkey Vaccine and Biotechnological Product Research and Production Centre by Duha Jeoloji & Jeoteknik (2021)

⁵¹ In the Building Earthquake Regulation, liquefaction is defined as a significant decrease in shear strength and stiffness parallel to the increase in pore water pressure under earthquake impacts on cohesive or low cohesion (PI<12%) soils located below the groundwater level and up to 20 m from the surface. A large part of the underground profile of the Project site was determined as clay units. In addition, with the increase in depth, the Standard Penetration Test values are higher than 20 m. Therefore, liquefaction problem is not expected in the Project site.</p>



Figure 6-4: Earthquake hazard map of Turkiye⁵²

Ankara province is surrounded by four main faults: North Anatolian Fault Zone (NAFZ) to the north, The Salt Lake Fault to the southeast, the Ezinepazarı Fault to the east and the Inonu-Eskisehir Fault Zone to the west and southwest. Ankara province is approximately 100 km away from the NAFZ. These faults have the potential to create an earthquake with magnitudes of greater than 7.0 on the Richter scale ($M \ge 7.0$). In addition to these main faults, there are numerous active faults within the province and its surroundings, including the city centre. These additional active faults can cause small- to medium-scale earthquakes (5.0 < M < 6.0) with possible losses.

Ankara has experienced a number of landslides, earthquakes, flooding events and other natural disasters according to the Spatial and Statistical Distribution of Natural Disasters in Turkiye: Natural Disasters Inventory report⁵³. However, as seen in Figure 6-5, none were in the vicinity of the Project site. Most recent significant earthquakes observed in Ankara were near Çankırı in 2019 (Mw 5.1) and 2000 (Mw 5.6) and, near Bala in 2008 (Mw 5.0), 2007 (Mw 5.7 and Mw 5.5) and 2005 (Mw 5.3). Site specific seismic risks and design parameters have been assessed in the Geotechnical Report prepared for the Project site.

⁵² Official website of AFAD (Disaster and Emergency Management Presidency) accessed from <u>https://deprem.afad.gov.tr/deprem-tehlike-haritasi?lang=en</u> on 16 March 2021

⁵³ Spatial and Statistical Distribution of Natural Disasters in Turkey: Natural Disasters Inventory, General Directorate of Natural Disaster Affairs, 2008. (https://www.academia.edu/15447190)



Figure 6-5: Distribution of natural disasters in Ankara⁵⁴

The Project site was identified as having a peak ground acceleration (PGA) of 0.168 and specified as DD-2 (earthquake ground motion level with 10% probability of exceedance in 50 years with reoccurrence period of 475 years) based on earthquake hazard map presented in Figure 6-6. The ground class is determined as ZD (Medium-dense to dense sand, gravel or very solid clay layers) as discussed in Section 6.2.2. According to the Table 3.1 of the Turkiye Building Earthquake Regulation⁵⁵, Building Use Class (BUC) is determined as "1" (buildings that need to be used after the earthquake, buildings where people stay for a long time and densely, buildings where valuable goods are stored and buildings containing dangerous substances) and Building Importance Coefficient (I) is determined as "1.5". The Earthquake Design Class to be taken as basis in the design has been determined as "2a" based on the BUC and the earthquake ground motion level (DD-2) according to Table 3.2 of the regulation.

⁵⁴ Spatial and Statistical Distribution of Natural Disasters in Turkey: Natural Disasters Inventory, General Directorate of Natural Disaster Affairs, 2008. (https://www.academia.edu/15447190)

⁵⁵ Official Gazette date/number:18.03.2018/30364



Figure 6-6: Earthquake hazard map (in terms of Peak Ground Acceleration for a 475-year recurrence period) in the Project site⁵⁶

According to the Geotechnical Report, there is no obstacle to construction in terms of natural disasters in the study area. In addition, there is no disaster area decision taken in accordance with the Law No. 7269 on Measures to be Taken and Aid to be Provided Due to Disasters Against Public Life. In the Ground and Foundation Survey Data Report prepared for the tender of Phase I, it is stated that the topographic slope of the site is around 0-5%, which would not allow the stability of the site to deteriorate as a result of construction and loading of the land. No active landslide event is observed, and it is seen that Project site does not carry a potential landslide risk. It is thus reported that there is no risk such as mass movement (landslide, rockfall, collapse, crypt, soil flow) and swelling, collapse, flood, overflow, avalanche potential caused by the topography and structure of geological units (rock/ground) identified in the Project site. Additionally, according to the Geotechnical Report, no problems with bearing capacity, settlement and liquefaction are expected in the Project site.

The necessary geotechnical parameters for foundation design of the Project were identified by the Geotechnical Report and are presented in Table 6-2 below.

Parameter	Value
Soil Type	High/Low Plasticity Clay
Thickness	12.50 m
Bearing Capacity	3.60 kgf/cm ²
Coefficient Of Soil Reaction	2000 t/m ³
Groundwater Level	3.00 m
Earthquake Ground Motion Level	DD2
Highest Ground Acceleration, PGA	0.168 g
Highest Ground Velocity	11.367 cm/s
Earthquake Design Class	DTS-2a

Table 6-2: The soil parameters recommended in the Geotechnical Report to be used in static calculations

⁵⁶ Parcel based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkey Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti. (2021)

Parameter	Value
Building Importance Coefficient	1.5
Building Use Class	BUC-1
	A (Administrative Building): 5
Puilding Height Close	C (R&D Building) – E (Experimental Animals Building): 6
	F-G-H: 7
	B (Glass Café) -D (Gallery Pass)- I-J: 8
Horizontal Sliding Speed Vs30 (Under Foundation)	244 m/s
	Ta = 0.108 s
Horizontal Elastic Design Spectrum	Tb = 0.538 s
	TL=6.000 s
	-Ta = 0.036 s
Vertical Elastic Design Spectrum	Tb = 0.179 s
	TL=3.000 s
Ground Bottom Level (Minimum from Lowest Level)	0.5
Suggested Excavation Slope	1y/1d
Recommended Base Type	Raft General Foundation
Recommended Improvement Method	60 cm granular material laying

6.2.4 Soils and Contaminated Land

The vicinity of the Project site can be mostly characterized as commercial/industrial since the closest facilities within a 1-kilometre radius of the site (to the north, south and southeast) include various factories and manufacturers as well as commercial areas. There are a number of private lands located to the west of the Çubuk Stream used for agricultural purposes. Furthermore, as stated by the MoH representatives, in the past, a horse farm was operated within the Project site premises to support serum production. The previous uses of the site and the present activities in the surroundings are potential sources of existing soil and groundwater contamination in the area. Spills and leaks of hazardous materials (including petroleum products) are common sources for hydrocarbon and heavy metal contamination in soils. As some categories of pollutants are persistent in soil and groundwater, their presence could also signal the presence of a wider range of other pollutants during monitoring. Therefore, it is useful to establish and document baseline levels of hydrocarbon and heavy metal contamination on site. For this purpose, a baseline study to determine existing soil quality within the Project site has been conducted within the scope of the ESIA.

For the baseline investigation study, the recreational area was selected as the indicative sampling location. The intention was to provide an assessment of soil quality on site with respect to pollutants which might be be present on site and to determine if further investigation/action may be required. A soil sample was collected, preserved and transported in accordance with the TS 9923 standard and analysed for the compounds defined in the generic pollutant limit values list in Annex-1 of the Regulation on Soil Pollution Control and Point-Source Contaminated Sites⁵⁷ in accordance with the standard test methods specific to pollutants (TS 8332, ISO 10390, EPA 3051A, EPA 6020B, EPA 8260D, EPA 5021A, TNRCC 1005/TNRCC 1006). The results of the soil investigation study are presented in Table 6-3 and the official laboratory results are provided in Annex E-3. The sampling location is shown in Figure 6-7.

⁵⁷ Official Gazette date/number: 08.06.2010/27605

Table 6-3: Results of the soil investigation study

Pollutant	Absorption through soil ingestion and skin contact	Inhalation of volatile substances in the external environment	Breathing fugitive dust in the external environment	Transpor pollutants groundwa drinking groundwa (mg/kg dr	t of s to ater and ater ry soil)	Test Result (mg/kg dry soil)
	(mg/kg dry soil)	(mg/kg dry soil)	(mg/kg dry soil)	SF = 10	SF = 1	-
Benzene	12	1	-	0.006	0.0006	< 10
Bromodichloromethane	10	-	-	0.003	0.0003	< 10
Bromoform	61	-	-	0.3	0.03	< 10
1,2-Dichlorobenzene	7039	222	-	11	1	< 10
1,4-Dichlorobenzene	118	9762	-	3	0.3	< 10
1,1-Dichloroethane	15643	1167	-	21	2	< 10
1,2-Dichloropropane	18	16	-	0.1	0.01	< 10
Ethylbenzene	7821	14	-	4	0.4	< 10
Carbon Tetrachloride	5	0.3	-	0.02	0.002	< 10
Chloroform	105	0.3	-	0.8	0.08	< 10
Chloromethane	49	2	-	0.01	0.001	< 10
Xylene	15643	298	-	81	8	< 10
Trichloroethylene	2	0.05	-	0.07	0.007	< 10
Toluene	6257	925	-	5	0.5	< 10
Total Petroleum Hydrocarbons (Aliphatic) (EC5 - EC8)	4693	-	-	4	0.4	< 100
Total Petroleum Hydrocarbons (Aliphatic) (EC8> - EC16)	7821	-	-	7	0.7	< 100
Total Petroleum Hydrocarbons (Aromatic) (EC5 - EC9)	15643	-	-	15	1	< 100
Total Petroleum Hydrocarbons (Aromatic) (EC9> - EC16)	1564	-	-	1	0.1	< 100
Total Petroleum Hydrocarbons (Aromatic) (EC16> - EC35)	2346	-	-	2	0.2	< 100
Antimony	31	-	-	2	0.2	0.464
Arsenic	0.4	-	471	3	0.3	18.2
Copper	3129	-	-	514	51	33.5
Barium	15643	-	433702	288	29	288
Beryllium	0.1	-	843	0.1	0.01	0.699
Mercury	23	3	-	3	0.6	< 0.1
Zinc	23464	-	-	6811	681	51.3
Silver	391	-	-	16	2	< 0.1
Cadmium	70	-	1124	27	3	0.179
Tin	46929	-	-	54794	5479	1.89
Cobalt	23	-	225	5	0.5	16.9

Pollutant	Absorption through soil ingestion and skin contact	Inhalation of volatile substances in the external environment	Breathing fugitive dust in the external environment	Transport pollutants groundwa drinking groundwa (mg/kg dr	t of s to ater and ater y soil)	Test Result (mg/kg dry soil)
	(mg/kg dry soil)	(mg/kg dry soil)	(mg/kg dry soil)	SF = 10	SF = 1	-
Chromium	235	-	24	900000	1	27.8
Lead	400	-	-	135	14	30.7
Molybdenum	391	-	-	14	1	1.12
Nickel	1564	-	-	13	1	39.7
Selenium	391	-	-	0.5	0.05	0.851
Thallium	5	-	-	2	0.2	0.281
Titanium	312857	-	-	-	146029	292
Vanadium	548	-	-	2556	256	31.1

Dilution factor SF "1" is used if the distance to the aquifer is less than 3 m, the aquifer is cracked or karstic, or the source area of the pollution is 10 ha or more; in other cases, SF is accepted as "10". Groundwater was encountered at depths between 3.0 to 8.0 m below ground level at the site and the area is less than 10 ha. Therefore, SF is accepted as "10" for the assessment of the baseline conditions.



Figure 6-7: Soil sampling location

Review of the laboratory results indicates no detectable concentrations of hydrocarbon compounds (i.e. TPH⁵⁸, BTEX⁵⁹ and VOC⁶⁰ parameters). The laboratory detection limits were above the respective generic limits values for the exposure pathways 'absorption through soil ingestion and skin contact' and 'inhalation of volatile substances in the external environment' for two volatile organic compounds: Carbon Tetrachloride and Trichloroethylene. In addition, laboratory detection limit for Benzene was above its respective generic limits value for 'inhalation of volatile substances in the external environment'. It should be noted that, for the analyzed parameters, the regulatory limit values for the exposure pathway of

⁵⁸ Total Petroleum Hydrocarbons

⁵⁹ Benzene, toluene, ethylbenzene and xylene

⁶⁰ Volatile Organic Compounds

'transport of pollutants to groundwater and drinking groundwater' were not taken into account in the soil quality assessment, since groundwater is not used for drinking water purposes in the Project area or wider Ankara region.

On the other hand, levels of heavy metal parameters Arsenic (18.2 mg/kg) and Beryllium (0.699 mg/kg) were detected above their respective regulatory limit values for 'absorption through soil ingestion and skin contact'. and level of heavy metal parameter Chromium (27.8 mg/kg) was detected above its respective regulatory limit value for 'breathing fugitive dust in the external environment'. The exceedances of Turkish regulatory standards were limited in extent and are most probably due to the naturally occurring conditions in the soil. It should be noted that the defined regulatory limit values for these heavy metals are considered to be based on extremely conservative assumptions and furthermore do not take into account background levels in soil. For reference, in a study investigating background levels of heavy metals in soils across the Ankara province⁶¹, mean levels of Arsenic and Chromium in 120 surface soil samples collected were reported as 13 (±18) mg/kg and 100 (±100) mg/kg respectively.

An asbestos investigation was also performed on site to determine if any asbestos contamination is present since such contamination would require removal, handling and disposal before the construction starts. The analysis was performed in accordance with VDI 3866 using a scanning electron microscope and energy distribution X-ray microanalysis (SEM/EDXA) method. As a result of the analysis, no asbestos was detected in the collected soil sample.Potential for existing land contamination risk of the Project site was also assessed during the site walkover conducted in December 2021 within the scope of ESIA studies. No significant sources of contamination such as hazardous materials or any visible signs of contamination including stained soil or noticeable odors were noted during walkover survey.

6.3 Assessment of Impacts

6.3.1 Methodology

Geology, soils and contaminated land impact assessment has been conducted through the use of primary data collected for the Project site prior to and during the ESIA, as well as secondary data based on desktop studies. The methodology adopted for the assessment is as follows:

- Establishment of baseline: Geological and soil conditions have been identified by using outcomes of the soil investigation study undertaken during the ESIA process and the reports of the site-specific ground survey studies carried out, and other relevant documents. The information and documentation gathered on the geology, soils and contaminated land assessment are listed in Section 6.2.1.
- Assessment of impacts: Possible impacts related to geology and soils have been assessed together with their significance levels. The significance criteria adopted for the assessment of impacts is provided in Section 6.3.2. Impact assessment covers:
 - Assessment of deviation from baseline conditions,
 - Assessment of potential impacts on key receptors associated with construction and operation phases of the Project.
- **Development of mitigation measures:** To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise the overall environmental impact from associated with the Project.

Key receptors which are anticipated to be sensitive to changes in the existing geological and soils conditions on site are considered to include human health (nearby communities, construction workers,

⁶¹ D. Y. Ozan, A. Omar and T. Gurdal, Multivariate Statistics to Investigate Metal Contamination in Surface Soil, Journal of Environmental Management, Vol. 86, No. 4, 2008, pp. 581-594.

operation phase employees), surface waters (Çubuk stream) and groundwaters, built environment and ecological receptors.

6.3.2 Determining Magnitude, Sensitivity, and Impact Significance

Table 6-4 presents the criteria for determining the sensitivity of receptors. High sensitivity reflects existing conditions with little capacity to absorb proposed changes or conditions that present minimal opportunity for mitigation. Magnitude is determined by the predicted deviation from the baseline conditions and the scale of impact. Table 6-5 presents the criteria for determining magnitude of impacts on geology, soils and groundwater.

Sensitivity	Definition	Examples
High	Little or no capacity to absorb	Areas within high-risk seismic zones
-	proposed changes or minimal opportunities for mitigation	Slope in a condition at or close to failure which may occur regardless of mitigation
		Groundwater vulnerability is classified as high; principal aquifer providing locally important resource or supporting river ecosystem
		Soil of excellent quality with no limitations, can support a very wide range of agricultural crops
		The soil quality plays an ecosystem role in terms of supporting biodiversity
		Built environment includes listed buildings, scheduled monuments
Medium	Limited capacity to absorb	Areas within medium risk seismic zones
	proposed changes or limited opportunities for mitigation	Slope condition worsened by construction works but not increased to failure, potentially small local failures manageable with standard mitigation approaches
		Moderate classification of groundwater vulnerability; secondary aquifer providing water for agricultural or industrial use with limited connection to surface water
		Soil of good quality with minor limitations, can support a wide range of agricultural crops
		The soil quality promotes biologically unique species or constitute a ground for essential habitat for such species
		Built environment includes sites with local interest for education or cultural appreciation
Low	Some capacity to absorb	Areas within low-risk seismic zones
	proposed changes or moderate opportunities for mitigation	Slope condition with minimal mitigation would not be affected by the construction / operation
		Deep secondary aquifer with poor water quality not providing baseflow to rivers; aquifer not used for water supplies (public or private).
		Soil of good to moderate quality with moderate limitations, can sometimes support a wide range of agricultural crops and pasture
		The soil quality promotes diverse habitat or population of flora and fauna
		Built environment includes infrastructure
Negligible	High capacity to absorb	Areas of no geological importance
	proposed changes or numerous opportunities for mitigation	Slopes that will not be affected by the works and will not require mitigation to support
		Non-aquifer
		Soil of poor quality with severe limitations, supports mainly scrubland, does not promote diverse habitat or populations

Table 6-4: Criteria for Determining Sensitivity

Table 6-5:	Criteria	for	Determining	Magnitude
------------	----------	-----	-------------	-----------

Magnitude	Definition	Examples
Major	Long term fundamental change to the specific environmental conditions assessed resulting in	Major impacts on the integrity of structures and functionality of the Project (e.g., collapse of the buildings) from earthquake loads Use and/or generation of large volume of hazardous materials

162

Magnitude	Definition	Examples
	Definition Ong term or permanent change, ypically widespread in nature regional national and hternational), would require ignificant intervention to return to vaseline; exceed national tandards and limits. Detectable change to the specific environmental conditions ussessed resulting in non- undamental temporary or permanent change. Medium term spatial extent beyond immediate Project site boundaries or local urea. Spatial extent of impact within the Project site. Meets minimum national standards and hermational guidelines. Detectable but minor change to he specific environmental conditions.	Site investigation data indicating onsite contamination due to current or former uses
	(regional national and international), would require	Physical removal or degradation (including loss of structure and contamination) of a large area of soil
	significant intervention to return to baseline; exceed national	Previous or ongoing activities on or near to a site where severe harm/improvement to a defined receptor is very likely
	standards and limits.	Pollution or loss of special characteristics of a water resource
Moderate	Detectable change to the specific environmental conditions	Moderate impacts on the integrity of structures and functionality of the Project (e.g., major cracks on the structures) from earthquake loads
	assessed resulting in non-	Use and/or generation of hazardous and non-hazardous materials
	fundamental temporary or permanent change. Medium term spatial extent beyond immediate Project site boundaries or local	Previous or ongoing activity where harm/improvement to a defined receptor is possible but severe harm/improvement is unlikely
		Site investigation data indicating moderate contamination
	area.	Impact on water resources, moderate changes insufficient to reduce water quality
Minor	Spatial extent of impact within the Project site. Meets minimum	Minor impacts on the integrity of structures and functionality of the Project (e.g., minor cracks on the structures) from earthquake loads
	national standards and international guidelines.	Generation of inert and non-hazardous waste materials which may be suitable for re-use on site.
	Detectable but minor change to the specific environmental	Physical removal, degradation (including loss of structure and contamination) or improvement of a minor area of soil
	conditions.	Site investigation data indicating significant contamination is unlikely Minor impact insufficient to alter characteristics of the water resource
Negligible	Temporary duration with no detectable impact. No perceptible	No impacts on the integrity of structures and functionality of the Project from earthquake loads
	change to the specific environmental conditions.	Temporary use of land (with soil surface) for the storage of excavated materials and construction equipment with no or little impact that is recoverable within a short time scale
		No loss or alteration of characteristics, features or elements; no observable impact in water resources

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 6-6.

Table 6-6: Impact Significant Matrix

	Sensitivity of Receptors					
Magnitude of Impact	Negligible	Low	Medium	High/Very High		
Negligible	Insignificant	Insignificant	Insignificant	Insignificant		
Minor	Insignificant	Minor	Minor	Moderate		
Moderate	Insignificant	Minor	Moderate	Major		
Major	Insignificant	Moderate	Major	Critical		

6.3.3 Impacts related to Seismic Risks

The characterization of geotechnical parameters has been undertaken in the Project site to define the engineering requirements of the Project structures to withstand the predicted seismic risks. As the Project site lies in a moderate risk seismic zone and the future site use is moderately sensitive national development, the sensitivity is considered to be medium.

No change in the seismology risk of the area is expected as a result of the Project, as none of the Project activities are expected to be of such powerful extent to influence the existing tectonic risks. However, major impacts on the integrity of structures and functionality of the Project (e.g. collapse of the buildings) from earthquake loads might occur during both construction and operation phases following an

163

earthquake event of large magnitude if the design did not consider the resulting earthquake loads. This might result in major impacts on the environment as well as on the community and worker health and safety following accidents, spills, fire, etc. related to the seismic incident. Furthermore, the Project will include ABSL3 units which can pose both chemical and infection risks if not managed properly. According to the information provided by MoH, the Project will be designed in accordance with the findings of the site specific geological/geotechnical investigation studies, relevant national regulatory requirements and international standards for protection against seismic activity to avoid seismic risks to as much as technically and financially feasible. Seismic isolators will be installed in the production buildings and raft foundations will be applied other buildings for protection against seismic risks. It is expected that all structures will be designed and constructed to withstand earthquake events with magnitudes up to 8.0. Through implementation of design measures described above, the magnitude of potential impacts related to seismic risks is predicted to be reduced to minor and the resulting impact significance is also considered to be minor.

The low seismic potential can also disrupt the Project construction activities at any time during construction, causing liquefaction in the alluvial soils, ground failure and surface rupture. However, according to the Geotechnical Report, impacts with bearing capacity, settlement and liquefaction are expected to be minor in the Project site.

6.3.4 Impacts on Soils

The urban development in the vicinity of the Project site can be mostly characterized as commercial and industrial. However, there are a number of private lands located to the west of the Çubuk Stream used for agricultural purposes. Çubuk stream flowing at an approximate distance of 15 m along the northwest boundary of the Project site is known to be adversely impacted by the industrial activities ongoing in the region and the Çubuk-I dam that the stream feeds are not used for water supply purposes but mainly flood control. As part of the ESIA, considering the minor risk of land contamination due to the previous use of the Project land, a soil investigation study was undertaken in the recreational area to establish baseline conditions in terms of soil quality. The results of the soil investigation did not indicate presence of adversely impacted soils. Based on these, the receptor sensitivity is considered to be low to medium.

The construction of the Project involves extensive groundworks for site clearance and topsoil removal, foundations, drainage and infrastructure, which increases the probability of soil compaction and erosion. Additionally, temporary use of land for construction can lead to adverse impacts on soil quality. The introduction of construction materials and processes can increase the risk of pollution and contamination due to the potential release of contaminants and hazardous materials from accidental leaks and spills. These spills may include spills of petroleum products (such as gasoline, diesel fuel and lubricating oil) during fuel loading and maintenance of the machinery operating at the site and spills due to storage of hazardous materials on site. The site clearance activities also have the potential pollution to nearby watercourses. This may ultimately contribute to the increased pollution of the Çubuk Stream which is already affected by industrial discharges in the area. Based on the current information available, the construction impacts on soils are deemed of minor to moderate magnitude and therefore the impact significance is considered to be moderate.

Generally, chemicals used in the laboratories are classified as hazardous and their use generates various hazardous wastes and wastewaters. If not managed properly, these may cause potential implications on soil quality due to possible spills and leaks in the laboratory and process units, storage tanks and infrastructure of the proposed facility. In addition, there is potential to affect groundwater and nearby surface water quality if mobilisation of contamination occurs. Poor management of hazardous wastes (especially medical wastes) and industrial/medical wastewaters generated at the site may result in an impact magnitude varying between minor to major depending on the magnitude and duration of the adverse events (spills, accidents, inappropriate storage practices). However, implementation of an operational ESMP during operation will ensure appropriate mitigation for the impacts related to soil

contamination due to hazardous materials. Furthermore, a waste building is planned within the Project design, that will ensure segregated storage of the hazardous and non-hazardous wastes prior to transportation and disposal. It is planned that all wastes generated during the operation phase of the Project will be transferred from the operation buildings to this building via underground galleries. The waste building and the infrastructure will be designed with the necessary protection systems against spills from wastes and wastewater generated at the site. Thus, overall a minor magnitude soils impact is predicted, with minor impact significance.

There is also the risk of contamination to surrounding soils through accidental spills and leaks from vehicles used to transport the hazardous materials to and from the facility. These contaminants can pose a risk of being washed into adjacent exposed soils and potentially into receiving waters. Risk of contamination during transportation is also considered to result in a minor significance considering that appropriate mitigation measures to prevent any spills and accidents will be taken.

6.4 Mitigation Measures

6.4.1 Design Phase

The following specific mitigation measures will be applied during the design phase of the Project:

- Seismic isolators will be applied to the design of the production buildings (at three blocks). Remaining buildings of the proposed facility (i.e., the Administrative Building, R&D Building and Experimental Animals Production/Test Building) will also be designed to be protective against seismic risks, with raft foundations that will spread the building loads uniformly on the ground. All structures will be designed and constructed to withstand earthquakes of magnitude up to 8.0.
- It will be ensured that systems such as HVAC, piping, electrical etc. will be designed and installed to be protected against seismic risks.
- All structures will be designed and constructed as per relevant Turkish legislations and international standards according to the earthquake resistance parameters defined in Section 6.2.3 and in accordance with the risk assessment presented in the site-specific Geotechnical Report, such as:
 - The clay and silt ratio in the filling material will not exceed 5% and the material gradation will be selected within the values given in the Highways Technical Specification. Compression will be carried out to provide 95% proctor firmness of the filling layer.
 - Vegetative soil, unqualified fill and decomposed-deteriorated layers that can be found in excavations will be completely removed, the foundations will be placed on a homogeneous layer by lowering them below the freezing depth and the non-engineered organic soil.
 - The selection of foundation type and dimensions will be made by adhering to the building loads and the values specified in the ground survey undertaken for the site.
 - The core periods and the amplification end values of the structures will be selected according to the calculated ground dominant vibration periods (see Section 6.2.3). The oscillation to be created by horizontal earthquake loads will be determined and design will prevent the ground and the structure from going into semi-harmonisation (resonance).
- The Technical Building will be designed with bunded double-walled fuel storage tanks of appropriate type and capacity to serve boilers and emergency generators, in accordance with applicable international standards. The wastewater drainage and decontamination systems of buildings will be sized to serve the peak loads of the proposed facility.

6.4.2 Construction Phase

A range of mitigation measures are proposed to avoid and/or mitigate potential seismicity/landside impacts and adverse soil impacts associated with the construction of the Project, including:

- Site-specific risks arising from natural hazards such as earthquake and landslides during the construction phase will be addressed in the relevant Emergency Preparedness and Response Plan.
- Excavation materials will never be loaded on the slopes. Excavation limits will be well defined, and the
 appropriate safe distance calculated before excavation works start. During the foundation excavations,
 all occupational safety measures will be taken, and excavation will not be carried out in a way that will
 cause the surrounding area and structures to slide.
- Good construction site practices in line with national regulations and international guidelines for protection of soils will be implemented. Best practice construction and material management techniques will be outlined in the Construction Site Management Plan and their appropriate application will be monitored by the construction contractor.
- Hazardous materials will be suitably stored to prevent leaks and spills. Adequate bunding will be
 provided for all fuel and chemical storage. Drip trays will be used to intercept leaks and spills during
 fuelling. Spill kits will be available to deal with accidental spillages or leaks to ground. The contractors
 will take all reasonable measures to prevent possible pollution of soils and watercourses. Spill
 management will be covered within the associated plans (i.e. Pollution Prevention Plan and the
 Hazardous Material Management Plan).
- Procedures will be set up for identifying and dealing with contaminated soils and materials if encountered during construction, including appropriate storage and disposal. Should any soils be suspected as being contaminated, then samples will be analysed to see if corrective action is required. Contaminated soils will be disposed of in an appropriately licensed disposal site by ensuring relevant transport procedures that follow the applicable national and international standards and guidelines.
- No refuelling or maintenance will take place near the Çubuk Stream.
- Measures will be taken for the protection of newly exposed soil surfaces from rainfall and wind erosion. Infiltration will be minimized and controlled by providing adequate drainage systems.
- The reuse of the excavated material as fill material to level off topography and for landscaping purposes will be implemented wherever practicable, or surplus construction material can be made available to third parties for reuse on local development projects if it cannot be utilized on site.
- Topsoil will be carefully removed from the areas to be impacted by construction activities and preserved for eventual use for landscaping and revegetating purposes. The segregated and stockpiled topsoil will be covered to prevent windborne dust emissions and soil loss. Slope of the stockpiling area will not exceed 5%.

6.4.3 Operation Phase

Mitigation measures to avoid and/or mitigate the potential soil impacts during the operation of the Project will include the following:

- Site-specific risks arising from natural hazards such as earthquake and landslides during the operation phase will be addressed in the Emergency Preparedness and Response Plan.
- Quality of the underlying soil will be preserved through implementation of effective hazardous material and waste management procedures. Materials and wastes (including medical wastes) will be handled according to the Hazardous Material Management Plan and Waste/Wastewater Management Plan.
- Fuels, oils and chemicals will be stored on an impervious base protected by bunds to 110% of capacity. Fuel will be stored in designated areas in double skinned bunded tanks. Any spillages from handling fuel and liquids will be immediately contained on site.
- Spill kits will be available to deal with accidental spillages or leaks to ground.
- Potentially contaminated materials will be removed from site as soon as practicable for authorised disposal and suitable treatment.
- It will be ensured that hazardous material and waste transport procedures follow the applicable national and international standards and guidelines.

• Surface runoff will be collected through a stormwater drainage system to be installed separated from process and domestic wastewater streams. Oil water separators and grease traps will be installed and maintained as appropriate at runoff areas with potential sources of contamination.

6.5 Compliance against National and International Requirements

6.5.1 Seismic Risks

The Project will be designed, constructed and operated in accordance with the relevant Turkish regulatory requirements (i.e. provisions of the Turkiye Building Earthquake Regulation⁶²) related to seismic design and risk assessment, the findings of the site specific geological/geotechnical investigation studies and international standards for protection against seismic activity.

For the Project, Building Use Class (BUC) is determined as "1" and Building Importance Coefficient (I) is determined as "1.5" according to the Table 3.1 of the above-mentioned regulation (see Table 6-7).

Table 6-7: Building	y Use Classes	and Building i	importance	Coefficients
---------------------	---------------	----------------	------------	--------------

Building Use Class (BUC)	Purpose of Use	Building Importance Coefficient (I)
	Buildings that need to be used after an earthquake, concentrated buildings where people stay for a long time, buildings where valuable goods are stored and buildings containing dangerous substances	
1	a) Buildings that must be used immediately after an earthquake (Hospitals, dispensaries, health centres, fire brigade buildings and facilities, PTT and other communication facilities, transportation stations and terminals, power generation and distribution facilities, province, district and municipality administration buildings, first aid and disaster relief facilities) planning stations)	1.5
	 b) Schools, other educational buildings and facilities, dormitories and dormitories, military barracks, prisons, etc. 	
	c) Museums	
	d) buildings where substances with toxic, explosive, flammable, etc. properties are located or stored	
	Buildings where people are concentrated for a short time	
2	Shopping centres, sports facilities, cinemas, theatres, concert halls, places of worship, etc.	1.2
	Other buildings	
3	Other buildings that are not included in the definitions given for Building Use Class of 1 and 2 (Houses, workplaces, hotels, building type industrial structures, etc.)	1.0

The Earthquake Design Class (EDC) to be taken as basis in the design has been determined as "2a" based on BUC and the DD-2 earthquake ground motion level (S_{DS}) according to Table 3.2 of the Turkiye Building Earthquake Regulation, as presented in Table 6-8.

Table 6-8: Earthquake Design Classes (EDC)

Short Period Design Spectral Acceleration Coefficient at DD-2	Building Use Class (BUC)		
Earthquake Ground Motion Level (S _{DS})	BUC=1	BUC= 2 and 3	
S _{DS} <0.33	EDC=4a	EDC=4a	
$0.33 \le S_{DS} \le 0.50$	EDC=3a	EDC=3	
$0.50 \le S_{DS} \le 0.75$	EDC=2a	EDC=2	

⁶² Official Gazette date/number:18.03.2018/30364

Short Period Design Spectral Acceleration Coefficient at DD-2	Building Use Class (BUC)	
Earthquake Ground Motion Level (S _{DS})	BUC=1	BUC= 2 and 3
$0.75 \leq S_{DS}$	EDC=1a	EDC=1

Seismic design parameters have been identified in the Geotechnical Report as per the Turkiye Building Earthquake Regulation using the AFAD (Disaster and Emergency Management Presidency) Turkiye Earthquake Hazard Maps Interactive Web Application⁶³ (see Table 6-9 below).

Table 6-9: Parameters defined in Ground Survey Report according to the Turkish Building Earthquake Regulation

Parameter	Value
Ground Class	ZD
Short Period Map Spectral Acceleration Coefficient (S_s)	0.394
Map Spectral Acceleration Coefficient for 1.0 Second Period (S1)	0.135
Short Period Design Spectral Acceleration Coefficient (S _{DS})	0.585
Design Spectral Acceleration Coefficient for 1.0 Second Period (S_{D1})	0.315
Local Ground Effect Coefficient for Short Period Region (F_s)	1485
Local Ground Effect Coefficient for 1.0 s Period (F1)	2330

In addition, Provisions of the Regulations for the Structures to be Built in Disaster Areas⁶⁴ and "Turkiye Building Code" of Disaster and Emergency Management Administration⁶⁵ will be strictly followed.

Also of relevance is the World Bank ESSs and EHS Guidelines with respect to Emergency Preparedness and Response, which state that projects should have an Emergency Preparedness and Response Plan that is commensurate with specific risks. This includes the requirement to assess the risk posed to the Project by geological, landslide and seismic hazards and formulate appropriate strategies that effectively reduce any potential impact associated with these hazards on the Project.

6.5.2 Soils and Contaminated Land

The prevailing legislation in Turkiye relating to environmental prevention and control is the Law on Environment No. 2872⁶⁶, which sets out that polluters are liable for damages caused to the environment and natural resources, and for compensation of such damages. Other legislation relevant to protection of soil quality under the Law on Environment includes those given in Table 6-10 below.

Table 6-10: National Regulations on Soils and Contaminated Land that are Relevant to the Project

Law/Regulation	Official Gazette Date/No	Scope	Relevance to the Project
Regulation on Soil Pollution Control and Point-Source Contaminated Sites	08.06.2010/ 27605	This regulation defines the principles and procedures to prevent soil pollution, to identify the sites where pollution exists and to remediate and monitor the contaminated sites. The generic limit values of contaminants defined in the regulation are taken into account in assessment of soil pollution.	The regulation requires all existing and proposed facilities included in Annex-2 of the regulation to declare a "Preliminary Operation Information Sheet" to the PDEUCC, which then assesses the site with respect to the evaluation criteria given in Annex-4 and may classify the site as a "suspicious site" warranting further assessment. Further assessment would include a quality investigation of

63 https://tdth.afad.gov.tr

⁶⁴ Official Gazette no/date: 26582/14.07.2007

⁶⁵ Official Gazette no/date: 30364/18.03.2018

⁶⁶ Official Gazette no/date: 18132/16.08.1983

Law/Regulation	Official Gazette Date/No	Scope Relevance to the Project	
			site soils and in case the generic limit values are exceeded, a risk assessment to identify site-specific contaminant limit values.
Regulation on Control of Excavated Soil, Construction and Demolition Wastes	18.03.2004/ 25406	In line this regulation, excavated land must be managed in such a way as to avoid harming the environment and human health. The regulation defines general rules about administrative and technical issues on the reduction, collection, temporary storage, recovery and disposal of excavation soil and construction and demolition wastes. Accordingly, the municipalities establish and operate all relevant recycling and disposal facilities.	According to the Article 14 of the regulation, precautions should be taken during excavation activities to reduce dust emissions, noise and visual impacts. The reuse of excavation soil primarily in the activity area shall be ensured. During excavation, the topsoil shall be collected separately from the subsoil and stockpiled for reuse. Slope of the stockpiling area should not exceed 5%. Losses during the storage of the topsoil should be prevented and the quality of the soil preserved. The separately collected topsoil shall be reused in parks, landscaping areas, agriculture and similar works. According to the Article 23 of the regulation, the generators of excavation soil and construction/demolition wastes are responsible of transporting/having them transported to appropriately permitted landfill sites of the municipalities with transportation permissions. Generators of excavation soil and construction/demolition waste above 2 tons shall apply to related district municipality boundaries and obtain a Waste Transportation and Acceptance Certificate

The key international standards and guidelines applicable to the Project relating to international best practice for the assessment and management of contaminated land and for pollution prevention and control include the following:

- World Bank ESS3: Resource Efficiency and Pollution Prevention and Management (2017)
- World Bank Group General EHS Guidelines: Environmental: 1.8 Contaminated Land (2007)
- World Bank Group EHS Guidelines for Construction and Decommissioning (2007)

The objective of the ESS3: Resource Efficiency and Pollution Prevention and Management is to avoid or minimize adverse impacts on human health and the environment, for the duration of a Project, by avoiding or minimizing polluting activities, avoiding emissions and promoting the use of sustainable resources. Specifically in relation to this assessment, actions include avoiding or minimizing the release of pollutants (to air, water and land), identifying and where necessary managing existing pollution, and avoiding the generation of hazardous and non-hazardous wastes. The WB guidelines for contaminated land provide a broad outline of the requirement for risk screening, risk management, detailed quantitative risk assessment and risk reduction measures, where risk factors: source, pathways and receptors are likely to co-exist. The risk screening involves identification of contamination, sampling and testing, evaluation of the results and verification of sensitive receptors and exposure pathways. Where necessary, a detailed risk assessment builds on the risk screening and involves detailed ground investigation to identify the scale of contamination.

With the implementation of mitigation measures described above, the significance of the residual impacts is estimated to become minor to insignificant.

6.7 Proposed Monitoring and Reporting

Procedures for monitoring the effectiveness of the mitigation measures proposed in this chapter are provided in the ESMP and will be expanded upon in the Project-specific Pollution Prevention Plans. During the construction and operation phases, monitoring of soils and contaminated land will take place through daily inspections and through sampling/analysis in case of any spills and incidents as needed. Any incidents identified during these inspections will be reported to the incident/accident management system of the Project. Moreover, non-conformities will be monitored in line with the ESMS and logged with the Incident Register Form. Additionally, ongoing monitoring and maintenance of the spill protection measures and drainage systems will be undertaken to reduce the impact significance related to potential soil contamination during both construction and operation. Additionally, the MoH will: (i) promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers (no later than 48 hours after learning of the incident or accident), (ii) provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and (iii) subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

7 HYDROLOGY AND HYDROGEOLOGY

7.1 Introduction

This chapter identifies and assesses the likely risks and impacts of the Project on the water environment. An analysis of baseline conditions for surface water and the groundwater as well as flood risks associated with the Çubuk Stream has been presented in Section 7.3. The assessment presented in this chapter considers the potential risks and impacts on water resources associated with construction and operation of the Project, including construction of the facility buildings, installation and maintenance activities of main infrastructure works, production of domestic and industrial/medical wastewater and stormwater discharge and hazardous material management.

The subsequent sections identify the relevant framework of national and international legislation and standards, assesses potential significant adverse impacts on the water resources before defining appropriate mitigation, and compensation and enhancement measures that will be implemented as part of the Project. The purpose of the assessment is to ensure that relevant national and international legislation and guidelines are complied with to ensure that water resources in the area are protected.

7.1.1 Study Area and Area of Influence

The area of influence regarding hydrology, hydrogeology, water quality and flood risk is the area that could potentially be affected by disturbance, contamination and increase in flood risk associated with the construction and operation of the Project. Key water resources which could be potentially affected have been considered in the assessment. The area of influence includes the areas directly within the Project site and downstream or downgradient of the site, as well as areas which are temporarily affected during construction including access routes. For surface waters, the area of influence will include the Çubuk Stream (which flows parallel to the Project site) and its downstream impacts south/southwest of the Project site. For groundwater, the area of influence could span much wider, depending on the groundwater sub-basin below the Project site.

7.2 Data Limitations

In undertaking the water resources and quality impact assessment, several data limitations have been identified.

The assessment of the existing groundwater and surface water conditions has been primarily undertaken based on limited publicly available information on regional watercourses, as well as current and historical practices and land use. Additionally, to establish the baseline pollution level associated with the Çubuk Stream, a surface water quality investigation was undertaken within the scope of this ESIA, however, it should be recognised that any such investigation only reflects a snapshot of the surface water conditions. Though the measurement results are considered to be representative, there is likely to be some variability in measurements over time.

In the assessment undertaken as part of this ESIA, there were some limitations in terms of flood hydrology data. The limited availability of publicly accessible historical and projected flood data in the Sakarya basin and its sub-basins has necessitated and resulted in assumptions and use of professional judgement in flood risk assessment approach.

7.3 Baseline

7.3.1 Overview

This section provides information on the existing water environment in the study area of influence, including water quality, hydrogeology and flood risk. The evaluation of baseline conditions has been made by using the following primary and secondary sources:

- Historical flood records, A site walkover to observe the environmental setting, existing water resources in the vicinity of the Project site, any visible signs of disturbance, contamination and location of any significant sources of contamination including urban and industrial wastewater discharges,
- A surface water quality investigation carried out within the scope of the ESIA process,
- Available ground survey studies, limited to areas directly impacted by construction activities of the Project:
 - Parcel based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkiye Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti. (2021)
 - Ground and Foundation Survey Data Report for the Phase 1 of the Turkiye Vaccine and Biotechnological Product Research and Production Centre by Duha Jeoloji & Jeoteknik (2021)
- Desk-based research of published literature on the existing status (hydrology, hydrogeology, surface water and groundwater quality, water abstraction and discharge, land drainage) of the water resources and flood risk to establish the existing water regime and consider its potential sensitivity to various activities associated with the Project,
- Review of information from publicly available sources of the Ministry of Agriculture and Forestry (MoAF) on the hydrogeology, hydrology and flood characteristics of the region (including the area where the Project will be developed) and the Ministry of Environment, Urbanization and Climate Change (MoEUCC) on the quality of the water resources and contaminated areas:
 - Atlas: Turkiye National Geographic Information Systems National Geographic Information Platform of the MoEUCC⁶⁷,
 - Ankara Environmental Status Report (2020)⁶⁸
 - National Basin Management Strategy (2014-2023)⁶⁹
 - Sakarya Basin Protection Action Plan (2013)⁷⁰,
 - Sakarya Basin Flood Management Plan (2018)⁷¹,
 - Strategic Environmental Assessment Scoping Report for Sakarya Basin Management Plan Development Project (2021)⁷².

⁶⁷ https://www.atlas.gov.tr/

⁶⁸ Ankara Environmental Status Report by the Ministry of Environment, Urbanization and Climate Change, 2020 (https://webdosya.csb.gov.tr/db/ced/icerikler/2020_ankara--cdr-20210728144247.pdf)

⁶⁹ National Basin Management Strategy by the Ministry of Agriculture and Forestry, 2014-2023 (https://www.tarimorman.gov.tr/SYGM/Belgeler/uhys%20belgesi%20(3).pdf)

⁷⁰ Sakarya Basin Protection Action Plan by the Ministry of Agriculture and Forestry, 2013 (https://www.tarimorman.gov.tr/SYGM/Belgeler/havza%20koruma%20eylem%20planlar%C4%B1/Sakarya_web.pdf)

⁷¹ Sakarya Basin Flood Management Plan by the Ministry of Agriculture and Forestry, 2018 (https://www.tarimorman.gov.tr/SYGM/Belgeler/Ta%C5%9Fk%C4%B1n%20Y%C3%B6netim%20Planlar%C4%B1/5)%2 0SAKARYA%20HAVZASI%20TA%C5%9EKIN%20YONETIM%20PLANI.pdf)

⁷² Strategic Environmental Assessment Scoping Report for Sakarya Basin Management Plan Development Project by the Ministry of Agriculture and Forestry, December 2021 (https://www.tarimorman.gov.tr/SYGM/Belgeler/Sakarya%20Havzas%C4%B1%20Nehir%20Havza%20Y%C3%B6netim %20Plan%C4%B1/SCED_Taslak%20(RAPOR)_REW-2.pdf)

7.3.2 Surface Water Resources

Turkiye is in the category of countries with water limitation having 1500 m³ of usable water per capita. The annual average precipitation in Turkiye is 574 mm (1981-2010) which corresponds to an average annual precipitation volume of 450 billion m³. The amount of usable surface water is estimated as 94 billion m³ per year, the operating reserve of groundwater that can be drawn is 18 billion m³ per year, therefore, the annual total of consumable surface and ground water potential is 112 billion m³. A total of 54 billion m³ of water is used annually of which, 40 billion m³ (74%) used in irrigation, 7 billion m³ (13%) as potable water and 7 billion m³ (13%) in industry⁷³.

Turkiye is divided into 25 hydrological basins and the total average annual flow is 186 billion m³. Ankara spans across the Sakarya Basin, Kızılırmak Basin and Konya Closed Basin (Figure 7-1), however approximately 70% of the province remains within the Sakarya Basin. The total area of river surfaces within the provincial border is 4385 ha. As seen in Figure 7-2, the Project site also remains within the Sakarya Basin⁷⁴.



Figure 7-1: Hydrological basins in Turkiye⁷⁵

content/uploads/2020/04/SuKaynaklariYonetimi_ve_GuvenligiOzellhtisasKomisyonuRaporu.pdf)

⁷³ Eleventh Development Plan (2019-2023) of Turkey, Water Resources Management and Security Special Commission Report (<u>https://www.sbb.gov.tr/wp-</u>

⁷⁴ Sakarya Basin Flood Management Plan (2018) accessed from <u>https://www.tarimorman.gov.tr/SYGM/Belgeler/Ta%C5%9Fk%C4%B1n%20Y%C3%B6netim%20Planlar%C4%B1/5)%2</u> <u>0SAKARYA%20HAVZASI%20TA%C5%9EKIN%20YONETIM%20PLANI.pdf</u> on 01 March 2021

⁷⁵ National Basin Management Strategy (2014-2023) accessed from <u>https://www.tarimorman.gov.tr/SYGM/Belgeler/uhys%20belgesi%20(3).pdf</u> on 01 March 2022



Figure 7-2: Project site within the Sakarya Basin⁷⁶



Figure 7-3: Stream Sub-basins of Sakarya Basin⁷⁷

⁷⁶ Sakarya Basin Flood Management Plan, 2018

⁽https://www.tarimorman.gov.tr/SYGM/Belgeler/Ta%C5%9Fk%C4%B1n%20Y%C3%B6netim%20Planlar%C4%B1/5)%2 OSAKARYA%20HAVZASI%20TA%C5%9EKIN%20YONETIM%20PLANI.pdf)

⁷⁷ Strategic Environmental Assessment Scoping Report for Sakarya Basin Management Plan Development Project, December, 2021

⁽https://www.tarimorman.gov.tr/SYGM/Belgeler/Sakarya%20Havzas%C4%B1%20Nehir%20Havza%20Y%C3%B6netim %20Plan%C4%B1/SCED_Taslak%20(RAPOR)_REW-2.pdf)

The main water resources in Ankara are part of the Sakarya Basin and its main tributaries Kirmir and Ankara Streams, large part of the Kızılırmak Basin and its main tributaries Delice, Acıçay and Devres Streams, part of the Konya Closed Basin and its main tributaries Büyük Melen, Küçük Melen and Gerede Streams, as well as part of the Western Black Sea Basin.

In Ankara, drinking and potable water is supplied from the following dams in operation: Çubuk-II (23 km north), Kayaş-Bayindır (19 km south), Kurtboğazı (30 km northwest), Çamlıdere (60 km northeast), Eğrekkaya (52 km northwest), Akyar (64 km northwest) and Kavşakkaya (24.5 km north) dams.⁷⁸

Watershed Characteristics

Sakarya Basin has a precipitation area of 58,160 km² corresponding to 7.5% of the area of Turkiye⁷⁹. It receives an average annual precipitation of 479 mm and annual total precipitation of 32 billion m³ with an annual flow of 12 billion m³. Sakarya Basin is composed of six different sub-basin areas; among them, the Project site is situated within the Ankara Stream sub-basin having a surface area of 3153 km². There are many streams within the Sakarya basin flowing towards the Black Sea via the Sakarya River. One of the important streams within Sakarya basin is the Ankara Stream which is 140 km long with 11.9 m³/sec flowrate and has important branches including Çubuk and Hatip Streams⁸⁰ (Figure 7-3).

Sakarya Basin is one of the basins where industrial activities and development in terms of economic and cultural activities, transportation and health are most intense in Turkiye due to its location. Industrial establishments from many different sectors operate in almost all of the basin, especially in Ankara, Eskişehir and Sakarya provinces. Kazan, Akyurt and Çubuk districts of Ankara province have become important industrial zones in recent years. On the other hand, water pollution in the Sakarya Basin increases rapidly in parallel with the population growth and industrialization, and some tributaries of the Sakarya basin are polluted due to discharge of domestic and industrial effluents, as well as agricultural activities⁸¹.

Surface Water Resources near the Project Site

The nearest water body to the Project site is the Çubuk Stream which is adjacent to the northwest boundary of the Project site (Figure 7-4 and Figure 7-5). The distance between the Çubuk stream and the nearest point of the main project complex (i.e. the Experimental Animals Production/Test Building) is approximately 92 meters. As observed during the site visit and field surveys conducted by the ESIA team, there is no surface water body within the Project site boundaries and there are no other major water bodies in close vicinity of the Project site.

⁷⁸ Ankara Environmental Status Report (2020) accessed from <u>https://webdosya.csb.gov.tr/db/ced/icerikler/2020_ankara--</u> <u>cdr-20210728144247.pdf</u> on 01 March 2021

⁷⁹ National Basin Management Strategy (2014-2023) accessed from <u>https://www.tarimorman.gov.tr/SYGM/Belgeler/uhys%20belgesi%20(3).pdf</u> on 01 March 2021

⁸⁰ Sakarya Basin Flood Management Plan (2018) accessed from <u>https://www.tarimorman.gov.tr/SYGM/Belgeler/Ta%C5%9Fk%C4%B1n%20Y%C3%B6netim%20Planlar%C4%B1/5)%2</u> <u>0SAKARYA%20HAVZASI%20TA%C5%9EKIN%20YONETIM%20PLANI.pdf</u> on 01 March 2021

⁸¹ Sakarya Basin Protection Action Plan (2013) accessed from <u>https://www.tarimorman.gov.tr/SYGM/Belgeler/havza%20koruma%20eylem%20planlar%C4%B1/Sakarya_web.pdf</u> on 01 March 2021



Figure 7-4: Surface water resources in the vicinity of the Project site



Figure 7-5: Çubuk Stream (Photographs taken near the northern site boundary)

Çubuk Stream rises from the Aydos Mountains in two branches 35 km north of the Project site and feeds the Çubuk-II Dam, which is 5 km north of Çubuk district. In the plain, Çubuk Stream feeds Çubuk-I Dam and afterwards, it passes through the city of Ankara, joins with Hatip Stream flowing from the east that is originating from Idris Mountains, takes the name Ankara Stream and finally merges with the Sakarya River. The part of the Çubuk stream that flows near the Project Site is the branch downstream of the Çubuk-II Dam which feeds the Çubuk-I Dam (Figure 7-6).



Figure 7-6: Çubuk-I and Çubuk-II Dams

Çubuk-I Dam was originally built for both flood protection and drinking water supply, however, as of August 1994, it is no more used for drinking water supply purposes due to heavy pollution in the dam reservoir. The responsibility for the operation, maintenance and repair of the recreational areas of the Çubuk-I Dam was transferred to the Ankara Metropolitan Municipality and it is currently used for flood conveyance purposes. Drinking water of Akyurt district is supplied from the Çubuk-II Dam.

The General Directorate of Water Management of the MoAF is carrying out the Sakarya Basin River Basin Management Plan project under the provisions of the Regulation on the Preparation, Implementation and Monitoring of Basin Management Plans⁸² and the EU Water Framework Directive (2000/60/AT) aiming at protection and planning of the river basins and wetlands in terms of physical, chemical and ecological aspects. According to the Strategic Environmental Assessment Scoping Report⁸³ of this project, Çubuk Stream is classified as a sensitive water body (i.e. water resources that are determined to be eutrophic or that may become eutrophic in the near future if necessary precautions are not taken, waters intended for drinking water that may contain high nitrate concentrations if measures are not taken, and water resources that require further treatment for other reasons) and the surface water quality status is determined as "poor". Furthermore, as per the Regulation on Determination of Sensitive

⁸² Official Gazette date/number: 17.10.2012/28444

⁸³ Strategic Environmental Assessment Scoping Report for Sakarya Basin Management Plan Development Project by the Ministry of Agriculture and Forestry, December 2021

⁽https://www.tarimorman.gov.tr/SYGM/Belgeler/Sakarya%20Havzas%C4%B1%20Nehir%20Havza%20Y%C3%B6netim %20Plan%C4%B1/SCED_Taslak%20(RAPOR)_REW-2.pdf)

Water Bodies and the Areas Affecting These Bodies and Improvement of Water Quality⁸⁴, the adjacent section of the Çubuk Stream to the Project site flowing towards Çubuk-I Dam remains in an urban sensitive area (i.e. urban wastewater drainage areas, which cause pressure on sensitive water bodies and interfere with water quality targets to be met) as presented in Figure 7-7.



Figure 7-7: Sensitive urban areas in the Sakarya Basin

The rehabilitation of Çubuk stream falls within the responsibility of the General Directorate of State Water Works (DSI). According to the consultations held with DSI within the scope of the ESIA, no rehabilitation works have been performed or are planned by DSI on the adjacent section of the Çubuk Stream. During the site visit undertaken as part of the scoping study, the ESIA team observed visible pollution and an untreated wastewater discharge into the stream near the north-western border of the Project site (see Figure 7-8 for location of the discharge). The source of the discharge is unknown.

Baseline water quality in the Çubuk stream was evaluated as part of the ESIA study through surface water quality sampling and analysis. Instantaneous grab sampling was performed near the downstream boundary of the Project site to understand the existing water quality conditions of the stream before the Project related activities start. The results of the water quality analysis and comparison of the results against the national water quality limit values are presented in Table 7-1 below and the official laboratory results are provided in Annex E-4. The sampling location is shown in Figure 7-8 below.

Annex 5 of the Surface Water Quality Regulation⁸⁵ classifies surface water quality as: (1) Class I: High quality water, (2) Class II: Less polluted water, and (3) Class III: Polluted water. When the detected levels of the conductivity, biological oxygen demand (BOD₅), Total Kjeldahl Nitrogen (TKN) and total phosphorus parameters in the collected surface water sample are considered, the water quality class is identified as 'Class III', which indicates polluted water with moderate water quality. Considering the land use and historical practices upstream of the sampling point, the observed level of pollution can be attributed to mainly industrial and agricultural activities and pollution sources.

⁸⁴ Official Gazette date/number:23.12.2016/29927

⁸⁵ Official Gazette date/number: 30.11.2012/28483

Parameter	Unit	Test	Water Quality Class Limit Values ⁸⁶			Class
		Result	I	I		_
рН	-	8.40	6.0-9.0	6.0-9.0	6.0-9.0	I
Conductivity	µS/cm	1182	< 400	1000	>1000	III
Oil and Grease	mg/L	< 10	< 0.2	0.3	> 0.3	I, II or III
Dissolved Oxygen	mg/L	6.93	> 8	6	< 6	II
Colour (436 nm)	m -1	0.8	RES 436 nm: ≤ 1.5	RES 436 nm: 3	RES 436 nm: 4.3	I
Colour (525 nm)	m -1	0.2	RES 525 nm: ≤ 1.2	RES 525 nm: 2.4	RES 525 nm: 3.7	I
Colour (630 nm)	m -1	0.1	RES 620 nm: ≤ 0.8	RES 620 nm: 1.7	RES 620 nm: 2.5	I
Biochemical Oxygen Demand (BOD5)	mg/L	12.7	< 4	8	> 8	Ш
Chemical Oxygen Demand (COD)	mg/L	30.1	< 25	50	> 50	II
Ammonium-Nitrogen	mg NH ₄ +/L	< 0.016	< 0.2	1	> 1	I
Nitrate-Nitrogen	mg NO ₃ -/L	4.92	< 3	10	> 10	II
Total Kjeldahl Nitrogen (TKN)	mg/L	11.6	< 0.5	1.5	> 1.5	III
Total Phosphorus	mg P/L	0.478	< 0.08	0.2	> 0.2	III
Fluoride	µg/L	228	≤ 1000	1500	> 1500	I
Manganese (Mn)	µg/L	133	≤ 100	500	> 500	II
Selenium	µg/L	1.11	≤ 10	15	> 15	
Sulphur	µg S/L	< 2	≤ 2	5	> 5	I

Table 7-1: Baseline water quality analysis results

Class I: High quality water meaning "Very Good" water status. Surface water courses (i) with high drinking water potential, (ii) that can be used for recreational purposes and swimming, (iii) that can be used for trout production, and (iv) that can be used for animal breeding and farming.

Class II: Less polluted water meaning "Good" water status. Surface water courses (i) with drinking water potential, (ii) that can be used for recreational purposes, (iii) that can be used for aquaculture other than trout and (iv) that can be used for irrigation purposes provided that necessary quality requirements are met.

Class III: Polluted water meaning "Moderate" water status. Industrial water (excluding facilities that require qualified water such as food and textiles) and water that can be used in aquaculture after appropriate treatment

179

⁸⁶ According to the Surface Water Quality Regulation, Annex 5, Table 2 (Quality Criteria in terms of General Chemical and Physicochemical Parameters by Classes of Inland Surface Water Resources)



Figure 7-8: Surface water sampling location

7.3.3 Groundwater Resources

Groundwater levels vary in the seventeen groundwater basins in Ankara, depending on hydrogeological, meteorological and topographic conditions, and water use. According to the measurements made in 2018, the groundwater level varies between 0.5-15 meters in the alluvial aquifers extending along the Çubuk plain, Kazan plain, Kızılırmak and its tributaries and Ankara Stream and its tributaries. Apart from these areas, groundwater level in the aquifers located on the slopes vary between 5-80 meters depending on the elevation. Ankara's total groundwater potential is 316.2 million m³/year and the amount of groundwater allocated in 2018 is 4,758,000 tons/year. The groundwater potential of Çubuk sub-basin is 9 million m³/year and groundwater quality of the sub-basin is indicated as "poor" due to nitrate pollution in the groundwater sub-basin⁸⁷.

⁸⁷ Ankara Environmental Status Report by the Ministry of Environment, Urbanization and Climate Change, 2020 (https://webdosya.csb.gov.tr/db/ced/icerikler/2020_ankara--cdr-20210728144247.pdf)


Figure 7-9: Water resources around the Project Site⁸⁸

Groundwater levels below the Project site were investigated during the ground survey studies conducted within the scope of the Project (see Section 6.2.2). According to the Geotechnical Report, there are no dry or wet streams identified in the study area (i.e. parcel 1555-4) and groundwater was encountered at depths between 3.0 to 8.0 m below ground level at borehole locations. It was reported that variations in groundwater level may adversely affect the building foundation in terms of concrete-iron life, building usage and settlement problems. For this reason, some measures have been proposed in the Geotechnical Report in order to protect building foundations from the effects of groundwater and surface water which are described in Section 7.5 in detail. As observed during the site visit conducted by the ESIA team, there is one groundwater well within the Project site boundaries, however, according to the information provided by MoH representatives this well is not in use.

7.3.4 Flood Risks

Baseline information on the flood risks have been primarily evaluated based on the Sakarya Basin Flood Management Plan⁸⁹ published in 2018 by the General Directorate of Water Management of MoAF. This general directorate has the responsibility of developing and implementing river basin management plans and coordinating water resources management between related institutions at the national level. A 'Basin Management Committee' is formed for each river basin by participation of all government agencies and public institutions related to water including NGOs, organized industrial zones and water associations.

According to the Sakarya Basin Flood Management Plan, Ankara has experienced a number of severe flooding events. A total of 259 important floods have been recorded in the Sakarya Basin between the years 1950 and 2018, a number of which have occurred within the Ankara province (Table 7-2). The most severe flood event experienced within the Sakarya Basin occurred in the Hatip Stream of Ankara in 1957, with a total number of 169 casualties. The severe floods recorded in Ankara also include one that occurred in the Çubuk Stream in 1968 resulting in seven casualties.

⁸⁸ https://www.atlas.gov.tr/

⁸⁹ Sakarya Basin Flood Management Plan by the Ministry of Agriculture and Forestry, 2018 (https://www.tarimorman.gov.tr/SYGM/Belgeler/Ta%C5%9Fk%C4%B1n%20Y%C3%B6netim%20Planlar%C4%B1/5)%2 0SAKARYA%20HAVZASI%20TA%C5%9EKIN%20YONETIM%20PLANI.pdf)

Flood impact area	Date	Death Toll
Hatip Stream	11/09/1957	169
Hatip Stream, İncesu, Dikmen, Kirazlı Streams	18/06/1961	3
Çubuk Stream	12/03/1968	7
Hatip Stream	12/03/1968	-
Mogan Lake	17/02/1969	-
İncesu Stream	01/03/1969	1
Polatlı district / Ağtldere, Kurudere Streams	01/06/1984	-
Kayaş, Abidinpaşa, Gülveren neighborhoods / Hatip, İncesu Streams	12/06/1988	13
Beypazarı district / Macun, Çamkoru, Çetin Streams	25/12/2001	-
Güdül district	25/12/2001	-
Çubuk Stream	28/12/2001	-
Polatlı district	07/06/2010	-
Polatlı district / Ankara Stream	30/05/2011	-

Table 7-2: Severe flooding events recorded in Ankara between 1950-2018

The floods occurring in the basin have been attributed by the Sakarya Basin Flood Management Plan to various causes including the inadequacy of existing flood control structures, settlement in stream beds due to unplanned urbanization, reduced capacity of the streams due to dumping of wastes into the stream beds, and deterioration of stream flow regimes and stream bed morphologies due to extraction of materials from stream beds. The Plan also summarizes the outcomes of the flood risk assessments carried out by the General Directorate of Water Management for the Sakarya Basin and sets out a set of flood control measures in areas regarded as carrying a high flood risk including the Çubuk Stream. The proposed control measures for the Çubuk Stream are all located downstream of Akyurt and there is no available information on whether these measures have been or are currently being implemented.

In the recent years, frequent flood and water overflow events occurred in the Ankara province that affected many people by causing casualties, injuries as well as damages to buildings. These include the severe floods observed in various districts of Ankara during the heavy precipitation events of June 2022, which also impacted the Akyurt district, resulting in two casualties in Akyurt and a total of four casualties across Ankara⁹⁰. Impacts in Akyurt reportedly occurred due to the overflowing of the Dolay Stream that passes through the district centre at an approximate distance of 11 km to the northeast of the Project site.

In the Flood Report²⁴ published by the TMMOB Chamber of Construction Engineers following the June 2022 flood events in Ankara, it is noted that the recorded rainfall amounts have a maximum recurrence period of 25-50 years and that significant damage to many structures in the floodplain may occur and result in many casualties if the precipitation intensity increases further to 50-100 years. The report highlights the efforts by relevant institutions in the recent years regarding flood risk assessments and flood planning of stream beds, however, it also emphasizes the delays concerning the implementation of these measures.

7.4 Assessment of Impacts

7.4.1 Methodology

The methodology adopted for the impact assessment is as follows:

• Establishment of baseline: Baseline conditions have been identified mainly by using secondary data based on desktop research of published literature on the existing status (hydrology, hydrogeology,

⁹⁰ Ankara Flood Report by the TMMOB Chamber of Construction Engineers Ankara Branch, June 2022 (https://ankara.imo.org.tr/Eklenti/7862,imo-ankara-subesi-ankara-su-baskinlari-raporupdf.pdf?0)

surface water and groundwater quality, water abstraction and discharge, land drainage) of the water resources and flood risk to establish the existing water regime and consider its potential sensitivity to various activities associated with the Project. Outcomes of the water quality investigation study undertaken within the scope of the ESIA process and the reports of the site-specific ground survey studies were also considered. The information and documentation gathered on the hydrology and hydrogeology are listed in Section 7.3.1.

- Assessment of impacts: Possible impacts related to hydrology and hydrogeology have been assessed together with their significance levels. The significance criteria adopted for the assessment of impacts is provided in Section 7.4.2. Impact assessment covers:
 - Assessment of deviation from baseline conditions
 - Assessment of potential impacts on key receptors associated with construction and operation phases of the Project
- Development of mitigation measures: To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise the overall environmental impact from associated with the Project.

Key receptors which are anticipated to be sensitive to changes in the existing hydrological and hydrogeological conditions on site are considered to include human health (nearby communities, construction workers, operation phase employees), surface waters and groundwaters, built environment and ecological receptors.

7.4.2 Determining Magnitude, Sensitivity, and Impact Significance

Assessment of impacts on hydrology, hydrogeology, water quality and flood risk is performed based on the evaluation of baseline conditions presented in Section 7.3. Table 7-3 presents the criteria that have been used for determining the sensitivity of receptors. High sensitivity reflects existing conditions with little capacity to absorb proposed changes or conditions that present minimal opportunity for mitigation. Impact magnitude is determined by the predicted deviation from the baseline conditions and the scale of impact. Table 7-4 presents the criteria that have been used for determining magnitude of impacts related to hydrology, hydrogeology, quality of water resources and flood risk. If the impact is negative then the effect is beneficial.

Sensitivity	Definition	Examples
High	Little or no capacity to absorb proposed changes or minimal opportunities for mitigation	High ecological quality water resource with ecological importance of national or international value (protected areas, habitat for protected species) or services (important fishery, flood conveyance, sediment transport) Water resource that serves urban water supply, major industrial use, or irrigational use Water resource belonging to Class I according to the national regulatory framework Surface water or groundwater body at high risk of depletion or pollution Pristine reach of river with natural flow, sediment and water quality regime Water resource receiving wastewater from urban area Receptor is at high risk from flooding and/or water body acts as an active floodplain or flood defence High groundwater vulnerability (principal aquifer providing a regionally important
Medium	Limited capacity to absorb proposed changes or limited opportunities for mitigation	resource or supporting a protected site)Water resource that supports diverse populations of aquatic habitat or provides ecosystem services to some extent (fishery, flood conveyance, sediment transport)Water resource that serves local water supply, minor industrial or minor irrigational use Water resource belonging to Class II according to the national regulatory framework Surface water or groundwater body at medium risk of depletion or pollution Village wastewater disposal Receptor is at moderate risk from flooding but does not act as an active flood plain or flood defence

Table 7-3: Criteria for Determining Sensitivity

Sensitivity	Definition	Examples
		Medium groundwater vulnerability, principal aquifer providing locally important resource or supporting river ecosystem
Low Some capacity to absorb proposed	Water resource that does not support diverse aquatic habitat and already significantly modified from natural condition	
	changes or moderate	Water resource with little or no community use
		Water resource belonging to Class III according to the national regulatory framework
mitigation	Water resource used for minor water supply to individual dwellings or farms	
	Isolated wastewater disposal	
	Receptor is at low risk from flooding	
	Low groundwater vulnerability; secondary aquifer providing water for agricultural or industrial use with limited connection to surface water	
Negligible	High capacity to	Water resource already significantly modified from natural condition and/or polluted
	absorb proposed changes or	Water resource lies outside the sphere of influence of the proposed development or is not dependent on hydrology
numerous opportunities for mitigation	numerous	Water resource not used for water supplies (public or private)
	mitigation	Non-aquifer, secondary aquifer with poor water quality not providing baseflow to rivers; non-aquifer or groundwater in deep aquifers that will not be impacted from project related activities

Table 7-4: Criteria for Determining Magnitude

Magnitude	Definition	Examples
Major Long term fundamental change to the specific environmental conditions assessed resulting in	Long term fundamental change to the specific environmental conditions assessed resulting in	The integrity of the water body is affected either in terms of quality or quantity and could result in permanent loss of defining quality or physical features.
	long term or permanent change, typically widespread in nature	Potentially severe effects on water quality which are likely to give rise to indirect ecological and/or socio-economic impacts.
	(regional national and international), would require significant intervention to return to	Discharges to groundwater are likely to cause breaches of discharge limits (over extended periods) and cause background levels to above the site specific long-term cancer and hazard risk levels in soils.
	standards and limits.	Impacts of existing groundwater environment yield capabilities are large and will significantly alter usage capability as to affect potential or existing groundwater resources users.
		Physical (property, agricultural fields, infrastructure etc.) or sensitive ecological receptors upstream or downstream of the water resource experience a "significant" increase in flood frequency.
		The function of the water body is impacted such that there is a substantive and permanent change (loss of flood storage / increased flood risk).
Moderate Detectable change to the specific environmental conditions assessed resulting in non- fundamental temporary or permanent change. Medium term spatial extent beyond immediate Project site boundaries or local area.	Detectable change to the specific environmental conditions assessed resulting in non-	Loss of, or alteration to quality and quantity of the baseline resource such that post-development characteristics or quality would be partially changed.
	fundamental temporary or permanent change. Medium term	Potential localized effects on water quality which are likely to give rise to indirect ecological and/or socio-economic impacts.
	Discharges to groundwater bodies are expected to cause breach of statutory limits (over limited periods) and cause background levels to be below the site specific but above the generic long-term cancer and hazard risk levels in soils.	
		Impacts of existing groundwater environment yield capabilities are medium and will alter usage capability as to affect potential or existing groundwater resources users.
		Physical (property, agricultural fields, infrastructure etc.) or sensitive ecological receptors upstream or downstream of the water resource experience an increase in flood frequency.
Minor	Spatial extent of impact within the project areas. Meets minimum national standards and international guidelines. Detectable but minor change to	Small changes to the baseline resource which are detectable, but the quality and quantity of the baseline situation would be similar to pre- development conditions and the manner of change would not materially affect the use or function of the feature.

Magnitude	Definition	Examples
	the specific environmental conditions.	Discharges into groundwater are expected to be within (but perhaps close to) statutory limits and will cause background levels to increase but remain below the generic risk levels for soils.
		Impacts of existing groundwater environment yield capabilities are small and will not alter usage capability.
		Physical (property, agricultural fields, infrastructure etc.) or sensitive ecological receptors upstream or downstream of the water resource within is likely to be affected by the affected drainage regime.
Negligible	Temporary duration with no detectable impact. No perceptible change to the specific environmental conditions.	No perceptible or very slight change from the baseline conditions, which is barely distinguishable, and approximates to the 'no-change' situation. Contamination of surface water that is temporary in nature and that do not degrade the existing surface water quality and well within natural fluctuations.
		Discharges into the groundwater environment are expected to be well within statutory limits.
		Impacts of existing groundwater environment yield capabilities are negligible
		No increase in flood risk.
		No likely alterations to existing drainage regimes and characteristics.

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 7-5.

Table 7	-5: Impac	t Significant	Matrix
---------	-----------	---------------	--------

Magnitude of Impact	Negligible	Low	Medium	High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

7.4.3 Impacts on Surface Waters and Groundwater

The nearest water body to the Project site is the Çubuk Stream flowing along the northwest boundary of the Project site towards the Çubuk-I Dam in the south, which is not used for drinking water supply but for flood conveyance. The baseline assessment related to surface waters has been presented in Section 7.3, which builds on primary and secondary data sources in relation to water resources. Accordingly, Çubuk Stream is defined as having poor surface water quality status⁹¹. Baseline water quality in the Çubuk stream was also evaluated as part of the ESIA through a surface water quality investigation study near the downstream boundary of the Project site, and based on the detected levels of measured parameters, the water quality class is identified as 'Class III' indicating polluted surface water according to the Surface Water Quality Regulation⁹². For the assessment performed in this ESIA report, Çubuk Stream is classified as low to medium sensitivity because it has no community use, the water quality is already significantly modified from natural condition due to industrial discharges, however it is important to prevent further contamination of the stream due to the Project.

Although there is no site-specific information regarding the groundwater quantity and quality, the groundwater potential of the Çubuk sub-basin is reported as 9 million m³/year and groundwater quality of

⁹¹ Strategic Environmental Assessment Scoping Report for Sakarya Basin Management Plan Development Project by the Ministry of Agriculture and Forestry, December 2021 (https://www.taimerman.gov.tr/CV/MPalastr/Callastre/Callastre/CAM/D14/2014attre/Callastre/Calla

⁽https://www.tarimorman.gov.tr/SYGM/Belgeler/Sakarya%20Havzas%C4%B1%20Nehir%20Havza%20Y%C3%B6netim %20Plan%C4%B1/SCED_Taslak%20(RAPOR)_REW-2.pdf)

⁹² Official Gazette date/number: 30.11.2012/28483

is indicated as "poor" due to the heavy nitrate pollution in the sub-basin⁹³. According to the Geotechnical Report⁹⁴ prepared for the Project, the groundwater depth beneath the site ranges between 3.0 and 8.0 m below ground level. As observed during the site visit conducted by the ESIA team, there is one groundwater well within the Project site boundaries which is currently not in use. According to the information provided by MoH representatives, groundwater will not be extracted and used during the construction and operation phases of the Project. Considering the depth of the groundwater and the existing pollution in the groundwater sub-basin, the sensitivity of the groundwater resources can be considered as low to medium.

Impacts during Construction

The nature of the activities carried out within the construction phase will be a risk to the groundwaters and surface waters in the vicinity of the Project site as well as downstream, in terms of surface runoffs and pollution during the site preparation, earthworks, construction of access roads and buildings, filling and concreting, and installation of infrastructure. During the construction phase of the Project, potential effects on groundwaters and surface waters could include temporary localised changes in hydrological and hydrogeological conditions, increased risk of pollution events, changes to landform causing increased erosion and sediment release into the nearby streams, and alteration of drainage paths due to loss of vegetation cover. Compaction of soils and habitat degradation resulting from an increase in off-road vehicle movements is also likely to affect drainage paths.

Temporary water supplies for camps and construction works from nearby water resources might potentially affect the quantity of water resources and water supply. Disposal of wastewater from construction sites might also result in pollution. On the other hand, there is an existing water and wastewater infrastructure in the Project site, therefore domestic wastewater generated at site during the construction phase will be directed to the sewerage system of ASKI and potable water will be supplied from the water supply line of the municipality.

Risk of pollution in the construction phase will be mainly due to the use of construction vehicles, generation of construction waste and potential release of contaminants into the groundwaters and adjacent surface waters. Dust creation, excavations and stockpiles of exposed soil may lead to high suspended solid/sediment loads within surface runoffs and impacts to the Çubuk stream especially during rainfall events. Potential release of contaminants into the groundwaters and the Çubuk stream may also occur via surface runoff and/or infiltration of spillages and leaks resulting from the use of hazardous materials (such as fuel oil, lubricants, paints) as well as construction materials (such as liquid cement, lime), and the refueling and maintenance of the equipment and vehicles used during construction.

Any contamination which occurs as a result of accidental spills might migrate and infiltrate into the groundwater table and/or impact the surface water causing deterioration of the water quality. The magnitude of the impacts during construction is assessed as minor to major depending on the scale and duration of the adverse events (spills, accidents, inappropriate storage practices) and timely response to the incidents. Consequently, the impact significance will range from minor to major. However, considering that the Project will implement measures to mitigate any potential adverse effects on surface water and groundwater quality during the storage, handling and transportation of hazardous materials, site drainage will be implemented at the Project site, and no direct discharges to the surface waters are expected to occur, the magnitude of impacts can be minimized. The significance of the impacts after mitigation is therefore deemed to be minor.

Overall, the construction activities will be carefully managed and monitored (using designated areas for stockpiled soil, perimeter drains/channels/bunds in place around working areas to collect site run-off, etc.)

⁹³ Ankara Environmental Status Report by the Ministry of Environment, Urbanization and Climate Change, 2020 (https://webdosya.csb.gov.tr/db/ced/icerikler/2020_ankara--cdr-20210728144247.pdf)

⁹⁴ Parcel based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkey Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti. (2021)

and appropriate measures for hazardous material spills will be taken. All impacts will be mitigated through best practice construction methods which will be specified in the relevant contracts and monitored through the ESMP.

Impacts during Operation

During the operational activities of the Project, potential adverse impacts include changes in groundwater quality and water quality in the Çubuk stream due to potential for contamination resulting from surface runoff, spills and accidental discharges, and any wastewater discharge to surface waters. As reported by the MoH, there is an existing wastewater infrastructure in the Project site, therefore domestic wastewater generated at site will be directed to the sewerage system of ASKI. Liquid wastes and industrial (including medical) wastewaters generated by the Project during the operation phase will also be discharged to the ASKI sewage system after pre-treatment at the Project facilities to bring the quality of wastewater to the discharge criteria defined in the Regulation on Wastewater Discharges to Sewerage System published by ASKI before treatment in the wastewater treatment facilities serving the city. Failure of the pre-treatment of liquid and industrial (including medical) wastewater generated by the Project would be a significant risk to both the operating wastewater treatment facilities of ASKI and threaten the community health and safety. Therefore, impacts related to wastewater discharges are classified as having major magnitude with low receptor sensitivity (i.e. having some capacity to absorb proposed changes or moderate opportunities for mitigation) and therefore considered as moderate.

During the operation of the Project, there will be no surface water or groundwater extraction and use, therefore magnitude of impacts on the quantity of the water resources will be negligible. However, accidental discharges and spills from hazardous material and waste storage/handling during operation, including refueling and loading/unloading, have the potential to contaminate groundwater and/or adjacent surface waters. These impacts are considered to have minor to major magnitude depending on the amount of spill and timely response to the incident, resulting in impacts of minor to major significance. The design of the Project will incorporate proper waste management, stormwater collection and site drainage measures. Furthermore, the operational activities will be carefully managed and specific measures set in the ESMP will be implemented. Thus, it is expected that the residual impacts on water resources will be insignificant.

7.4.4 Impacts Related to Floods

The findings of the Geotechnical Report prepared for the Project indicate that there is no obstacle to construction in terms of natural disasters in the study area. According to the report, the topographic slope of the site is around 0-5%, which would not allow the stability of the site to deteriorate as a result of construction and loading of the land. It is thus reported that there is no risk of flooding and overflow potentially caused by the structure of geological units identified in the Project site. Nevertheless, temporary dewatering of excavations may be required to reduce and manage groundwater levels during construction. An emergency response plan would be produced to communicate with site staff regarding the potential flood risk associated with specific higher risk works, which would also include procedures for site evacuation during flood events.

During the operation of the Project, impermeable areas including the building roofs, paved/concreted areas, and the loss of vegetation have the potential to increase surface runoff. Flooding may result in impacts with significance levels ranging from minor to major depending on the amount of surface water runoff generated during rainfall events. For this reason, the Project will implement a stormwater collection and discharge system through permeable surfaces and network. Within the scope of the stormwater system, surface waters will be collected with the rain harvesting principle in the basement of the Waste Building in a reinforced concrete storage tank with a capacity of 900 m³ which will be the source of the automatic irrigation system to be used for the landscape areas. The Project will also benefit from a recreational area, which could function as a temporary flood retention pond during heavy rainfall events supporting drainage. Therefore, given that good stormwater management practices are implemented on the Project design, floods due to heavy rainfall on the Project site will be prevented.

As for the surface water flooding risks, a review of the available baseline information indicates that potential flood occurrences in the Cubuk Stream could result in impacts of minor to major magnitude. The consequent significance of impacts would be minor to major in the absence of appropriate design and mitigation measures, assuming a medium sensitivity level for receptors. As reported by the MoH representatives, necessary consultations were made with the General Directorate of the State Water Works (DSI) regarding the flood risks and rehabilitation plans of the Cubuk stream considering the proximity to the Project site. An official letter was obtained from DSI on 28 February 2022 (see Annex A) which provided information to the MoH regarding flood level and flood plain boundary of the Cubuk Stream near the Project site. Accordingly, the hydraulic modelling run by DSI indicated that the flood level for the Project should be 921.50m and the provisions of article 5, item 10 of the Zoning Regulation for Planned Areas⁹⁵ should be followed in regard to the Project design as the site considered as a flood area. These data and information have been considered by MoH in the planning of the layout for the Project as well as the crest elevation of the structures (the upper level of the raised ground). In line with the regulation, the crest elevation has been determined by adding 1.50 meters to the flood level determined by the DSI. Note that the regulation also prohibits placement of any structures such as car park entranceexits, doors or windows below the specified level and requires that opinion of DSI or the relevant water and sewerage administration is sought in case of any uncertainties. The flood level requirement has also been incorporated in the draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans and associated documents⁹⁶ that have been developed for the area, as detailed in Chapter 12: Land Use and Zoning.

As noted above, the rehabilitation works as well as installation/maintenance of flood control structures at the Cubuk stream falls within the responsibility of the DSI. Flood control for Cubuk Stream is currently provided through the Cubuk-I Dam located downstream of Akyurt. According to the consultations held with DSI within the scope of the ESIA, no rehabilitation works of the stream bed have been performed or are currently planned by the DSI. The opinion letter obtained from DSI on 28 February 2022 indicates that the majority of Project area, including the kindergarten area, is under risk of a flood. The same opinion letter indicated the flood elevation as 921.50 m. For this reason, within the scope of the Project, a flood protection wall is planned to be built by MoH along the section adjacent to the Project site in order to provide extra protection against potential flood related risks. As suggested by the company who performed the architectural design of the facility (Mesart Mimarlık ve İnşaat A.S.), the recreational area between the main Project complex and the Cubuk stream would attenuate surface runoff during heavy rainfall events supporting drainage. The architectural designers have confirmed that in-depth risk assessment has been performed and the kindergarten to be located within the recreational area is designed to be protected against potential flood risks. Although the subject area is under risk of a flood in a no-action scenario, the MoH will ensure that necessary mitigation actions will be carried out in accordance with the provisions of paragraph 10 of Article 5 of the Planned Areas Zoning Regulation⁹⁷. The flood risks and prevention measures for the kindergarten area will once more be elaborated during the Preliminary Design Phase.

7.5 Mitigation Measures

The assessment has shown that water pollution could occur to surface waters and groundwater from a wide range of sources linked to the construction and operation of the Project. This section describes the specific mitigation measures that will be implemented to prevent and minimise these impacts.

The following specific mitigation measures will be applied during the design phase of the Project:

⁹⁵ Official Gazette date/number: 03.07.2017/30113

⁹⁶ Draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans and associated documents prepared by Özok Planlama İmar Mühendislik Ltd. Şti. (2022).

⁹⁷ Official Gazette date/number: 03.07.2017/30113

- Measures to prevent and minimise flood risks as required by the General Directorate of State Water Works (DSI) requested in their official letter to MoH dated 28 February 2022 will be implemented (see Section 7.4.4).
- A flood protection wall will be built along the section adjacent to the Project site in order to provide extra protection against potential flood related risks.
- Higher peak flows and faster runoff will be mitigated with permeable pavements, recreational areas and the plantation of trees and vegetation alongside watercourses. Rainwater harvesting will be implemented which may offset impacts of peak flows and the harvested water will be used for irrigation purposes saving on the use of water from the supply network.
- Areas will be specifically designated for loading and unloading (including refuelling). These areas shall be impermeable where the collection and disposal of any spills or leaks can be done so easily.
- The Technical Building will be designed with bunded double-walled fuel storage tanks of appropriate type and capacity to serve boilers and emergency generators, in accordance with applicable international standards. The wastewater drainage and decontamination systems of buildings will be sized to serve the peak loads of the proposed facility.
- The location of the kindergarten will be re-assessed during the Preliminary Design Phase considering the flood risks that exist in the region and prevention measures to be taken.

Specific mitigation measures to avoid and/or mitigate the potential impacts to surface water and groundwater during construction phase will include the following:

- Preventive measures such as best practice site management and effective site planning/layout will be implemented to minimise the risk of any pollution incidents finding their way to the receptors. These include measures such as using designated areas for storing materials, regular inspections at construction sites, and placement of sediment and oil/water traps.
- Construction workers and relevant staff will be trained related to the implementation of good construction site practices and on spill response and prevention measures.
- Areas will be specifically designated for loading and unloading (if concerning toxic substances), including refuelling. These areas shall be impermeable where the collection and disposal of any spills or leaks can be done so easily. Suitably sized impervious bunds or other containment will be installed where hazardous materials are stored and handled to prevent hazardous materials entering the site drainage.
- Materials will also be located away from any potential surface water receptors, ideally on raised ground where the likelihood of flooding is reduced. Stockpiles of soil will be stored as needed at designated areas.
- No fuelling of vehicles or equipment or hazardous materials storage will take place in excavated areas and all handling of hazardous materials will take place under special supervision.
- Areas specifically designed for the cleaning of equipment, machinery and vehicles will be made available within the construction site. Cleaning will be carried out on impermeable areas where the collection and disposal of the resulted wastewater is carried out without risk of leakages or spillages.
- Dewatering volumes and rates will be monitored throughout the excavation works.
- As part of the construction phase, it is expected that significant amounts of dust will be created and resettled. This process creates a substantial amount of material that will be mobilised through surface runoff and deposited in the drainage channels and the Çubuk Stream at points of particularly low flow, such as at culverts and reaches of thick vegetation. The siltation of the channels can cause flooding problems and reduce the volume of the drainage channels for transporting the resulting flow. The use of water as a dust suppression mechanism may further increase the sediment load entering the drainage channels. The following dust suppression methods will be undertaken to reduce the amount of dust created:
 - Minimising dust from material handling sources, such as conveyors and bins, by using covers and/or control equipment.

- Minimising dust from open area sources, including storage piles, by using control measures such as installing enclosures and covers.
- Planning land clearing, removal of topsoil and excess materials, location of haul roads, tips and stockpiles with due consideration to meteorological factors (e.g. precipitation, temperature, wind direction, and speed) and location of sensitive receptors.
- Designing, installing and applying a simple, linear layout for materials-handling operations to reduce the need for multiple transfer points.
- Compacting, periodically grading and maintaining roads.
- Vegetating exposed surfaces of stockpiled materials.
- To prevent impacts on the building foundation in terms of concrete-iron life and settlement problems due to variations in groundwater level, proposed measures in the Geotechnical Report will be implemented to protect building foundations from the effects of groundwater and surface water, such as:
 - Appropriate environmental and underground drainage systems will be installed to prevent surface and underground waters damaging the foundation over time considering seasonal conditions.
 - A "capping layer" with a minimum thickness of 30 cm will be formed under the building foundations to protect the building foundations from the effects of capillarity and to provide a healthy construction surface.
 - Due to the different floor numbers of the buildings, a 60 cm thick compacted granular material will be laid under the foundation as a precaution against the formation of different settlements on the ground and the capillary rise of the groundwater.
 - Igneous rocks (basalt, andesite, dolomite, etc.) will be used as filling material that will not be affected by groundwater.
 - The foundations will not be left exposed for a long time and their contact with the surface waters will be prevented.

The following mitigations will need to be implemented during both construction and operation phases:

- All staff and subcontractors will be required to report any incidents and these will be subject to investigation, and remedial and preventive actions will be taken as needed.
- No discharges of any contaminated water will be permitted to ground or surface waters.
- Best practices to minimise risk of pollution during construction and operation will be adopted.
- Regular periodic integrity testing for hazardous material storage equipment will be conducted and appropriate leak detection systems will be in place.
- All forms of waste disposal will be done in line with the applicable legislation. Waste disposal practices
 will be regularly monitored.
- Appropriate spill response kits including absorbent materials will be present on site. These will be kept at designated areas with specific instructions for their use. Site staff will be trained on the use of spill kits.
- Spill response will take place as quickly as possible. Contaminated materials will be collected and sent to appropriate disposal facilities.
- The Waste/Wastewater Management Plan and the Hazardous Material Management Plan will be implemented to ensure proper handling of wastes and hazardous materials during construction and operation of the Project.
- The Pollution Prevention Plan will be implemented to ensure mitigation of spills from hazardous materials during construction and operation of the Project.

7.6 Compliance with National and International Requirements

7.6.1 National Requirements

This section summarises the key legislation relevant to the protection of water environment within the study area, to be taken into account in the proposed development. Turkiye has a comprehensive framework of water resources and quality legislation, including the following:

Law/Regulation	Official Gazette Date/No	Scope	Relevance to the Project
Water Pollution Control Regulation	31.12.2004/ 25687	The regulation sets out the legal and technical principles to be followed in the control of water pollution. The regulation provides quality criteria for surface, marine and groundwaters, rules and principles for water pollution control, industry specific discharge standards, and the principles for discharging wastewater into the environment or the sewer system.	The wastewater to be generated during the construction and operation phases of the project is planned to be discharged to the municipal sewer system. Pursuant to the regulation, in a city and/or industrial area, connection to the sewer system is subject to a Wastewater Connection Permit to be issued by the wastewater infrastructure administration and the discharge quality criteria set forth in the regulation should be complied with.
Surface Water Quality Regulation	30.11.2012/ 28483	The regulation defines the procedures and principles for identification of biological, chemical, physicochemical and hydro- morphological qualities, classification and monitoring of quality and quantity of the surface waters and coastal & transitional waters, as well as set forth their utilization purposes and the measures to be taken in order to achieve good water conditions. Annex 5 of the regulation classifies surface water quality as: (1) Class I: High quality water, (2) Class II: Less polluted water, and (3) Class III: Polluted water.	Baseline conditions of the Çubuk stream was evaluated as part of the ESIA through a surface water quality investigation study. When the detected levels of the conductivity, BOD5, TKN and total phosphorus parameters are considered, the water quality class of Çubuk Stream near the downstream boundary of the Project site is identified as 'Class III', which indicates polluted water with moderate water quality.
Law on Groundwater No. 167	23.12.1960/ 10688	The law defines the legal framework for groundwater usage and requires that related permits are received from the State Water Works (DSI) for groundwater exploration and construction and operation of wells to be utilized for groundwater abstraction purposes.	Groundwater will not be extracted and used in the Project site during construction and operation phases of the Project for any purposes.
Regulation on the Protection of Groundwaters against Pollution and Deterioration	07.04.2012/ 28257	The regulation identifies relevant principles associated with the protection of groundwater quality, prevention of groundwater deterioration and pollution, and determination of the measures to remediate these waters. This regulation determines the groundwater quality parameters and threshold standards.	Although there is no site-specific information available regarding the groundwater quality for the Project site, it has been reported as "poor" due to the heavy nitrate pollution in the sub-basin ⁹⁸ . According to the Geotechnical Report prepared for the Project site, the groundwater depth ranges from 3 to 8 m below ground level.
Regulation on Control of Pollution Caused by Hazardous	26.11.2005/ 26005	This regulation includes the technical and administrative basis regarding the determination of hazardous substances in surface waters, estuary waters and regional waters, organization of pollution reduction programs, prevention and	Pursuant to the regulation, the Project should obtain a Connection Quality Control Permit Certificate from the municipality for discharge of wastewaters that contain dangerous substances listed in Annex-1 or

Table 7-6: National Regulations on Water Resources and Quality that are Relevant to the Project

⁹⁸ Ankara Environmental Status Report by the Ministry of Environment, Urbanization and Climate Change, 2020 (https://webdosya.csb.gov.tr/db/ced/icerikler/2020_ankara--cdr-20210728144247.pdf)

Law/Regulation	Official Gazette Date/No	Scope	Relevance to the Project
Substances in Aquatic Environment		monitoring of pollution, creating an inventory of hazardous substances discharged into water, and definition of discharge standards and quality criteria.	Annex-2 of the regulation into the sewage system.
Regulation on Wastewater Discharges to the Sewage System published by the Ankara Metropolitan Municipality General Directorate of Water and Sewage Authority (ASKI)	-	This regulation sets out the principles, methodologies and limitations related with the connection of the wastewater to the sewage system, discharge of the wastewater to the sewage system by vacuum trucks or similar, treatment of wastewater in cases where there is no sewage system and use and protection of sewage system.	The Project should comply with the limit values set out in Table-I, which is included in Article 17 of this regulation for the domestic and industrial wastewaters to be discharged to the sewage system.

7.6.2 International Requirements

The key international standards and guidelines applicable to the Project relating to international best practice for the assessment and management of water resources and for pollution prevention and control include the following:

- World Bank ESS3: Resource Efficiency and Pollution Prevention and Management (2017)
- World Bank ESS4: Community Health and Safety (2017)
- World Bank Group General EHS Guidelines: 1. Environmental and 3. Community Health and Safety (2007)
- World Bank Group EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007)
- World Bank Group EHS Guidelines for Health Care Facilities (2007)

The objective of the ESS3: Resource Efficiency and Pollution Prevention and Management is to avoid or minimize adverse impacts on human health and the environment, for the duration of a Project, by avoiding or minimizing polluting activities and promoting the use of sustainable resources. Specifically in relation to this assessment, actions include avoiding or minimizing the release of pollutants (to air, water and land), identifying and where necessary managing existing pollution, and avoiding the generation of hazardous and non-hazardous wastes. The ESS3 does not establish numerical standards for ambient surface water quality, but states that discharges of process wastewater, sanitary wastewater, wastewater from utility operations or stormwater should not result in contaminant concentrations in excess of local ambient water quality criteria. In addition, the ESS3 states that, when the project is a potentially significant consumer of water, measures will be adopted that avoid or reduce water usage so that the project's water consumption does not have significant adverse impacts on others.

The General EHS Guidelines for Environmental: Wastewater and Ambient Water Quality state that projects with the potential to generate process wastewater, domestic sewage or stormwater should incorporate the necessary precautions to avoid, minimize and control adverse impacts to human health, safety or the environment. The General EHS Guidelines for Environmental: Water Conservation state that water conservation programs should be implemented commensurate with the magnitude and cost of water use. Water conservation measures may include water monitoring/management techniques, process and cooling/heating water recycling, reuse, and other techniques, and sanitary water conservation techniques.

The WB EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing and the WB Group's EHS Guidelines for Health Care Facilities provide additional specific guidelines in relation to water conservation and effluent discharges for projects of this type. The guidelines also recommend various

measures to prevent, minimize and control wastewater effluents from pharmaceuticals and biotechnology manufacturing and health care facilities, and provide effluent limits for the industry which are applicable for direct discharges of treated effluents to surface waters.

Whilst there is no specific guidance in relation to flood risks, the ESS4: Community Health and Safety states that a project's direct impacts on priority ecosystem services may result in adverse health and safety risks and impacts to affected communities. For example, land use changes or the loss of natural buffer areas such as wetlands, mangroves and upland forests that mitigate the effects of natural hazards such as flooding, landslides and fire, may result in increased vulnerability and community safety-related risks and impacts. The General EHS Guidelines: Community Health and Safety states in relation to severe weather and facility shutdown that, workplace structures should be designed and constructed to withstand the expected elements for the region and have an area designated for safe refuge, if appropriate. Standard Operating Procedures (SOPs) should be developed for project or process shutdown, including an evacuation plan. Drills to practice the procedure and plan should also be undertaken annually.

7.7 Residual Impacts

Residual effects are those that remain after mitigation and/or enhancement measures have been implemented. A summary of impacts is presented in Section 7.4. Although the likelihood of the impacts will greatly be reduced with the application of mitigation, sensitivity of the receptors such as Çubuk Stream and groundwater resources does not change. The application of mitigation including best practice measures means that the significance of impact of spillages, leaks and pollution is reduced to minor to insignificant, as such mitigation would remove the risk of an incident occurring that could affect water resources. However, increased surface runoff is still likely despite the mitigation options, due to the increased impermeable area that will, in some cases, will be unavoidable.

7.8 Proposed Monitoring and Reporting

Procedures for monitoring the effectiveness of the mitigation measures proposed in this chapter are provided in the ESMP and will be expanded upon in the Project-specific Pollution Prevention Plans. In accordance with the site ESMP, ongoing monitoring and maintenance of the spill protection measures and drainage systems will be undertaken to reduce the impact significance related to potential groundwater and surface water contamination during both construction and operation.

Additionally, the MoH will: (i) promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers (no later than 48 hours after learning of the incident or accident), (ii) provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and (iii) subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

8 MATERIAL RESOURCES, WASTE AND WASTEWATER MANAGEMENT

8.1 Introduction

This chapter addresses the potential impacts regarding raw materials and resources required for all phases of the Project, as well as those related to generation and management of Project waste and wastewater. The chapter also describes the mitigation and management measures to prevent and reduce impacts related to material use and waste/wastewater management in accordance with the project requirements within the framework of national environmental legislation and international standards.

Waste generation during the construction and operation of the Project will include demolition waste, excavated soil, domestic waste, domestic and laboratory wastewater, hazardous waste, medical waste and non-hazardous waste. Potential impacts could include environmental impacts, health and safety impacts to the employees, and impacts to the community resulting from inadequate waste management during construction and operation phases.

8.1.1 Study Area and Area of Influence

The study area covers the Project site as well as the whole Ankara province for the identification of waste management facilities and practices which will be used to treat, manage and dispose of the wastes generated during different phases of the Project.

8.1.2 Data Limitations

A detailed Project construction programme has not yet been completed and therefore the exact quantities of materials to be procured and wastes generated are yet uncertain. Similarly, quantities of required input materials and associated waste streams for the operation phase will be determined at later stages of the Project and are subject to confirmation once a design & supply contractor has been engaged and the exact operation methodologies are determined. All waste streams presented in this chapter are based on current plans for the Project. Nevertheless, the principal materials and types of waste streams to be generated are believed to have been identified and therefore the management practices presented in this chapter would not be expected to change significantly as a result of modifications to the actual waste streams which are ultimately generated as a result of the Project.

The waste classification made in this chapter is majorly based on Turkish environmental legislation. The waste types provided are estimations relevant to each Project phase. Laboratory waste types are defined based on both the information obtained from MoH and expert judgement. Mitigation measures and management options are based on expert opinion and legislative knowledge, and cover requirements for proper waste management during all Project activities.

8.2 Baseline Description for Material Resources, Waste and Wastewater Management

8.2.1 Material Resources

Construction Phase

Construction activities include the extraction of materials, the manufacturing of products, the assembly of products into buildings, the maintenance and replacement of systems, and the ultimate disposal of construction waste. These activities all demand resource and water consumption during all phases of the construction.

For the construction phase of the Project, materials such as ready-mixed concrete, cement, reinforcement steel, structural steel, aluminum, brick, timber, plastics, glass, paints, fuels, fine and coarse aggregate are required. During construction, it is estimated that the following will be utilized at a minimum: approximately 4048 m³ of aggregate, 1900 m³ of concrete, 1685 tons of ribbed steel and 308 tons of structural steel. The ready-mixed concrete and aggregate are supplied from sources outside the Project site. No borrow areas, quarries or concrete batching plants are or will be operated by the contractor. The construction materials are transported from suppliers to the site via road transportation.

There is potable water usage by construction workers and for construction activities. The amount of potable water which will be used by the personnel during the construction phase is estimated at approximately 38 m³/day, based on 250 workers at the peak of construction⁹⁹. In addition, water will be used for dust suppression activities, spraying concrete, adding water to backfill material, equipment cleaning and site clean-up.

Operation Phase

Laboratories are some of the most resource-intensive buildings in terms of energy, water, materials and other resources. For this reason, resource efficiency and sustainability will be an integral part of the Project and efficiency opportunities are planned to be considered in the design and operation.

Various types of materials are used in BSL3 laboratory operations. For the sustainable operation of laboratories, supply chain management, consideration of reuse and recycling alternatives, proper design and management of logistics system, and management of resources gain importance. Principle material resources of a laboratory can be classified into three categories: reagents, consumables and durables.

- Reagents are chemicals and biological agents that are used in laboratory testing. The reagents vary
 widely in cost, stability, cold-chain requirements, availability and the hazards associated with each
 variant.
- Consumables are items that are used once while performing a test and are not reused. Consumables can include such test-specific items as microscope slides and cover slips. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, alcohol and gloves.
- Durables are items that can be reused for multiple tests. They include items such as glassware that can be washed, sterilized, and reused. This classification also includes equipment and instruments used for testing.
- A large number of different types of chemicals such as acids, alkalis, organic solvents and gases will be used in laboratory operations. These include high amounts of liquid disinfectants that are used for sterilisation and gas phase hydrogen peroxide used in room area decontaminations. Another area of use of chemicals is the effluent decontamination system, where liquid wastes will be decontaminated thermo-chemically.
- In laboratories, several types of disinfectants are utilized for sterilisation purposes. A list of chemical disinfectants and their activity levels is given in the Table 8-1 below.

Chemical	Concentration	Activity Level
Glutaraldehyde	Variable	Sterilisation
Glutaraldehyde	Variable	Intermediate to high-level disinfection

Table 8-1: Chemical Disinfectants¹⁰⁰

⁹⁹ Based on the information that daily domestic wastewater discharged per capita in Ankara was 151 L in 2020.

¹⁰⁰ Centers for Disease Control and Prevention, National Institutes of Health (2020). *Biosafety in Microbiological and Biomedical Laboratories*. U.S. Department of Health and Human Services, accessed from https://www.cdc.gov/labs/pdf/SF_19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf on 09 June 2022

Chemical	Concentration	Activity Level
Ortho-phthalaldehyde (OPA)	0.55%	High-level disinfection
Hydrogen peroxide	6-30%	Sterilisation
Hydrogen peroxide	3-6%	Intermediate to high-level disinfection
Formaldehyde	6-8%	Sterilisation
Formaldehyde	1-8%	Intermediate to high-level disinfection
Chlorine dioxide	Variable	Sterilisation
Chlorine dioxide	Variable	Intermediate to high-level disinfection
Peracetic Acid	0.08%-0.23% with peroxide concentrations of 1-7.35% Sterilisation	
Peracetic Acid	Variable	High-level disinfection
Hypochlorites	500–6000 mg/L Free available	Intermediate to high-level disinfection
Alcohols (ethyl, Isopropyl)	70%	Intermediate-level disinfection
Phenolics	0.5-3%	Low to intermediate-level disinfection

All chemicals to be used in the Project will be evaluated within the scope of the Regulation on Health and Safety Measures in Working with Chemicals¹⁰¹ according to the EINECS (European Inventory of Existing Commercial Chemical Substances) and CAS (Chemical Abstracts Service) registration number of chemical substances. All materials to be used in the facility, from the entrance to the facility to their use and storage, will be operated with standard operating procedures and records will be kept during the operation phase, within the scope of GLP and GMP compliance. In each unit, storage areas will be reserved for the relevant materials, ventilated chemical cabinets will be used in the warehouses and all materials will be indexed and stored according to their hazard classes. In the process management, material entry and exit from the relevant areas will be made by authorized personnel, and chemical usage and storage will be monitored. While purchasing chemicals, it will be obligatory to provide MSDS information together with the chemical in accordance with the relevant purchasing protocols of the MoH, and necessary training will be given to the personnel regarding the incoming chemical.

During the operation phase, there will be water uses related to general domestic (kitchen, toilets, landscaping, etc.) and operational use (steam boilers, laboratories, autoclaves, vaccine production). Daily water consumption for domestic usage is estimated at approximately 38 m³/day, assuming that 200 personnel will be employed during the operation phase and 50 visitors are expected daily. The potable water will be provided from the existing water supply line of the municipality. Potable water for the buildings will be supplied upon preliminary water treatment at the Technical Building. Purified water for laboratory and production operations will also be produced in the Technical Building.

8.2.2 Waste and Wastewater Management

Existing Waste and Wastewater Infrastructure in Ankara

The whole population in Ankara is provided with waste services¹⁰². There are three sanitary landfills (Mamak, Çadırtepe and Şereflikoçhisar) and 13 waste collection substations in Ankara. Wastes are collected in these stations and transferred to the landfills. A total of 2.36 million tons of municipal waste was collected in Ankara in 2018, approximately 60% of which was disposed of in solid waste landfills and 40% was subject to recycling. The average municipal waste amount generated per capita in Ankara is 1.18 kg/person-day which is slightly higher than the Turkiye average (1.16 kg/person-day). A total of

¹⁰¹ Official Gazette date/number: 12.08.2013/28733

¹⁰² Turkish Statistical Institute, Geostatistics Portal, accessed from https://cip.tuik.gov.tr/ on 10 January 2022

63,783 tons of hazardous waste was collected in Ankara in 2017. The recycling rate of hazardous waste in 2017 was 66.5%, which is below the overall rate of 84% in Turkiye¹⁰³.

In Akyurt District where the Project site is located, waste services are carried out by the district municipality. A total of 21,350 tons domestic waste was collected by the Akyurt Municipality in 2021¹⁰⁴ and sent to the Ankara Metropolitan Municipality's landfill area. Recently, the construction of waste transfer station of Akyurt Municipality was completed, and the wastes are temporarily stored in the transfer station prior to being transferred to the sanitary landfill. There exist two sanitary landfills in Ankara, namely Mamak and Çadırtepe (Sincan). The daily waste capacities of these facilities were reported as 1500 tons/day and 4000 tons/day respectively.¹⁰⁵ According to the information provided by MoH, it is understood that the domestic waste generated by the Project during construction and operation phases will be collected by Akyurt Municipality and disposed of at Mamak Sanitary Landfill having sufficient capacity for such wastes and operating in line with environmental legislations.

There are 11 designated licensed disposal sites in Ankara, used for the disposal of construction and demolition wastes generated in the province. The construction and demolition wastes generated by the Project activities will be transferred to the icensed construction & demolition waste disposal area that is managed by the Akyurt Municiality. Other types of wastes such as packaging wastes, waste oils and waste batteries are managed (treatment/recycling/disposal) by authorized companies. Medical wastes are collected and disposed of in the licensed Industrial and Medical Waste Disposal Facility located in Sincan district. Daily disposal capacity of the facility is reported as 4000 tons/day (currently has sufficient capacity for such wastes), with energy generation license capacity of 54.7 MW. The facility consists of the following units; landfill area, mechanical separation facility, biomethanization system, and an electric power generation system.

Daily domestic wastewater discharged per capita in Ankara was 151 L/Person-Day in 2020. Sewage network and wastewater treatment services are available for 98% and 64% of the population in the city respectively. The wastewater from central districts in Ankara are transferred to and treated in Ankara Tatlar Wastewater Treatment Plant (WWTP). The WWTP was established in 1997 with a treatment capacity of 765,000 m³/d. There are also WWTPs located in Cubuk, Akyurt, Elmadag, Ayas, Kazan and Kalecik districts. The wastewater generated from the Akyurt district is directed to Karaköy WWTP located approximately 5.7 km from the Project site. Karaköy WWTP started its operation in 2009 to treat wastewaters collected from a part of Pursaklar district, Akyurt district and Esenboğa, Sirkeli, Karacaören, Altınova, Sarayköy areas and the surrounding neighborhoods and settlements. Karaköy Wastewater Treatment Plant has been designed as an advanced biological treatment system (A2/O Process) with a 41,818 m³/day and 160,000 population equivalent wastewater treatment capacity. The WWTP is owned and operated by the Ankara Water and Sewerage Administration (ASKI) and the treated water is discharged to Çubuk Stream. The WWTP has sufficient capacity to treat the wastewater discharged to the sewerage system by the Project and has an environmental permit, discharges to receiving environment in line with discharge standards, and operates in line with environmental legislation including disposal of sludge generated at the WWTP.

As reported by MoH, there is an existing water and wastewater infrastructure in the Project site, therefore construction of any infrastructure is not expected. Domestic wastewater generated at site during the construction and operation phases will be directed to the sewerage system of ASKI. Liquid wastes and industrial wastewaters generated within the Project during the operation phase will be discharged to the ASKI sewerage system after pre-treatment at the Project facilities to bring the quality of wastewater to the

¹⁰³ Official website of MoEUCC - Environmental indicators of provinces accessed from <u>https://webdosya.csb.gov.tr/db/cevreselgostergeler/icerikler/ankara-cevre-gostergeler--20191115133720.xlsx</u> on 10 January 2022

¹⁰⁴ Annual Activity Report of Akyurt Municapality-2021, accessed from <u>https://www.akyurt.bel.tr/uploads/pages/faaliyet-raporlari/akyurt-belediyesi-2021-faaliyet-raporu.pdf</u> on 02 March 2023

¹⁰⁵ Accessed from <u>https://www.itcturkiye.com/tr/tesislerimiz/ankara-mamak.</u>

discharge criteria defined in the Regulation on Wastewater Discharges to Sewerage System published by ASKI and treated in the wastewater treatment facilities serving the district.

Waste Definitions

Different types of waste will be generated during all phases of the Project. The definitions of the expected waste types, according to the Turkish environmental legislation, are presented below:

- Domestic Waste: Commercial, industrial and institutional wastes, which are defined in section 20 of Annex 4 of the Waste Management Regulation¹⁰⁶, originating from households or similar in content or structure, for which the municipality is responsible.
- Biodegradable Waste: Wastes originating from parks, gardens, houses, restaurants, sales points, food production and similar facilities that can degrade in aerobic or anaerobic environment.
- Waste Electrical and Electronic Equipment (EEE): Refers to articles included in the categories given in Annex-1/A of the Regulation on Control of Waste Electrical and Electronic Equipment¹⁰⁷, designed for use with 1000 V with alternating current and direct current not exceeding 1500 V, dependent on electric current or electromagnetic field for proper operation, and articles for the production, transfer and measurement of these currents and fields. Waste EEE refers to the state of these items that have become waste and are no longer used.
- Excavation Soil: Rock and soil material formed as a result of excavation and similar activities carried out during the preparation of the land before the construction.
- Construction and Demolition Waste: Wastes generated during the construction of houses, buildings, bridges, roads and similar infrastructure and superstructures and repair, modification, renewal, demolition or natural disaster of those structures.
- Packaging Waste: All kinds of packaging and packaging components that comply with the waste definition in the Waste Management Regulation. Packaging wastes mentioned in this section refer to uncontaminated packaging materials suitable for recycling.
- Waste Oils: Mineral oils that are not suitable for their original use and whose waste codes are included in Annex-1 of the Regulation on Control of Waste Oils¹⁰⁸.
- Waste Tires: Tires that have been removed from a motor vehicle and has not been retreaded or regrooved, therefore reached end-of-life.
- Waste Battery and Accumulators: Used batteries and accumulators that are not reusable and need to be collected, transported and disposed of separately from domestic waste.
- Hazardous Waste: Wastes that have one or more of the dangerous properties given in Annex-3/A and that have an asterisk (*) next to the six-digit waste code in Annex-4 of the Waste Management Regulation.
- Non-hazardous Waste: Wastes that do not have an asterisk (*) in the Annex-4 waste list of the Waste Management Regulation.
- Waste Vegetable Oils: It refers to vegetable oils and used frying oils that comply with the definition of waste in the Waste Management Regulation.
- Domestic Wastewater: It refers to wastewater from toilets and restaurants, discharged to sewer to be treated in regional wastewater treatment facilities.
- Industrial Wastewater: It refers to wastewater that is contaminated with e.g., oil or particulate matter from site washing, equipment and vehicle cleaning, and other similar flushing activities.

¹⁰⁶ Official Gazette date/number: 02.04.2015/29314

¹⁰⁷ Official Gazette date/number: 22.05.2012/28300

¹⁰⁸ Official Gazette Date/Number: 21.12.2019/30985

Medical waste types are categorised as infectious wastes, pathological wastes, and sharps according to international legislation as well as Turkish Regulation on Control of Medical Waste¹⁰⁹. Medical waste types generated by the laboratories, which must also be classified according to their biosafety level, are given below:

- Infectious Waste: Known or likely to carry infectious agents; all kinds of body fluids, human tissues, organs, anatomical parts, autopsy material, placenta, fetus and other pathological material; especially blood and blood products, gloves, covers, sheets, bandages, plasters, tampons, swab. It also covers wastes such as body exudates of patients under quarantine, bacteria and virus-retaining air filters, laboratory cultures and culture stocks of infectious agents, all kinds of materials that have come into contact with infected animals and their interests and wastes from veterinary services.
- Pathological Waste: Includes tissues, organs, body parts, body fluids and fetus resulting from surgery, autopsy, anatomy or pathology study.
- Sharp-piercing Waste: It refers to wastes that can cause stinging, piercing, abrasions and injuries. Includes injector and all other medical intervention needles, lancet, capillary tube, scalpel, knife, serum set needle, surgical suture needles, biopsy needles, intraket, broken glass, ampoule, lam-lamella, broken glass tube and petri dishes.
- Laboratory Wastewater: Wastewater generated from the laboratory sinks and showers.
- The World Bank Group also defines the medical and hazardous waste types, and their treatment and disposal options in its EHS Guidelines for Health Care Facilities document published in 2007. The classification and treatment and disposal options, which has no defined gaps between Turkish Environmental Legislation, is given below in Table 8-2.

Type of waste	Summary of treatment and disposal options / notes
Infectious waste: Includes waste suspected to contain pathogens (e.g., bacteria, viruses, parasites, or fungi) in sufficient concentration or quantity to cause disease in susceptible hosts.	Waste Segregation Strategy: Yellow or red colored bag / container, marked "infectious" with international infectious symbol. Strong, leak proof plastic bag, or container capable of being autoclaved.
Includes pathological and anatomical material (e.g. tissues, organs, body parts, human fetuses, animal carcasses, blood, and other body fluids), clothes, dressings, equipment / instruments, and other items that may have come into	Treatment: Chemical disinfection; Wet thermal treatment; Microwave irradiation; Safe burial on hospital premises; Sanitary landfill; Incineration (Rotary kiln; pyrolytic incinerator; single- chamber incinerator; drum or brick incinerator)
contact with infectious materials. Infectious waste belongs to medical waste classification according to the Turkish Environmental Legislation*.	 Highly infectious waste, such as cultures from lab work, should be sterilized using wet thermal treatment, such as autoclaving. Anatomical waste should be treated using Incineration (Rotary kiln; pyrolytic incinerator; single-chamber incinerator; drum or brick incinerator).
Sharps: Includes needles, scalpels, blades, knives, infusion sets, saws, broken glass, and nails etc. Sharps waste belongs to medical waste classification according to the Turkish Environmental Legislation*.	 Waste Segregation Strategy: Yellow or red color code, marked "Sharps". Rigid, impermeable, puncture-proof container (e.g. steel or hard plastic) with cover. Sharps containers should be placed in a sealed, yellow bag labeled "infectious waste". Treatment: Chemical disinfection; Wet thermal treatment; Microwave irradiation; Encapsulation; Safe burial on hospital premises; Incineration (Rotary kiln; pyrolytic incinerator; single-chamber incinerator; drum or brick incinerator) Following incineration, residues should be landfilled. Sharps disinfected with chlorinated solutions should not be incinerated due to risk of generating POPs. Needles and syringes should undergo mechanical mutilation (e.g. milling or crushing) prior to wet thermal treatment
Pharmaceutical waste: Includes expired, unused, spoiled, and contaminated pharmaceutical products, drugs, vaccines, and sera that are no longer needed, including containers and	Waste Segregation Strategy: Brown bag / container. Leak- proof plastic bag or container.

Table 8-2: Treatment and Disposal Methods for Categories of Health Care Waste

¹⁰⁹ Official Gazette date/number: 25.01.2017/29959

Type of waste	Summary of treatment and disposal options / notes
other potentially contaminated materials (e.g. drug bottles vials, tubing). Pharmaceutical waste belongs to hazardous waste classification according to the Turkish Environmental Legislation*.	 Treatment: Sanitary landfill; Encapsulation; Discharge to sewer; Return expired drugs to supplier; Incineration (Rotary kiln; pyrolytic incinerator); Safe burial on hospital premises as a last resort (only for small quantities). Small quantities: Landfill disposal acceptable, however cytotoxic and narcotic drugs should not be landfilled. Discharge to sewer only for mild, liquid pharmaceuticals, not antibiotics or cytotoxic drugs, and into a large water flow. Incineration acceptable in pyrolytic or rotary kiln incinerators, provided pharmaceuticals do not exceed one percent of total waste to avoid hazardous air emissions. Intravenous fluids (e.g. salts, amino acids) should be landfilled or discharged to sewer. Ampoules should be crushed and disposed of with sharps. Large quantities: Incineration at temperatures exceeding 1200 °C. Encapsulation in metal drums. Landfilling not recommended unless encapsulated in metal drums and groundwater contamination risk is minimal.
Genotoxic / cytotoxic waste: Genotoxic waste may have mutagenic, teratogenic, or carcinogenic properties, and typically arises from the feces, urine, and vomit of patients receiving cytostatic drugs, and from treatment with chemicals and radioactive materials. Cytotoxic drugs are commonly used in oncology and radiology departments as part of cancer treatments. Genotoxic / cytotoxic waste belong to hazardous waste according to the Turkish Environmental Legislation*.	 Waste Segregation Strategy: See above for "infectious waste". Cytotoxic waste should be labeled "Cytotoxic waste". Treatment: Return expired drugs to supplier; Chemical degradation; Encapsulation; Inertization; Incineration (Rotary kiln, pyrolytic incinerator); Cytotoxic waste should not be landfilled or discharged to sewer systems. Incineration is preferred disposal option. Waste should be returned to supplier where incineration is not an option. Incineration should be undertaken at specific temperatures and time specifications for particular drugs. Most municipal or single chamber incinerators are not adequate for cytotoxic waste disposal. Open burning of waste is not acceptable. Chemical degradation and inertization should be a last resort waste disposal option
Chemical waste: Chemical waste: Waste may be hazardous depending on the toxic, corrosive, flammable, reactive, and genotoxic properties. Chemical waste may be in solid, liquid, or gaseous form and is generated through use of chemicals during diagnostic / experimental work, cleaning, housekeeping, and disinfection. Chemicals typically include formaldehyde, photographic chemicals, halogenated and nonhalogenated solvents, organic chemicals for cleaning / disinfecting, and various inorganic chemicals (e.g. acids and alkalis). Chemical waste belongs to hazardous waste according to the Turkish Environmental Legislation*.	 Waste Segregation Strategy: Brown bag / container. Leak-proof plastic bag or container resistant to chemical corrosion effects. Treatment: Return unused chemicals to supplier; Encapsulation; Safe burial on hospital premises; Incineration (Pyrolytic incinerator); Facilities should have permits for disposal of general chemical waste (e.g., sugars, amino acids, salts) to sewer systems. Small hazardous quantities: Pyrolytic incineration, encapsulation, or landfilling. Large hazardous quantities: Transported to appropriate facilities for disposal or returned to the original supplier using shipping arrangements that abide by the Basel Convention. Large quantities of chemical waste should not be encapsulated or landfilled.
Radioactive waste: Includes solid, liquid, and gaseous materials that have been contaminated with radionuclides. Radioactive waste originates from activities such as organ imaging, tumour localization, radiotherapy, and research / clinical laboratory procedures, among others, and may include glassware, syringes, solutions, and excreta from treated patients. Radioactive wastes are categorized as "nuclear and radioactive materials that contain activity concentrations above the designated limits and are not intended to be used again; and structures, systems, components and materials contaminated with radioactive material or that have become	Waste Segregation Strategy: Lead box, labeled with the radioactive symbol. Treatment: Radioactive waste should be managed according to national requirements and current guidelines from the International Atomic Energy Agency (IAEA (2003), Management of Waste from the Use of Radioactive Materials in Medicine, Industry and Research, IAEA Draft Safety Guide DS 160, 7 February 2003.

radioactive" according to Regulation on Radioactive Waste

Type of waste	Summary of treatment and disposal options / notes	
Management (09.03.2013/28582) released by Turkish Atomic Energy Agency.		
Waste with high content of heavy metals: Batteries, broken thermometers, blood pressure gauges, (e.g. mercury	Waste Segregation Strategy: Waste containing heavy metals should be separated from general healthcare waste.	
and cadmium content).	Treatment: Safe storage site designed for final disposal of hazardous waste.	
The waste belongs to hazardous waste classification according to the Turkish Environmental Legislation*.	 Waste should not be burned, incinerated, or landfilled. Transport to specialized facilities for metal recovery. 	
Pressurized containers: Includes containers / cartridges / cylinders for nitrous oxide, ethylene oxide, oxygen, nitrogen,	Waste Segregation Strategy: Pressurized containers should be separated from general healthcare waste.	
carbon dioxide, compressed air and other gases.	Treatment: Recycling and reuse; Crushing followed by landfill	
Pressurized containers belong to hazardous waste classification according to the Turkish Environmental Legislation*.	 Incineration is not an option due to explosion risks Halogenated agents in liquid form should be disposed of as chemical waste, as above. 	
General health care waste (including food waste and paper, plastics, cardboard)	Waste Segregation Strategy: Black bag / container. Halogenated plastics such as PVC should be separated from general health care facility waste to avoid disposal through incineration and associated hazardous air emissions from exhaust gases (e.g., hydrochloric acids and dioxins).	
	Treatment: Disposal as part of domestic waste. Food waste should be segregated and composted. Component wastes (e.g. paper, cardboard, recyclable plastics [PET, PE, PP], glass) should be segregated and sent for recycling.	

Construction Phase

It is expected that both non-hazardous and hazardous waste are likely to be produced during construction. The incremental increase in waste materials produced during construction would be minimal with respect to the overall waste production of the Project.

Non-hazardous solid waste generated at construction phase of the Project includes excess fill materials from grading and excavation activities, demolishing waste due to the demolition of the existing warehouse, wood, metal, timber, glass cullet, asphalt, paper and plastic and brick and concrete rubble, paper/cement bags, empty paint and solvent containers. Other wastes which will be generated by non-construction activities include food debris, contaminated water from washing, cleaning equipment, construction tools and vehicles, and domestic waste produced in the office, kitchen, and dormitories as part of the construction activities. No waste vegetable oils are expected to be generated during construction since food preparation will not be performed on site.

Hazardous solid waste includes contaminated soils, which could potentially be encountered on site due to previous land use activities, or small amounts of machinery maintenance materials, such as oily rags, used oil filters, and used oil, as well as spill clean-up materials from oil and fuel spills. Construction activities may pose the potential for release of petroleum-based products, such as lubricants, hydraulic fluids, or fuels during their storage, transfer, or use in equipment. Some of the waste materials such as paints, cement, adhesives and cleaning solvents contain hazardous substances. Additionally, asbestos containing materials may occur due to the demolition of the existing warehouse building on the Project site (i.e. Parcel 1555-4). In any case of discovery of asbestos in the building to be demolished, the Regulation on Control of Excavation, Construction and Demolition Waste¹¹⁰ requires that the principles of

¹¹⁰ Published in the Official Gazette Date/No: 18.03.2004/25406

Regulation on Health and Safety Precautions for Working with Asbestos¹¹¹ are followed in order to protect the health and safety of employees.

Inappropriate storage and disposal of construction waste could have medium or long-term environmental and public health impacts. Extent of this impact would be limited, given that the area where the Project is located has an existing waste collection system. This waste will be managed in collaboration with the municipality and through waste services with private companies, if required. Non-reusable and recyclable wastes will be disposed of to landfill and other wastes such as bricks, pieces of metals and wood will be recycled and reused. Techniques for preventing and controlling non-hazardous and hazardous construction site waste are provided in Section 8.4.2 in detail.

There is an existing wastewater infrastructure in the Project site, therefore domestic wastewater generated at site during the construction phase will be directed to the sewerage system of ASKI (Ankara Water and Sewerage Administration). The daily domestic wastewater generation at peak times during the construction phase of the Project is calculated as 19.2 m³/day.¹¹²

Industrial wastewater, which may be contaminated with oil and particulate matter from site washing, equipment and vehicle cleaning, and other flushing activities, will be pre-treated with sand trap and oil separator prior discharge to sewerage system of ASKI. Necessary pre-treatment installations will be constructed on-site.

Types of waste and wastewater that are expected to be generated in the construction phase of the Project are given in Table 8-3.

Waste Class	Waste Type	Relevant National Environmental Legislation
Excavation Soil, Construction and Demolition Waste	Excavated soil Construction waste	Regulation on Control of Excavation, Construction and Demolition Waste (18.03.2004/25406)
Domestic Waste	Household similar waste Biodegradable waste	Waste Management Regulation (02.04.2015/29314)
Domestic Wastewater	Black water Grey water	Water Pollution Control Regulation (31.12.2004 /25687), Regulation on Wastewater Discharges to the Sewage System published by ASKI (2011)
Packaging Wastes	Paper and cardboard Plastics Glass Metals	Regulation on Control of Packaging Waste (26.06.2021/31523)
Waste Oils	Hydraulic fluids, Lubricants	Regulation on Control of Waste Oils (21.12.2019/30985)
Waste Batteries		Regulation on Control of the Waste Batteries and Accumulators (31.08.2004/25569)
Waste Electric and Electrical Equipment		Regulation on Control of Waste Electrical and Electronic Appliances (22.05.2012 / 28300)
Hazardous Waste	Contaminated packaging Contaminated fabrics/filters Paints and chemicals Solvents Contaminated soil	Waste Management Regulation (02.04.2015/29314)

Table 8-3: Expected Waste Generation During the Construction Phase

¹¹¹ Published in the Official Gazette Date/No: 25.01.2013/28539

¹¹² Municipality wastewater statistics data of TurkStat were used for calculating the domestic wastewater generation. The average daily domestic generation of Ankara in 2020 is reported as 151 L/day.capita (TurkStat, Water and Wastewater Statistics, 2020. Accessed from <u>https://data.tuik.gov.tr/Bulten/Index?p=Su-ve-Atiksu-Istatistikleri-2020-37197</u> on 03 March 2023.

Waste Class	Waste Type	Relevant National Environmental Legislation	
Medical Waste	Basic infirmary waste	Regulation on Control of Medical Waste	
		(25.01.2017/29959)	
Non-hazardous waste	Metal scrap	Waste Management Regulation (02.04.2015/29314)	
(25 kg/day)	Wood scrap		
	Plastic scrap		
Waste Tyres		Regulation on the Control of End-of-life Tires (25.11.2006/ 26357)	
Industrial Wastewater	Contaminated flushing water	Water Pollution Control Regulation (31.12.2004/25687) and	
		Regulation on Wastewater Discharges to the Sewage System published by ASKI (2011)	

Operation Phase

During the operational phase of the Project, it is anticipated that various hazardous and non-hazardous materials/chemicals will be used in the facility and solid and liquid wastes will be generated as non-hazards and hazardous waste. Therefore, improper and inadequate waste handling, treatment and disposal can cause public health and environment risks.

A Waste Building is planned within the scope of the Project which will be used to store the hazardous and non-hazardous waste (including medical waste) before final transportation and disposal. All wastes generated in the operation of the Project will be transferred from the operation buildings to the Waste Building via underground galleries. On the basement floor of the Waste Building, there will be a rainwater storage depot (900 m³) and areas reserved for pumps. On the ground floor, there will be two waste storage rooms (cold rooms) and two reserved storage areas. There will be separate rooms/compartments allocated for domestic and medical wastes.

Waste types expected to be generated during the commissioning and operation phases of the Project are given below in Table 8-4.

Waste Class	Waste Type	Relevant National Environmental Legislation
Domestic Waste Max. 3 m³/day	Household similar waste Biodegradable waste	Waste Management Regulation (02.04.2015/29314)
Domestic Wastewater	Black water Grey water	Water Pollution Control Regulation (31.12.2004/25687), Regulation on Wastewater Discharges to the Sewage System published by ASKI (2011)
Packaging Wastes	Paper and cardboard Plastics Glass Metals	Regulation on Control of Packaging Waste (26.06.2021/31523)
Waste Oils	Hydraulic fluids, Lubricants	Regulation on Control of Waste Oils (21.12.2019/30985)
Waste Batteries	Waste bateries	Regulation on Control of the Waste Batteries and Accumulators (31.08.2004/25569)
Waste Electrical Equipment	Waste electrical equipment	Regulation on Control of Waste Electrical and Electronic Appliances (22.05.2012/28300)
Waste Vegetable Oil	Waste vegetable oil	Regulation on Control of Waste Vegetable Oil (06.06.2015/29378)
Hazardous Waste (5 L/day)	Contaminated packaging Contaminated fabrics/filters (HVAC filters) Paints and chemicals	Waste Management Regulation (02.04.2015/29314)

Table 8-4: Expected Waste Generation During the Operation Phase

Waste Class Waste Type		Relevant National Environmental Legislation	
	Solvents Cartridges Adhesives Animal shelter cleaning materials End-of-use animal shelter		
Medical Waste	Experimental serum from large animals Sharps and needles (5 kg/day) Expired medicine Animal food residues Infectious waste (7 m ³ /day) Pathological waste (max. 5 m ³ /day) Liquid waste (max. 20 m ³ /day)	Regulation on Control of Medical Waste (25.01.2017/29959)	
Laboratory Wastewater	Wastewater from all laboratory sinks and showers	Regulation on Control of Medical Waste (25.01.2017/29959)	
Non-hazardous waste (25 kg/day)	Metal scrap Wood scrap Plastic scrap	Waste Management Regulation (02.04.2015/29314)	
Radioactive Waste	Radioactive pharmaceuticals	Regulation Radioactive Waste Management (09.03.2013/28582)	

Table 8-5 below indicates the expected waste types to be generated in each Project area and building unit during the operation phase.

Tuble o o. Expedice Music Generation by Dunning During the Operation I have of the Project
--

Project Complex Area	Building Parts/Units	Biosafety Level	Expected Waste Classes/Types
Administrative Building	Depots Security Glass Cafeteria Administrative office / expert offices Technical areas Social areas Parking basement Guest house-12 single rooms	N/A	Domestic waste Domestic wastewater Packaging waste Hazardous waste Waste vegetable oil
Parking Lot (open area, i	multiple locations)	N/A	Packaging waste
Research and Development (R&D) Building (including a Biobank Unit)	Bacteria, virus, yeast R&D areas Biobank Unit	BSL3 —	HVAC filter Infectious waste Sharps and needles Expired medicine
Experimental Animals and Transgenic Organisms Production/Test	Animal production rooms/aquariums	ABSL3	Animal waste (full body) Animal parts / tissue Animal food residues
Building	Separate laboratories for in-vivo testing of experimental animals		Animal shelter cleaning materials End of used animal shelter HVAC filter Contaminated fabric/wipes
	Waste and decontamination areas		(accidents response) Expired medicine Experimental serum from large animals Liquid waste
Waste Centre	Rainwater tank (basement floor)	N/A	Contaminated fabrics
	Medical waste depots	BSL1	Contaminated packaging

Project Complex Area	olex Building Parts/Units		Expected Waste Classes/Types	
	Other material depots	N/A		
Loading/Unloading Area		N/A	Packaging waste	
Vaccine Production and	1. Immunoserum Purification/Filling Building	BSL3	HVAC filter	
Storage Buildings (three blocks)	2. Antigen-Antiserum Diagnostic Product/Quality Control Laboratory Production Building	-	Contaminated fabric/wipes (accidents response) Expired medicine	
	3. Vaccine and Antigen Production Building (Bacterial and viral pilot production, Inactive viral vaccines production, Recombinant vaccines production areas, quality control laboratories and raw material warehouses, product warehouses, personnel change areas)			
Technical Building	Heating and cooling systems	N/A	Waste oils	
Distilled water production unit		-	Contaminated fabrics	
	Main water units		Contaminated packaging	
	Generators	-	Waste chemicals	
	Compressors	-	Packaging waste Domestic waste	
	Mechanical and technical workshop	-		
	Medical gas centre	-		
	Pure steam production unit	-		
	Sterilized dry air production unit	-		
	Control air	-		
	Water tanks	-		
	Fire pump station	-		
	Electricity	-		
	UPS			
	MV panels	-		
Security Building	Information desk and x-ray unit	N/A	Domestic waste	
	Waiting room	-	Domestic wastewater	
	Meeting room		Packaging waste	
	Restrooms			
Observation Towers (5 points)		N/A	Domestic waste Packaging waste	
Open resting area	Security	N/A	Domestic waste	
Kindergarten	Classroom		Domestic wastewater Packaging waste	
-	Sleeping room	-		
-	Game room			

Wastewaters that will be generated by the Project activities will include:

- Domestic wastewater: As mentioned in the above subsection, there is an existing wastewater infrastructure in the Project site, therefore domestic wastewater generated at site during the operation phase will be directed to the sewerage system of ASKI (Ankara Water and Sewerage Administration). For the operation phase of the project, the average daily domestic wastewater generation within the facility is calculated as 30 m³/day¹¹³.
- Industrial wastewater: Effluents contaminated with oil and particulate matter from site washing, equipment and vehicle cleaning, and other flushing activities, will be pre-treated with sand trap and oil separator prior discharge to sewerage system of ASKI. Necessary pre-treatment installations will be constructed on-site.

¹¹³ The Project is expected to employ a total of approximately 200 operational staff most of whom will be civil servants of the MoH.

 Laboratory wastewater (liquid waste): Wastewater generated from the laboratory sinks, showers, autoclave chambers and floor drains, which will be pre-treated with a thermo-chemical effluent decontamination system (EDS) prior to being directed to the sewerage system of ASKI. An EDS is a system designed to sterilise biologically active materials in liquid waste material and may involve chemical or thermal methods, or a combination of both. For chemical treatment, oxidizing agents such as sodium hypochlorite and peracetic acid are generally used as they have a broad-spectrum antimicrobial activity. Effluents need to be neutralised before discharge in the sewage system to comply with the local standards in terms of pH, temperature, and chemical content. For thermal-based liquid waste treatment, a combination of heat and pressure is needed to ensure that all biohazardous materials are destroyed. Thermal-based EDS's usually operate between 121°C and 134°C or higher, depending on the biological agent to be inactivated. Thermo-chemical treatment has the advantage that no pressure vessel and no such high temperatures are needed as systems based on heat alone, and also, the system can switch between either chemical or thermal only treatment. The adequate temperature and chemical combination need to be determined for inactivating the agents used in the facility. The use of chemical disinfectants still requires adjusting the physical and chemical parameters of the effluent to comply with wastewater standards before release in the sewage system.¹¹⁴

The Project-specific Waste and Wastewater Management Plan, which also covers the management of medical waste generated in the laboratories, will be implemented during the operational phase to meet both national and international standards. If a proper management plan is not in position and maintained over time, the Project could result in significant negative impacts to both the workers and the public in general. Waste management strategies, methods and plans to mitigate such impacts are detailed in Section 8.4.3.

8.3 Assessment of Impacts

8.3.1 Methodology and Assessment Criteria

Impacts were assessed according to the national legislation and international standards (primarily World Bank and WHO) relevant to the nature of the Project, through the use of primary data provided by the MoH as well as secondary sources reviewed during desktop studies. Impact assessment has been conducted by firstly identifying materials used and wastes generated, defining the possible impacts in case of mismanagement of the materials and waste, and finally explaining the management options according to the legislation and standards.

The methodology adopted for the assessment is as follows:

- Establishment of baseline: Involved identifying the material resources use and waste generation during the Project lifecycle together with their possible outcomes (see Section 8.2).
- Assessment of impacts: Significance levels of possible impacts on key receptors related to material use and waste associated with construction and operation phases of the Project have been assessed. The significance criteria adopted for the assessment of impacts is provided in Section 8.3.2.
- **Development of mitigation measures:** To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise the overall environmental impact from associated with the Project. A number of unique mitigation and management measures are required for the operation phase of the Project, since each different biosafety level laboratory must apply related material and waste management to maintain biosafety.

¹¹⁴ Accessed from <u>https://www.biosafety.be/sites/default/files/2012_effluentdeconsystems_sbb_2505_58.pdf</u> on 07 March 2023.

8.3.2 Determining Magnitude, Sensitivity, and Impact Significance

Impact significance of utilization of material resources and waste generation as a result of the Project has been determined based on a function of the expected sensitivity of the receptors to material and waste related impacts and the resultant magnitude of any identified impact on the receptors.

The criteria used for determining sensitivity of the receptors (human and environment) and magnitude of defined impacts are provided in Table 8-6 and Table 8-7 respectively.

Sensitivity Definition (considers duration of the impact, spatial extent, reversibility and ability to consider the impact of th		
High	Waste and/or materials handling related impacts on a vulnerable receptor (human or ecological) with little or no capacity to absorb proposed changes or minimal opportunities for mitigation.	
Medium	Waste and/or materials handling related impacts on a vulnerable receptor (human or ecological) with limited capacity to absorb proposed changes or limited opportunities for mitigation.	
Low	Waste and/or materials handling related impacts on a vulnerable receptor (human or ecological) with some capacity to absorb proposed changes or moderate opportunities for mitigation.	
Negligible	Waste and/or materials handling related impacts on a vulnerable receptor (human or ecological) with good capacity to absorb proposed changes or and good opportunities for mitigation.	

Table 8-6: Criteria for Determining Sensitivity

Table 8-7: Criteria for Determining Magnitude

Magnitude	Definition (considers duration of the impact, spatial extent, reversibility and ability to comply with legislation)			
Major	Mismanagement of waste arising and/or materials results in a significant incident which potentially causes a fundamental change to the specific environmental conditions assessed, resulting in long term or permanent change, typically widespread in nature (regional national and international), would require significant intervention to return to baseline; exceed national standards and limits.			
Moderate	Mismanagement of waste arising and/or materials results in an incident that causes a detectable change to the specific environmental conditions assessed, resulting in non-fundamental temporary or permanent change.			
Minor	Mismanagement of waste arising and/or materials results in an incident that causes a detectable but minor change to the specific environmental conditions assessed.			
Negligible	Mismanagement of waste arising and/or materials results in an incident that causes no perceptible change to the specific environmental conditions assessed.			

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 8-8.

Table 8-8: Impact Significant Matrix

	Sensitivity of Receptors			
Magnitude of Impact	Negligible	Low	Medium	High/Very High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

Possible impacts on humans and the environment that will occur by the use of materials and generation of waste during the Project lifecycle are determined according to the methodology described here and given below for each project phase.

8.3.3 Construction Phase

Potential impacts during the construction phase associated with the use of raw materials include the utilization of potentially finite and/or scarce resources such as building materials and water, as well as handling of hazardous materials which may lead to contamination. The principal materials that are expected to be required/consumed as part of the construction include ready-mixed concrete, cement, reinforcement steel, structural steel, aluminium, brick, timber, plastics, glass, paints, fuels, fine and coarse aggregate. According to the information provided by the MoH, the construction materials required for the Project will be procured directly by the contractor from sources approved by MoH. Potential aggregate quarry sites (having appropriate licenses and/or permits) and other suppliers will be identified to supply the construction with locally available materials to the extent possible. Additionally, excavated material will be reused onsite as fill material to the maximum extent to level off topography and for landscaping purposes, which is considered as good practice.

No adverse impacts from extraction of raw materials or production of finished materials will be generated directly by the Project. It will be a priority for the contractor to minimize the use of material resources and to consider reuse, recycling, regeneration and energy conservation in the supply and disposal of construction materials. Therefore, the significance of potential impacts is expected to be minor.

Wastes will be generated during the construction phase of the Project for which appropriate waste management, minimisation and disposal practices will need to be established. The likely waste types from the construction phase of the Project include both hazardous and non-hazardous wastes. Potential hazardous waste materials to be generated during construction across the Project site includes: oils and solvents (including empty containers, oily rags, clean-up materials, hydraulic fluids, lubricants, etc.), paints, coatings, contaminated ground (potentially from leakage and spillage), used batteries, etc. Management of these hazardous wastes will require particular consideration, including final treatment or disposal options.

The possible impacts arising due to construction phase of the Project are defined in Table 8-9, including the sensitivity of receptors and anticipated magnitude and significance of the impacts. Significance of impacts arising from different types of waste to be generated during the construction phase are expected to vary from minor to critical. However, it is expected that the control measures described in Section 8.4.2 will be largely effective in avoiding the potential impacts typically associated with waste generation, especially hazardous waste, due to the construction activities.

Impact Source	Impact	Magnitude of the Impact	Possible Receptor/s and their Sensitivity	Significance of Impact
Excavation soil, demolition waste, topsoil removal (vegetation generation from landscaping) and demolition of the existing vaccine storage building in the Project area	 Fugitive dust emission on site Worker exposure to dust Worker exposure to asbestos (if any) Worker exposure to abandoned vaccines (i not removed prior to domolition) 	MINOR MAJOR (if asbestos exists) (if vaccines not removed)	Site workers – Low Çubuk stream – Low Soil – High Groundwater – Negligible Surroundings* – Low Site workers – High Çubuk stream – Low Soil – High Groundwater – High Surroundings – High	MODERATE
	 Contamination of surface water, groundwater and soil Traffic load 			
Construction waste generation from construction activities	 Contamination of surface water, groundwater and soil Traffic load 	MINOR	Site workers – Low Çubuk stream – Low Soil – Medium	MINOR

Table 8-9: Impact Assessment of Waste and Wastewater Generation During the Construction Phase

Impact Source	Impact	Magnitude of the Impact	Possible Receptor/s and their Sensitivity	Significance of Impact
	 Visual pollution 		Groundwater – Negligible Surroundings – Low	
Domestic waste generation such as household similar waste and biodegradable waste from site workers and site activities	 Contamination of surface water, groundwater and soil Vector generation Visual pollution Odour generation 	MODERATE	Site workers – Low Çubuk stream – Low Soil – Low Groundwater – Medium Surroundings – Low	MODERATE
Domestic wastewater (sewage) generation as black water and grey water from site workers and site activities	 Contamination of surface water, groundwater and soil with sewage water Vector generation Visual pollution Odour generation 	MAJOR	Site workers – Medium Çubuk stream – High Soil – High Groundwater – High Surroundings – Mediun	CRITICAL
Industrial wastewater generation as contaminated wastewater with oil and particulate matter (PM) from site activities	 Contamination of surface water, groundwater and soil with oil and PM Visual pollution 	MAJOR	Site workers – Medium Çubuk stream – High Soil – High Groundwater – High Surroundings – Mediun	CRITICAL
Packaging waste generation such as cardboard, plastic, glass, metal from site workers and construction material packaging	Contamination of surface water and soilVisual pollution	MODERATE	Site workers – Low Çubuk stream – High Soil – Medium Surroundings – Low	MAJOR
Waste oils generation such as hydraulic fluids and lubricants from maintenance activities	 Contamination of surface water, groundwater and soil Worker exposure Visual pollution 	MAJOR	Site workers – Medium Çubuk stream – High Soil – High Groundwater – High Surroundings – Low	CRITICAL
Waste batteries generation from site workers and site activities	 Contamination of surface water, groundwater and soil Visual pollution 	MAJOR	Site workers – Low Çubuk stream – High Soil – High Groundwater – Medium Surroundings – Low	CRITICAL
Waste tires generation from vehicle traffic	 Contamination of surface water and soil Visual pollution 	MINOR	Site workers - Low Çubuk stream – Medium Soil – Medium Surroundings – Low	MINOR
Waste electrical and electronical equipment generation from site and maintenance activities	 Contamination of surface water, groundwater and soil Visual pollution 	MAJOR	Çubuk stream – High Soil – Low Groundwater – Medium Site workers – Low Surroundings – Low	CRITICAL
Hazardous waste generation such as contaminated packaging, contaminated fabrics/filters, paint and chemicals, solvents and contaminated soil from site and maintenance activities	 Contamination of surface water, groundwater and soil Human exposure Visual pollution 	MAJOR	Site workers – High Çubuk stream – High Soil – High Groundwater – High Surroundings – Mediun	CRITICAL

Impact Source	Impact	Magnitude of the Impact	Possible Receptor/s and their Sensitivity	Significance of Impact
Non-hazardous waste such as metal scrap, wood scrap and plastic scrap	 Contamination of surface water, groundwater and soil Visual pollution 	MODERATE	Site workers – Low Çubuk stream – Low Soil – Medium Groundwater – Medium Surroundings – Low	MODERATE
Medical waste as basic infirmary waste		NEGLIGIBLE	Site workers – Low Çubuk stream – Low Soil – Low Groundwater – Low Surroundings – Low	INSIGNIFICANT

* "Surroundings" refer to both the environment and its communities around the project site.

8.3.4 Operation Phase

Laboratories are among the most resource-intensive buildings in terms of materials, water, energy and other resources. Considering the nature and scale of the Project, the magnitude of resource utilization impacts during the operation phase can be estimated as moderate. Therefore, integration of sustainability and resource efficiency practices to the Project will be essential. Considering that receptors with respect to material use are mainly ecological and also indirectly human-related (e.g. need of water and energy resources), the sensitivity of receptors is determined as medium. As a result, significance of impact for the operation phase is determined as moderate. However, when the resource management practices stated in Section 8.4.3 are applied, a sustainable operation of the Project shall be achieved, and the significance of impact can be minimized to minor significance.

The possible impacts associated with waste generation during the operation phase are defined in Table 8-10, including the sensitivity of receptors and anticipated magnitude and significance of the impacts. Significance of impacts arising from different waste types to be generated during the Project are expected to vary from minor to critical. However, it is expected that the control measures described in Section 8.4.3 will be largely effective in avoiding the potential impacts typically associated with waste and wastewater generation in biotechnology facilities and laboratories. Additionally, developing and following detailed waste management procedures is going to be fundamental to ensuring best practice is undertaken and becomes embedded into the operational philosophy of the Project.

Table 8-	-10: Impact	Assessment of	Waste and V	Wastewater	Gene	eration	n During	g the Op	pera	ation F	Phase
	_										

Impact Source	Impact	Magnitude of the Impact	Possible Receptor/s and their Sensitivity	Significance of Impact
Domestic waste generation such as household similar waste and biodegradable waste from human activities, restaurants and offices	 Contamination of surface water, groundwater and soil Vector generation Visual pollution Odour generation 	MODERATE	Facility personnel – Low Çubuk stream – Low Soil – Low Groundwater – Low Surroundings – Low	MINOR

Impact Source	Impact	Magnitude of the Impact	Possible Receptor/s and their Sensitivity	Significance of Impact
Domestic wastewater (sewage) generation as black water and grey water from human activities	 Contamination of surface water, groundwater and soil with sewage water Vector generation Visual pollution Odour generation 	MAJOR	Facility personnel – Medium Çubuk stream – High Soil – High Groundwater – High Surroundings – Medium	CRITICAL
Packaging waste generation such as cardboard, plastic, glass, metal from human activities, restaurants, offices and material purchasing	 Contamination of surface water and soil Visual pollution 	MODERATE	Facility personnel – Low Çubuk stream – High Soil – Medium Surroundings – Low	MAJOR
Waste oils generation such as hydraulic fluids and lubricants from maintenance activities	 Contamination of surface water, groundwater and soil Human exposure Visual pollution 	MAJOR	Site workers – Medium Çubuk stream – High Soil – High Groundwater – High Surroundings – Low	CRITICAL
Waste batteries generation from staff and operation activities	 Contamination of surface water, groundwater and soil Visual pollution 	MAJOR	Site workers – Low Çubuk stream – High Soil – High Groundwater – Medium Surroundings – Low	CRITICAL
Waste electrical and electronical equipment generation from operation and maintenance activities	 Contamination of surface water, groundwater and soil Visual pollution 	MAJOR	Site workers – Low Çubuk stream – High Soil – Low Groundwater – Medium Site workers – Low Surroundings – Low	CRITICAL
Waste vegetable oil generation from restaurants groun and so Visual polluti	mination MODERATE face dwater bil on	Site workers – L Çubuk stream – Soil – Medium Groundwater – Medium Surroundings –	ow MAJOR High Low	
Hazardous waste generation such as contaminated packaging, HVAC filters, paints, chemicals, solvents, animal shelter cleaning materials, end of used animal shelter, cartridges, adhesives from laboratories, offices and maintenance activities	 Human exposure Contamination of surface water, groundwater and soil Visual pollution 	MAJOR	Facility personnel – High Çubuk stream – High Soil – High Groundwater – High Surroundings – Medium	CRITICAL

Impact Source	Impact	Magnitude of the Impact	PossibleSignificance ofReceptor/s andImpacttheir Sensitivity
Medical waste generation such as experimental serum from large animals, animal parts / tissue, sharps and needles, expired medicine, animal food residues, liquid waste	 Contamination of surface water, groundwater and soil Human exposure Visual pollution Odour generation 	MAJOR	Facility personnel – CRITICAL High Experimental animals – High Çubuk stream – High Soil – High Groundwater – High Surroundings – Medium
Laboratory wastewater from all laboratory sinks, showers, autoclave chambers and floor drains (Different biosafety levels) (Should be separately collected)	 Contamination of surface water, groundwater and soil Human exposure Visual pollution Odour generation 	MAJOR	Facility personnel – CRITICAL High Experimental animals - High Çubuk stream – High Soil – High Groundwater – High Surroundings – Medium
Non-hazardous waste such as metal scrap, wood scrap and plastic scrap	imination of surface water, dwater and soil I pollution	MODERATE	Site workers – MODERATE Low Çubuk stream – Low Soil – Medium Groundwater – Medium Surroundings – Low
Radioactive waste generation as radioactive pharmaceuticals	n, plant MAJOR Facility per nimal Plants – Hi sure Animals – I Surroundin	sonnel – High gh High gs – High	CRITICAL

* "Surroundings" refer to both the environment and its communities around the project site.

8.4 Mitigation Measures

8.4.1 General

Minimisation and in some cases elimination of the defined impacts can be achieved by implementation of the mitigation measures defined in this section.

Although impacts related with materials use mostly result in indirect effects on the environment and human health, there exists several mitigation measures to be taken into account for the minimisation of related impacts, such as the listed below:

- Use natural resources as little as possible and to use clean technologies in order to minimize waste generation.
- Prefer environmentally friendly products and the products that will result in less negative impact on the environment and ecological systems once reached to end-of-life stage.
- Use of recycled products in order to reduce the use of natural resources and energy.
- Use energy-efficient equipment and processes during the Project lifecycle.

• The Project will minimize (and where possible avoid) the use of fluorinated gases in refrigeration, air conditioning and heat pump equipment and systems, and comply with the use and reporting requirements set forth in the applicable regulation in relation to all fluorinated gases.

Waste management is a series of techniques and principles which are implemented to keep the human health and environment safe and to keep the waste generation minimum. It has basic principles and philosophy to manage the waste properly, economically and safely. Thus, the general principles of waste management, which will be applied during both construction and operation phases of the Project, are given below to create a framework for the Project:

- Waste management will be done according to relevant Turkish Environmental Legislation as well as International Standards. Certain waste types must be managed according to related regulations.
- The primary purpose of the waste management practices shall be using methods and processes that will generate the minimum amount of waste during the Project lifecycle. In cases where that is not possible, it is critical to focus on implementing measures that will reduce the generated waste from Project-related activities.
- In cases where waste generation is unavoidable, it is essential to reuse, recycle and recover secondary raw materials, use them as an energy source or dispose of them in a hierarchical order.
- It is essential to use methods and processes that will not pose a risk to water, air, soil, plants, animals and people and to protect the environment and human health during collection, temporary storage, transportation and processing of wastes.
- It is essential that different types of wastes are classified and collected separately, without mixing with other wastes at their source/where they are produced.
- Certain waste types will be transported via licensed waste haulers as well as recycled and disposed in licensed facilities. Waste producer is responsible to use the licenced bodies for relevant operations.
- It is essential that the wastes are transported to the closest and most suitable facility to be processed using appropriate methods and technologies.
- Facilities must have a temporary waste storage area or building to store their waste onsite prior to sending to the licensed third-party waste management facilities.
- Each waste producer will prepare a Waste Management Plan and apply to the environmental authorities for approval and implementation of the plan. The medical waste management is integrated to the Waste and Wastewater Management Plan prepared for the Project¹¹⁵.
- Waste producer will declare the last years waste generation and management data using the online applications prepared by the Ministry of Environment, Urbanization and Climate Change (MoEUCC).
- The parties responsible for waste management are obliged to provide training to their relevant personnel in order to reduce the negative effects of waste on the environment and to manage it safely in the process from production to disposal.
- Wastewater will be managed according to relevant legislation, especially the wastewater from laboratories will not be mixed with domestic wastewater.
- Laboratory wastewater will be decontaminated in a wastewater decontamination unit prior to discharge to sewer.

In addition, the proposed Project will adhere to the application of salient practices from the WBG EHS Guidelines for Wastewater and Ambient Water Quality (Guideline Section 1.3), Hazardous Materials Management (Guideline Section 1.5) and Waste Management (Guideline Section 1.6) regarding material use, waste and wastewater management.

• Wastewater Management: Discharges of industrial wastewater, domestic wastewater, or stormwater into public wastewater treatment systems will follow the below defined measures:

213

¹¹⁵ Regulation on Control of Medical Waste (25.01.2017/29959) indicates that medical waste management plans can be integrated into the Waste Management Plan, which includes the management of all wastes.

- Pretreatment and monitoring requirements of the sewer treatment system into which it discharges will be met.
- It will be ensured that the Project do not interfere, directly or indirectly, with the operation and maintenance of the collection and treatment systems, or pose a risk to worker health and safety, or adversely impact characteristics of residuals from wastewater treatment operations.
- It will be ensured that the wastewater discharges are done into municipal wastewater treatment systems that have adequate capacity to meet local regulatory requirements for treatment of wastewater generated from the project.
- Waste Management: Will be addressed through a waste management system that addresses issues linked to waste minimization, generation, transport, disposal, and monitoring:
 - Waste Management Planning:
 - New waste sources will be reviewed during planning, siting, and design activities, including during equipment modifications and process alterations, to identify expected waste generation, pollution prevention opportunities, and necessary treatment, storage, and disposal infrastructure,
 - Data and information will be collected regarding the process and waste streams in existing facilities, including characterization of waste streams by type, quantities, and potential use/disposition,
 - Priorities will be established based on a risk analysis that takes into account the potential EHS risks during the waste cycle and the availability of infrastructure to manage the waste in an environmentally sound manner,
 - Opportunities will be defined for source reduction, as well as reuse and recycling,
 - Procedures and operational controls will be defined for on-site storage, treatment and final disposal.
 - Waste Prevention:
 - Raw materials or inputs will be substituted with less hazardous or toxic materials, or with those where processing generates lower waste volumes where applicable.
 - Good housekeeping and operating practices will be governed, including inventory control to reduce the amount of waste resulting from materials that are out-of-date, off-specification, contaminated, damaged, or excess to Project site needs.
 - Procurement measures which recognize opportunities to return usable materials such as containers and prevents the over ordering of materials will be instituted.
 - Hazardous waste generation will be minimized by implementing stringent waste segregation measures.
 - Recycling and Reuse:
 - Production processes will be evaluated, and potentially recyclable materials will be identified.
 - Recycling objectives will be identified, and waste generation and recycling rates will be tracked continuously during both phases of the Project.
 - Training and incentives will be provided to employees regarding waste management options.
 - Treatment and Disposal:
 - Treatment or disposal of the Project-related waste will be performed at permitted facilities specially designed to receive the waste.
 - Hazardous Waste Management:
 - Potential impacts and risks associated with the management of any generated hazardous waste during its complete life cycle will be clearly defined.

- It will be ensured that contractors handling, treating, and disposing of hazardous waste are reputable and legitimate enterprises, licensed by the relevant regulatory agencies and following good international industry practice for the waste being handled.
- Compliance with applicable local and international regulations will be ensured.
- Hazardous Materials Management: The overall objective of hazardous materials management is to avoid or, when avoidance is not feasible, minimize uncontrolled releases of hazardous materials or accidents (including explosion and fire) during their production, handling, storage and use through the main measures defined below:
 - Hazardous materials management priorities will be established based on a hazard analysis of risky
 operations that are identified for both construction and operation activities.
 - Use of hazardous materials is avoided or minimized, where practicable.
 - Uncontrolled releases of hazardous materials to the environment or uncontrolled reactions that might result in fire or explosion will be prevented.
 - Engineering controls (e.g., containment, automatic alarms, and shut-off systems) that commensurate with the nature of the hazard will be used.
 - Management controls (e.g., procedures, inspections, communications, trainings, and drills) will be implemented to address residual risks that have not been prevented or controlled through engineering measures.

Mitigation measures regarding material resources and waste management practices specifically related with construction and operation phases of the Project are detailed below.

8.4.2 Construction Phase

Material Resources

The following material use and handling measures will be considered and imbedded into the construction phase procedures as appropriate:

- Hazardous material handling and storage areas will be established during the construction phase. Details of correct procedures for handling and storing any hazardous materials will be defined and implemented through the Chemicals and Hazardous Materials Management Plan.
- Implement the Resource Efficiency Management Plan in order to make efficient planning of the construction activities to minimize materials and optimizing the use of resources to avoid potential wastage.
- Set up procedures for identifying and dealing with contaminated soils and materials if encountered during construction, including appropriate storage and disposal. Should any soils be suspected as being contaminated, then samples will be analysed to see if corrective action is required. Contaminated soils will be disposed of in an appropriately licensed disposal site.
- It will be ensured that relevant trainings are provided to the workers regarding material use and hazardous material and waste management measures.
- Assess environmental and social performance of a supplier to ensure that materials are sourced with sustainability principles. Establish systems and verification practices (i.e. purchasing/supplier evaluation procedure) to identify where the supply is coming from and the habitat type of the source area and to limit procurement to suppliers that can demonstrate that they are not contributing to significant conversion or degradation of natural or critical habitats where possible.
- Source materials from local suppliers wherever possible to minimize impacts of transport.
- Engage with suppliers to substitute raw materials or inputs with less hazardous or toxic materials wherever economically and technically feasible.

Waste and Wastewater

Techniques for prevention, minimization and control of waste related impacts during the construction phase include:

- The contractor shall collect and segregate the wastes properly to encourage recycling of some useful waste materials.
- Packaging waste will be separately collected in dedicated bins within the construction site. Necessary
 number of bins will be located at proper points in order to effectively collect the packaging materials.
 Paper and cardboard materials will not be wetted with liquid to increase the recycling and further
 recovery rate of the materials.
- Domestic waste will be separately collected in dedicated domestic waste bins.
- All waste bins will have its waste type label (e.g., Packaging waste, Domestic waste) and necessary detailed information about the excluded waste type on the bins.
- Waste oil will be analysed to claim it is non-hazardous with analyses made by laboratories authorized by the MoEUCC.
- Hazardous wastes will not be mixed with other waste types and will be transferred to the third-party licensed disposal facilities.
- Wastes will be temporarily stored at waste storage area at site that meets the regulatory requirements such as impermeable ground by concrete and geotextile layer, closed top but open sides, accesscontrol by locked entrance to avoid unauthorized access, equipped with drainage channel and pit to hold the possible spills, fire extinguisher, and spill response kit placement.
- Domestic waste will be collected from the site daily by the municipality and temporarily stored on site within the domestic waste containers until daily collection.
- Adequate secondary containment will be provided for fuel storage tanks and for the temporary storage of other fluids such as lubricating oils and hydraulic fluids.
- Impervious surfaces will be used for refuelling areas and other fluid transfer areas.
- Portable spill containment and clean-up equipment will be provided onsite at appropriate locations.
- Workers will be trained on the correct transfer and handling of fuels and chemicals and the response to spills.
- Hazardous materials and petroleum-based products in building systems (e.g. PCB containing electrical equipment, asbestos-containing building materials) will be assessed and removed prior to decommissioning activities, and their treatment and disposal will be appropriately managed.
 - In case of detection of asbestos-containing materials during any construction activities (particularly due to the demolition of the existing warehouse building on the Project site), below listed mitigation measures will be implemented:
 - Requirements of Turkish Regulation on Health and Safety Measures for Working with Asbestos will be strictly followed.
 - Works including asbestos removal will be done under the supervision of an "asbestos removal expert", who is expected to have a vocational training certificate.
 - The Provincial Directorate of Labour and Employment Institution will be informed.
 - Proper personal protective equipment and appropriate respiratory protection will be used.
 - Proper contamination measures will be conducted to keep the environment safe.
 - Necessary markings for asbestos will be posted within the construction site and warning signs will be hung where necessary.
 - Where asbestos removal is required, wetting agent will be used to keep asbestos dust to a minimum before dismantling.
 - Working and exposure time to asbestos will be recorded. Records are retained for at least 40 years after exposure to asbestos dust has ceased.
- The places reserved for eating and drinking will be chosen outside the areas where there is a risk of contamination with asbestos dust.
- Personal protective equipment will not be taken out of the workplace. Protective clothing is cleaned within the workplace or where cleaning work is conducted and will only be removed in closed containers.
- Asbestos wastes will be collected separately from other wastes and disposed of according to the requirements of Waste Management Regulation.
- Where asbestos-containing waste is needed to be stored temporarily, this hazardous waste will be kept in securely closed containers and will be appropriately labelled.
- Regarding the works including a risk of exposure to asbestos dust, a risk assessment will be made by considering the type and physical properties of asbestos and the degree of exposure of workers.
- Removed asbestos will not be reused for any purposes.
- Communiqué on Educational Programs on Asbestos Removal will be considered.
- Procedures will be set up for identifying and dealing with contaminated soils and materials if
 encountered during construction, including appropriate storage and disposal. Should any soils be
 suspected as being contaminated, then samples will be analysed to see if corrective action is required.
 Contaminated soils will be disposed of in an appropriately licensed disposal site.

Measures for prevention, minimization, and control of wastewater related impacts during the construction phase include:

- Develop and implement a construction site management plan.
- Apply good construction practices.
- Provide pre-treatment to the industrial wastewater prior to discharge to the sewer system.
- Implement the construction phase Waste and Wastewater Management Plan.
- Obtain necessary permits for connection to the municipal sewer system.
- Monitoring and recording keeping of wastewater discharges.

Aforementioned mitigation measures for the construction stage of the Project are summarized in

Table 8-11.

Table 8-11: Mitigation Measures / Management Options of the Waste and Wastewater Generation During the Construction Phase

Waste	Impact	Significance of the Impact	Mitigation Measure / Management Option (according to the Turkish Environmental Legislation)
Excavation soil, demolition waste and cleared vegetation	 Fugitive dust emission on site Worker exposure to dust Worker exposure to asbestos (if any) Worker exposure to abandoned vaccines (if not removed prior to demolition) Contamination of surface water, groundwater and soil Traffic load 	MODERATE CRITICAL (if asbestos exists) (if vaccines not removed)	Do not mix excavation soil with the demolition waste and topsoil. Reuse of the excavation soil in levelling and landscaping as appropriate. Wetting the soil with water spray during excavation to avoid excessive dust generation. Selectively demolish the existing building, remove the window glass, wooden parts, plastic materials, hazardous materials, asbestos containing materials (ACMs), and recyclables as well as abandoned vaccines prior to demolition works. Conduct ACM removal by authorized companies. Put the removed ACM in labelled bags with necessary precautions about asbestos and send the waste ACMs to licensed disposal facilities. Put the abandoned vaccines in labelled medical waste bag and send the licensed disposal facilities.

Waste	Impact	Significance of the Impact	Mitigation Measure / Management Option (according to the Turkish Environmental Legislation)
		·	Transfer the selected waste with appropriate vehicles to relevant licensed/permitted third-party waste management facilities according to the Turkish environmental legislation. Transfer the remaining demolition waste to the dedicated excavation waste disposal areas determined by the Ankara Metropolitan Municipality.
Construction waste	 Contamination of surface water, groundwater and soil Traffic load Visual pollution 	MINOR	Do not mix excavation soil with the construction waste. Transfer of the construction waste to dedicated disposal areas determined by Ankara Metropolitan Municipality.
Household similar waste and biodegradable waste	 Contamination of surface water, groundwater and soil Vector generation Visual pollution Odour generation 	MODERATE	Separate collection of domestic waste and storage in dedicated closed top domestic waste containers. Avoid mixing domestic waste with other waste types. Periodically deliver the domestic waste container to municipality collection truck (periodic collection by municipality) to further landfill disposal. If applicable, separately collect food waste for further composting.
Black water / Grey water	 Contamination of surface water, groundwater and soil Vector generation Visual pollution Odour generation 	CRITICAL	Direct discharge into the nearby sewage network with proper line connection and discharge permit.
Industrial wastewater	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Installation of necessary pre-treatment on-site. Pre-treatment with sand trap and oil separator then discharge to sewerage system of ASKI.
Cardboard, plastic, glass and metal packaging waste	Contamination of surface water and soilVisual pollution	MAJOR	Separate collection of packaging waste and storage in dedicated waste bins. Avoid wetting and mixing with other types of waste. Periodically transfer to licenced recycling facility with necessary documentations.
Hydraulic fluids and lubricants	 Contamination of surface water, groundwater and soil Worker exposure Visual pollution 	CRITICAL	Analyses for determination of the waste oil group (if only one waste oil source, no need for analysis). Separate collection of waste oils and storage in dedicated oil drums/containers. Do not mix different group waste oils with each other. Transfer of the waste oils to the licenced refinery, co-incineration or incineration facilities with licenced transporters, according to the waste oil analyses results.
Waste batteries	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Separate collection of waste batteries in waste battery box. Transfer to TAP (Portable Battery Manufacturers and Importers Association of Turkiye) for handling and final disposal.
Waste electrical and electronical equipment (WEEE)	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Separate collection of WEEE in dedicated containers. Transfer of the WEEE to licenced recycling and disposal facilities by the licenced transporters.
Waste tires	Contamination of surface water and soilVisual pollution	MINOR	During tire change, deliver the waste tires to the authorized dealer for recycling.
Contaminated packaging, contaminated fabrics/filters, paint and chemicals, solvents and	 Contamination of surface water, groundwater and soil Human exposure Visual pollution 	CRITICAL	Separate collection of hazardous waste and storage in containers labelled with waste code at dedicated designated areas in accordance with the proper storage measures that is needed to be taken. Do not store hazardous waste on site more than 6 months.

Waste	Impact	Significance of the Impact	Mitigation Measure / Management Option (according to the Turkish Environmental Legislation)
chemicals, contaminated soil			
Non-hazardous waste such as metal scrap, wood scrap and plastic scrap	 Contamination of surface water, groundwater and soil Visual pollution 	MODERATE	Separate collection, storage and transfer to licensed recycling facilities.
Medical waste as basic infirmary waste	Worker exposureVisual pollution	INSIGNIFICANT	Collect medical waste in red medical waste bag in the infirmary. Store the waste bags in the infirmary at a designated temporary storage area away from operation activities. Transfer of the small amount of medical waste to the nearby Local Health Clinic.

8.4.3 Operation Phase

Material Resources

Following material use and resource management practices will be applied for the sustainable operation of the Project:

- During the detailed design and procurement stage, sources will be identified for all materials and equipment to be used for the Project in consideration of environmental aspects. This will include using less harmful materials where possible and considering the impacts of extraction, processing and transport. In particular, it will be essential to source materials from locations as close as possible to the Project site to minimize the impact of transport, use recycled materials and materials certified as being from "green" or lower carbon sources where practicable.
- Integrate sustainability and resource efficiency practices into the Project during the design phase and address them during the supplier procurement process.
- Implement the Resource Efficiency Management Plan to efficiently plan the operation for minimizing materials and optimizing the use of resources to avoid potential wastage.
- During the operation, establish systems and verification practices (i.e. purchasing/supplier evaluation procedure) to identify where the supply is coming from and the habitat type of the source area and to limit procurement to suppliers that can demonstrate that they are not contributing to significant conversion or degradation of natural or critical habitats.
- Implement the Chemicals and Hazardous Materials Management Plan to manage and minimize potential impacts regarding the transportation, use, and storage of chemicals and hazardous materials during the operation phase that might effect the workers, communities and the environment.
- Hazardous materials will be stored within secured and designated areas of the facility in containers and tanks located in bunded areas which can hold a minimum of 110% of the total storage volume.

Since the Project is water-intensive in terms of laboratory operations, the following measures will be taken during design, procurement and operation phases of the Project to identify opportunities for water conservation:

- Assess water saving opportunities and water efficiency measures without compromising decontamination and sterilization:
 - Optimizing boiler performance and regular system maintenance.
 - Staff awareness of efficient use of water (catering, dishwashing, laundry).
 - Rainwater harvesting will be implemented which may offset impacts of peak flows and the harvested water will be used for irrigation purposes saving on the use of water from the supply network.

- The essential elements of water management during the operational phase of the Project will involve identification, regular measurement and recording of principal flows within the facility, definition and regular review of performance targets, regular comparison of water flows with performance targets to identify where action should be taken to reduce water use.
- Implementation of the operation phase Resource Efficiency Management Plan.

Energy Efficiency

Operation phase of the Project will be energy-intensive due to operational activities that will take place to ensure biosafety conditions of the facility. Therefore, the Project aims, to extend possible, adopting energy efficiency measures during operation activities in order to minimize negative impacts on the environment due to electricity use and heating purposes.

Please refer to Section 9.4.2 in Chapter 9: Air Quality for the measures that will be taken during procurement and operation phases of the Project to identify financially feasible opportunities for improvement in energy conservation.

General Waste

All waste types generated by the Project will be managed properly and in accordance with Turkish environmental legislation, as well as relevant international standards. General mitigation measures which will be implemented regarding the overall waste management are as follows:

- Planning: Waste management plans (including Medical Waste Management Plan) in accordance with the national and international standards will be developed and implemented. The management plan acknowledges the key waste management practices such as, waste minimization, proper collection, segregation, storage, transportation, treatment and disposal of the waste, which in turn ensures that personnel safety is maintained and environmental harm is minimized.
- Training: Laboratory staff will be trained on waste handling and disposal techniques. Correct and efficient waste management will only be achieved through rigorous training of employees, supervisors and managers.
- Minimization: Waste minimization will be integrated in the management plans to ensure that all laboratory section minimize their waste generation to the barest possible minimum at source. Accordingly, following strategies will be considered as waste minimization strategies:
 - Make purchasing restrictions to ensure the selection of less wasteful materials.
 - Recycle materials and products if applicable.
- Proper segregation of waste at source will be implemented. Segregation involves placing different classes of wastes into separate and appropriate temporary storage color-coded containers/bags as recommended by the national legislation and WHO.
 - Containers will be appropriate for the type of waste involved. Sharps will be placed in rigid, puncture-resistant containers made of glass, metal, rigid plastic, or cardboard. Liquid infectious wastes would be placed in capped or tightly stopped bottles or flasks; large quantities may be placed in containment tanks. Solid or semisolid wastes would be placed in tear-resistant plastic bags judged by their thickness or durability.
 - All waste bags or containers will be labelled. Basic label information would include type of waste in the container, name of the laboratory section, date of collection and warning of hazardous nature. Labelling is important to identify the source of the waste or date of generation in case of an accident or improper segregation of the waste, and to ensure that the workers responsible for waste management handle the different types of wastes safely.
 - Packaging waste will be separately collected in dedicated packaging waste bins within the facility.
 - Domestic waste will be separately collected in dedicated domestic waste bins.

- All waste bins must have its waste type label (e.g., Packaging waste, Domestic waste) and necessary detailed information about the excluded waste type on the bins.
- Waste vegetable oil from the restaurants will be collected in dedicated vegetable waste oil containers.
- Wastes marked with the letter "M" in the waste list is needed to be analysed to claim it is nonhazardous with analyses made by laboratories authorized by the MoEUCC.
- Storage: Separately collected waste will be temporarily stored onsite prior to transfer to further recycling and disposal. A waste building which has two cold storage rooms is planned to be built within the Project to fulfil this requirement. Waste building will be used to store all types of waste which will be generated during the operation phase, before sending the waste to licensed recycling or disposal facilities. All generated waste will be transferred from the operation buildings to the waste building via underground galleries. Waste management actions including the temporary storage on site will be given in the Waste Management Plan. Basic principles of temporary waste storage to be followed are given below:
 - Stored waste will be labelled with its characteristics as hazardous or non-hazardous waste, with the waste code, with the amount stored and the date of storage. Except for medical wastes, hazardous wastes are stored in the temporary storage area for a maximum of six months and non-hazardous wastes for a maximum of one year.
 - For the temporary storage of medical wastes, the provisions of the Regulation on Control of Medical Wastes¹¹⁶, which is in line with the international standards, will be applied.
 - If the hazardous waste amount will be less than 1000 kg/month, the temporary store area will be exempt from the temporary storage permit. On the contrary, if the hazardous waste amount will be 1000 kg/month or more, a temporary storage permit will be obtained from the provincial directorate.
 - Municipal waste, packaging waste, non-hazardous waste and medical waste temporary storage containers are exempt from the temporary storage permit.
 - Medical/laboratory waste storage requirements are defined below in accordance with the relevant regulations and standards.
 - In case of radioactive waste generation, first put the radioactive waste in tightly bound medical waste bag and then in a lead box. Label the bag and the box with the type of radioisotope and the date of storage. Store the radioactive waste until at least 10 half-lives have passed then measure the dose. If the radiation dose has fallen below the Legislation limits, treat the waste as medical waste. Inform the Turkish Energy, Nuclear and Mining Research Authority (formerly known as the Turkish Atomic Energy Authority).
 - Dangerous Goods and Hazardous Waste Compulsory Financial Liability Insurance must be obtained for hazardous waste temporary storage area, regardless of the amount.
- Waste transportation to recycling and disposal facilities: Waste recycling and disposal are the final step of waste management. All types of waste shall be sent to proper recycling and disposal facilities according to the legislative requirements via appropriate licensed vehicles.
- Monitoring: Regular visual inspection/audits for waste management strategies will be performed and audit mechanism will be integrated in the management plans.
 - All waste storage collection and storage areas will be inspected for evidence of accidental releases and to verify that wastes are properly labelled and stored.
 - Implementing regular audits of waste segregation and collection practices.
- Recording:
 - Tracking of waste generation trends by type and amount of waste generated.
 - Keeping records and documentation for the amount of waste generated and its destination.

¹¹⁶ Published in the Official Gazette dated 22/7/2005 and numbered 25883

BSL3 Laboratory and Vaccine Production Waste and Wastewater

The proposed BSL3/ABSL3 laboratories will have procedures for compliance with all applicable regulations for collecting, storing and processing sanitary liquid wastes, solid wastes and hazardous wastes generated during the activities in the complex. To apply the appropriate method for waste management, the laboratory will perform a risk assessment through taking the points below into consideration:

- Facilities and decontamination methods available,
- Type and volume of waste,
- Method of decontamination,
- Segregation categories (uncontaminated, contaminated, sharps, glass),
- Packaging, labelling and transport,
- Presence of radioactive material,
- Presence of chemicals, and
- Recycling and reuse requirements.

For management of the medical wastes produced within the scope of the Project, Regulation on Control of Medical Waste¹¹⁷ will be followed along with the international standards. According to the information received from the personnel responsible for the design of laboratories within the MoH, medical waste management systems within the scope of the Project will be designed in accordance with the following standards: WHO Laboratory Biosafety Guide, American National Institute of Health (NIH) standards, and TS EN 12128¹¹⁸. Solid and liquid form of medical wastes will be decontaminated in line with the defined decontamination procedures. Decontamination will be the responsibility of the person/laboratory generating the waste. Details about the waste management of biosafety laboratories will be given in Waste and Wastewater Management Plan under the light of above sources.

Mitigation measures proposed regarding waste management in BSL3 laboratories are presented below. Further details on waste decontamination procedures are discussed in *Chapter 14: Community, Health, Safety and Security.*

- Decontamination:
 - All waste materials produced in the BSL3 laboratory must be considered as contaminated.
 Decontaminated solid waste will be defined as medical waste. Medical wastes will be transferred to the Waste Building via galleries which are designed underground to be collected and disposed of in the medical waste disposal facilities by authorized companies. All wastes from BSL laboratories will be marked as "biohazard waste" prior to disposal in designated containers.
 - All the materials must be decontaminated before leaving the laboratory. These materials may cover the following:
 - All kinds of breeding culture material, stock cultures.
 - Any material contaminated with body fluids such as blood, peritoneum, pleura, pericardium and synovial fluids, amnion fluid, vaginal secretions, semen, and any material visibly contaminated with blood, excluding urine, sweat, tears, feces, saliva, sputum.
 - Any material that has come into contact with infectious agents (e.g., petri dishes, pipette tips).
 - All types of genetically modified organisms, vectors, live vaccine strains.
 - Double-doored autoclave will be used for sterilization / decontamination of materials.
 - Laboratory wastewater generated from the sinks and the showers must be decontaminated in the wastewater decontamination unit before discharged to the sewer network. Liquid wastes will be

¹¹⁷ Official Gazette date/number: 25.01.2017/29959

¹¹⁸ TS EN 12128: 2002: Bio-Technology Research-Development and Analysis Laboratories - Safety levels, risk areas, locations and physical safety rules for micro-biology laboratories

separately collected from the laboratory wastewater and stored in preliminary storage tanks and treated with thermo-chemical processes in the liquid waste decontamination unit planned to be installed at basement level of the Vaccine Production Building. After pH and temperature of the decontaminated wastewater is adjusted to comply with discharge criteria, it will be discharged to the sewerage system.

- All medical solid waste, microbial cultures and disposables will be decontaminated where the waste production takes place with either autoclave or hydrogen peroxide daily, prior to being taken out of the laboratory for disposal.
- The sterilized materials will be disposed from the part of the double-door autoclave that opens to the outer corridor and put in a medical waste bag and sent to the third-party incineration facility.
- Animals (dead) and animal residues (tissues, body parts, bodily fluids, etc.) which are classified as
 pathological waste will be autoclaved for decontamination. The autoclaved waste will then
 transferred to a third-party licensed incineration facility.
- Body fluids in animal cutting pans will be autoclaved.
- Ventilation filters will be changed annually by trained personnel. HEPA filters will be removed by decontaminating with a suitable disinfectant (formaldehyde, etc.), and each of them will be disposed of as medical waste by placing them in separate medical waste bags.
- Segregation and Collection: Proper segregation of waste at generation source is essential in managing biosafety laboratory wastes. Laboratory waste is medical waste which must not mixed with other types of waste. Basic principles of waste segregation and collection of waste in laboratories to be followed are given below:
 - Medical waste is separately collected from all other waste types.
 - Infectious wastes and pathological wastes are collected in red bags.
 - Sharp and penetrating wastes, separate from other medical wastes, are collected in the boxes or containers made of plastic or laminated cardboard with the same characteristics, which is resistant to puncture, tear, breakage and explosion, impermeable, impossible to open and mix, bearing the international biohazard mark and "Attention! Cutting and Piercing Medical Waste" phrase on it. Sharp-piercing waste containers are never compressed, opened, emptied or recycled after they are filled. In dealing with sharps:
 - Ensure fully and properly assembled safety boxes before lab activities.
 - Properly label the safety boxes.
 - Sharps containers will be placed in close proximity within arms reach.
 - Needles will not be recapped or bent when handling.
 - Syringe will be placed in a safety box immediately.
 - Seal and collect safety boxes when they are $\frac{3}{4}$ full and never empty or open.
 - Safety box will not be shaken to settle their contents.
 - Safety boxes will not be placed in high traffic areas (corridors outside laboratory rooms or sample preparation rooms) to prevent possible laboratory accidents.
 - Containers will not be placed on the floor or anywhere they could be knocked over.
 - Biohazard bags leaving the laboratory will be transported and stored in a safe way, by using a secondary container or a trolley or any other means that prevents contamination of the floor and walls of the storage site. The waste segregation and the collection frequency are summarized in Table 8-12 according to the national legislation, which are in line with the international standards and guidelines.

Waste categories	Colour of container and markings	Type of container	Collection frequency
Infectious waste	Red with biohazard symbol (marked as highly infectious waste)	Leak-proof autoclavable strong plastic bag placed	When ¾ is full or at least once a day
Sharps	Yellow, marked as sharps with biohazard symbol	Puncture-proof container	Filled to the line or 3/4
Pathological waste (Samples of Blood, Blood Products and Tissues of Animal Origin)	Red with biohazard symbol	Leak-proof autoclavable strong plastic bag	When ¾ or at least once a day.
Chemical Waste	Preferably plastic drums marked with appropriate hazard symbol	In sealed, screw-top containers (preferably plastic drums), not glass	On demand (depending on the SDS document of chemical)
Non-Hazardous Waste	Black	Plastic bag inside a container or container which is disinfected after use	When ¾ is full or at least once a day

Table 8-12: Waste segregation and the collection frequency

- There will be two 50-ton liquid waste tanks and two 5-ton decontamination tanks at the facility. Liquid wastes originating from BSL3 areas will be discharged to the sewer after decontamination. Liquid wastes generated in other laboratories and production areas will be collected in tanks than will be analysed and discharged to sewer if the limits are met. Otherwise, those liquid wastes are decontaminated in order to reach the limits like liquid wastes from BSL3 laboratories prior to discharge.
- The wastewater generated in the sinks and showers in the BSL3 laboratories will not be mixed into the domestic wastewater line; thus, the domestic wastewater lines and the laboratory wastewater lines will be separately designed and installed. Laboratory wastewater will be taken to the liquid waste tanks and given to the sewer after decontamination.
- Temporary Storage on Site¹¹⁹: Storage is classified into internal and external. Internal storage is the temporary placement of waste at the point of generation before transfer to external storage points. External storage refers to the transit point where waste is stored after removal from primary storage to the time it is collected and transported for treatment and final disposal. The storage areas will be totally enclosed and secured from unauthorized access, be inaccessible to animals and insects, and easy to clean and disinfect with an impermeable hard-standing base and ventilation. There would be planned periodic cleaning and disinfection of temporary storage areas and the containers. Spilled medical wastes will be collected with appropriate equipment and liquid wastes are collected with absorbent material. Collected wastes and contaminated absorbent materials are placed in medical waste bags and treated as medical waste.
 - Principles to be followed in laboratory waste temporary storage on site are given below:
 - An internal storage location for the laboratory wastes would be designated inside the BSL3 laboratory, appropriate to the quantity of waste produced bearing in mind the frequency of collection. The storage time for the laboratory wastes before it is transferred to the Waste Building would be on daily basis.
 - Laboratory medical waste will not be stored more than 48 hours in ambient temperature and one week at 4°C at the Waste Building.
 - The Waste Building (i.e. temporary waste storage area) will be a closed space with minimum two compartments. One will be used for medical waste and hazardous waste and the other one will be used for remaining waste types.

¹¹⁹ Surveillance and Control of Infectious Diseases Project (TR0802.16), National Microbiology Standards, LABORATORY SAFETY GUIDE, Ministry of Health, Public Health Institution of Turkey, Department of Microbiology Reference Laboratories, Ankara – 2014

- The capacity of the Waste Building will be large enough to accommodate at least two days' waste, easily accessible by the waste haulers, and the doors will be open out and in dimensions where wastes can be emptied easily.
- The proposed Project will establish two external cold storage rooms in the Waste Building. The requirements for external storage will include:
 - Ensure that waste is kept separated according to colour coded bags/containers.
 - The walls and floors would be smooth, without cracks, impervious, easy to clean and disinfect.
 - The site will be spacious, well ventilated and lit.
 - The site will be monitored for temperature and humidity.
 - All loading and unloading of waste would take place within the designated collection area.
 - Larger volume waste bins would be available at the external storage facility to receive waste containers from the internal storage points.
- Waste Transportation and Final Disposal: All medical waste will be sent to the licensed third-party
 medical waste management facilities or municipality facilities with licensed waste haulers according to
 legislative requirements. The transportation documentation will be prepared via the mobile waste
 monitoring system (MoTAT) of Ministry of Environment, Urbanization and Climate Change (MoEUCC)
 before transportation and kept for 5 years. Necessary online declarations to the ministry are done
 periodically by waste producer. According to the national environmental legislation, incineration
 furnace will not be used within the Project area.
 - On-site transportation: The on-site transport involves conveying of wastes from the various points of generation within a laboratory to a temporary storage location. The following points will be adhered to when carrying out on-site transportation and every effort will be made to avoid unnecessary handling of the laboratory wastes:
 - The vehicles and containers used for the transportation of the laboratory waste will not be used for other purposes.
 - Waste that has the potential to leak will be double bagged. All waste bags will be intact at the end of transportation.
 - Waste bags will be placed in appropriate containers before being placed directly into the transportation vehicle.
 - The collected waste will not be left unattended even temporarily anywhere other than at the designated storage room.
 - Containers will be covered with lids during storage and transport.
 - Waste management personnel will be properly trained and will use PPE (e.g., protective masks, gloves, goggles, clothing) during handling the waste as mentioned in the Waste and Wastewater Management Plan.
 - Off-site transportation: During the transportation of waste outside the complex following safety precautions would be included:
 - Staff will be properly trained in the handling, loading and unloading, transportation, emergency issues and disposal of waste.
 - It will be ensured that waste management personnel of the contracted external waste management companies use necessary PPE during handling of facility's waste.
 - Single-bagged waste and containers of sharps and liquids will be placed within a rigid/semi-rigid container.
 - Containers will be covered with lids during transportation.
 - Outside the complex, infectious waste will be transported in closed, leak-proof, rigid containers using trucks. Infectious waste will not be compacted before treatment.

- The vehicles used for the transportation of the laboratory wastes will not be used for other purposes. The vehicles will be fully enclosed to prevent any spillage in the facility premises or on the road during transportation.
- The vehicles will carry adequate supplies of plastic bags, all kinds of PPEs, disinfecting and emergency kits in case of any spillage/incident.
- Staff will be fully aware of emergency procedures for dealing with accidents and spillage.
- Wastewater discharge: Necessary permits for connection to the municipal sewer system will be obtained.
- Responsibilities in Laboratory Waste and Wastewater Management: There will be a Biosafety Board and a Biosafety Officer monitoring waste and wastewater management in BSL3 laboratories. Additionally, the Occupational Health and Safety unit will co-work with the personnel to implement and follow the health and safety procedures in management of waste/wastewater.
- Aforementioned mitigation measures related with the operation phase of the Project are summarized in Table 8-13.

Table 8-13: Mitigation Measures / Management Options of the Waste and Wastewater Generation During the Operation Phase

Waste	Impact	Significance of the Impact	Mitigation Measure / Management Option (according to the Turkish Environmental Legislation)
Household similar waste and	hold similar • Contamination of MI and surface water,	MINOR	Separate collection of domestic waste and storage in dedicated closed top domestic waste containers.
biodegradable	Vector generation		Avoid mixing domestic waste with other waste types.
waste	Visual pollutionOdour generation		Periodically deliver the domestic waste container to municipality collection truck (periodic collection by the municipality) to further landfill disposal.
			If applicable, separately collect food waste for further composting.
Black water / Grey water	 Contamination of surface water, groundwater and soil Vector generation Visual pollution Odour generation 	CRITICAL	Direct discharge into the nearby sewage with proper line connection and discharge permit.
Cardboard, plastic, glass and	 Contamination of surface water and soil 	MAJOR	Separate collection of packaging waste and storage in dedicated waste bins.
metal packaging	metal packaging • Visual pollution		Avoid wetting and mixing with other types of waste.
waste			Periodically transfer to licenced recycling facility with necessary documentation.
Hydraulic fluids	Contamination of	CRITICAL	Conduct analyses for determination of the waste oil group.
and lubricants	surface water, groundwater and soil		Separate collection of waste oils and storage in dedicated oil drums/containers.
	 Visual pollution 		Do not mix different group of waste oils with each other.
	·		Transfer of the waste oils to the licenced refinery, co- incineration or incineration facilities with licenced transporters, according to the waste oil analyses results.
Waste batteries	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Separate collection of waste batteries in battery box. Transfer to TAP (Portable Battery Manufacturers and Importers Association) for handling and final disposal.
Waste electrical and electronical equipment (WEEE)	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Separate collection of WEEE in dedicated containers. Transfer of the WEEE to licenced recycling and disposal facilities.
Waste vegetable oil	 Contamination of surface water, groundwater and soil 	MAJOR	Separate collection of waste vegetable oil in dedicated containers. Transfer to licenced recycling facilities.

Waste	Impact	Significance of the Impact	Mitigation Measure / Management Option (according to the Turkish Environmental Legislation)
	Visual pollution		
Contaminated packaging, contaminated fabrics/filters, paints, chemicals, solvents, cartridges, adhesives	 Contamination of surface water, groundwater and soil Human exposure Visual pollution 	CRITICAL	Separate collection of hazardous waste and storage in containers labelled with waste code at dedicated designated areas in accordance with the proper storage measures that are needed to be taken. Do not store hazardous waste on site more than 6 months.
Non-hazardous waste such as metal scrap, wood scrap and plastic scrap	 Contamination of surface water, groundwater and soil Visual pollution 	CRITICAL	Separate collection and transfer to the licensed recycling facilities.
Infectious wastes, pathological wastes, and sharps (Including liquid laboratory waste)	 Contamination of surface water, groundwater and soil Worker exposure Visual pollution 	CRITICAL	Collect infectious wastes and pathological wastes in red bags. Collect sharps in the sharps waste container. Decontaminate BSL3 level solid medical wastes with autoclave or hydrogen peroxide, where the waste generation takes place. Decontaminate BSL3 liquid medical wastes which are collected and stored in liquid waste storage tanks and decontaminate in the decontamination unit planned to be installed at the basement level of Vaccine Production Building. After pH and temperature of the decontaminated wastewater is adjusted to comply with discharge criteria, discharge into the sewer. Autoclave dead animals and animal residuals (e.g., tissues, body parts, bodily fluids) which are classified as pathological waste for decontamination. Then send the autoclaved residual waste to third-party licensed incineration facilities. Transfer the solid medical waste which was decontaminated, via galleries to Waste Building which are stationed in the underground. Followingly, send the medical waste from Waste Building to final licensed medical waste disposal facilities by licensed haulers.
Laboratory wastewater from all laboratory sinks, showers, autoclave chambers and floor drains	 Contamination of surface water, groundwater and soil Worker exposure 	CRITICAL	Decontaminate the laboratory wastewater in the wastewater decontamination unit via chemical process or autoclave, then discharge into sewer network with appropriate discharge permit. Collect the wastewater with double-walled and controllable pipeline and send to liquid waste storage tanks, then to the decontamination unit from animal BSL3 laboratory. Finally, discharge into sewerage network.
Radioactive waste	 Contamination of surface water, groundwater and soil Worker exposure 	CRITICAL	First put the radioactive waste in tightly bound medical waste bag and then in a lead box. Label the bag and the box with the type of radioisotope and the date of storage. Store the radioactive waste until at least 10 half-lives have passed then measure the dose. If the radiation dose has fallen below the Legislation limits, treat the waste as medical waste.

8.5 Residual Impacts

Although treatment and disposal of medical waste reduces risks, indirect health risks may occur through the release of toxic pollutants into the environment through treatment or disposal. For instance, landfills might contaminate drinking water resources if they are not properly constructed and operated. Occupational health and safety risks also exist at disposal facilities that are not well designed, run or maintained. The residual impact as a result of waste generation is estimated to be negligible when the

mitigation measures that are described above and in the Waste and Wastewater Management Plan (both for construction and operation) are fully implemented throughout the lifecycle of the Project.

With the implementation of the mentioned mitigation measures and waste management options, the following residual impacts are expected to remain:

- Acceptable increase of landfill use for the remaining part of the waste which cannot be reused, recycled, recovered, and
- Acceptable increase of construction and demolition waste dump site use especially during the decommissioning phase of the Project.

The main impact sources for the waste and wastewater management subject are generation of waste and wastewater. These sources and their impacts were grouped in general for all phases of the Project and it was aimed to be reflected with a broad perspective. According to the impacts assessment in previous sections, the highest significance of the impact was determined as critical. Thus, it was explained that if necessary mitigation measures are not applied, any significance of impact may be at the highest degree as critical. On the other hand, after implementation of the measures with a good management, it is assumed that the significance can be reduced considerably, even to to the level of insignificant.

Table 8-14 below summarizes the residual impacts that are expected to remain upon implementation of the mitigation measures that are indicated in Section 8.4.

Source	Impact	Mitigation Measure	Significance of the Impact Before the Measures	Significance of the Impact After the Measures	Residual Impact
Waste generation	 Contamination of the environment Human exposure Odour generation Dust generation 	water Management Plan	CRITICAL	INSIGNIFICANT	 Increase of landfill use Increase of construction and demolition waste dump site use Increase of waste management facilities' load Increase of waste transportation traffic
Domestic wastewater generation	 Contamination of the environment Human exposure Odour generation Vector generation 	ste and Waste	CRITICAL	INSIGNIFICANT	 Increase of sewer load Increase of domestic wastewater treatment plant load
Medical/ Laboratory waste generation	 Contamination of the environment Human exposure High biological risk exposure 	tion of the Wa	CRITICAL	INSIGNIFICANT	 Increase of waste management facilities' load
Laboratory wastewater generation	 Contamination of the environment Human exposure Odour generation Vector generation 	Implementa	CRITICAL	INSIGNIFICANT	 Increase of sewer load Increase of domestic wastewater treatment plant load

Table 8-14: Residual Impacts after the Application of Relevant Mitigation Measures

8.6 Compliance with National and International Requirements

8.6.1 National Requirements

All waste and wastewater management practices such as collection, storage, transport and disposal are required to be in full compliance with the national regulatory framework. Since the Waste Management Regulation is the framework regulation that regulates the basic principles of waste management in Turkiye, it is summarized in Table 8-15, and other Turkish regulations that govern the management of wastes and wastewater that will be generated during construction and operation of the Project are listed as follows:

- Waste Management Regulation (Official Gazette (OG) Date/ Number: 02.04.2015/29314)
- Regulation on Control of Medical Waste (OG Date/Number: 25.01.2017/29959)
- Regulation on Control of Packaging Waste (OG Date/Number: 26.06.2021/31523)
- Zero Waste Regulation (OG Date/Number: 12.07.2019/30829)
- Regulation on Control of Waste Oils (OG Date/Number: 21.12.2019/30985)
- Regulation on Control of Waste Batteries and Accumulators (OG Date/Number: 31.08.2004/25569)
- Regulation on Control of Excavated Soil, Construction and Demolition Wastes (OG Date/ Number: 18.03.2004/25406)
- Regulation on Control of End-of-Life Tires (OG Date/Number: 25.11.2006/26357)
- Regulation on Control of End-of-Life Vehicles (OG Date/Number: 30.12.2009/27448)
- Regulation on Control of Waste Vegetable Oils (OG Date/Number: 06.06.2015/29378)
- Water Pollution Control Regulation (OG Date/Number: 31.12.2004/25687)
- Regulation on Wastewater Discharges to the Sewage System published by ASKI (2011)
- Regulation on Environmental Permits and Licenses (OG Date/Number: 10.09.2014/29115)
- Communiqué on Road Transportation of Wastes (OG Date/Number: 18.01.2013/28532)
- Regulation on Road Transportation of Hazardous Materials (OG Date/Number: 24.10.2013/28801)
- Regulation on Control of Waste Electrical and Electronic Equipment (OG Date/Number: 22.05.2012/28300)
- Regulation on Wastes Generated from Radioactive Substances Use (OG Date/Number: 02.09.2004/25571)
- Regulation on Radioactive Waste Management (OG Date/Number: 09.03.2013/28582)
- Communiqué on Recycling of Certain Non-hazardous Wastes (OG Date/Number: 17.06.2011/27967)
- Regulation on Soil Pollution Control and Point Source Contaminated Sites (OG Date/Number: 08.06.2010/27605).
- Regulation on Demolition of Buildings (OG Date/Number: 13.10.2021/31627).

The main framework that determines waste management practices in Turkiye and specific requirements and best practices set for laboratory waste management by national institutions are detailed in Table 8-15 below.

Table 8-15: Nationally Set Requirements and Best Practices

Requ	uirement	Project Compliance			
Wast	/aste Management Regulation published by the Ministry of Environment, Urbanization and Climate Change				
Wast	e producer is responsible for:	Waste management hierarchy approach will be implemented during all Project phases and activities, is order of priority. Therefore, techniques for waste provention, reduction, request			
a. b. c.	Collecting their wastes separately and storing them temporarily, Preparing the officially required waste management plan intended to prevent and reduce waste which is generated in the facility and submitting the plan to the provincial directorate and getting approval	 recycle, recover and final disposal will be applied to protect human and environment health. Details regarding the implementation of waste management hierarchy are explained in the Waste and Wastewater Management Plan prepared for the Project. The Waste and Wastewater Management Plan (WWMP) is a separate document than the 			
d. e.	To keep records for the wastes it produces in line with the principles determined by the Ministry, and to make appropriate packaging and labelling, To keep municipal wastes ready for collection by keeping them closed in a way that will not harm the environment and human health in places where they are produced, such as	 ESIA report and includes all waste types and management options for these waste. The WWMP defines waste management system proposed for both construction and operation phases of the Project. According to Turkish environmental legislation, it is forbidden to collect waste types by mixing with each other. Therefore, all generated waste types within the Project phases will be 			
f.	given the obligation to collect, transport and dispose of within the scope of the relevant legislation, By documenting that the wastes defined with the (M) sign in Annex-4 of this Regulation and claimed not to contain the features specified in Annex-3/B, are non-hazardous with	 collected separately in dedicated waste bins/containers. The collected wastes will be temporarily stored on-site in the "Waste Building" prior to transfer to final recycling and/or disposal facilities. Temporary Waste Storage Permit will be obtained from the MoEUCC if necessary (depending on monthly amount of waste to be generated). 			
g. h.	analyses made by laboratories authorized by the Ministry, Obtaining permission from the provincial directorate for temporary storage areas where permission is required in accordance with the provisions of this Regulation, Sending their wastes to waste processing facilities that have obtained a	 Waste management records including information on type of waste that is generated, waste codes, waste amounts, storage date, proposed waste management options will be recorded through the necessary reports. Annual waste declarations will be made to the MoEUCC through MoTAT system and the printed declaration form will be kept for 5 years. 			
i.	permit/environmental license in accordance with the provisions of this Regulation and the principles determined by the Ministry, By filling in the waste declaration form including the information of the previous year, starting from January every year until the end of March at the latest, using the online applications prepared by the Ministry, approving it, printing it out and keeping a copy for five years, military units and institutions in written form. To send it to the Ministry by the Ministry of National Defence and the Chief of General Staff within the specified period and to keep a copy for five years,	 If necessary, waste will be analysed to be identify hazardous properties of it. All types of Project-related waste will be sent to the licensed third-party waste management facilities with the licensed waste haulers according to the type of waste and Turkish environmental legislation requirements. The transportation documentation will be prepared through the MoTAT system prior to transfer and kept for 5 years. Emergency response, restoring the accidental area and related topics and instructions are described in the Waste and Wastewater Management Plan to be implemented effectively. Waste management perspend will be trained regarding defining constraint collecting. 			
j. k.	While the wastes are sent to the disposal, the Transport Control Number (TKN) and Transport Verification Number (TDN) created through the online MoTAT system will be used and the parties will transfer the waste according to this system. In case the waste processing facility does not accept the waste, by directing the carrier to another facility or ensuring that the waste is processed in a suitable facility by ensuring that the carrier returns the waste,	 waste management personnel will be trained regarding defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that that might result from waste management activities. All waste management expenses will be met by the waste producer. 			

Requirement	Project Compliance
 To provide training of its employees responsible for the collection, transportation and temporary storage of the wastes they produce, and to take all kinds of measures related to health and safety, 	
m. In order to prevent pollution caused by accidental or deliberate spilling of wastes and similar events, by restoring the crime scene within one month at the latest, depending on the type of waste, and covering all expenses,	
n. In case of accidental or deliberate spillage of wastes and similar events, to inform the provincial directorate within 24 hours and to submit the report containing information on the accident date, accident location, type and amount of waste, cause of the accident, waste treatment type and rehabilitation of the accident site to the provincial directorate at the latest. by submitting it within 30 calendar days,	
 To apply to the Ministry to obtain compliance for wastes with the characteristics defined in the first paragraph of Article 19 of this Regulation, which can be considered as by-products, 	
 p. To meet the expenses made for the determination of the quality of the waste, its collection, transportation and processing, 	
The waste owner is obliged to manage their waste in accordance with the provisions specified in this Regulation.	
Standards of Accreditation in Health, Laboratory Kit V2.1/2020 published by the Ministry of	Health
Waste Management	
• Standard: Safe and effective management of waste produced at laboratory must be ensured to	protect human and environmental health.
Goal: To prevent waste from harming human health and the environment starting from the cor	position of the waste at laboratory until its delivery to the competent authority for the disposal.
Preparation of Waste Management Plan:	The Waste and Wastewater Management Plan is a separate document than the ESIA report
 A Waste Management Plan must be prepared at laboratory. The Waste Management Plan must include at least the following: 	prepared for the Project, and includes management options for all Project-related waste types. The Plan defines waste management system proposed for both construction and operation
 Source, amount and types of waste 	phases of the Project.
 Measures related to the minimization of waste at the source 	 Emergency response, restoring the accidental area and related topics and instructions are described in this Waste and Wastewater Management Plan to be implemented effectively.
 Equipment and tools to be used in waste management 	Waste management biorarchy approach will be implemented during all Project phases and
 Collection frequency and rules 	activities, in order of priority. Therefore, techniques for waste prevention, reduction, reuse.
 Temporary storage systems 	recycle, recover and final disposal will be applied to protect human and environment health.
 Cleaning and disinfection of relevant equipment 	Details regarding the implementation of waste management hierarchy are explained in the
 Measures to be taken in the case of an accident 	Waste and Wastewater Management Plan of the Project.
 Training of the personnel assigned to collect and transport waste 	Waste management personnel will be trained regarding defining, separating, collecting,
 Determining the institution to which the waste will be delivered 	labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that that might result from waste management activities
- Delivery of waste	energency response that that might result from waste management activities.

Requirement

Monitoring of waste processes

• Waste management supervisor must be identified

Waste Sorting at Source:

- Waste must be defined at least in the following categories/types:
 - Domestic Waste
 - General domestic waste
 - Packaging waste
 - Medical Waste
 - Infectious waste
 - Pathogenic waste
 - Sharp waste
 - Hazardous Waste
 - Radioactive Waste
- Waste generated must be sorted in accordance with their type.
- Waste must be put in separate bags/boxes having the required properties in accordance with their types.
- The amount of medical and hazardous waste must be measured and monitored on the basis of Laboratory. Processes related to waste should be examined in terms of requirements for reducing waste quantities.
- Arrangements must be made for recyclable waste.

Waste Transportation, Temporary Storage and Disposal Operations:

- · Waste must be collected by personnel trained to perform such tasks.
- The clothes worn by the personnel assigned with the collection and transportation of waste must possess the necessary properties.
- The collection and transport of waste should be carried out as far as possible from areas where human traffic is concentrated.
- Waste must be collected at the temporary storage area.
- There must be containers or temporary waste storerooms in sizes suitable to the size of Laboratory and having the suitable properties.
- Waste must be stored temporarily in such a way as not to exceed the maximum waiting period determined within the scope of the national legislation.
- The stored waste must be submitted to the competent authority for the final disposal.
- Waste store rooms must be cleaned and disinfected.

Certain personnel with necessary PPE (e.g., protective clothing, masks, goggles, gloves) will

 According to Turkish environmental legislation, it is forbidden to collect waste types by mixing with each other. Therefore, all generated waste types within the Project phases will be

Waste types within the Project are classified as construction, demolition, domestic, packaging.

Medical and hazardous waste types will be measured and recorded in accordance with the

 In case of radioactive waste generation, never use autoclave, first put the radioactive waste in tightly bound medical waste bag and then in a lead box. Label the bag and the box as

the radiation dose has fallen below the legislation limits, treat the waste as medical waste.

necessary and keep storing until at least 10 half-lives have passed then measure the dose. If

Inform the Turkish Energy, Nuclear and Mining Research Authority (TENMAK) regarding the

medical, hazardous, non-hazardous, waste oils, waste electrical and electronical equipment,

waste batteries, and laboratory wastewater. Those will be separately collected and stored on-

collected separately in dedicated waste bins/containers.

site in the Waste Building prior to transfer to relevant disposal facilities.

- be selected to collect and internally transport waste to the Waste Building. The Waste Building will be designed according to the requirements to temporarily store the waste apart from human traffic areas at a dedicated part of the Project.
- The collected waste types will be temporarily stored on-site in the "Waste Building" prior to transfer to final recycling and/or disposal. Temporary Waste Storage Permit will be obtained from the MoEUCC if necessary (depending on monthly amount of waste to be generated).
- Laboratory/medical waste storage duration will not exceed 48 hours in ambient temperature and 1 week at 4°C, within the storage area prior to transfer waste to licensed third-party waste management facilities.
- Rooms and the compartments within the Waste Building will periodically and regularly be cleaned and disinfected.

Project Compliance

relevant national regulation.

radioactive waste.

Requirement	Project Compliance
 Waste Management Trainings: Personnel working on waste management must be trained. Trainings must include at least the following: Types of waste and sorting of waste in accordance with their types Collection, transportation and temporary storage of waste Health risks, injuries and diseases which might be caused by waste Measures to be taken in the case of an accident or injury 	 Waste management personnel will be trained regarding defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that that might result from waste management activities
Turkish Scientific & Technological Research Council of Turkey (TÜBİTAK) Project Findings (Highly Pathogen Organisms and Principles of Operation ¹²⁰)	Project Name: Establishment of Biosafety Level 3 Laboratory Infrastructure to Study with
 Waste Transportation and Disposal: All waste materials produced in the BSL-3 Laboratory should be considered contaminated and must be decontaminated before leaving the laboratory, based on the basic rules in the DS/EN 12740 standard (Biotechnology-Laboratories for research, development and analysis - Guidance for containment of animals inoculated and testing of waste). It is necessary to use a double door autoclave for sterilization / decontamination of materials. In such highly sheltered laboratories, water flowing from taps and showers must be decontaminated before it enters the sewer. For this purpose, different systems such as liquid waste decontamination system and automated chemical decontaminated daily in autoclave bags. The sterilized materials are taken from the part of the double-door autoclave that opens to the outer corridor and put in a medical waste bag and sent to the "Medical Waste Storages" for incineration. Dead animal wastes are first placed in medical waste bags and then placed in solid lidded waste transport boxes with labels bearing the BSL 3 and medical waste emblem. At each stage, the outer surface is disinfected with a disinfectant spray. The output material is placed in the trap. After being kept under UV light for 30 minutes, it can be taken out to be treated the same as other medical wastes. Body fluids in animal slaughter pans are taken into suitable closed containers for autoclaving. Exhaust system filters are changed annually. The replacement of contaminated filters is carried out by trained personnel with personal protective equipment in accordance with the laberatory of the outer ordance with personal protective equipment in accordance with an expression. 	 All types of waste materials will be decontaminated before leaving the laboratory for final disposal. All wastewater from the sinks, showers, autoclave chambers and floor drains within the laboratory will be decontaminated in the wastewater decontamination unit prior to discharge to sewer. Double door autoclave will be used for decontamination. Animal carcasses will first be put in waste bags, then solid lidded transport boxes with labels bearing the BSL 3 and medical waste emblem, prior to disposal. The outer surface of the box will be disinfected with appropriate disinfectant. Materials which will be out from the laboratory will be placed in the trap and kept under UV light for 30 minutes prior to taken out to be treated the same as other medical wastes. Body fluids in animal slaughter pans will be autoclaved in closed containers. HEPA filters will be removed by trained personnel and will be decontaminated with appropriate disinfectant and disposed of as medical waste.

¹²⁰ Yücel, F., Ülbeği Polat, H., Akçael, E., & Deniz, T. (2014). Establishment of biosafety level 3 laboratory infrastructure to study with highly pathogen organisms and principles of operation: Review. Turkiye Klinikleri Journal of Medical Sciences. Turkiye Klinikleri. https://doi.org/10.5336/medsci.2013-37399

_				
	~	 ~ m	00	
RH		 		
	44	~		

Project Compliance

disinfectant (formaldehyde, etc.), and each of them is disposed of as medical waste by putting them in separate medical waste bags.

Wastewater Discharge Limits

The limit values to be complied for wastewaters to be discharged into the municipality sewerage network are mainly defined by the Water Pollution Control Regulation (OG Date/Number: 31.12.2004/25687). The local authorities (i.e. Municipalities) also define the limits for wastewater discharges in the light of Water Pollution Control Regulation requirements. Table 8-16 below indicates the pollution parameter limits set by the Water Pollution Control Regulation and Regulation on Wastewater Discharges to the Sewage System published by ASKI (2011).

Pollution Parameter	Limit Values Defined by ASKI's Regulation on Wastewater Discharges to the Sewage System	Limit Values Defined by the Water Pollution Control Regulation*
Temperature	40°C	40°C
рН	6.5 – 10	6 – 10
Suspended Solids	400 mg/L	500 mg/L
Oil and Grease	200 mg/L	150 mg/L
Tar and petroleum-based oils	50 mg/L	50 mg/L
Chemical Oxygen Demand (COD)	1000 mg/L	1000 mg/L
Biochemical Oxygen Demand (BOD)	500 mg/L	-
Sulphate	1000 mg/L	1700 mg/L
Total Sulphur	2 mg/L	2 mg/L
Fluoride	50 mg/L	
Chloride	5000 mg/L	10000 mg/L
Phenol	10 mg/L	20 mg/L
Free Chlorine	5 mg/L	5 mg/L
Total Nitrogen (TN)	60 mg/L	100 mg/L
Total Phosphorus (TP)	20 mg/L	10 mg/L
Detergent	5 mg/L	-
Arsenic (AS)	3 mg/L	3 mg/L
Total Cyanide (CN)	10 mg/L	10 mg/L
Lead (Pb)	3 mg/L	3 mg/L
Cadmium (Cd)	2 mg/L	2 mg/L
Total Chrome (Cr)	5 mg/L	5 mg/L
Chrome +6 (Cr ⁺⁶)	1 mg/L	-
Mercury (Hg)	0.2 mg/L	0.2 mg/L
Copper (Cu)	2 mg/L	2 mg/L
Nickel (Ni)	5 mg/L	5 mg/L
Aluminium (Al)	2 mg/L	-
Zinc (Zn)	5 mg/L	10 mg/L
Total Iron (Fe)	5 mg/L	-
Tin (Sn)	5 mg/L	5 mg/L
Antimony (Sb)	3 mg/L	-
Silver (Ag)	5 mg/L	5 mg/L
Boron (B)	3 mg/L	-
* For westowator infrastructure facilities	in which courses systems reculting in hislagia	al ar aguivalant tractment

|--|

For wastewater infrastructure facilities in which sewage systems resulting in biological or equivalent treatment

8.6.2 International Requirements

In addition to the Turkish legislation, waste and wastewater management practices for the Project will also need to abide with the following international guidelines and standards:

- WHO Laboratory Biosafety Manual, 4th edition (2020),
- World Bank ESS3: Resource Efficiency and Pollution Prevention and Management (2017)
- World Bank ESS4: Community Health and Safety (2017)
- World Bank Group General EHS Guidelines: 1. Environmental and 3. Community Health and Safety (2007)
- World Bank Group EHS Guidelines: 4. Construction and Decommissioning (2007)
- The World Bank Group EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007), and
- The World Bank Group EHS Guidelines for Healthcare Facilities (2007).

The conditions and guidelines set in the WHO, WBG and IFC guidance documents provide inherent mitigation measures against the impacts resulting from waste generation. The compliance status of the Project against these guidance documents are investigated in Table 8-17Table 8-17 in detail.

Table 8-17: Compliance with WHO Guidelines Related with the Project

Standard/ Guideline	Requirement	Project Compliance
World Bank ESS3: Resource Efficiency and Pollution Prevention and Management	 POLLUTON PREVENTION AND MANAGEMENT Management of hazardous and non-hazardous wastes: The Borrower (here the waste producer) will avoid the generation of hazardous and non-hazardous waste. Where waste generation cannot be avoided, the Borrower will minimize the generation of waste, and reuse, recycle and recover waste in a manner that is safe for human health and the environment. Where waste cannot be reused, recycled or recovered, the Borrower will treat, destroy, or dispose of it in an environmentally sound and safe manner that includes the appropriate control of emissions and residues resulting from the handling and processing of the waste material. If the generated waste is considered hazardous, the Borrower will comply with existing requirements for management (including storage, transportation and disposal) of hazardous wastes including national legislation and applicable international conventions, including those relating to transboundary movement. Where such requirements are absent, the Borrower will adopt GIIP alternatives for its environmentally sound and safe management and disposal. When hazardous waste management is conducted by third parties, the Borrower will use contractors that are reputable and legitimate enterprises licensed by the relevant government regulatory agencies and, with respect to transportation and disposal, obtain chain of custody documentation to the final destination. The Borrower will ascertain whether licensed disposal sites are being operated to acceptable standards, the Borrower will minimize waste sent to such sites and consider alternative disposal options, including the possibility of developing its own recovery or disposal facilities at the project site or elsewhere. 	 Waste management hierarchy approach will be implemented during all Project phases and activities, in order of priority. Therefore, techniques for waste prevention, reduction, reuse, recycle, recover and final disposal will be applied to protect human and environment health. Details regarding the implementation of waste management hierarchy are explained in the Waste and Wastewater Management Plan prepared for the Project. The collected waste will be temporarily stored onsite according to their types in the Waste Building prior to sending to final recycling and/or disposal facilities. Temporary Waste Storage Permit will be obtained from the MoEUCC if necessary (depending on monthly amount of waste to be generated). Ankara Province is capable to manage the Project waste by the existing third-party and Municipality owned waste management facilities; therefore, all types of Project-related waste will be sent to the licensed third-party waste management facilities with licensed waste haulers according to the waste type and Turkish environmental legislation requirements. The transportation documentation will be prepared through the MoTAT system of MoEUCC prior to transportation and kept for 5 years. No transboundary movement of waste is planned for the Project.
WBG EHS General Guidelines: Waste Management	GENERAL WASTE MANAGEMENT Waste Management and Planning: Facilities that generate waste should characterize their waste according to composition, source, types of wastes produced, generation rates, or according to local regulatory requirements. Effective planning and implementation of waste management strategies should include:	Waste management hierarchy approach will be implemented during all Project phases and activities, in order of priority. Therefore, techniques for waste prevention, reduction, reuse, recycle, recover and final disposal will be applied to protect human and environment health. Details regarding the implementation of works monogement hierarchy are

• Review of new waste sources during planning, siting, and design activities, including during equipment modifications and process alterations, to identify expected waste generation, pollution prevention opportunities, and necessary treatment, storage, and disposal infrastructure,

implementation of waste management hierarchy are explained in the Waste and Wastewater Management Plan prepared for the Project.

Standard/ Guideline	Requirement	Project Compliance
	 Collection of data and information about the process and waste streams in existing facilities, including characterization of waste streams by type, quantities, and potential use/disposition, Establishment of priorities based on a risk analysis that takes into account the potential EHS risks during the waste cycle and the availability of infrastructure to manage the waste in an environmentally sound manner, Definition of opportunities for source reduction, as well as reuse and recycling, Definition of procedures and operational controls for onsite storage, Definition of options / procedures / operational controls for treatment and final disposal. 	The Waste and Wastewater Management Plan is a separate document than the ESIA report prepared for the Project, and includes management options for all Project-related waste types. This Plan defines waste management system proposed for the operation phase of the Project. All types of Project-related waste will be transferred to the licensed third-party waste management facilities with licensed waste haulers according to the waste type and Turkish environmental legislation requirements as well as international standards. The transportation documentation will be prepared
		through the MoTAT system of MoEUCC prior to transportation and kept for 5 years.
	Waste Prevention:	Waste management hierarchy approach will be
	Processes should be designed and operated to prevent, or minimise, the quantities of wastes generated and hazards associated with the wastes generated in accordance with the following strategy:	in order of priority. Therefore, techniques for waste
	 Substituting raw materials or inputs with less hazardous or toxic materials, or with those where processing generates lower waste volumes 	final disposal will be applied to protect human and environment health. Details regarding the
	 Applying manufacturing process that convert materials efficiently, providing higher product output yields, including modification of design of the production process, operating conditions, and process controls 	implementation of waste management hierarchy are explained in the Waste and Wastewater
	 Instituting good housekeeping and operating practices, including inventory control to reduce the amount of waste resulting from materials that are out-of-date, off specification, contaminated, damaged, or excess to plant needs 	Management Plan prepared for the Project.
	 Instituting procurement measures that recognize opportunities to return usable materials such as containers and which prevents the over ordering of materials 	
	 Minimizing hazardous waste generation by implementing stringent waste segregation to prevent the commingling of non-hazardous and hazardous waste to be managed. 	
	Recycling and Reuse:	Waste management hierarchy approach will be
	In addition to the implementation of waste prevention strategies, the total amount of waste may be significantly reduced through the implementation of recycling plans, which should consider the following elements:	implemented during all Project phases and activities, in order of priority. Therefore, techniques for waste provention, reduction, reuse, recycle, recover and
	Evaluation of waste production processes and identification of potentially recyclable materials	final disposal will be applied to protect human and
	 Identification and recycling of products that can be reintroduced into the manufacturing process or industry activity at the site 	environment health. Details regarding the implementation of waste management hierarchy are

• Investigation of external markets for recycling by other industrial processing operations located in the neighbourhood or region of the facility (e.g., waste exchange)

explained in the Waste and Wastewater Management Plan prepared for the Project.

Standard/ Guideline	Requirement	Project Compliance
	Establishing recycling objectives and formal tracking of waste generation and recycling rates	Waste management personnel will be trained about
	 Providing training and incentives to employees in order to meet objectives 	defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that might result from waste management activities.
	Treatment and Disposal:	All types of Project waste will be sent to the licensed
	If waste materials are still generated after the implementation of feasible waste prevention, reduction, reuse,	third-party waste management facilities with licensed waste haulers according to the waste type and

recovery and recycling measures, waste materials should be treated and disposed of and all measures will be taken to avoid potential impacts to human health and the environment.

Selected management approaches should be consistent with the characteristics of the waste and local regulations, and may include one or more of the following:

- On-site or off-site biological, chemical, or physical treatment of the waste material to render it non-hazardous prior to final disposal
- Treatment or disposal at permitted facilities specially designed to receive the waste. Examples include: composting operations for organic non-hazardous wastes; properly designed, permitted and operated landfills or incinerators designed for the respective type of waste; or other methods known to be effective in the safe, final disposal of waste materials such as bioremediation.

HAZARDOUS WASTE MANAGEMENT

Waste Storage:

Hazardous waste should be stored so as to prevent or control accidental releases to air, soil, and water resources in area location where:

- Waste is stored in a manner that prevents the commingling or contact between incompatible wastes, and allows for inspection between containers to monitor leaks or spills. Examples include sufficient space between incompatibles or physical separation such as walls or containment curbs
- Store in closed containers away from direct sunlight, wind and rain
- Secondary containment systems should be constructed with materials appropriate for the wastes being contained and adequate to prevent loss to the environment
- Secondary containment is included wherever liquid wastes are stored in volumes greater than 220 litres. The available volume of secondary containment should be at least 110 percent of the largest storage container, or 25 percent of the total storage capacity (whichever is greater), in that specific location
- Provide adequate ventilation where volatile wastes are stored.

Hazardous waste storage activities should also be subject to special management actions, conducted by employees who have received specific training in handling and storage of hazardous wastes:

 Provision of readily available information on chemical compatibility to employees, including labelling each container to identify its contents The collected waste will be temporarily stored onsite according to their types in the Waste Building prior to sending to final recycling and/or disposal facilities. Temporary Waste Storage Permit will be obtained from the MoEUCC if necessary (depending on monthly amount of waste to be generated).

Turkish environmental legislation requirements.

Waste management personnel will be trained regarding defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that might be resulted due to waste management activities.

No hazardous waste storage through underground tanks or pipes is planned for the Project.

Standard/ Guideline	Requirement	Project Compliance
	Limiting access to hazardous waste storage areas to employees who have received proper training	
	 Clearly identifying (label) and demarcating the area, including documentation of its location on a facility map or site plan 	
	 Conducting periodic inspections of waste storage areas and documenting the findings 	
	Preparing and implementing spill response and emergency plans to address their accidental release	
	 Avoiding underground storage tanks and underground piping of hazardous waste 	
	Transportation:	All necessary precautions will be applied prior to
	On-site and Off-site transportation of waste should be conducted so as to prevent or minimize spills, releases, and exposures to employees and the public. All waste containers designated for off-site shipment should be secured and labelled with the contents and associated hazards, be properly loaded on the transport vehicles before leaving the site, and be accompanied by a shipping paper (i.e., manifest) that describes the load and its associated hazards, consistent with the guidance provided in Waste Management Plan.	transportation of waste.
	Treatment and Disposal:	All types of Project-related waste will be transferred
	In addition to the recommendations for treatment and disposal applicable to general wastes, the following issues specific to hazardous wastes should be considered:	to the licensed third-party waste management facilities with licensed waste haulers according to the waste type and Turkish environmental legislation
	Commercial or Government Waste Contractors: In the absence of qualified commercial or government- owned waste vendors (taking into consideration proximity and transportation requirements), facilities generating waste should consider using:	requirements as well as international standards.
	 Have the technical capability to manage the waste in a manner that reduces immediate and future impact to the environment 	
	Have all required permits, certifications, and approvals, of applicable government authorities	
	 Have been secured through the use of formal procurement agreements 	
	 In the absence of qualified commercial or government-owned waste disposal operators (taking into consideration proximity and transportation requirements), project sponsors should consider using: 	
	Installing on-site waste treatment or recycling processes	
	 As a final option, constructing facilities that will provide for the environmental sound long-term storage of wastes on-site (as described elsewhere in the General EHS Guidelines) or at an alternative appropriate location up until external commercial options become available 	
	Small Quantities of Hazardous Waste: Hazardous waste materials are frequently generated in small quantities by many projects through a variety of activities such as equipment and building maintenance activities. Examples of these types of wastes include: spent solvents and oily rags, empty paint cans, chemical containers; used lubricating oil; used batteries (such as nickel-cadmium or lead acid); and lighting equipment, such as lamps or lamp ballasts. These wastes should be managed following the guidance provided in the above sections.	
	Monitoring:	All waste management steps such as segregation, collection, storage, labelling, record keeping and site

Standard/ Guideline	Requirement	Project Compliance
	Monitoring activities associated with the management of hazardous and non-hazardous waste should include:	inspections will be performed effectively. Periodic
	 Regular visual inspection of all waste storage collection and storage areas for evidence of accidental releases and to verify that wastes are properly labelled and stored. When significant quantities of hazardo wastes are generated and stored on site, monitoring activities should include: 	site visits and audits will be held and results will be reported internally as per the required standards and best practices.
	 Inspection of vessels for leaks, drips or other indications of loss 	
	 Identification of cracks, corrosion, or damage to tanks, protective equipment, or floors 	
	 Verification of locks, emergency valves, and other safety devices for easy operation (lubricating if required and employing the practice of keeping locks and safety equipment in standby position when the area is not occupied) 	
	 Checking the operability of emergency systems 	
	 Documenting results of testing for integrity, emissions, or monitoring stations (air, soil vapor, or groundwater) 	
	 Documenting any changes to the storage facility, and any significant changes in the quantity of materials in storage 	
	Regular audits of waste segregation and collection practices	
	 Tracking of waste generation trends by type and amount of waste generated, preferably by facility departments 	
	 Characterizing waste at the beginning of generation of a new waste stream, and periodically documenting the characteristics and proper management of the waste, especially hazardous wastes 	
	Keeping manifests or other records that document the amount of waste generated and its destination	
	 Periodic auditing of third-party treatment, and disposal services including re-use and recycling facilities wh significant quantities of hazardous wastes are managed by third parties. Whenever possible, audits should include site visits to the treatment storage and disposal location 	۶n
	 Regular monitoring of groundwater quality in cases of Hazardous Waste on site storage and/or pretreatme and disposal 	ıt
	 Monitoring records for hazardous waste collected, stored, or shipped should include: 	
	 Name and identification number of the material(s) composing the hazardous waste 	
	 Physical state (i.e., solid, liquid, gaseous or a combination of one, or more, of these) 	
	 Quantity (e.g., kilograms or liters, number of containers) 	
	 Waste shipment tracking documentation to include, quantity and type, date dispatched, date transported and date received, record of the originator, the receiver and the transporter 	
	 Method and date of storing, repacking, treating, or disposing at the facility, cross-referenced to speci manifest document numbers applicable to the hazardous waste 	c
	Location of each hazardous waste within the facility, and the quantity at each location	
WBG EHS Guidelines for	WASTE MANAGEMENT	All waste types are separately defined in related sections of this chapter and in the Waste and

Standard/ Guideline	Requirement	Project Compliance
Health Care Facilities: Environment	Waste from health care facilities (HCF) can be divided into two separate groups. The first consists of general waste, similar in composition to domestic waste, generated during administrative, housekeeping, and maintenance functions. The second group consists of specific categories of hazardous health care waste.	Wastewater Management Plan prepared for the Project.
	Health care facilities should establish, operate and maintain a health care waste management system (HWMS) adequate for the scale and type of activities and identified hazards. Facility operators should undertake regular assessment of waste generation quantities and categories to facilitate waste management planning, and investigate opportunities for waste minimization on a continuous basis. In addition to the guidance provided on solid and hazardous waste management in the General EHS Guidelines, the HWMS should include the following components.	The Waste and Wastewater Management Plan includes all waste types, waste codes, and waste management options. The Plan defines the waste management system proposed for the Project, both for construction and operation phases.
	Waste Minimization, Reuse, and Recycling:	Waste management hierarchy approach will be
	Facilities should consider practices and procedures to minimize waste generation, without sacrificing patient hygiene and safety considerations, including:	implemented during all Project phases and activities, in order of priority. Therefore, techniques for waste
	Source reduction measures:	final disposal will be applied to protect human and
	 Consider options for product / material substitution to avoid products containing hazardous materials that require the product to be disposed as hazardous or special waste (e.g. mercury (Use of mercury- based medical devices (e.g. thermometers and blood pressure devices) should be avoided and / or replaced, with preference given to digital and aneroid alternatives) or aerosol cans), and preferring products with less packaging or products that weigh less than comparable products that perform the same function 	environment health. Details regarding the implementation of waste management hierarchy are explained in the Waste and Wastewater Management Plan prepared for the Project.
	 Use of physical rather than chemical cleaning practices (e.g. using microfiber mops and cloths), where such practices do not affect disinfection and meet relevant standards for hygiene and patient safety 	
	Waste toxicity reduction measures:	
	Consider options for product / material substitution for equipment containing mercury or other hazardous chemicals; products that may become hazardous waste when disposed; products made of polyvinyl chloride (PVC) (Products made of PVC may include intravenous (IV) bags, blood bags and tubing, basins, hemodialysis equipment, patient identification bracelets, bedpans, inflatable splints, respiratory therapy products, stationary supplies, catheters, lab equipment, drip chambers, medical gloves, thermal blankets, internal feeding devices, and packaging. When burned at certain temperatures, PVC has the potential to release); halogenated compounds (For example, minimize use of halogenated compounds through work practice modifications including use of citrus-based solvents rather than xylene); products that off-gas volatile organic compounds (VOCs), or products that contain persistent, bio-accumulative and toxic (PBT) compounds; products that contain substances which are carcinogenic, mutagenic or reproductive toxins (CMR)	
	 Use of efficient stock management practices and monitoring (e.g. for chemical and pharmaceutical stocks), including: 	
	 Small / frequent orders for products that spoil quickly and strict monitoring of expiry dates 	
	 Complete use of old product before new stock is used 	
	Maximization of safe equipment reuse practices, including:	

Standard/ Guideline	Requirement	Project Compliance
	 Reuse of equipment following sterilization and disinfection (e.g. sharps containers) 	
	Waste Segregation Strategies:	According to Turkish environmental legislation, it is
	At the point of generation, waste should be identified and segregated. Non-hazardous waste, such as paper and cardboard, glass, aluminium and plastic, should be collected separately and recycled. Food waste should be segregated and composted. Infectious and / or hazardous wastes should be identified and segregated according to its category using a color-coded system. If different types of waste are mixed accidentally, waste should be treated as hazardous. (Staff should not attempt to correct errors of segregation by removing contents of a waste	other. Therefore, all generated waste types by mixing with each other. Therefore, all generated waste types and chemicals used in laboratories within the facility will be collected separately in dedicated waste containers.
	receptacie, or placing one receptacie inside another) Other segregation considerations include the following:	Laboratory wastewater from the sinks, showers,
	Avoid mixing general nealth care waste with nazardous health care waste to reduce disposal costs;	autoclave chambers and floo drains will not be mixed with domestic wastewater to avoid chemical
	 Segregate waste containing mercury for special disposal. Management of mercury containing products and associated waste should be conducted as part of a plan involving specific personnel training in segregation and clean up procedures; 	and biological contamination. In addition, different types of medical waste will not mixed with each
	 Segregate waste with a high content of heavy metals (e.g. cadmium, thallium, arsenic, lead) to avoid entry into wastewater streams; 	other. Waste management personnel will be trained
•	 Separate residual chemicals from containers and remove to proper disposal containers to reduce generation of. Different types of hazardous chemicals should not be mixed; 	regarding defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that might result due to waste management activities.
	 Establish procedures and mechanisms to provide for separate collection of urine, feces, blood, vomits, and other wastes from patients treated with genotoxic drugs. Such wastes are hazardous and should be treated 	
	accordingly;	Any chlorine containing waste will be segregated to
	 Aerosol cans and other gas containers should be segregated to avoid disposal via incineration and related explosion hazard: 	
	 Segregate health care products containing PVC to avoid disposal via incineration or in landfills. 	standards, are detailly defined in the Waste and Wastewater Management Plan prepared for the Project.
<u>c</u> • •	On-site Handling, Collection, Transport and Storage:	Waste management personnel will be trained about
	 Seal and replace waste bags and containers when they are approximately three quarters full. Full bags and containers should be replaced immediately, 	defining, separating, collecting, labelling, preparing to transport, record keeping of waste as well as health risks and emergency response that that might
	 Identify and label waste bags and containers properly prior to removal, 	result due to waste management activities.
	 Transport waste to storage areas on designated trolleys / carts, which should be cleaned and disinfected regularly, 	Laboratory/medical waste storage time will not exceed 48 hours in ambient temperature and 1 week
	 Waste storage areas should be located within the facility and sized to the quantities of waste generated, with the following design considerations: 	at 4°C, within the storage area prior to transfer waste to licensed third-party waste management
	 Hard, impermeable floor with drainage, and designed for cleaning / disinfection with available water supply 	facilities. Waste will be temporarily stored in the Waste
	 Secured by locks with restricted access 	Building which is designed according to the
	 Designed for access and regular cleaning by authorized cleaning staff and vehicles 	requirements to temporarily store the waste apart

Standard/ Guideline	Requirement	Project Compliance
	 Protected from sun, and inaccessible to animals / rodents Equipped with appropriate lighting and ventilation Segregated from food supplies and preparation areas Equipped with supplies of protective clothing, and spare bags / containers Unless refrigerated storage is possible, storage times between generation and treatment of waste should not exceed the following: Temperate climate: 72 hours in winter, 48 hours in summer Warm climate: 48 hours during cool season, 24 hours during warm season Store mercury separately in sealed and impermeable containers in a secure location, Store radioactive waste in containers to limit dispersion, and secure behind lead shields. 	from human traffic areas in the dedicated area of the Project site.
	 Transport to External Facilities: Transport waste destined for off-site facilities according to the guidelines for transport of hazardous wastes / dangerous goods in the General EHS Guidelines, Transport packaging for infectious waste should include an inner, watertight layer of metal or plastic with a leak-proof seal. Outer packaging should be of adequate strength and capacity for the specific type and volume of waste, Packaging containers for sharps should be puncture-proof, Waste should be labelled appropriately, noting the substance class, packaging symbol (e.g. infectious waste, 	All types of Project-related waste will be transferred to the licensed third-party waste management facilities with licensed waste haulers according to the waste type and Turkish environmental legislation requirements as well as the relevant international standards. Additional management precautions will be taken for transfer of medical wastes in accordance with the national legislation and international standards
	 radioactive waste), waste category, mass / volume, place of origin within hospital, and final destination, Transport vehicles should be dedicated to waste and the vehicle compartments carrying waste sealed. 	where necessary.
	Treatment and Disposal Options: Facilities receiving hazardous health care waste should have all applicable permits and capacity to handle specific types of health care waste. Wastes from each category should be treated according to the treatment methods and technologies. When selecting a waste disposal technology, operators should consider other potential health and environmental issues that may be generated by the treatment. The main types of treatment and disposal technologies and techniques available for health care waste are listed below: Incineration Chemical disinfection Wet thermal treatment Microwave irradiation Landfill disposal	All types of Project-related waste will be transferred to the licensed third-party waste management facilities with licensed waste haulers according to the waste type and Turkish environmental legislation requirements. The transportation documentation will be prepared through the MoTAT system of the MoEUCC prior to transportation and kept for 5 years.
	Inertization	

Standard/ Guideline	Requirement	Project Compliance
	WASTEWATER	Laboratory wastewater from the sinks, showers,
	Process Wastewater:	autoclave chambers and floor drains will not be mixed with domestic wastewater to avoid chemical
	Wastewater from healthcare facilities (HCFs) often has a quality similar to urban wastewater. Contaminated wastewater may result from discharges from medical wards and operating theaters (e.g. body fluids and excreta, anatomical waste), laboratories (e.g. microbiological cultures, stocks of infectious agents), pharmaceutical and chemical stores: cleaning activities (e.g. waste storage rooms), and x-ray development facilities. Wastewater	and biological contamination. In addition, different types of medical waste will not be mixed with each other.
	may also result from treatment disposal technologies and techniques, including autoclaving, microwave irradiation, chemical disinfection, and incineration (e.g. treatment of flue gas using wet scrubbers which may contain suspended solids, mercury, other heavy metals, chlorides, and sulphates). Depending on the effectiveness of hazardous waste management practices (in particular waste segregation strategies described above), hazardous health care wastes may enter the wastewater stream, including microbiological pathogens (wastewater with a high content of enteric pathogens, including bacteria, viruses, and helminthes / parasitic worms), hazardous chemicals, pharmaceuticals, and radioactive isotopes.	Wastewater management practices are defined detailly in the Waste and Wastewater Management Plan prepared for the Project.

Pollution prevention measures to minimize the generation of wastewater include the following:

- Waste segregation measures should be employed to minimize entry of solid waste into the wastewater stream, including:
 - Procedures and mechanisms for separate collection of urine, feces, blood, and vomit from patients treated with genotoxic drugs to avoid their entry into the wastewater stream (as described above under waste segregation for hazardous and other wastes);
 - Collection of large quantities of pharmaceuticals for separate treatment or return to manufacturer. Small quantities of mild, liquid pharmaceuticals, excluding antibiotics or cytotoxic drugs, may be discharged to sewer systems with a large water flow.

Municipal Wastewater Treatment:

If wastewater is discharged to sanitary sewage treatment systems, the HCF should ensure that wastewater characteristics are in compliance with all applicable permits, and that the municipal facility is capable of handling the type of effluent discharged, as discussed in the General EHS Guidelines.

On-site Wastewater Treatment:

- In cases where wastewater is not discharged to sanitary sewage systems, HCF operators should ensure that wastewater receives on-site primary and secondary treatment, in addition to chlorine disinfection.
- Techniques for treating wastewater in this sector include source segregation and pretreatment for removal / recovery of specific contaminants such as radio isotopes, mercury, etc.; skimmers or oil water separators for separation of floatable solids; filtration for separation of filterable solids; flow and load equalization; sedimentation for suspended solids reduction using clarifiers; biological treatment, typically aerobic treatment, for reduction of soluble organic matter (BOD); biological or chemical nutrient removal for reduction in nitrogen and phosphorus; chlorination of effluent when disinfection is required; dewatering and disposal of residuals as hazardous medical / infectious waste.

Standard/ Guideline	Requirement	Project Compliance
	 Additional engineering controls may be required for (i) removal of active ingredients (antibiotics and miscellaneous pharmaceutical products, among other hazardous constituents), and (ii) containment and treatment of volatile constituents and aerosols stripped from various unit operations in the wastewater treatment system. 	
	 Wastewater generated from use of wet scrubbers to treat air emissions should be treated through chemical neutralization, flocculation, and sludge settling. Sludge should be considered hazardous, and may be treated off-site in a hazardous waste facility, or encapsulated in drums with mortar and landfilled. Sludge treatment should include anaerobic digestion to ensure destruction of helminthes and pathogens. Alternatively, it can be dried in drying beds before incineration with solid infectious wastes. 	
	Other Wastewater Streams & Water Consumption:	
	Guidance on the management of non-contaminated wastewater from utility operations, non-contaminated stormwater, and sanitary sewage is provided in the General EHS Guidelines. Contaminated streams should be routed to the treatment system for industrial process wastewater. Recommendations to reduce water consumption, especially where it may be a limited natural resource, are provided in the General EHS Guidelines.	
WHO Laboratory	CORE REQUIREMENTS	"Maximum Containment Measures" (defined below)
Biosafety Manual ¹²¹	Decontamination and waste management:	will be applied for the laboratory waste and wastewater management.
	 Any surface or material known to be, or could potentially be, contaminated by biological agents during laboratory operations must be correctly managed to control biological risks. Core biosafety requirements for the handling of contaminated waste material require that processes for the identification and segregation of contaminated materials be adopted before decontamination and/or disposal. 	J
	 Where decontamination cannot be performed in the laboratory area or onsite, the contaminated waste must be packaged in an approved (that is leak-proof) manner for transfer to another facility with decontamination capacity. 	
	A summary of different categories for segregating laboratory waste and their recommended treatment is given below:	
	 Uncontaminated (non-infectious) material: Can be reused or recycled or disposed of as general municipal waste 	
	 Contaminated sharps (needles, scalpels, knives and broken glass): Must be collected in puncture-proof containers fitted with covers and treated as infectious 	
	 Contaminated material for reuse or recycling: Must be first decontaminated (chemically or physically) and then washed; thereafter it can be treated as uncontaminated (non-infectious) material 	
	 Contaminated material for disposal: Must be decontaminated onsite or stored safely before transportation to another site for decontamination and disposal 	

¹²¹ Biosafety programme management. Geneva: World Health Organization; 2020 (Laboratory biosafety manual, fourth edition and associated monographs).

Standard/ Guideline	Requirement	Project Compliance
	 Contaminated material for incineration: Must be incinerated onsite or stored safely before transportation to another site for incineration Liquid waste (including potentially contaminated liquids) for disposal in the sanitary sewer system: Should be decontaminated before disposal in the sanitary sewer 	
	 HEIGHTENED CONTROL MEASURES Decontamination and waste management: Waste generated by procedures using heightened control measures should preferably be decontaminated onsite, or close to the laboratory, to minimize the risk of exposure or release during waste transportation. Where onsite decontamination is not possible, solid waste must be appropriately packaged, stored (if required) and transferred as soon as possible to another facility with decontamination capabilities. Infectious waste must first comply with any applicable transportation regulations if it is to be removed from the laboratory for decontamination and disposal. Consideration should be given to transporting waste in sealed and leak-proof containers. 	"Maximum Containment Measures" (defined below)will be applied for the laboratory waste and wastewater management.
	 MAXIMUM CONTAINMENT MEASURES Decontamination and waste management: All waste leaving the laboratory must be treated so that it is thoroughly decontaminated and presents no infectious threat. Methods for disinfection and decontamination of material leaving the laboratory must be validated each time they are used to verify their effectiveness. All effluents from the suit area, decontamination chamber, suit shower and cabinet line (biological safety cabinets or isolators) must be decontaminated before final discharge using either heat or chemical treatment. Effluents may also require subsequent correction to a neutral pH and suitable temperature before discharge. A double-door, pass-through autoclave must be available in the laboratory area. Other methods of decontamination must be available for equipment and items that cannot withstand steam sterilization, for example, an air lock fumigation chamber. Containment drain(s) should only be installed if shown to be required by the risk assessment, for example, large animal facilities. More information on best practice for decontamination can be found in Monograph: decontamination and waste management. 	 All generated waste types and chemicals used in laboratories within the Project phases will be collected separately in dedicated waste bins/containers. In BSL3 and BSL2 laboratories, with the assumption that all wastes are biologically contaminated: All types of waste materials will be decontaminated before leaving the laboratory to disposal. All wastewater from the sinks and the showers within the laboratory will be decontaminated in wastewater decontamination prior to discharge to sewer. Double door autoclave will be used for decontamination.

8.7 Proposed Monitoring and Reporting

Procedures for monitoring the effectiveness of the mitigation measures proposed in this chapter will be expanded upon in the project-specific Waste and Wastewater Management Plan, Resource Efficiency Management Plan and Chemical and Hazardous Materials Management Plan developed for construction and operation phases of the Project. These plans will define and explain chemicals and materials used and waste types generated during the Project, corresponding management practices, legal responsibilities and monitoring requirements.

According to the Turkish regulatory requirements, generation of certain waste types in a facility should be monitored, recorded and declared to the MoEUCC website. With this approach, monitoring and reporting shall be implemented during all project phases. Monitoring and reporting activities will cover the following:

- Monitoring of the waste segregation, collection, storage and labelling for proper implementation and recording the observations in periodic check lists,
- Record keeping of the official documentation of waste transfers to third-party waste management facilities,
- Documenting the agreements with the third-party waste management facilities,
- Documenting the licenses of the third-party waste management facilities and waste haulers,
- Form keeping of the annual waste declarations of waste management,
- Staff waste management training records,
- Documenting the insurances,
- Securing the official domestic wastewater sewage connection document and/or discharge permit,
- Regular monitoring and record keeping of domestic wastewater discharges.
- Regular monitoring and record keeping of wastewater (industrial) collected/treated and discharged.
- Implementing internal audits,
- Securing and documenting the official letters related with waste and wastewater management from the authorities, and
- Documenting the environmental officials' audit documents.

Additionally, the MoH will:

- i. promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers (no later than 48 hours after learning of the incident or accident),
- ii. provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and
- iii. subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

9 AIR QUALITY

9.1 Introduction

The potential emission sources, air pollutants and air quality impacts on receptors during the construction and operation phases of the Project are described in this chapter. The chapter evaluates the baseline ambient air quality conditions in the Project location, identifies the potential Project-related impacts and outlines the necessary measures for mitigation.

During the construction phase activities, the Project related air quality impacts will mainly occur due to dust (particulate matter, PM) emissions from the earthworks, as well as the release of exhaust emissions from construction equipment and vehicles (mainly PM, SO₂, NO₂). Operation phase air quality impacts will occur due to mainly PM, SO₂, NO₂, and VOC emissions as well as greenhouse gas (GHG) emissions resulting from production and combustion activities.

9.1.1 Study Area and Area of Influence

The Project is planned to be established in Akyurt district of Ankara province. The area of influence (AoI) was determined in accordance with Regulation on the Control of Air Pollution Originating from Industry (RCAPOI)¹²² Annex II, and presented in Figure 9-1.

The impact area defined in the RCAPOI is "the area with a radius of 50 (fifty) times the chimney heights from the center of the emissions. In facilities where the effective height of emissions from the ground $(\Delta h+h)$ is less than 30 m, the facility impact area is a square-shaped area with a side length of 2 km. If the surface distribution of the non-stack emission sources (area source) is greater than 0.04 km², the plant impact area is a square-shaped area with a side length of the middle of the source square". The project consists of various resources including point, area and line types. Maximum stack height projected as 15 m. Considering the regulation terms and to cover near residential areas and other sensitive receptors, 3 km diameter area was selected as AoI for the air quality impact modelling studies.

Note that in terms of greenhouse gas emissions, the impacts are not localized and the AoI is global.

¹²² Official Gazette Date/Number: 03.07.2009/27277



Figure 9-1: Impact Area Selected for the Air Quality Modelling Study

9.1.2 Data Limitations

A detailed program had not yet been prepared for the construction and operation phases of the Project at the time of writing this report. However, given information regarding the construction phase include the following:

- Construction contractor will not install concrete batching plants on or near the construction site. It is known that concrete and aggregates will be supplied by competent companies from outside the Project site.
- No blasting will be carried out for the excavations.
- Construction materials will be stored in selected temporary storage areas within the Project site.

Project information and documentation used by the ESIA team as basis for air quality assessment were limited. As the design for the Project is at a relatively early stage, there are uncertainties regarding the instruments, equipment, and processes to be employed during the operation. In order to determine the potential air quality effects of the Project activities, assumptions and data from relevant international references were used. A 'worst case scenario' is assumed to take place at sensitive receptors that are located closest to the project site. In determining sensitive receptors, the site selection criteria specified in the national legislation were complied with.

9.1.3 Air Quality Standards Specified for the Project

The ambient air quality limit values determined for the Project in accordance with national legal requirements and applicable international standards for key pollutant parameters, by considering the more stringent ones, are as summarized in Table 9-1. For further details of national and international compliance requirements please refer to Section 9.5 of this chapter.

Table 9-1: Ambient Air Quality Standards

Parameter	Averaging Period	Turkish Limit Values ¹²³ (μg/m³)	EU Limit Values ¹²⁴ (µg/m ³)	WHO/WBG Limit (Guideline) Values ¹²⁵ (μg/m ³)	Project Standards (μg/m³)		
PM ₁₀	24 hours	50 (not to be exceeded more than 35 times a year)	50 (not to be exceeded more than 35 times a year)	50	50		
	Annual	40	40	20	20		
PM _{2.5}	24 hours	-	-	25	25		
	Annual	-	20	10	10		
SO ₂	Hourly	350 (not to be exceeded more than 24 times a calendar year)	350 µg/m ³ (not to be exceeded more than 24 times a calendar year)	-	350		
	24 hours	125 (not to be exceeded more than 3 times a calendar year)	125 μg/m ³ (not to be exceeded more than 3 times a calendar year)	20	20		
	Annual	20	20	-	20		
NO ₂	Hourly	200 (not to be exceeded more than 18 times a calendar year)	200 (not to be exceeded more than 18 times a calendar year)	200	200		
	Annual	40	40	40	40		
VOC	Hourly	280	-	-	280		
	STL	70	-	-	70		
HCI	STL	150	-	-	150		
	LTL	60	-	-	60		
HF	Hourly	30	-	-	30		
	STL	5	-	-	5		
PM Deposition	STL	390	-	-	390		
	LTL	210	-	-	210		

9.2 Baseline Description

9.2.1 Climate and Meteorological Conditions

In Ankara province, climate differences are observed among districts. In the south, the steppe climate is observed which carries the distinctive features of the Central Anatolian climate, and in the north, the mild and rainy conditions of the Black Sea climate can be seen. In this region, where the land climate prevails, winter is cold, and summer is hot and dry. July to August are the warmest months and January to February are the coldest months of the year.

¹²³ Ambient air quality limit values as given in the Regulation on the Control of Air Pollution Originating from Industry for the period 2019-2023 and 2024 and beyond

¹²⁴ Directive 2008/50/EC on Ambient Air Quality

¹²⁵ WHO Ambient Air Quality Guidelines, WBG General EHS Guidelines: Environmental – Air Emissions and Ambient Air Quality

Meteorological data on temperature, precipitation, relative humidity, pressure and wind flow (data recorded at the Ankara meteorological station, elevation from sea level: 959 m) obtained from national General Directorate of Meteorology are described in following sub-sections.

Temperature

The annual mean temperature, annual mean maximum temperature and annual mean minimum temperature observed in Ankara are 10.2 °C ,16.9 °C and 3.7 °C, respectively. The minimum and maximum temperatures measured in the province during a 60-year period are -28.0 °C in January and 41.2 °C in July, respectively. Monthly average values of temperature parameters based on data collected for the period 1960-2020 are provided in Table 9-2.

Temperature parameters	Jan	Feb	Mar	Apr	Мау	Jun	July	Aug	Sep	Oct	Νον	Dec
Mean temp. (°C)	-1.5	0.2	0.2	4.5	9.6	14.1	18.0	21.6	21.6	17.1	11.3	5.0
Mean high temp. (°C)	3.2	5.6	11.0	16.4	21.1	25.4	29.2	29.4	25.2	19.1	12.1	5.6
Mean low temp. (°C)	-5.4	-4.4	-1.3	2.9	7.0	10.1	13.2	13.3	8.8	4.2	-0.7	-2.9
Max.recorded temp. (°C)	16.0	20.6	25.6	29.9	32.7	36.0	41.2	39.0	37.9	32.8	23.5	18.4
Min.recorded temp. (°C)	-28.0	-27.3	-23.4	-9.6	-6.0	0.0	3.4	3.3	-2.4	-9.5	-12.7	-23.4
Mean daily sunshine (hrs)	2.7	3.7	5.0	6.1	8.1	9.9	11.1	10.7	8.8	6.5	4.5	2.4

Table 9-2: Average temperature and sunshine data for a period	l of 60	years	(1960-2020)
---	---------	-------	-------------

Precipitation

Based on the meteorological data obtained from the Ankara regional meteorological station between 1960 and 2020, the highest average rainfall has been recorded in May as 49.6 kg/m² while the lowest average rainfall has been recorded during August as 13.0 kg/m². Within this 60-year period, the annual mean of the total precipitation is recorded as 414.9 kg/m² and the number of rainy days per year averages to 108.42 (see Table 9-3).

Table 9-3: Precipitatio	n data for Anka	ra for a period of 60	years (1960-2020)
-------------------------	-----------------	-----------------------	-------------------

Precipitation Parameters	Jan	Feb	Mar	Apr	Мау	Jun	July	Aug	Sep	Oct	Nov	Dec
Mean number of days with precipitation	12.56	11.57	10.90	11.44	12.84	9.30	3.97	3.43	4.13	7.41	8.51	12.36
Mean total monthly precipitation	46.5	36.5	39.3	44.4	49.6	37.6	15.0	13.0	16.8	29.8	33.4	53.0

Humidity and Pressure

Based on the meteorological data obtained from the Ankara regional meteorological station for the 60 year period, the average monthly humidity in the region ranges from 49.9% in August to 80.7% in December (see Table 9-4). The highest humidity has been recorded as 97.3% in January and March, and the lowest humidity was recorded as 16.2% in September. The annual mean pressure has been recorded as 907.0 hPa between 1960 and 2020.
Humidity and pressure parameters	Jan	Feb	Mar	Apr	Мау	Jun	July	Aug	Sep	Oct	Nov	Dec
Ave. humidity (%)	79.9	75.9	68.8	64.6	64.0	59.5	50.8	49.9	53.9	63.9	73.3	80.7
Min. humidity (%)	43.2	35.8	21.9	20.6	22.4	21.6	17.6	17.1	16.2	20.4	28.7	42.0
Max. humidity (%)	97.1	97.0	97.1	96.7	95.7	93.1	88.7	89.1	92.9	96.3	97.3	97.0
Mean pressure (hPa)	908.1	906.6	905.6	904.7	905.8	905.7	904.9	905.7	907.9	910.0	910.2	908.9
Max. pressure (hPa)	925.6	923.8	925.7	919.6	916.8	915.9	914.4	914.8	918.8	922.1	922.7	925.4
Min. pressure (hPa)	875.7	884.8	876.0	884.6	891.6	892.0	891.8	894.1	891.0	891.4	888.8	881.5

Table 9-4: Relative humidity	and pressure data for a	period of 60 years (1960-2020)
------------------------------	-------------------------	--------------------------------

Wind Characteristics

The prevailing wind direction in Ankara is North (N). Wind rose of the long-term meteorological observations is given in Figure 9-2.



Figure 9-2: Akyurt wind rose

The 60-year average wind speed is 2.33 m/s. Maximum wind speed was recorded as 40.6 m/s. Monthly average wind speed for the 60-year period is given in Table 9-5.

Table 9-5: Month	y average wind s	peed between the	years 1960-2020
------------------	------------------	------------------	-----------------

Wind speed (m/s)	Jan	Feb	Mar	Apr	Мау	Jun	July	Aug	Sep	Oct	Nov	Dec
Average wind speed	1.8	2.2	2.5	2.6	2.3	2.3	2.9	2.8	2.2	1.8	1.6	1.8
Maximum Wind speed and direction	S 36.0	SSW 28.1	SW 34.8	WSW 31.7	SSW 29.8	SW 32.2	SW 31.8	SE 40.6	SW 33.3	SW 27.8	W 25.2	SW 30.6

9.2.2 Air Quality Baseline Conditions

There is no site-specific air quality data publicly available for the Project site. However, the National Air Quality Monitoring Network (NAQMN) provides measurements of air pollutants (PM₁₀, PM_{2.5}, SO₂, CO, NO₂, NO_x, O₃, Ascol, Benzo(a)pyrene (BAp), Benzene, Cd, Ni, Pb) throughout Turkiye. The official website of the NAQMN provides real-time air quality monitoring data and the air quality index of each station recorded at the monitoring stations. There are eighteen air pollution monitoring stations that are integrated into the NAQMN in Ankara. There is no air quality measurement station in the immediate vicinity of the Project site. Therefore, no preliminary data could be obtained for the site. The nearest stations are Keçiören and Siteler stations which are located southwest of the Project site at distances of 13.5 km and 14.4 km respectively (see Figure 9-3). Keçiören station provides regular and continuous data for PM_{2.5}, PM₁₀, SO₂, NO₂, NO_x and O₃ parameters, therefore is selected as the representative monitoring station. However, since CO is not monitored at Keçiören Station, data from Siteler Station was taken into account for CO.



Figure 9-3: Locations of representative air quality monitoring stations in Ankara

An overview of national (RAMAQ - Regulation on Assessment and Management of Air Quality¹²⁶) and international ambient air quality standards is provided in Table 9-6 below. Data from the above air quality monitoring stations for the period between 1 January 2021 and 1 January 2022 were used to obtain the short and long-term data provided in Table 9-6the table for comparison of the existing air quality against the regulatory standards.

Table 9-6: EU Council Directive 2008/50/EC, Turkish (as per RAMAQ Annex 1) and WBG General EHS Guidelines Ambient Air Quality Standards

Pollutant	Short and Long-Term Values	Representative Station	Turkish Standards (as of 2022)	EU	WBG
SO ₂ (µg/m ³)	Maximum Hourly	86.7	350	350	-
	Maximum Daily	15.4	125	125	-
	Annual**	7.7	20	20	20
PM ₁₀ (µg/m ³)	Maximum Daily	126.5 (65 exceedances)	50	50	50

126 Official Gazette Date/Number: 06.06.2008/269899

Pollutant	Short and Long-Term Values	Representative Station	Turkish Standards (as of 2022)	EU	WBG
	Annual	35	40	40	20
PM _{2.5} (µg/m ³)	Maximum Daily	70.2 (36 exceedances)	-	25	25
	Annual	13.1	-	-	10
NO ₂ (µg/m ³)	Maximum Hourly*	599.1 (236 exceedances)	220	200	200
	Annual*	60.0	44	40	40
NO _X (µg/m ³)	Annual**	103.6	30	30	-
CO (mg/m ³)	Daily (8-hr)	8.6***	10	10	-
O ₃	Hourly average from May to July (µg/m ³ .hour) - AOT40**	4876	18000	18000	-
	Maximum Daily 8-hr average in 1	120.1 (1 exceedance)	120	120	-

* In accordance with the calendar to fully adopt EU limit value (01 January 2024), limit value in 2021 has been found by equally decreasing tolerance value specific to nitrogen dioxide.

**Limit values for the protection of vegetation

*** Data from Siteler Station is used since no CO measurement data is available from Keçiören Station.

As shown in Table 9-6, maximum daily average concentration of PM₁₀ has exceeded the Turkish, EU and WBG standards (50 μ g/m³) 65 times in 1 year. (Annual PM₁₀ is lower than the national and EU standard (40 μ g/m³); however, the annual average PM₁₀ concentration does not comply with the WBG limit value (20 μ g/m³). The maximum daily average concentration of PM_{2.5} has also exceeded the EU and WBG standards (25 μ g/m³) 36 times in 1 year. Similarly, maximum hourly NO₂ concentration has exceeded the Turkish and EU standard (50 μ g/m³) 236 times in 1 year. The annual concentration of NO₂ and NO_x also exceeds the national, WBG and EU standards. According to the measurements, hourly, daily and annual concentrations of SO₂ comply with Turkish and EU standards. As indicated in Table 9-6, daily average values of CO comply with the 8-hr average limit values defined in Turkish and EU standards.

There are several emission sources in the Project area including industry and heavy traffic on the highway leading to the Esenboğa Airport to the east of the facility. The shoe factory (YDS) and mattress factory (İşbir) are the closest emission sources to the Project site. Besides, the settlement located in the southeast of the facility (Saracalar) has the potential to cause intense emissions especially in the winter season because of heating. As fossil fuels such as coal are used for heating purposes in the area, main emission parameters will be combustion gases (PM, NO_x, SO_x, CO etc).

9.2.3 Air Quality Baseline Measurements

Since the above data cannot fully represent the site conditions due to the distance between the Project site and the monitoring stations, baseline air quality measurements have been included in the area surrounding the Project site within the scope of the ESIA study. In this context, the following were carried out by an accredited laboratory:

- passive samplings (for NO₂, SO₂, HCI, HF and volatile organic compounds VOC) at eight locations for two months in one-month periods which means each location has two results,
- active samplings (for particulate matter PM_{2.5} and PM₁₀) were carried out at two locations for a onemonth period which means each location has 30 results, and
- dust deposition measurements were carried out at two locations for two months in one-month periods which means each location has two results.

In selecting measurement locations, sensitive receptors were considered (i.e. residential). In addition to these, agricultural lands and non-industrial workplaces (such as Otonomi) were also accounted for as receptors. Measurement locations are given in Figure 9-4: .



Figure 9-4: Baseline Ambient Air Quality Measurement Locations (PM_x: Particulate matter and dust deposition monitoring locations, PAS_x: Passive gas sampling locations)

Inhalable dust in ambient air (PM₁₀ and PM_{2.5}) analysis was carried out in accordance with TS EN 12341 'Ambient Air - Standard Gravimetric Measurement Method for Determination of PM₁₀ and PM_{2.5} Mass Concentrations of Suspended Granular' international standard. According to this standard, dust is accumulated on a filter and analysis is conducted gravimetrically in laboratory conditions.

NO₂, SO₂, HCI, HF and VOC measurements were carried out by passive sampling tubes. Exposure time of the sampling tubes is 8 weeks and shelf life is 3 months. Measurements were carried out between 21.01.2022 – 22.03.2022 by monthly periods at eight locations. Passive samplers were located at 1.5-4.0 meters above from ground level, at least 1.5 meters away from buildings (or from impact area) as required by RCAPOI Appendix-2.h.4. Sampling was conducted according to the TS EN 13528-1 Ambient air quality - Diffusive samplers for the determination of concentrations of gases and vapours - Requirements and test methods (Part 1: General requirements, Part 2: Specific requirements and test methods, and Part 3: Guide to selection, use and maintenance).

The baseline ambient air quality measurement results are given in Table 9-7 for dust emissions (average of 30 daily measurements) and for dust deposition emissions (average of two monthly measurements) and in Table 9-8 for gas emissions (average of two monthly measurements).

	,	(
Measurement	Description of the Receptor	PM ₁₀ (μg/m³)	PM _{2.5}	Dust Deposition (µg/m³)		
Location			(µg/m) -	STV*	LTV*	
1	Rural Receptor	57.816	12.798	56.04	54.25	
2	Residential Receptor	65.246	13.410	53.83	53.80	
Turkish Limit Va	lues ¹²⁷	50	-	390	210	
EU Limit Values	128	50	-	-	-	
WHO/WBG Limit (Guideline) Values ¹²⁹		50	25	-	-	
Project Standard	ds	50	25	390	210	

Table 9-7: Baseline Ambient Air Quality (Dust and Dust Deposition) Measurement Results

*STV stands for Short Term Value and LTV stands

for Long Term Value

Table 9-8: Baseline Ambient Air Quality (Gas) Measurement Results

Measurement Location	Description of the Receptor	SO₂ (µg/m³)	NO₂ (µg/m³)	HCI (µg/m³)	HF (µg/m³)	VOC (STL*) (µg/m³)
PT-1	Rural Receptor	0.0011	<0.0004	2.2124	<0.0358	1.43
PT-2	Commercial Receptor	<0.0002	<0.0004	<0.4084	<0.0358	1.61
PT-3	Residential Receptor	<0.0002	<0.0004	2.7576	<0.0358	1.51
PT-4	Commercial Receptor	<0.0002	<0.0004	3.3054	<0.0358	1.48
PT-5	Residential Receptor	<0.0002	<0.0004	3.2413	<0.0358	1.15
PT-6	Residential Receptor	<0.0002	<0.0004	3.9983	<0.0358	2.81
PT-7	Residential Receptor	<0.0002	<0.0004	3.4568	<0.0358	1.21
PT-8	Residential Receptor	<0.0002	<0.0004	2.1726	<0.0358	1.24
Turkish Limit V	alues ¹⁴ (µg/m³)	350 (Hourly)	200 (Hourly)	150 (STL)	30 (Hourly)	280 (Hourly)
EU Limit Value	s ¹⁵ (µg/m³)	350 (Hourly)	200 (Hourly)	-	-	-

¹²⁷ Ambient air quality limit values as given in the Regulation on the Control of Air Pollution Originating from Industry for the period 2019-2023 and 2024 and beyond

¹²⁸ Directive 2008/50/EC on Ambient Air Quality

¹²⁹ WHO Ambient Air Quality Guidelines, WBG General EHS Guidelines: Environmental – Air Emissions and Ambient Air Quality

Measurement Description of the	SO₂	NO₂	HCI	HF	VOC (STL*)
Location Receptor	(µg/m³)	(µg/m³)	(µg/m³)	(µg/m³)	(µg/m³)
WHO/WBG Limit (Guideline) Values ¹⁶ (μg/m ³)	20 (Daily)	200 (Hourly)	-	-	-
Project Standards	350	200	150	30	280
	(Hourly)	(Hourly)	(STL)	(Hourly)	(Hourly)

The baseline ambient air quality measurement results indicate that levels of PM₁₀ at 1 and 2 are above the Project standards. It should be noted that the measurements are carried out during the winter months and atmospheric inversion conditions must be taken into account. The measurement results for dust deposition, SO₂, NO₂, HCl, HF and VOC are significantly below the Project standards. The laboratory result forms are presented in Appendix E.

The results of the baseline ambient air quality measurements were used to inform the air quality dispersion modelling study undertaken to assess the potential air quality impacts of the Project during construction and operation of the proposed Project. The results of the study are presented in Section 9.3 below.

9.2.4 Greenhouse Gases and Climate Mitigation

According to the national and global scale predictions, Ankara is expected to face drought and related risks that will arise due to climate change in the near future. It has been noted in the scenario of the Intergovernmental Panel on Climate Change (IPCC) that, if the necessary mitigation measures are not taken, the annual average temperatures in Turkiye will rise by 2.5-4 °C until 2050²¹. It has also been reported that southern provinces will face a serious drought threat, while the risk of flooding will increase in the northern regions. Ankara is also counted among the provinces that will be exposed to significant drought risks.

In Turkiye, several steps regarding climate change mitigation have been and are being taken in both national and local level. Turkiye became a party to the United Nations Framework Convention on Climate Change (UNFCCC) in 2004 and signed the Paris Agreement in 2016, however, only recently (October 2021) ratified the agreement. Being responsible for 0.7% of total global emissions since the industrial revolution, Turkiye committed to "up to 21% reduction in GHG emissions from the Business as Usual (BAU) level by 2030". This reduction is aimed to be realised through the measures to be taken and policies to be implemented in the energy, industrial processes, agriculture, land use and waste sectors across the economy.

Ankara Metropolitan Municipality has published the Ankara Province Local Climate Change Action Plan (YIDEP) to focus on several topics such as the risks that arise due to climate change, the mitigation and adaptation measures that might be adopted to minimize the adverse effects of climate change, and how to reduce vulnerability of the city and its habitants by increasing climate resilience. The action plan covers GHG emissions of the Ankara province in 2019, the GHG projections between the years 2019-2050 within the borders of the province, and the suggested emission minimization measures. The report also covers vulnerability and risk analysis of the city regarding the impacts of climate change, and the adaptation measures to be taken.

The calculations made within the scope of the main categories of the GPC (Global Protocol for Community-Scale Greenhouse Gas Emissions Inventories) standard (GPC Basic) indicate that approximately 22.9 million tons (4.05 tons/capita) of greenhouse gas emissions were generated in Ankara Province in 2019¹³⁰. Distribution of the GHG emissions of Ankara within the scope of GPC Basic are shown in Figure 9-5.

¹³⁰ Ankara Metropolitan Municipality (2022). Ankara Province Local Climate Change Action Plan. Accessed from <u>ANKARA</u> <u>ILI SERA GAZI EMISYON ENVANTERI RAPORU</u>



Figure 9-5: GHG Emissions of Ankara Province in 2019 according to GPC Basic⁸

Laboratory requirements present several design challenges and lead to operational buildings that are intensive users of energy and other resources. Since laboratories demand thermal comfort requirements, rooms kept at different air pressure, a need for sufficient clean air all year around, substantial hot water and power requirements supported by a reliable power supply, and much more, they are among resource-intensive buildings. As indicated in Table 9-9 below, laboratories where biological research and experimentation is carried out, ventilation and keeping the mandatory environmental conditions demand high energy consumption while laboratory instrumentation are indicated as consuming medium level of energy. Assuring energy efficiency at the design and operation stages of the laboratories and associated units is essential in order to reduce the carbon emissions intensity.

Туре ^а	Chemical	Biological	Instrumentation
Ventilation ^b	High	Medium/High	Low
Equipment ^c	Low	Medium	High
Laboratory Conditions ^d	Low	High	Medium

Table 9-9: Energy Demand by Laboratory Type¹³¹

^a Chemical: These laboratories are fume cupboard intensive and are devoted to organic, inorganic and analytical chemistry.

Biological: These laboratories employ a mix of fume cupboards and safety cabinets; they typically operate with a range of thermal environments (e.g., cold rooms and hot rooms) and varying levels of containment to contain toxic and infectious biological materials. These laboratories are often defined by bio-safety levels and may require decontamination procedures.

Instrumentation: Experimental work is more instrumental than practical, involving materials testing or electronics, and as such there are high-connected power loads with a variety of electrically powered instruments leading to relatively high air conditioning loads and process water cooling requirements.

¹³¹ McCann, A. (2005). Energy Efficiency in Laboratory Buildings. A thesis submitted for the Degree: MSc Energy Systems & the Environment, Department of Mechanical Engineering University of Strathclyde, Glasgow, U.K. accessed from <u>https://www.esru.strath.ac.uk/Documents/MSc_2005/mccann.pdf</u> on 07 June 2022.

Typeª	Chemical	Biological	Instrumentation	
^b Ventilation rates; low = r	o fume cupboards or safety	cabinets, high = fume cup	boards and/or safety cabinets	
^c Equipment loads; low = 0	0 to 50 W/m ² , medium = 50 t	to 100 W/m ² , high = 100 to	o 150 W/m ² (electrical and thermal)	
^d Laboratory conditions; Ic	w = 21/24 °C and 40/60% R	H, medium = 21 +/-1 ^o C a	and 55% RH+/-5%, high = cold rooms to $-5 +/-1$	⁰ C
and hot rooms 40 +/-1 °C				

9.3 Assessment of Impacts

9.3.1 Methodology

The air quality impact assessment has been conducted through the following steps:

- Establishment of baseline: Ambient air quality conditions within the Project Aol have been identified by conducting baseline measurements as described above in Section 9.2.
- Assessment of impacts: Possible impacts related to air quality and emissions have been assessed together with their significance levels. The significance criteria adopted for the assessment of impacts is provided in Section 9.3.2. Impact assessment covers:
 - Assessment of deviation from baseline conditions: An air quality dispersion modelling study was carried out by using AERMOD View – Gaussian Plume Air Dispersion Model software to estimate Project emissions and their contribution to the baseline conditions for both construction and operation phases of the Project.
 - Assessment of potential impacts on key receptors associated with construction and operation phases of the Project. Key receptors which are anticipated to be sensitive to changes in the existing air quality conditions on site are considered to include human health (nearby communities, businesses, Project employees), and ecological receptors.
- Development of mitigation measures: To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise the overall environmental impact from associated with the Project.

The AERMOD model was employed in the air quality modelling study. AERMOD model, which was developed by United States Environmental Protection Agency (US EPA), is one of the most advanced computer models estimating hourly, daily and annual ground level concentrations (GLCs) on the basis of the real time values. The model enables the calculation of different dispersion models for different sources (point, volume, line) from isolated stacks to fugitive pollutants. Additionally, it can consider conditions like aerodynamic waves and turbulence. Latest version of the software (i.e. AERMOD 21112) which was released in April 2021 is used.

Hourly meteorological data for the modelling study were obtained from the Esenboğa Airport Meteorological Station which is run by General Directorate of Meteorology. In order to determine the representative meteorological year, the prevailing wind direction was reviewed for long term meteorological data from 1960-2021 meteorological bulletin and this data was compared with each year's prevailing wind directions. Based on the results of this assessment, meteorological data of 2020 were used for the modelling study. As a result of the modelling study, dispersion maps were generated for the parameters listed below:

- Short term and long-term emission dispersions of PM deposition parameter,
- Maximum daily and annual average emission dispersions of PM₁₀ and PM_{2.5} parameters for the construction phase,
- Maximum hourly average emission dispersions for VOC parameter for the operation phase,
- Maximum hourly and annual average emission dispersions for NO₂, SO₂ parameters for the operation phase.

9.3.2 Determining Magnitude, Sensitivity and Impact Significance

The significance of potential impacts is a function of the presence and sensitivity of receptors and magnitude of the impact. The magnitude of air quality impacts is determined taking the sensitivity of the receiving environment into account. Sensitive receptors with the potential to be affected by the Projectrelated emissions have been determined by a field study conducted by the air quality experts. At sensitive receptors, the magnitude of impacts of air pollutant parameters depends on factors such as the prevailing wind conditions of the region, precipitation or vegetation. While evaluating the contribution of the Project to the air quality, the change in the concentrations (process contribution) caused by the Project in sensitive receptors has been taken into account. Changes in ambient concentrations over 25% of the relevant standards are considered to represent an impact of 'Major' magnitude as the WBG General EHS Guidelines note that Projects should: "...prevent or minimize impacts by ensuring that ...emissions do not contribute a significant portion to the attainment of relevant ambient air quality guidelines or standards. As a general rule, this guideline suggests 25 percent of the applicable air quality standards to allow additional future sustainable development in the same airshed." The guidelines classify 'poor quality airsheds' as those where relevant standards are exceeded significantly. Therefore, receptors experiencing existing ambient pollutant concentrations above the relevant standards are concluded to be of 'High' sensitivity. For each of the key pollutants and averaging periods assessed, a number of ambient air quality standards are applicable.

Table 9-10 and Table 9-11 present the approach used to define the receptor sensitivity and magnitude of air quality impacts associated with the Project.

Ground Level Pollutant Concentrations in Relation to Standard	Receptor Sensitivity
Above Standard	High
75 to 100% of the Standard	Medium
50 to 75% of the Standard	Low
Below 50% of the Standard	Negligible

Table 9-10: Determination of Receptor Sensitivity - Operational Phase

Change in Concentrations as % of Standard	Impact Magnitude
Increase >25%	Major
Increase 15-25%	Moderate
Increase 5-15%	Minor
Increase <5%	Negligible

Finally, the impact significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 9-12.

Table 9-12: Impact Significant Matrix

Magnitude of Impact	Sensitivity of Receptors						
	Negligible	Low	Medium	High/Very High			
Negligible	Insignificant	Insignificant	Insignificant	Insignificant			
Minor	Insignificant	Minor	Minor	Moderate			
Moderate	Insignificant	Minor	Moderate	Major			
Major	Insignificant	Moderate	Major	Critical			

9.3.3 Construction Phase

Construction Phase Emissions

Air quality impacts which arise during the construction of the Project include the following:

- Dust arising from on-site construction activities of the project area, stripping of vegetative soil, loading and transporting on trucks – dust generated by construction activities can be mechanically transported off site by wind or re-suspension by vehicles.
- Emissions associated with on-site plant and vehicles typically Particulate Matter, Sulphur dioxide (SO₂) and Nitrogen oxides (NO_x).

Emissions from on-site construction activities:

Construction phase emission factors are derived from the EMEP/EEA Air Pollutant Emission Inventory Guidebook 2019-2. A.5.b-Construction and Demolition- Non-residential Construction Tier 1 Emission Factors which are shown in Table 9-13.

Table 9-13: Emission Factors for Non-residential Construction

Parameter	Emission Factor	Unit
PM ₁₀	1.0	kg/[m ² .year]
PM _{2.5}	0.1	kg/[m ² .year]

Necessary measures will be taken during the construction phase of the Project for dust suppression. Western Regional Air Partnership reports an overall dust suppression efficiency of about 50% on average¹³². Therefore, it is assumed that watering that will routinely take place in heavy construction activities during dry periods will result in an overall emission reduction of 50%.

Emissions from vehicle engine activities at the site:

Engine emission factors are derived from the *EMEP/EEA Air Pollutant Emission Inventory Guidebook* 2019-Non-Road mobile sources and machinery. Vehicle emission factors are shown in Table 9-14. Average fuel consumption is compiled from heavy duty machine producers as 25 L/h (20 kg/h = 0.02 t/h).

Table 9-14: Vehicle Emission Factors

Parameter	Emission Factor Non-Road (g/kWh-equipment)
NO _x	32,629 g/tones fuel
СО	10,774 g/tonnes fuel
PM ₁₀	2104 g/tonnes fuel
PM _{2.5}	2104 g/tonnes fuel
SO ₂	14 g/kg fuel*
VOC	3377 g/tonnes fuel
Fuel consumption	20,000 g/h
* Calculated by 0.7% Sulphur content	

Because of the lack of explicit data, sample data was used in accordance with the EMEP/EEA 1.a.4 Section 3.2.3

Engine emissions include engine emissions from all motor vehicles that can be used for the Project. Information on equipment that is planned to be used in the Project is presented in Table 9-15.

¹³² Countess Environmental (2006). Western Regional Air Partnership (WRAP) Fugitive Dust Handbook Contract No. 30201-111. Western Governors' Association, Denver.

Type of Equipment	Number
Bored Pile Machine	2
Tower Crane (8 tonnes)	2
Tractor Loader	1
Tractor	1
Road Roller (10t/3t)	1
Mobile Crane (35 tonnes)	1
Mini Loader	1
Compactor	1
Generator (105 kW)	2
Total	12

Table 9-15: Number of Equipment to be Used in the Construction Phase of the Project

According to this information, emission calculations are shown in Table 9-16.

 Table 9-16: Emission Calculations According to the Number of Equipment to be Used in the

 Project

Pollutant	Emission Factor	Fuel Consumption (t/h)	Emission per Vehicle (kg/h)	Number of Vehicle	Total Emission (kg/h)	Threshold Value (kg/h)
NO _X	32,629 g/tonnes fuel	0.02	0.65258	12	7.83	40
CO	10,774 g/tonnes fuel	0.02	0.21548	12	2.58	500
PM	2,104 g/tonnes fuel	0.02	0.04208	12	0.50	10
SO ₂	14 g/kg fuel	0.02	0.28	12	3.36	60
VOC	3,377 g/tonnes fuel	0.02	0.06754	12	0.81	30

According to Table 9-16, since levels of the exhaust emissions arising from all motor vehicles are quite low by the national threshold values which are used to determine whether modelling study is necessary or not, engine emissions can be considered as negligible and are not included in the air quality modelling study.

Dispersion Modelling Results (Construction Phase)

Construction activities associated with the proposed Project is associated with the site preparation and building activities. These activities are expected to result in temporary dust and gas emissions.

Construction activities include two main parts. The first one is earthworks and site preparation of the Project area. In this part, particulate matter will be generated from excavation, loading and unloading processes as well as engine emissions from construction equipment and vehicles. The second one involves building construction. In this part, construction equipment movements including cement mixers, trucks, backhoes, asphalt pavers etc. will cause particulate matter emissions from land and engine emissions.

Maximum Air Pollution Contribution Values (APCV-model results) determined by the modelling studies for PM₁₀, PM_{2,5} and PM deposition are provided in Table 9-17. These results are the maximum predicted values across the study area.

Table 9-17	: Modelling	Results	for	Construction	Phase
-------------------	-------------	---------	-----	--------------	-------

Parameter	Averaging Period	Maximum APCV	Coordinates (X,Y)	Project Standards
PM10 (µg/m3)	Daily	12.95	496795, 4437546	50

Parameter	Averaging Period	Maximum APCV	Coordinates (X,Y)	Project Standards
	Annual	1.82	497201, 4436967	20
PM2.5 (µg/m3)	Daily	0.13	496795, 4437546	25
	Annual	0.018	497201, 4436967	10
PM Deposition (mg/m2day)	Short Term	3.47	497633, 4437310	390
	Long Term	0.73	497117, 4436989	210

According to Table 9-17, PM_{10} , $PM_{2.5}$ and PM deposition values which are calculated by air quality modelling study is comply with project standard.

The cumulative assessment of air quality contribution values resulting from the construction phase of the Project, along with background measurements, is summarized in Table 9-18 and Table 9-19 according to daily and yearly periods.

Table 9-18: Daily or Short-Term Cumulative Evaluation of the Construction Phase

Measurement Location	Background Concentration (Monitoring Results)			Air Emissions due to Project Activities (Modelling Results)			Cumulative Value at the Measurement Points (Monitoring+Modelling)		
	PM Deposition (mg/m²day)	ΡΜ10 (μg/m³)	PM2.5 (μg/m³)	PM Deposition (mg/m²day)	ΡΜ10 (μg/m³)	PM2.5 (μg/m³)	PM Deposition (mg/m²day)	ΡΜ10 (μg/m³)	PM2.5 (µg/m³)
1	53.80	57.816	12.798	2.51	5.36	0.05	56.31	63.17	12.85
2	54.25	65.246	13.410	3.47	7.46	0.07	57.72	72.71	13.48
Project Standard (24 hours) (μg/m³)	-	50	25	-	50	25	-	50	25
Project Standard (STL) (mg/m²day)	390	-	-	390	-	-	390	-	-

Table 9-19: Yearly	v or Long-Term	Cumulative Evaluation	of the Construction Phase
Tuble 5 15. Tean	y or conground		

Measurement Location	easurement Background Concentration Air Emissions due to Project ocation (Monitoring Results) Activities (Modelling Results)			Project Results)	Cumulative Value at the Measurement Points (Monitoring+Modelling)				
	PM Deposition (mg/m ² day)	PM10 (µg/m³)	PM2.5 (μg/m³)	PM Deposition (mg/m²day)	ΡΜ10 (μg/m³)	PM2.5 (µg/m³)	PM Deposition (mg/m²day)	РМ10 (µg/m³)	PM2.5 (µg/m³)
1	53.80	57.816	12.798	0.31	0.93	0.01	54.11	58.75	12.81
2	54.25	65.246	13.410	0.33	0.80	0.01	54.58	66.01	13.42
Project Standard (Annual) (μg/m³)	-	20	10	-	20	10	-	20	10
Project Standard (LTL) (mg/m²day)	210	-	-	210	-	-	210	-	-

Short term and long-term emission dispersions for PM deposition parameter are shown in Figure 9-6 and Figure 9-7 respectively. Maximum daily and annual average emission dispersions for PM_{10} and $PM_{2.5}$ parameters are shown in Figure 9-8 through Figure 9-11. In the figures, the Project site location is indicated in red.



Figure 9-6: Short Term PM Deposition Emissions for Construction Phase



Figure 9-7: Long Term PM Deposition Emissions for Construction Phase



Figure 9-8: Maximum Daily Average PM10 Emissions for Construction Phase



Figure 9-9: Maximum Annual Average PM10 Emissions for Construction Phase



Figure 9-10: Maximum Daily Average PM2.5 Emissions for Construction Phase



Figure 9-11: Maximum Annual Average PM2.5 Emissions for Construction Phase

Potential Impacts

An evaluation of dust potential that may occur within the scope of the construction phase of the proposed Project and expected significance of impacts, assuming that watering will routinely take place in heavy construction activities during dry periods resulting in an overall emission reduction of 50%, are summarized in Table 9-20.

Activity	Potential Dust Raising Activities	Potential Impact	Receptor	Receptor Sensitivity	Impact Magnitude	Impact Significance
Site Preparation & Building Construction	Vegetation Clearance Earthmoving Excavation works	Construction Dust	1	High	Minor	Moderate
	Load and unloading Movement of Construction Vehicles Transportation and handling soil/ materials	Construction Dust	2	High	Minor	Moderate

Table 9-20: Cumulative Evaluation of the Construction Phase

Additionally, both direct and indirect¹³³ GHG emissions are expected to occur during the construction phase of the Project. The potential sources of GHG emissions will include direct emissions associated with onsite heating and exhaust from diesel engines of construction vehicles/equipment, as well as indirect emissions associated with electricity consumption from the power grid as well as those that will occur due to transportation of employees travelling to and from the construction site. The relevant mitigation measures are discussed in Section 9.4 of this chapter.

9.3.4 Operation Phase

Emission Standards

For the operation phase of the Project, potential air emissions that may occur from ventilation shafts, pure natural gas fired steam generator and steam boilers have been taken into consideration (see Table 9-21). Note that there will no medical waste incineration at the proposed facility.

Table 9	9-21:	Equip	oment to	be U	sed in the	e Ope	erat	ion Phase o	of th	ne Project
_	~ —				-	-			_	-

Type of Equipment	Number	Capacity (MW)	Fuel
Steam Boiler	1	5	Natural Gas
Pure Steam Generator	1	5	Natural Gas
Ventilation Shaft	1	Process	Process
Total	3	-	

The Turkish Regulation on the Control of Air Pollution Originating from Industry (RCAPOI) imposes limit and threshold values for industrial facilities emission sources. The WBG Environmental, Health and Safety Guidelines also have emission standards for combustion facilities. These emission standards and threshold values are given in Table 9-22. Note that limit values and guideline values are the values that must be complied with and threshold values are the values that are used to make decisions about modelling and measurement.

Table 9-22: Industrial Emission Standards	Fable 9-22: Industri	al Emission	Standards
---	----------------------	-------------	-----------

Pollutant	IFC Guideline Values for Gas Fuel Combustion $(mg/Nm_3)^1$	RCAPOI Limit Value (mg/Nm ₃)	RCAPOI Threshold Value (kg/h) ⁷
NO _X	320 (Boilers) 200 (Gas Engines)	800² (Boilers) 500³ (Gas Engines)	40
СО	-	100² (Boilers) 650³ (Gas Engines)	500
VOC	-	_*	30

¹³³ The U.S. EPA defines 3 types of emissions: Scope 1: Direct Emissions, Scope 2: Electricity Indirect Emissions, and Scope 3: Other Indirect GHG Emissions (U.S. EPA Center for Corporate Climate Leadership, 2020, GHG Inventory Guidance)

Pollutant	IFC Guideline Values for Gas Fuel Combustion (mg/Nm ₃) ¹	RCAPOI Limit Value (mg/Nm ₃)	RCAPOI Threshold Value (kg/h) ⁷
SO _X	-	100 ² (Boilers)	60
		60 ³ (Gas Engines)	
PM	-	10 ² (Boilers)	10
		130 ³ (Gas Engines)	
		140-180 ⁵ (Process emissions)	
HCI ⁻	-	5 ⁶	20
HF ⁻	-	30 ⁶	2

¹ IFC Environmental, Health, and Safety Guideline Air Emission and Ambient Air Quality Table 1.1.2

² IAPCR Annex 5 Section 2.5

³IAPCR Annex 5 Section 2.7.1

⁴IAPCR Annex 1 Table 1.2.2

⁵ IAPCR Annex 1 Section b.1. Diagram 1

⁶ IAPCR Annex 1 Table 1.2.1

⁷ IAPCR Annex 2 Table 2.1

*VOC limits are given separately for each component.

Operation Phase Emissions

Emissions from Steam Boiler and Pure Steam Generator:

The flue gas emissions that will arise from operation of the steam boiler have been calculated using the Table 3.26 (Tier 2 emission factors for non-residential sources, medium-sized (> 1 MWth to \leq 50 MWth) boilers burning natural gas) in Section 3.3.2 of the document named the EMEP/EEA Air Pollutant Emission Inventory Guidebook 2019-1. A.4 Small Combustion. Calculations assuming a steam boiler capacity of 5 MW are given in Table 9-23. Gas flow rate within the stack is projected as 40,000 m³/h.

Table 9-23: Steam Boiler	Emission	Calculations
--------------------------	----------	--------------

Tier 2 Emission Factors for non-residential sources, medium-sized (> 1 MWth to \leq 50 MWth) boilers burning natural gas ¹⁷		Emission Calculation Mass Flow (E) = Emission Factor X Capacity Concentration (C) = E x Gas Flow Rate	Emission standards and thresholds
Pollutant	Unit (g/GJ)		
NO _X	40	E _{NOX} = 40 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.72 kg/h	40
		$C_{NOX} = (0.72 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 18 \text{ mg/m}^3$	320
CO	30	$E_{CO} = 30 \text{ g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.54 kg/h}$	500
		$C_{CO} = (0.54 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 13.5 \text{ mg/m}^3$	100
VOC	2	E _{VOC} = 2 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.036kg/h	30
		$C_{VOC} = (0.036 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 0.9 \text{ mg/m}^3$	_*
SO _X	0.3	E _{SOX} = 3 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.054 kg/h	60
		$C_{SOx} = (0.054 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 1.35 \text{ mg/m}^3$	100
PM ₁₀	0.45	E _{PM10} = 0.45 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.0081 kg/h	10
		C_{PM10} = (0.0081 kg/h) / (40,000 m ³ /h) x (1,000,000 mg/kg) = 0.2 mg/m ³	10
PM _{2.5}	0.45	E _{PM2.5} = 0.45 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.0081 kg/h	10
		$C_{PM2.5} = (0.0081 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 0.2 \text{ mg/m}^3$	10

*VOC limits are given separately for each component

The flue gas emissions that will arise from the pure steam generator during the operation phase have been calculated using the *Table 3.30 (Tier 2 emission factors for non-residential sources, reciprocating engines burning gas fuels) in Section 3.3.2* of the document named *the EMEP/EEA Air Pollutant Emission*

Inventory Guidebook 2019-1. A.4 Small Combustion. Calculations assuming a steam boiler capacity of 5MW are given in Table 9-24. Gas flow rate within the stack is projected as 40,000 m³/h.

Tier 2 Emission factors for non-residential sources, reciprocating engines burning gas fuels ¹⁷		Emission Calculation Mass Flow (E) = Emission Factor X Capacity - Concentration (C) = E x Gas Flow Rate	Emission standards and thresholds
Pollutant	Unit (g/GJ)		
NO _X	135	E _{NOX} = 135 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 2.43 kg/h	40
		C_{NOX} = (2.43 kg/h) / (40,000 m ³ /h) x (1,000,000 mg/kg) = 60.7 mg/m ³	500
CO	56	E _{co} = 56 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 1 kg/h	500
		$C_{co} = (1 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 25 \text{ mg/m}^3$	650
VOC	89	E _{voc} = 89 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 1.602 kg/h	30
		$C_{VOC} = (1.602 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 40 \text{ mg/m}^3$	_*
SO _x	0.5	E _{SOX} = 0.5 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.009 kg/h	60
		$C_{SOx} = (0.009 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 0.2 \text{ mg/m}^3$	60
PM ₁₀	2	E _{PM10} = 2 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.036 kg/h	10
		$C_{PM10} = (0.036 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 0.9 \text{ mg/m}^3$	130
PM _{2.5}	2	E _{PM2.5} = 2 g/GJ x 5 MW x 3.6 GJ/MW*h x 1 kg / 1000 g = 0.036 kg/h	10
		$C_{PM2.5} = (0.036 \text{ kg/h}) / (40,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 0.9 \text{ mg/m}^3$	130

Table 9-24: Pure Steam Generator Emission Calculations

*VOC limits are given separately for each component

Emissions from Ventilation Shaft:

In pharmaceutical manufacturing facilities, volatile organic carbon (VOC) emissions may originate from reactor vents, filtration systems in the separation process, valves and various unit equipment. Particulate matter may originate from secondary manufacturing. Low levels of HCl and HF emissions are also probable. For calculation of emissions from the ventilation shaft within the Project, a literature review was conducted to determine the typical values obtained in emission measurements of active pharmaceutical industry facilities. Calculations were performed according to the parameters given in Table 9-25. Gas flow rate within the stack is projected as 22,000 m³/h.

Table 9-25: Typical Measurement Results of the Emissions Sources from the Active Pharmaceutical Industry Facilities

Parameter	Emissions Mass Flow (E) Obtained from sample facility Concentration (C) = E x Gas Flow Rate	Emission standards and thresholds
VOC	E _{voc} = 0.4304 kg/h	30
VUC	$C_{VOC} = (0.4304 \text{ kg/h}) / (22,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 19.6 \text{ mg/m}^3$	_*
Durat	E _{dust} = 0.1 kg/h	10
Dusi	$C_{dust} = (0.1 \text{ kg/h}) / (22,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 2.5 \text{ mg/m}^3$	150
	E _{HCL} = 0.006 kg/h	20
HCI-	$C_{HCl} = (0.006 \text{ kg/h}) / (22,000 \text{ m}^3/\text{h}) \times (1,000,000 \text{ mg/kg}) = 0.15 \text{ mg/m}^3$	5
	E _{HF} =0.006 kg/h	2
	$C_{HF} = (0.006 \text{ kg/h}) / (22,000 \text{ m}^3/\text{h}) \text{ x} (1,000,000 \text{ mg/kg}) = 0.15 \text{ mg/m}^3$	30

*VOC limits are given separately for each component

Dispersion Modelling Results (Operation Phase)

Maximum Air Pollution Contribution Values (APCV-model results) determined by the modelling studies for NO₂, PM₁₀, PM_{2,5}, SO₂, CO, VOC, HCI- and HF- are presented in Table 9-26. This table shows the locations where the maximum concentrations are predicted, and the distribution maps show the distribution of the pollutants in the whole study area. The results indicate the maximum NO₂, SO₂, PM₁₀, PM_{2.5}, CO, VOC, HCI⁻ and HF⁻ APCV from the project are below the national and international standards for all averaging periods.

Parameter	Averaging Period	Maximum APCV	Coordinates (X,Y)	Project Standards
NO (ug/m^3)	Hourly	5.64	497177,4437382	200 µg/m³
NO ₂ (µg/m ³)	Annual	0.34	497201,4436967	40 µg/m³
DM (ug/m ³)	Daily	0.014	497201,4436967	50 μg/m³
F Wi ₁₀ (µg/m)	Annual	0.004	497201,4436967	40 µg/m³
PM (ug/m ³)	Daily	0.014	497201,4436967	10 µg/m³
FINI _{2.5} (µg/11 ⁺)	Annual	0.004	497201,4436967	20 µg/m³
SO2 (µg/m³)	Hourly	0.18	497177,4437382	350 µg/m³
	Daily	0.042	497177,4437382	125 µg/m³
	Annual	0.011	497201,4436967	20 µg/m³
CO (µg/m³)	Maximum Daily 8 Hours Average	1.36	497201,4436967	10000 μg/m³
$VOC (ug/m^3)$	Hourly	18.16	497635,4435490	280 µg/m³
VOC (µg/m²)	Short term value	1.04	497177,4437382	70 μg/m³
	Short term value	0.25	497635,4435490	150 µg/m³
HUI (µg/m°)	Long term value	0.014	497177,4437382	60 μg/m³
$HE^{-}(ua/m^{3})$	Hourly	0.25	497635,4435490	30 µg/m³
пг (µу/Ш*)	Short term value	0.014	497177,4437382	5 μg/m³

Table 9-26: Modelling Results for Operation Phase

The cumulative assessment of air quality contribution values resulting from the operation phase of the Project, along with background measurements, are summarized in Table 9-27 and Table 9-28 according to hourly and yearly periods, respectively. Maximum hourly and yearly average emission dispersions for all pollutant parameters are shown in Figure 9-12 through Figure 9-25.

Measurement Location		Backgroun	d Concen	tration (µg/m	³)	А	Air Emissions due to Project Activities (µg/m³)				Cumulative Value at the Measurement Points (µg/m³)				
	SO ₂	NO ₂	VOC	HCI	HF	SO ₂	NO ₂	voc	HCI	HF	SO ₂	NO ₂	voc	HCI	HF
PT-1	0.0011	<0.0004	1.43	2.2124	<0.0358	0.10	3.11	4.21	0.06	0.06	0.1011	3.11	5.64	2.2724	<0.0958
PT-2	<0.0002	<0.0004	1.61	<0.4084	<0.0358	0.07	2.23	6.75	0.10	0.10	0.07	2.23	8.36	<0.5084	<0.1358
PT-3	<0.0002	<0.0004	1.51	2.7576	<0.0358	0.03	0.94	4.40	0.06	0.06	0.03	0.94	5.91	2.8176	<0.0958
PT-4	<0.0002	<0.0004	1.48	3.3054	<0.0358	0.18	5.64	8.82	0.13	0.13	0.18	5.64	10.30	3.4354	<0.1658
PT-5	<0.0002	<0.0004	1.15	3.2413	<0.0358	0.02	0.78	2.83	0.04	0.04	0.02	0.78	3.98	3.2813	<0.0758
PT-6	<0.0002	<0.0004	2.81	3.9983	<0.0358	0.10	3.24	5.25	0.07	0.07	0.10	3.24	8.06	4.0683	<0.1058
PT-7	<0.0002	<0.0004	1.21	3.4568	<0.0358	0.05	1.67	9.27	0.13	0.13	0.05	1.67	10.48	3.5868	<0.1658
PT-8	<0.0002	<0.0004	1.24	2.1726	<0.0358	0.06	1.83	9.80	0.14	0.14	0.06	1.83	11.04	2.3126	<0.1758
Project Standard (Hourly) (µg/m ³)	350	200	280	60	5	350	200	280	60	5	350	200	280	60	5

Table 9-27: Comparison of the Operation Phase Emissions Cumulative Evaluation with Hourly Limit Values

Table 9-28: Comparison of the Operation Phase Emissions Cumulative Evaluation with Yearly Limit Values

Measurement Location		Background Concentration (µg/m³)					Air Emissions due to Project Activities (µg/m³)				Cumulative Value at the Measurement Points (µg/m³)				
	SO ₂	NO ₂	voc	HCI	HF	SO ₂	NO ₂	voc	НСІ	HF	SO ₂	NO ₂	VOC	HCI	HF
PT-1	0.0011	<0.0004	1.43	2.2124	<0.0358	<0.01	0.09	-	0.01	0.01	0.0.0111	0.09	1.43	<2.2224	<0.0458
PT-2	<0.0002	<0.0004	1.61	<0.4084	<0.0358	<0.01	0.08	-	0.01	0.01	<0.01	0.08	1.61	<0.4184	<0.0458
PT-3	<0.0002	<0.0004	1.51	2.7576	<0.0358	<0.01	0.02	-	<0.01	<0.01	<0.01	0.02	1.51	<2.7676	<0.0458
PT-4	<0.0002	<0.0004	1.48	3.3054	<0.0358	<0.01	0.30	-	0.01	0.01	<0.01	0.30	1.48	<3.3154	<0.0458
PT-5	<0.0002	<0.0004	1.15	3.2413	<0.0358	<0.01	0.02	-	<0.01	<0.01	<0.01	0.02	1.15	<3.2513	<0.0458
PT-6	<0.0002	<0.0004	2.81	3.9983	<0.0358	<0.01	0.09	-	0.01	0.01	<0.01	0.09	2.81	<4.0083	<0.0458
PT-7	<0.0002	<0.0004	1.21	3.4568	<0.0358	<0.01	0.11	-	0.01	0.01	<0.01	0.11	1.21	<3.4668	<0.0458
PT-8	<0.0002	<0.0004	1.24	2.1726	<0.0358	0.01	0.21	-	0.01	0.01	0.0102	0.21	1.24	<2.1826	<0.0458
Project	20	40	280	60	5	20	40	280	60	5	20	40	280	60	5
Standard															
(Hourly) (µg/m³)															



Figure 9-12: Maximum Hourly Average VOC Emissions for Operation Phase



Figure 9-13: Maximum 8-Hour Average CO Emissions for Operation Phase



Figure 9-14: Maximum Hourly Average NO₂ Emissions for Operation Phase



Figure 9-15: Maximum Yearly Average NO₂ Emissions for Operation Phase



Figure 9-16: Maximum Hourly Average SO₂ Emissions for Operation Phase



Figure 9-17: Maximum Yearly Average SO₂ Emissions for Operation Phase



Figure 9-18: Maximum Hourly Average HCI Emissions for Operation Phase



Figure 9-19: Maximum Daily Average HCI Emissions for Operation Phase



Figure 9-20: Maximum Hourly Average HF Emissions for Operation Phase



Figure 9-21: Maximum Daily Average HF Emissions for Operation Phase



Figure 9-22: Maximum Hourly Average PM10 Emissions for Operation Phase



Figure 9-23: Maximum Annual Average PM10 Emissions for Operation Phase



Figure 9-24: Maximum Hourly Average PM2.5 Emissions for Operation Phase



Figure 9-25: Maximum Annual Average PM2.5 Emissions for Operation Phase

Potential Impacts

Emissions will occur from process and combustion units including ventilation shafts, pure steam generator and steam boilers within the scope of the operation phase. Assessment of potential impacts for pollutants NO₂, PM₁₀, PM_{2,5}, SO₂, CO, VOC, HCI- and HF- at the monitoring locations are provided in Table 9-29 through Table 9-30.

Table 9-29: Cumulative Evaluation of PM₁₀ for the Operation Phase

	PN	l ₁₀ Values (μg/m³)		Deily		Annual			
Sampling	Background	Modellin	ng Result	-	Daily					
Location	Long Term	Daily	Annual	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
1	57.816	0.006	0.0008	High	Negligible	Insignificant	High	Negligible	Insignificant	
2	65.246	0.007	0.001	High	Negligible	Insignificant	High	Negligible	Insignificant	
Limit values	40	50	40							

*Maximum of the daily sampling results

Table 9-30: Cumulative Evaluation of PM_{2.5} for the Operation Phase

	PM _{2.5} Values (μg/m³)				Deily		Annual			
Sampling	Background	Modelli	ng Result	_	Dally		Ailiudi			
Location	Long Term	Daily	Annual	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
1	12.798	0.006	0.0008	High	Negligible	Insignificant	High	Negligible	Insignificant	
2	13.410	0.007	0.001	High	Negligible	Insignificant	High	Negligible	Insignificant	
Limit values	40	50	40							

*Maximum of the daily sampling results

Table 9-31: Cumulative Evaluation of SO₂ for the Operation Phase

	S	O₂ Values (μg/m³)		Hourby		Annual				
Sampling	Background	Modelling Result		_	Hourry		Annual				
Location	Long Term	Hourly	Annual	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance		
PT-1	0.0011	0.10	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-2	<0.0002	0.07	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-3	<0.0002	0.03	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-4	<0.0002	0.18	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-5	<0.0002	0.02	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-6	<0.0002	0.10	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-7	<0.0002	0.05	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
PT-8	<0.0002	0.06	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant		
Limit values	20	350	20								

Table 9-32: Cumulative Evaluation of NO₂ for the Operation Phase

	N	O₂ Values (μg/m³	')		House			Annual		
Sampling	Background	Modelling Result		-	Houriy		Allitua			
Location	Long Term	Hourly	Annual	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
PT-1	<0.0004	3.11	0.09	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-2	<0.0004	2.23	0.08	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-3	<0.0004	0.94	0.02	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-4	<0.0004	5.64	0.30	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-5	<0.0004	0.78	0.02	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-6	<0.0004	3.24	0.09	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-7	<0.0004	1.67	0.11	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-8	<0.0004	1.83	0.21	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
Limit values	40	200	40							

Table 9-33: Cumulative Evaluation of	VOC for the 0	Operation Phase
--------------------------------------	---------------	------------------------

	V	OC Values (µg/m³)		Hourby		Daily			
Sampling	Background	Modellin	Modelling Result		nouny		Daily			
Location	Long Term	Hourly	Daily	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
PT-1	1.43	4.21	0.65	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-2	1.61	6.75	0.65	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-3	1.51	4.40	0.35	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-4	1.48	8.82	1.05	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-5	1.15	2.83	0.20	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-6	2.81	5.25	0.70	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-7	1.21	9.27	0.56	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-8	1.24	9.8	0.83	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
Limit values	70	280	70							

Table 9-34: Cumulative Evaluation of HCI⁻ for the Operation Phase

	н	Cl Values (µg/m³)	l i		Hourby		Daily			
Sampling	Background	Modellin	g Result	—	Hourry					
Location	Long Term	Hourly	Daily	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
PT-1	2.2124	0.06	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-2	<0.4084	0.10	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-3	2.7576	0.06	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-4	3.3054	0.13	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-5	3.2413	0.04	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-6	3.9983	0.07	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-7	3.4568	0.13	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-8	2.1726	0.14	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
Limit values	60	150	60							

Table 9-35: Cumulative Evaluation of HF⁻ for the Operation Phase

	H	IF Values (μg/m³)			Hourty		Doily			
Sampling	Background	Modellin	Modelling Result		Hourry		Daily			
Location	Long Term	Hourly	Daily	Sensitivity Score	Magnitude Score	Impact Significance	Sensitivity Score	Magnitude Score	Impact Significance	
PT-1	<0.0358	0.06	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-2	<0.0358	0.10	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-3	<0.0358	0.06	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-4	<0.0358	0.13	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-5	<0.0358	0.04	<0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-6	<0.0358	0.07	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-7	<0.0358	0.13	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
PT-8	<0.0358	0.14	0.01	Negligible	Negligible	Insignificant	Negligible	Negligible	Insignificant	
Limit values	5	30	5							

Additionally, both direct and indirect GHG emissions are expected to occur during the operation of the facility. The potential sources of GHG emissions are presented in Table 9-36. Focusing on efficiency at the design and operation of the buildings and technical systems of the laboratories can reduce carbon emissions intensity while also generating operational cost savings. The relevant mitigation measures are discussed in Section 9.4 of this chapter.

Table 9-36: Operation Phase GHG Emission Sources

Type of Emission*	Emission Source
Direct Emissions	Emissions associated with the steam boiler and pure steam generator, and ventilation shaft.
	Fugitive emissions associated with the refrigerant use (HCFC).
Indirect Emissions	Electricity Consumption
	The consumption of electricity from the electricity grid.
	Transportation
	Transportation of employees travelling to and from the facility.
* The LLS EDA defines 2 t	unce of amignione: Seene 1: Direct Emignione, Seene 2: Electricity Indirect Emignione, and Seene

* The U.S. EPA defines 3 types of emissions: Scope 1: Direct Emissions, Scope 2: Electricity Indirect Emissions, and Scope 3: Other Indirect GHG Emissions¹³⁴

9.4 Mitigation Measures

9.4.1 Construction Phase

During the construction phase of the Project, dust emission will occur due to excavation activities and movements of construction machinery. Secondly, exhaust emissions from the engines of the vehicles will occur. Mitigation measures for controlling air emissions from construction phase activities will include:

- 20kph speed limit will be applied on unpaved surfaces close to settlements.
- Covers and/or control equipment will be used to minimize dust from material handling.
- Stockpiling of stripped surface material, e.g. rock, sand and soil will be limited. Stockpiles will be kept as enclosed as possible or covered.
- Stockpiles will be placed as far away from receptors as possible.
- Wind breaks or dust protection systems (including sprinklers) will be built around the main construction
 activities where necessary and, if possible, near potentially dusty works to minimize the impact on
 nearby receptors.
- Dust suppression techniques (with water or non-toxic chemicals) will be applied in order to minimize dust caused by vehicle movements.
- Vehicles will be kept clean so that no dirt is carried on the vehicles into and out of the area.
- Good practice will be applied for selection of Project vehicles that meet the latest emission standards (e.g. EURO 3 or US EPA Tier 2 emission standards) and maintained in a reasonable working order.
- Emissions from road and off-road vehicles will comply with national or regional programs.
- The Air Quality Management Plan and the Traffic Management Plan will be implemented.
- The WBG General EHS Guidelines: Construction and Decommissioning document will be complied with concerning emission abatement techniques during the construction phase, including:
 - Minimizing dust from material handling sources, such as conveyors and bins, by using covers and/or control equipment (water suppression, bag house or cyclone),
 - Minimizing dust from open area sources, including storage piles, by using control measures such as installing enclosures and covers, and increasing the moisture content,

¹³⁴ U.S. EPA Center for Corporate Climate Leadership (2020). GHG Inventory Guidance. Accessed from <u>GHG Inventory</u> <u>Development Process and Guidance | US EPA</u>

- Dust suppression techniques should be implemented, such as applying water or non-toxic chemicals to minimize dust from vehicle movements,
- Selectively removing potential hazardous air pollutants, such as asbestos, from existing infrastructure prior to demolition,
- Training of personnel/workers on the relevant management plans and monitoring of relevant parameters (such as PM₁₀ and PM_{2.5}), as necessary.

As noted above, during the construction phase of the Project, both direct GHG emissions (associated with onsite heating and exhaust from diesel engines of construction vehicles/equipment) and indirect GHG emissions (associated with electricity consumption from the power grid as well as those that will occur due to transportation of employees) are expected to occur. The relevant mitigation measures that will be implemented by the Project to minimize such GHG emissions will include:

- Managing exhaust emissions from mobile sources including compliance with national programs, adherence to manufacturer recommended maintenance programs and employee training on driving practices reducing fuel consumption.
- Use of energy efficient equipment and vehicles.
- Enhancement of energy efficiency at the construction practices and site management.
- Prioritization of local procurement and local employment to the extent possible.
- Provision of shuttle services for transportation of the construction employees to and from the construction site.

9.4.2 **Operation Phase**

During the operation phase of the Project, emissions generation equipment will include steam boilers, pure steam generators and ventilation systems. The reduction techniques to be considered for the control of air emissions at this phase will include:

- The design of the laboratories and process units will comply with the global standards for ventilation and filtration rules set out by the WHO Laboratory Biosafety Manual and other applicable international guidelines (including NIH, BMBL, TS EN 12128). Please refer to section 2.7.2 for details on these rules and standards.
- Purification of the gas flow by collecting vapours by means of air aspirators and removing them with control devices (Blow: G4+F7+F9+H14 HEPA filtration, Exhaust: G4+H14 HEPA filtration. G4+H14+H14 HEPA is applied in BSL3 Areas.) ¹³⁵
- The efficiency of steam, raw steam, hot water and similar transmission systems will be ensured, and their maintenance will be done regularly. Combustion systems operating with high efficiency will be operated using equipment with high energy efficiency.
- The design of the stacks will comply with the Regulation on the Control of Air Pollution Originating from Industry Annex-4 requirements.
- Necessary stack emission measurements (for SO₂, NO₂, CO, PM, VOC, HF- and HCI- parameters) will be periodically conducted and reported in accordance with the Regulation on the Control of Air Pollution Originating from Industry and Regulation on Environmental Permits and Licences.
- The Air Quality Management Plan will be implemented.

F7 class HEPA filters are designed to remove 80-90% of air-borne particles of size more than 0.4 micron.

F9 class HEPA filters are designed to remove more than 95% of air-borne particles of size more than 0.4 micron.

¹³⁵ G4 class HEPA filters are designed to remove 80-90% of air-borne particles of size more than 10 microns.

H14 class HEPA filters are considered medical grade filters able to capture significant percentages (99.995%) of particles smaller than 0.3 micron.

• The Project will minimize (and where possible avoid) the use of fluorinated gases in refrigeration, air conditioning and heat pump equipment and systems, and comply with the use and reporting requirements set forth in the applicable regulation in relation to all fluorinated gases.

Energy consumption within the laboratories will also have an indirect impact on the air quality. Therefore, resource efficiency and sustainability must be an integral part of the Project operations. To minimize potential GHG impacts, energy management at the facility level will be considered in the context of overall consumption patterns, including those associated with production processes and supporting utilities, as well as overall impacts associated with emissions from power sources.

The following measures will be taken during design, procurement and operation phases of the Project to identify financially feasible opportunities for improvement in energy conservation:

- Implementation of the Resource Efficiency Management Plan prepared for the Project
- Electricity generation from photovoltaic (PV) panels will be incorporated to the design stage of the Project. It is anticipated that a portion of the electricity demand will be supplied from the PV panels to be installed on rooftops of units within the facility.
- A systematic analysis of energy efficiency improvements and cost reduction opportunities will be performed.
- An energy management program will be implemented including identification and regular measurement of principal energy flows within the facility, definition of energy performance targets, and regular comparison of energy flows with performance targets to identify where action should be taken to reduce energy use.
- Opportunities in system design, process heating, heating load reduction, heat distribution systems, energy conversion system efficiency, process cooling will be discussed in the procurement stage with the companies.
- Prioritize energy efficiency in the buildings with low-energy design.
 - Passive efficiency measures (increase the insulation of walls or windows, reduce the need for artificial lighting, maximize opportunities for daylighting and natural ventilation where appropriate)
 - Active efficiency measures (minimize energy demand from building services: space heating and cooling, hot water, lighting, auxiliary loads, and equipment: computers, plug in devices, laboratory equipment)

9.5 Compliance with National and International Requirements

The key national and international standards and guidelines that the Project will follow regarding air quality are summarized in this section.

9.5.1 National Requirements

The legislation on air quality and emissions in Turkiye are summarized in Table 9-37 together with the relevant requirements for the regulatory compliance of the Project.

Law/Regulation	Official Gazette Date/No	Key Articles and Relevance to the Project
Regulation on the Control of Air Pollution Originating from Industry (RCAPOI)	03.07.2009/ 27277	The regulation controls emissions from industries and energy producing installations to protect human health and prevent air pollution. The regulation requires operators to ensure that emission control systems in workplaces are in place and compliant with the standards set out in the regulation. <i>Relevant requirements:</i> Air Emissions Permit (within the scope of the Environmental Permit), Emissions Measurement Report (required for Air Emissions Permit)

Table 9-37: National Regulations on Air Quality that are Relevant to the Project

Law/Regulation	Official Gazette Date/No	Key Articles and Relevance to the Project
Regulation on Environmental Permits and Licenses	10.09.2014/ 29115	The regulation defines the permitting procedures and principles for the activities/facilities listed in the annexes of the regulation. Within the scope of this regulation, facilities are classified based on their environmental impacts as follows: (a) Facilities with a high pollution impact on the environment (Annex-1 list); and (b) Facilities with a pollution impact on the environment (Annex-2 list). The facilities that are included in these lists are required to obtain an integrated environmental permit (Annex-1 facilities from MoEUCC, Annex-2 facilities from PDoEUCC). An environmental permit covers at least one of the following: air emissions, wastewater discharge, noise control, deep-sea discharge or hazardous materials discharge. A Temporary Operation Permit is issued for a period of one year until the requirements of the environmental permit (regarding air emissions). Note that the Project is listed in Annex-2 list of the subject regulation (i.e. 4.4 - Facilities where pharmaceutical products are produced).
Air Quality Assessment and Management Regulation	06.06.2008/ 26898	The purpose of this regulation is to set out the air quality targets, to assess the air quality, to protect the current condition where the air quality is good and to improve it where needed. The regulation sets limits for ambient air quality parameters in Annex-1 and Annex-1A.
Regulation on the Control of Odorous Emissions	19.07.2013/ 28712	The regulation sets out the legal and technical principles and procedures regarding the control and minimization of the odorous emissions.
Regulation on the Control of Air Pollution Caused by Heating	13.01.2005/ 25699	The regulation aims to mitigate the negative impacts of the pollutants (such as those emitted to air in the form of heat, smoke, dust, gas, vapor and aerosol) emitted from combustion plants used for heating purposes in housing, housing estate, cooperative, school, university, hospital, companies, authorities, social rest establishments, industry and similar locations. This regulation sets out the properties of the combustion plants to be used for heating purposes and operational procedures, principles, quality criteria of solid, liquid and gas fuels to be used in the combustion plants as well as emission limits. <i>Relevant requirements:</i> Keeping the records of measurements, control and emission certificates
Regulation on Control of Exhaust Gas Emissions	11.03.2017/ 30004	The regulation determines the required principles and procedures to ensure reduction of exhaust gas pollutants and their control by monitoring, in order to preserve the environment from pollution caused by motor vehicles in traffic. <i>Relevant requirements:</i> Exhaust measurement stamp and exhaust emission certificate for vehicles
Regulation on Greenhouse Gas Emissions	17.05.2014/ 29003	The regulation sets forth the principles and procedures for monitoring and reporting of greenhouse gases (GHG) generated by facilities performing specific activities listed in Annex-1 of the regulation. Facilities subject to the regulation include oil refineries, combustion plants with thermal power equal to or greater than 20 MW, and certain steel and iron production facilities. The regulation is based on the United Nations Framework Convention on Climate Change and the Kyoto Protocol, which was ratified by the Turkish parliament in 2009 with Law No. 5836.
		therefore is not subject to monitoring and reporting of GHG.
Regulation on Fluorinated Greenhouse Gases	29.06.2022/ 31881	The regulation sets procedures and principles on the use of products and equipment that contain fluorinated greenhouse gases in order to control emissions occurring due to use of those gases. The regulation places quotas on import of hydrofluorocarbons for refrigeration, air conditioning and heat pump systems starting from the year 2023. The regulation also bans the placing on the market of stationary refrigeration systems containing hydrofluorocarbons with a Global Warming Potential (GWP) of 2500 or more from 1/1/2025 and with a GWP of 150 or more as of 1/1/2029, <i>Relevant requirements:</i> The Project should minimize (and where possible avoid) the use of fluorinated gases in refrigeration, air conditioning and heat pump equipment and systems and comply with the use and reporting requirements set forth in the regulation in relation to all fluorinated gases.
Regulation on Ozone-Depleting Substances	07.04.2017/ 30031	This regulation determines the procedures and principles regarding the use and termination of substances controlled by the Montreal Protocol on Substances that Deplete the Ozone Layer, to which Turkiye is a party. The Montreal Protocol aims to phase down the consumption and production of the different ozone-depleting substances in a stepwise manner, with different timetables for developed and developing countries.

Law/Regulation	Official Gazette Date/No	Key Articles and Relevance to the Project
		Chemicals that may cause fugitive emissions will not be used within the processes, except for pressurized refrigerant gases (hydrochlorofluorocarbons - HCFCs), medical gases, and fire extinguishers. The necessary adjustments and management regarding those substances will be carried out according to the regulation.

National regulations regarding the energy efficiency requirements for the facility are given in Table 9-38.

Law/Regulation	Official Gazette Date/No	Key Articles and Relevance to the Project
Regulation on Increasing Efficiency in the Use of Energy Sources and Energy	27.10.2011/ 28097	The regulation sets forth the principles and procedures of increasing the efficient use of energy resources and energy and to prevent waste of energy. According to the regulation, industrial facilities which annually consume 1000 tons equivalent petroleum (TEP) of energy and above employ a certified employee as energy manager. Commercial and service buildings which occupy a construction area of 20,000 m ² and above or annually consume 500 TEP of energy and above and public sector buildings which occupy a construction area of 10,000 m ² or annually consume 250 TEP of energy and above employ a certificated employee as energy manager. In such cases that it is not possible to employ an energy manager among the employees, this service is supplied from external energy managers or companies. Pursuant to article 9 of the regulation, total annual energy consumption is calculated using coefficients provided in Annex-2.
Regulation on Energy Performance in Buildings	05.12.2008/ 27075	The regulation defines the principles of energy performance requirements for buildings. Article 25 involves provisions regarding the preparation of an Energy Identification Document. <i>Relevant requirements:</i> Energy Identification Document

Table 9-38: National Regulations on Energy Efficiency that are Relevant to the Project

Within the framework of national legislation, limit values for all types of industrial activities are given in the Regulation on the Control of Air Pollution Originating from Industry (RCAPOI). Ambient air limit values are provided in Annex-2 Table 2.2 of RCAPOI and these limit values will decrease gradually over the years until 2024. The limit values for key parameters given in Table 12 of the RCAPOI are summarized in Table 9-39.
Parameter	Period	Unit	Limit Value [µg/m³] [Deposition mg/m²day]						
			2014	2015	2016	2017	2018	2019- 2023	2024 and later
	Hourly (not to be exceeded more than 24 times a calendar year)	µg/m³	500	470	440	410	380	350	350
SO ₂	Daily		250	225	200	175	150	125	125
	LTL	_	60	60	60	60	60	60	60
	**Annual and winter semester (1 October-31 March)	_	20	20	20	20	20	20	20
NO ₂	Hourly (not to be exceeded more than 18 times a calendar year)	µg/m³	300	290	280	270	260	250	200*
	Calendar year	_	60	56	52	48	44	40*	40
PM ₁₀	24 hours (not to be exceeded more than 35 times a calendar year)	µg/m³	100	90	80	70	60	50	50
	Annual	_	60	56	52	48	44	40	40
PM _{2.5}	24 hours		-	-	-	-	-	-	-
	Annual		-	-	-	-	-	-	-
	STL		150	150	150	150	150	150	150
HCL	LTL	– μg/m°	60	60	60	60	60	60	60
	Hourly	ug/m ³	30	30	30	30	30	30	30
пг	STL	– µg/m-	5	5	5	5	5	5	5
VOC	Hourly	ug/m ³	280	280	280	280	280	280	280
	STL	– µg/m	70	70	70	70	70	70	70
PM	STL	ma/m²de:	390	390	390	390	390	390	390
Deposition	LTL	- mg/m²day	210	210	210	210	210	210	210

Table 9-39: Limit Values Stipulated in the RCAPOI

9.5.2 International Requirements

World Bank Environmental and Social Standards (ESS) and EHS Guidelines

The key international standards and guidelines applicable to the Project relating to international best practice for the assessment and management of air quality include the following:

- World Bank ESS3: Resource Efficiency and Pollution Prevention and Management (2017)
- World Bank Group General EHS Guidelines (2007)
- World Bank Group EHS Guidelines for Construction and Decommissioning (2007)

The objective of the WB ESS3: Resource Efficiency and Pollution Prevention and Management is to avoid or minimize adverse impacts on human health and the environment, for the duration of a Project, by avoiding or minimizing polluting activities, avoiding emissions and promoting the use of sustainable resources. Accordingly, project implementers should consult the General EHS Guidelines or other internationally recognized sources, as appropriate, during the evaluations and selecting resource efficiency and pollution prevention and control techniques for the project. When the project is evaluated at the national legislative level, stricter limit values need to be taken into account if these levels differ from the levels and measures presented in the EHS Guidelines.

The WBG guidelines refer to World Health Organization (WHO) limit values to evaluate emissions. WHO defines limit values in the 'Air quality guidelines for particulate matter, nitrogen dioxide, and sulphur dioxide' document. These limit values are shown in Table 9-40, including the guidelines and limit values

for air quality that have been determined by the European Union in various Council Directives (EU Council Directive 2008/50/EC on health-based standards and targets for a range of pollutants in ambient air).

Parameter	Averaging Period	EU Limit Values ¹³⁶ (μg/m ³)	WHO/WBG Limit (Guideline) Values ¹³⁷ (μg/m ³)
SO ₂	Hourly	350 (not to be exceeded more than 24 times a calendar year)	-
	24 hours	125 (not to be exceeded more than 3 times a calendar year)	20
NO ₂	1 hour (for the protection of the human health)	200 (not to be exceeded more than 18 times a calendar year)	200
	Calendar year (for the protection of the human health)	40	40
PM ₁₀	24 hours (for the protection of the human health)	50 (not to be exceeded more than 35 times a year)	50
	Calendar year (for the protection of the human health)	40	20
PM _{2.5}	24 hours	-	25
	Annual	20	10

Table 9-40: Limit Values Stipulated in the International Legislation (WBG and EU)

The World Bank Environment, Health and Safety (EHS) Guidelines are technical reference documents containing industry-specific examples of Good International Industry Practices (GIIP). The EHS Guidelines contain performance levels and metrics that are deemed achievable with existing technology at new facilities at reasonable cost. The limit values in the Environmental, Health, and Safety Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007) that were taken into account in the evaluation of Project-related emissions and are presented inTable 9-41.

Table 9-41: WBG EHS Guidelines Emission Standards

Pollutant	Units	WBG
Active Ingredient (each)	mg/Nm ³	0.15
Particulate Matter	mg/Nm ³	20
Total Organic Carbon	mg/Nm ³	50
Hazardous Air Pollutants	kg/year	900-1,800 ⁽³⁾
Total Class A ⁽¹⁾	mg/Nm ³	20 ⁽⁴⁾
Total Class B ⁽²⁾	mg/Nm ³	80 ⁽⁵⁾
Benzene, Vinyl Chloride, Dichloroethane (each)	mg/Nm ³	1
VOC	mg/Nm ³	20-150 ⁽⁶⁾ , 50 ⁽⁷⁾
Bromides (as HBr)	mg/Sm ³	3
Chlorides (as HCl)	mg/Sm ³	30
Ammonia	mg/Sm ³	30
Arsenic	mg/Sm ³	0.05
Ethylene Oxide	mg/Sm ³	0.5
Mutagenic Substance	mg/Sm ³	0.05

¹³⁶ Directive 2008/50/EC on Ambient Air Quality

¹³⁷ WHO Ambient Air Quality Guidelines, WBG General EHS Guidelines: Environmental – Air Emissions and Ambient Air Quality

Pollutant	Units	WBG
1. Class A compounds are those that may cause significant harm to human substances, as well as others identified in the EU Directive 1999/13/EC on the Use of Organic Solvents in Certain Activities and Installations. Example chloride, carbon tetrachloride, chlorofluorocarbons, ethyl acrylate, halons, m trichloroethylene, and trichlorotoluene.	health and the environment. T he Limitation of Emissions of V of Class A compounds include aleic anhydride, 1,1,1 trichlorc	They include Montreal Protocol Volatile Organic Compounds due to le: acetaldehyde, acrylic acid, benzyl bethane, trichloromethane,
2. Class B compounds are organic compounds of less environmental impact	than Class A compounds. Ex	xamples include: toluene, acetone
 and propylene. 3 Process-based annual mass limit 900: Actual HAP emissions from the su 	m of all process vents within a	a process: 1 800: Actual HAP
emissions from the sum of all process vents within processes.		
4. Applicable when total Class A compounds exceed 100 g/hr.		
5. Applicable when total Class B compounds, expressed as toluene, exceed	the lower of 5 t/year or 2 kg/h	nr.
6. EU Directive 1999/13/EC. Facilities with solvent consumption > 50 tonnes	/year. Higher value (150) to b	be applied for waste gases from any
technique which allows the reuse of the recovered solvent. Fugitive emission	n values (non including solver	nt sold as part of products and
preparations in a sealed container): 5 percent of solvent input for new faciliti	es and 15 percent for existing	facilities. Total solvent emission
limit values: 5 percent of solvent input for new facilities and 15 percent for ex	disting facilities.	

7. Waste gas

Additionally, the WBG Environmental, Health and Safety Guidelines also sets forth emission standards for combustion facilities, which are provided in Table 9-42 below.

Table 9-42: WBG Emission Standards for Small Combustion Facilities

Pollutant	IFC Guideline Values for Gas Fuel Combustion (mg/Nm ₃) ¹
NO _X	320 (Boilers)
	200 (Gas Engines)

¹ IFC Environmental, Health, and Safety Guideline Air Emission and Ambient Air Quality Table 1.1.2

International Requirements on GHGs and Climate Mitigation

In regard to greenhouse gases, the WB ESS3: Resource Efficiency and Pollution Prevention and Management (2017) requires the projects to consider alternatives and implement technically and financially feasible and cost-effective options to reduce the GHG emissions during the design and operation. These options may include, but are not limited to, alternative project locations, adoption of renewable or low carbon energy sources, sustainable agricultural, forestry and livestock management practices, the reduction of fugitive emissions, and the reduction of gas flaring. The WB ESS3 also outlines the requirements that must be followed when calculating GHG emissions. The following requirement is stipulated: 'for projects that are expected to or currently produce more than 25,000 tonnes of CO₂-equivalent annually, the client will quantify direct emissions associated with the off-site production of energy used by the project.'. However, the proposed Project is not anticipated to fall into this category.

The United Nations Framework Convention on Climate Change (UNFCCC) was established in 1992 with the objective to achieve the 'stabilisation of greenhouse gas concentrations in the atmosphere, at a level that would prevent dangerous anthropogenic interference with the climate system. Such a level should be achieved within a time frame sufficient to allow ecosystems to adapt naturally to climate change, to ensure that food production is not threatened and to enable economic development to proceed in a sustainable manner.'. Turkiye became a party to the UNFCCC in 2004 and signed the Paris Agreement in 2016. However, although submitted its Intended Nationally Determined Contribution (INDC)¹³⁸ to UNFCCC in 2015, Turkiye has ratified the Paris Agreement in October 2021. The agreement is a legally binding international treaty which entered into force on 4 November 2016. A total of 193 parties (192 countries plus the European Union) have joined the Paris Agreement. The agreement sets long-term goals to guide all parties: (i) substantially reduce global GHG emissions to limit the global temperature increase in this century to 2 degrees Celsius while pursuing efforts to limit the increase even further to 1.5 degrees; (ii) review countries' commitments every five years; (iii) provide financing to developing

¹³⁸ Turkey Intended Nationally Determined Contributions (INDC), accessed from <u>https://www4.unfccc.int/sites/submissions/INDC/Published%20Documents/Turkey/1/The_INDC_of_TURKEY_v.15.19.30</u> <u>.pdf</u> on 09 September 2021

countries to mitigate climate change, strengthen resilience and enhance abilities to adapt to climate impacts.

Turkiye has ratified several additional international conventions and agreements with respect to climate mitigation include those listed below:

- European Green Deal: The European Union has developed and adopted the European Green Deal on 11 December 2019, aiming to shape all aspects of economic, commercial and social development with a green transformation perspective on the way to achieving carbon-neutrality by 2050. To achieve climate neutrality, a 90% reduction in transport emissions is needed by 2050. Therefore, a reduction in emissions from transportation methods with a strategy on sustainable mobility is a target area within the European Green Deal. Turkiye has published the "Green Deal Action Plan" in 2021 within the scope of harmonization with the EU Green Deal and EU legislation. The action plan includes 32 targets and 81 actions under 9 main headings: (1) Carbon border adjustment; (2) Green and circular economy; (3) Green finance; (4) Affordable and clean energy supply; (5) Sustainable agriculture; (6) Sustainable smart transportation; (7) Tackling climate change; (8) Diplomacy; and (9) European green deal information and awareness activities¹³⁹.
- Kigali Amendment to the Montreal Protocol: The amendment is a legally binding international agreement to gradually reduce the consumption and production of hydrofluorocarbons (HFCs). The Montreal Protocol was originally created to preserve and restore the ozone layer; participating countries agreed to phase out chlorofluorocarbons (CFCs), gases that had been causing ozone depletion. HFCs do not contain chlorine, so they do not cause ozone depletion, and therefore have been replacing CFCs under the Protocol. However, HFCs are powerful greenhouse gases that contribute to climate change, therefore this amendment adds HFCs to the list of chemicals mentioned in the Montreal Protocol. Turkiye has become a party to the Kigali Amendment on 21 November 2021.

9.6 Residual Impacts

With the implementation of mitigation measures described above and assuming that emissions management is in conformity with provisions of the relevant national legislation and international guidelines, the significance of the residual impacts of construction phase dust are estimated to be reduced from minor to insignificant.

Significance levels of impacts from operation phase pollutant gases before and after mitigation are considered to be insignificant.

9.7 Proposed Monitoring and Reporting

Air quality monitoring and regular inspections will be conducted during construction and operation according to the Air Quality Management Plan requirements. Air quality monitoring activities will include the following:

- Quarterly monitoring of particulate matter (PM₁₀ and PM_{2.5}) levels during the construction phase
- Daily monitoring of dust through visual observations during the construction phase
- Annual stack emissions monitoring at all emission points (i.e. HVAC system, steam boilers and pure steam generators) during the operation of the Project
- Annual ambient air quality monitoring at sensitive receptors during the operation of the Project

The facility is considered to be listed in Annex-2 (Facilities with a polluting effect on the environment) of the Regulation on Environmental Permits and Licences¹⁴⁰. Therefore, an Environment Permit regarding

¹³⁹ Turkey Green Deal Action Plan-2021 accessed from

https://ticaret.gov.tr/data/60f1200013b876eb28421b23/MUTABAKAT%20YE%C5%9E%C4%B0L.pdf on 09 September 2021

¹⁴⁰ Official Gazette Date/Number: 10.09.2014/29115

the air emissions of the facility shall be obtained from the PDoEUCC in line with the Regulation on Environmental Permits and Licences. Necessary emissions monitoring and reporting activities will be conducted periodically as per the requirements of the Regulation on the Control of Air Pollution Originating from Industry and the Regulation on Environmental Permits and Licences.

10 NOISE AND VIBRATION

10.1 Introduction

This chapter addresses the noise and vibration impacts for the construction and operation phases of the Project. The assessment aims to determine the significance of impacts by analysing the current ambient conditions and possible project impacts at proposed receptor locations. The specific objectives of the impact assessment are to: i) determine the existing background noise levels, ii) assess noise impacts on sensitive receptors, iii) identify the vibration impact and iv) suggest mitigation measures and determine the residual impacts.

Prior to the noise and vibration modelling study, baseline noise measurements were carried out at the nearest receptors to obtain background data before the start of the construction phase of the Project. Noise and vibration modelling studies covering the Project area of influence were then undertaken to analyse the impact of noise and vibration generated by construction and operation. The anticipated activities at the site are modelled using the CadnaA acoustical software. The results of the modelling studies were compared with the national and international standards considering cumulative noise level that is the sum of modelled noise level and background (baseline) noise level.

Noise and vibration related definitions, regulations and legal background, the methodology followed, results of noise modelling, potential impacts and proposed mitigation measures are presented in this chapter.

10.1.1 Study Area and Area of Influence

The nearest residential area is located approximately of 500 m southeast of the Project site in Saracalar neighbourhood. The immediate vicinity of the Project site is surrounded by vaccine storage facility of the General Directorate of Public Health (GDPH), road vehicles sales businesses (Otonomi), industrial establishments and agricultural lands. The nearest residential properties are located on Özal Boulevard (D180) at a distance of 500 m from the Project site. The nearest settlement is the Balıkhisar neighbourhood, which is located approximately 3 km northeast of the Project site.

Özal Boulevard which lies 150 m east of the Project site boundary and Esenboğa Airport located approximately 3 km north of the Project site are the main environmental noise sources in the area. Industrial facilities including İşbir Mattress, İşbir Mattress Foam, MAN, YDS, and commercial businesses of Otonomi are the secondary noise sources.

Within the scope of the ESIA study, the Project's area of influence has been determined based on the noise modelling results. As a conservative approach, while defining the area of influence for the noise modelling, a basic propagation model was developed to determine the distance in which noise levels drop below 40 dBA, a value 5 dBA lower than the WBG General EHS Guidelines night-time noise level limit (45 dBA) for residential, institutional and educational areas. The noise map which was created through the modelling study is presented in Figure 10-1. According to the noise map, the noise levels decrease below 40 dBA approximately within 2.5 km radius around the Project site.



Figure 10-1: Area of influence

10.1.2 Data Limitations

In performing noise level prediction studies for the operation phase, the provisional noise sources outlined in section 10.5.1 of this chapter have been considered. However, as described in *Chapter 2: Project Description,* specific operational equipment are planned to be procured and installed through the 'Design and Supply' model based on the general technical specifications to be issued. Hence the final quantities, qualifications and capacities of such equipment will be further assessed by MoH during the procurement process and therefore, confirmed noise sources will become available at later stages of the Project. Due to the uncertainties regarding the sound power level information of operational equipment, databases of the consulting company were used.

Additionally, for construction noise modelling, construction machinery and equipment were assumed to be operating continuously and homogeneously within the Project site, since specific locations and working periods for the machinery were not certain at the time of the modelling study.

On the other hand, noise sources during construction and operation used in the modeling studies are based on the maximum number of machinery and equipment that will be required according to the provisional information provided by the MoH, i.e., the modelling studies were conducted based on the worst-case scenario. Therefore, it is expected that changes in the outcomes of impact assessment and final impact significance determined for sensitive receptors will be negligible.

100 dB(A)

10.1.3 National and International Requirements

In this part, the national and international legal requirements and applicable standards for the noise and vibration assessment for both construction and operation phases of the Project are described. The assessment of compliance against indicated requirements are presented in Section 10.7.

10.1.3.1 National Requirements

Environmental noise is regulated by the Turkish Regulation on Environmental Noise Control (RENC)¹⁴¹. The regulation represents a revised version of the former noise management regulation of Turkiye, namely Regulation on the Assessment and Management of Environmental Noise (RAMEN)¹⁴², which was prepared in accordance with the EU Environmental Noise Directive (END) (i.e. Directive 2002/49/EC relating to the assessment and management of environmental noise). With the publication of RENC, RAMEN has been repealed. The regulation uses the same noise indicators and standard methods as the EU END, and sets out noise limits applicable to various sources of noise (e.g. industrial areas, transportation sources and working spaces) for three time periods (day, evening and night).

According to RENC Article 13(1), the limits for noise generating from construction activities are defined in Annex-2 of the regulation. The regulation does not define specific limit values for construction sites, therefore the limits defined for "businesses" in Annex-2 of the regulation are taken into consideration and are presented in Table 10-1Hata! Başvuru kaynağı bulunamadı.. Accordingly, the allowable noise limit a pplicable to construction phase activities of the Project is baseline noise level + 5 dB(A). In accordance with the RENC, there are certain timeframes during the day that outdoor construction activities are allowed to take place, as given in Table 10-2. Accordingly, the construction site activities are supposed to be performed between 10.00 - 22.00.

able 10-1: Environmental Noise Limits (RENC)					
Noiso Sourco	Massuring Parameter	Environmental Noise Level			
	Measuring Farameter	Day	Evening	Night	
Industrial Facilities, Transportation Sources	LA _{eq,5min}	65 dB(A)	60 dB(A)	55 dB(A)	
Businesses that broadcast music	LA _{eq 63-250 Hz}	60 dB(A)	55 dB(A)	50 dB(A)	
Businesses	LA _{eq,5min}	Baseline	+ 5 dB(A)	Baseline + 5 dB(A)	
More than one business	LA _{eq,5min}	Baseline	+ 7 dB(A)	Baseline + 5 dB(A)	

LCmax

. T

Table 10-2: Allowable timeframes for outdoor activities in residential areas (RENC)

Activity	Allowable Time Range
Construction Site Activities	10.00 – 22.00
Outdoor activities that cause environmental noise	10.00 - 01.00
Use of fireworks	20.00 – 22.00

Regarding the operation phase of the Project, the environmental noise level limits for industrial facilities according to the RENC are presented in Table 10-1Hata! Başvuru kaynağı bulunamadı., which gives m aximum allowable environmental noise levels that shall be met at the nearest off-site receptor. Accordingly, the determined noise limits are Lday=65 dBA, Leve=60 dBA and Lnight =55 dBA for the operation phase.

All Sources

¹⁴¹ Official Gazette date/number: 30.11.2022/32029

¹⁴² Official Gazette date/number: 04.06.2010/27601, repealed with the publication of RENC on 30.11.2022

The standard methods recommended in END and RENC selected for noise level analysis are:

- ISO 1996-1: 2016: Description, measurement and assessment of environmental noise Part 1: Basic quantities and assessment procedures
- ISO 1996-2:2017: Description, measurement and assessment of environmental noise Part 2: Determination of sound pressure levels,
- ISO 9613-2: Acoustics Abatement of sound propagation outdoors, Part 2: General method of calculation,
- Construction Machine/Equipment Sound Power Level Analysis: FHWA¹⁴³ Roadway Construction Noise Model.

The environmental vibration limits for construction activities given in RENC are presented in Table 10-3. The selected vibration limit for the Project is residential/transient vibration of 10 mm/s.

Location	Allowable ppv (mm/s)			
Location	Continuous Vibration	Transient Vibration		
Residential	5	10		
Industrial & Commercial	15	30		
Historical and Natural Structures	2	5		

Table 10-3: Vibration Limits for Construction (RENC)

The applicable standards for construction and operation phases are as follows:

- FTA: Federal Transit Administration, Railway Vibrations
- BS 5228-1:2009: Vibration for blasting and construction vibrations

10.1.3.2 International Requirements

The Project will follow the international policy for assessment of noise outlined in the WBG General Environmental, Health and Safety (EHS) Guidelines. In terms of allowable noise levels, the WBG guidelines refer to the World Health Organization (WHO) Guidelines for Community Noise (WHO, 1999).

The WBG General EHS Guidelines set limits for noise for two types of receptors and two time periods, and require that noise levels do not exceed these limits or result in a maximum increase of 3 dBA in background levels at the nearest receptor location off-site (see Table 10-4). The associated noise limits will be applicable for both the construction and operation phases.

The Project area is highly industrial and commercial. On the other hand, the identified receptors within the area of influence have different categories including residential receptors. Therefore, noise limits for the Project are determined as L_{day} =55 dBA and L_{night} =45 dBA for the construction and operation phases.

Table	10-4:	WBG	Noise	Level	Guidelines
-------	-------	-----	-------	-------	------------

Receptor	Daytime (07:00 - 22:00)	Night-time (22:00 - 07:00)
Residential areas	55 dBA	45 dBA
Commercial/industrial areas	70 dBA	70 dBA

The vibration impacts are assessed in accordance with BS 5228-2:2009 - Code of Practice for Noise and Vibration Control on Construction and Open Sites document, which defines vibration limits for humans and that could result in cosmetic damage to buildings. The lower limit for vibration that may cause cosmetic damage to residential buildings is 50 mm/s, while the limit of human perception is much lower (Table 10-5 and Table 10-6**Hata! Başvuru kaynağı bulunamadı.**). In order to be on the safe side and s

¹⁴³ U.S. Department of Transportation Federal Highway Administration

imulate a worst-case scenario for this Project, a vibration limit of 0.3 mm/s is determined for the residential receptors.

Table 10-5: Guidance on Effects of Vibration Levels on Humans

Vibration level [mm/s]	Effect
0.14	Vibration might be just perceptible in the most sensitive situations for most vibration frequencies associated with construction. At lower frequencies, people are less sensitive to vibration.
0.3	Vibration might be just perceptible in residential environments.
1.0	It is likely that vibration of this level in residential environments will cause complaint but can be tolerated if prior warning/explanation has been given to residents.
10	Vibration is likely to be intolerable for any more than very brief exposure to this level.

Table 10-6: Transient Vibration Guide Values for Cosmetic Damage of Buildings¹⁴⁵

Type of building	Peak component particle velocity in frequency range of predominant pulse [mm/s]		
	4 Hz to 15 Hz	15 Hz and above	
Reinforced or framed structures	- 50	50	
Industrial and heavy commercial buildings	- 50		
Unreinforced or light framed structures	15.00	20-50	
Residential or light commercial buildings	- 15-20		
Note: Values referred to are at the base of the building			

10.2 Methodology and Assessment Criteria

10.2.1 Definitions

Before explaining the undertaken studies, it would be helpful to provide definitions of basic acoustical terms and concepts, as given in Table 10-7 below.

Term	Definition
Sound	Sound is vibrational disturbance, exciting hearing mechanisms, transmitted in a predictable manner determined by the medium through which it propagates. To be audible, the disturbance must fall within the frequency range 20 Hz to 20,000 Hz.
Noise	Noise is typically defined as "unwanted sound", sound being the human sensation of pressure fluctuations in the air. Sound levels are expressed in decibels (dB) on a logarithmic scale, where 0 dB is nominally the "threshold of hearing" and 120 dB is nominally the "threshold of pain".
Baseline Noise	Prevailing noise in a specified environment measured in the absence of the noise being studied.
Decibels (dB)	The unit describing the amplitude of the sound. The human ear responds to sound logarithmically. The bel is logarithm of the ratio between two power levels and decibel is 0.1 bel.
Frequency	The measure of the rapidity of alterations of a periodic signal, expressed in cycles per second or Hz.

Table 10-7: Basic acoustical terms and concepts

¹⁴⁴ BS 5228-2:2009. Code of practice for noise and vibration control on construction and open sites: Vibration

¹⁴⁵ BS 7385-2:1993. Evaluation and measurement for vibration in buildings. Guide to damage levels from ground-borne vibration

Term	Definition
Sound Pressure Level (L _P)	A logarithmic measure of the effective sound pressure of a sound relative to a reference value. It is measured in decibels (dB) above a standard reference level. The commonly used "zero" reference sound pressure in air is 20 μ Pa RMS (root mean square), which is usually considered the threshold of human hearing (at 1 kHz).
Sound Power Level (L _w)	Ten times the logarithm of the ratio of the sound power under consideration to the standard reference power of 1 picowatt (pW). The quantity obtained is expressed in decibels.
Equivalent Sound Level (L _{eq})	Quantifies the noise environment as a single value of sound level for any desired duration. Leq correlates well with the effects of noise on people. Leq is also sometimes known as Average Sound Level.
Noise Barrier	A physical obstruction that is constructed between the noise source and the noise sensitive receptor(s) that lowers the noise level, including standalone noise walls, noise berms (earth or other material) and combination berm/wall systems.
A-Weighting	Several methods are available to characterize sound. The most common is the A-weighted sound level or dBA. This scale gives greater weight to the frequencies of sound to which the human ear is most sensitive.
C-Weighting	A measure of sound pressure level designed to reflect the response of the human ear, for higher levels above 100 dB when the human ear's response is flatter.
L _{Aeq}	A-weighted equivalent sound pressure level.
L _{Amax}	The maximum A-weighted sound pressure level detected in the measurement time domain.
LCeq	C-weighted equivalent sound pressure level.
L _{day}	Equivalent continuous sound pressure level for reference time interval day.
Leve	Equivalent continuous sound pressure level for reference time interval evening.
Lnight	Equivalent continuous sound pressure level for reference time interval night.
L _{dn}	Day-night weighted sound pressure level. Daytime defined as between 07h-22h and night- time defined as 22h-07h.
L _{den}	Day, evening-night weighted sound pressure level. Daytime defined as between 07h-19h, evening time defined as 19h-23h, night-time defined as 23h-07h.
Point Source	A source of sound which is concentrated to a point.
Area Source	A source of sound which is distributed over an area.
Line Source	A source of sound emanating from a linear geometry.
Sound	Sound is vibrational disturbance, exciting hearing mechanisms, transmitted in a predictable manner determined by the medium through which it propagates. To be audible, the disturbance must fall within the frequency range 20 Hz to 20,000 Hz.

The threshold of perception of the human ear is approximately 3 dB and a 5 dB change is considered to be clearly noticeable to the ear (Table 10-8). This is primarily due to the logarithmic measurement metric typically associated with decibels.

Table 10-8: Perception of sound

Change in sound level	Perceived Change to the Human Ear
± 1 dB	Not perceptible
± 3 dB	Threshold of perception
± 5 dB	Clearly noticeable
± 10 dB	Twice as loud
± 20 dB	Four-fold change

10.2.2 Methodology

To evaluate the existing ambient noise in the area of influence, baseline noise measurements were conducted at four sensitive receptor locations. Three of the measurement locations were selected from the residential properties within 500 m distance from the Project site. One receptor location was selected inside the Project boundary to help detection of potential environmental noise on the planned facility and kindergarten associated with the facility.

A noise model was developed using commercial noise modelling software CadnaA from Datakustik. The model assumptions, calculation parameters and sound source levels for the modelling and the methods are described in this section.

For construction noise modelling, the following assumptions have been made:

- Machinery and equipment are assumed to be operating simultaneously within the Project site.
- In order to create a worst-case scenario, all given machine and equipment are assumed to operate for 24 hours at full power homogeneously dispersed to the construction zone.
- Area sources were used as a noise source in the model for the construction phase due to the mobility
 of the construction machines and equipment and lack of information on specific working locations and
 time periods.
- For construction vibration calculations, machinery and equipment list provided by the MoH and the reference vibration values were used.

For operation noise modelling, the following assumptions have been made:

- In order to create a worst-case scenario, all given machinery and equipment are assumed to operate for 24 hours at full power simultaneously.
- It was assumed that the air conditioning units will be located on the roof of the buildings based on the consultation with MoH, since the specific locations of the operational equipment had not been decided at the time of the noise modelling study.
- Noise sources in the technical systems building were modelled on the facade of the building as area noise sources.
- Vehicle movements in the loading/unloading area and open car parking areas in the facility were modelled.
- When the modelling of noise sources as machinery and equipment, measurement results and in house data obtained in similar projects and Frekans (i.e. the consulting company which conducted the modelling study) databases were used as noise emission data.
- For operation vibration calculations, machinery and equipment in the technical system building were taken into consideration.

Since sound propagation is hugely affected by terrain which can act as an obstacle to noise, information on ground topography was considered in the noise model. Ground topography data for the Project site and the noise propagation pathway was obtained from the Digital Elevation Model Dataset from NASA, Reverb Earth Science Discovery Tool.

For construction noise modelling, the sound power levels (L_w) of the related construction machinery and equipment defined in the BS 5228-1:2009+A1:2014 - Code of Practice for Noise and Vibration Control on Construction and Open Sites - Noise standard were used. The total sound power level is distributed over the construction area using the formula below.

 $L_w''=L_w-10*log(S_1/S_0)$

- L_w": Total Sound Power Level / Area (dBA/m²)
- L_w: Sound Power Level (dBA)

- S₁: Construction Area (m²)
- S₀: Reference Area, 1 m²

Since brands, models and sound power levels of the machinery and equipment to be used in the operation phase have not been determined at the time of the modelling study, measurement results and available data obtained in similar projects and database of Frekans were used as noise emission data for the operational noise sources. Vehicle movements during loading/unloading and car parking activities were also integrated into the model.

In addition to L_w , the type of the noise source is an important parameter for the noise model. Different types of noise sources can be used in the model including point, line and area sources. Please refer to modeling assumptions above for the types of noise sources used in the construction and operation noise modeling studies.

Another important parameter for the noise model is the ground sound absorption (G). The value of G varies between 0 for hard - reflective surfaces and 1 for soft - absorptive surfaces. When calculating noise propagation, G was considered as 0.5 for the Project site.

Meteorological data (average relative humidity, average temperature, wind frequencies) is included in the noise mapping software to calculate the most suitable sound propagation conditions. For meteorological attenuation, C_{met} parameter was used in the model to the optimum conditions of the noise propagation. C_{met} has been considered as 1.5, 0.7 and 0 for day, evening and night periods, respectively.

Buildings were introduced to the noise propagation model where relevant data exists. The information on buildings which are outside of the Project site was obtained from the open-source online maps. The average height information of the buildings, determined as a result of site observations, was assigned to the model. The height information for buildings within the Project site were taken from the layout plan drawing.

10.2.3 Determining Magnitude, Sensitivity, and Impact Significance

The significance criteria that were used for noise assessment were established by identifying the impact magnitudes and receptor sensitivity. Sensitivity criteria for the assessment of noise impacts are assigned in Table 10-9.

Sensitivity	Definition
High	Lack of ability to recover the initial properties and functions. Irreversible disturbances may be caused by minor impacts. Recreational facilities, educational facilities, and health care centers.
Medium	Limited / low ability to recover the initial properties and functions. Measures to minimize disturbance of ecosystems are required. Residential buildings, hotels.
Low	High ability to recover the initial properties and functions, minor changes of spatial and dynamic indicators. Office buildings, farm buildings, industrial or commercial facilities.
Negligible	-

Table 10-9: Criteria for Determining Sensitivity

The magnitude of a noise impact is the measure of the degree to which noise limit values are exceeded at receptors. The World Bank Group criteria were considered in determining impact magnitude. Any levels greater than the WBG's noise level guidelines or exceedance of baseline noise levels by more than 3 dBA will be noted down as exceedance. Criteria to classify the magnitude of a noise impact during construction and operation are detailed in Table 10-10.

Table 10-10: Criteria for Determining Magnitude due to Construction and Operational Noise

Magnitude	Criteria* - Exceedance of noise limits WBG (dBA)
Negligible	<1

Magnitude	Criteria* - Exceedance of noise limits WBG (dBA)
Minor	1-3
Moderate	3-5
Major	>5
*Criteria for residential, in L _{night} = 45 dBA	nstitutional and educational areas: Day time: $07:00 - 22:00$, L_{day} = 55 dBA; Nighttime: $22:00 - 07:00$,

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 10-11.

Table 10-11: Impact Significance Matrix

	Sensitivity of Receptors			
Magnitude of Impact	Negligible	Low	Medium	High/Very High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

10.3 Baseline Conditions and Measurements

To evaluate the existing ambient noise in the area of influence, baseline noise measurements were conducted at four sensitive receptor locations (Table 10-12 and Figure 10-2). Three of these measurement locations (1, 2, 3) were selected from the residential properties within 500 m distance from the Project site. One receptor location was selected inside the Project boundary (4) to help detection of potential environmental noise on the planned facility and kindergarten associated with the facility. The identified receptors are predicted to have different impact sensitivity and significance levels (Table 10-12).

Table 10-12: Summary information on receptors

No	Comment	Extent	Impact Sensitivity	Distance to project border (m)	Coordinate, X	Coordinate, Y
1	Residential Building	Local	Medium	413	497540.00 d E	4436786.00 m N
2	Residential Building	Local	Medium	430	497271.00 d E	4436677.00 m N
3	Residential Building	Local	Medium	570	496329.00 d E	4437250.00 m N
4	Project Site representing kindergarten	Local	High	0	497036.01 d E	4437277.28 m N



Figure 10-2: Project site and receptor locations

Noise measurements were conducted for a period of 48 hours (as in one-hour intervals) between 27-29 December 2021. For methodology, ISO 1996-2:2017: Description, Measurement and Assessment of Environmental Noise standard was followed. Weighted average ambient noise levels for international standards (i.e., L_{dn}: day-night weighted sound pressure level - daytime defined as between 07h-22h and night-time defined as 22h-07h) and national standards (i.e., L_{den}: day-evening-night weighted sound pressure level - daytime defined as 19h-23h, night-time defined as 23h-07h) were determined.

Measurement results are presented in Table 10-13 and Table 10-14.

Measurement Point	L _{day} (dBA)	L _{eve} (dBA)	L _{night} (dBA)
Point 1	59.8	59.4	54.1
Point 2	71.8	70.2	66.7
Point 3	57.5	57.9	54.5
Point 4	52.3	51.1	46.9
Limit Values for RENC (dBA)	65	60	55

Table 10-13: Baseline Measurement Results for RENC(Lden)

Table 10-14: Baseline Measurement Results for Noise Level Guidelines as per WBG General EHS Guidelines Standards (L_{dn})

Measurement Point	L _{day} (dBA)	L _{night} (dBA)
Point 1	59.7	54.8
Point 2	71.5	67.1
Point 3	57.4	55.7
Point 4	52.0	47.7
Limit Values for WBG (dBA)	55	45

The Project site lies under the landing and take-off route of Esenboğa Airport. Furthermore, Özal Boulevard which is a four-lane double road connecting Ankara to Esenboğa Airport and northern provinces lies about 150 m east of the Project site boundary. The noise impact due to airport operations and the heavy traffic load on Özal Boulevard is observed to cause maximum observed noise levels higher than L_{Amax}= 70 dB and exceedances of the World Bank noise limits of L_{day} 55 dBA and L_{night} 45 dBA on the nearby residential receptors. As per the RENC, it is observed that there are limit exceedances in noise levels for day, evening and night times in Point 2. This situation can also be linked to the fact that Point 2 is the nearest point to the highly used Özal Boulevard and to nearby bus stops (please refer to Figure 13-5).

The noise impact of the Project during the construction and operation phases is expected to be masked by the existing ambient noise levels where receptors 1 and 2 are located. These two locations represent nearly %90 of the residential receptors around the Project site. The distance between receptor 2 and Project location is approximately 570 m. This large distance is likely to attenuate the noise emissions associated with the operation phase of the Project. On the other hand, the impact of construction activities will need to be assessed further for this location. Accordingly, the likelihood of a potential construction and operation noise impact and existing ambient noise levels have been further investigated at the receptors through noise modelling studies (Section 10.4).

10.4 Noise Modelling and Mapping

10.4.1 Noise Sources

The construction noise model was developed based on the types and maximum quantities of machinery and equipment that will be required for earthworks, structural works and finishing as provided by the MoH (presented in Table 10-15: Construction Machinery and Equipment). Specific locations and working periods for the machinery were not certain at the time of the modelling study. In order to create a worst-case scenario, it was assumed that all equipment and machinery would be operating at the same time. Additionally, all given machinery and equipment were assumed to operate for 24 hours at full power homogeneously dispersed to the construction zone.

A corridor of approximately 280 m x 200 m was considered for construction machinery working simultaneously. Total sound power level was calculated as 70 dBA/m² for the working area corridor.

Machine/Equipment	Quantity	Total Sound Pressure Level Point Source L _{pA} @ 10m	L _w (dBA)
Bored Piling Machine	2	71	99
Tower Crane	2	82	110
Excavator/Tractor	2	83	111
Roller 10t/3t	1	82	110
Mobile Crane	1	67	95
Mini Loader	1	75	103
Compactor	1	-	105
Generator (105kW)	2	73	101
Approximate Construction Area (m ²)	51,000		
Total Sound Power Level LwA (dBA)	116		
Total Sound Power Level / Area (dBA/m ²)	~70		

Table 10-15: Construction Machinery and Equipment

The main noise sources during operation will be the equipment related to energy generation including pumps, compressors, steam generators, and the heating and cooling system including fans, variable

refrigerant volume (VRV) systems, air handling units (AHU), cooling towers. The machinery and equipment list is presented in Table 10-16. Noise generated by the equipment in the technical building and on the roofs was modelled for the operation phase. In order to create a worst-case scenario, all given machinery and equipment are assumed to operate for 24 hours at full power simultaneously.

In addition, vehicle movements were also modelled for the operation phase. It was assumed that the total sound power level will be 80 dBA/m² at the loading/unloading area in the worst-case scenario. Parking activities at the open car parking areas (capacity of 240 cars) were also integrated in the noise model.

Machine/Equipment		Quantity	Total L _w (dBA)				
Indoor	Pump	60	115				
(Technical Building)	Compressor	6	105				
	Steam Power Plant	2	113				
	Power Generator	4	101				
Total Sound Power Level L_{wA} (dBA)	117					
Noise Source Area (m ²)		1574					
Total Sound Power Level		86 dBA/m ²					
Roof	Fan	4	110				
(Technical Building)	VRV*	10	99				
	AHU	6	95				
	Chiller	6	96				
Total Sound Power Level L _{wA} (dBA)	110					
Noise Source Area (m ²)		1535					
Total Sound Power Level		79 dBA/m ²					
Roof	VRV*	10	99				
(Other Buildings)							
Total Sound Power Level L _{wA} (dBA)	99					
Noise Source Area (m ²)		200					
Total Sound Power Level		76 dBA/m ²					
* It was assumed that all buildings accept the Waste Storage Building have 10 VPV units on the roof 10xE-E0 VPV/ Units							

Table	10-16: O	peration	Machinery	/ and	Eaui	oment
I GOIO	10 10.0	poration	maorinior		-901	

f It was assumed that all buildings except the Waste Storage Building have 10 VRV units on the roof. 10x5=50 VRV Units

10.4.2 Results of Noise Modelling

The results of the noise modeling study (source effects at the receiving points) are presented in this section and the results are summarized in Table 10-17 through Table 10-20. Please note that the cumulative noise levels and exceedances are presented in Section 10.6.

Since there is no hourly source (no difference between a noise source operating between e.g. 9:00-10:00 and 15:00-16:00 during the day in the noise model) and all limit values in regulations and standards have been set according to periods (Lday, Leve, Lnight), the outputs of the model are presented as period averages.

Construction phase noise levels at receptor points are presented in Table 10-17 and Table 10-18. Receiving point 4 was not included in the assessment for construction phase. Since it will serve as a kindergarten during operation, this receptor was only taken into consideration for the operation phase.

Table 10-17: Construction	Noise Mode	I Results (for	RENC), Lder
---------------------------	------------	----------------	-------------

Receiving Point	L _{day} (dBA)	L _{eve} (dBA)	L _{night} (dBA)
Point 1	42.6	43.2	43.7

Receiving Point	L _{day} (dBA)	L _{eve} (dBA)	L _{night} (dBA)	
Point 2	42.7	43.3	43.9	
Point 3	36.5	37.3	38.0	
Limit Values for RENC (dBA)	Baseline + 5 dBA	Baseline + 5 dBA	Baseline + 3 dBA	

Table 10-18: Construction Noise Model Results (for WBG standards), Ldn

Receiving Point	L _{day} (dBA)	Lnight (dBA)
Point 1	42.6	43.7
Point 2	42.7	43.9
Point 3	36.5	38.0
Limit Values for WBG (dBA)	55	45

The noise maps generated for the construction phase with respect to L_{day} and L_{night} (in accordance with the WBG standards) are presented in Figure 10-3 and Figure 10-4, respectively.



Figure 10-3: Construction Phase Noise Map Lday



Figure 10-4: Construction Phase Noise Map Lnight

Operation noise levels at receptor points are presented in Table 10-19 and Table 10-20.

Receiving Point	L _{day} (dBA)	L _{eve} (dBA)	L _{night} (dBA)
Point 1	42.0	42.4	42.8
Point 2	42.3	42.9	43.4
Point 3	35.5	36.2	36.8
Point 4	48.2	48.3	48.5
Limit Values for RENC (dBA) ¹⁴⁶	65	60	55

Table 10-19: Operation Noise Model Results, Lden

Table 10-20: Operation Noise Model Results, Ldn

Receiving Point	L _{day} (dBA)	L _{night} (dBA)
Point 1	42.0	42.8
Point 2	42.3	43.4
Point 3	35.5	36.8
Point 4	48.2	48.5
Limit Values for WBG (dBA)	55	45

¹⁴⁶ Limit values for the operation phase are accepted as the noise level limits for industrial facilities determined in Annex-2 Table 1 of the RENC. The noise maps generated for the operation phase with respect to L_{day} and L_{night} (in accordance with the WBG standards) are presented in Figure 10-5 and Figure 10-6, respectively.



Figure 10-5: Operation Phase Noise Map Lday



Figure 10-6: Operation Phase Noise Map Lnight

10.5 Calculation of Vibration Levels

Vibration Source Levels for Construction Equipment

10.5.1 Vibration Sources

In order to simulate the maximum vibration that may occur at receptors, calculations and assessment were conducted in terms of environmental vibration generated by construction machinery. Calculations were made according to the information and reference vibration levels gathered from the Federal Transit Administration (FTA) Railway Vibrations document. Reference vibration levels for specific equipment to be used for construction activities are given in Table 10-21. No blasting activity is required for the Project.

The major vibration source for the construction phase is pile-driving activities. Therefore, the reference vibration value is accepted as 'pile driver (impact) - upper range' for the worst-case scenario.

		.p			
Equipment		PPV at 25 ft (in/sec)	Approximate L_v^* at 25 ft		
Pile driver (impact)	Upper range	1.518	112		
	Typical	0.644	104		
Pile driver (sonic)	Upper range	0.734	105		
	Typical	0.170	93		
Clam shovel drop (slurry w	/all)	0.202	94		
Hydromill roller	In soil	0.008	66		
	In rock	0.017	75		
Vibratory roller		0.210	94		
Hoe ram		0.089	87		
Large bulldozer		0.089	87		
Caisson drilling		0.089	87		
Loaded trucks		0.076	86		
Jackhammer		0.035	79		
Small bulldozer		0.003	58		
*RMS velocity in decibels (VdB) re 1 micro-inch/second					

Table 10-21: Reference Vibration Levels of Construction Equipment (FTA Document)

The peak particle velocities at the identified receptors are calculated with reference vibration velocities and distances in between the working area and receiving points as shown in the following equation:

$$PPV_{receptor} = PPV_{reference} \times (d_{ref}/d_{rec})^{1.5}$$

- PPV: peak particle velocity (mm/s)
- d_{ref}: reference distance (m)
- d_{rec}: receptor distance (m)

During the operation phase of the Project, the machinery and equipment that are located in the technical building and on the roof floors are not expected to cause environmental vibration propagation at receptor locations.

10.5.2 Results of Vibration Level Calculations

The vibration effect with respect to the distance and limit values is shown in Figure 10-7. Critical distance evaluation for main construction activities indicates that safe distance from construction site before



vibration level falls below the 0.3 mm/s level (defined in BS 5228-2:2009¹⁴⁷) is 200 m and 10 mm/s level (defined in RENC) is 20 m.

Figure 10-7: Construction Vibration Levels and Limit Values

10.6 Assessment of Impacts and Regulatory Compliance

10.6.1 Assessment of Noise Impacts

Main noise sources during construction activities include use of construction machinery and equipment that will be required for earthworks, structural works and finishing. Increased noise levels during construction activities have the potential to result in negative impacts to the background noise levels creating health risks at nearest sensitive receptors. The actual impact level will depend also on aspects such as the type of equipment used, time period and duration, as well as the perception of specific noise patterns (e.g., continuous, regular intervals, irregular).

The main noise sources during operation will be the equipment related to energy generation and heating and cooling systems including pumps, compressors, steam generators, fans, variable refrigerant volume systems, air handling units and cooling towers. Additionally, there will be vehicle movements within the Project site including loading/unloading and car parking areas.

In view of the above, in order to predict the impacts of the Project on the existing background noise conditions, baseline measurements and a sound propagation modeling study were conducted as described in detail in the above sections to research potential noise impact in the vicinity of the Project site.

Noise assessment results including cumulative noise levels that take into account both the measured background noise and the modeled noise as a result of the Project activities are provided in Table 10-22 and Table 10-23 below for comparison with WBG limit values¹⁴⁸. Cumulative noise levels were evaluated

¹⁴⁷ BS 5228-2:2009 - Code of Practice for Noise and Vibration Control on Construction and Open Sites

¹⁴⁸ WBG limit values were taken into consideration for the assessment of noise impacts since they are more conservative with respect to the national limit values for noise and therefore have been accepted as Project standards.

against limit values in order to determine the significance of impacts. Sensitivity, magnitude and significance of noise impacts were evaluated based on the criteria presented in Section 10.2.3.

Receiving Point	Model Re (dBA)	esult L _{eq}	Baseline	L _{eq} (dBA)	Cumulat (dBA)	tive Level	Determ Limit Va	ined WBG alue (dBA)*	Limit Exceedance (dBA)	Assessment Result		
	L _{day}	Lnight	Lday	Lnight	L _{day}	Lnight	L _{day}	Lnight		Sensitivity	Magnitude of Impact	Impact Significance
1	42.6	43.7	59.7	54.8	59.8	55.1	62.7	57.8	None	Medium	Negligible	Insignificant
2	42.7	43.9	71.5	67.1	71.5	67.1	74.5	70.1	None	Medium	Negligible	Insignificant
3	36.5	38.0	57.4	55.7	57.4	55.7	60.4	58.7	None	Medium	Negligible	Insignificant
*Calculated by adding 3 dBA to the baseline L _{eq} value												

Table 10-22: Construction Phase Noise Assessment Results (WBG, Ldn)⁵

Table 10-23: Operation Phase Noise Assessment Results (WBG, Ldn)¹⁴⁹

		(dBA)		Limit Va	alue (dBA)*	Exceedance (dBA)	Assessment	Result	
t L _{day}	Lnight	L _{day}	Lnight	L _{day}	Lnight		Sensitivity	Magnitude of Impact	Impact Significance
59.7	54.8	59.8	55.0	62.7	57.8	None	Medium	Negligible	Insignificant
71.5	67.1	71.5	67.1	74.5	70.1	None	Medium	Negligible	Insignificant
57.4	55.7	57.4	55.7	60.4	58.7	None	Medium	Negligible	Insignificant
52.0	47.7	53.5	51.1	55.0	50.7	<1	High	Negligible	Insignificant
h } }	ht Lday 59.7 71.5 57.4 52.0	Lday Lnight 59.7 54.8 71.5 67.1 55.7 52.0 47.7	bd Senine Leg (d.D.r.) Connecta ht Lday Lnight Lday 59.7 54.8 59.8 71.5 67.1 71.5 57.4 55.7 57.4 52.0 47.7 53.5	bit Lday Lnight Lday Lnight 59.7 54.8 59.8 55.0 71.5 67.1 71.5 67.1 57.4 55.7 57.4 55.7 52.0 47.7 53.5 51.1	bit Series Led (dBA) Constraint of Lorest Determinative Lorest Determina	bit Series Leq (dBA) Connection Determined (dBA)* ht Lday Lnight Lday Lnight Lday Lnight Lday Lnight Lday Lnight Solution <thsolution< th=""> <thsolution< th=""></thsolution<></thsolution<>	aq baseline Leq (uBA) outnutative Level betchnined TDC Limit Value (dBA)* Exceedance (dBA) nt Lday Lnight Lday Lnight Lday Lnight Lday Lnight Lday Lnight Source (dBA)* Exceedance (dBA) 5 59.7 54.8 59.8 55.0 62.7 57.8 None 6 71.5 67.1 71.5 67.1 74.5 70.1 None 3 57.4 55.7 57.4 55.7 60.4 58.7 None 5 52.0 47.7 53.5 51.1 55.0 50.7 <1	aq Descrime Leq (dDA) Outminative Level Determined WDC Limit Value (dBA)* Exceedance (dBA) nt Lday Lnight Lday Lnight Lday Lnight Sensitivity 5 59.7 54.8 59.8 55.0 62.7 57.8 None Medium 7 71.5 67.1 71.5 67.1 74.5 70.1 None Medium 3 57.4 55.7 57.4 55.7 60.4 58.7 None Medium 5 52.0 47.7 53.5 51.1 55.0 50.7 <1	aqDescrime Leq (dDA)Outnutative Level (dBA)Determined Troc Limit Value (dBA)*Exceedance (dBA)ntLdayLnightLdayLdayLdayLnightSensitivityMagnitude of Impact559.754.859.855.062.757.8NoneMediumNegligible71.567.171.567.174.570.1NoneMediumNegligible357.455.757.455.760.458.7NoneMediumNegligible552.047.753.551.155.050.7<1

*Calculated by adding 3 dBA to the baseline $L_{\mbox{\scriptsize eq}}$ value

¹⁴⁹ Since baseline noise levels are higher than the generic WBG limits (Criteria: Day time: 07:00 – 22:00, L_{day}= 55 dBA; Night-time: 22:00 – 07:00, L_{night}= 45 dBA), applicable limit values have been determined by adding 3 dBA to the baseline L_{eq} values, and maximum level of exceedance (Table 10-4) has been taken into account in the noise assessment.

Baseline noise levels obtained from the environmental noise survey at the selected receptor locations exceed the international (WBG) limits. For this reason, specific limit values for the Project have been determined by adding 3 dBA to the baseline L_{eq} values. Comparison of cumulative noise levels against the determined noise limits reveals that cumulative noise levels are in compliance with limit values, except a slight exceedance (<1 dBA) observed at Receptor 4 for the operation phase during the night-time period. Note that Receptor 4 was selected inside the Project boundary to help detection of potential environmental noise effects on the planned facility and kindergarten associated with the facility.

As presented in the assessment tables, 'insignificant' final impact significance is observed for construction and operation phases for all receiving locations. In determining significance level, defined impact assessment criteria given in Table 10-10 have been taken into account.

As explained earlier, the noise modelling study considered a worst-case scenario, including simultaneous and continuous operation of all equipment and machinery. Considering this approach, the exceedance of background noise levels is expected to be lower than the calculated values.

Elevated background (baseline) noise levels at and near the Project site lies are attributed mainly to the proximity to the Esenboğa Airport as well as the Özal Boulevard, as discussed in Section 10.4 above. This situation may require noise barriers and window insulation at the planned facility especially for the kindergarten and buildings where quiet working conditions are essential. In addition, the impact on the experimental animals needs to be considered.

10.6.2 Assessment of Vibration Impacts

During the construction phase, potential vibration impacts will be related to the use of construction machinery at the Project site. Increase in vibration may result in disturbance to the occupiers of dwellings and other noise sensitive buildings that are close to the Project site boundaries. Vibrational limit values defined in RENC is 10 mm/s (for discontinuous vibration), and 0.3 mm/s in BS 5228-2:2009 for residential environment. According to the vibration level calculations, there is no limit exceedance observed for construction vibration at the selected receptor points. Assessment results are presented in Table 10-24.

Receptor Points	Distance (m)	Impact / Level	Limit National	Limit International	Exceedance
1	413	0.0966 mm/s	10 mm/s	0.3 mm/s	-
2	430	0.0910 mm/s	10 mm/s	0.3 mm/s	-
3	570	0.0596 mm/s	10 mm/s	0.3 mm/s	-

Table 10-24: Summary	Results for	Construction	Vibration
Table 10-24. Summar	y Results for	Construction	VIDIALION

Critical distance evaluation has also been conducted (presented in Figure 10-7). The critical distance from the construction zone is calculated as 20 m according to the RENC, and 200 m according to the BS 5228-2: 2009 for main construction activities. None of the studied receptors are within the critical distance. Thus, no impact is expected from constructional vibration activities as long as necessary precautions are taken and proper warnings are delivered. During the operation phase of the Project, the machinery and equipment that are located in the technical building and on the roof floors are not expected to cause environmental vibration propagation at receptor locations. Thus, no vibration impact is foreseen during the operation phase.

10.7 Mitigation Measures

10.7.1 Design Phase

The following specific mitigation measures will be applied during the design phase of the Project:

- Due to the elevated background (baseline) noise levels at the Project site, noise barriers and window insulation will be considered at the planned facility especially for the kindergarten and buildings where quiet working conditions are essential.
- Machinery, equipment and vehicles with lower sound power levels and reduced-sound models will be preferred and procured at the design and supply stage.
- Noisy equipment (e.g., generators, compressors) will be located away from noise sensitive receptors when designing the facility layout.
- The design of the technical building will be made such that the indoor noise levels at the laboratories and buildings do not exceed the regulatory and international standards.
- Buildings will be designed with adequately isolated inner walls where noise generating systems (i.e., compressors, generators) will be located.
- Silencer implementation to fans will be considered at the design stage.
- Application of noise barriers will be considered where necessary.
- In terms of indoor noise levels, sound insulation of the building elements (generator, chiller, compressor, engine and pump groups, etc.) will be made in accordance with the Regulation on the Protection of Buildings Against Noise¹⁵⁰. It will be ensured that required conditions are met with the performance evaluations undertaken during the operation phase.

10.7.2 Construction Phase

No limit exceedance was observed for the construction impact of noise and vibration. Therefore, it is not expected that strict mitigation measures will be required. However, the project will adhere to the application of salient practices from the WBG EHS Guidelines for Construction and Decommissioning providing specific guidance on prevention and control of noise and vibrations. Following measures would be beneficial to mitigate any impact.

- Construction Site Management Plan and a construction phase Noise Management Plan will be established and implemented to optimize construction activities;
 - Earth-moving and noisy equipment will be kept as far away from sensitive areas as feasible on the construction site.
 - Activities that cause noise and vibration will be spread over time so that multiple activities that generate noise and vibration do not occur at the same time and their cumulative impacts are mitigated.
 - Night-time activities will be avoided, pile driving activities will not be conducted at night-time period and weekends.
 - Baseline noise measurement assessment will be taken into account when construction activities are planned. At low baseline noise hours and at the weekends, truck activities will be limited and low noise generating activities will be scheduled.
 - Construction workers will be trained on relevant management plans and be aware of the sensitive nature of workplaces they are operating in and advised to limit verbal noise or other forms of noise.
 - Noise and vibration will be minimized at the Project site and surrounding areas through instructing construction truck drivers to switch off vehicle engines while offloading materials and to shut down or throttled down to a minimum when not in operation.
- The construction Traffic Management Plan will be implemented to properly manage traffic during construction activities. Accordingly,
 - Speed limit applications will be applied throughout the Project site for the vehicles that will transport construction materials/equipment.

¹⁵⁰ Official Gazette Date/Number: 31.05.2017/30082

- Construction traffic through the settlements will be avoided and project transportation through community areas will be minimized whenever alternative routes and/or service roads are available.
- Mitigation measures related to the construction machinery and equipment will be taken;
 - Proper machinery, equipment and vehicles with lower sound power levels and reduced-sound models will be preferred.
 - Construction contractor will be required to avoid use of old or damaged machinery with high level of noise emissions that would have a negative impact in the environment and to ensure that equipment is properly serviced and efficient.
 - Maintenance of construction vehicles will be conducted regularly by means of a regular vehicle maintenance and repair program as per the recommendations of the manufacturer to minimize extraneous noises caused by poor performance.
 - All generators and heavy-duty equipment will be insulated or placed in enclosures to minimize disrupting ambient noise levels.
- Health and safety of construction workers will be protected from any possible noise impact generated at the construction site. Adequate personal protective equipment will be provided to workers.
- Noise and vibration monitoring will be performed during the construction phase with periodical construction site inspections to assess the compliance with construction phase Noise Management Plan, national and international requirements and good construction practices.
- Local communities will be engaged to minimize any disturbance and effect on the safety, health of people in the nearby buildings;
 - Construction activities will be planned in consultation with local communities so that activities with the greatest potential to generate noise are planned during periods of the day that will result in least disturbance.
 - Complaints on noise and vibration disturbances will be recorded, assessed and necessary preventive measures will be taken.
- Necessary consent will be obtained from the MoEUCC in case construction activities will be undertaken during evening and night-time. Noisy activities taking place within construction sites will be located away from the residential areas to the extent possible.
- Trainings to construction workers will be provided on the relevant management plans.

10.7.3 Operation Phase

As the results presented in Section 10.6 indicates, final impact significances for all receptors are evaluated to be 'insignificant'. Therefore, it is not expected that strict mitigation measures will be required. However, following operational measures will be taken, as necessary:

- An operational phase Noise Management Plan will be developed and implemented to minimize operational noise emissions.
- All noise generating equipment and machinery during operation will be placed in buildings with isolated walls.
- Low-noise equipment will be used during operation phase as far as possible.
- Periodical maintenance of machinery and equipment will be performed.
- Additional noise barriers will be applied if required in the future.

10.8 Residual Impacts

Considering that 'insignificant' final impact significance is observed for all receiving locations for both construction and operation phases of the Project, and the noise modelling study and vibration calculation were conducted based on the worst-case scenario; the significance of the residual impacts of

construction and operation phase noise levels due to the Project are estimated to be minor to insignificant.

Construction phase noise impacts will be temporary and can be fully mitigated with the implementation of measures mentioned above. No residual impact is expected on nearest receptors by the operation of the equipment located in the technical building and on the roofs, as well as the vehicle movements during the operation phase considering that the abovementioned mitigation measures are applied.

However, it is still important to note that some assumptions used in these studies are subject to change during later stages of the Project and there may be other sources which were not foreseen at this stage that may have an additional impact on noise levels. Necessary assessments will be made and respective mitigation measures will be taken as appropriate, in case such changes result in additional impact on noise levels.

10.9 Proposed Monitoring and Reporting

Noise and vibration monitoring and reporting will be performed by the Project to assess the compliance with the construction and operation phase Noise Management Plans, national and international requirements and good construction practices. Although only 'insignificant' impacts are foreseen due to the activities of the Project and a robust noise monitoring and reporting program is not deemed required; it is important that regular monitoring is conducted to understand whether any changes occur with respect to the assessment results presented in this ESIA study. Such changes may occur due to other sources which were not foreseen at this stage that may have additional impact on noise levels during both construction and operation phases.

The monitoring activities will include performing periodic noise measurements (as per the timeframes determined in the Noise Management Plans), performing site visits to ensure that necessary noise barriers are used (if needed) and necessary noise protection equipment are used by the workers (especially during the construction phase), and finally, record-keeping of any grievances related to noise generation due to Project activities to be able to make further assessment and management.

11 SOCIO-ECONOMIC BASELINE

11.1 Introduction

The aim of the socioeconomic impact assessment is to generally characterize the potential risks and impacts regarding socioeconomic conditions associated with construction and operational phases of the Project (i.e., poverty, employment, education, livelihoods, migration, gender equality, daily activities and access to health services) and design appropriate mitigation measures in order to prevent, minimize or compensate/offset the adverse impacts on socioeconomic conditions.

The socioeconomic baseline data includes quantitative and qualitative data collected from field surveys complemented by secondary resources such as Turkish Statistical Institute (TurkStat).

Subsequent sections present the evaluation of existing socioeconomic conditions in Ankara province and in Akyurt district (Section 11.2), description of methodology and assessment criteria and assessment of potential impacts of the Project on socioeconomic conditions (Section 11.3), determination of mitigation and enhancement measures (Section 11.4), compliance against national and international requirements (Section 11.5) and proposed monitoring and reporting (Section 11.7).

11.1.1 Study Area and Area of Influence

The Project site is located in Balıkhisar neighbourhood of Akyurt district approximately 20 km north of the Ankara city centre. There are business areas, factories and agricultural lands surrounding the Project site. The local area of influence for social impact assessment has been selected to be the area with a radius of 5 km around the Project site and social consultations have been targeted towards eight neighbourhoods located within three districts (i.e., Akyurt District, Pursaklar District and Çubuk District) in this area. Accordingly, the neighbourhoods within the area of influence are as follows:

Neighbourhoods with settlements in close proximity to the Project site:

- Balıkhisar (Akyurt District), centre located approximately 5 km to the northeast, with a population of 964 people
- Saracalar (Akyurt District), centre located approximately 1 km to the south, with a population of 1148 people
- Saray Gümüşoluk (Pursaklar District), centre located approximately 3 km to the west, with a
 population of 1251 people
- Altınova (Pursaklar District), centre located approximately 2 km to the south, with a population of 3974 people

Neighbourhoods within 5 km radius:

- Güzelhisar (Akyurt District)
- Saray Cumhuriyet (Pursaklar District)
- Yenice (Çubuk District)
- Dumlupinar (Çubuk District)

Project's direct impact area mainly includes businesses and industrial facilities. The nearest residential building (4-floor building) is located to the southeast with 250 m distance to the Project site. On the other hand, the nearest residential setting is located approximately 500 m southeast of the Project site.

The closest facilities within a 1-kilometre radius of the Project site include the Vaccine and Pharmaceuticals Storage Warehouse of General Directorate of Public Health (neighbouring the Project site to the east), Otonomi (a road vehicles sales point neighbouring the Project site to the south with a

total of approximately 2000 employees), YDS Factory (a safety shoe manufacturer neighbouring the Project site to the northeast with a total of approximately 1000 employees), İşbir Mattress Factory (neighbouring the Project site to the north with a total of 300 employees), İşbir Mattress Foam Factory (with a total of 150 employees), Halkbank Warehouse and Social Facilities, Borusan Automotive, and Man Turkiye (automative manufacturer). Additionally, a shopping mall (i.e., Otonomi Outlet Shopping Mall and Wellness Centre) is planned to be developed in the vacant land adjacent to the Project site to the southeast (i.e. parcel 1555-23), however, the timeline for construction of this project is currently unknown¹⁵¹.

11.1.2 Methodology

As part of the ESIA process, it is necessary to define the existing socioeconomic conditions in the Project's impact area in detail. In line with this necessity, the methodological approach of the socioeconomic baseline data collection and assessment consists of two stages: socioeconomic secondary data collection and site visits.

Assessment of socioeconomic impacts is performed based on the evaluation of baseline conditions presented in Section 11.2. The process of impact assessment includes the analysis of the qualitative and quantitative socioeconomic data, understanding of potential project impacts and development of mitigation mechanisms to minimise any potential adverse impacts. The residual impacts are then assessed. The methodology followed a participatory approach whereby comments, concerns and questions of stakeholders and Project Affected Persons (PAPs) are recorded and responded to through active stakeholder engagement.

Socioeconomic secondary data

For significant impacts and key issues determined during the scoping stage, information regarding the existing socioeconomic conditions was collected based on existing published documents, reports, and plans. Data including demographic characteristics, socioeconomic variables and characteristics of the Project impacted neighbourhoods on a province, district and neighbourhood basis were collected through available official statistical data derived from the TurkStat, Ministry of Industry and Technology, Ministry of Health, Turkish Development Agency, etc. In addition, a detailed requested information list was sent to the MoH. Documents and information provided by the MoH are listed below:

- Summary of the Project (including simplified process flow diagram), definitions of the facility components and capacities (including layouts)
- Any assessments related to the site selection that is undertaken by the MoH
- Satellite image and maps of the area on the land envisaged for the Project site
- Project site boundaries and layout of the latest version

Site visits, surveys and interviews

In order to obtain the most recent data for particular issues about Akyurt district and the Project site together with its surrounding areas, data were collected through consultations with key external stakeholders, focus group meetings, and quantitative socioeconomic household surveys with PAPs during the site visits conducted in Ankara in June 2022 within the scope of the stakeholder engagement activities.

Meetings were conducted with a broad array of stakeholders ranging from the local and regional authorities to NGOs, in order to understand the Project's envisioned beneficial or adverse impacts,

¹⁵¹ The Otonomi Outlet Shopping Mall and Wellness Centre is proposed to be developed by Söğüt İnşaat A.Ş. Final Environmental Impact Assessment (EIA) report for the project was prepared, and EIA positive decision was obtained in line with the provisions of Turkish EIA Legislation in 2017.

consultation, grievance mechanisms, relevance of the Project components and coordination among them. The list of stakeholders consulted is presented in *Chapter 5: Stakeholder Engagement*.

Qualitative consultations were complemented with quantitative household socioeconomic surveys. Based on the preliminary assessment of the social experts, a minimum of 92 household surveys were initially planned in the four targeted neighbourhoods. The sampling distribution was identified with regards to the number of households of the neighbourhoods. Stratified sampling method¹⁵² was used. 70% of the surveys were applied in the inner vicinity (Saray Gümüşoluk and Saracalar) and the remaining 30% were applied in the outer vicinity (Altınova and Balıkhisar). At the 95% confidence level¹⁵³ and 10 confidence interval¹⁵⁴, the minimum sample size by neighbourhoods were calculated as follows:

Name of the neighbourhood	Distance of the centre of the neighbourhood from the Project site (km)	Population (as of 2022)	Estimated Household Number	The sample size (number of household surveys to be conducted)
Balıkhisar	3	964	298	14
Saracalar	1	1148	352	32
Altınova	2	3974	1191	14
Saray Gümüşoluk	3	1251	387	32
Total	-	7337	2228	92

Table 11-1: The number of household surveys for each neighbourhood

Eventually, 109 socioeconomic household surveys were carried out with the Project Affected Persons (PAPs) residing in the impact area (Table 11-2). In order to follow a gender-sensitive approach, special attention was given to including women in the surveys. Women constitute 46.8% of total persons surveyed, while men account for 53.2%. Regarding the neighbourhood-based distribution of 109 surveys, 37 were conducted in Saray Gümüşoluk, 32 in Saracalar, 26 in Balıkhisar, and 14 in Altınova. Additionally, four focus group meetings were conducted with women residing in Balıkhisar, Saracalar, Saray Gümüşoluk, and Altınova neighbourhoods to gain a deeper understanding of women's concerns and questions regarding the Project. In total, focus group meetings with the participation of 21 women were completed.

No	District	Neighborhood	Female	Male	Total
1	Akyurt	Balıkhisar	13	13	26
2	Akyurt	Saracalar	12	20	32
3	Pursaklar	Altınova	6	8	14
4	Pursaklar	Saray Gümüşoluk	20	17	37
		Total	51	58	109
		%	46.8	53.2	100

Table 11-2: Gender distribution of PAPs surve	eyed in June 2022 (by neighbourhoods)
---	---------------------------------------

¹⁵² In stratified sampling, first the population is divided into smaller subgroups, or strata, based on shared characteristics of the members (for our research, the characteristic is the impact level of the community members based on the distance between their place of residence and the Project site), then participants are randomly selected among these subgroups to form the final sample.

¹⁵³ A confidence level is a statistical way to measure how the sample represents the population in a research. The most commonly used value in confidence level is 95%. A 95% confidence level is a range of values that the researcher can be 95% certain about the values in the sample contain the true mean of the population.

¹⁵⁴ Confidence interval (also called margin of error) is a plus-or-minus figure that explains how much a researcher can expect the survey results to reflect the views from the overall population.

In order to obtain in-depth data at the neighbourhood level, mukhtar interviews were also conducted. Eight surveys were conducted with the mukhtars of the neighbourhoods considered to be impacted by the Project. Moreover, as the direct neighbouring parcels are businesses and factories, business surveys were conducted at nine businesses within the impact area of the Project with 17 PAPs from these workplaces.

11.1.3 Data Limitations

During the impact assessment process, details regarding the construction period of the Project, including the commencement and end dates of the construction phases, the number and qualifications of the employees, detailed accommodation conditions, etc. were very limited. In addition, there were no statistics publicly available on employment status, labour force participation and unemployment rates, work branches and livelihoods of the residents neither at district nor at neighbourhood level.

11.2 Baseline Conditions

11.2.1 Overview

The socioeconomic baseline conditions for the Project are presented in this section. The baseline data have been derived from available secondary data (i.e. existing published documents, reports, plans), the documents and information provided by the MoH, and field surveys.

As part of baseline studies, site visits to the Project site and surrounding neighbourhoods were conducted to assess the potential impacts of the Project on socioeconomic conditions. During the site visits, socioeconomic field surveys¹⁵⁵ were conducted with the PAPs who agreed to participate in the survey. All personal information is omitted due to privacy laws.

Previous findings of the social site visits which had been conducted during scoping phase were also considered during the socioeconomic impact assessment.

11.2.2 Population and Demographics

Ankara is the capital and second most populated province in Turkiye, with a population of almost 5.8 million¹⁵⁶. Ankara province has 25 districts, and the population of each district is provided in Table 11-3. The most urbanized and densely populated districts are Çankaya and Keçiören followed by Yenimahalle, Mamak, Etimesgut, Sincan and Altındağ (as shown in Figure 11-1). One of the districts of Ankara is the Akyurt district, in which the Project site is located.

District	Total population	Area (km²)	Population Density (km²)	Annual Population Change (‰)
Çankaya	942 553	454.2	2075.19	-7.1
Keçiören	939 279	152.2	6171.35	-3.8
Yenimahalle	704 652	232.1	3035.98	1.2
Mamak	687 535	345.7	1988.82	7.5
Etimesgut	614 891	283.2	2171.23	13.8
Sincan	572 609	862.3	664.05	19.7
Altındağ	413 994	158.2	2616.90	15.4

Table 11-3: Population of Districts in Ankara¹⁵⁷ (2022)

¹⁵⁵ The questionnaires utilized during the socioeconomic field surveys are provided in Annex G of the ESIA report.

¹⁵⁶ TurkStat, Address Based Population Registration System Results, 2022. https://data.tuik.gov.tr/Bulten/Index?p=49685 Accessed from on 16 October 2023.

¹⁵⁷ TurkStat, Address Based Population Registration System Results by Neighbourhoods, 2022. <u>https://data.tuik.gov.tr/Bulten/Index?p=49685</u> Accessed from on 16 October 2023.

District	Total population	Area (km²)	Population Density (km ²)	Annual Population Change (‰)
Pursaklar	162 389	133.7	1214.58	16.8
Gölbaşı	150 047	1513	99.17	48.4
Polatlı	128 378	3527	36.40	6.7
Çubuk	95 449	1167	81.79	43.8
Kahramankazan	59 123	615.5	96.06	20.7
Beypazarı	48 357	1732	27.92	-0.7
Elmadağ	44 379	632.1	70.21	3.2
Akyurt	40 625	374.4	108.51	51.4
Şereflikoçhisar	33 140	2105	15.74	-10.1
Haymana	26 872	1631	16.48	-3.6
Kızılcahamam	26 553	2000	13.28	-15.2
Nallıhan	26 016	2220	11.72	-48.1
Bala	20 521	1017	20.18	-112.6
Ayaş	12 998	1017	12.78	-7.3
Kalecik	12 794	1047	12.22	23.1
Çamlıdere	8 100	782.5	10.35	-30.4
Güdül	8 079	601.4	13.43	-9.4
Evren	2 952	245.7	12.01	-4.4



Figure 11-1: Population Density of Ankara Districts (Green to red: Least to most populated)¹⁵⁸

The population of Akyurt was reported as 40,625 in 2022, which constitutes 0.70% of the total population of Ankara province¹⁵⁹. The district covers a total of 374.4 km² area and the population density is 108.5 people per square kilometre. As per the data obtained from TurkStat, Akyurt is the eleventh least populated district of Ankara among 25 districts in 2022. The population has increased by 5.1% between 2021 and 2022. The reasons behind this increase were explained by the Mayor of Akyurt as increasing migration rates from other districts and provinces as a result of increasing industrial enterprises and job opportunities within the district. The Mayor of Akyurt stated that over the last ten years, Akyurt has been home to an increasing number of internal migrants due to its proximity to the city centre and the advancement of transportation network. Those who migrated to Akyurt mainly came from the Central Anatolia, Eastern Anatolia, and Southeastern Anatolia regions. There are over 10,000 people from provinces such as Çorum, Çankırı, and Yozgat, as well as Ağrı, Erzurum and Diyarbakır. With development of the economic opportunities offered in the district, the number of people coming to the district to work has also increased. For this reason, the daytime population of Akyurt is usually raised to around 70,000.

In Akyurt, women represent 48% of the total population. Out of the total 40,625 population in Akyurt, 32% is between the ages of 0-19, 56.7% is between the ages of 20-59, and 11.3% is older than 60¹⁶⁰.

¹⁵⁸ Accessed from <u>https://www.citypopulation.de/en/turkey/admin/TR510__ankara/</u> on 22 January 2023.

¹⁵⁹ TurkStat, Address Based Population Registration System Results, 2022. https://data.tuik.gov.tr/Bulten/Index?p=49685 Accessed from on 16 October 2023.

¹⁶⁰ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

Akyurt consists of 26 neighbourhoods, including six central neighbourhoods and 20 villages**Hata! B aşvuru kaynağı bulunamadı.**. Three of the eight neighbourhoods affected by the Project – Balıkhisar, Saracalar, and Güzelhisar neighbourhoods – are located within the borders of Akyurt district.

- According to the information provided by the TurkStat for 2022 population statistics¹⁶¹, Balıkhisar is home to 964 residents, of which 501 are males, and 463 are females. Covering 10.5 km² area, Balıkhisar neighbourhood has lost its population by approximately 29% from 2011 to 2021. The age distribution of the current population estimates that the elderly constitutes 18.6% of the total population. According to the information provided by the mukhtar during the mukhtar surveys in June 2022, the rate of tenants among Balıkhisar residents is lower than that of homeowners. Based on the data obtained during the household surveys in June 2022, the average number of persons living in the households in Balıkhisar is 2.15, with a range of 1 to 8.
- Having 1,148 residents, including 597 males and 551 females¹⁶², Saracalar neighbourhood covers an area of 7.0 km². As the compared data on the population of Saracalar in 2011 and 2021 point out, there has been a 33.7% decrease in population over these ten years. The reason behind this decrease was asked from the mukhtar of Saracalar during the survey in June 2022. He reported that the residents in Saracalar emigrated to other districts/neighbourhoods for economic reasons. Since there were limited job opportunities around the neighbourhood, some residents preferred to move to other residential areas. The elderly population constitutes 18% of the Saracalar population. The mean value of number of persons living in a household is calculated as 2.9. As in Balikhisar, it is stated by the mukhtar of Saracalar during the survey conducted in June 2022 that the number of tenants is lower than that of homeowners in Saracalar.
- Based on the statistical data of TurkStat for 2022 population¹⁶³, there are 516 males and 476 females

 a total of 992 residents. with the elderly constituting 18% of the population in Güzelhisar neighbourhood. This neighbourhood covers an 11.9 km² area. The population has decreased by 12% from 2011 to 2021. Similar to the population movements in Saracalar, Güzelhisar has been subject to emigration. The mukhtar of Güzelhisar neighbourhood stated during the mukhtar surveys carried out in June 2022 that the residents in Güzelhisar moved to other districts/neighbourhoods for economic reasons and finding better job opportunities. There are no tenants in this neighbourhood as reported by the mukhtar of Güzelhisar.

Of the remaining five neighbourhoods, Saray Gümüşoluk, Altınova and Saray Cumhuriyet are located within the borders of the Pursaklar district which has 21 neighbourhoods and a total population of 162,389. The population of these three neighbourhoods is 1,251; 3,974; and 14,913 respectively.

Covering a 0.75 km² area, Saray Gümüşoluk is a home to 588 females and 663 males as of 2022 based on the data of TurkStat¹⁶⁴. The number of people over age 60 accounts for 13%. With a minimum number of 1 and a maximum number of 5, the average number of persons living in the household is calculated as 3.8 according to the information collected during the household surveys. The population, whose majority is landowners as reported by the mukhtar in June 2022, has not changed significantly since 2011.

324

¹⁶¹ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶². Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶³. Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶⁴ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.
Having the largest population among the Project neighbourhoods, Saray Cumhuriyet is home to 7,457 males and 7,456 females¹⁶⁵. Saray Cumhuriyet has been subject to zoning in recent years, which lead the neighbourhood to experience a sharp population growth (%81.1 percent) and a mass housing settlement over the period from 2011 to 2021. This neighbourhood has a younger population compared to other neighbourhoods, with an elderly rate of 8%. However, unlike the other ones, the number of tenants is higher than that of homeowners in this neighbourhood according to the information provided by the mukhtar during surveys in June 2022.

According to the Address-Based Population Recording System of Turkiye, the population of Altınova neighbourhood has grown by 278% from 2011 to 2021¹⁶⁶. Out of the total population reported in 2022, there are 2,027 men and 1,947 women whose age distribution also shows a younger population with an approximately 7.5% elderly rate. It is estimated that there are average 3.5 persons living in the households. The mukhtar of Altınova reported during the survey in June 2022 that the number of homeowners is higher than the number of tenants in Altınova neighbourhood.

The remaining two neighbourhoods within the area of influence of the Project are situated in Çubuk district with a population of 95,449 residents living in 84 neighbourhoods. The total number of residents living in these two neighbourhoods, Dumlupinar and Yenice, are 4,518 and 920 respectively¹⁶⁷.

- Dumlupinar has 1401 males and 3,117 females, of which 3.3% comprises the elderly population¹⁶⁸. As reported by the mukhtar of Dumlupinar neighbourhood in June 2022, the population has decreased almost 10% from 2011 to 2012 for similar reasons to the neighbourhoods in the Project area of influence, however a sharp increase (threefold) was noted within the past year. It was stated by the mukhtar that the number of homeowners is higher than the number of tenants.
- Yenice neighbourhood is home to 920 residents, of which 460 are females and 460 are males¹⁶⁹. The elderly constitutes 18% of the total Yenice population and the population has decreased by 34 percent over the ten years from 2011 to 2021. According to the information provided by the mukhtar during the mukhtar surveys in June 2022, the majority of the population is homeowners.

Based on the results of the mukhtars surveys, it is analysed that Altınova and Saray Cumhuriyet neighbourhoods are considered urban, Balıkhisar, Saracalar and Saray Gümüşoluk neighbourhoods are semi-urban and Güzelhisar, Dumlupınar and Yenice neighbourhoods are rural settlements (Table 11-4).

No	District	Neighborhood	Characteristics of the neighborhood
1	Akyurt	Balıkhisar	Semi-urban
2	Akyurt	Saracalar	Semi-urban
3	Akyurt	Güzelhisar	Rural
4	Pursaklar	Saray Gümüşoluk	Semi-urban
5	Pursaklar	Altınova	Urban
6	Pursaklar	Saray Cumhuriyet	Urban

¹⁶⁵ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶⁶ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶⁷ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶⁸ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁶⁹ Retrieved from <u>https://www.endeksa.com/tr/</u> Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

No	District	Neighborhood	Characteristics of the neighborhood
7	Çubuk	Dumlupınar	Rural
8	Çubuk	Yenice	Rural

Official statistical data obtained from TurkStat have shown that the total population of eight neighbourhoods has become 28,680 as of 2022¹⁷⁰. The total number of households in these neighbourhoods on the other hand is 12,991 with a minimum of 652 (Balıkhisar) and a maximum of 5,885 (Saray Cumhuriyet).

Table 11-5: The distribution of population and number of households of the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

No	District	Neighborhood	Number of households (in winter)	Number of households (in summer)
1	Akyurt	Balıkhisar	400	450
2	Akyurt	Saracalar	400	400
3	Akyurt	Güzelhisar	500	600
4	Pursaklar	Saray Gümüşoluk	376	376
5	Pursaklar	Altınova	1,000	1,000
6	Pursaklar	Saray Cumhuriyet	5,000	5,000
7	Çubuk	Dumlupınar	400	400
8	Çubuk	Yenice	300	300
		Total	8,376	8,526

Except for Balıkhisar and Güzelhisar neighbourhoods, whose populations increase during the summer months, the population of other neighbourhoods does not change seasonally. Similarly, 89.9% of persons surveyed during the household surveys stated that they live in their neighbourhood permanently rather than living there seasonally. With respect to the ownership status distribution within the Project affected neighborhoods, an average of 80% of the households in the surveyed neighborhoods are homeowners.

Table 11-6: Ownership status distribution of houses within the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

No	District	Neighborhood	% Landowners	% Tenants
1	Akyurt	Balıkhisar	90	10
2	Akyurt	Saracalar	80	20
3	Akyurt	Güzelhisar	100	0
4	Pursaklar	Saray Gümüşoluk	95	5
5	Pursaklar	Altınova	70	30
6	Pursaklar	Saray Cumhuriyet	40	60
7	Çubuk	Dumlupınar	90	10
8	Çubuk	Yenice	70	30
		Mean	80	20

¹⁷⁰ Retrieved from https://www.endeksa.com/tr/ Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

Based on the household socioeconomic survey results, the demographic information of the head of the households within the Project affected neighbourhoods is given in Table 11-7 below. Accordingly:

- 90.8% of households demonstrate a nuclear family type.
- 87.2% of the household heads are male and the average age is 55.5.
- Approximately 87.2% of household heads are married.
- 36.7% of household heads are primary school graduates, %23.9 are high school and 22.9% are secondary school graduates. The rest is distributed among illiterate, college graduates and university graduates.
- 36.7% of household heads are retired, while 19.3% are craftsmen/freelancers and 10.1% are farmers. No one has specified the main source of livelihood as animal husbandry.
- 73.4% of household heads has social security insurance.
- In total, 81.7% of household heads are homeowners.

	District Akyurt							Pursal	dar								
	Neighbourhood	Balık	hisar		Saraca	alar		Altınov	/a		Saray	Gümüşc	oluk	Total			
	Item	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	%
Family Type	Nuclear	20	1	21	28	3	31	10	1	11	30	6	36	88	11	99	90.8
	Extended	2	2	4	1	-	1	2	-	2	-	-	-	5	2	7	6.4
	Alone	-	1	1	-	-	-	1	-	1	1	-	1	2	1	3	2.8
	Total	22	4	26	29	3	32	13	1	14	31	6	37	95	14	109	100
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100
Age	Mean	64.7	83.8	-	55.3	59	-	47.1	46	-	49.7	59.5	-	-	-	-	-
	Minimum	43	71	-	35	47	-	34	46	-	28	52	-	-	-	-	-
	Maximum	81	93	-	80	67	-	64	46	-	87	66	-	-	-	-	-
Marital Status	Married	22	-	22	27	2	29	12	-	12	29	3	32	90	5	95	87.2
	Single	-	-	-	-	1	1	1	-	1	-	3	3	-	1	1	0.9
	Widow	-	4	4	-	1	1	-	-	-	1	-	1	3	7	10	9.2
	Divorced	-	-	-	1	-	1	-	1	1	-	-	-	1	1	2	1.8
	Lives separately	-	-	-	-	-	-	-	-	-	1	-	-	1	-	1	1.8
	Total	22	4	26	29	3	32	13	1	14	31	6	37	95	14	109	-
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100
Educational Status	Literate	-	1	1	-	-	-	-	-	-	1	-	1	1	1	2	1.8
	Primary school	11	-	11	10	1	11	2	-	2	12	4	16	35	5	40	36.7
	Secondary school	8	-	8	8	2	10	2	-	2	5	-	5	23	2	25	22.9
	High school	2	-	2	8	-	8	5	-	5	10	1	11	25	1	26	23.9
	College	-	-	-	3	-	3	1	-	1	-	-	-	4	-	4	3.7
	University	-	-	-	-	-	-	3	1	4	3	-	3	6	1	7	6.4
	Illiterate	1	3	4	-	-	-	-	-	-	-	1	1	1	4	5	4.6
	Total	22	4	26	29	3	32	13	1	14	31	6	37	95	14	109	-
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100

Table 11-7: Demographic information of the head of the households within the Project affected neighbourhoods (based on the findings of the household socio-economic surveys in June 2022)

	District	Akyu	rt					Pursal	dar								
	Neighbourhood	Balık	hisar		Saraca	alar		Altinov	/a		Saray	Gümüşo	luk	Total			
	Item	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	Male	Female	Total	%
Basic Livelihood	Farmer	2	-	2	1	-	1	-	-	-	7	1	8	10	1	11	10.1
	Retired	15	3	18	11	1	12	3	-	3	4	3	7	33	7	40	36.7
	Craftsman/Freelance	4	-	4	6	-	6	-	-	-	11	-	11	21	-	21	19.3
	Officer	-	-	-	1	1	2	5	1	6	1	1	2	7	3	10	9.2
	Worker/Employee	1	1	2	1-	1	11	4	-	4	7	-	7	22	2	24	22
	Other	-	-	-	-	-	-	1	-	1	1	1	2	2	1	3	2.8
	Total	22	4	26	29	3	32	13	1	14	31	6	37	95	14	109	-
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100
Social Security	SSI ¹⁷¹	13	3	16	24	3	27	13	1	14	18	5	23	68	12	80	73.4
Status	GHI ¹⁷²	1	-	1	1	-	1	-	-	-	1	-	1	3	-	3	2.8
	Bagkur ¹⁷³	8	1	9	3	-	3	-	-	-	11	1	12	22	2	24	22
	N/A	-	-	-	-	-	-	-	-	-	1	-	1	1	-	1	0.9
	Other	-	-	-	1	-	1	-	-	-	-	-	-	1	-	1	0.9
	Total	22	4	26	29	3	32	13	1	-	31	6	37	95	14	109	-
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100
Home Ownership	Owner	18	4	22	21	1	22	12	-	12	27	6	33	78	11	89	81.7
	Tenant	1	-	1	6	2	8	1	1	2	3	-	3	11	3	14	12.8
	User	3	-	3	2	-	2	-	-	-	1	-	1	6	-	6	5.5
	Total	22	4	26	29	3	32	13	1	14	31	6	37	95	14	109	-
	%	84.6	15.4	100	90.6	9.4	100	92.9	7.1	100	83.8	16.2	100	87.2	12.8	100	100

¹⁷¹ SSI (Social Security Insurance) is the social security system provided to all contracted employees working in a private workplace.

¹⁷² GHI (General Health Insurance) is the social security system provided for the households whose average household income is below the national minimum wage in Turkiye.

¹⁷³ Bagkur is the social security system that covers tradesmen, craftsmen and other freelancers in Turkiye.

The household socioeconomic survey results also demonstrate the demographic information of the household members within the Project affected neighbourhoods, as in the table below. Based on these results, it can be stated that:

- Average number of persons living in the household is 3.54, ranging from 1 to 9.
- 50.5% of household members are female.
- The population between the ages of 41-64 is higher than the rest. Those under 5 years old has the least ratio among the age groups.
- Among household members, there are 84 persons with disabilities including chronic diseases, and mental and physical conditions.
- Eight participants stated that they receive fuel and food aid and cash from the social services in their districts.

Table 11-8: Household information within the Project affected neighbourhoods (based on the findings of the household socioeconomic surveys in June 2022)

Торіс	District	Akyurt		Pursaklar			
	Neighbourhood	Balıkhisar	Saracalar	Altınova	Saray Gümüşoluk	Total	%
Number of	Mean	2.15	3.37	3.64	3.81	-	-
persons living in	Minimum	1	2	1	1	-	-
the nousehold	Maximum	8	5	9	5	-	-
Gender	Male	41	54	30	66	191	49.5
distribution	Female	45	54	31	65	195	50.5
	Total	86	108	61	131	386	-
	%	22.3	28	15.8	33.9	-	100
Age distribution	0-5 years old	3	4	10	4	21	5.5
	6-14 years old	4	17	13	20	54	14.1
	15-18 years old	6	4	2	8	20	5.2
	19-40 years old	22	30	20	40	112	29.2
	41-64 years old	35	38	16	50	139	36.2
	65 years and older	16	13	1	8	38	9.8
	Total	86	106	62	130	384	-
	%	22.4	27.6	16.1	33.9	-	100
Number of	Primary School	2	12	8	7	29	34.5
students	Secondary School	3	3	5	12	23	27.4
	High School	3	4	2	8	17	20.2
	College/University	1	2	2	10	15	17.9
Number of	Number	9	21	17	37	84	-
disabled persons	%	10.7	25	20.2	44.1	-	100
Disabled person	Her/Himself	-	1	-	1	2	-
proximity status	Spouse	1	2	-	2	5	-
	Child	1	-	-	1	2	-
	Mother/Father	1	-	1	-	2	-
	Other	-	1	-	-	1	-
Disability status	Physically Disabled	1	-	-	1	2	-
	Mentally Disabled	-	1	-	-	1	-
	Chronic Patient	1	3	-	3	7	-
	Elderly in Need of Care	1	-	-	-	1	-
	Number	1	4	-	3	8	-

Number of	%	12.5	50	-	37.5	-	100
persons receiving support from Social Services	Support Type	Fuel	Cash Food Fuel	-	Cash Fuel	-	-

11.2.3 Economy

According to a study conducted in 2012¹⁷⁴, industry has been at the forefront of economic activities in Akyurt district. There were 113 small, medium and large-scale industrial facilities and factories in the district for that time and a total of 24,099 people worked in these enterprises. There were also many workplaces in the service sector and the total number of tradesmen and craftsmen in Akyurt was reported as 303. The Esenboğa International Airport is a predominant factor for the development of commercial activities in the region. The presence of automotive manufacturers such as Otonomi and Man Turkiye has increased job opportunities and human mobility, as well. Currently, it was stated by the representatives of Akyurt Municipality that there are nearly 300 industrial enterprises indicating that Akyurt has started to become a prominent centre of industrialization. The International Fair Centre, which is currently in planning, stands at an important point in terms of commercial and industrial development in the region.

The health industry is currently developing in Akyurt as various pharmaceutical warehouses, vaccine warehouse of the MoH and companies producing medical products are already located in the district. The results of the surveys conducted with the workplaces during the stakeholder engagement activities also reflect the profile of commercial and industrial enterprises in Akyurt. There are many workplaces from different business lines. Employees of these workplaces reside in different parts of Ankara, including Akyurt, Pursaklar and Çubuk (please see Table 11-9 for detailed information).

Table 11-9: Data on facilities, business enterprises and factories located in the Project affected neighbourhoods (based on the findings of the business interviews in June 2022)

No	District	Neighborhood	Name of workplace	Area of service	Number of employees	Female employees	Residency of employees
1	Akyurt	Saracalar	Borusan Oto	Automotive	>50 and <250	>10 and <50	From all over Ankara
2	Akyurt	Saracalar	MAN	Factory	>4,000	>250 and <500	From all over Ankara
3	Akyurt	Balıkhisar	Özkan Otomotiv	Automotive	<10	NA	Akyurt, Pursaklar
4	Akyurt	Balıkhisar	Halk Bankası Malzeme Deposu	Logistics	>10 and <50	<10	From all over Ankara
5	Akyurt	Balıkhisar	İşbir Sünger	Factory	>250 and <500	>10 and <50	From all over Ankara
6	Akyurt	Balıkhisar	İşbir Yatak	Factory	>50 and <250	>10 and <50	Akyurt, Pursaklar Çubuk
7	Akyurt	Balıkhisar	İşbir Optik	Factory	>50 and <250	>10 and <50	From all over Ankara
8	Akyurt	Balıkhisar	ÖSYM E-Sınav Merkezi	Public services	>10 and <50	NA	Keçiören
9	Akyurt	Balıkhisar	Türkplast Sağlık Ürünleri	Pharmaceutical	>500 and <1,000	>250 and <500	From all over Ankara

Main economic activities by neighbourhoods identified during the mukhtar's interviews are listed in Table 11-10. Accordingly, income earned by working as a blue-collar worker in the private sector comes first in the basic livelihoods ranking of the five neighbourhoods. Agricultural activities, on the other hand, come first in Güzelhisar and Saray Gümüşoluk, and trade in Dumlupınar. In the second place, agriculture,

¹⁷⁴ Serim, A. (2012). Akyurt (Ankara) ilçesinin coğrafi etüdü. Geographical Study of Akyurt District (Ankara). Doctoral dissertation, Necmettin Erbakan University (Turkiye).

retirement and trade demonstrate an almost equal distribution. Animal husbandry, on the other hand, is ranked third as the main economic activity only in Dumlupinar and Yenice.

Table 11-10: Main economic activities within the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

No	District	Neighborhood	Main Economic Activity								
NO	District	Neighborhood	1	2	3						
1	Akyurt	Balıkhisar	Blue-collar worker in private sector	Agriculture	Trade						
2	Akyurt	Saracalar	Blue-collar worker in private sector	Retirement	-						
3	Akyurt	Güzelhisar	Agriculture	Trade	Retirement						
4	Pursaklar	Saray Gümüşoluk	Agriculture	Retirement	-						
5	Pursaklar	Altınova	Blue-collar worker in private sector	Retirement	-						
6	Pursaklar	Saray Cumhuriyet	Blue-collar worker in private sector	Trade	Retirement						
7	Çubuk	Dumlupınar	Trade	Agriculture	Animal husbandry						
8	Çubuk	Yenice	Blue-collar worker in private sector	Agriculture	Animal husbandry						

11.2.4 Income Distribution

According to the gross domestic product (GDP) calculations at the provincial level conducted in 2021, Ankara reached the second highest GDP with 462.2 billion Turkish Liras (TRY). The GDP of Ankara constituted 9.2% of the total share in Turkiye¹⁷⁵. Additionally, the TurkStat annually reports the average equivalent household expendable income of provinces. Accordingly, the annual average equivalent household expendable income in Turkiye was 37,400 TRY in 2020. Ankara remained above the average income of Turkiye with 46,516 TRY¹⁷⁶.

According to district-based statistics¹⁷⁷, the average household size in Akyurt, Pursaklar and Çubuk is estimated as 3.31, 3.43 and 3.19 people respectively. As of June 2022, the average household income for these three districts, on the other hand, is sequentially calculated as 6,630; 7,716; and 6,387 TRY¹⁷⁸. These incomes are slightly above the hunger threshold – 6,319 TRY - and are way below the poverty line, which is 20,818 TRY¹⁷⁹.

In addition to the data provided above, brief information on income distribution Project affected neighbourhoods is listed below¹⁸⁰:

¹⁷⁹ <u>https://www.turkis.org.tr/mayis-aclik-yoksulluk-siniri/</u>

¹⁷⁵ TurkStat, GDP calculations by provinces, 2021. Accessed from <u>https://data.tuik.gov.tr/Bulten/Index?p=II-Bazinda-Gayrisafi-Yurt-Ici-Hasila-2021-45619&dil=1</u> on 23 January 2023.

¹⁷⁶ TurkStat, Income and Living Conditions Survey Regional Results, 2021 (https://data.tuik.gov.tr/Bulten/Index?p=Incomeand-Living-Conditions-Survey-Regional-Results-2021-45582)

¹⁷⁷ Accessed from <u>https://www.endeksa.com/tr/analiz/ankara/akyurt/demografi</u>,

https://www.endeksa.com/tr/analiz/ankara/pursaklar/demografi, https://www.endeksa.com/tr/analiz/ankara/cubuk/demografi on 19 December 2022. Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁷⁸ Accessed from <u>https://www.endeksa.com/tr/analiz/ankara/akyurt/demografi</u>,

https://www.endeksa.com/tr/analiz/ankara/pursaklar/demografi, https://www.endeksa.com/tr/analiz/ankara/cubuk/demografi on 19 December 2022. Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

¹⁸⁰ Accessed from <u>https://www.endeksa.com/tr/analiz/ankara/akyurt/demografi</u>,

https://www.endeksa.com/tr/analiz/ankara/pursaklar/demografi, https://www.endeksa.com/tr/analiz/ankara/cubuk/demografi on 19 December 2022. Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

- **Balıkhisar:** The average household income in Balıkhisar is stated as 6,725 TRY of which 10.6% is spent on rent and housing expenses, 8.6% on transportation expenses and 7.7% on food and non-alcoholic beverages. The number of residents located in the neighbourhood is 652.
- **Saracalar:** In this neighbourhood, the average household income is calculated as 6,449 TRY. Similar to Balikhisar, 10.7% of the household income is spent on rent and housing expenses, 9.3% on transportation and 8.2% on food and non-alcoholic beverages. The number of residents in Saracalar is 607.
- **Güzelhisar:** The average household income in Güzelhisar neighbourhood is 6,662 TRY. Based on the distribution of consumption expenditures, it is estimated that the average money spent on rent and housing expenses, transportation and food and non-alcoholic beverages constitutes 10.7%, 8.7% and 7.7% of the average household income respectively. There are 1,816 residences in Güzelhisar neighbourhood.
- **Saray Gümüşoluk:** There are 945 residences in Saray Gümüşoluk neighbourhood, where the average household income is 7,103 TRY. Consumption expenditures of the residents are the same as in the previous neighbourhood mentioned above.
- Saray Cumhuriyet: The consumption trends of the residents demonstrate that people spend 11.3% of their household income on rent and housing expenses, while 9.2% on transportation and 8% on food and non-alcoholic beverages. The household income is calculated as 7,280 TRY in this neighbourhood where 5,876 residents are located.
- Altınova: The average household income of 7,040 TRY is mostly spent on rent, housing, and transportation expenses. Altınova neighbourhood has 1,566 residences.
- **Dumlupinar:** There are 655 residences in Dumlupinar neighbourhood, and the average household income is 6936 TRY which is mostly spent on rent, housing and transportation expenses.
- **Yenice:** The average household income in Yenice neighbourhood is 6,707 TRY. The distribution of consumption expenditures shows that the average money spent on rent and housing expenses, transportation and food and non-alcoholic beverages constitutes 10.3%, 8.4% and 7.4% of the average household income respectively. There are 854 residences located in this neighbourhood.

11.2.5 Employment and Livelihood

There are no official statistics available on employment status, labour force participation and unemployment rates, work branches and livelihoods of the residents neither on a district nor on a neighbourhood basis. Therefore, data provided in this section is based on the analysis of mukhtar interviews and household surveys.

Based on the mukhtar interviews, there are a total of 757 small and medium-sized businesses throughout the neighbourhoods affected by the Project. 66.1% of these businesses are located in Saracalar neighbourhood while the lowest number are registered in the Saray Gümüşoluk neighbourhood of the Pursaklar district with a rate of 0.67%. The disproportionately high number of workplaces in Saracalar is due to Otonomi (which has around 700 independent enterprises) located in this neighbourhood. Otonomi area is concentrated with workplaces, auto-galleries and hotels which are followed by factories (please see Table 11-11 for detailed information).

Table 11-11: Distribution of businesses in within the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

			Lines of businesses in neighborhoods									
No	District	Neighborhood	Market	Restaurant	Coffee shop	Small shops	Factories	Workplace hotel and auto gallery	Total			
1	Akyurt	Balıkhisar	2	2	-	1	150	2	157			

			Lines of businesses in neighborhoods								
No	District	Neighborhood	Market Restaurant Coffee Small rhood shop shops		Factories	Workplace, hotel and auto gallery	, Total				
2	Akyurt	Saracalar	2	2	-	2	-	500 ¹⁸¹	506		
3	Akyurt	Güzelhisar	2	2	1	1	2	-	8		
4	Pursaklar	Saray Gümüşoluk	1	-	-	-	-	4	5		
5	Pursaklar	Altınova	3	3	1	3	-	2	12		
6	Pursaklar	Saray Cumhuriyet	20	10	3	20	-	-	53		
7	Çubuk	Dumlupınar	3	1	1	2	-	1	8		
8	Çubuk	Yenice	3	2	-	-	-	3	8		
		Total	36	22	6	29	152	512	757		
		Percentage	5%	3%	1%	4%	20%	68%	100%		

Based on the results of the mukhtar interviews, there are 245 unemployed persons in the eight neighbourhoods. However, none were encountered in four neighbourhoods during the household surveys. One third of the respondents are retired. Of active population, one third of responds are workers, or small business owners, followed by farmers, as described in Table 11-12 below.

Table 11-12: Distribution of working status of residents surveyed within the Project affected neighbourhoods (based on the findings of the household socio-economic surveys in June 2022)

No	District	Neighborhood	Farmer	Retired	Small business	Officer	Worker	Housewife	Other	Total
1	Akyurt	Balıkhisar	4	20	7	-	3	4	1	39
2	Akyurt	Saracalar	1	13	6	2	11	-	-	33
3	Pursaklar	Altınova	-	3	-	6	4	-	1	14
4	Pursaklar	Saray Gümüşoluk	9	10	11	2	9	2	1	44
		Total	14	46	24	10	27	6	3	130 ¹⁸²
		Percentage	10.8	35.3	18.5	7.7	20.8	4.6	2.3	100

Concerning the 245 unemployed persons identified during the mukhtar interviews conducted in June 2022, there is a high expectation of the mukhtars and the respondents of household surveys regarding the employment opportunities that the Project may create, especially during the construction phase. On the other hand, local employment opportunities may be limited in the operation phase of the Project since the mukhtars reported that the unemployed persons are mostly unskilled, semi-skilled or have irrelevant skills when the Project's labour needs are considered. The Project has a competent human resource need for its operation phase in certain services as described in *Chapter 16: Labour and Working Conditions*.

11.2.6 Vulnerable Groups

The World Bank directive on Addressing Risks and Impacts on Disadvantaged or Vulnerable Individuals or Groups published in March 2021¹⁸³ defines disadvantaged or vulnerable groups as those "who, by virtue of, for example, their age, gender, race, ethnicity, religion, physical, mental or other disability, social, civic or health status, sexual orientation, gender identity, economic disadvantages or indigenous status, and/or dependence on unique natural resources, may be more likely to be adversely affected by

¹⁸² Even though 109 household surveys were conducted, some heads of the households are both retired and still working, therefore, 21 of them selected an occupation together with the "retired" choice.

¹⁸¹ Data based on mukhtars' statement

¹⁸³ Accessed from https://ppfdocuments.azureedge.net/9598117e-421d-406f-b065-d3dfc89c2d78.pdf on 23 January 2023.

the project impacts and/or more limited than others in their ability to take advantage of a project's benefits". Accordingly, the vulnerable groups relevant to the Project are identified as women, poor, elderly and persons with disabilities. Brief information on these groups is provided below:

- Women: Results of the mukhtar interviews revealed that there are 126 female household heads living in the eight neighbourhoods within the study area (Table 11-13). Of those, household surveys were conducted with seven women living in Balıkhisar, Saracalar, Altınova and Saray Gümüşoluk. Two of the surveyed women have multiple vulnerabilities (ages over 65 and having chronical diseases). Of those seven women, five are widow, one is a divorcee and the other one is single. Data on their educational status show that three women are illiterate, three women are primary school graduates and one woman holds a bachelor's degree. One is a tenant while the remaining ones are homeowners.
- Elderly: According to the data provided by the Akyurt and Pursaklar Social Assistance and Solidarity Foundation, there are a total of 37 elderly persons receiving aid from the government in Balıkhisar, Saracalar, Güzelhisar, Altınova, Saray Cumhuriyet and Saray Gümüşoluk (see Table 11-15). During the socioeconomic studies, ten elderly people who identified themselves as heads of household were surveyed (Table 11-14). The age distribution of these participants, all of whom were men, ranged from 66 to 87. One is illiterate, three are secondary school graduates while the rest is primary school graduates. All are homeowners.
- **Persons with disabilities:** According to the Disability and Aging Statistical Bulletin of February 2022¹⁸⁴, the ratio of persons with disabilities to the total population of Ankara province is 3.2%. However, there is no official statistical data available regarding persons with disabilities on a district basis. Mukhtars of the eight Project affected neighbourhoods reported that there are a total of 21 persons with disabilities. However, this information does not seem accurate considering that official data on the number of persons receiving disability pension in Balıkhisar, Saracalar, Güzelhisar, Altınova, Saray Cumhuriyet and Saray Gümüşoluk is reported as 90 by the Akyurt and Pursaklar Social Assistance and Solidarity Foundation. Moreover, three persons with disabilities introduced themselves as heads of their households during the household surveys. Their age was reported as 50, 74 and 92. Two of them were married while the other was a widow. One is literate, the others are primary school and secondary school graduates respectively.
- **Poor:** There is no official data published on the number of poor people or households. However, the mukhtars of the eight neighbourhoods stated that there are 206 households who can be considered as very poor and destitute (see Table 11-13).
- Syrians under Temporary Protection (SuTP): As of January 2023, there are 96,100 SuTP in Ankara¹⁸⁵. District based Syrian population data are not publicly available. However, according to the national news report, there were 619 SuTP in Akyurt district in February 2022, which constituted less than 1% of total Syrian population in Ankara province at that time¹⁸⁶. As reported by the district governor, the mayor and the mukhtars in June 2022, there were no SuTP living in Balıkhisar and Saracalar neighbourhoods.
- Agricultural land users: It was observed during the site visits that there are agricultural areas in close proximity to the Project site. The lands used for agricultural purposes are across the Çubuk Stream and there are no agricultural lands near the Project site. Two formal renters and users of these agricultural lands were consulted in June 2022 as a part of the stakeholder engagement. On the basis of the information provided by the renters and users, no vulnerable groups were identified amongst the agricultural land users utilizing the agricultural areas in close proximity to the Project site.

¹⁸⁴ Ministry of Family and Social Services, General Directorate of Disabled and Elderly Services, 2022 (<u>https://www.aile.gov.tr/eyhgm/sayfalar/istatistikler/engelli-ve-yasli-istatistikl-bulteni/</u>)

¹⁸⁵ Accessed from <u>https://www.goc.gov.tr/gecici-koruma5638</u> on 23 January 2023.

¹⁸⁶ Accessed from <u>https://www.hurriyet.com.tr/yazarlar/dogahan-giritlioglu/pilot-ilceden-588-suriye-aile-tasindi-42009564</u> on 23 January 2023.

Table 11-13: Distribution of the vulnerable groups within the Project affected neighbourhoods	
(based on the findings of the mukhtar interviews in June 2022)	

			Vulnerable Groups							
No	District	Neighborhood	Very poor and destitute family Persons w disabilities		Female Head of Household	Those receiving support from Social Assistance and Solidarity Foundation				
1	Akyurt	Balıkhisar	5	2	1	20				
2	Akyurt	Saracalar	-	6	4	50				
3	Akyurt	Güzelhisar	2	5	40	40				
4	Pursaklar	Saray Gümüşoluk	15	1	10	15				
5	Pursaklar	Altınova	30	2	15	70				
6	Pursaklar	Saray Cumhuriyet	150	-	50	150				
7	Çubuk	Dumlupınar	4	2	5	15				
8	Çubuk	Yenice	0	3	1	60				
		Total	206	21	126	420				

Table 11-14: Vulnerable groups surveyed within the Project affected neighbourhoods (based	on
the findings of the household socioeconomic surveys in June 2022)	

No	District	Neighborhood	Female Headed Household	Disabled Headed Household	Elderly Headed Household	Other	Total
1	Akyurt	Balıkhisar	2	1	5	-	7
2	Akyurt	Saracalar	1	-	3	2	6
3	Pursaklar	Altınova	1	-	-	-	1
4	Pursaklar	Saray Gümüşoluk	2	2	2	-	6
		Total	6	3	10	2	21

Table 11-15: Data provided by Al	yurt and Pursaklar Social Assistance and Solidarity	Foundation
----------------------------------	---	------------

No	District	Neighborhood	Number of persons receiving elderly pension	Number of persons receiving widow's pension	Number of persons receiving disability pension	Number of those receiving a pension for relatives of persons with disability
1	Akyurt	Balıkhisar	3	-	3	-
2	Akyurt	Saracalar	9	-	5	-
3	Akyurt	Güzelhisar	1	-	6	-
4	Pursaklar	Altınova	3	2	15	1
5	Pursaklar	Saray Gümüşoluk	2	1	1	-
6	Pursaklar	Saray Cumhuriyet	19	3	60	5
		Total	37	6	90	6

11.2.7 Education

Ankara provides broad opportunities in terms of educational attainment. In this context, the education level of the population is higher in comparison to most provinces in Turkiye. Out of approximately 4.4 million people that are older than 15-year-old and residing in Ankara, 1.66 million have completed primary education, 1.25 million have completed high school, 1.27 million have completed university or other higher educational institutions (including those who earned a master's or doctorate degree). The rest

includes people who are illiterate, who are literate but do not have a diploma, and who did not share information about their educational level¹⁸⁷.

Based on the data provided by the TurkStat, the distribution of education level of the population aged 25 and over living in Akyurt, Pursaklar and Çubuk districts is given Table 11-16. Accordingly, there are a total of 4036 illiterate people living in these three districts. The total number of primary, secondary, high school and university graduates is 40,314, 25,094, 45,529 and 30,414 respectively. Those who earned a master's or doctorate degree, on the other hand, is reported as 3219 and 336. When the distribution of education levels is analysed, it is seen that primary school graduates are dominant in Akyurt with 15.7%, high school graduates in Pursaklar with 16.7% and primary school graduates with 17.3% in Çubuk.

No	District	Literate	Primary school graduates	Secondary school graduates	High schoolUniversity graduates graduates		Those holding a master's degree	Those holding a doctorate degree
1	Akyurt	597	6,090	3,568	5,678	3,177	267	16
2	Pursaklar	1,821	18,448	13,602	26,636	19,118	2,218	246
3	Çubuk	1,618	15,776	7,924	13,215	8,119	734	80
	Total	4,036	40,314	25,094	45,529	30,414	3,219	336

Table 11-16: Education levels on district basis¹⁸⁸

There are no official statistics on the educational status of residents on a neighbourhood basis. However, information was obtained from the mukhtars about the number of students in the neighbourhoods (see Table 11-17). According to this information, there are a total of 10,509 students attending schools with different education levels in eight neighbourhoods. 32% of them are high school students, 29% are primary school students, 29% are secondary school and 7% are university students. The rate of kindergarten students is 3%.

			Number of Students							
No	District	Neighborhood	Kindergarten	Primary School	Secondary School	High School	University	Total		
1	Akyurt	Balıkhisar	12	95	100	20	20	247		
2	Akyurt	Saracalar	7	60	30	30	20	147		
3	Akyurt	Güzelhisar	15	60	60	30	10	175		
4	Pursaklar	Saray Gümüşoluk	0	150	100	100	50	400		
5	Pursaklar	Altınova	150	500	500	1,100	100	2,350		
6	Pursaklar	Saray Cumhuriyet	100	2,000	2,000	2,000	500	6,600		
7	Çubuk	Dumlupınar	25	150	150	60	15	400		
8	Çubuk	Yenice	15	65	65	30	15	190		
		Total	324	3,080	3,005	3,370	730	10,509		

Table 11-17: Distribution of students by level of schools within the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

According to the analysis results regarding the education levels of the household heads, 36.7% of the household heads are primary school graduates, 23.9% are high school graduates and 22.9% are secondary school graduates (Table 11-18). The ratio of university and vocational school or higher

¹⁸⁷ TurkStat, Attained education level by provinces for the population 15 years of age and over, 2008-2020. Accessed from https://data.tuik.gov.tr/Kategori/GetKategori?p=egitim-kultur-spor-ve-turizm-105&dil=1 on 07 January 2022.

¹⁸⁸ TurkStat, 2022 (<u>https://data.tuik.gov.tr/</u>)

education graduates is 10.1% in total. While the rate of illiterate people is 4.6%, the rate of those who are literate but have not completed any school is 1.8%.

Table 11-18: Educationa	al status of the household heads surveyed within the Project affected
neighbourhoods (based	I on the findings of the household socioeconomic surveys in June 2022)

÷	Neighborhoo d		Educational Status									
District		Gender	Literate	Primary School	Secondar y School	High School	Vocational School of Higher Education	Universit	yllliterate	Total	%	
	Balıkhisar	Male	-	11	8	2	-	-	1	22	84.6	
Akyurt		Female	1	-	-	-	-	-	3	4	15.4	
		Total	1	11	8	2	-	-	4	26	100	
	Saracalar	Male	-	10	8	8	3	-	-	29	90.6	
		Female	-	1	2	-	-	-	-	3	9.4	
		Total	-	11	10	8	3	-	-	32	100	
	Altınova	Male	-	2	2	5	1	3	-	13	92.9	
F		Female	-	-	-	-	-	1	-	1	7.1	
akla		Total	-	2	2	5	1	4	-	14	100	
urs	-	Male	1	12	5	10	-	3	-	31	83.8	
Δ.	Saray Gümüsoluk	Female	-	4	-	1	-	-	1	6	16.2	
	Gamaçoran	Total	1	16	5	11	-	3	1	37	100	
		Male	1	35	23	25	4	6	1	95	87.2	
	Total	Female	1	5	2	1	-	1	4	14	12.8	
		Total	2	40	25	26	4	7	5	109	100	
		%	1.8	36.7	22.9	23.9	3.7	6.4	4.6	-	100	

11.2.8 Agriculture and Livestock Activities

Agriculture and livestock activities have great significance in provision of raw materials to the livestockbased industry as well as providing adequate and balanced nutrition for the growing population in Turkiye. In line with this significance, actions related to improvements in agricultural and livestock conditions and activities have been listed in Ministry of Agriculture and Forestry 2019-2023 Strategic Plan¹⁸⁹. In 2021, agricultural production amounts were approximately 61.7 million tons in cereals and other plant products, 31.8 million tons in vegetables, and 24.9 million tons in fruits, beverages and spice plants¹⁹⁰. Additionally, as of 2021, there are approximately 76 million cattle (i.e., cattle, buffalo and calf) and small ruminants (i.e., sheep and goat) in Turkiye¹⁹¹. Poultry farming, beekeeping and sericulture are among other livestock activities in Turkiye. As of 2022, around 2.2 million farmers are registered to the Farmer Registration System (FRS) of Ministry of Agriculture and Forestry¹⁹².

¹⁸⁹ Ministry of Agriculture and Forestry, 2019-2023 Strategic Plan. Accessed from <u>https://www.tarimorman.gov.tr/SGB/Belgeler/stratejikplan.pdf</u> on 29 June 2022.

¹⁹⁰ TurkStat, Plant Production Statistics, 2021. Accessed from <u>TÜİK Kurumsal (tuik.gov.tr)</u> on 22 July 2022.

¹⁹¹ TurkStat, Number of cattle and small ruminants in Turkey, 2021. Accessed from <u>https://biruni.tuik.gov.tr/medas/?locale=tr</u> on 29 June 2022.

¹⁹² The information is based on the data collected by Ministry of Agriculture and Forestry. Accessed from https://www.trthaber.com/haber/ekonomi/ciftci-sayisi-en-fazla-il-ordu-

^{680105.}html#:~:text=Tar%C4%B1m%20ve%20Orman%20Bakanl%C4%B1%C4%9F%C4%B1%20verilerinden,380%20ile% 20Ordu'da%20bulunuyor. on 22 July 2022.

The amount of agricultural lands in Ankara has decreased by around 10% due to industrial activities and urbanization since 2014¹⁹³. Yet, Ankara is still the second province that has the largest area of agricultural lands (11.64 million decares) following the Konya province¹⁹⁴. Additionally, Ankara has the highest number of cattle and small ruminants in Turkiye after Van and Konya, with total number of cattle and small ruminants of around 2.9 million as of 2021¹⁹⁵. As stated in the Guide for Agricultural Investments in Ankara¹⁹⁶, the existence of large pasture areas offers a convenient setting to the households in rural areas for small ruminants livestock activities. Even though there are also poultry farming and beekeeping activities in Ankara, relevant data are not available.

The main means of living in Akyurt district are agriculture, livestock and industry. The most recent data regarding agricultural activities in the district were obtained from the Akyurt Municipality and Akyurt Directorate of Agriculture and Forestry during the stakeholder engagement activities. Currently, total agricultural area in Akyurt is 19,574 hectares and only 525 hectares of the land are irrigated land. Majority of the lands are used for cereal production. Main agricultural plants produced in Akyurt district are barley, wheat, corn, bean, lentil, chickpea, forage crop and oat. There are 1059 farmers registered to the FRS of Ministry of Agriculture and Forestry in Akyurt district, of which 29 are registered in Balıkhisar, 21 registered in Güzelhisar and one registered in Saracalar. Further information regarding agricultural activities in selected neighbourhoods is provided in Table 11-19**Hata! Başvuru kaynağı bulunamadı.**.

Table 11-19: Information on agricultural activities in neighbourhoods in close proximity of the
Project site (based on the data obtained from Akyurt and Pursaklar District Directorates of
Agriculture and Forestry)

Neighborhood	District	Number of farmers registered in FRS	Total agricultural area registered to FRS (hectare)	Cereals (hectare)	Orchard (hectare)	Forage crops (hectare)	Irrigated Iand (hectare)
Balıkhisar	Akyurt	29	725	705	-	-	20
Saracalar	Akyurt	1	15	9	-	-	6
Güzelhisar	Akyurt	21	631	620	-	-	11
Altınova	Pursaklar	1	431	431	-	-	-
Saray Gümüşoluk	Pursaklar	42	553	553	72	29	-
Saray Cumhuriyet	Pursaklar	1	-	-	-	-	-

As of 2021, there were approximately 25,000 cattle and small ruminants in Akyurt district¹⁹⁷. During the interviews conducted with stakeholders, it was learned that there used to be large-scale cattle breeding farms having capacities ranging from 500 to 5000 in the Project area. However, in order to ensure odour safety in the vicinity of Esenboğa Airport, animal husbandry has been prohibited in certain regions with the decision of Ankara Metropolitan Municipality Council dated 09.08.2018 and numbered 1255. According to this restriction, new livestock facilities are not allowed to be established in the "No Livestock Zone", while the existing ones are limited to having a maximum of 5 cattle and 10 small ruminants. Data

https://www.aa.com.tr/tr/ekonomi/ciftci-sayisinda-ordu-tarim-arazisinde-konya-zirvede/2586828 on 22 July 2022.

https://www.tarimorman.gov.tr/SGB/TARYAT/Belgeler/il_yatirim_rehberleri/ankara.pdf on 29 June 2022.

¹⁹³ The Union of Agriculture and Forest Workers, Agricultural Sector Statistics, 2020. Accessed from <u>https://www.tocbirsen.org.tr/uploads/documents/2020</u> Rakamlarla_Tar%C4%B1m_Sekt%C3%B6r%C3%BC-min.pdf on 21 July 2022.

¹⁹⁴ The information is based on the data from Ministry of Agriculture and Forestry. Accessed from

¹⁹⁵ TurkStat, Number of cattle and small ruminants in Ankara, 2021. Accessed from <u>https://biruni.tuik.gov.tr/medas/?locale=tr</u> on 29 June 2022.

¹⁹⁶ Ministry of Agriculture and Forestry – Strategy Development Department Agricultural Investor Consulting Office, Guide for Agricultural Investments in Ankara, 2022. Accessed from

¹⁹⁷ TurkStat, Number of cattle and small ruminants in Ankara, 2021. Accessed from <u>https://biruni.tuik.gov.tr/medas/?locale=tr</u> on 29 June 2022.

for livestock activities in the Project affected neighbourhoods in Akyurt and Pursaklar districts were collected during the stakeholder engagement activities, as given in Table 11-20 below.

Table 11-20: Total number of cattle and small ruminants in neighbourhoods in close proximity of the Project site (based on the data obtained from Akyurt and Pursaklar District Directorates of Agriculture and Forestry)

Neighbourhood	District	The number of cattle	The number of small ruminants	Total number of cattle and small ruminants
Balıkhisar	Akyurt	56	386	442
Saracalar	Akyurt	27	0	27
Güzelhisar	Akyurt	1,105	346	1,451
Altınova	Pursaklar	49	0	49
Saray Gümüşoluk	Pursaklar	424	595	1,019
Saray Cumhuriyet	Pursaklar	75	0	75

Authorities stated that there has been a decrease in the number of farmers and registered agricultural lands as a result of high input costs and low profit of agricultural products. Furthermore, increasing land and housing prices due to expansion of industrial and commercial investments motivate the farmers who do not want to engage in agriculture anymore to sell their land as a lucrative way for income generation. According to the results of the mukhtar surveys, the total agricultural land distribution in the selected neighbourhoods in close proximity of the Project is given in Table 11-21.

Table 11-21: Distribution of total agricultural land within the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

No	District	Neighborhood	Cereals (decare)	Irrigated land (decare)	Total	Household's average agricultural land (decare)
1	Akyurt	Balıkhisar	8,000	0	8,000	200
2	Akyurt	Saracalar	0	0	0	0
3	Akyurt	Güzelhisar	4,000	0	4,000	150
4	Pursaklar	Saray Gümüşoluk	5,000	0	5,000	50
5	Pursaklar	Altınova	0	0	0	0
6	Pursaklar	Saray Cumhuriyet	0	0	0	0
7	Çubuk	Dumlupınar	2,000	1,000	3,000	50
8	Çubuk	Yenice	2,500	500	3,000	50
		Total	21,500	1,500	23,000	
		Percentage	93%	7%	100%	

As mentioned before, there are agricultural lands near the Project site. During the social site visits held in June 2022 within the scope of the stakeholder engagement activities, two users of these agricultural lands were interviewed. They stated that the agricultural lands near the Project area have many shareholders (around 72 different shareholders) and all lands are leased for agricultural activities. The farmers occasionally visit the lands from March to June and they visit the lands daily between June and October for cultivation. They utilize Çubuk Stream for irrigation. For the harvest process, they employ 6-8 seasonal workers coming from surrounding neighbourhoods. Labourers mostly cultivate barley, parsley, tomato and mint.

11.2.9 Gender Equality

Gender equality is a significant parameter that is influential on employment opportunities, educational attainment, poverty reduction and policymaking. According to the World Bank's Turkiye Country Gender Assessment 2017¹⁹⁸, Turkiye has two major barriers to maintain gender equality, which are lower levels of school enrolment of girls and less labour force participation among women. Providing vocational training for women to improve their skills and competencies can increase the rate of women in labour market. Moreover, enabling better childcare support can lead to better balance between work and family for women since women are traditionally expected to be responsible for taking care of children.

Similar to the report published by the World Bank, World Economic Forum (WEF) has been publishing Global Gender Gap Report annually for years, in which almost every country is included. The ranking criteria in the index are economic participation and opportunity, educational attainment, health and survival, and political empowerment. In the report of 2021, Turkiye has been ranked as 133rd in terms of gender equality among 156 countries¹⁹⁹. Global Gender Gap report shows that gender equality has decreased in Turkiye over 15 years, as shown in the Table 11-22 below.

Parameter	Rank in 2006	Rank in 2021
Economic participation and opportunity	106	140
Educational attainment	92	101
Health and survival	85	105
Political empowerment	96	114
Overall gender gap	105	133

Table 11-22: Comparison of gender equality in Turkiye based on WEF Global Gender Gap Index¹⁹⁹

In Turkiye, a gender equality report named Gender Equality Scores of 81 Provinces in Turkiye²⁰⁰ was published in 2020 with the joint work of the Union of Chambers and Commodity Exchanges of Turkiye (TOBB), Turkish Industrial Development Bank (TSKB) and Turkish Economic Policy Research Foundation (TEPAV). The report evaluates the gender equality by considering three main indexes: i) representation in politics and economics, ii) participation in production activities, and iii) education. Accordingly, Ankara is among the five provinces in Turkiye that have less gender gap in educational attainment. When general index values of the report are considered, Ankara is ranked as 16th province in gender equality and has higher rankings than Turkiye overall for all the indexes measured in the report. Details are provided in Table 11-23.

Index	Index value of Ankara	Index value of Turkiye
Representation in politics and economics	0.109	0.092
Participation in production activities	0.493	0.477
Education	0.913	0.843
Gender equality in general	0.505	0.471

¹⁹⁸ The World Bank, Turkey Country Gender Assessment 2017, January 2018. Accessed from <u>Turkey Country Gender</u> <u>Assessment 2018 | Country Gender Assessment (worldbank.org) on 19 July 2022.</u>

¹⁹⁹ World Economic Forum, Global Gender Gap Report, 2021. Accessed from

https://www3.weforum.org/docs/WEF_GGGR_2021.pdf on 29 June 2022.

²⁰⁰ Union of Chambers and Commodity Exchanges of Turkey (TOBB) - Turkish Industrial Development Bank (TSKB) -Turkish Economic Policy Research Foundation (TEPAV), Gender Equality Scores of 81 Provinces in Turkey, 2020. Accessed from

https://www.tepav.org.tr/upload/mce/2020/haberler/tobb tskb tepav 81 ilde turkiyenin toplumsal cinsiyet esitligi karnesi. pdf on 30 June 2022.

There is no published information to make interpretations regarding the gender equality status of Akyurt district. However, it was mentioned in the Activity Report of Akyurt Municipality (2021)²⁰¹ that the Workful Hands Agricultural Development Cooperation (Hamarat Eller Tarımsal Kalkınma Kooperatifi) has been established by Akyurt Municipality for women working in agricultural activities. Fair participation of women in the production activities, trainings, seminars and workshops were encouraged and supported by the municipality through the establishment of this association. The aim of the association is to provide opportunities for women both in economic and occupational development.

In neighbourhoods within the social study area, most of the daily activities and labour are distributed between males and females based on traditional gender-based division which may lead to gender inequality since inclusion of women in economic life and occupational development is limited. The main ideology in the traditional gender-based division of labour is that men in the household are the breadwinners that provide the household income while women are expected to carry out domestic activities.

Findings of the focus group interviews held with women within the scope of the stakeholder engagement activities in June 2022, that can be the indicators of lower levels of gender equality within the neighbourhoods around the Project site, are as follows:

- Majority of women are housewives while few work as cleaners or blue-collar workers in factories. They
 are usually responsible for domestic works such as cooking, cleaning, and taking care of children and
 the elderly within the family. Also, women grow vegetables and fruits in their own garden.
- They spend most of their time at home, the houses of their relatives or public places such as school gardens and parks. Usually, they do not leave the neighbourhood unless there are health problems that necessitate going to the hospital.
- Reportedly, one of the biggest problems for women in the selected neighbourhoods is limited availability of public transportation means that will allow them to go outside of the neighbourhood for bazaars, hospitals, shopping malls, etc. There are few minibuses and municipal buses operating between the centre and neighbourhoods.

11.2.10 Health Services

In Turkiye, universal health services are provided within the scope of the general health insurance system. Under this system, people who are registered to the Social Security Institution (SSI) can receive complementary medical treatment in the hospitals that have an agreement with SSI.

The MoH has taken some steps to reduce unequal access to health services and strengthen the health system since 2003. A program named "2003-2013 Health Transformation Program" has been implemented²⁰². In this period, Public Private Partnership (PPP) model was adopted to constitute a modern health infrastructure in Turkiye. Some of the actions taken as a part of the programme are listed below:

- Health-related investments (i.e., mobile health services and higher employment of health staff) were prioritised for the rural or less developed areas.
- Community Health Centres and Family Practice Centres were established in all provinces.
- Cancer early detection, screening and training centres were established in all provinces and the services are provided free of charge.

²⁰¹ Akyurt Municipality, Activity Report, 2021. Accessed from <u>https://www.akyurt.bel.tr/uploads/pages/faaliyet-raporlari/akyurt-belediyesi-2021-faaliyet-raporu.pdf</u> on 30 June 2022.

²⁰² Atasever, M. (2014). Türkiye sağlık hizmetlerinin finansmanı ve sağlık harcamalarının analizi 2002-2013 dönemi (Financing of health services in Turkey and analysis of health expenditures 2002-2013 period). Accessed from <u>https://sgb.saglik.gov.tr/Eklenti/34227/0/turkiye-saglik-hizmetlerinin-finansmani-ve-saglik-harcamalarinin-analizi-2002-2013donemipdf.pdf</u> on 30 June 2022.

- MoH Communication Centre (SABIM) was established in order to enable communication channels and for citizens, in which they can seek their rights and raise their requests or grievances.
- Extended Immunisation Program was initiated, and the vaccination program was made more comprehensive to involve additional vaccines such as rubella, mumps and meningitis.
- The quality of public hospitals was improved to provide better medical services in line with the demands.

In the following years, the MoH developed another program named "2023 Vision in Health" that would cover the period between 2013 and 2023. Similar to the Health Transformation Program, the aim is to constitute and sustain a health system that provides quality services for each citizen including vulnerable groups (i.e., the disabled, the poor, the elderly). During this period, the construction of city hospitals through the Public Private Partnership (PPP) model in which health facilities, research and development units, high technology centres, social living areas, health sciences universities and large recreation areas are located together has gained acceleration.

Another progress for improving health systems and services in Turkiye is the Health System Strengthening and Support Project (HSSSP), of which Component 4: Strengthening Capacity of MoH to respond to COVID-19 includes the proposed Project as described in the relative sections of this ESIA report. For some statistical studies, the provinces and regions of Turkiye are categorized as per the classification used by the European Union countries, which is called "Nomenclature of Territorial Units for Statistics (NUTS)". There are three NUTS levels in Turkiye, NUTS1 consists of 12 territorial units, NUTS2 consists of 26 sub-territorial units, and NUTS3 refers to the 81 provinces of Turkiye.

Ankara is amongst the TR5 – Western Anatolia Territorial Unit at NUTS1 level together with Konya and Karaman provinces. According to the Annual Health Statistics Newsletter of 2021²⁰³, there are a total of 135 hospitals in the TR5 territorial unit. 51 of these are private hospitals whereas 13 are the university hospitals. The remaining 71 hospitals in TR5 are the ones that are operated by the MoH.

As of 2020, the most recent available data for district-based statistics, there are a total of 83 hospitals (including both public and private hospitals) and 1,727 family health centres in Ankara²⁰⁴. Eleven of the public hospitals in Ankara are training and research hospitals²⁰⁵. Additionally, Ankara has one city hospital and one integrated health campus. Ankara City Hospital has been in operation and providing health services since 2019 whereas Etlik Integrated Health Campus has become operational in September 2022.

Akyurt district has one public hospital (Akyurt Public Hospital) which is located approximately 14 km to the northeast of the Project site. There are no private hospitals in Akyurt. However, Pursaklar and Çubuk which are neighbouring districts of Akyurt have four private hospitals and medical centres (Devapark Hospital, Dalmed Dialysis Centre, A Life Kuzey Ankara Hospital and Duru Medical Centre).

Based on the findings of the household surveys and mukhtar interviews in June 2022, Balıkhisar neighbourhood has one family health centre utilized by residents in Balıkhisar. Residents of Saracalar and Güzelhisar neighbourhoods also use this health centre since they do not have one in their own neighbourhood. Residents in Saray Gümüşoluk and Saray Cumhuriyet neighbourhoods use Saray Family Health Centre. Altınova neighbourhood has one family health centre. Similarly, Yenice neigbourhood has a family health centre which is commonly used by both residents from Dumlupınar and Yenice.

https://sbsgm.saglik.gov.tr/Eklenti/44131/0/saglik-istatistikleri-yilligi-2021-haber-bultenipdf.pdf on 23 January 2023.

²⁰³ Ministry of Health, Annual Health Statistics Newsletter of 2021. Accessed from

²⁰⁴ Ministry of Health, Annual Health Statistics, 2020. Accessed from <u>https://dosyasb.saglik.gov.tr/Eklenti/43399,siy2020-tur-</u> <u>26052022pdf.pdf?0</u> on 18 July 2022.

²⁰⁵ Ministry of Health - Ankara Provincial Health Directorate, Education and Research Hospitals List, 2021. Accessed from https://ankaraism.saglik.gov.tr/TR-69493/egitim-ve-arastirma-hastaneleri.html on 18 July 2022.

Findings of mukhtar interviews conducted in June 2022 show that residents in Saracalar, Güzelhisar, Saray Gümüşoluk and Saray Cumhuriyet visit Pursaklar Public Hospital other than family health centres. Individuals in Dumlupinar and Yenice prefer to use Çubuk Public Hospital in addition to family health centres. Akyurt Public Hospital is mostly preferred by residents in Güzelhisar whereas residents in Balıkhisar visit Ankara City Hospital. No epidemic history has been reported in neighbourhoods other than the COVID-19 pandemic.

Table 11-24: Data regarding the health services within the Project affected neighbourhoods
(based on the findings of the mukhtar interviews in June 2022)

			Health Services		
No	District	Neighborhood	Location of family health centre to be benefited	Location of the most frequently used hospital	Epidemic History (Except for COVID-19)
1	Akyurt	Balıkhisar	Balıkhisar	Ankara City	Not reported
2	Akyurt	Saracalar	Balıkhisar	Pursaklar	Not reported
3	Akyurt	Güzelhisar	Balıkhisar	Akyurt	Not reported
4	Pursaklar	Saray Gümüşoluk	Saray	Pursaklar	Not reported
5	Pursaklar	Altınova	Altınova	Pursaklar	Not reported
6	Pursaklar	Saray Cumhuriyet	Saray	Pursaklar	Not reported
7	Çubuk	Dumlupınar	Yenice	Çubuk	Not reported
8	Çubuk	Yenice	Yenice	Çubuk	Not reported

11.2.11 Vaccine Studies and R&D Laboratories in Turkiye

Vaccine production studies in Turkiye started during the Ottoman Empire period. In earlier years of the 18th century, the first vaccine was produced in Istanbul province in order to prevent the spread of smallpox. In the 19th century, a team involving a professor from the Mekteb-i Tibbiye-i Askeriye-i Şahane (the first medical school established) and two district governors had been assigned as assistants of Louis Pasteur, who was a pioneer scientist in infectious diseases such as rabies and vaccine studies. In January 1887, Daûl-Kelp and Bacteriology Operating Room (Rabies Treatment Institution) was established. This institution was the first rabies centre in the east and the third in the world. Later, diphtheria serum was also produced in this centre. In the following years, various centres and laboratories to conduct bacteriology research as well as vaccine production for smallpox, diphtheria and rinderpest diseases were established²⁰⁶.

After the establishment of the Republic of Turkiye, vaccine studies gained acceleration. Developments during this period are chronologically listed below:

- Tuberculosis vaccine production started in 1927. Production was centralized with the establishment of Institute of Public Health (Hıfzısıhha Enstitüsü) in 1928.
- Tetanus and diphtheria vaccines continued to be produced between 1931 and 1996.
- In 1937, rabies serum started to be produced. In 1940, cholera vaccines were delivered to China during the cholera epidemic. Production of typhus vaccine and scorpion serum started in 1942.
- In 1947, the Biological Control Laboratory was established.
- Until the end of 1940s, vaccines for typhoid, typhus, diphtheria, cholera, pertussis, tetanus, and rabies were mass-produced.

²⁰⁶ Ministry of Health, General Directorate of Public Health – Vaccine Portal, History of Vaccine in Turkey. Accessed from https://asi.saglik.gov.tr/genel-bilgiler/33-asinin-tarihcesi on 20 July 2022.

- Tetanus, gangrene, diphtheria, rabies and anthrax scorpion serums were produced in the serum farm established in 1968.
- Typhus vaccine production ended in 1971 and smallpox vaccine production in 1980 with the disappearance of these diseases in the country. Vaccine production in Turkiye was terminated with the discontinuation of rabies vaccine production in 1996 and tuberculosis vaccine production in 1997.
- Scorpion and diphtheria serum production still continues by the GDPH under the MoH.

Since the beginning of the first vaccine production and application in the Ottoman Empire, vaccine logistics, implementation and prevention of diseases have been carried out by the state free of charge. With the end of vaccine production, vaccines started to be purchased and procured. In the 2000s, interest in production of vaccines in Turkiye has increased again²⁰⁷.

As a consequence of Covid-19 pandemic, the need for domestic vaccine research and production for Covid-19 and other possible epidemic disease arose one more time. In line with this need, the Project was introduced and İt was decided by the MoH to establish a BSL3 laboratory suitable for vaccine production and animal experiments as an integrated part of the Project.

The MoH recognizes the significance of having BSL3 laboratories that consist high-technology equipment for medical research. In Turkiye, a number of BSL2 and BSL3 laboratories are established under the responsibilities of governmental authorities as well as several universities (such as Ankara University, Erciyes University and Koc University). TUBITAK (the Scientific and Technological Research Council of Turkiye) Marmara Research Centre Genetic Engineering and Biotechnology Institute also operates BSL3 laboratories. In addition to these, there are different biosafety level laboratories working on human and animal health established by private companies (such as Dollvet Biotechnology Inc., Vetal Animal Health Products Inc.). Most of the governmental laboratories in Turkiye are research-based laboratories, while the laboratories owned by private companies are also used for production purposes.

11.2.12 Governance and Community Organization

According to the results of the mukhtars surveys held within the ESIA scope in June 2022, there are four community associations established, three in Akyurt and one in Çubuk. The number of members of these associations varies between 35 and 200. The oldest one was established in 2004 and the newest one in 2014, all of them are actively operating.

No	District	Neighborhood	Name of the organization established	Туре	Objective	Number of members	Establish ment Year	Status
1	Akyurt	Balıkhisar	Balıkhisar Dayanışma ve Güzelleştirme Derneği	Association	Local solidarity among neighbourhoods	137	2010	Active
2	Akyurt	Saracalar	Saracalar Dayanışma ve Güzelleştirme Derneği	Association	Local solidarity among neighbourhoods	35	2005	Active
3	Akyurt	Güzelhisar	Güzelhisar Dayanışma ve Güzelleştirme Derneği	Association	Local solidarity among neighbourhoods	200	2014	Active

Table 11-25: Organizations within the Project affected neighbourhoods (based on the findings of the mukhtar interviews)

²⁰⁷ Ministry of Health, General Directorate of Public Health – Vaccine Portal, History of Vaccine in Turkey. Accessed from https://asi.saglik.gov.tr/genel-bilgiler/33-asinin-tarihcesi on 20 July 2022.

No	District	Neighborhood	Name of the organization established	Туре	Objective	Number of members	Establish ment Year	Status
4	Çubuk	Dumlupınar	Dumlupınar Dayanışma ve Güzelleştirme Derneği	Association	Local solidarity among neighbourhoods	170	2004	Active

11.2.13 Public Infrastructure

Mukhtar and household surveys presented questions about infrastructure and transportation services. The data obtained are analysed below. Considering the quality of infrastructure of the districts, it is seen that there are some differences on the basis of neighbourhoods.

- All infrastructural services in Balıkhisar, except the poor sewer system, were assessed as having medium quality.
- In Saracalar, the infrastructural quality was evaluated as good in general except for the sewage, roads and the internet connection which have medium quality.
- In Güzelhisar, infrastructure services were generally evaluated as good except for the roads with medium quality.
- The services in the Saray Gümüşoluk neighbourhood, apart from the poor signalling related to the mobile phones, were evaluated as good and sewage system as medium.
- All infrastructural services were assessed as good in Altınova and Saray Cumhuriyet neighbourhoods.
- In Dumlupinar neighbourhood, no problems were reported other than poor cell phone signals.
- On the other hand, there is an infrastructure problem in the Yenice neighbourhood as a result of the lack of natural gas infrastructure, poor quality of drinking and potable water and the medium level of other services. Only cell phone signals were found to have good quality.

Table 11-26: Infrastructure quality within the Project affected neighbourhoods (based on the findings of the mukhtar interviews and household surveys conducted in June 2022)

			Infrastruc	ture Quality	/				
No	District	Neighborhood	Sewage	Roads	Drinking- potable water	Electricity	Internet Na ga Medium Mu Medium Gu Good Gu Good Gu	Natural gas	Cell phone
1	Akyurt	Balıkhisar	Poor	Medium	Medium	Medium	Medium	Medium	Medium
2	Akyurt	Saracalar	Medium	Medium	Good	Good	Medium	Good	Good
3	Akyurt	Güzelhisar	Good	Medium	Good	Good	Good	Good	Good
4	Pursaklar	Saray Gümüşoluk	Medium	Good	Good	Good	Good	Good	Poor
5	Pursaklar	Altınova	Good	Good	Good	Good	Good	Good	Good
6	Pursaklar	Saray Cumhuriyet	Good	Good	Good	Good	Good	Good	Good
7	Çubuk	Dumlupınar	Good	Good	Good	Good	Good	Good	Poor
8	Çubuk	Yenice	Medium	Medium	Poor	Medium	Medium	N/A	Good

When the transportation preferences of the residents are analysed, it is seen that public transportation is the most preferred (Table 11-27). Residents usually use public bus and minibus as substitutes for each other. On the other hand, private vehicle use came first in Balıkhisar, Güzelhisar and Dumlupınar neighbourhoods.

Table 11-27: Most preferred means of transportation within the Project affected neighbourhoods
(based on the findings of the mukhtar interviews and household surveys conducted in June 2022)

No	District	Neighborhood	Most Preferred Means of Transportation			
			1	2	3	
1	Akyurt	Balıkhisar	Private vehicle	Shared taxi (dolmush)	Public bus	
2	Akyurt	Saracalar	Minibus	Public bus	Private vehicle	
3	Akyurt	Güzelhisar	Private vehicle	Public bus	-	
4	Pursaklar	Saray Gümüşoluk	Public bus	Private vehicle	-	
5	Pursaklar	Altınova	Public bus	Private vehicle	-	
6	Pursaklar	Saray Cumhuriyet	Minibus	Public bus	-	
7	Çubuk	Dumlupınar	Private vehicle	Public bus	Minibus	
8	Çubuk	Yenice	Public bus	Minibus	Private vehicle	

Finally, participants were asked what the most critical problem in their neighbourhood was. According to the responses received, common problems were identified as zoning status²⁰⁸, transportation and sewer system (Table 11-28)²⁰⁹.

Table 11-28: Most crucial problems within the Project affected neighbourhoods (based on the	è
findings of the mukhtar interviews and household surveys conducted in June 2022)	

No	District	Neighborhood	Most Crucial Problem			
	District		1	2	3	
1	Akyurt	Balıkhisar	Zoning status	Sewer system	Transportation (Public bus and frequency of trip)	
2	Akyurt	Saracalar	Zoning status	None	None	
3	Akyurt	Güzelhisar	Sewer system	Drinking water infrastructure	Transportation (Public bus and frequency of trip)	
4	Pursaklar	Saray Gümüşoluk	Cell phone infrastructure	None	None	
5	Pursaklar	Altınova	Inadequate social areas and facilities	None	None	
6	Pursaklar	Saray Cumhuriyet	Transportation (Public bus and frequency of trip)	None	None	
7	Çubuk	Dumlupınar	Cell phone infrastructure	None	None	
8	Çubuk	Yenice	Zoning status	Lack of natural gas infrastructure	Sewer system	

At the time of the site visit in June 2022, the participants interviewed and surveyed did not report any conflicts within the community or between the community and other parties deriving from the issues mentioned above.

²⁰⁸ For the settlements that are within the 5 km distance to the airport, there is a zoning restriction on the buildings. The zoning status problem refers to the restriction to construct high-rise buildings in these settlements.

²⁰⁹ These problems stated by the mukhtars and household members are not caused by the Project, but are general problems specific to the neighbourhoods.

11.3 Assessment of Impacts

11.3.1 Determining Magnitude, Sensitivity, and Impact Significance

Determining the significance of socioeconomic impacts is one of the main purposes of this assessment which enables the identification of necessary mitigation and benefit enhancement measures. A social impact can be either beneficial or adverse and is assessed by comparing the quality of the baseline conditions with the predicted quality of the social environment once the Project is in place.

In order to describe the significance of an impact it is important to distinguish between two concepts, magnitude (of impact) and sensitivity (of receptors). The sensitivity of receptors is related to their socioeconomic vulnerability, measured by their capacity to cope with social impacts that affect their access to or control over additional or alternative social resources of a similar nature, ultimately affecting their wellbeing. Sensitive or vulnerable receptors generally have less means to absorb adverse changes, or to replicate beneficial changes to their resource base than non-sensitive or non-vulnerable receptors. The guideline criteria used to categorise the sensitivity of receptors and the definition used to determine the magnitude of impacts are presented in Table 11-29 and Table 11-30, respectively.

Definition
A highly vulnerable receptor with very little capacity and means to absorb socioeconomic shocks and take advantage of opportunities.
A vulnerable receptor with some capacity and means to absorb socio-economic shocks and take advantage of opportunities.
A non-vulnerable receptor with limited capacity and means to absorb socio-economic shocks and take advantage of opportunities.
A non-vulnerable receptor with plentiful capacity and means to absorb socio-economic shocks and take advantage of opportunities.

Table 11-29: Criteria for Determining Sensitivity

Table 11-30: Criteria for Determining Magnitude

Magnitude (positive or negative)	Definition (considers duration of the impact, spatial extent and reversibility
Major	A probable impact that affects the wellbeing of groups of many people or business entities within a widespread area beyond the project life.
Moderate	A possible impact that will likely affect either the wellbeing of a group of people or business entities beyond the local area of influence into the wider area of influence or continue beyond the project life.
Minor	An impact that may affect the wellbeing of a small number of people and/or households or businesses, or occurs exceptionally, mostly within the project area of influence and does not extend beyond the life of the project.
Negligible	An impact that is localised to a specific location within the project's site boundary and is temporary or unlikely to occur with no detectable effect on the wellbeing of people or a business entity so that the socio- economic baseline remains consistent.

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 11-31.

Table 11-31: Impact Significant Matrix

	Sensitivity of Receptors			
Magnitude of Impact	Negligible	Low	Medium	High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

11.3.2 Impacts on Socio-economy

The Project's potential socioeconomic impacts during construction and operation are summarized in this section. The impact area was determined during the scoping phase of the Project, accordingly neighbourhoods within 5 km of the Project site are included in the Project's broader impact area, whereas neighbourhoods in direct vicinity of the Project are defined as Project's direct impact area. The key potential socioeconomic impacts identified can be summarized as follows:

- National benefits of contribution to national vaccine production and skilled workforce during operation
- Local benefits during construction and operation related to creation of employment opportunities
- · Benefits to the local economy through supply of goods and materials
- Potential negative impacts on surrounding receptors (i.e., agricultural lands, neighbouring business facilities) and vulnerable groups (especially women) during construction activities

Population and Demographics

The Project is located in an already urbanized setting with industrialized areas and business facilities. As interpreted during the mukhtar interviews conducted in June 2022, populations in the majority of the neighbourhoods do not change seasonally. Permanent residing is common in most of the neighbourhoods near the Project site. Considering both the demographic information of the household members within the Project affected neighbourhoods based on the findings of household socioeconomic surveys and potential impacts of the Project, no impact on the demographic structure of the neighbourhoods (i.e., household size, family type, gender distribution) is expected. However, the Project is expected to cause a minor labour influx which may impact population. Overall, it is considered that during the construction phase social receptors of the Project have medium sensitivity regarding the impact on population and demographics. The magnitude of this impact is minor, which corresponds to an impact with minor significance level.

During the operation phase, employment created by the Project is not expected to induce any additional labour pressure on the existing population size. With negligible sensitivity of the receptors regarding population and demographics, this impact has negligible magnitude with insignificant significance level.

Economy

During the construction phase, the Project components will require procurement sources for various goods and materials. This will have a positive impact especially on economic development of local and regional enterprises that could provide the required sources for the Project's construction activities. With medium sensitivity on economic conditions of the local and regional enterprises, this impact has moderate magnitude and moderate significance level.

During the operation of the Project, vaccine production will contribute not only to economic conditions in Akyurt district but also to overall Turkiye's economy. Social receptors' sensitivity on this impact which has major magnitude is high and the impact is considered as a critical positive impact.

Employment

Based on the results of the mukhtar interviews, there are a total of 245 unemployed people residing in the eight neighbourhoods considered to be affected from the Project. The neighbourhoods in the Project's impact area have local employment expectations for unskilled and semi-skilled job opportunities for the construction phase of the Project. The neighbourhoods can provide as many as 250 people as workforce to be utilized during construction (see Table 11-32 below). While employment creation is a positive impact, not utilizing local labour would be a negative impact and poses a risk. Therefore, the receptors' sensitivity in regard to local employment is assessed as medium whereas the magnitude of this impact is moderate with overall moderate adverse impact.

No	District	Neighbourhood	Local Employment Request			
	District		Male	Female	Total	
1	Akyurt	Balıkhisar	10	20	30	
2	Akyurt	Saracalar	25	25	50	
3	Akyurt	Güzelhisar	30	10	40	
4	Pursaklar	Saray Gümüşoluk	20	0	20	
5	Pursaklar	Altınova	10	10	20	
6	Pursaklar	Saray Cumhuriyet	20	0	20	
7	Çubuk	Dumlupınar	40	10	50	
8	Çubuk	Yenice	15	5	20	
		Total	170	80	250	

Table 11-32: Local employment for unskilled people requested by mukhtars of the Project affected neighbourhoods (based on the findings of the mukhtar interviews in June 2022)

Regarding the operation phase, there is no local employment expectation from the residents in the neighbourhoods affected from the Project. Therefore, this impact has negligible sensitivity and minor magnitude, with insignificant significance level.

On the other hand, the Project is estimated to create a number of employment opportunities in line with the specific human resource needs for the operation phase. Accordingly, the need for qualified staff to provide services within the certain aspects of the Project will positively contribute to the development of such skills and experience. The potential workforce within the national labour market has high sensitivity regarding the employment creation of the Project. This impact has major magnitude and is considered as a critical positive impact.

Livelihood

Construction related adverse impacts (especially dust creation) may lead to loss of income and loss of livelihoods for businesses and agricultural producers in the vicinity. Especially, the productions of some business facilities/factories throughout the neighbourhoods affected by the Project are sensitive to dust and particles, and they might be adversely impacted from the Project's construction works. Therefore, there is a high sensitivity of the social receptors on livelihood impacts. The magnitude of these impacts would be minor with moderate significance level.

There are no impacts foreseen during operation phase of the Project in terms of livelihood.

Education

There are no existing schools in the vicinity of the Project area, however, there is a national exam facility (ÖSYM) which holds exams over the weekends on designated days. Even though the facility is distant, it may be impacted from the noise deriving from the Project's construction activities. The social receptors within the national exam facility are considered to have medium sensitivity regarding the education impact, and this impact has minor magnitude, with minor significance level.

There are no impacts foreseen during operation phase of the Project in terms of education.

Agriculture and Livestock Activities

Akyurt district has limited livestock activities due to the restrictions regarding the decision of Ankara Metropolitan Municipality Council. Similarly, few households' main economic activity is agriculture based on the findings of the mukhtar interviews. Majority of the individuals within the affected neighbourhoods are working in private sector as blue-collar workers rather than agriculture or animal husbandry. Only one agricultural land is in the close proximity of the Project site, which is mostly used by the labourers coming from neighbourhoods in the north, who utilize Çubuk stream for irrigation during summer months. A flood protection wall is planned to be built by MoH along the section of the stream adjacent to the Project site within the scope of the Project. In case such construction works affect water availability, the livelihoods of agricultural land users could be adversely affected. The magnitude of this impact would be moderate and the sensitivity of the agricultural labourers regarding this impact would be high which correspond to major level of significance.

Other than the potential adverse impact on the agricultural land mentioned above, the Project is not expected to induce any pressure on agriculture and livestock activities during construction or operation, as it does not limit agriculture and livestock production, or acquire any land that may impact farming and grazing. Therefore, the sensitivity of the social receptors with regards to this impact is negligible. The magnitude of the impact is also negligible, with insignificant significance level.

Gender and Vulnerable Groups

The Project's identified vulnerable groups do not reside in close proximity to the Project site. Therefore, the Project's construction activities are not expected to lead to any adverse impact on vulnerable groups and hence they are considered to have medium sensitivity. The magnitude is negligible, with insignificant significance level. However, it is necessary to inform the workforce employed during the construction phase of the Project and the female workers working in the business facilities and factories around the Project site about the gender-sensitive approach. Accordingly, female workers and any female residing nearby the Project site should be aware of the grievance mechanism of the Project that they can report any incidents or their concerns regarding sexual exploitation and abuse (SEA) and sexual harassment (SEA/SH) if there are any.

During the operation phase, the Project needs to consider gender equality in employment, as well as the sensitivity towards the vulnerable groups defined within the scope of the Project. Additionally, the workforce employed for the operation phase of the Project and the female workers working in the business facilities and factories around the Project site will be informed about the grievance mechanism of the Project that they can report their concerns regarding sexual exploitation and abuse (SEA) and sexual harassment (SEA/SH)if there are any. Vulnerable groups have medium sensitivity while the magnitude of the impacts would be moderate, with moderate significance level.

Health Services

Findings of the mukhtar interviews concluded that residents in the Project affected neighbourhoods mostly utilize Ankara City Hospital, Akyurt Public Hospital, Pursaklar Public Hospital, Çubuk Public Hospital and/or family health centres within the neighbourhoods. None of these hospitals or family health centres are in the close proximity to the Project site. There are no adverse impacts on access of the PAPs to the health services and provision of health services during the construction phase. Therefore, with negligible sensitivity on the PAPs, health services impact has negligible magnitude, with insignificant significance level.

During operation, the Project will be beneficial to health services by production of vaccines and improving the access to vaccine for all residents in Turkiye. Social receptors have high sensitivity regarding this impact, which has major magnitude. Overall, this improvement is concluded to be a critical positive impact.

Public Infrastructure

The Project is expected to impact road infrastructure due to acquisition of road crossing through the Project site boundaries continuing along the Otonomi. This road is used by people who would like to access Otonomi, nearby factories and agricultural producers in the vicinity. Also, the road is unofficially utilized for test drives by the enterprises and clients of Otonomi. These users of the road have medium sensitivity regarding this impact. A new access road is planned to be built by MoH outside the Project site boundaries running parallel to the Çubuk Stream and put into service before the closure of the existing access road to enable continued traffic flow around the Project site. Therefore, the magnitude of impacts will be minor. Eventually, the significance level of the impact is considered to be minor.

11.4 Mitigations and Enhancement Measures

11.4.1 Construction Phase

Regarding the potential impacts of the Project on socio-economy during the construction phase, the following mitigation and enhancement measures will be applied:

- Development of an Employment and Procurement Strategy to ensure maximization of opportunities for local people and businesses,
- Procurement of goods from local suppliers to the extent possible.

There is a high expectation by the PAPs for local employment generation during the construction phase of the Project. Accordingly, the below-mentioned mitigation and enhancement measures are proposed:

- Maximising local employment during construction and provide a fair and transparent recruitment process,
- Implementation of the grievance mechanism to receive, record, respond to grievances.

In order to mitigate the impacts related to livelihood conditions of the nearby business facilities and factories during the construction phase of the Project, the following will be ensured:

- Application of the good construction site practices,
- Application of the dust suppression methods to keep airborne dust at acceptable levels, such as water spraying at dust generating areas especially during dry weather conditions,
- Implementation of the grievance mechanism to receive, record, respond to grievances.

Regarding the impacts on agricultural labourers, the following mitigation measures will be applied during the construction phase of the Project:

- The construction activities will be timed such that the Project will not affect activities of the agricultural land users. Income and production losses, if any, of the users of the agricultural land will be compensated in compliance with the requirements of the World Bank's ESF,
- Households engaging in agricultural activities will be informed about the Project and Project-related activities before the construction,
- Implementation of the public grievance mechanism.

The impacts of the Project regarding public infrastructure are mostly related to the closure of the road between parcel 1555-4 and the recreational area. Considering this, the following mitigation and enhancement measures will be adopted:

- Implementation of the Traffic Management Plan,
- Ensuring that road health and safety measures are implemented and regularly monitored,
- Ensuring that road signs and diversions are in place,
- Implementation of the grievance mechanism to receive, record, respond to grievances.

352

There are potential impacts of the Project regarding gender and vulnerable groups during the construction phase. The relevant mitigation and enhancement measures to be applied are listed below:

- Development of a SEA/SH policy and procedure,
- Ensuring that SEA/SH policy is implemented during construction by contractors,
- Implementation of the grievance mechanism to receive, record, respond to grievances (including grievances on SEA/SH)

11.4.2 Operation Phase

The Project is estimated to create impacts on socio-economy during the operation phase. Therefore, the following mitigation and enhancement measures will continue to be implemented:

- Implementation of the priorly developed Employment and Procurement Strategy to ensure maximization of opportunities for people and local businesses in line with the operation phase activities,
- Proceeding to procure goods from local suppliers to the extent possible.

The closure of the road between parcel 1555-4 and the recreational area will have an impact on social receptors during both the construction and operation phases of the Project. Therefore, the same mitigation and enhancement measures will continue to be applied during the operation as listed below:

- Implementation of the priorly developed Traffic Management Plan,
- Ensuring that road health and safety measures are implemented and regularly monitored,
- Ensuring that road signs and diversions are in place,
- Implementation of the grievance mechanism to receive, record, respond to grievances.

During the operation phase of the Project, there is a possibility of vulnerable/disadvantaged groups/individuals to be impacted from the Project due to SEA/SH risks. In order to mitigate the risks and impacts, the following measures will be taken:

- Implementation of the priorly developed SEA/SH policy and procedure,
- Ensuring that SEA/SH policy is implemented during operation phase by all of the facility staff,
- Implementation of the grievance mechanism to receive, record, respond to grievances (including grievances on SEA/SH).

11.5 Compliance with National and International Requirements

11.5.1 National Requirements

The Project will comply with the applicable national legislation to the Project that are given in Table 11-33.

Table 11-33: Related National Legal Framework

Law/Regulation	Official Gazette (OG) date	OG number
Law on Protection of Family and Prevention of Violence against Women (6284)	20.03.2012	28239
Law on Right to Information (4982)	24.10.2003	25269
Law on Preservation of Personal Data (6698)	07.04.2016	29677
Regulation on the Principles and Procedures for Enforcement of the Law on the Right to Information	27.04.2004	25445
Law on Use of the Right to Petition (3071)	10.11.1984	18571
Law on People with Disabilities (5378)	07.07.2005	25868
Law on Education and Primary Education (222)	12.01.1961	10705

Law/Regulation	Official Gazette (OG) date	OG number
Law on Higher Education (2547)	06.11.1981	17506
Law on Agriculture (5488)	25.04.2006	26149
Law on the Protection of Farmers' Goods (4081)	10.07.1941	4856
Public Health Law (1593)	06.05.1930	1489

Details on the Legislation related to Socioeconomy

Socioeconomic characteristics cover several variables. The population movements, educational level, income distribution, main economic sources, livelihood activities, employment rates, vulnerability, and gender-related practices are evaluated as a part of the socioeconomic impact assessment carried out in the neighbourhoods that are in close proximity to the Project site. In this regard, mitigation and enhancement measures for the social impacts of the Project are defined by consideration of applicable national legislation as well as relevant international standards.

Turkish legislation has some laws and regulations that are applicable to the socioeconomic variables assessed throughout the ESIA studies of the Project, which are listed in detail below.

Vulnerable groups:

Law on Protection of Family and Prevention of Violence against Women No. 6284 regulates the procedures and principles regarding the measures to be taken in order to protect women, children and family members who have been subjected to violence or who are at risk of violence, and to prevent violence against these people.

Law on People with Disabilities No. 5378 aims at ensuring the disabled people benefit from their fundamental rights and freedoms through full and effective participation in social life on an equal basis with other individuals. The Law commits to preventing the discrimination based on disability.

There are potential impacts of the Project regarding vulnerable groups during both construction and operation phases. The relevant mitigation measures that will be applied to prevent the risks and impacts are listed in Section 11.4.

Education:

Law on Education and Primary Education No. 222 and Law on Higher Education No. 2547 regulate the basic education and training procedures and principles that need to be applied by all national educational institutions in Turkiye. As per the outcomes of the ESIA studies, the Project is not anticipated to create any impact on the educational services provided in the neighbourhoods that are in close proximity to the Project site.

Agriculture and livestock:

Law on Agriculture No.5488 determines the necessary policies to be implemented in the agricultural sector. The Law also makes arrangements for the development and support of the sector as well as the rural areas in line with national development plans and strategies.

Law on the Protection of Farmers' Goods No. 4081 defines the farmers' goods to be protected. One of the goods that are under protection is stated as the movable and immovable goods used in or related to agriculture.

As stated earlier, the agricultural labourers using the agricultural lands near the Project site, Since they utilize Çubuk Stream for irrigation, they might be adversely impacted from the rehabilitation works of the stream bed. In this regard, a number of mitigation measures that will be applied during the construction phase of the Project are defined in in Section 11.4.

Health services:

Public Health Law No. 1593 regulates all health-related issues that are under the responsibility of the public state services. These issues involve improving the sanitary conditions of the country, combating all diseases or other harmful factors that negatively affect the health of the nation, ensuring the healthy growth of the future generations and verifying the people have access to medical and social assistance.

The main objectives of the Project include enhancing the national vaccine research and development capacity, strengthening the capacity to combat pandemics/epidemics risks at national or international level, and improving the infrastructure in Turkiye for experimental animal production to support vaccine-related studies. The Project will contribute to the communities in terms of providing improved health services related to vaccines to prevent/combat diseases, pandemics and epidemics, which are regulated under this Law.

11.5.2 International Requirements

The socio-economic studies of the ESIA process have been undertaken to promote the Project's compliance with the Environmental and Social Standards (ESSs) of the World Bank's Environmental and Social Framework (ESF) which became effective in October 2018. Accordingly, the detailed socioeconomic baseline information of the PAPs (including affected households and vulnerable groups identified within the scope of the Project) has been collected within the scope of the ESIA and analysed in line with the World Bank ESSs.

In particular, the following World Bank ESSs have been considered in the assessment and will be complied with throughout the lifetime of the Project:

- ESS2: Labour and Working Conditions: Applicable for addressing the socio-economy impacts in respect of the following:
 - Local and national employment generation as a part of the Project,
 - Economic growth at local, regional and national levels as a result of the Project,
 - Labour and working conditions of all Project workers (including Project Implementation Unit members, contracted workers and primary suppliers),
 - Protection of the Project workers and the workers in the Project affected business facilities and factories by considering their health and safety as well as SEA/SH-related issues.
- ESS4: Community Health and Safety: ESS4 is also applicable by considering the Project activities, the Project's impacts on the infrastructure and the Project-related traffic and road safety risks that communities might be exposed to.
- ESS10: Stakeholder Engagement and Information Disclosure: It is necessary to consult and engage with PAPs and vulnerable groups identified within the scope of the Project.

11.6 Residual Impacts

Residual impacts are the impacts that remain even after the proposed mitigation measures have been implemented. For the impacts identified during the socioeconomic impact assessment of the Project, it is expected that residual adverse impacts will remain at insignificant level as long as the mitigation measures that are described above are fully implemented throughout the lifetime of the Project. Benefits would include increased research and workforce capacity as well as public health preparedness.

11.7 Proposed Monitoring and Reporting

It is necessary to implement a monitoring system throughout the Project for the impacts identified during the socioeconomic impact assessment. The monitoring system will determine the effectiveness of mitigation measures which are defined above. When the potential impacts of the Project are considered,

it is necessary to consult and engage with the social receptors and PAPs during both the construction and operation phases of the Project. The following monitoring and reporting activities will be regularly applied:

- Monthly and annual reporting on monitoring and compliance
- Implementation of Community Health and Safety Management Plan including regular monitoring and reporting as per the Plan
- Implementation of Traffic Management Plan including regular monitoring and reporting as per the Plan
- Development and implementation of the Employment and Procurement Strategy as well as associated monitoring and reporting
- Collection of data on local employment (local referring to Project Affected Neighbourhoods)
- The records of the community grievances received and responded
- Reporting related to the stakeholder consultation meetings held

12 LAND USE AND ZONING

12.1 Introduction

This chapter identifies the predicted impacts of the proposed Project design on the land use and assesses their significance. The approach adopted for the assessment is as follows:

- Examination of existing regional and local zoning plans that cover the Project site,
- Evaluation of existing land uses within and around the Project site by conducting site visits and reviewing aerial photographs and satellite images, and
- Assessment of potential impacts of the proposed Project related to land use and zoning.

The land use patterns in and in the surroundings of the Project site and the available regional and local zoning plans that cover the Project site are discussed in Section 12.3.

No land acquisition or restriction on the land use is expected by the MoH regarding the Project. Moreover, no economic and/or physical displacement is anticipated due to the direct impacts of the Project.

12.1.1 Study Area and Area of Influence

The study area is determined in line with the approach set out in Section 4.6.2. Therefore, the study area primarily includes the parcels where the private lands and vacant lands around the Project site are located. These lands are mostly utilized for agricultural purposes and industrial activities. Please refer to Figure 12-4 for the land use patterns in the study area. The area of influence is not expected to extend beyond the physical boundary of the Project, since no additional land acquisition or restriction on the land use is foreseen by the MoH for the Project or its components.

12.1.2 Data Limitations

The land use and zoning assessment presented in this chapter is based on both publicly available sources and the draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans prepared by the consultancy company contracted by the MoH²¹⁰ and associated documentation to be submitted to the MoEUCC, as referred to in relevant sections. However, it should be noted that the above-mentioned zoning plans were in the draft during the ESIA process of the Project. As of February 2023, the land allocation process was still ongoing, The zoning plans will be finalized after a 30-day suspension period prior to the Phase II construction activities of the Project. Note that the ongoing Phase I construction activities are in compliance with the existing zoning plans.

12.2 National and International Requirements

The Project will comply with the relevant national legislation governing land use planning and zoning matters. The key national laws and regulations that are applicable to proposed developments and that have been considered in this assessment are provided below in Table 12-1.

Law/Regulation	Official Gazette (OG) date	OG number
Law on Expropriation (2942)	08.11.1983	18215
Public Finance Management and Control Law (5018)	24.12.2003	25326
Zoning Law (3194)	09.05.1985	18749

Table 12-1: Key National Legislation Related to Land Use

²¹⁰ Draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans prepared for Ankara Akyurt Balıkhisar neighbourhood parcel 1555-4 and its surroundings by Özok Planlama İmar Mühendislik Ltd. Şti. (2022)

Law/Regulation	Official Gazette (OG) date	OG number
Law on Soil Protection and Land Use (5403)	19.07.2005	25880
Spatial Plans Development Regulation	14.06.2014	29030
Planned Areas Zoning Regulation	03.07.2017	30113

When any land acquisition or expropriation is required, Law on Expropriation No. 2942 is applied within the scope of the national legislation. The Law defines certain principles and procedures to be followed during compensation of assets or properties that will be expropriated. Additionally, the people affected from the expropriation need to be consulted on compensation value in line with this Law. The scope of the Law does not include informal land users or squatters, only compensations for legal titles are covered within the Law. However, since the ownership of the two parcels that the Project will be constructed on belongs to the MoH, this Law is not required to be applied. The MoH confirmed that the Project will not make any additional land acquisition or expropriation. The Project will not have negative impacts on livelihoods resulting from land acquisition. Additionally, there is no informal user on the Project land and it belongs to the MoH.

As per the World Bank's Environmental and Social Framework (ESF) ESS5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement, project-related land acquisition and restrictions on land use can have adverse impacts on communities and persons such as involuntary resettlement, physical and/or economic displacement. In accordance with ESS5, projects should implement a Resettlement Plan (RP) in the event of physical displacement and economic displacement defined as loss of income or livelihood due to land acquisition or obstructed access to resources (land/water) caused by the project or associated facilities. In addition, the RP prepared for physical displacement should have a Livelihood Restoration Plan (LRP). Depending on the scale and impact of the economic displacement, the RP should also have an LRP. Field studies and investigations pointed out that ESS5 is out of scope of the Project.

ESS5 does not apply to impacts on incomes or livelihoods that are not a direct result of land acquisition or land use restrictions imposed by a project. The non-land based impacts on incomes or livelihoods are covered under ESS1 together with other social risks and impacts of the Project (i.e. disproportionate impacts on vulnerable and disadvantaged groups, prejudice or discrimination toward individuals or groups in providing access to development resources and project benefits, and negative economic and social impacts associated with land and natural resource tenure, food security and land values).

In addition to the World Bank ESF, the following guidelines of the World Bank have been utilized during the assessment:

• World Bank Guidance Note for Borrowers: ESS5: Land Acquisition Restrictions on Land Use and Involuntary Resettlement (2018)

12.3 Baseline Description

12.3.1 Overview

In this section, the land use patterns in and in the surroundings of the Project site (through the outcomes of the site visits undertaken within the scope of the ESIA study and reviewing both aerial photographs and satellite images) are described. Available regional and local zoning plans that cover the Project site are also discussed.

The following information sources have been utilized during the assessment:

• Google Earth Satellite Images,

- 1/100,000 scaled Environmental Plan of Ankara Province for 2038 with approval date/registration number: 13.01.2017/116²¹¹,
- The cancellation decision of Ankara 9th Administrative Court dated 28.09.2020 and numbered E:2018/551, K.2020/1610 for 1/100,000 scaled Environmental Plan of Ankara Province for 2038²¹²,
- Draft 1/1000, 1/5000 and 1/25,000 scaled zoning plan amendments and associated documents²¹³,
 - 1/1000 Implementation Zoning Plan Amendment for Ankara Akyurt Balıkhisar neighbourhood parcel 1555-4 and its surroundings,
 - 1/5000 Zoning Plan Amendment for Ankara Akyurt Balıkhisar neighbourhood parcel 1555-4 and its surroundings,
 - 1/25,000 Zoning Plan Amendment for Ankara Akyurt Balıkhisar neighbourhood parcel 1555-4 and its surroundings,
 - Plan Notes for 1/1000, 1/5000 and 1/25,000 scaled zoning plans,
 - Zoning Plan Amendment Explanation Report of Ankara Akyurt Balikhisar neighbourhood parcel 1555-4 and its surroundings,
- Ankara Metropolitan Municipality Başkent Ankara 1/25,000 Master Zoning Plan for 2023, Plan Report, 2006, Approval date: 6.02.2007²¹⁴,
- Parcel Based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkiye Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti., 2021, and
- The Turkish Republic Akyurt District Governorship Directorate of Food, Agriculture and Livestock, 2017, Briefing Report of Activities in 2017 (For January-December Period)²¹⁵.

12.3.2 Project Site Location and Features

The province of Ankara covers an area of 26,897 km² and lies between latitude 39°57' N and longitude 32°53' E. Ankara is located at an altitude of approximately 890 m above sea level²¹⁶. The province has seven neighbours: Çankırı in the northeast, Bolu in the northwest, Konya in the south, Kırşehir and Aksaray in the southeast, Kırıkkale in the east, and Eskişehir in the west. Ankara province comprises of 25 districts and one of them is Akyurt district in which the Project site is located.

Figure 12-1 below demonstrates the geographical position of the Akyurt district. Akyurt consists of 26 neighbourhoods including six central neighbourhoods and 20 villages. The Project site is located in Balıkhisar neighbourhood (neighbourhood centre located approximately 3 km to the northeast of the site) of Akyurt district to the northeast of Ankara. The closest neighbourhoods are Saracalar (approximately 1 km to the south), Saray Gümüşoluk (approximately 3 km to the west) and Altınova (approximately 2 km to the south). Neighbourhoods located between 3 and 5 km radius of the Project site are Güzelhisar, Saray Cumhuriyet, Dumlupınar and Yenice.

²¹¹ Accessed from <u>https://www.ankara.bel.tr/files/5915/2766/6564/Pafta.pdf</u> on 27 July 2022.

²¹² Accessed from <u>https://www.ankara.bel.tr/files/2022/06/08/5326ccc5c3ea248646a89b51ae85134f.docx</u> on 27 July 2022.

²¹³ Draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans and associated documents prepared by Özok Planlama İmar Mühendislik Ltd. Şti. (2022).

²¹⁴ Accessed from <u>https://www.ankara.bel.tr/ankara-buyuksehir-belediyesi-nazim-plan</u> on 27 July 2022.

²¹⁵ The Turkish Republic Akyurt District Governorship Directorate of Food, Agriculture and Livestock, 2017, Briefing Report of Activities in 2017 (For January-December Period). Accessed from

https://ankara.tarimorman.gov.tr/Belgeler/Akyurt%20Brifing%202017.docx on 07 July 2022.

²¹⁶ Ankara, the Capital City of Turkish Republic where the cultures blended, Ankara Directorate of Culture and Tourism, 2013



Figure 12-1: Location of Ankara Province and Akyurt District (Prepared through ArcMap 10.8.1)

The Project site consists of two land plots with a total area of 79,331 m²: the main project complex area (i.e., parcel 1555-4) and the recreational area. According to the land registry records²¹⁷, the main Project complex area is planned to be built on parcel 1555-4 with the size of 47,589 m². There are two main roads in close proximity of the Project site, namely Ankara-Çubuk Highway and Özal Boulevard (approximately 150 m northeast and east of the Project boundary). Çubuk Stream flows along the northwest boundary of the Project site and the other side of the stream is within the boundaries of the Pursaklar district. The Project site is located 16 km south of Çubuk district, 11 km southwest of the centre of Akyurt district, and 8 km northwest of Pursaklar district²¹⁸. The distance of the Project site from Ankara city centre is approximately 20 kilometres. Ankara Esenboğa Airport is located approximately 3 kilometres to the northeast of the Project site are illustrated in Figure 12-2.

²¹⁷ Accessed from <u>https://parselsorgu.tkgm.gov.tr/</u> on 28 July 2022.

²¹⁸ The calculations reflect the approximate distances which are based on air-line distance measurements on Google Maps.


Figure 12-2: Project site and its parcel division (Prepared through ArcMap 10.8.1)

Specific features of the Project site and the Project are given below^{219,220,221}:

- The Project site consists of the main project complex area and the proposed recreational area (shown in Figure 12-2). The main project complex (including mainly but not limited to experimental animal production/testing units, laboratory units and vaccine production units) will be built on the land registered as parcel 1555-4. The parcel is owned by the treasury and allocated to the MoH (please refer to Annex I for the title deed).
- Parcel 1555-4 has the status of registered land, while the lot where recreational area is planned to be developed is unregistered land. According to article 47 of the Public Finance Management and Control Law (No. 5018)²²², the Ministry of Environment, Urbanization and Climate Change (MoEUCC) has the authority to allocate immovables under the private ownership of the treasury to the rule and disposal of the state. As per the law, the area between parcel 1555-4 and Çubuk Stream which is designed as a recreational area for the Project will be assigned to the MoH. As of February 2023, the land allocation

²¹⁹ Zoning Plan Amendment Explanation Report of Ankara Akyurt Balıkhisar Neighbourhood parcel 1555-4 and its surrounding by Özok Planlama İmar Mühendislik Ltd. Şti. (2022)

²²⁰ Certificate of ownership, which was shared by MoH.

²²¹ Ankara Province, Akyurt District, Block 1555, Lot 4, Turkey Vaccine and Biotechnological Product Research & Production Centre Building 1st Stage Construction and Ground Survey Geotechnical Report, 2021.

²²² Official Gazette date/number: 24.12.2003/25326

process was still ongoing, The zoning plans will be finalized after a 30-day suspension period prior to the Phase II construction activities of the Project. Note that the ongoing Phase I construction activities are in compliance with the existing zoning plans.

- The adjacent lot to the Project site (i.e., parcel 1555-5) which has been allocated to the General Directorate of Public Health (GDPH) of MoH, is currently occupied by a Vaccine and Pharmaceuticals Storage Warehouse that includes cold storage rooms with temperatures of -80 to -20 degrees where vaccines are stored. The facility also operates a depot that is located on the Project site (i.e., on 1555-4) currently used for storage of vaccine equipment. This structure will be demolished, and the site will be cleared for the construction of the Project. On the other hand, all structures and storage areas within the parcel 1555-5 will continue to be operational.
- No infrastructure and/or upper structure is present in the lot where recreational area is planned to be developed.
- There is an existing road, crossing through the Project site boundaries from north to south (between parcel 1555-4 and the recreational area), that will be no longer operational once the Project is realized. A new access road (20 m wide) is planned to be built outside the Project site boundaries running parallel to the Çubuk Stream and put into service before the closure of the existing access road by MoH within the scope of the Project to enable continued traffic flow around the Project site.
- Çubuk Stream flows along the northwest boundary of the Project site. The distance between the stream and the nearest point of the main project complex (i.e., the Experimental Animals Production/Test Building) is approximately 92 meters. As observed during the site visit and field surveys conducted by the ESIA team, there is no surface water body within the Project site boundaries.
- It was observed during the site visit undertaken by the ESIA team during scoping phase of the ESIA
 process that excavation materials were temporarily deposited at several locations of the Project site.
 As reported by the representatives of the GDPH Vaccine and Pharmaceuticals Storage Warehouse, in
 the past, a horse farm was operated within the Project site to support serum production.
- There are a number of private lands (around 72 different shareholders) located to the west of the Çubuk Stream and all lands are leased for agricultural activities. Previously, it had been observed during the site visit undertaken by the ESIA team that some plastic fruit/vegetable racks have been temporarily piled up on the recreational area by the land users (those who undertake agricultural activities on the leased lands). During the interview conducted with two agricultural land users within the scope of the stakeholder engagement activities in June 2022, the agricultural land users reported that they relocated the racks themselves after having been informed by a Project team member. The land users stated that they did not receive any support from the Project team. As per the ESS5 requirements, such support should have been proposed to them and documented. Yet, they had adequate time for the relocation and they did not have difficulty during the relocation. No grievances were raised by the land users regarding this issue as well as the Project. Their only concern was related to the timeline of the rehabilitation works that will be carried out on the Çubuk Stream. They requested such rehabilitation works to be conducted in winter and noted that otherwise, their income would be affected negatively. In this regard, the timeline of the rehabilitation works will be closely followed by the MoH and the agricultural land users will be consulted on the issue in order to avoid any adverse impacts. During the interview in June 2022, the Project information document was distributed to the land users and they were also informed by the social experts of the ESIA team about the ways to access to the grievance channels to raise their grievances, concerns or requests.
- The boundaries of parcel 1555-4 have been fenced, which will be removed and reconstructed in accordance with the proposed design as described in *Chapter 2: Project Description*. Early site preparation works and excavation activities at the main project complex area were initiated at the time of drafting this ESIA report.
- Two dormitories are under construction for accommodation of approximately 50 workers on site during the construction phase of the Project (in parcel 1555-4).
- The elevation of the Project site ranges from 293 to 296 meters.

• The slope within the Project site is between 0-5%.

There are no settlers, informal users, squatters or users identified within the Project site. Moreover, the site is not used for any agricultural or commercial activities. The MoH and mukhtar of Balıkhisar also confirmed that there are no settlers, informal users, squatters or renters on the Project site. A number of photos of the Project site taken during the site visit in December 2021 are given below.



Photo 12-1: Photos from the Project site (Photos were taken in December 2021)

Currently, no additional land acquisition is foreseen by MoH for the Project or its components, and no economic and/or physical displacement is anticipated. The land allocated is in an urban setting, surrounded by factories and commercial enterprises as explained in Section 12.3.4 in detail. There are no residential properties in the immediate vicinity of the Project site. Therefore, land acquisition assessment and Resettlement Plan (RP) or Livelihood Restoration Plan (LRP) development are out of the ESIA scope of the Project.

12.3.3 Previous Land Use Patterns

The previous land use patterns of the Project site were reviewed using Google Earth satellite imageries between 2002 and 2021 (Figure 12-3). In 2002, the whole parcel 1555-4 and proposed recreational area were observed to be vacant land. As evident by Figure 12-3, the vicinity of the Project site has been developed between 2002 and 2018 by factories and commercial enterprises.



Figure 12-3: The previous land use patterns of the Project site (Project site boundary is indicated in blue line)

As the Google Earth satellite imageries between 2002 and 2014 are compared, a remarkable change is observed at the northeast of the Project site as to the progress of development of various factories and commercial enterprises (i.e. Otonomi, a road vehicles sales point that includes over 700 independent businesses, neighbouring the Project site to the south, YDS Factory, a safety shoe manufacturer, neighbouring the Project site to the northeast, İşbir Mattress Factory neighbouring the Project site to the north, and ÖSYM, the national exam centre). On the contrary, the west side of the Çubuk Stream has not changed in terms of land use (private lands used for agricultural purposes).

In 2014, the MoH GDPH Vaccine and Pharmaceuticals Storage Warehouse was built in the adjacent lot to the Project site (i.e. parcel 1555-5). As shown in Figure 12-3, the road crossing through the Project site boundaries (between parcel 1555-4 and the recreational area) was constructed in July 2015. The warehouse located on the Project site that is currently used for storage of vaccine equipment was constructed in 2018 near the south-eastern boundary of the parcel. As noted earlier, the parcel 1555-4 for a period of time was used as a horse farm to support serum production. Aerial views indicate that the undeveloped part of the parcel has been used for deposition of debris materials since 2014.

12.3.4 Surrounding Land Use

The Project site is located within the boundaries of Balıkhisar neighbourhood of Akyurt district which is greatly industrialized. The approximate land distribution in Akyurt district as well as the Pursaklar and Çubuk districts, which are also considered to be within the scope of area of influence, are presented in Table 12-2 below.

				-		
Land use	Akyurt		Pursaklar		Çubuk	
	Hectare (ha)	%	Hectare (ha)	%	Hectare (ha)	%
Agricultural	19,365	54.29	7,000	52	52,897	46
Forest	250	0.69	235	2	19,388	31
Meadow and pasture	2,126	5.88	1,140	9	36,000	17
Non-agricultural	14,158	39.14	5,000	37	7,115	6
Total	36,169	100	13,375	100	115,400	100

Table 12-2: Approximate land distribution in Akyurt, Pursaklar and Çubuk districts^{223,224}

The surrounding land use of the Project was verified through site visits, use of aerial photographs and review of regional and local zoning plans for classification and delineation of the land use patterns and identification of potential developments around the Project site. The surrounding land use of the Project site is illustrated in Figure 12-4 through ESRI ArcMap 10.8.1 by using colour coding defined in the Spatial Plans Development Regulation²²⁵.



Figure 12-4: Existing land use of the bounded area

Source: Prepared through ArcMap 10.8.1.

²²³ The data regarding the land use in Pursaklar district are accessed from <u>http://www.pursaklar.gov.tr/tarim</u> and the data regarding the land use in Çubuk district are accessed from

https://ankara.tarimorman.gov.tr/Belgeler/%C3%87ubuk%20Brifing%202017.docx on 26 July 2022.

²²⁴ The Turkish Republic Akyurt District Governorship Directorate of Food, Agriculture and Livestock, 2017, Briefing Report of Activities in 2017. Accessed from <u>https://ankara.tarimorman.gov.tr/Belgeler/Akyurt%20Brifing%202017.docx</u> on 07 July 2022.

²²⁵ Official Gazette date/number: 14.06.2014/29030

Residential Areas

The Project site is in Balıkhisar neighbourhood, and the nearest residential building (4-floor building) is located to the southeast at 250 m distance to the Project site. On the other hand, the nearest residential setting is located approximately 500 m southeast of the Project site.

The closest neighbourhoods are Saracalar (approximately 1 km to the south), Balıkhisar (approximately 3 km to the northeast), Saray Gümüşoluk (approximately 3 km to the west) and Altınova (approximately 2 km to the south). The distribution of the number of houses within 5 km radius of the Project site based on Endeksa database are presented in Table 12-3.

District	Neighbourhoods	Number of estimated residential houses
Akyurt	Balıkhisar	652
Akyurt	Saracalar	607
Akyurt	Güzelhisar	1,816
Pursaklar	Saray Gümüşoluk	945
Pursaklar	Altınova	1,566
Pursaklar	Saray Cumhuriyet	5,876
Çubuk	Dumlupınar	655
Çubuk	Yenice	845
	District Akyurt Akyurt Akyurt Pursaklar Pursaklar Pursaklar Çubuk	DistrictNeighbourhoodsAkyurtBalıkhisarAkyurtSaracalarAkyurtGüzelhisarPursaklarSaray GümüşolukPursaklarAltınovaPursaklarDumlupınarÇubukYenice

Table 12-3: Number of estimated residential houses by nei	ghbourhoods ²²⁶
---	----------------------------

Water Course/Riverbed

Çubuk Stream flows along the northwest boundary of the Project site. The distance between the Çubuk Stream and the nearest point of the main project complex (i.e. the Experimental Animals Production/Test Building) is approximately 92 m. According to the observations and professional judgement of the biodiversity expert during the site visit undertaken within the scope of the ESIA process, the scarcity of fauna and flora elements suggested that the water is heavily polluted and deoxygenated. An active discharge of untreated wastewater to the Çubuk Stream was also observed. To evaluate the baseline water quality of the Çubuk stream, a surface water sample was collected near the downstream boundary of the Project site as part of the ESIA study (as detailed in Section 7.3). The results of analysis indicated elevated levels of pollutants in the surface water sample and hence the water quality class is identified as 'Class III' according to the regulatory framework, which is representative of polluted water with moderate water quality.

As observed, there is no surface water body within the Project site boundaries and there are no other major water bodies in close vicinity of the Project site.

The agricultural land users interviewed within the scope of the stakeholder engagement activities conducted in June 2022 stated that timing of any stream remediation/rehabilitation works in Çubuk stream is significant as they draw water from the stream for irrigation during summer months. They requested such rehabilitation works to be conducted in winter and noted that otherwise, their income would be affected negatively. According to the consultations held with the General Directorate of the State Water Works (DSI), no rehabilitation works of the stream bed have been performed or are currently planned by the DSI on this section of the stream. However, within the scope of the Project, a flood protection wall and a 20m wide access road are planned to be built along the section of the stream adjacent to the Project

²²⁶ Accessed from <u>https://www.endeksa.com/tr/analiz/ankara/akyurt/demografi</u>,

https://www.endeksa.com/tr/analiz/ankara/pursaklar/demografi, and

https://www.endeksa.com/tr/analiz/ankara/cubuk/demografi on 19 December 2022.

Please note that the website includes both public and private data on the basis of the TurkStat data. To access private data, premium version of the website was utilized.

site. The timeline of the rehabilitation works will be closely followed by the MoH and the agricultural land users will be consulted on the issue in order to avoid any adverse impacts.

Agricultural Areas

There are a number of private lands (with around 72 different shareholders) located in the west side of the Çubuk Stream approximately 30 m from the northern boundary of the Project site and all lands are leased for agricultural activities. There are several tents and prefabricated structures within the private agricultural lands (as shown in Photo 12-2).



Photo 12-2: Tents and prefabricated structures around the Project site (Photos were taken in December 2021)

During the scoping site visit, no habitants (i.e., seasonal workers, permanent residents) were observed to reside in these tents and structures. However, findings of the interview conducted with two agricultural land users within the scope of the stakeholder engagement activities in June 2022 indicate that the tents/structures are occasionally used by the agricultural workers coming to the lands from March to June and visiting the lands daily between June and October for cultivation. Detailed baseline information and assessment on the surrounding agricultural land users are presented in *Chapter 11: Socio-economy* of this ESIA report.

Factories and Commercial Enterprises

The closest facilities within a 1-kilometre radius of the Project site include Otonomi (a road vehicles sales point, neighbouring the Project site to the south), YDS Factory (a safety shoe manufacturer, neighbouring the Project site to the northeast), İşbir Mattress Factory (neighbouring the Project site to the north), İşbir Mattress Factory (neighbouring the Project site to the north), İşbir Mattress Foam Factory, Halkbank Warehouse and Social Facilities, Borusan Automotive, and Man Turkiye (automative manufacturer). In addition, Vilsan Veterinary and Medicine Industry (2 km to the north), Turkish Medicine and Serum Industry (6 km to the northeast), TTS Türktıpsan A.Ş. (7 km to the northeast), Türkiye Plastic Medical Products A.Ş. (6 km to the northeast) and some other medical device companies have started to operate in close proximity of the Project site in recent years.

Governmental Institutions

ÖSYM (Student Selection and Placement Centre) exam centre is located approximately at 200 m to the northeast of the Project site.

As noted above, the Project neighbours the parcel 1555-5, which has been allocated to MoH and is currently occupied by the GDPH Vaccine and Pharmaceuticals Storage Warehouse including cold storage rooms with temperatures of -80 to -20 degrees where vaccines are stored. All structures and storage areas within the parcel 1555-5 will continue to be operational.

Transportation Infrastructure

The Project site is easily accessible by the existing road infrastructure and air transportation due to its proximity to Esenboğa Airport. Ankara Esenboğa Airport is located approximately 3 kilometres to the northeast of the Project site.

The access to Akyurt from other districts of Ankara is maintained via urban public transportation. Özal Boulevard is one of the main roads connecting the northeast of Ankara to the city centre. The Project site is located approximately 150m away from Ankara Çubuk Highway and Özal Boulevard. Özal Boulevard passes through Saracalar neighbourhood connecting the city centre ultimately to Esenboğa Airport. The other main road connecting Ankara to Çankırı as well as Pursaklar to Akyurt district centre is Çankırı Boulevard crossing at approximately 550m distance to the southeast of the Project site. The main entrance and exit of the Project site are planned to be at the intersection of parcel 1555-4 and the recreational area, on the General Özkan Özgün Street running parallel to the northern site boundary. This road is connected to Özal Boulevard. The detailed road network around the Project site is presented in *Chapter 13: Traffic Impact* of this ESIA report.

12.3.5 Planned and Ongoing Developments on the Surrounding Area

There is an existing road crossing through the Project site boundaries (between parcel 1555-4 and the recreational area) that will be closed once the Project is operational. A new access road is planned to be built outside the Project site boundaries running parallel to the Çubuk Stream and put into service before the closure of the existing access road. Although road constructions are usually undertaken by municipalities, this new road will reportedly be constructed by MoH within the scope of the Project to enable continued traffic flow around the Project site.

Regarding the parcellation of the Project site, as mentioned above, necessary applications will be made by the MoH to the MoEUCC regarding the merge of the two adjacent parcels (i.e. parcel 1555-4 and the unregistered parcel where recreational area is planned to be developed). As reported by the MoH representatives in February 2023, the land allocation process is still ongoing since the zoning plans have not been suspended yet. After the 30-day suspension period, the zoning plans will be finalized. Subsequently, the title deed registration process will begin. Once the land allocation process is finalized, the merged parcels will be assigned a new name. The process is expected to take approximately two or three months. The works on the parcels will be finalized prior to the Phase II construction works. Therefore, no delay is foreseen in the Project schedule.

A shopping mall (i.e.# Otonomi Outlet Shopping Mall and Wellness Centre) is planned to be developed in the vacant land adjacent to the Project site to the southeast (parcel 1555-23) by Söğüt İnşaat²²⁷. Final EIA Report for the Otonomi Outlet Shopping Mall and Wellness Centre was prepared, and an EIA positive decision was obtained in 2017 from the MoEUCC in line with the provisions of Turkish EIA Legislation. However, the timeline for construction of the project is currently unknown.

Additionally, as explained in *Chapter 13: Traffic Impact* of this ESIA report, there are planned new and/or additional roads, intersections and railway systems in the vicinity of the Project site according to the

²²⁷ Söğüt İnşaat Taahhüt Petrol Madencilik Gida Nakliyat İç ve Diş Ticaret A.Ş.

Başkent Ankara 1/25,000 scaled Zoning Plan for 2023. These road developments were planned as part of general city planning and therefore are not related with the Project. For this reason, any land take that may occur related with these proposed developments are out of the scope of the proposed Project.

Findings of the interviews held in June 2022 within the scope of the stakeholder engagement activities indicated that one notable project in planning is the International Fair Centre with a total footprint area of 300,000 m² to be constructed in Akyurt. The representatives of Akyurt Industrialists' and Businessmen's Association (AKSIAD) believes that the International Fair Centre is likely to make a significant contribution to the socio-economic development of Akyurt and increase the mobility in the region. The timeline for construction of the project is currently unknown.

12.3.6 Regional Plans and Zoning

In urban planning, there are different scaled plans proposed for different purposes. 1/250,000 and 1/100,000 plans are upper-scale plans and include spatial strategies of cities/regions. Following the finalization of the upper scale plans, 1/25,000 and/or 1/5000 scaled zoning plans and 1/1000 scaled implementation zoning plans are developed setting out sectoral developments and land use decisions. The 1/100,000 scaled Environmental Plan of Ankara Province for 2038 has been approved in 2017. However, it has been cancelled with the decision of Ankara 9th Administrative Court dated 28.09.2020 and numbered E:2018/551, K.2020/1610.

The 1/25,000 scaled Başkent Ankara Master Zoning Plan has been reviewed within the scope of this assessment. In line with the 1/25,000 zoning plan, the 1/5000 zoning plan and the 1/1000 implementation zoning plan are also available, however those plans, and their associated reports/notes are not publicly accessible.

As reported by the representatives of MoH, all zoning plans covering the Project area (1/25,000 and 1/5000 zoning plans and 1/1000 implementation zoning plan) require amendments to incorporate the proposed Project to the existing zoning. Pursuant to the article 8 of the Zoning Law No. 3194²²⁸, while upper-scale plans are issued by the MoEUCC, 1/5000 and 1/1000 scaled zoning plans are developed by the relevant municipalities. However, article 9 of the same law also states that when amendments are required related to projects of public interest including public buildings, the MoEUCC may instruct the relevant municipality through the governor's channel or, if necessary, directly approve the relevant part of the zoning plan. Accordingly, revised zoning plans²²⁹ have been prepared for submission to the MoEUCC for approval, by a consultancy company contracted by the MoH (Ozok Planlama Imar Muhendislik Ltd. Sti.). The amendment process is likely to be finalized before the end of 2022.

The zoning plans that have been reviewed are provided in Table 12-4 below.

Name of the plan	Prepared by	The year of preparation	Target year
Başkent Ankara 1/25,000 Master Zoning Plan for 2023	Ankara Metropolitan Municipality	2006	2023
Draft 1/1000 Implementation Zoning Plan Amendment Explanation Report	Ozok Planlama Imar Muhendislik Ltd. Sti.	2022	-
Draft 1/5000 Zoning Plan Amendment Plan Notes	Ozok Planlama Imar Muhendislik Ltd. Sti.	2022	-
Draft 1/25,000 Zoning Plan Amendment Plan Notes	Ozok Planlama Imar Muhendislik Ltd. Sti.	2022	-

Table 12-4: Reviewed zoning plans

²²⁸ Zoning Law No.3194,1985 (https://www.mevzuat.gov.tr/MevzuatMetin/1.5.3194.pdf)

²²⁹ Draft 1/1000, 1/5000 and 1/25,000 scaled zoning plans prepared for Ankara Akyurt Balıkhisar neighbourhood parcel 1555-4 and its surroundings by Özok Planlama İmar Mühendislik Ltd. Şti. (2022)

Başkent Ankara 1/25,000 Master Zoning Plan for 2023 that was developed in 2006 divided the city into six main planning zones/regions. Akyurt is included in the Northern Planning Region. The vision of this plan was as follows:

- Preserving and developing the natural, environmental, historical and cultural heritage value of the city,
- Fairly offering high quality to the citizens of the city in every aspect of urban life, and
- Developing a participatory approach in urban decision-making mechanisms²³⁰.

The 1/25,000 Scaled Master Zoning Plan is more of a strategic document and has adopted the idea of defining zoning issues in subscale zoning plans. The section of the 1/25,000 scaled plan showing Akyurt district is indicated in Figure 12-5 below with the red dashed circle.



Figure 12-5: The section of Başkent Ankara 1/25,000 Master Zoning Plan - Akyurt for 2023²³¹

In the draft 1/25,000 Zoning Plan Amendment, both the registered parcel 1555-4 and the unregistered land where the recreational area will be developed within the scope of the Project are designated as "Health Area". Except for this amendment, the existing 1/25,000 scaled Başkent Ankara Master Zoning Plan for 2023 provisions will be followed. Note that the zoning status of 1555-4 has not been changed (remained as "Health Area") with the proposed zoning plan amendment.

According to the draft 1/5000 Zoning Plan Amendment, implementational decisions and construction conditions are defined in the 1/1000 Implementation Zoning Plan Amendment.

The draft 1/1000 Implementation Zoning Plan Amendment defines the registered parcel 1555-4 and the unregistered land in the Project site as "Healthcare Facility Area". It is stated in the plan that facilities to be built in the Healthcare Facility Area will serve functions such as health centre, community health

²³⁰ Ankara Metropolitan Municipality Başkent Ankara 1/25,000 Master Zoning Plan for 2023, Plan Report, 2006

²³¹ Ankara Metropolitan Municipality Başkent Ankara 1/25,000 Master Zoning Plan for 2023

centre, vaccine production centre, vaccine research centre, vaccine storage facility, maternity clinic, dental health centre, and facilities that are complementary to these facilities.

The plan revisions have taken the geotechnical study²³² undertaken for the Project site as a basis. The construction conditions of the area were previously defined to be FAR (Floor Area Ratio)²³³: 0.60 and H_{max} (Maximum Height)²³⁴: 13.50 m in the approved 1/1000 scaled Implementation Zoning Plan. In the draft 1/1000 Implementation Zoning Plan Amendment, the construction conditions have been revised as E: 2.00 and H_{max} : 30.50 m. In addition, the building approach distances are defined as 15 m from the northeast facade and 5 m from the other facades in the zoning amendment.

Apart from the construction conditions, it is also stated in the zoning plan amendment that a 140 m² transformer/substation area is planned in the north to meet the technical infrastructure needs. Furthermore, a new access road (20 m wide) is included in the plan outside the Project site boundaries running parallel to the Çubuk Stream to enable continued traffic flow around the Project site.

The land use distributions set out by the 1/1000 Implementation Zoning Plan Amendment are provided in Table 12-5.

Land use	Surface (m ²)	Ratio (%)
Healthcare facility	79,331	76.28
Transformer	140	0.13
Passive green space	2,486	2.39
Water surface	9,895	9.51
Roads	12,147	11.68
Total	103,999	100.00

Table 12-5: 1/1000 Implementation Zoning Plan Amendment Land Use Distributions²³⁵

Considering the flood risks, the 1/1000 Implementation Zoning Plan Amendment states that the provisions of article 5, item 10 of the Zoning Regulation for Planned Areas²³⁶ will be followed. In line with the regulation, the crest elevation will be determined by adding 1.50 m to the flood level of 921.50 m set out by the General Directorate of State Water Works (DSI) by their official letter to MoH dated 28 February 2022. Note that the regulation also prohibits placement of any structures such as car park entrance-exits, doors or windows below the specified level and requires that opinion of DSI or the relevant water and sewerage administration is sought in case of any uncertainties.

12.4 Assessment of Impacts

12.4.1 Methodology

The methodology adopted for the impact assessment is as follows:

²³² Parcel Based Ground and Foundation Survey Geotechnical Report for the Phase 1 of the Turkey Vaccine and Biotechnological Product Research and Production Centre Building in Parcel 1555-4 in Akyurt, Ankara by URD İnşaat Mühendislik Çelik Sanayi ve Tic. Ltd. Sti., 2021

²³³ In the Zoning Regulation for Planned Areas (published in the Turkish Official Gazette dated 03 July 2017 and number 30113), FAR is defined as the ratio of the sum of all floor areas of the building to the area of the zoning parcel. Accessed from <u>https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=23722&MevzuatTur=7&MevzuatTertip=5</u> on 17 January 2023.

²³⁴ In the Zoning Regulation for Planned Areas (published in the Turkish Official Gazette dated 03 July 2017 and number 30113), H_{max} is defined as the maximum height that the building can rise from the point of elevation to the roof level. Accessed from <u>https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=23722&MevzuatTur=7&MevzuatTertip=5</u> on 17 January 2023.

²³⁵ Adapted from the Draft 1/1000 Implementation Zoning Plan Amendment Explanation Report, 2022

²³⁶ Official Gazette date/number: 03.07.2017/30113

- Establishment of baseline: Baseline conditions have been identified by using primary data (including draft zoning plans shared by the MoH with the ESIA team, as well as outcomes of the site visits undertaken during the ESIA process and the consultations held with key stakeholders within the scope of the stakeholder engagement activities) and secondary data collected through desktop research of documentation related to current and historic land use in and in the surroundings of the Project site (such as aerial images and publicly available regional and local zoning plans). The information and documentation gathered on the land use and zoning are listed in Section 12.3.1.
- Assessment of impacts: Possible impacts related to land use and zoning have been assessed together with their significance levels. This included assessment of deviation of land use patterns from baseline conditions and potential impacts on key receptors associated with construction and operation phases of the Project. The significance criteria adopted for the assessment of impacts is provided in Section 12.4.2.
- **Development of mitigation measures:** To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise any land use impact associated with the Project. The residual impacts are then determined.

12.4.2 Determining Magnitude, Sensitivity, and Impact Significance

The definitions used in determining the sensitivity of land and land users/occupiers to a change by nature of their character, quality and recognised value according to the criteria set out in Table 12-6. The magnitude of impact of the Project on the land and land users/occupiers have been categorised using the criteria presented in Table 12-7.

Sensitivity	Definition
High	Land and land users/occupiers which by nature of their character, quality and recognised value could be sensitive to change, and could not be substituted. Occupiers of residential properties and associated outdoor areas.
Medium	Land and land users/occupiers which by nature of their character, quality and value would be moderately sensitive to change, with some features or elements that could be substituted. Workers in predominately outdoor professions (e.g. farmers).
Low	Land and land users/occupiers which by nature of their character, quality and value may not be particularly sensitive to change, and which could be substituted or improved. Additionally, workers in predominately indoor professions (e.g. factories and offices).
Negligible	Land and land users/occupiers which by nature of their character, quality and value are unlikely to be sensitive to change, and which could be easily substituted or improved. Additionally, no receptors in close surrounding.

Table 12-6: Criteria for Determining Sensitivity

Table 12-7: Criteria for Determining Magnitude of Impacts on Land Use

Magnitude	Criteria
Major adverse	Physical and economic displacement ²³⁷ impacts on local people residing in and using land within the Project site or in the immediate area neighbouring the Project site. Residents to be physically displaced and required to permanently relocate.
Moderate adverse	Economic displacement impacts on local people residing in and/or using land within the Project site or in the immediate area neighbouring the Project site, with no involuntary resettlement foreseen.
Minor adverse	Loss of access to communal property and/or natural resources.
Negligible	No physical and economic displacement impacts on local people. No loss of access to communal property and/or natural resources.

²³⁷ Physical displacement can be considered as relocation or loss of shelter, and economic displacement as loss of assets or access to assets that leads to loss of income sources or other means of livelihood,

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 12-8.

		Sens	itivity of Receptors	
Magnitude of Impact	Negligible	Low	Medium	High/Very High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

Table 12-8: Impact Significant Matrix

12.4.3 Impacts Related to Land Use

No land acquisition or restriction on the land use is foreseen by the MoH regarding the Project. Parcel 1555-4 of the Project site is owned by the treasury and reportedly allocated to the MoH. In line with the Public Finance Management and Control Law (No. 5018), the unregistered land proposed as a recreational area for the Project between parcel 1555-4 and the Çubuk Stream will also be allocated to the MoH for development of the Project. Note that as per the law, the Ministry of Environment, Urbanization and Climate Change has the authority to allocate immovables under the private ownership of the treasury to the rule and disposal of the state. Necessary land use applications in this regard, including amendment of relevant zoning plans and merge of the two adjacent parcels in line with the Zoning Law (No. 3194), will be made to the MoEUCC, and the process is expected to be finalized before the end of 2022. Currently, no additional land acquisition is foreseen by MoH for the Project or its components.

No informal settlers/users of land were identified in the Project site during the ESIA study. The land allocated is in an urban setting, surrounded by factories and commercial enterprises, and there are no residential properties in the immediate vicinity of the Project site. The Project is not expected to result in physical and economic displacement impacts on local people residing in and using land in the project's immediate area of influence. Therefore, ESS5: Land Acquisition, Restrictions on Land Use and Involuntary Resettlement of the World Bank's ESF is not considered to be relevant to the proposed Project. Consequently, Resettlement Plan (RP) or Livelihood Restoration Plan (LRP) development and implementation are considered out of the ESIA scope.

Although the proposed Project area is located in a developed urban setting, the site itself is characterised as a vacant land with soil cover and its existing character will be changed to industrial upon construction of the Project. The Project is expected to generate some adverse impacts on the local natural environment, in particular, the natural floodplain and drainage patterns will be altered through the site area. The required flood mitigation measures to protect the site are detailed in *Chapter 7: Hydrology and Hydrogeology*. Adverse impacts on flora and fauna due to the change of the land character and corresponding mitigation measures are discussed in *Chapter 17: Biodiversity* of this ESIA report.

There are a number of private lands located on the west side of the Çubuk Stream approximately 30 m from the northern boundary of the Project site, which are leased for agricultural activities. The agricultural land users interviewed within the scope of the stakeholder engagement activities stated that they draw water from the stream for irrigation during summer months and therefore any stream remediation/ rehabilitation works could affect their livelihoods. According to the consultations held with the General Directorate of the State Water Works (DSI), no rehabilitation works of the stream bed are currently planned by the DSI. However, a flood protection wall is planned to be built by MoH along the section of the stream adjacent to the Project site within the scope of the Project. In case such construction works affect water availability, the livelihoods of agricultural land users could be adversely affected. Those

people are considered vulnerable and likely to have limited means to absorb adverse impacts related to income and production losses, and therefore assigned high sensitivity. The magnitude of resultant impacts would be moderate, which would correspond to a major level of significance.

12.5 Mitigation Measures

The following specific mitigation measures will be applied during the construction phase of the Project:

- Households engaging in agricultural activities will be informed about the Project and Project-related activities before the construction.
- The timeline of the rehabilitation works will be closely followed in order not to affect the agricultural land users.
- The agricultural land users will be consulted on the Project and related activities in order to avoid any adverse impacts.
- The construction activities will be timed such that the Project will not affect activities of the agricultural land users. Income and production losses, if any, of the users of the agricultural land will be compensated.
- Continuous consultation and engagement will be carried with the agricultural land users during the construction. Public grievance mechanism will be implemented.

Since no impact related to land use is expected during the operation phase of the Project, no mitigation is necessary. However, it is recommended to introduce public grievance mechanism for Project-related land use concerns and grievances.

12.6 Residual Impacts

Residual effects are those effects that remain after mitigation has been implemented. It is expected that residual land use related impacts will be insignificant after the mitigation measures that are described above are implemented.

12.7 Proposed Monitoring and Reporting

The Project is required to implement a monitoring system throughout the Project for the potential impacts regarding land use and zoning. The effectiveness of mitigation measures will be closely monitored through the grievances received via the public grievance mechanism of the Project.

Additionally, regular consultations and stakeholder engagement activities with the agricultural land users will be carried out in line with the Stakeholder Engagement Plan. The consultations, activities and grievances will be reflected in the SEP that will be updated annually.

13 TRAFFIC IMPACT

13.1 Introduction

This chapter focuses on the potential traffic and transport impacts associated with construction and operation of the Project. It considers the impacts generated from internal Project traffic, transportation of materials and equipment to the site, transport of products and wastes from the site and commute of personnel and visitors to and from the Project site.

The assessment presented in this chapter considers the potential impacts of construction and operational movements by road only. It considers the receptors which may potentially be sensitive to the operational, safety and environmental impacts of staff, visitor and transport vehicle movements and the significance of these impacts.

13.1.1 Study Area and Area of Influence

The study area is determined in line with the approach set out in Section 4.6.2. Therefore, the study area primarily includes the proposed access roads within the Project site as well as the existing and proposed transportation network and access roads around the Project site and communities settled along those roads. The area of influence extends with regard to the main commuting and transport routes of users of the site including workers, visitors as well as goods and vehicles.

13.1.2 Data Limitations

The data assessed in this chapter relies on the accuracy, sufficiency and consistency of the secondary data sources, as well as information provided to ESIA Team by or on behalf of the MoH. It should be noted that impacts arising from Project related transportation activities and increased traffic loads are not quantified but are assessed mainly qualitatively, on the basis of expert judgement.

13.2 Baseline Description

13.2.1 Transportation Infrastructure in Ankara Province

Ankara, the capital city of Turkiye, is located in Central Anatolia Region of Turkiye. The neighbouring cities of Ankara are Kırıkkale in the east, Çankırı in the northeast, Bolu in the northwest, Eskişehir in the west, Konya in the south, Kırşehir and Aksaray in the southeast. Ankara is the second most populated province in Turkiye with a population of almost 5.75 million²³⁸.

Ankara province is in the jurisdiction of 4th Regional Directorate of General Directorate of Highways, which is in charge of 55,153 km² area, together with Bolu, Eskişehir, Düzce and Kırıkkale provinces²³⁹. As of 2022, Ankara has approximately 1,640 kilometres length of state and provincial roads (including asphalt, stabilized, earth, stone block, primitive roads)²⁴⁰. The road network in and around Ankara province is illustrated in Figure 13-1.

²³⁸ Turkish Statistical Institute, Address Based Population Registration System Results, 2021. (Last access on 16 February 2022, official website: <u>https://data.tuik.gov.tr/Bulten/Index?p=Adrese-Dayali-Nufus-Kayit-Sistemi-Sonuclari-2021-45500&dil=</u>1).

²³⁹ Last access on 10 March 2022, official website:

https://www.kgm.gov.tr/Sayfalar/KGM/SiteTr/Bolgeler/4Bolge/Bolge4.aspx

²⁴⁰ Last access on 10 March 2022, official website: <u>https://www.kgm.gov.tr/SiteCollectionDocuments/KGMdocuments/Istatistikler/DevletIIYolEnvanter/IllereGoreDevletVeIIY</u> <u>ollari.pdf</u>



Figure 13-1: Road Network in and around Ankara Province²⁴¹

There are a number of main roads providing access to neighbouring cities; the Eskisehir Highway (D200) provides connection to Eskisehir province to the southwest, Anadolu Highway (E89) provides connection to Bolu and Istanbul provinces to the northwest, Konya-Ankara Highway (D750) connects Ankara to Konya to the south as well as Ankara-Çankırı Boulevard (D140) connects Ankara to Çankırı to the northeast (as illustrated in Figure 13-2).

The urban development in Ankara is concentrated at the center of the city (i.e. mainly Altindag, Cankaya, Etimesgut, Golbasi, Kecioren, Yenimahalle, Mamak, Pursaklar, Sincan and Yenimahalle districts). There are a number of roads providing access from city center to the districts. Moreover, Ankara Ring-Road (Beltway) provides easier connection in between the districts of Ankara. The main roads and highways in and around Ankara province are shown in Figure 13-2.

²⁴¹ Last access on 10 March 2022, official website: <u>https://www.kgm.gov.tr/Sayfalar/KGM/SiteTr/Bolgeler/4Bolge/Harita.aspx</u>



Figure 13-2: Main roads and highways in and around Ankara province (the blue shaded area indicates the Project site)

In addition to the highways, Ankara also has an advanced transportation network and a wide infrastructure in terms of airways and railways. Ankara Esenboğa Airport, which provides significant means of travel in Ankara with both domestic and international network, is located northeast of Ankara province. In 2021, daily average number of passengers using Esenboğa Airport was recorded as 19,200 (including all domestic and international arrivals and departures)²⁴².

In terms of railway transportation, Ankara provides services for passengers and goods at local, regional, national and international levels. In recent years, the projects focusing on establishment of high-speed trains all around Turkiye have gained acceleration. Ankara-Istanbul high-speed train network that extends through Eskişehir, Bilecik and Kocaeli provinces and Ankara-Karaman high-speed train network extending through Konya province are the two existing lines in operation. In 2021, around 23.5 million passengers travelled via high-speed train²⁴³ (corresponding to 65,000 passengers per day on average).

13.2.2 Transportation Infrastructure in Akyurt District

Ankara province has 25 districts and one of them is Akyurt district in which the Project site is located. Akyurt consists of 26 neighbourhoods including six central neighbourhoods and 20 villages. The population of Akyurt was reported as 38,588 in 2021, which constitutes 0.67% of the total population of Ankara province. Among 25 districts, Akyurt is the 11th least populated district of Ankara.

Ankara Esenboğa Airport, one of the ÖSYM (Student Selection and Placement Centre) exam centres, GDPH Vaccine and Pharmaceuticals Storage Warehouse, and several factories and commercial enterprises are established in Akyurt district. These facilities have led Akyurt to have a sufficient transport

²⁴² Ministry of Transport and Infrastructure - General Directorate of State Airports Authority, Annual Passenger Statistics for Airports, 2021. Accessed from <u>YOLCU.pdf (dhmi.gov.tr)</u> on 20 July 2022.

²⁴³ Turkish State Railways Corporation, Number of Passengers Travelled via High-Speed Train, December 2021. <u>TCDD</u> <u>TAŞIMACILIK GENEL MÜDÜRLÜĞÜ YENİ YILDA 6. YAŞINI KUTLUYOR - TCDD Taşımacılık AŞ Genel Müdürlüğü</u> (tcddtasimacilik.gov.tr)

infrastructure for easy access. The access to Akyurt from other districts of Ankara can be maintained via urban public transportation.

The General Directorate of Electricity, Gas and Bus Management (EGO) of Ankara province, which provides public transportation (bus) services around the province, offers bus lines that provide bilateral services between central districts and Akyurt. Ulus, a neighbourhood within Altındağ district, is the main connection point of EGO buses that serves Akyurt. Other than EGO buses, it is possible to access to Akyurt via private minibuses.

In Figure 13-3 below, average daily traffic values of the state roads in Akyurt for 2020 are provided by vehicle types. Accordingly, the state roads providing access to Akyurt district have a traffic volume that range between 6,000 and 70,000 vehicles per day. The closest state roads to the Project site have a daily traffic volume ranging from approximately 33,000 to 50,000 vehicles.



Figure 13-3: State Roads Volume (Daily) Map of Akyurt District in Ankara Province as of 2020 (Project site is indicated in the figure)²⁴⁴

The Project site is easily accessible by the existing road infrastructure and air transportation due to its proximity to Ankara Esenboğa Airport (approximately 3 km to the north). The Project site is located 150m away from Ankara Çubuk Highway (2x3 lanes) and Özal Boulevard (2x3 lanes), which is one of the main roads connecting the northeast of Ankara to the city centre. Along its route, Özal Boulevard passes through Saraçalar, connecting the city center ultimately to Esenboğa Airport. The other main road connecting Ankara to Çankırı as well as Pursaklar to Akyurt District center is Çankırı Boulevard (2x2 lanes) crossing at approximately 550m distance to the southeast of the Project site.

There are a number of alternative routes to access the Project site;

• **Route Description 1 (From Çubuk District Center):** The Project site is easily accessible from Çubuk District center via Ankara Çubuk Highway. After reaching ÖSYM e-Exam center on Ankara Çubuk road, take a right turn and follow General Özkan Özgün Street to reach the Project site.

²⁴⁴ 4th Regional Directorate of General Directorate of Highways - Ankara. Accessed from the following website on 23 February 2022:

https://www.kgm.gov.tr/SiteCollectionDocuments/KGMdocuments/Trafik/trafikhacimharitasi/2020HacimHaritalari/Bolge4.pdf.

- Route Description 2 (From Esenboğa Airport): Follow Özal Boulevard and take a right turn before Akyurt-Çankırı Bridge Junction (Otonomi No.3 gate direction). Follow the paved road to the Project site.
- **Route Description 3 (From City Center):** From Turgut Özal 2 Boulevard (D200), follow Şehit Ömer Halisdemir Boulevard and Erbakan Boulevard to Esenboğa Junction and then stay on Özal Boulevard (D140). Finally, it is possible to access to the Project site by following Özal Boulevard and take a U-turn from roundabout (from Otonomi direction) then follow the abovementioned Route Description 2.
- **Route Description 4 (From Akyurt District Center):** From Akyurt District center, it is possible to access the Project site by following Çankırı Boulevard (D140). After reaching the Akyurt-Çankırı Bridge Junction, which is located approximately 550 m to the southeast of the Project site, the Otonomi No.3 gate direction can be followed to reach the Project site.

Closer view of the road network in the vicinity of the Project site is shown in Figure 13-4.



Figure 13-4: Road network in the vicinity of the Project site

The Project site can also be accessed from Ankara city centre via public buses and minibuses easily. The closest bus stops and minibus stop (departure point providing access to Ulus) are located at approximately 150 m to the east on Özal Boulevard and 300 m to the southeast of the Project site. The bus and minibus stop near the Project site are shown in Figure 13-5.



Figure 13-5: Bus stations in the vicinity of the Project site (the approximate locations of the nearby bus stops were taken from google earth pro satellite images)

13.2.3 Use of Existing Road Infrastructure by Nearby Facilities

Close-up street views of streets/roads in the vicinity of the Project site from satellite imageries by using Google Earth street view are provided in



Source: Mott Macdonald

Figure 4-1. During the site visits undertaken within the scope of the ESIA process, visual observations of road conditions at selected locations in the vicinity of the Project site were made. The condition of the streets/roads, crossings and intersects based on visual observation are briefly summarized in Table 1-1 below.

Mott MacDonald | Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project Environmental and Social Impact Assessment Report



Figure 13-6: Close-up views of the streets/roads in the vicinity of the Project site by using Google Earth street view









382

No referring to the visuals indicated in Figure 13-6	Name of the street/road and/or view description	Location	Width	Condition
1	Ankara Çubuk Highway	150 m to the east of the Project site	Approximately 11 m width at each direction	Paved surface Sideways at each direction Separated lanes (2x3 lanes) at each direction
2	General Özkan Özgün Street (right turn from Ankara Çubuk Highway)	Parallel to the northern site boundary	Approximately 13- 15 m	Paved surface No separated lanes No sideways
3	General Özkan Özgün Street (taken in front of the entrance of YDS Company)	Parallel to the northern site boundary	Approximately 13- 15 m	Paved surface No separated lanes No sideways Parking at two directions (services, buses of nearby facilities/companies etc.) Limited driving space
4	Unnamed road (between parcel 1555-4 and the recreational area)	Crossing through the Project site boundaries from north to south	Approximately 13 m	Paved surface No separated lanes Narrow sideways at one direction
5	General Özkan Özgün Street extension and Dumlupınar Village Road	Parallel to the northern site boundary	Approximately 5-6 m	Paved surface No separated lanes No sideways No barriers along the crossing/bridge The width may not be sufficient to allow concurrent passage of two vehicles (especially heavy vehicles)
6	Unnamed road (between parcel 1555-4 and the recreational area)	Crossing through the Project site boundaries from north to south and continuing along the Otonomi	Approximately 13 m	Paved surface No separated lanes Two sideways at each direction (starting from the border of the Otonomi's parcel)
7	Unnamed road (providing access through Akyurt-Çankırı Bridge Junction to Özal and Çankırı Boulevards)	500 m from the southern end of the Project site	Approximately 12 m at each direction	Paved surface Separated lanes Sideways at each direction

Table 13-1: The condition of the roads/streets based on visual observation

The condition of abovementioned roads was generally observed as good. All major arteries in the vicinity of the Project site have paved surface.

It is important to understand existing transport/traffic conditions in the vicinity of the Project site which will form the base for the impact assessment study. In order to assess the intensity and characteristics of vehicle movement in the vicinity of the Project site, consultations were held with representatives of the surrounding facilities within the scope of the stakeholder engagement activities. These facilities include GDPH Vaccine and Pharmaceuticals Storage Warehouse, YDS Factory, İşbir Mattress Factory (a shoe manufacturer neighbouring the Project site to the northeast), İşbir Mattress Factory (neighbouring the Project site to the north), İşbir Mattress Foam Industry (located approximately 165m to the north) are provided through General Özkan Özgün Street.

General Özkan Özgün Street separates YDS and İşbir Mattress Factory from the Project site (the street is jointly used by both facilities). The main entrance of the existing GDPH Vaccine and Pharmaceuticals Storage Warehouse, which is located in parcel 1555-5 adjacent to the Project site, is also provided through the General Özkan Özgün Street.

As observed during the site visits, shuttle services, mini and midibuses as well as private vehicles from the nearby facilities use General Özkan Özgün street for parking purposes at two directions, significantly reducing the width of the street. Safe access must be maintained to the existing facilities/companies. With the current condition of the General Özkan Özgün Street, the additional traffic due to the realization of the Project could therefore increase road safety risks.

İşbir Mattress Foam Industry employs approximately 150 employees (working in two shifts). As reported by the facility representatives during the consultation activities, the Facility has 12 shuttle services and 20 cars and most of the workers use service buses. Reportedly, these service buses use General Özkan Özgün street as well as the unnamed road between parcel 1555-4 and the recreational area. The arrival and departure times of the service buses is 7:45 in the morning and 18:15 in the evening.

İşbir Mattress Factory has around 300 employees and the estimated arrival time of eight employee shuttles to the Factory is 7:40 in the morning and departure time is at 18:05 in the evening. As stated by the representatives of the facilities, employees rarely leave the factory during work hours, they stay inside the factory for lunch breaks and other breaks. The employee services, mini and minibuses as well as private cars use General Özkan Özgün street and the unnamed road between parcel 1555-4 and the recreational area for access. It was stated by the facility representatives during the consultation activities that alternative routes can be used for transportation purposes and access.

Approximately 1000 employees work in YDS Factory. Most employees work in one shift (working hours are 8:30-16:00), while some departments work in three shifts. Representatives of YDS Factory and İşbir Mattress Foam Industry did not express any concerns about the road network that may be used jointly by these facilities and the Project. It was stated that there are alternative access roads for use of employee shuttles and other vehicles in case of traffic congestion that may occur due to construction activities of the Project. It was also noted that the construction of the previously built vaccine depot on parcel 1555-5 did not have any significant impacts.

Otonomi hosts around 700-750 independent enterprises and employs over 2000 workers. There are no shuttle services available for Otonomi employees. All employees arrive in and leave Otonomi either by private cars or public transportation options. Three gates (entrances) of Otonomi (namely Gate No. 1, 2 and 4) provide direct access from Özal Boulevard while Gate No. 3 is positioned on the unnamed road accessible through the Akyurt-Çankırı Bridge Junction. The busiest gates are Gate No.1 and Gate No.3. Reportedly, approximately 2000 vehicles enter Otonomi through those two gates daily. As reported by the representatives of Otonomi within the scope of the consultations held during stakeholder engagement activities, the section of the unnamed road (between parcel 1555-4 and the recreational area) that will be closed as a result of the Project, is currently unofficially used for test drives by the enterprises and clients of Otonomi.

13.2.4 Future Developments

Baskent Ankara 1/25,000 scaled Zoning Plan for 2023 that has been developed in 2006 divided the city into six main planning zones²⁴⁵. Akyurt is included in the Northern Planning Region. According to the Plan, there are planned new and/or additional roads, intersections and railway systems in the vicinity of the Project site. The planned new road and railway systems are indicated with approximate locations and routes in Figure 13-7.

²⁴⁵ Baskent Ankara 1/25,000 scaled Zoning Plan for 2023 (website: <u>https://www.ankara.bel.tr/ankara-buyuksehir-belediyesi-nazim-plan/1-25-000-baskent-ankara-nazim-mar-plani</u>)



Figure 13-7: Planned major road and railway systems in the vicinity of the Project site (approximate locations and routes were taken from 1/25,000 scaled Zoning Plan, 2023²⁴⁶)

13.3 Assessment of Impacts

13.3.1 Methodology

Traffic and transportation impact assessment has been conducted through the use of primary data collected (i.e. outcomes of the consultations held with key stakeholders within the scope of the stakeholder engagement activities undertaken during ESIA process) and secondary data based on desktop studies. The methodology adopted for the assessment is as follows:

- Establishment of baseline: Current traffic conditions and transport infrastructure have been identified by using present traffic flow data, photographs of the road network around the Project site taken by the ESIA team, and other relevant documents. Information gathered on existing access routes in order to characterise the baseline is provided in Section 13.2.
- **Assessment of impacts:** Possible traffic and transport impacts associated with construction and operation phases of the Project have been assessed together with their significance levels. The significance criteria adopted for the assessment of impacts is provided in Section 13.3.2.
 - Assessment of increases in baseline conditions,
 - Assessment of potential environmental and social impacts arising from increased traffic (i.e., dust, road safety implications and accessibility of other users as a result of cancellation of roads and abnormal loads of transportation),
 - Assessment of cumulative impacts arising from other readily known developments, future transportation developments and infrastructural plans.

²⁴⁶ Baskent Ankara 1/25,000 scaled Zoning Plan for 2023 (website: <u>https://www.ankara.bel.tr/ankara-buyuksehir-belediyesi-nazim-plan/1-25-000-baskent-ankara-nazim-mar-plani</u>)

• **Development of mitigation measures:** To reduce any significant impacts to an acceptable level and to identify good practice measures to minimise the overall environmental impact from traffic and transportation associated with the Project.

The necessary information and documentation for the traffic and transportation assessment has been collected from the sources listed below:

- The official website of General Directorate of Highways (<u>http://www.kgm.gov.tr</u>): To obtain data regarding state road networks and traffic volumes in and around Akyurt district
- The official website of Turkish Statistical Institute (<u>https://www.tuik.gov.tr</u>): To collect data on socioeconomic and demographic characteristics of the population in Ankara province and Akyurt district
- 1/25,000 scaled Ankara Zoning Plan, 2023²⁴⁷: To collect information about current transportation conditions and future plans (if any) in Ankara

13.3.2 Determining Magnitude, Sensitivity, and Impact Significance

The significance of potential impacts is a function of the presence and sensitivity of receptors and the magnitude of the impact in terms of duration, spatial extent, reversibility and likelihood of occurrence.

The magnitude of transport impacts is, to an extent, subjective. The determination of the magnitude will therefore be based upon professional judgement taking into account the perceived sensitivity of the receiving environment.

The criteria for determining sensitivity and magnitude are defined in Table 13-2**Hata! Başvuru kaynağı b ulunamadı.** and Table 13-3, respectively.

Sensitivity of Receptors	Definition
High	Vulnerable receptor (human or infrastructure) with very little or no capacity to absorb proposed changes or minimal opportunities for mitigation (e.g. Receptors located up to 0-5 meters from the access road and absence of any traffic barrier or road that is oversaturated at least two days per week).
Medium	Vulnerable receptor (human or infrastructure) with limited capacity to absorb proposed changes or limited opportunities for mitigation (e.g. Receptors located at 5-10 meters from the access road with limited traffic barriers such as low fence or green buffer or road at capacity most days).
Low	Vulnerable receptor (human or infrastructure) with some capacity to absorb proposed changes or moderate opportunities for mitigation (e.g. Receptors located at 10-15 meters and have fences and green buffer or road with occasionally at capacity).
Negligible	Vulnerable receptor (human or infrastructure) with good capacity to absorb proposed changes and good opportunities for mitigation (e.g. Receptors are located 15 m and above and have sufficient fences and green buffer or minor road that is occasionally used).

Table 13-2: Criteria for Determining Sensitivity

Table 13-3 below summarises the specific criteria for determining the magnitude of impacts.

Table 13-3: Criteria for Determining Magnitude

Magnitude	Definition (considers duration of the impact, spatial extent and reversibility)
Major	Fundamental change to the specific environmental conditions assessed resulting in long term or permanent change, typically widespread in nature (regional national and international), would require significant intervention to return to baseline; exceed national standards and limits. Rehabilitation is required or the baseline will not be recovered.

²⁴⁷ 1/25,000 scaled Ankara Zoning Plan, 2023 (Last access on 10.03.2022, official website:

https://www.ankara.bel.tr/ankara-buyuksehir-belediyesi-nazim-plan/1-25-000-baskent-ankara-nazim-mar-plani)

Magnitude	Definition (considers duration of the impact, spatial extent and reversibility)
Moderate	Detectable change to the specific environmental conditions assessed resulting in non-fundamental temporary or permanent change on a local / national level with moderate recovery periods to baseline conditions.
Minor	Detectable but minor, short term and local change, to the specific environmental conditions assessed and recovery requires little or no intervention.
Negligible	No perceptible change to the specific environmental conditions assessed.

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 13-4.

			Sensitivity of Rec	eptors
Magnitude of Impact	Negligible	Low	Medium	High
Negligible	Insignificant	Insignificant	Insignificant	Insignificant
Minor	Insignificant	Minor	Minor	Moderate
Moderate	Insignificant	Minor	Moderate	Major
Major	Insignificant	Moderate	Major	Critical

13.3.3 Construction Phase

Additional traffic load on the existing road network will be generated by transportation of materials and equipment/consumables, transport of wastes and excavation materials from the site and daily commute of personnel to and from the Project site. The construction programme and the Project components are reviewed in *Chapter 2: Project Description* of this ESIA report.

As discussed in Section 13.2.3, there is an existing road, crossing through the Project site boundaries from north to south (between parcel 1555-4 and the recreational area), that will be closed once the Project is operational. During the construction period, this road will remain open and the entrance and exit to the construction site will be provided from this road (especially during the construction activities within the recreational area). Note that a new access road is planned to be built outside the Project site boundaries running parallel to the Çubuk stream and put into service before the closure of the existing access road. Although road constructions are usually undertaken by municipalities, this new road will reportedly be constructed by MoH within the scope of the Project to enable continued traffic flow around the Project site for vehicles of the nearby facilities.

Main and local roads will be utilised as required during construction dependent upon the point of origin of plant/materials etc. The heavy vehicles will be transporting ready mix concrete and other construction materials mainly from Pursaklar (in the west) and Çubuk (in the north) districts. The maximum number of daily heavy vehicles operating to and/or from the Project site during the construction phase is estimated to be 130. The probable traffic routes to be used by transport vehicles associated with the construction activities of the Project are shown in Figure 13-8 below.



Figure 13-8: Probable route alternatives to be used by construction vehicles

There will also be additional traffic load due to daily commute of construction workers to and from the Project site. At present, it is expected that the majority of the workers will reside in Ankara (outside the Project site). Currently, there are approximately 80 workers in the Project site for existing construction works. It is estimated that there will be around 250 workers at peak during the construction phase of the Project. Two dormitories are under construction for accommodation of approximately 50 workers on site during the construction phase of the Project. Shuttle services will be available for other workers. There will also be some provision for car parking within the Project site for shuttle buses and private cars of the employees.

Vehicle traffic generated by transport of construction materials/equipment and personnel may create increased traffic loads and increased risk of traffic-related accidents or injuries on the transportation routes. Sensitive receptors will include the settlements and communities adjacent to these routes. In accordance with the significance criteria, the sensitivity of the receiving road network and communities is considered to be low on the local network and negligible close to Ankara centre, and the magnitude of impact is considered to be moderate. Consequently, the significance of traffic and transport related impacts during the construction phase is assessed to be minor.

13.3.4 Operation Phase

Additional traffic load on the existing road network during the operation phase is anticipated to be significantly lower than those associated with construction of the Project. The operational phase traffic will be generated from delivery of materials (including consumables and chemicals), outbound transport of products and wastes, visits by maintenance personnel and site visitors, and daily commute of facility personnel to and from the Project site.

Once operational, approximately 200 staff are expected to be employed, most of whom will be civil servants or contracted workers. Most personnel are expected to live in various neighborhoods and districts of Ankara. There will be a shuttle service for the personnel. It is likely that some personnel might use their private cars to commute to the facility. Additionally, it is one of the aims of the Project to bring

teams and people together from both private sector and academies for developing technologies. Depending on the type and number of academical meetings/organizations to be held in the facility, the number of visitors and associated traffic movements may vary. Necessary arrangements are considered in the Project design such as providing temporary accommodation facilities (approximately 17 rooms), dedicated car parking areas as well as facilitating separate safe access for personnel and visitors. The internal vehicle and pedestrian access and number/position of parking areas have been incorporated to the design²⁴⁸. There will be also a bike path included in the design of the recreational area.

The main entrance and exit of the Project site are planned to be at the intersection of parcel 1555-4 and the recreational area, on the General Özkan Özgün Street running parallel to the northern site boundary. The layout showing the internal traffic flow arrangements within the Project site is provided in Figure 13-9.



Figure 13-9: Layout and Internal traffic flow within the Project site

The Project is not expected to generate high volume of external vehicular and pedestrian traffic and the related impacts will be mainly localised. The Project site is not situated within an already congested transport network.

The operation of the Project is not expected to significantly affect the existing number of movements on the local road network. The majority of the workforce will be transported by shuttle services as well as

²⁴⁸ The following parking arrangements are incorporated in the design of the Project: An open visitor parking area for ten cars will be available outside the site entrance near the Security Building. There will also be open car parking areas at the main project complex area (i.e. parcel 1555-4) and recreational area dedicated for both employees and visitors. Open car parking areas dedicated for employees will be available at five locations (with an estimated total capacity of 131 cars) in the main project complex area. A total of 99 cars will be able to park in the recreational area (parking area for ten cars in front of the kindergarten and parking area for 89 cars dedicated for visitors). Additionally, there will be a basement level parking garage with a total footprint of 171.72 m².

public transportation. However, the additional movements created by the material, product and waste transportation/shipment could have an impact on the traffic and congestion including:

- Impacts related with any improper management of internal traffic flow (i.e. circulation routes for pedestrian, visitors/personnel cars/shuttles, logistics and test animals),
- Impacts related with traffic load increase on local roads used by other industrial/commercial facilities,
- Impacts related with increased risk of traffic-related accidents or injuries on the transportation routes,
- Impacts related with biosafety and biosecurity risks associated with transportation of bio-hazardous
 materials (please refer to Chapter 14: Community Health and Safety for details),
- Impacts on the potential road users regarding the cancellation of the existing road crossing through the Project site boundaries from north to south (between the parcel no: 1555-4 and the recreational area).

As noted above, upon closure of the road between parcel 1555-4 and the recreational area during the operation phase, a new access road is planned to be built outside the Project site boundaries running parallel to the Çubuk stream within the scope of the Project to enable continued traffic flow around the Project site for vehicles of the nearby the facilities.

Sensitive receptors will include the settlements and communities adjacent to the transportation routes used by the Project. In accordance with the significance criteria, the sensitivity of the receiving road network and communities is considered to be low on the local network and negligible close to Ankara centre, and the magnitude of impact is minor. Consequently, the significance of traffic and transport related impacts during the construction phase is assessed to be minor.

13.4 Mitigation Measures

13.4.1 Design Phase

The following specific mitigation measures will be applied during the design phase of the Project:

- It will be ensured that pedestrian safety measures are incorporated into the design of the facility. Priority will be given to pedestrian circulation and as such it will be ensured that vehicular circulation is separated safely from pedestrian circulation. Necessary traffic control measures will be applied including the provision of sideways and pedestrian crossings.
- It will be ensured that the design is walking and disabled friendly (such as provision of ramps instead of steps).
- Safety zones within the facility will be clearly identified (zoning and identities using colour and icon coding) to inform users of accessibility to the specified/dedicated areas.
- There will be entrance-exit points dedicated for cars/pedestrians (visitor and staff/personnel) and trucks which will provide safe access and transportation at the Project site.
- Different entrance-exit doors in the buildings for services, transfer animals and materials will be allocated in the design of the Project.
- For various transportation alternatives such as taxi, cars, motorcycle etc., there will be a dedicated point reserved for pick-up/drop-off in front of the Project site (outside of the main gate) which will avoid potential traffic issues.
- Clear signages shall be provided at loading/unloading area within the facility.
- Traffic calming measures will be applied such as textured pavement for both vehicular and pedestrian routes, raised crossings, warning signages and speed controls (i.e., humps or vehicle gantry).
- In order to promote reducing the carbon footprint, electric vehicle charging points might be facilitated within the Project site which may help encourage drivers to consider eco-friendly private vehicles over conventional combustion engine vehicles.

13.4.2 Construction Phase

A range of measures are proposed to mitigate the adverse impacts of traffic movements associated with construction of the Project, including both physical and management measures. The following specific mitigation measures will be applied during the construction phase of the Project:

- A construction Traffic Management Plan (TMP) will be developed which provides a guide as to the type of measures which will be needed to mitigate the impact of construction traffic movements on the local road and highway network and on the local communities as well as to enhance the efficient transport of supplies and materials to the Project site, while minimising congestion and disruption. The TMP will draw on international best practice in developing and ensuring the implementation of suitable strategies.
- Contractor will comply with the national regulations and ensure that the construction site is properly secured, and construction related traffic is regulated.
- Traffic and transport management will be carefully planned and performed considering the industrial, commercial and residential developments in the vicinity of the Project site. Hence, the probable congestion and traffic accidents will be prevented (peak and off-peak hours).
- All vehicles will enter and exit the Project site in a forward direction. Vehicle manoeuvring will not be allowed on public roads.
- Excavated material will be recycled and reused on site for foundation construction and suitable structural filling wherever possible to reduce the number of vehicle movements on local road network. Excess material will be transported to local disposal sites.
- Earthen material vehicle movements will avoid peak times.
- Good site visibility will be ensured in order not to allow drivers lines of sight to be obstructed by structures.
- Disruption to road users will be minimised as far as possible by utilising the Project site for the storage
 of materials and by providing onsite parking to reduce congestion on the road during materials
 delivery.
- The Project will ensure the implementation of Air Quality Management Plan and the Noise and Vibration Control Plan to mitigate any potential adverse impacts to the environment and communities resulting from air and noise emissions related to construction traffic.
- Ongoing consultation will be undertaken with stakeholders (especially with neighboring facilities and muhktars/district representatives) to inform them about the construction program and transportation routes.
- Separated pedestrian walkway routes and safe passages will be provided in the construction site.
- Appropriate warning signs, barriers and traffic diversions, will be placed, as necessary.
- Training of workers on TMP and regular monitoring of traffic measures will be undertaken.

13.4.3 Operation Phase

The following specific mitigation measures will be applied during the operation phase of the Project:

- Lower speed limits and traffic control measures will be applied within the Project site and at external transport routes.
- A TMP will be developed for the operation phase outlining safety measures for internal traffic management including vehicle operations, use of access roads, vehicle and pedestrian routes, use of parking facilities, use of loading and unloading areas.
- For external traffic, TMP will include route planning, speed limits, vehicle safety standards, transportation timing, training requirements as well as worst-case accident scenarios, extraordinary events such as malicious attack, terrorism, and considering biosafety and biosecurity aspects (please

refer to *Chapter 14: Community Health and Safety* for mitigation measures to be taken against biosafety and biosecurity risks associated with transportation of bio-hazardous materials).

- It will be ensured that traffic and transport procedures follow the applicable national and international standards and guidelines.
- The emergency teams of the Project will be furnished and trained to respond to traffic related emergencies.
- Information signs will be positioned which display any necessary information regarding units, buildings and facility in the form of layout maps, plans and floor descriptions recommended to be placed at entrances, lobbies, and any locations within the facility where people can easily access/see.
- Safe working environment for drivers and transportation staff and supply of necessary PPEs will be ensured.
- Bus services will be provided for personnel living in nearby settlements to avoid number of private cars on local road network.
- Necessary communication and collaborations with local/governmental authority, NGOs, neighboring facilities and commercial organizations regarding traffic and transport management will be undertaken.
- Training on TMP and regular monitoring will be undertaken.

13.5 Compliance with National and International Requirements

13.5.1 National Requirements

The applicable key national legislation applicable to the traffic assessment and their relevance to the Project are described below:

Law/Regulation	Official Gazette Date/No	Scope	Relevance to the Project
Highway Traffic Law No. 2918	18.10.1983/ 18195	Highway Traffic Law defines the main rules and regulations regarding highway traffic safety, traffic signs, structures, facilities and technical principles. The purpose of the law is to maintain traffic order in terms of life and property safety on highways and to determine the measures that need to be taken in all matters concerning traffic safety.	According to the law, vehicles must be registered according to the principles specified in the relevant regulations and a registration certificate should be obtained. The motor vehicles must be kept in accordance with the technical conditions set out by the regulations and must be inspected within the period specified in the regulations. Vehicle operators should hold valid driving licenses according to the class of the vehicles.
Road Traffic Regulation	18.07.1997/ 23053	This regulation specifies the principles and procedures for implementation of the traffic regulations and other measures concerning traffic safety in line with the Road Traffic Law No. 2918.	The Project should comply with the traffic safety rules set out by the regulation in the use of the highways and other public roads.
Road Transport Regulation	08.01.2018/ 30295	This regulation sets forth provisions regarding management of road transportation activities and the rights, responsibilities, obligations, qualifications and licensing of parties engaged in transportation, agency, freight forwarding, transport operation, transport warehouse operation, cargo industry, distribution operation, terminal operation, and similar activities.	The Project should ensure that the transportation contractors carrying passengers and materials by motor vehicles comply with the provisions of the regulation and hold necessary certifications. Transportation services should comply with the provisions of the regulation regarding all vehicles, tools, equipment, facilities, management principles and employees. As of 2024, the goods, cargo and passenger movements carried by companies engaged in

Table 13-5: National Regulations on T	raffic Safety that are Releva	int to the Project
---------------------------------------	-------------------------------	--------------------

Law/Regulation	Official Gazette Date/No	Scope	Relevance to the Project
			transportation activities will be tracked and controlled through an Electronic Transport Tracking and Control System (U-ETDS).
Regulation on Road Transportation of Hazardous Materials	24.04.2019/ 30754	The regulation defines the transportation conditions of hazardous materials and the responsibilities, rights, provisions and working conditions of the senders, receivers, loaders, unloaders, packaging parties, transporters and drivers. This regulation is issued in accordance with the provisions of the <i>European Agreement</i> <i>Concerning the International Carriage of</i> <i>Dangerous Goods by Road (ADR)</i> . Under the regulation, entities that transport hazardous materials are required to hold one of the authority certificates C1, C2, K1, K2, L1, L2, M1, M2, M3, N1, N2, R1, R2.	The Project should comply with the provisions of the regulation regarding the transportation of hazardous materials by motor vehicles and ensure that necessary Certificates of Authorization are secured by the transportation contractors. The transportation conditions for hazardous materials consumed or produced by the Project should conform to the requirements defined by the regulation related to vehicle properties, packaging, loading/unloading activities and personnel competence.
Regulation on Safe Transportation of Radioactive Substances	08.07.2005/ 25869	The regulation aims to protect the public and employees from radiation and maintain radiation safety during transportation of radioactive substances by road, railway, air or sea.	The Project should comply with the safety rules set out by the regulation in the transportation of the radioactive substances during the operation phase including loading, transport, unloading, temporary storage and delivery of radioactive substances.

13.5.2 International Requirements

Traffic and transport impact assessment has been conducted in line with the World Bank ESS1: Assessment and Management of Environmental and Social Risks and Impacts, and ESS 4: Community Health and Safety, as well as the World Bank's good practice note and guideline on road traffic safety. The overview of the international requirements applicable to the Project are listed in Table 13-6 below.

Document	Key Policies and Objectives
World Bank ESF ESS1: Assessment and Management of Environmental and Social Risks and Impacts	 Assessing, managing and monitoring environmental and social risks and impacts in the project area of influence associated with each phase of the project
	• Adopting a mitigation hierarchy approach to avoid, or where avoidance is not possible, minimize or reduce risks and impacts to acceptable levels, mitigate, and where significant residual impacts remain, compensate for or offset them, where technically and financially feasible
	• Establishing and implementing appropriate management systems to promote improved environmental and social performance
World Bank ESF ESS4: Community Health and Safety	• Anticipating and avoiding adverse impacts on the health and safety of project-affected communities during the project life cycle
	 Identifying, evaluating and monitoring the potential traffic and road safety risks to workers, affected communities and road users throughout the project life cycle and, where appropriate, developing measures and plans to address them
	• Avoiding or minimizing community exposure to project-related traffic and road safety risks
World Bank Good Practice Note: Environment & Social	• Engagements with stakeholders to explore potential traffic and road safety risks arising throughout the project life cycle
	 Identification of risk mitigation measures that need to be embedded in the project's environmental and social documents, designs and activities throughout the project cycle as a key outcome of the traffic impact assessment

 Table 13-6: The World Bank Documents of Traffic and Road Safety

Document	Key Policies and Objectives
Framework for IPF Operations Road Safety (2019) ²⁴⁹	
World Bank Guide for Road Safety Interventions: Evidence of What Works and What Does Not Work (2021) ²⁵⁰	• Building road safety capacity by considering roads and roadsides, speeds, road users, and vehicles
	• Developing and adopting ambitious strategies and road safety targets with regular reporting

In addition to the abovementioned World Bank ESSs and guidelines related with road traffic safety, the following standards and guidelines, that are important in terms of biosafety and biosecurity aspects, have also been considered during the assessment (further assessments in terms of biosafety and biosecurity aspects discussed in *Chapter 14: Community Health, Safety and Security);*

- UN Model Regulations on the Transport of Dangerous Goods, 2021
- WHO Guidance on regulations for the Transport of Infectious Substances, 2021
- OIE (World Organisation for Animal Health) Terrestrial Manual, Chapter 1.1.3: Transport of Biological Materials, 2018

13.6 Residual Impacts

Residual impacts are those impacts that remain after mitigation has been implemented. Following mitigations, it is expected that residual impacts will be confined to impacts on the local road network arising from construction and operation traffic (minor adverse impacts).

13.7 Proposed Monitoring and Reporting

A monitoring system will need to be implemented throughout the Project. Monitoring will be undertaken to determine the effectiveness of mitigation measures in terms of safety and nuisance. The monitoring activities to be implemented to ensure compliance with the legal and international requirements will include periodic checking, recording and reporting of incidents and accidents, traffic control measures, driver competency, vehicle maintenance, contractor management and community grievances related to traffic and transport safety.

Due to the potential impacts of the Project, surveys and reporting will be required and will also include the following:

- Traffic movement surveys to determine the scale of impact on critical highway routes through sensitive areas (to be updated if significant change in the construction program, schedule etc.) and ongoing consultation with associated local authorities,
- Road accident surveys/checklists to maintain a database of all road incidents involving vehicles associated with the Project.

Additionally, the MoH will: (i) promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers, including, inter alia, cases of sexual exploitation and abuse (SEA), sexual harassment (SH), and accidents that result in death, serious or multiple injury, any COVID-19 outbreak in the Project (no later than 48 hours after learning of the incident or accident), (ii) provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating

²⁴⁹ Turner, B., Job, S. and Mitra, S. (2021). Guide for Road Safety Interventions: Evidence of What Works and What Does Not Work. Washington, DC., USA: World Bank. (Last access on 28 February 2022, official website: <u>https://openknowledge.worldbank.org/bitstream/handle/10986/35176/Guide-for-Road-Safety-Interventions-Evidence-of-What-Works-and-What-Does-Not-Work.pdf?sequence=7&isAllowed=y)</u>

²⁵⁰ World Bank (2019). Good Practice Note: Environment & Social Framework for IPF Operations Road Safety. Washington DC.: World Bank. (Last access on 01 March 2022, official website:

http://pubdocs.worldbank.org/en/648681570135612401/Good-Practice-Note-Road-Safety.pdf).

immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and (iii) subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

14 COMMUNITY HEALTH, SAFETY AND SECURITY

14.1 Introduction

This chapter provides an assessment of the Project health, safety and security aspects that may impact workers and nearby communities during the construction and operation phases and sets out the mitigation measures to avoid or minimize the risks together with the residual impacts that are foreseen to remain. In accordance with the requirements of the World Bank ESF ESS4: Community Health and Safety, potential risks and significant adverse impacts related to the air quality, noise, road traffic, community health and exposure to disease, life and fire safety, infrastructure safety, labour influx and security requirements are covered in this chapter.

The risks and impacts of the Project in the context of health and safety of the nearby communities will be managed through a Community Health and Safety Management Plan to be implemented by MoH. This plan will include measures to address the identified risks and ensure the disclosure of relevant Project-related information to enable the affected communities to understand the risks and impacts. Additional management plans related to protection of community health and safety will be required including plans to prevent and respond to incidents and emergencies, as well as plans to protect the health, welfare and security of the community from any adverse effects related to generation of noise and dust, road traffic and security operations, as explained further below.

The chapter covers specific background details on:

- National legislation framework and international standards, policy requirements and guidelines against which to assess the impacts of the Project on community health, safety and security matters,
- Determines magnitude, sensitivity, and impact significance on community health, safety and security issues,
- Establishes biosafety and biosecurity management with all possible emergency scenarios during design, construction and operation of biosafety laboratories and vaccine production facilities,
- Informs about dust and noise, waste management, biosafety and biosecurity, infrastructure safety, life and fire safety, security and traffic related requirements and emergency issues management including exposure of communities to disease/infections, and
- Final remarks on any residual impacts and monitoring and reporting.

14.1.1 Study Area and Area of Influence

The Project site is located in Balıkhisar neighbourhood of Akyurt district of Ankara, which is in the Central Anatolian region of Turkiye, with a total area of approximately 87,500 m² including a recreational area. The project site is between Akyurt and Pursaklar district centres, roughly 10 kilometres away from either way. The immediate land use around the Project site is described in *Chapter 12: Land Use and Zoning* and shown in Figure 12-4. The area of influence that is likely to be affected by the Project activities has been determined to include the following (Figure 14-1):

- Nearby villages,
- Nearby business areas such as Otonomi, manufacturing facilities, proposed shopping centre,
- Nearby roads, and
- Esenboğa Airport and its facilities.


Figure 14-1: Area of Influence

14.1.2 Data Limitations

The Project complex will be established according to the guidelines and requirements of international institutions such as WHO, NIH, CDC and World Bank, as well as national legislation outlined in Section 14.5 of this chapter. The mentioned requirements are essential not for just design and construction, but they are also significant for commissioning, certification, operation and maintenance of the proposed project complex. Although there are international guidelines and standards present, there are no established national legislation or guidelines in Turkiye specifically for BSL3 and ABSL3 from design to operation and maintenance stage.

There are also a number of uncertainties regarding the Project design at the current stage, limiting the ability to assess the environmental, health and safety impacts on communities. Information on the following issues are not yet available:

- Technical details on the main facility components including the Research and Development (R&D) Building, the Vaccine Production Building and the Experimental Animals Production/Test Building
- Structure and capacity of the research units, production units and test rooms according to type of organism/animal group and relevant HVAC system engineering details
- Details on decontamination systems and their capacities, and associated HVAC system engineering details
- List of equipment and their capacities
- Details on the biobank system
- Details and capacity of activities in Project for short, medium and long-term
- Safe off-site transport planning
- Details on the information system (this might have an impact on biosecurity system engineering)

14.2 Baseline Description

14.2.1 Background

Laboratories are classified based on a biocontainment designation system as biosafety level (BSL) 1, 2, 3 and 4 depending on the risk grade of studied biological agents and have varying design features, containment facilities and operational procedures as summarized below (see also Table 14-1):

- Biosafety Level-1 (BSL1) represents basic level of containment that relies on standard microbiological practices. In these laboratories, no special primary or secondary barriers are recommended, other than a sink for hand washing.
- Biosafety Level-2 (BSL2) represents clinical, diagnostic, teaching and other laboratories in which work is done with broad spectrum of indigenous moderate risk agents. Primary hazards to personnel working with agents relate to the accidental percutaneous or mucous membrane exposures, or ingestion of infectious materials. Personal protective equipment should be used as appropriate. Secondary barriers such as hand washing sinks and waste decontamination facilities must be available to reduce potential environmental contamination.
- Biosafety Level-3 (BSL3) represents, clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious and potentially lethal infection. More emphasis is placed on primary and secondary barriers to protect personnel in contiguous areas, the community and the environment from exposure to potentially infectious aerosols.
- Biosafety Level-4 (BSL4) represents practices with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy. The facility is generally in a separate building or completely isolated zone with complex, specialized ventilation requirements and waste management systems to prevent release of viable agents to the environment.

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic Biosafety Level 1	Basic teaching research	GMT**	None; open bench
2	Basic Biosafety Level 2	Primary health services; diagnostic services, research	GMT plus protective clothing biohazard sign	Open bench plus BSC* for potential aerosols
3	Containment Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing-controlled access directional airflow	BSC and/or other primary devices for all activities.
4	Maximum containment Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC and or positive pressure suits in conjunction with Class II BSCs, double ended autoclave (through the wall), filtered air.
*BSC bio	logical safety cabinet: **GM	IT good microbiological tech	iniques	<i>/</i>

Table 14-1: The summary of risk groups to biosafety levels, practices and equipment²⁵¹

Biological agents requiring BSL3 and BSL4 containment pose a high risk to workers, communities and possibly to the environment, and these agents should be managed by trained professional staff using appropriate techniques. To implement a laboratory biosafety program, it is important to understand the principles of cleaning, disinfection, sterilization and decontamination. The terms are often misused and misunderstood. The definitions and capabilities of each inactivation procedure are briefly discussed below. Further discussion on specific inactivation methodologies applicable to the Project are provided in Section 14.5 of this chapter.

Cleaning: Cleaning is the removal of gross contamination from a surface to the extent necessary for further processing for intended use. Cleaning can be used to remove microorganisms and other associated contaminants (e.g. blood, tissues, culture media) from a surface by physical means but may not provide any antimicrobial activity. Cleaning is often an essential pre-requisite to disinfection or sterilization processes to ensure the optimal activity of the antimicrobial effects of these processes.

²⁵¹ Laboratory Biosafety Manual, 3rd Edition, WHO, 2004

- Disinfection: Disinfection is generally a less-lethal process than sterilisation; it eliminates nearly all
 recognized pathogenic microorganisms, but not necessarily all microbial forms (e.g. bacterial spores)
 present on inanimate objects. The effectiveness of a disinfection procedure is controlled by several
 factors, each one of which may have a pronounced effect on the end results:
 - Nature and number of contaminating microorganisms (especially the presence of bacterial spores),
 - Amount of organic matter present (e.g. soil, feces, blood),
 - Type and condition of surfaces, instruments, devices and materials to be disinfected,
 - Temperature, and
 - Contact (exposure) time.
- Sterilisation: It is the action of freeing an item, device or solution completely from all forms of living microorganisms, including spores and viruses. Sterilization can be accomplished by dry or moist heat, gases and vapours (e.g. chlorine dioxide, ethylene oxide, formaldehyde, hydrogen peroxide, methyl bromide, nitrogen dioxide, ozone, propylene oxide), plasma sterilization technology and radiation (e.g. gamma, e-beam in industry). From an operational standpoint, a sterilization procedure cannot be categorically defined because the likelihood that an individual microorganism survives is never zero. Rather, the procedure is defined as a process, after which the probability of a microorganism surviving on an item subjected to treatment is less than one in one million.
- Decontamination: The primary objective of decontamination is to reduce the level of microbial contamination so that transmission of infection is prevented. In laboratory settings, decontamination of items, used laboratory materials and regulated laboratory wastes is often accomplished by a sterilization procedure such as steam autoclaving, the most cost-effective way to decontaminate a device or an item. The presence of any organic matter necessitates longer contact time with a decontamination method if the item or area is not pre-cleaned. When steam sterilization is used to decontaminate laboratory waste that contains items that have a high bioburden and there is no precleaning (i.e. infectious waste), the cycle times are generally longer and should be verified and validated for the typical load. Validation involves the combined use of thermocouples and biological indicators placed throughout the load to ensure penetration of steam into the waste. Verification can be accomplished by routine monitoring of the steam sterilization cycles (i.e. cycle times, pressure, temperature) and by placing biological indicators within the load. In addition to time, temperature may also be increased to ensure inactivation of pathogens. Chemical disinfectants used for decontamination range in activity from high-level disinfectants (e.g. high concentrations of sodium hypochlorite [chlorine bleach]), which might be used to decontaminate spills of cultured or concentrated infectious agents in research or clinical laboratories, to low-level disinfectants or sanitizers for general housekeeping purposes or spot decontamination of environmental surfaces in healthcare settings. If dangerous and highly infectious agents are present in a laboratory, the methods for decontamination of spills, laboratory equipment, biological safety cabinet or infectious waste are very significant and may include prolonged autoclave cycles, incineration or gaseous treatment of surfaces. A general guideline for disinfection and sterilization activities is given in Figure 14-2.



Figure 14-2: Guideline for Disinfection and Sterilization

14.2.2 Biosafety and Biosecurity

Biological risk management is the effective management of risks posed by working with infectious agents and toxins in laboratories. It includes a set of practices and procedures that ensure the biosafety and biosecurity of infectious agents and toxins. It is essential to properly assess potential biosafety and biosecurity risks and establish appropriate risk control measures that can reduce risks without hindering scientific processes and progress. These measures should comply with national standards and regulatory procedures and be proportionate to the assessed biosafety and biosecurity risks. The concepts of biosafety and biosecurity are defined below:

- Biosafety is the containment principles, technologies and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release. Biosafety level 3 in the scope of the Project is the appropriate definition for agents with known aerosol transmission potential for agents that can cause serious and potentially fatal infections, and which are domestic or exotic in origin.
- Biosecurity is separated from biosafety and is a set of principles, technologies and practices that are
 implemented for the protection, control and accountability of biological materials and/or the equipment,
 skills and data related to their handling. Biosecurity aims to prevent unauthorized access, loss, theft,
 misuse, diversion or release of biological materials that could be used to harm humans, livestock,
 agriculture or the environment. While there is potential for malicious use of these biological agents,
 their use is valuable for many legitimate and benign diagnostic, commercial, medical and research
 applications.

The internationally accepted rules and guidelines to ensure biosafety and biosecurity in laboratories are published in the WHO Laboratory Biosafety Manual. The manual adopts a risk assessment approach and has been in broad use at all levels of laboratories and other biomedical sectors globally, serving as a de facto global standard that presents best practices and sets trends in biosafety. In addition to core requirements, design features and heightened control measures indicated in the 4th edition of the manual, design and operation considerations for BSL laboratories are detailed in the associated seven monographs.

International efforts have sought safe and secure strategies against infectious disease threats and established the Global Health Security Agenda (GHSA) compromised of nearly 70 countries and major international organizations (such as WHO, OIE, FAO). The GHSA encourages countries around the world to make new concrete commitments and transform global health security in support of the International Health Regulations (IHR). IHR 2005 is a legally binding agreement of 196 countries to build the capability to detect, assess, respond and report potential public health emergencies worldwide. There is no one-size-fits-all strategy to a biosafety management system however, 15 key essential elements and

framework jobs have been described to capacitate a country's biosafety and biosecurity²⁵². Steps of a BMS cycle is given in Figure 14-3.



Figure 14-3: Biosafety Management System Cycle²⁵³

It is essential to properly assess potential biosafety and biosecurity risks and establish appropriate risk control measures that can reduce risks without hindering scientific processes and progress. These measures should comply with national standards and regulatory procedures and be proportionate to the assessed risks. Steps of a risk assessment framework for biological risks are given below in Figure 14-4Hata! Başvuru kaynağı bulunamadı.

²⁵² Orelle at al. (2021). National Biosafety Management System: A Combined Framework Approach Based on 15 Key Elements. Frontiers in Public Health

²⁵³ Laboratory Biosafety Manual: Biosafety programme management, 4th Edition, WHO, 2020.



Figure 14-4: Risk Assessment Framework

Details of the generally accepted biological risk assessment methodologies and specific measures to address biosafety and biosecurity risks of the Project are provided in Section 14.5 of this chapter.

Country Context

In 2011, representatives from 32 countries gathered in Turkiye for a workshop organized by the United States National Research Council on anticipating biosecurity challenges of the global expansion of high-containment biological laboratories including Turkiye. According to the country overview of Turkiye published following the workshop²⁵⁴, there are rules and legislation regarding establishing and running analysis laboratories for food, animal feed, water, genetic testing, etc. however, no legal framework is available regarding establishing a high BSL laboratory in Turkiye, which remains the case. Biosecurity laws and directives are mostly concerned with Genetically Modified Organisms (GMOs) and their distribution, use, import and export.

Turkiye signed the Cartagena Protocol on Biosafety in 2000 and it was ratified in the parliament in 2003. Turkiye started to prepare a Biosecurity Law in 2002 in compliance with the Cartagena Protocol and received project funding from the United Nations Environment Program, the Global Environment Facility (UNEP-GEF). This project, entitled 'Project on the Development of the National Biosafety Framework of Turkiye' was completed in 2005. Later in 2009, the Ministry of Agriculture and Forestry (MoAF) finalized the Biosecurity Law, and it was approved by the parliament in 2010. The law does not cover medical or cosmetic products that are approved by the MoH, however, bans the production and release of any GMOs. Accordingly, a Biosecurity Board involving scientists and experts was established by a directive from MoAF. The board consists of nine members, four from the MoAF, two from the MoEUCC, one from the MoH, one from the Ministry of Industry and Commerce and one from the Undersecretariat of Foreign Trade. The main duties of the board are to form committees for evaluations of activities related to GMOs and related products, to prepare evaluation reports, to submit decisions regarding prohibition, recall, destruction and similar sanctions based on monitoring reports to the MoAF, to prepare reports that will form the basis for the preparation of emergency action plans for the prevention of possible damages on biodiversity, agricultural production and human health in case any accidents occur, to make recommendations to the MoAF regarding the conditions that must be complied with by private sector research institutions to be authorized on GMOs and their products.

²⁵⁴ Öktem H.A. (2012). – E6: country overview for Turkey: biosecurity laws and regulations in Turkey. In Biosecurity challenges of the global expansion of high-containment biological laboratories (Committee on Anticipating Biosecurity Challenges of the Global Expansion of High Containment Biological Laboratories, eds). National Academies Press, Washington, DC, United States of America, 169–170 accessed from https://nap.nationalacademies.org/read/13315/chapter/24 on 10 June 2022.

The MoH of Turkiye recognizes the significance of having BSL3 laboratories that consist high-technology equipment for medical research. A number of BSL2 and BSL3 laboratories are established under the responsibilities of governmental authorities as well as several universities (such as Ankara University, Erciyes University and Koc University). The Scientific and Technological Research Council of Turkiye (TUBITAK) Marmara Research Centre Genetic Engineering and Biotechnology Institute also operates BSL3 laboratories. In addition to these, there are different biosafety level laboratories working on human and animal health established by private companies (such as Dollvet Biotechnology Inc., Vetal Animal Health Products Inc.). Most of the governmental laboratories in Turkiye are research-based laboratories, while the laboratories owned by private companies are also used for production purposes.

Even though there is no general biosafety manual available for BSL3 activities in Turkiye, there exist experience and know-how on working according to the GMP and OECD GLPs, as well as the International Organisation for Standardization accreditation standards such as ISO 17025 and ISO 15189. TURKAK, the national accreditation body of Turkiye, is recognised internationally and signed Mutual Lateral Agreement (MLA) with European Accreditation in ISO standards. In terms of OECD GLPs, TURKAK is a signatory to the Mutual Acceptance of Data (MAD) with OECD. Additionally, the National Microbiology Standards, Laboratory Safety Guideline was prepared and published in 2018 by the Presidency of Public Health Institution of Turkiye.

The threats that may arise from the use of advanced technologies also apply to infectious pathogens that affect humans because of their potential uses for biology, health and bioterrorism. Bioterrorism includes the abuse of GMOs, the threat of pandemics and infectious diseases, the seizure and use of biological weapons by military units or terrorists. Therefore, the publication of articles that are considered valuable information that can help bioterrorists requires caution about the open publication of sensitive information. In Turkiye, studies have started to be carried out in the MoH and MoAF against biological terrorism. However, there is not yet a structure established within a certain program with relevant legislation and guidelines.

14.2.3 Exposure to Disease and Infections

Several epidemics have occurred in Turkiye to date, including the global pandemic of COVID-19, i.e. the coronavirus disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The first case in Turkiye was recorded on 11 March 2020. Since then, 16,873,793 confirmed cases of COVID-19 have been recorded in the country, with 101,139 deaths reported to WHO and a total of 152,284,195 vaccine doses administered as of 27 September 2022. The MoH controls and monitors the pandemic and the Ministry of Labour and Social Security takes measures to regulate working life, to facilitate and protect labour peace and employee-employer relations, and to monitor the implementation of measures to ensure occupational health and safety during the pandemic. Risks and precautions in the workplaces were published by the MoH on 2 September 2021 and pandemic management and working guideline was published on 17 November 2021. In this guideline, the precautions to be taken in all businesses, measures to protect clients and personnel, and cleaning, disinfection and ventilation measures were identified. On 26 April 2022, it was announced that the obligation to use masks in indoor spaces was lifted and the mandate continued only in public transportation and health institutions. In addition, coronavirus contact tracing system inquiry would no longer be required when entering public buildings. The latest announcements made on 29 May 2022 indicated that the obligation to wear masks in public transportation vehicles was also lifted.

A number of other epidemics had impacted Turkiye in the past, whose fatality decreased with the more effective measures taken after the 1840s; Cholera, last seen in 1970; Smallpox, which has been brought under control by vaccination of all children since 1891; Spanish Flu, which decreased with the end of World War I; Malaria, which was last seen in 2014 with 233 cases; HIV/AIDS, which has been seen since 1985 and has a total of 21,520 cases; Influenza Virus (H1N1) with a total of 13,591 cases; and MERS, which was reported in October 2014 as the only case in Turkiye.

Laboratory-acquired infections (LAIs) are defined as all microbial infections acquired through laboratories or laboratory-related activities, whether they are symptomatic or asymptomatic in nature. A research study has confirmed 11 LAIs associated with biological select agents and toxins (BSATs) releases in an average annual population of approximately 10,000 individuals with approved access to BSATs²⁵⁵. The report aimed to measure the monitoring of potential theft, loss or release of BSATs. No cases of fatality or secondary human-to-human transmission was reported. These LAIs were associated with either unrecognized exposures or presumptive exposures to BSAT aerosols.

According to a survey of clinical laboratory directors who participate in ClinMicroNet (an online forum sponsored by the American Society of Microbiology) conducted in the US between 2002-2004, 33% of the laboratories reported the occurrence of at least one laboratory-associated infection. The three most common laboratory-acquired infections were shigellosis, brucellosis and salmonellosis³. The Belgian Institute of Public Health has published a report in 2012 for 309 LAI cases, and reported that the predominant infections were Salmonella spp., Brucella spp. and Neisseria meningitidis according to an online survey between 2007-2012. The routes and causes of LAIs according to this dataset are presented in Figure 14-5.



Figure 14-5: Routes of exposure and causes of LAIs based on literature

In a survey study performed in 2016 with 23 laboratories, only four of the surveyed laboratories reported 15 LAIs caused by four different pathogenic organisms²⁵⁶. Bacterial infections predominated, particularly biosafety level 3 bacteria belonging to the following species: Mycobacterium tuberculosis (10 cases), Coxiella burnetii (2 cases) and Brucella melitensis (2 cases). The remaining case was caused by a biosafety level 2 virus. The majority of the LAIs (73%) occurred in a BSL3 laboratory in the context of microbiology activities (42 %), followed by microscopy (22%) and cell culture (22%) activities.

The current Ebola crisis reveals that priority must be given to infectious diseases due to the potential consequences to human and society. The reason for severe acute respiratory syndrome (SARS CoV) outbreak in 2004 was the mishandling of the virus resulting in tertiary infections and physician deaths in China. As in foot-and-mouth outbreak in the UK in 2007, humans are not the unique possible victims of biological hazards as cattle were also heavily affected. The suspected reason was cracked piping from two laboratories working on this virus.

Brucella is the known LAI in Turkiye. In a study conducted with 667 laboratory workers in Turkiye, 5.8% stated that they had Brucelosis²⁵⁷.

Through application of good microbiological practices from design to operation, the probability of an LAI event is low. The types of incidents involved in the infection and probable cause of the incidents are

²⁵⁵ Henkel et al. (2012). Monitoring select agent theft, loss and release reports in the United States—2004–2010. Appl Biosafety 17:171–180

²⁵⁶ Wurtz N, Papa A, Hukic M, Di Caro A, Leparc-Goffart I, Leroy E, Landini MP, Sekeyova Z, Dumler JS, Bădescu D, Busquets N, Calistri A, Parolin C, Palù G, Christova I, Maurin M, La Scola B, Raoult D. Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. Eur J Clin Microbiol Infect Dis. 2016 Aug;35(8):1247-58. doi: 10.1007/s10096-016-2657-1. Epub 2016 May 27. PMID: 27234593; PMCID: PMC7088173.

²⁵⁷ Sayın Kutlu S et al. (2012). Laboratory-acquired brucellosis in Turkey. J Hosp Infect, 80: 326–330.

provided in Figure 14-6 and Figure 14-7, respectively. If the proposed BSL3 laboratory would adhere to the WHO guidelines, CDC BMBL Guideline, WBG EHS guidelines and OSHA standards, and has a wellestablished system for emergency preparedness and response, events affecting the facility staff, community and environment would be minimal.



Figure 14-6: Incidents involved in the infection²⁵⁸





The US Department of Army created an accident scenario using *Coxiella burnetii* (*C.burnetii*) in accordance with Biological Defence Safety Program, Technical Safety Requirements (5, 32 CFR 627). According to the Control of Communicable Diseases Manual²⁵⁹, this organism has an unusual stability, can reach high concentrations in animal environments and is relatively resistant to many disinfectants. The US CDC states that *C.burnetii* probably presents the greatest risk of laboratory infections as the organism is highly infectious and remarkably resistant to drying and other environmental conditions²⁶⁰. The estimated human infective dose (HID) with a 25 to 50 percent chance of containing the disease through the inhalation route for Q fever is 10 organisms. *C. burnetii*, is considered representative of all

²⁵⁸ Wurtz N, Papa A, Hukic M, Di Caro A, Leparc-Goffart I, Leroy E, Landini MP, Sekeyova Z, Dumler JS, Bădescu D, Busquets N, Calistri A, Parolin C, Palù G, Christova I, Maurin M, La Scola B, Raoult D. Survey of laboratory-acquired infections around the world in biosafety level 3 and 4 laboratories. Eur J Clin Microbiol Infect Dis. 2016 Aug;35(8):1247-58. doi: 10.1007/s10096-016-2657-1. Epub 2016 May 27. PMID: 27234593; PMCID: PMC7088173.

²⁵⁹ Benenson (1995). Abram S. Benenson Editor, "Control of Communicable Diseases Manual," American Public Health Association, 16th ed.

²⁶⁰ CDC 1999: Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories" US Department of Health and Human Services, Public Health Service, CDC and National Institutes of Health (NIH), Fourth Edition, Washington, DC. (For C.burnetii).

levels of BSL1, BSL2 and BSL3 laboratory microorganisms because it is highly durable, infectious and transmissible, and has excellent environmental survivability. If proper precautions are taken against the accidental scenarios, that would significantly reduce the possible outcomes related with this microorganism at the proposed facility.

Research laboratories are needed in order to characterize highly dangerous human and animal pathogens, assist in disease surveillance and produce vaccines. However, they are complex systems with inherent risks since laboratory personnel may be exposed to various hazards, especially biological and chemical, during their routine activities. In a study performed in 2020 to reflect the employee safety and biosafety applications in microbiology laboratories in Turkiye²⁶¹, a total of 1072 personnel working in the medical microbiology laboratories of 23 hospitals (14 medical faculty hospitals, seven MoH training and research hospitals and two state hospitals) were provided with a questionnaire about the rules, opinions, attitudes and behaviours regarding health and safety practices. Some of the results of the study are: (i) Half of the personnel of the university and research hospitals and two-thirds of the state hospitals personnel consumed food and beverages in the laboratories: (ii) in state hospitals, the absence of separate resting room (35%), the personnel finding their own knowledge and practices "inadequate" (28.9%), laboratory coats washed at home (95%) were higher compared with other hospitals; (iii) periodical health checks were not performed in one-third of personnel; (iv) as the age of the personnel progresses, food and beverage consumption in the laboratory, not being outside the laboratory with protective equipment and the history of laboratory acquired infections increases. As a result, although advances have been made in employee safety practices in medical laboratories in Turkiye in recent years, it has been suggested that it is not yet sufficient. These results indirectly reflect the profile of research laboratories in Turkiye and point out the importance of GLP and training of the laboratory staff to prevent community from exposure to any infections or diseases.

14.2.4 Infrastructure

Başkent Electricity Distribution Corporation (Başkent EDAŞ) provides electricity distribution for the population in seven provinces including Ankara. Regarding natural gas distribution, Başkent Natural Gas Distribution Corporation (Başkentgaz) delivers the services for the residents in Ankara. Ankara Water and Sewerage Administration (ASKI) affiliated to Ankara Metropolitan Municipality is the organisation responsible for providing infrastructural services for water and sewerage systems in Ankara province.

The interviews and surveys that were conducted during the stakeholder engagement studies conducted in June 2022 aimed to provide baseline information regarding the current conditions of infrastructure services (including sewerage, water, electricity, internet, natural gas and cell phone) in Akyurt district and the neighbourhoods near the Project site. It was stated that the water and sewerage systems have been improved in the recent years by ASKI, however, interviews with ASKI indicated that investments are required in the region to further improve the wastewater collection infrastructure. Table 14-2 summarizes the condition of various infrastructural services in the Project area at neighbourhood level. Please see the relevant subsection in *Chapter 11: Socio-economic Baseline* for further information.

Table 14-2: Infrastructure quality within the Project affected neighbourhoods (based on the
findings of the surveys and mukhtar interviews in June 2022)

			Infrastructure Quality									
District	Settlement	Sewerage	Potable water	Electricity	Internet	Natural gas	Cell phone					
Akyurt	Balıkhisar	Poor	Medium	Medium	Medium	Medium	Medium					
Akyurt	Saracalar	Medium	Good	Good	Medium	Good	Good					

²⁶¹ Köroğlu, M., Altındiş, S., Aydemir, Ö., Yüksel, B., Demiray, T., Erkorkmaz, Ü., Aslan, F. G., Otlu, B., & amp; Altındiş, M. (2020). Mikrobiyoloji Laboratuvarlarında çalışan Güvenliği ve Biyogüvenlik Uygulamaları Açısından türkiye'de çok Merkezli Bir değerlendirme. Mikrobiyoloji Bulteni, 54(3), 347–367. <u>https://doi.org/10.5578/mb.69634</u> accessed from http://www.mikrobiyoloji Laboratuvarlarında çalışan Güvenliği ve Biyogüvenlik Uygulamaları Açısından türkiye'de çok Merkezli Bir değerlendirme. Mikrobiyoloji Bulteni, 54(3), 347–367. https://doi.org/10.5578/mb.69634 accessed from https://doi.org/10.5578/mb.69634 accessed from https://www.mikrobiyolbul.org/managete/fu folder/2020-03/2020-54-3-347-367.pdf on 10 June 2022.

		Infrastructure Quality									
District	Settlement	Sewerage	Potable water	Electricity	Internet	Natural gas	Cell phone				
Akyurt	Güzelhisar	Good	Good	Good	Good	Good	Good				
Pursaklar	Saray Gümüşoluk	Medium	Good	Good	Good	Good	Poor				
Pursaklar	Altınova	Good	Good	Good	Good	Good	Good				
Pursaklar	Saray Cumhuriyet	Good	Good	Good	Good	Good	Good				
Çubuk	Dumlupınar	Good	Good	Good	Good	Good	Poor				
Çubuk	Yenice	Medium	Poor	Medium	Medium	N/A	Good				

In the recent years, frequent flood and water overflow events occurred in the Ankara province that affected many people by causing casualties, injuries as well as damages to buildings. These include the severe floods observed in various districts of Ankara during the heavy precipitation events of June 2022 which also impacted the Akyurt district, resulting in two casualties in Akyurt and a total of four casualties across Ankara²⁶². As indicated in relevant chapters of this ESIA report, the Project will be designed in consideration of protection against flood risks.

Any infrastructural pressure and risks that may affect the community around the Project site during both construction and operation phases need to be integrated to the Project-specific Emergency Preparedness and Response Plans.

14.2.5 Life and Fire Safety and Emergency Response

Ankara Metropolitan Municipality Fire Department provides 24/7 firefighting service with 175 vehicles and 1070 personnel at 46 fire stations in 25 districts within the provincial borders of Ankara. Fire Response Department operates a total of 46 fire stations (20 group chiefs and 26 stations) to respond to fire incidents. The closest station to the Project site is the Akyurt Fire Station which is located at 10 km distance to the Project site. Individuals or legal entities who want to open a new business are required to obtain a compliance report from the Fire Department within the scope of operating license review procedures.

Disaster and Emergency Management Authority (AFAD) is an institution working to prevent disasters, minimize disaster-related damages, plan and coordinate post-disaster response, and promote cooperation among various government agencies. In this regard, AFAD introduced a disaster management model which prioritizes Turkiye's transition from crisis management to risk management, which came to be known as the Integrated Disaster Management System. AFAD currently has 81 provincial branches across Turkiye in addition to eleven search and rescue units. Over the past seven years, AFAD successfully coordinated Turkiye's response to a number of devastating earthquakes and floods.

There are police departments and police headquarters, which are located in central and outer districts operating under the Ankara Police Department. The outer district police department, situated in Akyurt district, is 12 km from the Project site, and the headquarters is 13 km from the Project site which are both located in the Yeşiltepe neighbourhood.

14.2.6 Air Quality, Noise and Traffic

Baseline descriptions with respect to ambient air quality and noise conditions in the Project area are described in the relevant chapter of this ESIA report, *Chapter 9: Air Quality* and *Chapter 10: Noise and*

²⁶² Ankara Flood Report by the TMMOB Chamber of Construction Engineers Ankara Branch, June 2022 (https://ankara.imo.org.tr/Eklenti/7862,imo-ankara-subesi-ankara-su-baskinlari-raporupdf.pdf?0)

Vibration, respectively. Baseline description related to road traffic and transportation around the Project site is provided in *Chapter 13: Traffic Impact*.

14.2.7 Community Grievances

In Turkiye, community grievances are collected through several national mechanisms including SABIM (MoH Communication Centre) and CIMER (Turkish Presidential Communication Centre). Related grievances received through CIMER are also conveyed to SABIM. The "Foreigners Communication Centre" (YIMER) provides an opportunity for foreigners to convey grievances. These national mechanisms will be utilized to receive grievances, by providing the necessary software integrations to filter and direct the Project-related grievances.

Community grievances will also be received and managed at contractor and consultant level. The main contractors of the Project to be employed for both construction and operation phases will establish their own public grievance mechanism specific for the Project and assign a community liaison officer for management of the Project-related grievances. These grievance mechanisms to be established by the contractors will be integrated to the existing system within the Project Grievance Mechanism.

Communities and individuals who believe that a World Bank-supported project has or is likely to have adverse effects on them, their community, or their environment have the opportunity to submit their grievances through existing project-level grievance redress mechanisms or the World Bank's Grievance Redress Service (GRS).

The public grievance mechanism of the Project will be suitable for receiving anonymous grievances. SEA/SH cases will be recorded and analysed as a part of the current grievance mechanism of Project. However, they will be approached in a more sensitive way and in an immediate timeframe.

All processes of the grievance mechanism from reporting to resolution will be in line with the principles laid out in the World Bank ESF ESS10: Stakeholder Engagement and Information Disclosure. For more details on the Project Grievance Mechanism, please see *Chapter 5: Stakeholder Engagement* of this report and the Stakeholder Engagement Plan prepared for the Project.

14.3 Assessment of Impacts

14.3.1 Methodology and Assessment Criteria

Investigation was conducted to identify the community health, safety and security impacts that might arise during the Project lifecycle, together with their possible outcomes. Possible impacts have been assessed together with their significance levels. This included assessment of deviation of community health, safety and security from baseline conditions and potential impacts on key receptors associated with construction and operation phases of the Project. The significance criteria adopted for the assessment of impacts is provided in Section 14.3.2 of this Chapter.

The assessment of community health, safety and security impacts has been performed according to the national legislation and international standards relevant to the nature of the Project. A comprehensive array of mitigation and good practice measures to be implemented to avoid or reduce any significant impacts to an acceptable level during design, construction, and operation of the Project are also proposed. The residual impacts are then determined.

14.3.2 Determining Magnitude, Sensitivity and Impact Significance

The sensitivity of community receptors has been determined through consideration of their vulnerability to impacts, which is measured by their capacity to cope with impacts that affect their access to or control over additional or alternative social resources of a similar nature, ultimately affecting their wellbeing. Sensitive or vulnerable people are generally considered to have less means to absorb adverse changes

408

or shocks than less-sensitive or less-vulnerable receptors. Similarly, they may be less able to maximise and build on beneficial changes to their resource bases.

EU requires certain projects (private or public) that are likely to have significant effects on the environment, to conduct an environmental impact assessment (EIA) in line with the EIA Directive 85/337/EEC which requires public consultation throughout project development, impact assessment and project implementation. Additionally, a range of public plans and programs (i.e., concerning land use, transport, energy, waste or agriculture) are subject to a similar process called a strategic environmental assessment (SEA), where environmental considerations are already integrated at the planning phase, and possible consequences are taken into account before a project is approved or authorized so as to ensure a high level of environmental protection. In both cases, consultation with the public is a central aspect, which goes back to the Aarhus Convention, a multilateral environmental agreement under the auspices of the United Nations Economic Commission for Europe (UNECE), which entered into force in 2001 and to which the EU and all its member states are parties. It guarantees three rights to the public: public participation in environmental decision-making, access to environmental information held by public authorities (i.e., on the state of the environment or of human health where affected by the former), and the right of access to justice where the other two rights have been disregarded.

presents the guideline criteria that have been used to categorise sensitivity of receptors.

Sensitivity of Receptors	Definition
High	An already vulnerable receptor with very little capacity and means to absorb proposed changes or with very little access to alternative similar sites or services.
Medium	An already vulnerable receptor with limited capacity and means to absorb proposed changes or with little access to alternative similar sites or services.
Low	A non-vulnerable receptor with some capacity and means to absorb proposed changes and with some access to alternative similar sites or services.
Negligible	A non-vulnerable receptor with plentiful capacity and means to absorb proposed changes and with good access to alternative similar sites or services.

Table 14-3: Criteria for Determining Sensitivity

Magnitude of the community impacts has been determined by considering the extent to which receptors gain or lose access to or control over community resources, resulting in a beneficial or adverse effect on their individual and collective wellbeing. Wellbeing is considered as the financial, physical and emotional conditions and quality of life of people and communities. Table 11-30 below summarises the specific criteria for determining the magnitude of community impacts.

Table 14-4: Criteria for	Determining Magnitude
--------------------------	-----------------------

Magnitude (positive or negative)	Definition (considers duration of the impact, spatial extent and reversibility)							
Major	A highly likely impact that would have implications beyond the Project life affecting the wellbeing of many people across a broad cross-section of the population and affecting various elements of the communities' resilience.							
Moderate	A likely impact that continues over a number of years throughout the Project life and affects the wellbeing of specific groups of people and affecting specific elements of the communities' resilience.							
Minor	A potential impact that occurs periodically or over the short term throughout the life of the Project affecting the wellbeing of a small number of people and with little effect on the communities' resilience.							
Negligible	A potential impact that is very short lived so that the baseline remains largely consistent and there is no detectable effect on the wellbeing of the communities' resilience.							

Likely effects are evaluated taking into account the interaction between the magnitude and sensitivity criteria as presented in the effect evaluation matrix in Table 11-31 below. Impacts that have been

evaluated as being 'Moderate' or 'Major' are significant impacts, while impacts that are 'Minor' or 'Negligible' are not significant.

Table 14-5: Impact Significant Matrix

Sensitivity of Receptors									
Magnitude of Impact	Negligible	Low	Medium	High					
Negligible	Insignificant	Insignificant	Insignificant	Insignificant					
Minor	Insignificant	Minor	Minor	Moderate					
Moderate	Insignificant	Minor	Moderate	Major					
Major	Insignificant	Moderate	Major	Critical					

14.3.3 Construction Phase

There are a number of activities in the construction phase which if not mitigated are likely to cause disturbance to local communities, including the following:

Project related labour influx

Potential health, safety and security related impacts may occur due to the influx of labour force to the area will be handled in compliance with World bank ESS2 requirements. Within the scope of the Project, it is anticipated that a maximum of 250 people will be employed during the construction phase. Additionally, two dormitories will be constructed for accommodation of approximately 50 workers on site during the construction. Potential impacts due to influx of workers can lead to adverse impacts on local communities which may include increased volume of traffic and higher risk of accidents, social conflicts with communities, increased risk of spread of communicable diseases, and increased rates of illicit behaviour and crime. The sensitivity of the receptors is rated medium and magnitude of potential impacts minor. Hence significance of the impact is determined as minor.

Dust and noise

Construction will cause disturbance in the form of dust, air emissions, noise and vibrations for people living and working near to the Project site. Dust will be arising from onsite construction activities of the Project, including stripping of vegetative soil, loading and transporting on trucks, and onsite and offsite construction traffic, which might be mechanically transported by wind or re-suspension by vehicles. Noise and vibration impacts may occur due to operation of the construction machinery and equipment onsite. The construction related dust and noise dispersion modelling results indicate that significance of impacts on nearby sensitive receptors related to dust and noise occurring from building construction activities (including vehicle movements) could be minor and insignificant, respectively. Please refer to *Chapter 9: Air Quality* and *Chapter 10: Noise* of this ESIA report for further details.

Traffic and transportation

Project truck and vehicle movements and personnel transportation will increase existing traffic volumes and may cause congestion in narrow roads of the local network. Additionally, the increased number of heavy vehicles using the road may also cause road safety risks. This could be a particular problem for vehicles travelling behind large trucks as there are few safe passing places. Vehicle traffic generated by transport of construction materials, equipment and personnel may create increased traffic loads and increased risk of traffic-related accidents or injuries on the transportation routes. Sensitive receptors will include the settlements and communities adjacent to these routes. In accordance with the significance criteria, the sensitivity of the receiving road network and communities is considered to be low on the local network and negligible close to Ankara centre, and the magnitude of effect moderate. Consequently, the significance of traffic and transport related impacts during the construction phase is assessed to be minor. For further discussion of traffic and transportation related impacts, see *Chapter 13: Traffic Impact*.

Hazardous materials and waste management

Various waste types will be generated during the construction phase of the Project, such as excavation soil, demolition waste, domestic waste and wastewater, packaging waste, waste oils, waste batteries and hazardous material including contaminated packaging, contaminated fabrics and chemicals from site and maintenance activities. Detailed assessment on waste management related impacts and mitigation measures are covered in *Chapter 8: Material Resources, Waste and Wastewater Management* of this ESIA report. In terms of community health and safety, there will be risks to the local community associated with the storage and use of hazardous chemicals and wastes which, through strict measures and management, will be limited to the Project area and will not extend beyond the life of the construction phase.

14.3.4 Operation Phase

Potential risks to community health, safety, security and wellbeing will occur due to the Project during the operational phase, however these impacts are of nature that can be mitigated through appropriate environmental and social management planning and design features. The potential risks to the community might include:

Project related labour influx

It is expected that approximately 200 personnel will be employed during the operation of the Project and commute daily to the campus. In addition, a guest house consisting of twelve rooms is planned within the Administrative Building for accommodation of guest researchers and academics. Common areas such as dining halls are planned for 300 people taking into account the visitors. The MoH will undertake necessary security arrangements throughout the facility in accordance with the national regulations as well as BSL3 requirements. Due to the limited number of people to be employed and the strict containment and security measures to be applied within the Project site, labour influx during the operation is not expected to generate significant risks to the nearby communities. Hence, the related impacts are anticipated to be insignificant.

Air quality and noise

Impacts related to generation of air and noise emissions during the operation of the Project are addressed in detail in relevant chapters of this ESIA report (*Chapter 9: Air Quality* and *Chapter 10: Noise*) and are summarized below.

There will be potential impacts on the air quality in the area surrounding the Project site during the operation phase. These impacts will be mainly related with exhaust emissions from generators and combustion units (boiler systems) and fugitive emissions released from sources such as medical waste storage areas and laboratories that may be potentially contaminated with biological agents, pathogens or toxic materials. The necessary exhaust control systems including high grade HEPA filtration will be included in the design to eliminate the fugitive emissions and no significant impacts will occur. Related to the generators and combustion units, results of the air emission modelling study showed that the significance of emission impacts are expected to be minor at sensitive receiver locations.

The modelling of noise associated with the operation of the equipment related to the heating and cooling system including boilers, cooling towers, as well as open car parking areas showed that similar to the construction phase, insignificant final impact significance is observed for all receiving locations.

Traffic and transportation

There will also be impacts related to increased local traffic due to the Project as well as increase in associated air and noise emissions from road traffic. Additional traffic loads on the existing road network during the operation phase is anticipated to be much lower than those associated with construction of the Project. The operational phase traffic will be generated due to delivery of materials (including consumables and chemicals), outbound transport of products and wastes, visits by maintenance

personnel and site visitors, and daily commute of facility personnel to and from the Project site. Sensitive receptors will include the settlements and communities adjacent to the transportation routes used by the Project. In accordance with the significance criteria, the sensitivity of the receiving road network and communities is considered to be low on the local network and negligible close to Ankara centre, and the magnitude of effect is minor. Consequently, the significance of traffic and transport related impacts during the construction phase is assessed to be minor. For further assessment on traffic related impacts, please see *Chapter 13: Traffic Impact* of this ESIA report.

Hazardous materials and waste management

Various types of hazardous materials will be used and waste will be generated during the operation phase of the Project, resulting in impacts of varying levels of significance. Detailed assessment of impacts due to different types of waste during the commissioning and operation phases of the Project are given in *Chapter 8: Material Resources, Waste and Wastewater Management* of this ESIA report.

There will be health and safety risks to the workers and local community posed by the storage and use of hazardous chemicals, solvents, disinfectants and flammable materials (such as formaldehyde, chloroform, phenol, ethyl alcohol, isopropyl alcohol, amyl alcohol and sodium hypochlorite) which will require effective management. Additionally, an array of non-hazardous and hazardous wastes will be generated including process/laboratory wastewaters and medical waste in the form of infectious waste, pathological wastes and sharps which may cause public health and environmental risks. Since the operation phase involves laboratory work and working with biological organisms and cultures, impacts may include potential exposure of laboratory providers and personnel to infections and diseases such as pathogens and other potential infectious materials during collection, handling, treatment and disposal of waste. If unmitigated, the above impacts are considered to be adverse impacts of minor to critical significance. Therefore, a set of comprehensive mitigation measures will be required, as elucidated in the relevant sections. The most fundamental among these are decontamination procedures, applied in work environments as well as to wastes and wastewaters prior to leaving the BSL laboratories.

Biosafety and biosecurity

If biological risk management is not given due importance, it may appear as a regional epidemic, countrylevel epidemic or pandemic and cause public health problems that seriously affect the public and nations. The sensitivity of the receptors is rated high and magnitude of potential impacts if unmitigated is major. The resulting impact significance associated with potential biosafety and biosecurity risks is therefore critical.

During the operation of the facilities, adverse impacts may occur on workers and communities in case of design and management failures such as inadequate biological risk management, unsafe laboratory practices, improper management of ventilation of the units, improper management of laboratory security, unsafe animal handling conditions and procedures, improper management of medical and laboratory wastes, and similar. Additional risks against which measures are needed during operation of the Project (including during the transportation activities) include accidents, emergencies, sabotage, terrorism and similar. Such occurrences may result in aerosol transmission of agents that can cause serious and potentially fatal infections, as well as diversion or release of biological materials that could be used to harm humans.

To prevent infections among personnel and the public and protect the environment and animal population from harm by avoiding the inadvertent release of biological materials, the Project will strictly adhere to national regulations and internationally accepted standards/directives. A comprehensive biosafety and biosecurity program shall be adopted to be able to keep track of biological risks that may arise. A biosafety manual specific to the facility and standard operating procedures (SOPs) will be implemented throughout the operation. The Project will also employ qualified research and production personnel with specific training in BSL facility procedures, handling of pathogenic agents and wastes, operating equipment and handling of test animals. Further mitigation measures that will be required during the design and operation of the Project are detailed in Section 14.5.

Infrastructure safety, life and fire safety and emergency response

Potential risks during the operation of the Project will include fires, explosions, leakages and pathogenic material releases that may occur unexpectedly due to equipment and infrastructure failures, accidents, employee errors, sabotages and natural disasters (such as flooding events, earthquakes and similar). The facility may experience unintentional or intentional incidents and emergencies despite effective life and fire safety (L&FS) systems and risk control measures in place. Effective incident and emergency response would reduce the consequences of these events through planning and preparation for potential incidents and may help detect, communicate, assess, respond to and recover from actual events.

Emergency scenarios in laboratories may also include incidents such as hazardous material spillage, infectious substances spillage, contamination of equipment and facilities, and personnel exposures (e.g. ingestion of potentially infectious material or contact due to puncture cuts and abrasions). The result of these emergency situations might threat health and safety of the staff, community and ecological systems.

The occurrence of a large-scale disease outbreak or other health emergency due to operation of the BSL laboratories could entail serious social and economic consequences. Considering the high sensitivity of the human receptors considering such events and the potentially major magnitude of L&FS and biological risks and impacts, their significance level is assessed to be critical if not properly mitigated during the lifetime of the Project. The necessary design features to prevent biological and L&FS risks as well as the emergency management measures to be employed during the operation are discussed below in Section 14.5.

As described earlier, a kindergarten facility is planned to be built within the recreational area which will serve only the children of operational staff of the Project. Considering the high sensitivity of the children and the potentially major magnitude of L&FS and biological risks and impacts, all life and fire safety systems and equipment for the kindergarten facility will be designed and installed using appropriate standards and sound engineering practices. Additionally, a specific Life and Fire Safety Plan will be prepared for the facility by a suitably qualified professional, identifying major risks, applicable codes and standards, and mitigation measures including how to respond to fire and other emergencies such as a pathogen release associated with the Project or disease outbreak. The necessary design features and emergency management and evacuation procedures for the kindergarten facility are discussed below in Section 14.5.10.

14.4 Mitigation during Construction

14.4.1 General

General mitigation measures and strategies that will be implemented for addressing community health and safety related risks during the construction phase are summarized below:

- Implementation of good construction site practices in line with national regulations and international guidelines as outlined in the Construction Site Management Plan to be developed by the contractor.
- Implementing the Community Health and Safety Plan and the Security Plan
- Implementing the Emergency Preparedness and Response Plan
- Strict adherence to the design codes and standards
- Keeping ongoing consultation with communities and stakeholders
- Monitoring feedbacks and grievances received from workers, communities and stakeholders

14.4.2 Project Related Labour Influx

It will be ensured that measures and precautions to protect the health, safety and security of the nearby communities and the workers in terms of Project related labour influx are taken effectively. Detailed

description of mitigation measures related to labour influx are given in *Chapter 11: Socio-economic Baseline* and *Chapter 16: Labour and Working Conditions* of this ESIA report and summarized below:

- Development of plans and procedures related with human resources,
- Implementation of the Human Resources Management Plan/Labour Management Procedures (HRMP/LMP),
- Ensuring that the main contractor and its subcontractors follow national legislation for the employment of construction workers,
- Ensuring that workers' Grievance Mechanism is in place,
- Preparation of a Gender Based Violence (GBV), Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH) policy and procedure,
- Ensuring that the workers' Code of Conduct includes appropriate and proportional security measures for women workers (e.g. lighting, alarms, separate toilets),
- Assuring regular monitoring regarding health, safety and security measures,
- Considering ways to minimize/control movement in and out of construction areas/site for security purposes,
- For the workers who are accommodated onsite in dormitories, require them to minimize contact with people outside the construction area/site,
- Checking and monitoring health conditions of workers and other people entering the construction site,
- Providing daily briefings to workers prior to commencing work, focusing on COVID-19 specific considerations including cough etiquette, hand hygiene and distancing measures,
- Requiring workers to self-monitor for possible symptoms (fever, cough) and to report to their supervisor if they have symptoms or are feeling unwell,
- Preventing a sick worker or a worker from an affected area or who has been in contact with an infected person from entering the construction area, referring them to local health facilities if necessary or requiring them to isolate at home for 14 days.

14.4.3 Dust and Noise

According to the dust and noise assessment results, the construction phase impacts of dust and noise are not predicted to be substantial. Therefore, it is not expected that strict mitigation measures will be required for assuring community health, safety and security. However, the Project will adhere to the application of salient practices from the WBG EHS Guidelines for Construction and Decommissioning, providing specific guidance on prevention and control of dust and noise effects. The detailed description of mitigation measures to be followed in case of occurrence of impacts are given in *Chapter 9: Air Quality* and *Chapter 10: Noise and Vibration* of this ESIA report, and summarized below:

- Construction Site Management Plan and construction phase Air Quality Management Plan and Noise Management Plan will be implemented to optimize construction activities.
- The construction Traffic Management Plan will be implemented to properly manage traffic during construction activities.
- Mitigation measures related to the construction machinery and equipment will be taken.
- Health and safety of construction workers will be protected from any possible noise and dust impacts generated within the construction site. Adequate personal protective equipment will be provided to workers.
- Ambient air and noise monitoring will be performed during the construction phase with periodical construction site inspections and regular checks to assess the compliance with construction phase Noise Management Plan and the Air Quality Management Plan, national and international requirements and good construction practices.

- Local communities will be engaged to minimize any disturbance and effect on the health of people in the nearby buildings.
- Trainings to construction workers will be provided in accordance with the relevant management plans.

14.4.4 Traffic and Transportation

Several measures are proposed to mitigate the adverse impacts of traffic movements associated with the construction of the Project on community health and safety. Mitigation measures are detailed in *Chapter 13: Traffic Impact* of this ESIA report, and summarized below:

- Contractor will comply with the national and local legislation and ensure that the construction site is properly secured and construction related traffic is regulated. The Traffic Management Plan will be implemented.
- Traffic and transport management will be carefully planned and performed considering the industrial, commercial and residential developments in the vicinity of the Project site. Hence, the probable congestion and traffic accidents will be prevented (peak and off-peak hours).
- Ongoing consultation will be undertaken with stakeholders (especially with neighbouring facilities and mukhtars/district representatives) to inform them about the construction program and transportation routes.
- Installing necessary safety signs at roads to prevent road related accidents and providing appropriate training for drivers (e.g., speed limits, safe driving rules).

14.4.5 Hazardous Materials and Waste Management

Waste and materials management related impacts are of high significance for community health and safety; therefore, the Project will strictly adhere to the application of practices from the WBG EHS Guidelines for Construction and Decommissioning. Description of the mitigation measures to be taken during the construction phase of the Project for assuring community health and safety are given in *Chapter 8: Material Resources, Waste and Wastewater Management* of this ESIA report, and also summarized below:

- Material Resources: Hazardous material handling and storage areas will be established during the construction phase. Details of correct procedures for handling and storing any hazardous materials will be defined and implemented through the Hazardous Materials Management Plan.
- Waste Management: It is critical to implement the techniques for prevention, minimization and control of waste related impacts during the construction phase to minimize possible impacts on nearby communities and workers. These measures include applying good construction practices, implementation of the construction phase Waste and Wastewater Management Plan, and monitoring and recordkeeping of waste generation and disposal activities as well as wastewater discharges. It is also essential that relevant trainings are provided to the workers regarding necessary waste management measures.

14.5 Mitigation during Design and Operation

14.5.1 General

The following general design and operational strategies will be applied to prevent any risks associated with community health, safety and security during the operation of the Project:

- Designing facilities, units and access roads considering biosafety and biosecurity aspects for the neighbouring communities and businesses.
- Designing the structures for seismic resilience and against flooding risks.
- Implementing the following as part of the ESMS: Emergency Preparedness and Response Plan, Security Plan, Community Health and Safety Plan, Hazardous Materials Management Plan, Waste

and Wastewater Management Plan, Air Quality Management Plan, Noise Management Plan and Pollution Prevention Plan.

- Adopting a biosafety program and a biosecurity program for the Project. Biosafety and biosecurity programs to be adopted will be in line with the principles, requirements and methodologies/procedures described in sections 14.5.6 and 14.5.7.
- Developing a laboratory-specific biosafety manual and SOPs containing sufficient information to describe biosafety and containment procedures as defined in section 14.5.6 for the biological materials in use, as well as appropriate agent-specific decontamination methods as defined in section 14.5.5. A template for the outline of the biosafety manual of the Project is provided in Annex F.
- Establishing a biosafety committee and appointing biosafety officers.
- Applying good microbiological practices throughout the whole R&D and production activities.
- Establishing necessary precautions and emergency procedures against all possible microbial and/or biobank release during the operational activities of the Project (both from units inside the facility and outside of the facility such as transport). Communication and coordination with authorities and surrounding facilities for risk and emergency management.
- Keeping records of incidents and accidents. Incidents that may result in exposure to infectious
 materials will be immediately evaluated and treated according to procedures described in the
 laboratory biosafety manual.
- Security will be provided in a manner that does not jeopardize the community's safety or relationship with the community and that is consistent with national requirements. International best practice will be applied to hiring, training and mobilizing security staff. The MoH will ensure that security personnel have not been involved in past abuses and are adequately trained.
- Ongoing information disclosure and consultation with communities, monitoring feedbacks and grievances. Increasing biosecurity awareness through the stakeholder engagement activities throughout the Project.

14.5.2 Air Quality and Noise

Mitigation measures that will be taken to avoid or reduce the potential community impacts related air and noise emissions during the operation of the Project are described in *Chapter 9: Air Quality* and *Chapter 10: Noise and Vibration* of this ESIA report, and summarized below:

- Operational phase Air Quality Management Plan and Noise Management Plan will be implemented to minimize air and noise emissions due to operational phase activities.
- The design of the laboratories and process units will comply with the global standards for ventilation, filtration and noise insulation rules set out by international organisations.
- The efficiency of steam, raw steam, hot water and similar transmission systems will be ensured, and their maintenance will be done regularly. Combustion systems will be operated using equipment with high energy efficiency.
- The design of the stacks will comply with relevant national legislation and standards.
- Noise barriers and window insulation will be considered at the planned facility especially for the kindergarten and buildings where quiet working conditions are essential.
- The design of the technical building and operational systems will be made such that the noise levels and air emission levels due to operation activities do not exceed the regulatory and international standards.
- All noise generating equipment and machinery during operation will be placed in buildings with isolated walls.
- Necessary monitoring activities (i.e., periodical maintenance, site inspections, emission measurements) will be performed during the operation phase.

- Any necessary consents for the operation phase activities will be obtained from the MoEUCC regarding air emissions and noise.
- Trainings to construction workers will be provided in accordance with the relevant management plans.

14.5.3 Traffic and Transportation

The risks associated with increased traffic and the air and noise emissions from road traffic during the operation phase of the Project shall be mitigated through implementing the Traffic Management Plan. Relevant mitigation measures are summarized below:

- Lower speed limits and traffic control measures will be applied within the Project site and at external transport routes. Appropriate training for drivers (e.g. speed limits, safe driving rules) will be provided.
- For external traffic, the Traffic Management Plan will include route planning, speed limits, vehicle safety standards, transportation timing, training requirements as well as worst-case accident scenarios, extraordinary events such as malicious attack, terrorism, and considering biosafety and biosecurity aspects.
- The emergency teams of the Project will be furnished and trained to respond to traffic related emergencies.
- Necessary communication and collaborations with neighboring facilities and communities regarding traffic and transport management.

For further discussion of measures to be taken regarding the traffic related impacts, please see *Chapter 13: Traffic Impacts.* Measures to be taken against biosafety and biosecurity risks associated with transportation of bio-hazardous materials are given below.

14.5.4 Hazardous Materials and Waste Management

General mitigation measures and strategies that will be implemented for risks associated with hazardous substances are listed below:

- Hazardous materials will be stored within secured and designated areas of the facility in containers or tanks located in bunded areas which can hold a minimum of 110% of the total storage volume.
- Small amounts of chemicals necessary for daily use will be stored in the laboratory. Bulk stocks will be kept in specially designated rooms and buildings.
- Replacement of the hazardous substances with less hazardous substitutes.
- Implementation of engineering and administrative control measures to avoid or minimize the release of hazardous substances into the environment.
- Communicating chemical hazards to workers through labelling and marking according to national and internationally recognized requirements and standards, including the Materials Safety Data Sheets (MSDS) or equivalent. Any means of written communication would be in an easily understood language and be readily available to exposed workers and first-aid personnel.
- Training workers in the use of the available information (such as MSDSs) and safe work practices.

The operation of the Project will generate different types of liquid and solid wastes. The wastes will be infectious or non-infectious in nature and will include cultures and stocks of infectious agents, pathological wastes, waste human blood and blood products, sharps used in animal care, biological laboratory wastes among others. All contaminated materials or liquids leaving the laboratory will be decontaminated onsite to allow further safe handling and transported safely to a licenced treatment facility. Please see *Chapter 8: Material Resources, Waste and Wastewater Management* of this report for detailed waste management measures and strategies. Methodologies for decontamination are detailed below.

14.5.5 Decontamination

Community health and safety will be ensured through good laboratory practices and implementation of effective decontamination techniques within the laboratories. The general measures to be applied are as follows:

- In Project activities, decontamination and sterilisation will be undertaken through use of chemical disinfection, autoclaving and pressurised rooms. To ensure an appropriate laboratory management system, factors for transmission of infection (e.g., aerosol generation, contact, indirect contact), methods for sterilization and disinfection, and levels of antimicrobial activity will be reviewed.
 - Chemical disinfection: Chemical disinfection is a method of decontamination that involves the application of a chemical, or mixture of chemicals, to an inanimate surface or material to inactivate viable biological agents or reduce their number to a safe level. Disinfectants are usually the preferred method for decontamination of surfaces; however, this is generally not required for regular cleaning of floors, walls, equipment and furniture as a core requirement for biosafety. Disinfectants will be used after a spill, or where contamination is known or suspected to have occurred. Disinfection of surfaces (and materials where applicable) will also be performed after work has been completed on the bench and periodically as part of a cleaning regime.
 - Autoclaving: The autoclave is utilized to decontaminate infectious materials and waste before moving these materials to the other areas of the facility. Autoclaving uses high temperatures (for example, 121°C, 134°C) applied as moist heat (steam) under pressure to destroy microorganisms. The holding time, temperature and pressure used for the autoclave cycle help determine the efficiency of inactivation. Autoclaves must therefore be equipped with systems to check these parameters. A written log will be maintained to record, for each cycle performed, the time, date, operator name, and type and approximate amount of waste that was treated. The autoclaving in the laboratory shall be performed according to TS EN 12347: Biotechnology - Performance criteria for steam sterilizers and autoclaves for destroying and preventing the release of microorganisms in biotechnological processes. Air evacuated from the autoclave chamber prior to decontamination cycle must be filtrated through a HEPA filter before released.
 - Pressurised rooms: Two laboratory designs can be used for laboratories employing maximum containment measures. The first is a cabinet line facility, where all work is carried out in a closed system of class III Biological Safety Cabinets (BSCs), within a negative-pressure laboratory. The second is a facility where operators work in positive-pressure encapsulating suits in open-fronted BSCs, also in a negative-pressure laboratory. Negative-pressure laboratories has a completely closed cabinet barrier system working under negative pressure that isolates the biological material from the surrounding laboratory environment. Cabinet/isolator is equipped with filters for inlet and exhaust air, entry ports such as double-door autoclave, fumigation chambers and/or dunk tanks.
- To overcome the non-biological hazards arising from the use of chemical disinfectants, appropriate non-biological risk control measures will be applied.
- For sterilization of the equipment, steam (wet) sterilization will be applied at 121-134°C for between 15-45 minutes and dry air sterilization will be applied at 300°C for 3 minutes. Gas phase H₂O₂ (hydrogen peroxide) decontamination will be applied for room area decontaminations.
- Protective clothing requirements will be adhered to in the clean room and BSL1-2-3 laboratories. In accordance with the GMP, health screenings, periodical health monitoring and vaccinations (based on product to be produced) of the personnel will be obligatory and followed by the quality assurance unit.
- Chemical disinfectants will be selected, stored, handled, used and disposed of with care, following manufacturers' instructions. PPE will be used to reduce the likelihood of exposure of personnel to both the chemical hazard and any biological agents present.
- Aerosol-generating procedures will be conducted in containment.

- Appropriate antimicrobial products will be selected to ensure the product's performance against the target microorganism and the product label instructions will be adhered to. Chemical agents for decontamination will be handled by paying attention to instructions for their use and safety data sheets; by ensuring they are used safely and by ensuring that appropriate precautions and protections are used.
- Gloves will be worn when handling biohazardous materials and hazardous chemicals, including those
 used in disinfection and decontamination. Hand hygiene will be performed after removing gloves, after
 touching potentially contaminated surfaces with bare hands, after completing work and before exiting
 the laboratory.
- Decontamination of the entire laboratory shall be considered when there has been gross contamination of the space, significant changes in laboratory usage, major renovations, or maintenance shutdowns. Selection of the appropriate materials and methods used to decontaminate the laboratory will be based on a risk assessment.
- Decontamination processes will be verified on a routine basis.
- Decontamination of all cultures, stocks and other potentially infectious materials will be done before disposal, consistent with applicable institutional, local and national requirements. Mitigations and specifications related to medical waste are discussed in *Chapter 8: Material Resources, Waste and Wastewater Management* in detail.

Decontamination can be achieved with processes of cleaning, disinfection or sterilization. The method in decontamination for waste, surfaces, laboratory devices or specimens is based on either chemical or physical as steam exposure or treatment with chemicals (see Table 14-6).

Method	Decontaminants					
	Gas/Vapour	Formaldehyde				
		Hydrogen peroxide				
		Chlorine dioxide				
	Liquid	Phenols				
_		Peroxides				
Chemica		Hypochlorite				
		Chlorine Dioxide				
		Peracetic acid				
		Formaldehyde				
		Glutaraldehyde				
		Quaternary ammonium compounds				
		Alcohols				
_	Heat	Autoclave				
sica		Incineration				
hys		Hot air oven				
<u>ц</u>		Boiling				

Table 14-6: Chemical and Physical Categories for Decontamination

Primary and secondary containment recommendations for BSL1, BSL2 and BSL3 laboratories are described in detail in the BMBL²⁶³. The recommendations for typical BSL3 practices and laboratory configurations in the following bullets will help to develop decontamination and waste management policies and practices:

²⁶³ CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020.

- Laboratory will be separated from areas that are open to unrestricted traffic flow within the building. Laboratory access will be restricted.
- All windows in the laboratory will be sealed.
- Access to the laboratory is through two self-closing doors. A clothing change room anteroom will be included in the passageway between the two self-closing doors.
- Showers will be installed to be used when zoonotic risk group 3 pathogens are being used.
- The sink will be hands-free or automatically operated. It would be located near the exit door.
- An eyewash station will be readily available in the laboratory.
- Spaces around the doors and ventilation openings will be capable of being sealed to facilitate space decontamination.
- Seams, floors, walls and ceiling surfaces will be sealed.
- Floors will be slip resistant, impervious to liquids and resistant to chemicals. Consideration will be given to the installation of seamless, sealed, resilient or poured floors, with integral cove bases.
- Walls will be constructed to produce a sealed smooth finish that can be easily cleaned and decontaminated.
- Ceilings will be constructed, sealed and finished in the same general manner as walls.
- Laboratory furniture such as benches, cabinets and equipment will be accessible for cleaning.
- HEPA filter housings will have gas-tight isolation dampers, decontamination ports and/or bag-in/bagout (with appropriate decontamination procedures) capability. The HEPA filter housing will allow for leak testing of each filter and assembly. The filters and the housing will be certified at least annually.
- HEPA filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified. Class III BSCs must be directly (hard) connected through the second exhaust HEPA filter of the cabinet.
- Equipment that may produce infectious aerosols will be contained in primary barrier devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters will be tested and/or replaced whenever required (at least annually).
- Vacuum lines will be protected with HEPA filters or their equivalents. Filters will be replaced as needed. Liquid disinfectant traps may be required.
- A method for decontaminating all laboratory wastes will be available in the facility, preferably within the laboratory (e.g., autoclave, chemical disinfection).
- Decontamination of the entire laboratory will be considered when there has been gross contamination
 of the space, a significant change in laboratory usage, a major renovation, or a maintenance
 shutdown. Selection of the appropriate materials and methods used to decontaminate the laboratory
 will be based on the risk assessment.
- Facility design consideration will be given to means of decontaminating large pieces of equipment before removal from the laboratory.

Disinfection

Disinfection is described as a process to eliminate viable biological agents from items or surfaces for further safe handling or use. When selecting a disinfectant to use in the disinfection process, four factors are taken into consideration: antimicrobial efficiency, safety, environmental impact and compatibility with the material of the surface and/or laboratory equipment being decontaminated. It is aimed to have the following specifications for a disinfectant:

- rapid and efficient action on biological materials,
- broad range of application,
- effective at the lowest concentration possible,
- active at all temperatures,
- low toxicity,
- not inactivated by organic matter,
- compatibility with all materials (i.e. non-corrosive),
- stable,
- degradable, and
- environmentally friendly.

The main disinfectant classes and their activity levels are given in Table 14-7.

Table 14-7: The main disinfectant classes and their activity levels

Disinfection Class	Alcohols	Aldehyde	Chlorines	lodophor	Oxidising	Phenols	Quaternary Ammonium
Example	70% Ethyl alcohol	Formaldehyde	Na-hypochlorite	Povidone	H_2O_2	Hexachlor ophene Cresol	Benzalkonium chloride
Activity Level	Moderate	High Moderate	Moderate	Moderate Low	High Moderate	Moderate Low	Low

Chemical disinfectants are classified according to their active ingredients and their properties in Table 14-8.

Table 14-8: Chemical disinfectants according to their active ingredients and their properties

			Α	ctivit	ty Spe	ectrum			
		Bac	teria	١	Virus		Fung	ji	Contact Time
Chemical	Common Form	Vegetative	Mycobacteria	Spores	Enveloped	Non- enveloped	Fungi	Spores of Fungus	
Chlorines	Liquid, powder and tablet	+	+	+	+	+	+	+	usually short; bacteria spores longer (≥30minutes)
lodophor	Liquid solution and iodophor	+	L	L	+	L	+	L	short time for enveloped virus & vegetative bacteria; contact time changes for other microorganism / products
Alcohols	Ethyl alcohol, IPA	+	+	-	+	L	+	-	short time for enveloped virus & vegetative bacteria; longer time for fungi & mycobacteria
Phenols	Broad kinds, used generally with detergents	+	С	-	+	-	С	-	
Quaternary Ammonium Compounds	Broad kinds, used generally with detergents	+	-	-	+	-	+	-	
Glutaraldehyde	2% acidic solution supported with bicarbonate	+	+	+	+	+	+	+	≥20 minutes for mycobacteria and non- enveloped virus; >3 hours for bacteria spores
Formaldehyde	Solid paraformaldehyde or formalin (%37)	+	+	+	+	+	+	+	

		Activity Spectrum							
		Bacteria		۱	Virus		Fungi		Contact Time
Chemical	Common Form		teria		q	q		of	
		Vegetativ	Mycobact	Spores	Envelope	Non- envelope	Fungi	Spores Fungus	
H ₂ O ₂	%6 and %30 solutions	+	+	+	+	+	+	+	Short contact time with %6 H2O2 for all viruses, vegetative bacteria, fungi, mycobacteria & some bacteria spores. For sporicidal activity, longer contact time and higher concentration are required
Chlorhexidine	%4 solution in detergents or concentrated alcohol-based mixtures	+/L*	-	-	+	-	L	-	
+: Effective; L: Lin * Effective to Gran	nited activity C: Change n (+) bacteria; limited ac	able act ctivity for	ivity; - [.] Grar	: Not n (-) t	effect bacter	ive ia			

Disinfectants are categorized as high, intermediate of low level according to their activity levels:

- High-level disinfectants: They are chemicals with sporicidal properties. Sterilization is also possible if a sufficiently long contact time is provided, therefore they are also called chemical sterilizers. For high level disinfection while the application time is 5-20 minutes, ≥3 hours for sterilization. High-level disinfectant recipes approved by the FDA of the US: 2-3% glutaraldehyde, 1.12% glutaraldehyde + 1.93% phenol/phenate, 7.5% hydrogen peroxide, 7.5% hydrogen peroxide + 0.23% peracetic acid and 0.55% ortho-phthalaldehyde (OPA).
- Intermediate-level disinfectants: Usually <10 minutes, mycobacteria such as *M. tuberculosis*, vegetative bacteria, fungi and viruses are inactivated, not affecting spores. These types of germicides are approved by EPA (Environmental Protection Agency) of the US and they are defined as tuberculoside. Chlorinated products, alcohols (60-95% ethanol or isopropanol), phenol and phenol compounds, iodophors are classified in this group. 70% ethyl alcohol is commonly used for surface disinfection.
- Low-level disinfectants: Usually ≤10 minutes, they are effective against some vegetative microorganisms and large enveloped viruses. They are ineffective against bacterial spore, mycobacteria and non-enveloped viruses. Quaternary ammonium compounds, some phenols, some iodophors, ethyl or isopropyl alcohol, sodium hypochlorite low level containing 100 ppm free chlorine are classified in this group.

Sterilization

Sterilization process is used to destroy all microorganisms on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item. The concept of what constitutes "sterile" is measured as a probability of sterility for each item to be sterilized. This probability is commonly referred to as the sterility assurance level (SAL) of the product and is defined as the probability of a single viable microorganism occurring on a product after sterilization. SAL is normally expressed a 10⁻ⁿ. For example, if the probability of a spore surviving were one in one million, the SAL would be 10^{-6 264}. Sterilization methods include dry hot air, steam (humid hot air), gases (ethylene oxide, ozone), plasma (hydrogen peroxide), irradiation, filtration for filterable liquids and methods such as chemical sterilization. Most commonly used sterilization method in medical and BSL3 laboratories is steam sterilization, which is conducted by the use of autoclaves. The validation and commissioning stages of autoclaving procedures

²⁶⁴ Favero MS. (2001). Sterility assurance: Concepts for patient safety. In: Rutala WA, ed. Disinfection, sterilization and antisepsis: principles and practices in healthcare facilities. Washington, DC: Association for Professional in Infection Control and Epidemiology, 110-9.

are a vital part of design, construction and operation in BSL3/ABSL3 facilities. The common autoclaving protocols for sterilizing different types of wastes are given in Table 14-9.

Material	Temperature (ºC)	Time (hour)
Infectious waste	121(°C)	1 hr
Liquid waste	121(ºC)	1 hr
Animal carcasses waste	121(°C)	8 hrs
Cell culture / Liquid media	121(°C)	15 minutes

Table 14-9: The c	ommon autoclaving	protocols for	different type of	wastes
-------------------	-------------------	---------------	-------------------	--------

Dry heat is used for some materials (glassware, instruments and anhydrous materials) that are sensitive to moisture or the corrosion it may cause. Dry heat requires higher temperatures and longer exposure times than autoclaving. Dry heat is needed for 2-4 hours at 160°C to sterilize a load requiring 30 minutes at 121°C in an autoclave. Another dry heat protocol is at 300°C for 3 minutes. This method may also be validated by using spore vials as in autoclave.

Sterilization procedure will be monitored routinely by using a combination of mechanical, chemical and biological indicators to evaluate the sterilizing conditions and indirectly the microbiologic status of the processed items. The mechanical monitors for steam sterilization include the daily assessment of cycle time and temperature by examining the temperature record chart (or computer printout) and an assessment of pressure via the pressure gauge. Chemical indicators certified against EN ISO 11140 are convenient, inexpensive, and indicate that the item has been exposed to the sterilization process. Chemical indicators will be used in conjunction with biological indicators. Biological indicators certified with EN ISO 11138 series are recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e. Bacillus spores), and not by merely testing the physical and chemical conditions necessary for sterilization²⁶⁵. Spores used to monitor a sterilization process have demonstrated resistance to the sterilizing agent and are more resistant than the bioburden found on medical devices. B. atrophaeus spores (10⁶) are used to monitor ETO and dry heat, and G. stearothermophilus spores (10⁵) are used to monitor steam sterilization, hydrogen peroxide gas plasma, and liquid peracetic acid sterilizers. The next generation of biological indicator is self-contained in plastic vials containing a sporecoated paper strip and a growth media in a crushable glass ampoule. Since sterilization failure can occur (about 1% for steam) a procedure to follow in the event of positive spore tests with steam sterilization has been provided by CDC²⁶⁶. The types of biological indicators are shown in Figure 14-8.



Figure 14-8: The types of biological Indicators

Considering the variable and possibly unknown nature of agents to be used in containment facilities; decontamination of facilities, equipment and personal protection equipment is as important as the research being performed within the facility. No waste materials would be removed from the laboratories unless those materials are first autoclaved or decontaminated by a method approved and managed by the laboratory EHS unit and Biosafety Committee. There are several materials that require special

²⁶⁵ Greene VW. (1992). Control of sterilization process. In: Russell AD, Hugo WB, Ayliffe GAJ, eds. Principles and practice of disinfection, preservation and sterilization. Oxford, England: Blackwell Scientific Publications, 605-24.

 ²⁶⁶ Kleinegger et al., (2001). The effects of contamination on biological monitoring. Infect. Control Hosp. Epidemiol. 22:391 2.

decontamination methods in order to assure safe removal from the BSL3 laboratories. These materials are biological samples needing further analysis, laboratory equipment and laboratory clothing. Biological materials that would be removed from the BSL3 laboratories would undergo a decontamination process that would be validated using biological indicators certified against EN ISO 11138 series. Once validated, electronic monitoring and charting of the processes would verify the decontamination cycle. These materials would be packaged in sealed containers that would circulate through a disinfectant dunk tank, fumigation chamber or an airlock in order to decontaminate the container. This material would then be irradiated using a gamma cell machine used to render various BSL3 organisms non-viable and, therefore, appropriate for research in BSL2 laboratories. This sterilized liquid would then be piped to a biowaste cooker and heated under pressure until the temperature reaches.

General Steps for Decontamination in a BSL3 Laboratory

- Waste decontamination:
 - Waste from BSL3 facilities is autoclaved in the laboratory and packed as "biohazard waste" to
 ensure it is incinerated as a final method of disposal. Laboratories would be responsible for
 autoclaving the waste material prior to shipment. Following completion of laboratory work in the
 BSL3 facilities, workspace areas would be disinfected using a newly prepared 1:10 bleach solution
 or other approved disinfectant.
 - Liquids are inactivated by autoclaving or with household bleach. A minimum contact time of 30 minutes is required. The liquid is then disposed of down the sink using large amounts of water followed by a disinfectant.
 - Solid wastes are inactivated by autoclaving. Autoclaves are operated as described above. The biohazard autoclave bags should not be taped closed. After autoclaving, all waste leaving the facility must be doubled bagged before placing in a box-bag unit.
- Decontamination in BSC:
 - Decontaminate interior surfaces (work surface, grilles, sides, back and inside front view screen) with an appropriate disinfectant after removal of all materials, cultures and apparatus.
 - If using 10% bleach solution on work surfaces, allow it to air dry then follow up with 70% ethanol wipe to prevent rusting of stainless-steel surface.
 - Decontaminate liquid waste with household bleach diluted 10% against the volume of the waste.
 Allow at least a 30-minute contact time for full decontamination.
 - Transport waste to autoclave in a leakproof container.
- Decontamination of spore forming microorganisms:
 - Bacterial spores, by nature, are resistant to extreme physical, chemical and thermal conditions, and are second only to prions in their resistance to different types of decontamination. A particular care and diligence will be used to decontaminate equipment and apparatus used for work with sporeforming agents. Adequate sterilization requires direct exposure to 121°C for at least 90 minutes. Chlorine (0.01-5%) is less positive and glutaraldehyde (2%) is positive against spores.
- Decontamination procedures for prions:
 - Prions are characterized by resistance to conventional inactivation procedures including irradiation, boiling, dry heat and chemicals (formalin, beta-Propiolactone, alcohols). Current methods for inactivation of prions are based on the use of sodium hypochlorite, sodium hydroxide, and the moist heat of autoclaving in combination.
- Decontamination of hazardous biological toxins:
 - Decontaminate work surfaces with 5-10% household bleach or 0.1N sodium hydroxide.
 - Treat liquid waste with 50% household bleach (soak overnight). For T-2 mycotoxin use a combination of 50% household bleach and 0.25N sodium hydroxide.
 - Collect and autoclave waste at the end of the day.

- Autoclave or chemically disinfect contaminated protective clothing before reuse.
- Room decontamination:
 - Room decontamination will be performed with gas phase of H₂O₂ in accordance with the relevant protocols. On the other hand, H₂O₂ would not be allowed to be used for live animals. Vapor phase hydrogen peroxide is effective at a 30% concentration (less than 10 mg/litre) to disinfect surfaces. The higher the temperature, the less contact time is needed. The end products of disinfection are non-toxic (water and oxygen) which makes vapor phase hydrogen peroxide safer to use than other gas disinfectants. However, hydrogen peroxide vapor is corrosive to some materials and degrade natural rubber and nylon.
 - Room disinfection is also performed using UV-C at 254nm. The UV-C impact distance is limited to 1-2 meters and is affected by ambient temperature. The lamps require wiping to prevent dust accumulation with ex. 91% isopropyl alcohol or 70% ethyl alcohol for every 2-4 weeks. The number of UV lamps to be placed in a room varies according to the dimensions of the laboratory doom (see Table 14-10).
 - The equipment to be used will come from the sterilization area as clean material. All the contaminated materials will exit after autoclaving.

	Ceiling height: 2.7–3m		
	Room length:3–4 m Room length:3–4 m		
	Width: 3-4m	Width: 5.5–7 m	
90% air disinfection	1 at 15 Watt (W)	3 at 15 W or 1 at 30 W or 1 at 40W	
99% air disinfection	2 at 15W or 1 at 30W	6 at 15 W or 2 at 30 W or 2 at 40W	

Table 14-10: The number of UV-C lamps according to the room dimension

- Decontamination of biological waste including animal carcasses:
 - The proposed laboratories would include a multi-sterilization system for BSL3/ABSL3, tissue digesters for animal waste and a dedicated liquid effluent decontamination system.
 - The multi-sterilization system would include a sufficient number and volume of autoclaves. Animal carcass materials would be placed on rack sterilizers for easy entry/exit of large materials while smaller autoclave models would be used for general laboratory waste. Once waste material has been autoclaved in biodegradable bags, they are removed from the BSL3/ABSL3 through the contained space.
 - A dedicated liquid effluent decontamination system would treat all liquid wastewater from the BSL3 facilities, including both autoclave drains and chemical disinfectant wash waste. The liquid waste would be plumbed through a dedicated drainage system directly into the cook tanks for processing prior to discharge to the municipality sanitary system.
 - Animal waste, discarded surgery and necropsy tissues, and whole carcasses can also be decontaminated by chemical means. Alkaline hydrolysis is a process by which animal carcasses and tissues are subjected to a strong alkali, high temperature and high pressure. A tissue digester would be one example of a decontamination technology that relies on an alkaline hydrolysis process. In general, this method involves a temperature of 150°C and a pressure of 483 kPa (70 psi), with a total process time of 3-8 hours; however, the exact temperature and time required to achieve effective decontamination is dependent on factors such as the pathogen of concern, and the size/amount of the carcass/tissue to be decontaminated. Rendering is a process by which animal carcasses and tissues are subjected to high temperature and pressure. When properly processed, the final product is somewhat dry and can be sent for disposal (i.e. to landfill).

14.5.6 Biosafety

A biosafety program shall be adopted by the Project to be able to keep track of biosafety risks that may arise and measures to be taken regarding these biosafety risks. The aim of a biosafety program is to design and prevent infections and illnesses among personnel and to protect the public, the environment

and animal population from harm by preventing the inadvertent release of biological material. An effective biosafety program will promote and reinforce safe work practices, improve safety performance and increase regulatory compliance through a combination of training, documentation, inspections, evaluation, review and clear communication. The extent of the biosafety program will depend on the nature (i.e. size, structure, complexity) of the organization and the activities performed by it. The necessary elements of the biosafety program are outlined below:

- Biosafety manual
- Biosecurity plan
- Medical surveillance and evaluation program
- Training program
- Good Microbiological Practices (GMPs) and SOPs
- Emergency response planning
- Regulatory compliance

Effective management of a biosafety programme is needed to ensure the following activities:

- Commitment of top management to appropriately address and manage the risks associated with the biological agents being handled.
- Appoint the responsible people for biosafety.
- All risks related to work activities have been identified, understood and controlled to an acceptable and practical level.
- Practice and policies to control risks have been put in place and are monitored regularly to ensure continued effectiveness and relevance.
- An appropriate training framework for personnel is in place for biosafety practices and biosecurity awareness.
- The roles and responsibilities of all personnel are clearly set out and understood.
- Laboratory activities in relation to laboratory biosafety and its associated policies and procedures are compatible with national and international guidelines and regulations.
- Complex organizations such as R&D and production facilities require having biosafety personnel dedicated to ensuring that the goals of the biosafety program are met.

The main bullets of a biosafety program are as follows:

- Administrative Control: An important element in success of any biosafety program is a strong commitment and involvement by everyone within the organization, including senior management, supervisors, the biological safety officer (BSO) and individual personnel. The administrative controls implemented from the highest levels of the organizational structure (i.e. senior management) by means of policies and procedures help protect workers throughout the organization from exposure to human and animal pathogens and toxins.
- **Biosafety Policy:** A well established and integrated biosafety policy into a pre-existing health and safety policy or plan, which is specific to the organization, is encouraged. The biosafety policy covers the guiding principles and the applicable biosafety and biosecurity standards (if prepared together) (e.g. the World Bank Group's applicable EHS guidelines, WHO Laboratory Biosafety Manual, ISO standards, OECD Principles of Good Laboratory Practice, and the national regulations presented in Section 14.5 of this chapter). A policy can establish the internal accountability system with respect to pathogens, toxins and other regulated infectious material. Communication is an important aspect in the biosafety policy for all personnel in ensuring that all workers are aware and informed of their responsibilities as well as the consequences for non-compliance.
- **Purpose of Program:** The program intends to describe the planned work to be performed in a containment zone and document the scope of a facility's activities. It includes pathogens, toxins and other regulated infectious material (e.g. infected or intoxicated animals, animal products or by-

products that contain a pathogen or toxin) the facility plans to use or in use. It is considered as a good starting point for outlining the program intent. From there, the activities planned in an organisation may include *in vitro* activities with pathogens and toxins (e.g. routine diagnostic activities, scientific research, or large-scale production), and *in vivo* activities with pathogens and toxins (e.g. work with small-sized animals or large-sized animals). Where *in vivo* work with pathogens and toxins is to be performed, the program intent includes a list of all animal species that will be used. In containment zones where non-indigenous animal pathogens or emerging animal disease pathogens are handled, changes to program intent (e.g. introduction of a new pathogen or toxin or introduction of a new animal species) or to SOPs that may impact biocontainment or biosafety are submitted to the authorising authority (if available) prior to implementing the change to allow that the changes are acceptable in order to maintain containment.

- **Role and Responsibilities:** Defining and assigning roles and responsibilities for all facility personnel who may come into contact with biological materials play an important role to implement the biosafety program successfully. The personnel team will include management, scientific, technical and administrative personnel. The roles and responsibilities assigned in managing a biosafety programme are outlined below^{267,15}.
 - Senior or top management is in charge of planning and preparing policies and guidelines, as well
 as for the ongoing support of the biosafety programme. They are responsible for ensuring funding
 to support the programme and for providing oversight of the implementation and ongoing review of
 the programme components.
 - Biosafety committee is an institutional committee that shall be constituted to act as an independent review group for biosafety issues; it reports to senior management. The committee shall:
 - a. have documented working procedures,
 - b. include a representative cross-section of expertise, appropriate to the nature and scale of the activities undertaken,
 - c. ensure issues addressed are formally recorded, actions allocated, tracked and closed out effectively, and
 - d. meet at a defined and appropriate frequency and/or when otherwise required.

The defined or expected role from the committee will include:

- a. participating in the development of bio-risk policies covering biosafety, biosecurity and SOPs,
- b. approving proposals for new work or significant modifications to the potential risk associated with existing activities,
- c. reviewing and approving protocols and risk assessments for work involving biological materials, and
- d. reviewing information relating to significant accidents / incidents, data trends, associated local / organizational actions and associated communication needs.
- Biosafety officer (BSO) is a person to provide advice and guidance to personnel and management on biological safety issues. Their role and knowledge are key to developing, implementing, maintaining and continually improving a biosafety and biosecurity programme. The BSO will have sufficient training and experience so that they are competent to perform the role, and they will be allocated enough time and resources to do the job effectively.
- Laboratory personnel and support personnel are the personnel within the organization who have access to the laboratory space or to the biological materials in the facility and are responsible for supporting and contributing to a biosafety programme. Occupational health, facility management, security management and animal handling could be included in this context. Their role in this respect is described in CWA 15793 (Laboratory bio-risk management standard). The laboratory director/manager is responsible for implementing and promoting biosafety to ensure the safety of

²⁶⁷ CWA 15793:2008 Laboratory Bio-risk Management Standard

all personnel, contractors and visitors to the facility, and to protect the public and the environment from hazards arising from the work being performed in the laboratory. Laboratory and support personnel are responsible for applying biosafety in their daily activities.

- Bio-risk management advisor is a competent individual who provides advice and guidance on biorisk management. This individual shall report directly to the responsible senior manager and have delegated authority to stop work in the event that it is considered necessary to do so. This role shall be independent of those responsible for implementing the programme of work.
- Scientific management advisor is an individual with responsibility for the scientific programme within the facility and shall be designated with responsibilities relevant to biological risk management.
- Risk Assessments and Planning: Risk assessments are performed in order to identify hazards and appropriate mitigation strategies and to evaluate whether or not existing mitigation measures are sufficient with the level of risk. In biosafety or biosecurity risk assessment, it may be required to review existing inventories (including material in long-term storage) and research activities in order to develop an accurate perspective of the risks present in the organisation. A detailed present and planned activities situation survey will also be conducted to update the laboratory design, engineering and SOPs. There are many types of risk assessments related to handling biological materials. Overarching and local risk assessment (LRA) are examples. LRAs are agent-specific risk assessments and conducted to identify hazards based on the nature of biological material with which the activities will be carried out. The steps in LRA are:
 - Identify the tasks and SOPs
 - Break down tasks into steps
 - Determine potential exposure risks for each step
 - Define appropriate mitigation strategies for each risk

The comprehensive risk assessment identifies potential hazards through a systematic review of the type of biological material that is present, including the identification of personnel who are handling it, the locations where the material is handled and stored, and the activities being conducted (e.g. routine diagnostic activities, scientific research, large scale, recombinant work, animal work). A comprehensive risk assessment generates a biosafety program risk mitigation strategy, which includes the use of engineering in design and construction, operation, maintenance and administrative controls, practices and procedures, and training. The assessment includes wide-ranging activities against hazards and possible exposure or release scenarios. A comprehensive risk assessment provides a top-down view of the risks associated with the biosafety program and may be in conjunction with LRAs. A proper biological risk management plan is proactive and begins at the early phase of planning stages of facility construction and continues after operation begins. The approach also includes early public engagement and for successful risk management, this engagement will be preserved throughout the lifetime of the facility.

Risks can be evaluated by identifying the likelihood of an event occurring and the consequence of that event²⁶⁸. Risk control measures can reduce the risks to an acceptable residual risk level to allow the laboratory activities to start. Steps of risk assessment management is given in Table 14-11.

Step 1:	Step 2:	Step 3:	Step 4:	Step 5:
Gather	Evaluation of	Develop a Risk	Select And	Review Risks and Risk
Information	Risks	Control Strategy	Implement Risk	Control Measures
			Control Measures	••••••
-A low infectious dose transmitted through aerosols	-Low volume is less likely to produce aerosol	-Present set up in the laboratory is sufficient	-Ensure proper operation and training for the laboratory	-Observe the laboratory activities carried out as written in SOPs

Table 14-11: An Example of Risk Assessment Management at 3 Different Levels of Risk

²⁶⁸ Canada Biosafety Handbook, 2nd edition, 2016.

Step 1: Gather Information	Step 2: Evaluation of Risks	Step 3: Develop a Risk Control Strategy	Step 4: Select And Implement Risk Control Measures	Step 5: Review Risks and Risk Control Measures
-Performed by competent personal in a diagnostic laboratory	-Heat-fixation results in partial inactivation		activities and preparation SOPs.	-Conduct a review in the event of an incident, or changes in biological materials and SOPs
-Small volume of liquid culture	-Liquid media propagation	-Core requirements in BSL laboratories	In addition to above measures:	In addition to above measures
centrifugation to prepare cryogenic storage -Biological agent as infectious material is transmitted through aerosols	-Small sample volume with high concentration -Aerosol production is possible	-In addition, increased control measures such as safety to reduce the aerosol risk to an acceptable risk level	 Increased control measures (respiratory protective equipment, safe and secure centrifugation, biosafety cabinet) Working with Good Microbiological Practices and SOPs in competency for staff and all accident scenarios 	-Observation in following increased control measures (e.g. annual) -Perform periodic review and evaluate the effectiveness of the selected heightened control measures
-Large-scale	-Liquid media propagation	-Core requirements in BSL laboratories	In addition to above measures:	In addition to above measures
-Biological agent as infectious material is transmitted through aerosols -A competent personal working in a pharmaceutical industry	-Large sample volume with high concentration	-In addition, increased control measures such as equipment and/or facility enhancements) to reduce the risk of a potential aerosol exposure or release of high-risk pathogen to an acceptable risk -Ensuring additional laboratory safety design criteria	-Dividing the laboratory processes in relation to risk (e.g. higher risk field, ventilation, waste issues) -Ensure proper selection of processes and practices	-Frequent and routine incident exercises -Regular evaluation/training/mentorship programme for laboratory activities and/or the procedures

- Biological risk is influenced by the physical state of organisms and the specific manipulations carried out. The literature and peers' evaluation may recommend alternative or new methods supplementing or replacing high-risk activities with low-risk methods. Alternative biological risk reduction methods may include use of microvolumes, using alternative methods such as molecular biology approaches in order to avoid culture and propagation of the biological material, inactivating clinical specimens before analysis, and use of non-infectious control and production strains.
- Measuring Program Effectiveness: Management systems work in a cycle of planning, implementing, measuring and improving (or the "Plan-Do-Check-Act cycle", as described by the ISO standards where the continual improvement is indispensable). The points taken into consideration are:
 - Incident reporting and investigations
 - Records and inventories
 - Authorized persons
 - Internal inspections and audits
 - Regulatory authority requirements and reporting

14.5.7 Biosecurity

Laboratory biosecurity refers to institutional and personnel security measures designed to prevent the loss, theft, misuse, diversion or intentional release of biological agents being handled in the laboratory. Addressing laboratory biosecurity risks in many ways parallels and complements that of biosafety risk management. Effective biosafety practices are the foundation of laboratory biosecurity, and biosecurity

risk control measures must be performed as an integral part of an institution's biosafety programme management. Biosecurity policies must be established and maintained through regular vulnerability, threat and biosecurity risk assessments, and regular reviewing and updating of procedures. Checks for compliance with these procedures, with clear instructions on roles, responsibilities and remedial actions, will be integrated into a laboratory biosecurity programme. The biosecurity policies and procedures of the Project will include the following:

- Risk and threat assessments
- Facility security plans
- Physical security
- Data and electronic technology systems
- Security policies for personnel
- Policies regarding access to laboratory and animal areas
- Specimen accountability
- Receipt of agents into the laboratory
- Transfer or shipping of agents from the laboratory
- Emergency response plans
- · Reporting of incidents, unintentional injuries and security breaches

In the establishment of a laboratory biosecurity program, interdisciplinary and intra-institutional cooperation and discussions across academic and operational groups are required. The biosecurity program is also expected to include development of SOPs for storage, use and transfer, a comprehensive training program and an approach to the hiring and employment process of facilities (including the probationary period sufficient to gauge a person's ability or willingness to follow regulations)²⁶⁹

It is essential to properly assess potential biosecurity risks associated with a BSL3 facility. To achieve this, an approach similar to the biosafety risk assessment framework is undertaken, with specific focus on biosecurity to identify whether an institution possesses biological agents that may be attractive to those who may wish to use them maliciously. As with biosafety, the biosecurity risk assessment process also includes the development of a strategy to manage the biosecurity risk by selecting and implementing biosecurity risk control measures. In many cases, this can be combined with biosafety programme management, although it may need to be a stand-alone programme when the biosecurity risks identified are severe and/or numerous.

This section describes some of the key elements of a laboratory biosecurity programme, including its risk assessment framework. Detailed information on performing risk assessments can be found in the following documents:

- WHO: Laboratory Biosafety Manual and Associated Monographs: Risk Assessment (4th edition)
- WHO: Biorisk Management Laboratory Biosecurity Guidance

The biosecurity risk assessment will follow the following framework:

- Gather information: Collect information on the type of biological agents available, their physical location, the personnel required to access the laboratory premises either to handle the agents or for other reasons such as service and maintenance, and those responsible for the biological agents.
- Evaluate the risks: Assess how the information gathered relates to the likelihood of someone gaining access to the identified biological agents and the consequences of a deliberate release of those agents. Compare the two factors to establish what the overall/initial risks are.

²⁶⁹ Jonsson et al., (2014). Challenges and Practices in Building and Implementing Biosafety and Biosecurity Programs to Enable Basic and Translational Research with Select Agents. J Bioterror Biodef. Suppl 3(15): 12634

- Develop a risk control strategy: Determine the minimum-security standards required for work to be allowed to proceed with the identified biological agents (that is the acceptable risk).
- Select and implement risk control measures: Biosecurity risk control measures can include both
 procedural and physical security systems. The risk assessment will include a clear definition of the
 threats the risk control measures are designed to protect against and clarify the performance
 requirements of any physical security systems. Assessment of the suitability of personnel, securityspecific training and rigorous adherence to pathogen protection procedures are ways to enhance
 laboratory biosecurity.
- Review risks and risk control measures: The biosecurity programme will be verified through periodic exercises and drills. Likewise, the laboratory biosecurity protocol will be established to identify, report, investigate and remedy breaches in laboratory biosecurity. The involvement and roles and responsibilities of public health and security authorities in the event of a security breach must be clearly defined.

A laboratory's biosecurity program addresses the following elements to be considered successful: security (physical and information), accountability, personnel responsibility or reliability, transport control, emergency and incident response, emerging biological risks, and dual use research. The essential components of a biosecurity program are detailed below:

- Physical security control: Physical security countermeasures are used to prevent unauthorized access of outside adversaries (those who do not have a legitimate presence in the facility and have malicious intent such as criminals, terrorists and extremists/activists) and also to minimize the threat from insiders (those who have a legitimate presence in the facility such as employees and approved visitors) who do not require access to a particular asset. Physical security systems promote not only biosecurity objectives, but also directly support biosafety by limiting access to the laboratory and other potentially hazardous areas. An effective physical security system incorporates a variety of elements to enhance a facility's capability to deter, detect, assess, delay, respond to and recover from a security incident. These elements include boundaries, access controls, intrusion detection, alarm assessment and response, and they are typically graded. A graded protection system increases security incrementally and forms risk-based layers of protection around the facility's assets. The highest level of protection will be given to those assets whose loss, theft, compromise and/or unauthorized use will have the most damaging effect on national and potentially international security and/or the health and safety of employees, the public and the environment. These elements will be selected and implemented after a site-specific biosecurity risk assessment to ensure that they are all practical, sustainable and commensurate with identified risks. The following measures will be taken into consideration to ensure the adaptation of a well-managed physical security system within the Project:
 - The Project will consist of two phases with different security levels: i) Phase I includes the Administrative, R&D and Experimental Animals Production and Test Buildings and ii) Phase II includes the Production Building, Waste Building, Technical Building, Loading/Unloading Area and the recreational area.
 - In order to protect buildings/units positioned under Phase II with a higher security level, secondary security control between Phase I and Phase II will be provided through fence line.
 - A card system will be applied to provide secondary security control either for cars/trucks and workers/staff.
 - There are two different entrance-exit points dedicated for cars/pedestrians (visitor and staff/personnel) and trucks which will provide safe access and transportation inside the campus. Additionally, different entrance-exit doors in the buildings for services, transfer animals and materials are allocated in the design of Phase I.
 - To ensure the security of the Project, five observation points have been planned. This number may be increased in the final design based on the security needs.
 - In addition to the observation points, J9 type security walls will be established along the Project site borders and CCTV systems will be available.

- Single point for entrance and exit of the guests, personnel and cargo can slow down the evacuation speed in case of an emergency. Therefore, emergency exits will be planned in appropriate locations of the Project site.
- Information control: Processes and procedures must also be used to protect the confidentiality and integrity of sensitive information held in the laboratory that could be used with malicious intent. Within the scope of the biosecurity programme, it is important to identify, label and protect sensitive information against unauthorized access. Sensitive information includes research data, diagnostic results, information on animal experiments, lists of key personnel (for example, IT and biosafety contacts), security plans, access codes, passwords, storage locations and biological agent inventories. Confidential information that is protected or restricted from unauthorized or accidental access and/or dissemination and sharing sensitive information with unauthorized individuals must be strictly prohibited. The laboratory working on biological materials for R&D and production purpose requires to maintain a secure database system stored on site, which needs to be established according to ISO 27001 in compliance with 21 CFR Part 11 of FDA. Software programs, including those that will implement bar code facilitated tracking to track all biological material samples and ancillary data, would be necessary. The software in use would meet GMP, GLP and known/accepted international regulations in terms of validation and confidentiality (such as ISO 27001 and OECD GLP Guidance Document for Computerized Systems). It is important to keep in mind that this is a significant issue in biobanking which the Project will have. Additionally, the Project must have protocols in place and be able to produce documentation for the transfer and accountability of inventories when the investigator responsible for the inventory departs the entity. Finally, a software tracking program must have the flexibility to be modified as new national and international rules and guidelines are developed.
- Accountability (inventory responsibility): A well-established system of accountability is essential for maintaining biosecurity. Biological material inventories are required to provide information with regard to material identity, source, date of receipt, number of vials, and volumes for each stock held at the particular site. The inventory also facilitates tracking personnel access to each agent and is a permanent record of the addition and removal of vials from each stock. This inventory may be maintained electronically on a secured computer or server, managed by customized software. A second point of accountability is shipment and receipt records of biological materials and the corresponding SOPs detailing critical aspects of this process. The SOPs provide guidance on the process for obtaining any necessary legal permits for transfer or import/export as well as proper shipment packaging and documentation practices for those samples. All shipment tracking documentation is maintained to ensure continuity and coordination among the sender and receiver and overseeing the transfer. Importantly, shipment loss or package damage is required to be reported immediately to appropriate personnel/authorities according to SOPs. Employees working within biosafety laboratories will be trained to comprehend the reporting structure in the event of a theft, loss or release of biological material. Losses involving biological materials are reported to the top management, he/she is the responsible party for contacting the appropriate personnel/authorities according to SOPs within the earliest time.
- Personnel responsibility or reliability: The effectiveness of any procedural controls for biosecurity are ultimately determined by the training, capability, reliability and integrity of the personnel. A policy of personnel responsibility assures that workers with access to biological materials do not pose a risk of inappropriate behaviour. It ensures that daily work practices and procedures are being performed by competent appropriate personnel who behave in a reliable manner. In addition to laboratory personnel, laboratory access request and approval processes for visitors and other outside personnel must be established to ensure that there is a legitimate need for access, and that appropriate vetting and escorting procedures are followed. Laboratory biosecurity training will be provided in addition to biosafety training for all personnel according to the outcomes of the risk assessment. Such training will help personnel understand the need to protect biological agents and the rationale for the specific biosecurity measures that have been put in place. It will also include a review of relevant national standards and the institution-specific procedures. Security-related roles and responsibilities of personnel in everyday and emergency scenarios will also be defined. Not all positions present the
same level of biosecurity risk and training and requirements should be commensurate with those risks. Succession planning will be in place for management, scientific, technical and administrative personnel to ensure that critical knowledge of the safe and secure operation of the facility does not lie with just one individual in the event of unavailability or departure. Documented procedures for terminated or departing personnel must be established (such as transfer of accountability for inventories and equipment, retrieval of property belonging to the laboratory, cancellation of access). Procedures that will be incorporated when implementing personnel management programmes include establishing specifications for assessing suitability before employment, developing procedures to ensure only approved individuals are able to access at-risk biological agents, and regulating the sharing of keys, combinations, codes, key cards or passwords.

- **Transport control:** The transfer of biological agents must comply with national and international rules for packaging, marking, labelling and documentation as outlined in the WHO Laboratory Biosafety Manual (4th edition) and associated monographs. This process will be controlled to a level proportionate with the assessed biosecurity risks of the biological agent being transported to ensure proper oversight within the biosecurity programme. Procedures may include ensuring that biological agents are ordered from legitimate providers and that they reach their intended destination using approved couriers. Procedures for shipper, carrier and receiver responsibilities to ensure that biosecurity risks are controlled will be written and followed as appropriate. Transfers will be prearranged and preapproved by responsible parties and use chain of custody documentation for proper record keeping. Inventories must be updated to reflect incoming and outgoing specimens, including internal and external transfers.
- Emergency/incident response: There is a possibility that the facility may experience unintentional or intentional incidents or emergencies despite existing prevention or risk control measures. Effective incident response is a risk control strategy that can reduce the consequences of these unknown events through planning and preparation for potential incidents (such as discrepancies found in inventories, missing biological agents or unauthorized persons in the laboratory), and may help detect, communicate, assess, respond to and recover. An incident response protocol will be written and followed to ensure proper reporting, and to facilitate investigation, root-cause analysis, corrective action and process improvement. Drills and exercises can also be used in the planning and preparation stages to test the responses to simulated incidents or emergencies. They can help identify gaps and other improvement opportunities. Emergency response plans will include detailed procedures to be followed to maintain laboratory security integrity in the event of a disaster (e.g., natural disaster, fire, sabotage, infrastructure failure, biological/chemical spills, workplace violence, theft). Plans should be reviewed and updated at least annually, and the information obtained through drills, incident reports and investigations will be used to make necessary adjustments and improvements.
- Emerging biological risks: Emerging biological risks include GMOs, synthetic biology, gain-offunction research, stem cell research, gene editing and gene drives. Advances in life sciences research are inextricably linked to improvements in human, plant and animal health. Promotion of high-quality life sciences research that is conducted responsibly, safely and securely can improve global health security and contribute to economic development, evidence-informed policy-making, and public trust and confidence in science. However, countries, laboratories and scientists must also consider the risks posed by incidents and/or the potential deliberate misuse of life sciences research and select appropriate risk control measures to minimize those risks in order to conduct necessary and beneficial life sciences research. When considering the ethical issues related to life sciences in a risk assessment, no single solution or system will suit all countries, institutions or laboratories. Each country or institution that assesses the extent to which it has systems and practices in place to handle the risks posed by incidents or the potential deliberate misuse of life sciences research will need to decide which measures are most appropriate and relevant according to their own national circumstances and contexts. When dealing with such a problem, do not focus on any one particular issue or technology, but rather use one framework for which risks can be assessed and managed regardless of the technology involved.

• **Dual use research:** Awareness of the dual use of agents, equipment and technology will also be considered in the development of laboratory biosecurity programmes. The Project will take responsibility for the dual-use nature of such agents and experiments, such as genetic modification, and follow national guidelines in order to decide on the adoption of appropriate biosecurity measures to protect them from unauthorized access, loss, theft, misuse, diversion or intentional release. The potential misuse of biosciences is a global threat that requires a balanced approach to laboratory biosecurity so that legitimate access to important research and clinical materials is preserved.

A biological risk assessment template according to the WHO Laboratory Biosafety Manual, Biosafety Programme Management Monograph is given in Table 14-12.

	Step 1:	Step 2:			Step 3:	Step 4:	
	Asset identification	Risk identificati	ion and assessm	ent	Risk control	Risk acceptance	and reviewing
	Asset inventory	Risk scenarios	Likelihood	Consequences	Control measures	Vulnerability assessment	Reviewing risk management
Description	Tangible and intangible all assets in the inventory	All possible incident scenarios in relation to all the assets listed	Possibility of risk occurring if control measure is not in place.	Consider the overall consequences (ex. relevant population, the extent)	The appropriate risk control measures to minimize	Evaluation of effectiveness of the risk control measures	Review risk control measures whether the control measures are acceptable or not. If not, update with additional measures. Perform the biosecurity risk assessment routinely when there are changes and has an impact on the risk.
Examples	 information animals floor plans equipment software documented information personnel contractors 	 deliberate or accidental loss unauthorized release diversion sabotage theft espionage misuse terrorism extortion 	 very low (1) low (2) moderate (3) high (4) very high (5) 	 harm, disease or death on animals and humans financial losses negative effect on the reputation of the organization 	Personnel: • security screening • insider threat training • security barriers • access control systems • entry and exit records Emergency response: • release recovery procedure • incident reporting	 very low (1) low (2) moderate (3) high (4) very high (5) 	 acceptable or not acceptable

Table 14-12: Risk Assessment Template

Finally, to ensure a successful biosafety and biosecurity management programme, the following steps will be implemented by MoH at the national level:

- Establishing a National Biosafety Committee (NBC) and nomination of a National Biosafety Contact Point Person (NBCP) and a deputy.
- Establishing biosafety and biosecurity national policies.
- Monitoring and evaluation of the implementation of the biosafety management framework.
- Organization of biosafety and biosecurity training of trainers.
- Adaptation and development of the biosafety training package for wider group at nationwide.
- Identification, adaptation or development of a biosafety and safety laboratory assessment package.

- Conduct a national biosafety assessment using this developed package.
- Training of national biosafety officers on assessment processes using this developed package.
- Development of a national biosafety and biosecurity guideline.
- Implementation of cascade trainings on biosafety and biosecurity at subnational levels.
- Adaptation and development of comprehensive national regulations on biosafety and biosecurity.
- Adaption, development, harmonization of national SOPs for biosafety and biosecurity.
- Reviewing and ensuring appropriate IATA (International Air Transport Association) training and certification at national level.
- Development or strengthening of (national) capacity of biomedical engineers to maintain biosafety equipment.
- Development and implementation of biosafety curricula for initial and recurrent trainings.

14.5.8 Infrastructure Safety

Infrastructural safety of the Project will be ensured through the following design features:

- The BSL3 laboratories will consist of an anteroom and laboratory rooms which will have gas
 impermeable walls, ceilings and floors and will be designed for ease of maintenance and access to
 critical mechanical equipment (e.g., ventilation ducts, fans, piping). The laboratories will consist of
 high-quality room construction with special consideration given to joints, finishes and penetrations.
- All tall and/or heavy fixtures and equipment (e.g., BSCs, autoclaves, freezers, incubators) will be fitted with a seismic anchoring system/device engineered to withstand earthquake stresses equal to 7.0 on the Richter scale.
- The following will be provided in all BSL3 facilities:
 - Controlled access
 - Physical separation from access corridor
 - Personnel shower (optional depending on risk assessment)
 - Anteroom; two self-closing interlocked doors
 - Single pass air directional air flow
 - Air pressure differential (ranging from -10 to -60 Pa as per the risk assessment)
 - Exhaust system independent from remainder of the building
 - Supply system independent from remainder building
 - HEPA filtered exhaust
 - Supply exhaust fans interlocked with supply fans
 - Redundant exhaust fan (N+1)
 - Utilities backflow prevention
 - Minimum 6-12 air changes per hour
 - Autoclaves available in facility (within facility preferable)
 - Sealed windows and penetrations
 - Seamless floors
 - Monolithic ceiling
 - Chemical resistant floors walls ceiling doors and frames
 - Chemical resistant piping fixtures and casework
 - BSL3 laboratory on emergency power
 - Laboratory lighting and biosafety cabinets on emergency Inverter/UPS
 - HVAC failure alarm
 - Pressure differential monitors

- Deep sealed floor traps
- Hand wash sinks and emergency eye wash
- Surface mounted sealed lighting
- Less than 60 dB noise level
- Lighting (300-600 Lux)
- BSC shall be located out of the mainstream of traffic
- Isolation dampers in ventilation system
- In order to minimize biological risks of the facility in the event of an earthquake, seismic isolation will be applied to the three blocks to be built as production buildings of the Project. The remaining structures are designed to have raft foundations that will also be protective against seismic risks. All buildings within the main project complex area will be designed to be connected to each other through 4x4 m wide galleries to be built on the basement floor which will ease safe operational management. All structures will be designed in accordance with the Turkiye Building Earthquake Regulation²⁷⁰ published by AFAD.
- The Project will obtain electric power supply from the local distribution company and will have
 adequate emergency power supply through onsite generators. Lightning protection will be designed to
 meet electrical safety requirements. Measures to prevent electrical incidents and short-circuit will
 include design and installation of the electrical system with full electrical safety equipment such as fireresistant materials, automatic circuit breaker to protect overload and short circuit, electrical leakage
 protection, etc. Work items will be arranged to comply with the safety rules for firefighting and
 prevention system. Exposed or faulty electrical devices, such as circuit breakers, panels, cables, cords
 that can pose serious electrical risks will be continuously monitored. A technician will oversee and
 provide maintenance during operation for any electric malfunctioning.
- As recommended by the CEN documents CWA 15793 and CWA 16393, the laboratory management shall ensure that facilities, equipment and processes are designed and run in a safe and secure way with respect to biological risk management. Design of facilities and processes and the selection of equipment will consider the following:
 - validation that design, equipment and processes are consistent with biological risk assessment,
 - facilities and equipment are designed to operate and be maintained in a sustainable and efficient manner,
 - consultation of future facility stakeholders or uses, and
 - acceptance criteria for design, construction, operation and modification.
- To evaluate the safety and security of facilities, documentation for the equipment and processes will include those describing the use and function, relevant national and international standards and guidelines, drawings and specifications, operation and maintenance manuals and procedures, commissioning and decommissioning documentation, validation reports, as well as operation, maintenance, calibration and failure history.

14.5.9 Life and Fire Safety and Emergency Response

The Project will be designed to prevent the life and fire safety (L&FS) risks through the implementation of the Regulation on the Protection of Buildings from Fire²⁷¹ together with national legislation related to health and safety, labour practices, environmental legislation and other laws and regulations specific to the Project and the internationally accepted L&FS standards such as EU Directive Safety at Work and International Code Council (ICC) 2021 International Fire Code. All necessary fire detection, protection and prevention will be provisioned in the laboratories. Consideration shall be given to the fire safety strategy during the design stage, including:

²⁷⁰ Official Gazette No/Date: 30364/18.03.2018

²⁷¹ Official Gazette No/Date: 26735/12.12.2007

- The construction will meet applicable building codes and required structural, electrical and fire standards.
- Operational aspects such as equipment provision and building and engineering layouts will be provided. Fire exit route will be displayed with location of the nearest exit.
- Fire suppression will be provided by a standard wet-pipe fire sprinkler system. Waterflow alarms will
 be connected to the facility's fire alarm monitoring station so that designated responders will be
 notified. Water used for fire suppression that might become pooled on the building floor will be
 discharged from the floor drains to a retention tank system, for containment, characterization and
 disinfection as needed, prior to discharge to the sanitary sewer system.
- Wall-mounted ABC dry chemical fire extinguishers will be used and mounted according to the risk assessment for L&FS.
- Laboratory-safe refrigerators or metal flammable cabinets will be used to store flammable and combustible materials.
- The alarm system of the L&FS will contain:
 - Alarms clearly visible and audible throughout the facility above ambient noise levels (low-frequency alarms for animal facilities).
 - Alarms will be connected to the building control system and to campus public safety department.
 - Alarms will be differentiated from each other so that each can be easily identified.
 - Alarms will be on UPS power.

A L&FS Master Plan will be developed by the relevant contractor identifying major fire risks, applicable codes, standards and regulations, and mitigation measures. The master plan with regards to the facility complex shall be prepared by a suitably qualified professional, and adequately cover the issues addressed briefly in the following points:

- Fire prevention: The identification of fire risks and ignition sources, and measures needed to limit fast fire and smoke development.
- Means of exit: Includes all design measures that facilitate a safe evacuation by occupants in case of fire or other emergency.
- Detection and alarm systems: The detection and alarm/alert system for the facility staff, emergency response teams, occupants and civil defence (e.g. fire and emergency alarm systems that are both audible and visible).
- Compartmentation: All measures to prevent or slow the spread of fire and life safety subjects.
- Fire suppression and control: Includes all automatic and manual fire protection installations, such as automatic sprinkler systems, manual portable extinguishers and fire hose reels.
- Emergency response planning: Include a set of scenario-based procedures to assist staff and emergency response teams during real life emergency and training exercises. This plan will also assess local fire prevention and suppression capabilities.
- Operation and maintenance: Requires and establishes schedules for mandatory regular maintenance and testing of life and fire safety features to ensure that mechanical, electrical, and civil structures and systems are at all times in compliant with national and international regulation when in operation.
- Review and approval of L&FS master plan will be conducted by a suitably qualified and competent
 professional. S/He shall conduct the review as part of the project completion test at the time of L&FS
 systems testing and commissioning, and certify that construction of these systems has been carried
 out in accordance with the accepted design. The certification may be carried out by an accredited
 organisation according to ISO standards (45001), OSHA of Turkiye or US OSHA regulation or
 equivalent standard/ regulations. In accreditation, Turkish Accreditation Agency (TURKAK) is
 preferred.

All laboratory facilities must have good safety standards for all such non-biological hazards to make sure that necessary non-biological risk control measures are in place. Relevant authorities will be consulted where necessary. Spill kits, first-aid kits, including medical supplies such as bottled eye washes and bandages, must be available and easily accessible to personnel. These kits and materials must be checked periodically to make sure products are within their use-by dates and are in sufficient supply. Eyewash stations will also be checked regularly for correct functioning.

All incidents must be reported to the appropriate personnel, usually a laboratory supervisor, in a timely manner. A written record of accidents and incidents must be maintained, in line with national regulations where applicable. Any incident that occurs must be reported and investigated in a timely manner. Results from incident investigations must be used to update laboratory procedures and emergency response.

A specific emergency programme will be devised for BSL3/ABSL3 laboratories. National and local health authorities will actively cooperate in preparing this programme. Other emergency services, for example, fire, police and designated receiving hospitals, will also be involved. The closest hospital to the facility is Akyurt State Hospital and it provides 24-hour service. The following measures will be taken by the Project:

- Training and documentation studies for emergency situations will be carried out and emergency response teams will be formed. All these activities will generally be followed by the laboratory OHS unit.
- The BSL3/ABSL3 laboratories will establish advance coordination with local police, fire, and other emergency responders to assist community emergency responders in planning for emergencies in biological material laboratory and animal areas. Discussion would address security concerns associated with sharing of sensitive information regarding secure work areas.
- Circumstances that might require the emergency relocation of select agents to another secure location will be considered.
- Employees will be trained and will conduct exercises of the emergency response plan at least annually.
- The laboratories within the Project will develop laboratory emergency plans and integrate with facility-wide emergency plans. These plans would include adverse event assessments such as laboratory and animal facility accidents, bomb threats, floods, earthquakes, power outages and other natural or man-made disasters. The laboratory would include the BSL3 and ABL3 administrators, scientific directors, principal investigators, laboratory workers, maintenance and engineering support staff, facility safety officers, and facility security officials in emergency planning. Provisions will be included in emergency plans for immediate notification of and response by laboratory directors, laboratory workers, safety office personnel or other knowledgeable persons when an emergency occurs. Key procedures to be developed will include the following among others:
 - Administration (e.g., policy, purpose, distribution, definitions)
 - Organization of emergency areas (e.g., command centres, medical stations)
 - Roles and responsibilities
 - Communication systems
 - Emergency response procedures
 - Emergency resources
 - Training and updating
 - Checklists
 - Business continuity and contingency
- A protocol for emergency evacuation will be deployed at all Project components as part of emergency response procedures. A specific focus shall be given to the kindergarten as the users of the kindergarten will be children who are considered to be a high risk group.

Additionally, an Emergency Preparedness and Response Plan, incorporated into and consistent with the facility's overall OHS will cover the following:

- Planning coordination: Procedures would be prepared for:
 - Informing the public and emergency response agencies,
 - Documenting first aid and emergency medical treatment,
 - Taking emergency response actions, and
 - Reviewing and updating the emergency response plan to reflect changes and ensuring that employees are informed of such changes.
- Emergency equipment: Procedures would be prepared for using, inspecting, testing and maintaining the emergency response equipment.
- Training:
 - Employees would be trained on emergency response procedures.
 - Include emergency response training details in the comprehensive site work plan.
 - Ensure that PPEs and other equipment for emergency response in the emergency response plan are identified.
 - Site-specific emergency response procedures would be shared to relevant personnel.
 - Regular training would be provided to employees as part of the overall training program for site operations.
- In the development of the plan, the following items will be considered:
 - Identification of high-risk organisms,
 - Location of high-risk areas (e.g., laboratories, storage areas, animal facilities),
 - Identification of at-risk personnel and populations,
 - Identification of responsible personnel and their duties (e.g., biosafety officer, safety personnel, local health authority, clinicians, microbiologists, veterinarians, epidemiologists, and fire and police services),
 - Lists of treatment and isolation facilities that can receive exposed or infected persons,
 - Transport of exposed or infected persons,
 - Lists of sources of immune serum, vaccines, drugs, special equipment and supplies, and
 - Provision of emergency equipment (e.g., protective clothing, disinfectants, chemical and biological spill kits, decontamination equipment and supplies).

14.5.10 Life and Fire Safety at the Kindergarten Facility

The Project will prepare and implement a Life and Fire Safety Plan for the proposed kindergarten facility for laboratory staff's children, addressing life and fire safety risks including how to respond to fire and other emergencies such as a pathogen release associated with the Project. A summary of the life and fire safety systems and measures required for the kindergarten facility is provided in this section. Please refer to the Annex A of the Community Health and Safety Management Plan developed for the operation phase of the Project for details on additional life and fire safety measures to be taken at the facility.

The kindergarten facility will be designed in line with the following life and fire safety requirements:

- Life and fire safety design and operation criteria for the kindergarten building should incorporate national building codes and fire department regulations and be complemented with international standards including the NFPA where necessary.
- All life and fire safety design elements shall be compliant with NFPA 101: Life Safety Code.
- Minimum design requirements for the kindergarten building shall comply with building construction types specified in section 16.1.6 of the NFPA 101.

- The building occupancy requirements defined by the NFPA for daycares and educational facilities will be applied. According to NFPA 101, the occupant load factor for day-care use is one person for every 3.3 square meters.
- The kindergarten building will be equipped with fire detection and suppression equipment to protect life and property from fire. These will include automatic fire sprinkler systems, fire extinguishers, smoke and fire detection systems, evacuation alarms, and a central monitoring service.
- Pre-designated external assembly points and emergency access routes will be provided for the kindergarten building within the recreational area.
- Hazardous areas include those rooms or spaces such as boiler and furnace rooms, hazardous
 materials storage, janitor closets, laundry rooms and maintenance spaces. These areas are required
 to be separated from the other parts of the building by a minimum of a 1-hour fire resistance rating and
 be protected by a fire sprinkler or other fire suppression system.
- Interior finish of the building will be in accordance with section 10.2 of NFPA 101. Interior wall and ceiling finish materials shall be Class A in stairways, corridors, and lobbies; in all other occupied areas, interior wall and ceiling finish shall be Class A or Class B. Interior floor finish shall be Class I or Class II within all corridors and exits.
- Special protective covers for all electrical receptacles shall be installed in all occupied areas. Any heating equipment in spaces occupied by children shall be provided with partitions, screens or other means to protect children under six years of age from hot surfaces and open flames.
- The kindergarten facility shall be equipped with a fire detection and alarm system in accordance with section 9.6 of the NFPA 101: Life Safety Code. The fire detection and alarm system of the building will be designed to include the following features:
 - Initiation of the required fire alarm system shall be by manual means and by operation of any required smoke detectors, and required sprinkler systems.
 - Occupant notification shall be by means of audible and visible alarm.
 - Fire department notification shall be provided.
 - A smoke detection system shall be installed in multi-room daycare centres, with placement of detectors on each story in front of doors to the stairway and in the corridors of all floors. Detectors also shall be installed in lounges, recreation areas and all sleeping rooms.
- Automatic sprinklers and other extinguishing equipment to be installed at the kindergarten facility shall comply with section 9.7 of the NFPA 101: Life Safety Code. Fire extinguishers are required to be installed throughout the facility, which should be selected, installed and maintained in accordance with the guidance provided in NFPA standards for portable fire extinguishers.
- Since the building will be protected throughout by an approved, supervised automatic sprinkler system, corridor walls shall not be required to be rated for fire resistance, provided that such walls form smoke partitions in accordance with section 8.4 of the NFPA 101.
- The kindergarten building shall be equipped with adequate means of egress to enable evacuation by staff and occupants in case of fire or other emergency. All means of egress shall be designed in accordance with both chapter 7 and section 16.2 of NFPA 101: Life Safety Code. Means of egress will be designed to comply with the following minimum requirements:
 - A minimum of two exits shall be provided for every story of the building. Exits should be accessible from every part of every story and mezzanine. Discharge from exits shall be arranged in accordance with NFPA 101.
 - Components of means of egress for day-care facilities may include doors, stairs, smokeproof enclosures, ramps, horizontal exits, exit passageways, fire escape ladders, alternating tread devices and areas of refuge.
 - The exit doors shall be designed in compliance with NFPA 101 and be able to be opened readily any time the building is occupied. If locks are provided, they should not require the use of a key, tool or special knowledge or operation from the side of egress.

- Any exit door from an area having an occupant load of 100 or more persons may be provided with a latch/lock if it is panic hardware or fire exit hardware. Special locking arrangements may include delayed-egress locking systems and access-controlled egress door assemblies.
- Closet door latches and door latches to storage areas, kitchens and other similar spaces will be such that children can open the door from inside the space. No door locking mechanism can be installed.
- Because the facility serves children, every bathroom door lock will be designed to allow opening of the locked door from the outside by the staff.
- Any room without fire sprinklers or a door leading directly to the outside, must be furnished with an
 outside window that meets the specifications of NFPA for an emergency rescue must be provided.
- To allow occupants to finish exiting the area in a safe and efficient manner, travel distances specified in NFPA 101 should be allowed for. Dead-end corridors should not exceed 15 m and common path of travel should not exceed 30 m, provided that the building is protected throughout by an approved and supervised automatic sprinkler system. Distance between any point in a sleeping room and an exit access should not exceed 30 m.
- All means of egress shall have exit signs compliant with NFPA 101.
- Emergency lighting will be provided in interior stairs, corridors and limited access portions of the building. Emergency lighting systems will be arranged to provide the required illumination automatically in the event of any power outage, to allow building occupants to exit quickly and safely during evacuation.
- The exit access corridors will be illuminated continuously.

The LF&S Plan to be developed for the kindergarten will cover the following:

- Building occupancy requirements defined by the NFPA 101: Life Safety Code. The number of building occupants will not be allowed to exceed the maximum occupant load at any one time.
- A list of major fire hazards associated with the normal use and occupancy of the building, including maintenance and housekeeping procedures.
- Floor plan drawings showing the locations of exits, primary evacuation routes, secondary evacuation routes, accessible egress routes, areas of refuge (if any), areas for assisted rescue, manual fire alarm boxes, portable fire extinguishers, fire alarm annunciators and controls.
- Site plans showing the occupancy assembly point and the normal routes of fire department vehicle access.
- Specific roles and responsibilities of staff related to emergency preparedness and response at the kindergarten as well as relevant training requirements.
- The preferred and any alternative means of reporting fires and other emergencies to the fire department or other designated emergency response organizations.
- Specific life and fire safety management requirements and procedures for daycare facilities.
- Life and fire emergency response and evacuation procedures, including specific measures and procedures to be implemented in case of a pathogen release or disease outbreak (e.g. wearing a face covering when inside the building and continue to wear it outside in the designated evacuation area).
- Specific strategies to be developed for protection and evacuation of children, including procedures for assisted rescue for children.
- Monitoring and maintenance requirements for ensuring kindergarten life and fire safety.

All occupants of the kindergarten facility including teaching personnel, staff and students need to be aware of the emergency procedures and be able to take necessary actions in the event of an emergency, including responding to the building fire alarms and promptly evacuating the building. The following measures will need to be implemented to ensure effective life and fire emergency response at the facility:

- In the event of an emergency, it is critical that emergency responders are able to easily access the building and emergency equipment. Pre-designated emergency access routes provided for the kindergarten building may not be blocked at any time.
- Occupants must be able to exit the facility quickly and efficiently in an emergency situation that requires evacuation. The exit access (the pathway leading to an exit door) must be properly maintained to be accessible and unobstructed at all times.
- All emergency equipment including fire suppression systems, fire alarms and lighting installed to illuminate exit access pathways, exit doors and exit discharge areas must be checked and inspected periodically for operability.
- An emergency kit with goggles and surgical masks should be kept available at all times to be provided to occupants in the event of a pathogen release event or communicable disease outbreak.
- In cases where a lockdown is required, a method of notifying the building occupants of the lockdown should also be available, which will be separate and distinct from the fire alarm signal.

In the event of an emergency requiring evacuation or when the building fire alarm system is activated, the following steps should be followed:

- Upon hearing the fire alarm, the occupants must evacuate the building immediately and in an orderly manner, taking only personal belongings that are easily accessible.
- Designated teachers and staff should follow the procedures for assisted evacuation of all children.
- Extinguishment of fire should be attempted only if safe to do so and only by staff properly trained in the use of portable fire extinguishers.
- The last occupant to leave a room should close the doors leading to the exit corridor and exits. Elevators will not be used.
- Any equipment or devices that should not be left unattended will be shut down, only if it does not compromise any person's safety.
- Persons with mobility disabilities should evacuate if able, report to an area of refuge (if available) or stay in place for assisted rescue. People with speech impairment should carry a whistle or have other means of attracting attention.
- All occupants must proceed to the nearest designated assembly point.
- After evacuation is completed, procedures for accounting for employees and occupants should be implemented. It should also be ensured that any visitors are safely evacuated from the building.

Regular operation, monitoring and maintenance of the building and the fire and life safety systems will involve the following:

- Regular maintenance and testing of life and fire safety features will be undertaken to ensure that mechanical, electrical and civil structures and systems are at all times in conformance with design criteria and required operational readiness.
- Emergency drills will be conducted at monthly intervals and will include all occupants of the facility including children. Children should be aware of necessity to follow directions of their instructors, evacuation leaders and fire representatives in case of emergencies.
- Fire prevention inspections shall be conducted monthly by a trained senior member of the staff. A copy of the latest inspection shall be posted in a conspicuous place in the facility.
- Adequate staff shall be on duty and alert in the facility at all times when children are present.
- Staff will be on the lookout for fire and life safety hazards, exits that are blocked, doors that are in disrepair, any issues with fire alarm or fire sprinkler components, electrical hazards and any issues that are not in compliance with NFPA and legal requirements.
- If the building is protected by fire sprinklers, up to 50% of the wall area can be covered with children's artwork and teaching materials.

14.6 Compliance with National and International Requirements

14.6.1 National Requirements

As a result of an increase in research and commercial activities in biotechnology along with the progress of membership negotiations with the European Union, Turkiye has established several regulations having biosafety provisions. However, there is no specific biosafety and biosecurity legislation on high BSL laboratories. Moreover, although the words safety and security exist separately in Turkish, Turkiye is lacking the clear expression of exact meanings of the words safety and security in the national legislation.

The related Turkish legislation has been examined with respect to biological risk management, biosafety, laboratory safety, and the references are summarized below.

Legislation of the Ministry of Agriculture and Forestry

Although the MoAF has enacted a Biosecurity Law, the law aims to ensure food safety rather than biosecurity. It is stated that food safety will be achieved by providing biosafety processes from the production process to the table.

- Biosecurity Law²⁷²
 - In 2009, MoAF finalized the law which was approved by the parliament in 2010. The law does not cover medical or cosmetic products that are approved by the MoH, however, bans the production and release of any GMOs.

Legislation of Ministry of Health

The MoH has not passed a law regulating biosafety and biosecurity. Regulation on Working Procedures and Principles of Laboratories for Public Health Services, Regulation on Infectious Diagnosis and Clinical Sample Transport with Infectious Substances and Regulation on Medical Laboratories have biosafety measures at various levels, but there is no reference to biosecurity.

- The Law on Ordinary Bacteriology and Chemistry Laboratories Which Perform Serial Evaluation and Analysis and Seek Mass Customs²⁷³
 - In 1927, pursuant to the law it was decided to close the laboratories opened without any permission obtained from the ministry.
- Regulation on Medical Laboratories²⁷⁴
 - The authority of the MoH was defined with the statement "In publicly owned institutions/ organizations, the ministry may allow the establishment of supervised service laboratories, and the tests determined by the Ministry are carried out in those laboratories". It is stipulated that the permission to be a reference laboratory on a test basis can be given with the permission of the MoH in line with the principles determined by the MoH.
 - The regulation does not refer to any international standard in terms of quality, but it refers to the standards of the MoH in the statement "Laboratories provide service in accordance with the quality standards published by the ministry".
 - The regulation does not impose restrictions on the storage of samples by public and private laboratories. This means that public or private laboratories are allowed to hold as many samples as they require. This is considered as a concern from the biosafety point of view since it makes it easier for samples to be reached and targeted by bioterrorists.
 - The statement "The doors of the medical laboratory technical areas should be automatic sliding doors or doors that can be opened outwards in an emergency so as not to hinder the exit.

²⁷² Official Gazette Date/Number: 08.03.2010/27533

²⁷³ Official Gazette Date/Number: 30.03.1927/580

²⁷⁴ Official Gazette Date/Number: 09.10.2013/28790

Arrangements are made to prevent unauthorized persons from entering the medical laboratory" is the only clause describing biosafety measures.

- The biosafety level of the medical laboratory is requested to be at least in accordance with the "physical protection level 2" conditions in the TS EN 12128 standard. According to international regulations, medical laboratories working with microorganisms in the risk group 3 or 4 list, respectively, must comply with the conditions of "physical protection level 3" or "physical protection level 4". Although this requirement refers to laboratory biosafety, detailed provisions on biosecurity, biosafety and laboratory safety are not available.
- It is stated that, the management of medical wastes belonging to the medical laboratory should be performed in accordance with the Regulation on Control of Medical Wastes²⁷⁵.
- Regulation on the Working Procedures and Principles of Laboratories for Public Health Services²⁷⁶
 - The definition of Non-Clinical Laboratory Unit is given as "It makes physical, chemical, biological, microbiological, toxicological and similar non-clinical analyses of physical/biological/environmental factors affecting human health in determined non-clinical samples, within the planning and permission of the General Directorate". The "Sampling Handbook" has been prepared by the MoH General Directorate of Public Health, and the necessary information and procedures regarding compliance with biosafety rules have been included in this guide.
- Regulation on Infectious Diagnosis and Clinical Sample Transport with Infectious Substances²⁷⁷
 - Sets out rules explaining the transport activities of infectious substances, diagnostic samples and clinical samples by air, sea, rail or road, together with responsibilities of senders, receivers, packers, carriers and characteristics of the packages. Within the regulation stating that only licensed medical laboratories are authorized to send samples for examination purposes abroad, the entry and exit of human-sourced biological samples into Turkiye for examination purposes are subject to the approval of the MoH.

Legislation of the Ministry of Transport and Infrastructure

The requirements of the European Agreement on the International Carriage of Dangerous Goods by Road (ADR), the International Directive on the Carriage of Dangerous Goods by Air (IATA-DGR), the European Agreement on the Carriage of Dangerous Goods by Rail (RID) and the European Agreement on the Carriage of Dangerous Goods by Sea are enacted in Turkish legislation with,

- The Regulation on the Transport of Dangerous Goods by Road²⁷⁸
- The Regulation on the Transport of Dangerous Goods by Air²⁷⁹
- The Regulation on the Transport of Dangerous Goods by Rail²⁸⁰
- The Regulation on Carrying of Dangerous Loads by Sea and Loading Safety²⁸¹, respectively.

In the European Agreements on the Carriage of Dangerous Goods, the title of Class 6.2 covers infectious substances as substances that are known or reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, parasites, fungi) and other substances such as prions that can cause disease in humans or animals. Class 6.2 substances are subdivided as follows: I1 Infectious substances affecting humans, I2 Infectious substances affecting only animals, I3 Clinical waste, I4 Biological substances. The regulations in the Turkish legislation follow the Agreements and require the

²⁷⁵ Official Gazette Date/Number: 25.01.2017/29959

²⁷⁶ Official Gazette Date/Number:09.03.2019/30709

²⁷⁷ Official Gazette Date/Number: 25.09.2010/27710

²⁷⁸ Official Gazette Date/Number: 18.06.2022/31870

²⁷⁹ Official Gazette Date/Number: 13.04.2018/30390

²⁸⁰ Official Gazette Date/Number: 16.07.2015/29418

²⁸¹Official Gazette Date/Number: 14.11.2021/31659

transport of dangerous substances in a controlled and safe manner, without harming human health and with the least negative impact on the environment.

Legislation of the Ministry of Labour and Social Security

The Ministry of Labour and Social Security has introduced laws and regulations to ensure occupational health and safety which include rules to be followed on biosafety as described below. Additional legislation outlining obligations in regard to general OHS aspects are provided in *Chapter 16: Labour and Working Conditions*.

- Regulation on the Prevention of Risks of Exposure to Biological Factors²⁸²
 - Biological agents are classified in this Regulation according to the infection risk level as indicated below:
 - Group 1 biological agents: Biological agents that are not likely to cause disease in humans.
 - Group 2 biological agents: Biological agents that can cause human disease, harm employees, but are not likely to spread to the community, and generally have effective prevention or treatment.
 - Group 3 biological agents: Biological factors that cause severe human diseases, pose a serious danger to workers, have a risk of spreading to the community, but generally have effective prevention or treatment.
 - Group 4 biological factors: Biological factors that cause severe diseases in humans, pose a serious danger to employees, have a high risk of spreading to society, but do not have effective prevention and treatment methods.
 - In any study where there is a risk of exposure to substance and biological agents, the type, level and duration of the worker's exposure are determined in order to assess any risk to the worker's health and safety and to determine the precautions to be taken.
 - With the regulation, working processes and technical control measures are regulated in such a way
 as to prevent the spread of biological agents to the environment or to ensure that they are present
 in the environment at a minimum level.
 - Collective protection measures are taken, or personal protection methods are applied in cases where exposure cannot be prevented by other means.
 - The safe collection, storage and removal of biological wastes from the workplace by employees after appropriate processes are carried out by appropriate methods, including the use of safe and special containers.
 - With the regulation, it is obligatory to make an emergency action plan in order to protect the employees from exposure that will occur as a result of the disappearance of the physical protection of biological agents in group 3 or group 4. In laboratories where studies with group 2, group 3 and group 4 biological agents are carried out for research, development, teaching or diagnosis purposes, the regulation requires that the biological, personal and laboratory safety specified in the regulation be taken to minimize the risk of infection.

Legislation of the Ministry of Environment, Urbanization and Climate Change

The Environmental Law No. 2872²⁸³ is Turkiye's primary framework for environmental legislation and is supported by a series of laws, regulations and communiques. It lays out the main responsibilities and requirements of the institutional authorities and the businesses regarding protection and preservation of the environment. The key regulations under the Environmental Law relevant to community health and safety include the following:

²⁸² Official Gazette Date/Number:15.06.2013/28678

²⁸³ Official Gazette Date/Number: 11.08.1983/18132

- Medical Waste Control Regulation²⁸⁴
 - It is prohibited to directly or indirectly discharge medical wastes to the receiving environment in a way that harms the environment and human health.
 - Persons, institutions and organizations responsible for the management of medical wastes are obliged to take the necessary measures to reduce the harmful effects of these wastes on the environment and human health.
 - Wastes with sharp and penetrating properties, apart from other medical wastes will be collected in boxes or containers made of plastic or laminated cardboard with the same characteristics, indicating that it is a sharps medical waste. Sharp-piercing waste containers cannot be compressed, opened, emptied or recovered after they are full.
 - Medical waste bags should be kept in a medical waste container or bucket during storage. The medical waste container or bucket must be made of orange colour plastic material that is resistant to puncture, tear, breakage and explosion, waterproof and leakproof, bearing the "International Biohazard" emblem and the medical waste inscription.
 - The regulation has made it mandatory to document that sterilization systems comply with national and/or internationally accepted standards in terms of mechanical safety (high cabin pressure, resistance to temperature, etc.) and sterilization performance.
 - Biological indicators are used at least once a week for sterilization of infectious waste. As a result
 of the detection of microbial growth as a result of the biological indicator, the system should be
 stopped and maintenance should be provided by the manufacturer, distributor company or
 authorized service of the device.
- Regulation on Environmental Impact Assessment (EIA)²⁸⁵
 - EIA regulation is largely in line with the EU Directive on the assessment of the effects of certain public and private projects on the environment (2011/92/EU), including relevant key steps such as monitoring, public consultation, scoping, disclosure and auditing. The EIA Regulation divides projects into two categories: (i) Annex-I Projects; projects that have significant potential impacts and require an EIA and (ii) Annex-II Projects, those that are likely to have significant impacts on the environment and subject to screening.
 - In order to assess the national EIA requirements applicable to the proposed Project, the official view of the MoEUCC was requested by the MoH on 10 August 2020. In their response letter dated 13 August 2020, MoEUCC stated that production of pharmaceutical product active substances is addressed under the Annex-I of the EIA Regulation "article 35 facilities where active substances of agricultural pesticides and/or pharmaceutical products are produced", and production of pharmaceutical products/medicines is addressed under the Annex-II of the EIA Regulation "article 4a facilities where agricultural pesticides and pharmaceutical products (excluding vaccine and serum production) and plant growth regulators are produced". Since it was reported that production of active substances of pharmaceutical products will not be undertaken by MoH within the scope of the Project, it does not fall under the Annex-I of the regulation. As the Annex-II explicitly excludes vaccine and serum production, the Project does not fall under the Annex-II of the regulation either. Therefore, the Project is "exempted" under the EIA Regulation. .
- Regulation on Prevention and Mitigation of Major Industrial Accidents²⁸⁶
 - The regulation is in line with the relevant EU directive (Directive 2012/18/EU) and applies to lower and higher tier establishments where hazardous substances are present or likely to be generated as a result of an accident, in quantities equal to or in excess of the quantities listed in Annex-1.

²⁸⁴ Official Gazette Date/Number: 25.01.2017/29959

²⁸⁵ Official Gazette Date/Number: 29.07.2022/31907

²⁸⁶ Official Gazette Date/Number: 30.12.2013/28867

- The operator takes all measures necessary to prevent major accidents and to limit their consequences for human health and the environment. The legally required measures include preparation of emergency plans, safety reporting, and major accident prevention policy.
- Regulation on Fire Protection of Buildings²⁸⁷
 - This regulation sets out the procedures and principles to protect any building, workplace, facility
 etc. against fire. Facilities employing more than 30 employees is required to obtain a Fire Safety
 Report which proves that the precautions taken against fire in the workplace are sufficient.

14.6.2 International Requirements

This section provides an overview of the international regulatory framework and applicable standards for the Project, which include international requirements including the Environmental and Social Framework of the World Bank and relevant European Union (EU) directives.

As there is no established legislation for BSL laboratories in Turkiye, internationally established standards and guidelines (CDC's Office of Safety, Health and Environment, National Institute of Health, World Health Organization's Centre for Applied Biosafety, etc.) are being used and followed in Turkiye.

Therefore, the MoH will ensure that the Project will be operated in compliance with the GMP (Good Manufacturing Practice) requirements of WHO. WHO guidelines (i.e. WHO Laboratory Biosafety Manual, 4th edition) define specific requirements with respect to ventilation hygiene and clean room standards. The laboratories will be certified in accordance with WHO guidelines by a third party and therefore, the design, construction and operation of the laboratories will follow these requirements. While national regulations are being considered to be in line with the WHO standards, the Project will be governed by the WHO standards which are currently more stringent and thus will be applied.

With respect to the certification of BSL laboratories, the Project will majorly refer to the international standards, guidelines and regulations listed below, but not limited to:

- WHO Laboratory Biosafety Manual, 3rd edition, 2004 and 4th edition, 2020,
- CWA 15793:2008 Laboratory Biorisk Management Standard
- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th edition, 2020,
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019,
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006.

Detailed information and lists of international standards and guidelines are provided in below subsections.

International Standards and Directives

There are various international standards available that can be applied for containment laboratory planning, construction, operation and safety. These standards originate from different organizations/committees including, but not limited to, International Organization for Standardization, European Committee for Standardization and United Nations.

The international standards that will be followed during the Project activities are described in Table 14-13.

²⁸⁷ Official gazette date/no: 19.12.2007/26735

Table 14-13: International Standards to be followed by the Project

Standard	Scope
European Standard EN 12128: Biotechnology-Laboratories for research development and analysis, containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements addresses the physical containment elements of the microbiology laboratory	Specifies minimum physical requirements for biological safety for laboratories at four reference physical containment levels which are appropriate for handling microorganisms of different risk groups. This European Standard primarily addresses the containment of microorganisms which can present a risk to human health. It applies to microbiology laboratories where the handling of microorganisms in bacteriology, mycology, virology, parasitology and/or genetic modification is carried out.
European Committee for Standardization - (CEN)/CR 12739: Biotechnology - Laboratories for research, development and analysis - Report on the selection of equipment needed for biotechnology laboratories according to the degree of hazard,	Describes the principles which guide the selection of equipment to be used in a biotechnology laboratory.
CEN/CWA 15793 Laboratory Bio Risk Management Standard	Bio-risk management standard that addresses bio-risk holistically, and is directly applicable for controlling hazardous biological agents and toxins in the laboratory.
CEN/CWA 16393	Guidelines for the implementation of CWA 15793:2008
DIN 1946 Ventilation and Air Conditioning DIN EN 1886 Ventilation for Buildings – Air Handling Units – Mechanical Performance EUROVENT Certification (third party product performance certification for Heat Ventilation Air Conditioning and	Set standards for requirements regarding air conditioning system, ventilation for buildings, heat ventilation, refrigeration strength and leakage of circular sheet metal ducts.
EN 12237:2003 Ventilation for Buildings. Ductwork. Strength and Leakage of Circular Sheet Metal Duct	
ISO 35001: 2009 Bio-risk Management for Laboratories	Defines a process to identify, assess, control and monitor the risks associated with hazardous biological materials
Standards of Accreditation in Health – Laboratory Kit (National Standard)	"SAS Laboratory Kit" which enlightens "Turkiye Accreditation in Health System". This set was developed for laboratories consists of two parts including standards, assessment criteria and guidelines.
TS 12124 EN ISO 14644 Clean Rooms and Related Controlled Environments	Clean room certification: Identification of clean room class, HEPA filter system sealing, air flow, number of air change, room pressure difference, room temperature and humidity, room sound level tests
TS EN 12128: 2002: Bio-Technology Research- Development and Analysis Laboratories - Safety levels, risk areas, locations and physical safety rules for micro-biology laboratories	This standard is structured on ISO 3864 (Safety colours and signs), ISO 7000 (Graphical symbols for use on equipment), ISO 8995 (Principles of visual ergonomics-The lightning of indoor work systems)
	Sets standards on containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements.
TS EN 12469 Biotechnology – Performance Criteria regarding Microbiological Safety Cabinets NSF/ANSI 49: Biosafety Cabinetry: Design, Construction,	Sets standards for certification of biological safety cabinets.
Performance and Field Certification	
IS EN 12347 Biotechnology-Performance Criteria for Steam Sterilizators and Autoclaves	Sets standards for autoclave performance qualification for first and periodic inspection.
TS EN ISO 17665-1	
TS EN ISO 17665-2	
TS EN 285	
TS EN 13060	
Prevention of Biologic Factors Exposures Regulation (In compliance with European Union: Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work)	Regulates the minimum provisions regarding the prevention and protection of health and safety risks that may arise or may arise from the exposure of employees to biological factors in the workplace.

Standard	Scope
ANSI Z9.14: Testing and performance verification methodologies for ventilation systems for BSL3 & ABSL3 facilities	In testing and performance verification methodologies for ventilation systems for BSL3 & ABSL3 facilities
ISO 20387: Biotechnology-Biobanking-General requirements for biobanking	This standard defines general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data collections of appropriate quality.
ISO/TS 20388: Biotechnology-Biobanking- Requirements for animal biological material	It defines requirements for the collection, reception, preparation, preservation, transport, storage, distribution, destruction and disposal of biological materials obtained from animals, excluding humans.
EN ISO 11138-1:2017	Sets standards for sterilization of health care products.
ISO 11140-1:2014	Sterilization of health care products-Chemical indicators — Part 1: General requirements
ISO 35001: 2009 Bio-risk Management for Laboratories	Defines a process to identify, assess, control and monitor the risks associated with hazardous biological materials
ISO 45001: Occupational health and safety management systems	It is a global management system for occupational health and safety. It provides guidance on how to develop an effective approach to managing workplace health and safety in any company or organization that employs people.
ISO/IEC 27001: Information Security Management	Mandates requirements that define how to implement, monitor, maintain and continually improve the ISMS. It also prescribes a set of best practices that include documentation requirements, divisions of responsibility, availability, access control, security, auditing, and corrective and preventive measures.
UN Model Regulations on the Transport of Dangerous Goods, 2021	Provide guidance on the transport of dangerous goods by all modes of transport except by bulk tanker.

The EU directives that are applicable to the Project activities are listed in Table 14-14.

Table 14-14: Applicable EU Directives

EU Directive	Date	No
Waste Management and Clean Technology		
Waste Framework Directive	19.11.2008	2008/98/EC
Safety at Work		
Introduction of measures to encourage improvements in the safety and health of workers at work	12.06.1989	89/391/EEC
Minimum health and safety requirements for the use by workers of personal protective equipment at the workplace	30.11.1989	89/656/EEC
Minimum safety and health requirements for the workplace	30.11.1989	89/654/EEC
Prevention from sharp injuries in the hospital and healthcare sector	10.10.2010	2010/32/EU
Protection of workers from risks related to exposure to biological agents at work	18.09.2000	2000/54/EC
The inland transport of dangerous goods	24.09.2008	2008/68/EC
The Transport of Dangerous Goods by Road	21.11.1994	94/55/EC
The Transport of Dangerous Goods by Rail	23.07.1996	96/49/EC
The control of major-accident hazards involving dangerous substances	24.07.2012	2012/18/EU
Biosafety		
Community code relating to medicinal products for human use	06.11.2001	2001/83/EC
Quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components	27.01.2003	2002/98/EC
Quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells	31.03.2004	2004/23/EC

EU Directive	Date	No
Protection of animals used for scientific purposes	22.09.2010	2010/63/EU
Monitoring of zoonoses and zoonotic agents	17.11.2003	2003/99/EC
Community code relating to medicinal products for human use	06.11.2001	2001/83/EC
Laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use	8.11.2003	2003/94/EC
Laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products	8.04.2005	2005/28/EC
The Contained Use of Genetically Modified Microorganisms Regulation	06.05.2009	2009/41/EC

International Guidelines

The international documents of the World Bank, World Health Organization (WHO) and other relevant institutions that are mentioned in this sub-section have been taken into account during the ESIA process covering laboratory activities in R&D and production and biobanking with biosafety and biosecurity aspects.

WBG Guidelines

The World Bank Guidelines that have been and will be taken into account during the Project are listed below:

- The World Bank's Environmental and Social Framework (ESF), 2017
 - ESS 1: Assessment and Management of Environmental and Social Risks and Impacts
 - ESS2: Labor and Working Conditions
 - EES 4: Community Health and Safety
 - ESS 10: Stakeholder Engagement and Information Disclosure
- The World Bank Group's Environment, Health and Safety (EHS) General Guidelines, 2007
- The World Bank Group's EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing, 2007
- The World Bank Group's EHS Guidelines for Healthcare Facilities, 2007

WHO Guidelines

The WHO publishes the Laboratory Biosafety Manual to encourage countries to accept and implement basic concepts in biological risk management and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. The Project will ensure that the operation phase will be in compliance with the assigned biosafety level and that appropriate practices and procedures are observed by the WHO. The International Health Regulations (IHRs) represents an obligation for all WHO Member States to work together for global health security. The IHRs have a purpose to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade. WHO guidelines that will be taken into account during the Project lifecycle are listed below:

- WHO The International Health Regulations (2005),
- WHO Biorisk Management: Laboratory Biosecurity Guidance (2006),
- WHO Laboratory Biosafety Manual and Associated Monographs (4th Edition, 2020),
- WHO On Implementing Regulatory Requirements for Biosafety and Biosecurity in Biomedical Laboratories A Stepwise Approach (2020),
- WHO Good Manufacturing Practices for Biological Products, Annex 2 (2016),
- WHO White Paper-Establishing Manufacturing Capabilities for Human Vaccines (2017), and

• WHO Guidance on regulations for the Transport of Infectious Substances (2021).

OECD Guidelines

OECD Good Laboratory Practices Guidance documents are beneficial in routine laboratory data management, recording with data security during its life cycle:

- No 1: OECD Principles on Good Laboratory Practice
- No 17: Application of GLP Principles to Computerised Systems
- No. 22: GLP Data Integrity

U.S. Food and Drug Administration (FDA) Guidelines

- FDA Vaccine and Related Biological Product Guidances,
- FDA Chemistry, Manufacturing, and Controls (CMC) and Current Good Manufacturing Practice (CGMP) Guidances,
- FDA Development and Licensure of Vaccines to Prevent COVID-19, Guidance for Industry (2020),
- 21 Code of Federal Regulations (CFR) Food and Drugs:
 - 21 CFR Part 11: Electronic Records; Electronic Signatures
 - 21 CFR Part 200: General (Drugs)
 - 21 CFR Part 210: Current Good Manufacturing Practice in Manufacturing Processing, Packing, or Holding of Drugs
 - 21 CFR 600: Biological Products
 - 21 CFR 610: General Biological Products Standards
 - 42 CFR 73: Public Health- Quarantine, Inspection, Licensing-Select Agents and Toxins
 - 9 CFR 121: Animals and Animal Products- Viruses, Serums, Toxins and Analogous Products; Organisms and Vectors-Possession, Use and Transfer of Select Agents and Toxins
 - 7 CFR 331: Agriculture- Regulations of the Department of Agriculture- Possession, Use and Transfer of Select Agents and Toxins
 - 32 CFR 627: Biological Defence Safety Program, Technical Safety Requirements

Other Relevant International Guidelines

- U.S. Centers for Disease Control and Prevention (CDC) Biosafety in Microbiological and Biomedical Laboratories (BMBL) (6th Edition, 2020)
- U.S. National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- OIE (World Organisation for Animal Health) Terrestrial Manual, Chapter 1.1.3: Transport of Biological Materials (2018)
- ICAO (International Civil Aviation Organisation) Technical Instructions for the Safe Transport of Dangerous Goods by Air (2021-2022 Edition)
- Occupational Safety and Health Administration (OSHA). Controlling Electrical Hazards. Washington (DC): U.S. Department of Labour (2002)
- National Fire Protection Association Standard for Electrical Safety in the Workplace (2021)

International Conventions

Turkiye has ratified several international conventions and agreements with respect to environmental issues. Those conventions and agreements that could have relevance to the Project are listed below:

- Biological and Toxin Weapons Convention (1972): To effectively prohibit the development, production, acquisition, transfer, stockpiling and use of biological and toxin weapons. The convention has reached almost universal membership with 184 States Parties and four Signatory States.
- World Health Assembly WHA58.29 Enhancement of Laboratory Biosafety (2005)

14.7 Residual Impacts

The community health and safety topic is of major concern to the Project since magnitude of associated impacts with respect to biosafety and biosecurity aspects if unmitigated is major and the sensitivity of the receptors is considered to be high. In this context, it is anticipated that if the related mitigation measures for construction and operation of the Project are strictly followed, the overall residual risks and impacts detected on community health, safety and security would be insignificant to moderate, with added health benefits of valuable national research and medical applications.

14.8 Proposed Monitoring and Reporting

Community health, safety and security is considered as a common concern and is covered in several individual chapters referred to in Section 14.3 of this chapter. Therefore, in addition to the monitoring and reporting requirements of the Community Health and Safety Plan and the Security Plan developed for construction and operation phases of the Project, the proposed monitoring and reporting will include those outlined in chapters 8, 9, 10, 12, 13 and 16 as well as the ESMP and associated management plans.

The monitoring activities will assess the level of implementation of the mitigation measures identified for the Project within the scope of the construction and operation phase management plans. The monitoring and performance measurement for the construction and operation phase Community Health and Safety Management Plans will focus on key community health and safety indicators, including the following:

- Continuous monitoring of accidents and incidents involving workers and members of the local population during construction and operation phase activities of the Project.
- Continuous monitoring of ambient dust and noise levels.
- Continuous monitoring and recordkeeping of waste generation and disposal activities as well as wastewater discharges.
- · Continuous monitoring of recorded grievances.
- Continuous monitoring of worker health.

Additionally, the MoH will:

- i. promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers, including, inter alia, cases of sexual exploitation and abuse (SEA), sexual harassment (SH), and accidents that result in death, serious or multiple injury, any COVID-19 outbreak in the Project (no later than 48 hours after learning of the incident or accident),
- ii. provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and
- iii. subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

15 ANIMAL WELFARE

15.1 Introduction

This section focuses on the potential environmental and social impacts of the proposed Project within the context of animal welfare. Maintaining animal welfare in laboratory is essential to reduce the human-inflicted pain, stress and suffering of test animals. Laboratory animal welfare is also closely linked to scientific quality, as good animal welfare conditions are beneficial to the reliability of produced scientific data.

This section assesses the significance of potential impacts arising from animal welfare issues associated with design and operation of the Project on receptors that may potentially be sensitive to such effects and offers relevant mitigation and management measures.

15.1.1 Study Area and Area of Influence

The area of influence within the context of animal welfare is regarded as the whole Project area footprint, however, primarily the units where animals are produced, housed, used, rehabilitated and transported. The potential animal welfare impacts that may arise in all processes during the operation of the Project, including emergency management, have been evaluated.

15.1.2 Limitations

As the issue of animal welfare is multidimensional and comprise many aspects such as good health, comfort and expression of behaviour, it is not easy to evaluate with predictive/numerical measures. Its overall assessment requires a multi-criteria evaluation. The set of criteria set should be exhaustive (no missing items), legible (necessary items) and agreed by stakeholders.²⁸⁸ Although there are several studies on the establishment and operation of effective protocols for the welfare assessment of animals used in research and testing, there is still reliance on subjective assessments and individual opinions.

Nevertheless, several ethical principles and technical standards related to production, housing, care and procedural implementation are laid out in legal texts and guidelines. The responsibility for related practices is shared between the researchers, the animal welfare units of the laboratories and the ethics committees which will evaluate the ethical suitability of each study.

The impacts arising from animal welfare issues related to the Project are assessed qualitatively on the basis of expert judgement and mitigations proposed based on the regulatory framework and best practice. The assessment presented herein relies on the accuracy, sufficiency and consistency of all information provided to the ESIA team by or on behalf of the MoH. It should be noted that at the time of this assessment, design features of the Project and technical details on the Experimental Animals Production/Test Building and the structure, numbers and capacities of test rooms according to type of organisms and animal groups were yet undefined.

15.2 Baseline Description

15.2.1 Conceptual Framework for Animal Welfare

Animal welfare, developed as a separate scientific discipline as a result of joint efforts of veterinarians, physiologists, behavioral scientists and ethologists, aims to determine the basic facts about the biological

²⁸⁸ Hawkins P. et all (2011): A guide to defining and implementing protocols for the welfare assessment of laboratory animals: eleventh report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement. Laboratory Animals, (45): 1–13.

and psychological needs of animals and to better understand their behavior.²⁸⁹ The concept of animal welfare has been evolving over time in line with ethical, scientific and policy developments. It is now more complex and developed than in early days when it was considered only in relation to absence of cruelty or 'unnecessary suffering'. Meanwhile it is generally defined using a number of concepts including: sentience; needs, interests and emotions; physical, mental and natural states ('telos'); and the five freedoms.²⁹⁰ It considers that animals should have a good quality of life (enjoying physical, mental and emotional well-being including the ability to live meaningful and natural lives, where they are able to meet their species-specific and ethological needs and behaviors) and a humane death.²⁹¹

Since 1968, the World Organization for Animal Health (WOAH - previously OIE) has been developing international standards aimed at improving animal health, animal welfare and veterinary public health worldwide. These standards are published in the Terrestrial Animal Health Code²⁹². The definition of animal welfare currently used by WOAH provided in article 7.1.1 of this code is as follows:

"Animal welfare means the physical and mental state of an animal in relation to the conditions in which it lives and dies."

"An animal experiences good welfare if the animal is healthy, comfortable, well nourished, safe, is not suffering from unpleasant states such as pain, fear and distress, and is able to express behaviors that are important for its physical and mental state."

"Good animal welfare requires disease prevention and appropriate veterinary treatment, shelter, management and nutrition, a stimulating and safe environment, humane handling and humane slaughter or killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment."

The 'Guiding Principles for Animal Welfare' as defined in article 7.1.2 of this code are as follows:

- 1. That there is a critical relationship between animal health and animal welfare.
- 2. That the internationally recognized 'five freedoms' (freedom from hunger, thirst and malnutrition; freedom from fear and distress; freedom from physical and thermal discomfort; freedom from pain, injury and disease; and freedom to express normal patterns of behavior) provide valuable guidance in animal welfare.
- 3. That the internationally recognized 'three Rs' (reduction in numbers of animals, refinement of experimental methods and replacement of animals with non-animal techniques) provide valuable guidance for the use of animals in science.
- 4. That the scientific assessment of animal welfare involves diverse elements which need to be considered together, and that selecting and weighing these elements often involves value-based assumptions which should be made as explicit as possible.
- 5. That the use of animals in agriculture, education and research, and for companionship, recreation and entertainment, makes a major contribution to the wellbeing of people.

Brambell R. (1965): Report of the Technical Committee to enquire into the welfare of animals kept under intensive livestock husbandry systems. Her Majesty's Stationery Office, London, UK.

²⁸⁹ Başağaç R.T. (2005): Hayvan Refahı ve Hayvanların Bilimsel Araştırmalarda Kullanılması. Türkiye'de Birinci Hayvan Refahı ve Veteriner Hekimliği Eğitimi Konferansı Bildiriler Kitabı, Pozitif Matbaacılık, Ankara, s. 93-98.

²⁹⁰ Five Freedoms' were originally published by the UK's Farm Animal Welfare Council – FAWC (it was renamed to Animal Welfare Committee -AWC on 1 October 2019) in 1979 (although they originated in the 'Brambell Report', which dated back to 1965), and have been adapted slightly since their formulation.

FAWC (1979): Five Freedoms. Press Statement (Dec 5th, 1979), Surrey, UK.

²⁹¹ World Animal Net: Animal Welfare. (Last access on 1 August 2022, official website: https://worldanimal.net/animal-welfare).

²⁹² WOAH (2022): Terrestrial Animal Health Code. (Last access on 2 August 2022, official website: https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-onlineaccess/?id=169&L=1&htmfile=sommaire.htm).

- 6. That the use of animals carries with it an ethical responsibility to ensure the welfare of such animals to the greatest extent practicable.
- 7. That improvements in farm animal welfare can often improve productivity and food safety, and hence lead to economic benefits.
- 8. That equivalent outcomes based on performance criteria, rather than identical systems based on design criteria, be the basis for comparison of animal welfare standards and recommendations.

As one of the medical authorities for the health and welfare of animals, the American Veterinary Medical Association (AVMA) offers the following eight integrated principles for developing and evaluating animal welfare policies, resolutions and actions:²⁹³

- The responsible use of animals for human purposes, such as companionship, food, fiber, recreation, work, education, exhibition and research conducted for the benefit of both humans and animals, is consistent with the Veterinarian's Oath.
- Decisions regarding animal care, use and welfare shall be made by balancing scientific knowledge and professional judgment with consideration of ethical and societal values.
- Animals must be provided water, food, proper handling, healthcare and an environment appropriate to their care and use, with thoughtful consideration for their species-typical biology and behavior.
- Animals should be cared for in ways that minimize fear, pain, stress and suffering.
- Procedures related to animal housing, management, care and use should be continuously evaluated, and when indicated, refined or replaced.
- Conservation and management of animal populations should be humane, socially responsible and scientifically prudent.
- Animals shall be treated with respect and dignity throughout their lives and, when necessary, provided a humane death.
- The veterinary profession shall continually strive to improve animal health and welfare through scientific research, education, collaboration, advocacy, and the development of legislation and regulations.

Today, animal welfare is divided into many sub-fields dealing with different animal species and different practices. One of them includes the welfare of animals used for scientific purposes.²⁹⁴ Although the use of animals for scientific purposes dates back to ancient Greece and the earliest medical experiments their suffering had been ignored for centuries.^{295,296,297}

Experiments on animals began to be discussed in terms of morality in the nineteenth century and some restrictions were introduced, but this issue gained a different dimension with 'The Principles of Humane Experimental Technique'²⁹⁸ published in 1959 by the scholars of the Universities Federation for Animal Welfare (UFAW). The book laid out the principles of the three Rs – Replacement, Reduction and Refinement.

Three Rs have provided a framework for performing more humane animal research and a clear set of directions for improving the welfare of animals used. In addition, they have helped to improve scientific

²⁹³ AVMA: AVMA Animal Welfare Principles. (Last access on 1 August 2022, official website: https://www.avma.org/resources-tools/avma-policies/avma-animal-welfare-principles).

²⁹⁴ European Commission: Animals used for scientific purposes. (Last access on 28 July 2022, official website: https://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm).

²⁹⁵ Von Staden H. (1989): Herophilus: The Art of Medicine in Early Alexandria. Cambridge University Press, Cambridge, UK.

²⁹⁶ Baumans V. (2004): Use of animals in experimental research: an ethical dilemma? Gene Therapy, (11): 64-66.

²⁹⁷ Franco N. H. (2013): Animal experiments in biomedical research: A historical perspective. Animals, 3 (1): 238-273.

²⁹⁸ Russell W.M.S. & Burch, R.L. The Principles of Humane Experimental Technique. Methuen & Co Ltd.: London, UK, 1959.

outcomes. They have raised the profile of animal welfare amongst biomedical researchers and stimulated research on alternatives, more humane methodologies and better housing and husbandry²⁹⁹. Moreover, they have been embedded in national and international legislation and regulations on the use of animals in scientific procedures, as well as in the policies of organizations that fund or conduct animal research³⁰⁰.

While the three Rs have remained much the same since the original publication, there have been minor changes of emphasis and of definition. Here in Table 15-1, the basic and updated definitions of these principles are indicated.

Three Rs	Basic Definition	Updated Definition
Replacement	Avoiding or replacing the use of animals in areas where they otherwise would have been used.	Accelerating the development and use of predictive and robust models and tools, based on the latest science and technologies, to address important scientific questions without the use of animals.
Reduction	Minimizing the number of animals used consistent with scientific aims.	Appropriately designed and analysed animal experiments that are robust and reproducible, and truly add to the knowledge base.
Refinement	Minimizing the pain, suffering, distress or lasting harm that research animals might experience.	Advancing research animal welfare by exploiting the latest in vivo technologies and by improving understanding of the impact of welfare on scientific outcomes.

Table 15-1: The basic and u	updated definitions	of the	three R	S
-----------------------------	---------------------	--------	---------	---

* https://www.nc3rs.org.uk/who-we-are/3rs

Replacement refers to technologies or approaches which directly replace or avoid the use of animals in experiments where they would otherwise have been used. The term includes absolute (full) replacement (i.e., replacing animals with inanimate systems such as human volunteers, tissues and cells, mathematical and computer models, established cell lines) as well as relative (partial) replacement which includes invertebrates such as *Drosophila*, nematode worms and social amoebae, and immature forms of vertebrates. Partial replacement also includes the use of primary cells (and tissues) taken from animals killed solely for this purpose (i.e. not having been used in a scientific procedure that causes suffering).³⁰¹

Reduction refers to the methods that minimize the number of animals used per experiment or study consistent with the scientific aims. It is essential for reduction that studies are appropriately designed and analyzed to ensure robust and reproducible findings. Reduction approaches at different levels could have similar or complementary effects. In order to differentiate between these approaches, the following three level concept of reduction have been proposed³⁰²: (i) Intra-experimental Reduction, which focuses on the reduction of the number of animals used within individual experiments. (ii) Supra-experimental Reduction, which a series of experiments takes place and which is independent of the individual scientific procedure. (iii) Extra-experimental Reduction, which means reduction by means of developments that are not directly related to the animal procedures. Reduction strategies or approaches at three levels are indicated in Table 15-2.

²⁹⁹ Hubrecht R.C. & Carter E. (2019): The 3Rs and Humane Experimental Technique: Implementing Change. Animals, 9 (754): 1-10.

³⁰⁰ National Centre for the Replacement Refinement & Reduction of Animals in Research: The 3Rs. (Last access on 28 July 2022, official website: https://www.nc3rs.org.uk/who-we-are/3rs).

³⁰¹ National Centre for the Replacement Refinement & Reduction of Animals in Research: The 3Rs. (Last access on 28 July 2022, official website: https://www.nc3rs.org.uk/who-we-are/3rs).

³⁰² de Boo J., Hendriksen C. (2005): Reduction Strategies in Animal Research: A Review of Scientific Approaches at the Intra-experimental, Supra-experimental and Extra-experimental Levels. ATLA (33): 369-377.

Table 15-2: Reduction strategies or approaches at three levels

Reduction strategies or approaches			
Extra-experimental level	 GLP and GMP Harmonisation of guidelines New research strategies New production strategies 		
Supra-experimental level	 Education and training Ethical review Reduction of breeding surplus Re-evaluation of laboratory animal specifications Re-use of animals and longitudinal studies 		
Intra-experimental level	 Experimental design Random screening Pilot studies Retrospective analysis 		

Refinement refers to the methods that minimize the pain, suffering, distress or lasting harm that may be experienced by research animals, and which improve their welfare. Refinement applies to all aspects of animal use, from their housing and husbandry to the scientific procedures performed on them. Examples of refinement include ensuring the animals are provided with housing that allows the expression of species-specific behaviors, using appropriate anesthesia and analgesia to minimize pain, and training animals to cooperate with procedures to minimize any distress.³⁰³ Modern non-invasive imaging methods, developments in bioanalytical techniques, methods of improving the housing and care quality of animals through enrichment (environmental, social, physical) and nutritional expertise support are extremely important in terms of providing the principle of Refinement.³⁰⁴

In the recent years, new principles have been added to the three Rs by various academic, social communities and non-governmental organizations. These principles, compiled from various sources^{305,306,307,308,309} are briefly as follows:

- Responsibility: This principle includes institutional or personal (researchers) responsibilities to animals, the public, the scientific community, and sponsoring institutions.
- Rehabilitation: This principle refers to the care and/or rehabilitation of animals after the procedure. All
 researchers using experimental animals have a moral responsibility to the animals after use. This
 principle is a legal requirement in India.
- Respect: This refers to the respect anyone involved in the experiment is required to show for the creatures involved.
- Review: Review is important in identifying and evaluating tools for assessing the risk of bias and/or other methodological criteria of animal studies.
- Re-use: As a reduction strategy, this principle is the reuse of laboratory animals within permissible conditions.

³⁰³ National Centre for the Replacement Refinement & Reduction of Animals in Research: The 3Rs. (Last access on 28 July 2022, official website: https://www.nc3rs.org.uk/who-we-are/3rs).

³⁰⁴ MacArthur Clark J. (2018): The 3Rs in research: a contemporary approach to replacement, reduction and refinement. British Journal of Nutrition, 120(S1): S1–S7.

³⁰⁵ Pereira S., Tettamanii M. (2005): Ahimsa and Alternatives - The Concept of the 4th R. The CPCSEA in India. ALTEX. 22(1): 3-6.

³⁰⁶ The Directive 2010/63/EU. (Last access on 28 July 2022, official website: https://eur-lex.europa.eu/eli/dir/2010/63/oj).

³⁰⁷ Vesterinen H.M., Sena E.S., Egan K.J., Hirst T., Churolov L., Currie G., Antonic A., Howells D.W. and Macleod M.R. (2013): Meta-analysis of data from animal studies: A practical guide. Journal of Neuroscience Methods, (221): 92-102.

³⁰⁸ Krauth D., Woodruff T.J. and Bero L. (2013): Instruments for assessing risk of bias and other methodological criteria of published animal studies: a systematic review. Environmental Health Perspectives 121(9):985–992.

³⁰⁹ The CPCSEA guidelines for the reuse and rehabilitation of dogs. (Last access on 30 July 2022, official website: http://cpcsea.nic.in/WriteReadData/userfiles/file/CPCSEA_guidelines_for__dog_reuse_and_rehab.PDF).

15.2.2 Specific Conditions of the Project within the scope of Animal Welfare

Within the proposed Project, animal experiments involving risk grade 3 agents will be conducted in ABSL3 level laboratories which require specific practices for biosafety and animal welfare management. The experimental animals will be produced and accommodated in the Experimental Animals and Production/Test Building. The building will be divided into sections according to the species and types of animals and will consist of a basement and four floors. Footprint area and total operational area will be 1671.26 m² and 7075.59 m² respectively. For details of Project components and capacities, including layouts, please refer to *Chapter 2: Project Description*.

The Project is planned to host around 6000-7000 experimental animals including scorpion, rat, snake, rabbit, mouse, fish (i.e., zebra fish, axolotl fish, amphibious fish). Horse and poultry will not be produced or used in the facility. Similarly, small-head, non-primates and pigs will not be produced. However, in case of need, limited numbers of small-head animals (such as Rhesus monkey and Sus domesticus) may be used on project basis. These animals will be procured from licensed and certified national and international establishments within authorized permissions.

The number of animals to be used will be calculated by power analysis. The species such as rabbit, mouse, rat will be produced as inbreed, outbreed, hybrid or SPF (specific pathogen free) type according to requirements. In the Experimental Animals and Production/Test Building, it is planned to house about 150-300 scorpions, 1500 rats, 500 rabbits, 2000 mice, 1000 SPF transgenic mice and 500-1000 zebrafish. The maximum capacity of the facility for Rhesus monkey and Sus domesticus has been determined as 20 and 14, respectively.

The production, housing, use, rehabilitation and transportation of animals and emergency management will be carried out in accordance with the national and international regulatory framework as well as the international guidelines provided in Section 15.6. Accordingly, the general design and functions of the facility, environmental factors and conditions associated with animal care will be in accordance with the relevant provisions of the applicable directives and regulations.³¹⁰

Legislation on animal experimentation stipulates that an ethical decision is made whether an animal experiment is to be authorized and lays down the basic parameters for that decision. Legislation also includes assignment of this responsibility to authorities and other bodies, particularly so-called ethics committees. In this framework, all scientific studies within the Project involving animal experiments will be carried out with the approval of an ethics committee (i.e. the Local Ethics Committee for Animal Experiments, HADYEK) to be established when the facility becomes active. Thus, the principles of ethical approaches to experimental animals will be evaluated in the scientific projects.

15.3 Assessment of Impacts

15.3.1 Methodology

Assessment of animal welfare impacts has been performed based on the evaluation of baseline conditions presented in Section 15.2, gathered through the use of primary data provided by the MoH and secondary data based on literature review and desktop studies. The related national and international standards and guidelines (see Section 15.6) were taken as basis in the evaluation of the data. Possible

³¹⁰ Annex III of the Directive 2010/63/Eu of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (Last access on 28 July 2022, official website: https://eurlex.europa.eu/eli/dir/2010/63/oj).

Annex of the Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes (Official Gazette date/number: 13.12.2011/28141)

Annex of the Regulation on the Welfare and Protection of Aquatic Vertebrates Used for Scientific Purposes (Official Gazette date/number: 20.04.2019/30751)

animal welfare impacts associated with the Project have been assessed together with their significance levels.

The possible environmental and social impacts of the Project in terms of animal welfare were evaluated under the following topics:

- Impacts in terms of animal use ethics
- Impacts on quality of scientific research
- Economic impacts
- Impacts on education

15.3.2 Determining Magnitude, Sensitivity, and Impact Significance

The significance of potential impacts is a function of the presence and sensitivity of receptors and the magnitude of the impact in terms of duration, spatial extent, reversibility and likelihood of occurrence. Sensitive or vulnerable receptors are generally considered to have less means to absorb adverse changes than non-sensitive or non-vulnerable receptors.

Assessment of animal welfare impacts has been performed based on the guideline criteria defined in Table 15-3 and Table 15-4 for determining sensitivity and magnitude, respectively.

Sensitivity of Receptors	Definition
High	Vulnerable receptors (animals / scientific data) with very little or no capacity to absorb adverse and / or unsuitable animal welfare conditions
Medium	Vulnerable receptors (animals / scientific data) with limited capacity to absorb adverse and / or unsuitable animal welfare conditions
Low	Vulnerable receptors (animals / scientific data) with some capacity to absorb adverse and / or unsuitable animal welfare conditions
Negligible	Vulnerable receptor (animals / scientific data) with good capacity to absorb adverse and / or unsuitable animal welfare conditions

Table 15-3: Criteria for Determining Sensitivity

Table 15-4 below summarises the specific criteria for determining the magnitude of impacts.

Table 15-4: Criteria for Determining Magnitude

Magnitude	Definition (considers duration of the impact, spatial extent and reversibility)		
Major	Fundamental changes in many dimensions and components of animal welfare		
Moderate	Detectable changes in many dimensions and components of animal welfare		
Minor	Detectable but minor changes in many dimensions and components of animal welfare		
Negligible	Non-detectable changes in many dimensions and components of animal welfare		

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 15-5.

Table 15-5: Impact Significant Matrix

	Sensitivity of Receptors				
Magnitude of Impact	Negligible	Low	Medium	High/Very High	
Negligible	Insignificant	Insignificant	Insignificant	Insignificant	
Minor	Insignificant	Minor	Minor	Moderate	
Moderate	Insignificant	Minor	Moderate	Major	

Sensitivity of Receptors					
Magnitude of Impact	Negligible	Low	Medium	High/Very High	
Major	Insignificant	Moderate	Major	Critical	

15.3.3 Impacts in Terms of Animal Use Ethics

The use of animals in research is an issue that many people feel strongly about. The ethical assessments related to the use of animals in research are wide-ranging. It is commonly believed that it may be necessary to use laboratory animals in some cases in order to create improvements for people, animals or the environment. At the same time, the general opinion is that animals have a moral status and that our treatment of them should be subject to ethical considerations. Such views are reflected in the following positions: ³¹¹

- 1. Animals have an intrinsic value which must be respected.
- 2. Animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration.
- 3. Our treatment of animals, including the use of animals in research, is an expression of our attitudes and influences us as moral actors.

The guidelines reflect all these positions, and stipulate principles such as the three Rs and considerations that can be used as tools when balancing between harm and benefit. These principles can establish absolute limits for experiments on animals, even when there are great benefits. These principles also state what can reasonably be considered harm and benefit, and the principles thus facilitate good assessments. The ethics of use of experimental animals is evaluated together with the following points:

- Respect for animals' dignity
- Responsibility for considering options (Replace)
- The principle of proportionality: responsibility for considering and balancing suffering and benefit
- Responsibility for considering reducing the number of animals (Reduce)
- Responsibility for minimising the risk of suffering and improving animal welfare (Refine)
- Responsibility for maintaining biological diversity
- Responsibility when intervening in a habitat
- Responsibility for openness and sharing of data and material
- Requirement of expertise on animals
- Requirement of due care

Since animal welfare is a middle ground where these principles are reconciled with animal rights, it is essential for the facility to have the necessary animal welfare standards, both in relation to laboratory animal rights and public conscience. According to the information provided by MoH, the proposed Project will establish necessary animal welfare standards. Moreover, establishment of these standards is also a legal necessity for the facility to be licensed and start its operations.

From a conservative viewpoint, considering the high sensitivity of receptors and moderate magnitude of adverse impacts, without any mitigation, the significance of animal welfare impacts during the operation phase would be assessed as major. However, it should be noted that a detailed evaluation of each scientific research project will be performed by the local ethics committee to be established, compliance will be ensured, and a set of mitigation measures set out in Section 15.4 will be applied to address these impacts.

³¹¹ The Norwegian National Research Ethics Committee: Ethical Guidelines for the Use of Animals in Research. (Last access on 20 July 2022, official website: https://www.forskningsetikk.no/en/guidelines/science-and-technology/ethical-guidelines-for-the-use-of-animals-in-research/).

15.3.4 Impacts on Quality of Scientific Research

When their physical and psychological wellbeing is maintained, the stress response of animals to the environment and manipulations is minimised, resulting in more stable biochemical indicators.³¹² For this reason, good animal welfare is closely linked to the quality of research data derived from laboratory animals, their validity as models of human disease, the number of animals required to reach statistical significance and the reproducibility of in vivo studies.³¹³ "Good welfare equals good science" has become the mantra ever since Trevor Poole first highlighted the relationship between research animal welfare and the quality of science³¹⁴, and in the intervening decades, the evidence base for this relationship has been steadily growing.

Animal welfare means how an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if, as indicated by scientific evidence, it is healthy, comfortable, well-nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Obviously, there are cases in research in which a high degree of suffering may need to occur to achieve the scientific objectives (which would be assessed case-by-case before authorization is granted), however, in all cases every effort should be made to minimize unnecessary harm because animals with compromised welfare have disturbed behaviour, physiology and immunology. This can lead to unreliable conclusions and/or unwanted variation in scientific output, affecting both the reliability and repeatability of experiments.³¹⁵ Therefore, this strong link between animal welfare and scientific outcomes needs to be carefully considered by both researchers and the mechanisms involved in the evaluation of studies (i.e., the animal welfare unit, the ethics committees, and referees and journal editors at the publication stage of research).

Since the Project will be built in accordance with national and international standards and guidelines, the physical and infrastructure conditions of all units will have standards suitable for animal welfare. During the operation phase of the Project, approval of the local ethics committee will be obtained in accordance with the relevant legislation for all studies and procedures to be performed on animals. Thus, every planned research will be evaluated in terms of animal welfare and three Rs before it is started, and research that are not deemed appropriate will not be permitted. Without such initial evaluation and necessary mitigations to ensure animal welfare in laboratories, the significance of negative animal welfare impacts on scientific outputs would be critical considering their high sensitivity and the potentially major magnitude of the above discussed impacts.

15.3.5 Economic Impacts

Another issue to be considered in this section is economic impacts. A system or procedure is sustainable if it is acceptable now and if its expected future effects are also acceptable, in particular in relation to resource availability, consequences of functioning and morality of action³¹⁶.

An animal use system may be unsustainable for the following reasons:317,318

Consuming a lot of resources until they become unusable,

³¹² Guo, M., Wang, Y., Liu, J., Huang, Z., Li, X. (2019). Biosafety and data quality considerations for animal experiments with highly infectious agents at ABSL-3 facilities. Journal of Biosafety and Biosecurity, 1(1), 50–55. https://doi.org/10.1016/j.jobb.2018.12.011

³¹³ Prescott. M.J. & Lidster K. (2017): Improving quality of science through better animal welfare: the NC3Rs strategy. Lab. Animal 46: 152-156.

³¹⁴ Poole T. (1997): Happy animals make good science. Lab. Animal, 31: 116–124.

³¹⁵ Prescott. M.J. & Lidster K. (2017): Improving quality of science through better animal welfare: the NC3Rs strategy. Lab. Animal 46: 152-156.

³¹⁶ Broom D.M. (2016): Livestock sustainability and animal welfare. In: Proceedings of International Meeting of Advances in Animal Science, Vol. 1, Galoá, pp.1-15.

³¹⁷ Bennett R.M., Anderson J. & Blaney R.J.P. (2002): Moral intensity and willingness to pay concerning farm animal welfare issues and the implications for agricultural policy. Journal of Agricultural and Environmental Ethics, 15: 187–202.

³¹⁸ Broom D.M. (2014): Sentience and Animal Welfare. 1st Edition, CABI, Wallingford, the UK.

- Having too many resources to prevent the system from working,
- Any influence deemed unacceptable by public,
- Poor welfare conditions,
- Insufficient protection,
- Inefficient use,
- Unacceptable genetic modification.

Constructing the Project in accordance with national and international animal welfare standards and using laboratory animals in accordance with the 3R principle is extremely important for the sustainable use of resources and will prevent negative environmental and socioeconomic impacts. In addition, it is believed that the animal welfare conditions in the facility will be decisive in the approach of research funders who have high expectations about the use and care of animals, and this will be reflected in their policies and the terms and conditions of grant awards resulting in economic benefits.

15.3.6 Impacts on Education

Modern biomedical research is progressing at an unusual pace. Sophistication of methods exposes studies to an increasing number of potentially complicating factors, many totally unknown so far. The animal facilities must be able cope with the change, and all persons down to the lowest level should be considered key members of the research teams. The laboratory animal science and welfare is an essential issue and to ensure this, proper and continuous education and training are required.³¹⁹

European Convention and related Directive requires 'competency' of all personnel (such as scientists, specialists, animal technicians and research technicians) working with laboratory animals. For this competency, it has become a necessity to establish training and certification programs. All curricula of these training and certification programs include welfare issues related to housing and care procedures and the three Rs as guiding principles.³²⁰

In Turkiye, researchers who carry out animal experiments and the technical personnel who take care of animals must be trained and certified in accordance with the applicable legislation. In addition, they are required to participate in vocational trainings of the Vocational Qualifications Authority which defines occupational standards for both laboratory animal caretakers and laboratory animal technical personnel.³²¹ Apart from this, those responsible for the occupational health and safety of all parties working with and taking care of experimental animals should also be trained. Thus, risk factors that may occur for both human and animal health are minimized. When the Project is evaluated from this point of view, it can be concluded that the processes related to animal welfare may also have positive effects on education.

15.4 Mitigation Measures

15.4.1 Design Phase

A number of measures will be implemented during the design phase in order to mitigate the impacts due to animal welfare practices of the Project as follows:

• In each unit where animals will be produced, cared, housed and will be subjected to experimental treatment, all conditions related to animal welfare will be complied with international and national regulations and standards, as detailed in Table 15-6 below.

³¹⁹ Nevalainen T. (2007) Research, Animals and Welfare: Regulations, alternatives and guidelines. In: The Welfare of Laboratory Animals (Ed. C. Phillips), Springer, The Netherlands, pp. 15-22.

³²⁰ Başağaç Gül R.T. (2009): Bilimsel Araştırmalar ve Hayvan Deneyleri. Bilim Etiği ve Bilim Tarihi (Genişletilmiş 2. Baskı -Ed. B. Arda), Ankara Üniversitesi Basımevi, Ankara, s.189-215.

³²¹ MYK Web Portalı (2022): Ulusal Meslek Standartları. (Last access on 20 July 2022, official website: https://portal.myk.gov.tr/index.php?option=com_meslek_std_taslak&view=taslak_listesi_yeni&msd=2)

- Standards on physical structures in the holding, procedure and service rooms will be ensured.
- Appropriate environment and environmental control (including lighting, noise, ventilation and temperature) for the care and housing of experimental animals will be ensured.

15.4.2 Operation Phase

The following mitigation measures will be implemented during the operation phase of the Project:

- A Local Ethics Committee for Animal Experiments will be established.
- An Animal Welfare Unit will be established responsible for addressing and monitoring issues of animal welfare.
- Personnel with adequate training on animal welfare and animal health will be employed.
- Standard Operational Procedures (SOPs) for production, care and treatment of each animal species will be developed and implemented throughout the operation.
- Animal handling procedures will comply with all international and national standards and requirements, including those provided in Table 15-6 below.
- Appropriate maintenance of animal housing facilities will be undertaken.
- Emergency action plans will be prepared against foreseeable negativities.
- Control, inspection and sanction mechanisms will be made effective.
- Up-to-date information on this subject will be followed.
- The Animal Welfare Management Plan will be implemented.
- Ongoing information disclosure and consultation will be undertaken with stakeholders including animal welfare awareness organizations and feedbacks will be monitored.

15.4.3 Compliance against Applicable Standards and Requirements

A range of measures, including both physical and management measures, will be implemented by the Project as outlined in Table 15-6, to ensure compliance with applicable standards and requirements as well as to mitigate any adverse impacts associated with animal welfare. Such standards and requirements will be related to the physical facilities for animal care and handling, environmental control, as well as procedures for care of animals.

Table 15-6: Applicable Design/Management Requirements and Corresponding Measures to Ensure Compliance of the Project

Applicable Design/Management Requirements		Measures to be Taken to Ensure Compliance of the Project	
1.	Physical facilities		
1.1 Functions and general design			
•	All facilities shall be constructed so as to provide an environment which takes into account the physiological and ethological needs of the species kept in them. Facilities shall also be designed and managed to prevent access by unauthorized persons and the ingress or escape of animals.	The Experimental Animals Production/Test Building will be equipped with ABSL3 level laboratories. The construction of the facilities will be carried out taking into account the relevant EU Directive and national legislation. Standards suitable for the physiological and ethological needs of experimental animals are clearly shown in these references.	
•	Establishments shall have an active maintenance program to prevent and remedy any defect in buildings or equipment.	• Annex III of the Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (https://eur-lex.europa.eu/eli/dir/2010/63/oj).	
		 Annex of the Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes (Official Gazette date/number: 13.12.2011/28141) 	
		· .	

Ар	plicable Design/Management Requirements	Measures to be Taken to Ensure Compliance of the Project	
		 Annex of the Regulation on the Welfare and Protection of Aquatic Vertebrates Used for Scientific Purposes (Official Gazette date/number: 20.04.2019/30751) 	
1.2	2 Holding rooms		
•	Establishments shall have a regular and efficient cleaning schedule for the rooms and shall maintain satisfactory hygienic standards.	The hygiene standards of the holding rooms will be constructed in accordance with the EU Directive and national legislation.	
•	Walls and floors shall be surfaced with a material resistant to the heavy wear and tear caused by the animals and the cleaning process. The material shall not be detrimental to the health of the animals and shall be such that the animals cannot hurt themselves. Additional protection shall be given to any equipment or fixtures so that they are not damaged by the animals nor do they cause injury to the animals	Walls and ceilings will be smooth, moisture resistant, nonabsorbent, and resistant to damage from impact. They will be free of cracks, unsealed utility penetrations, and imperfect junctions with doors, ceilings, floors, walls and corners. Surface materials will be capable of withstanding cleaning with detergents and disinfectants and the impact of water under high pressure. The use of curbs, guardrails or bumpers, and	
•	themselves. Species that are incompatible, for example predator and prey, or animals requiring different environmental conditions shall	corner guards will be considered to protect walls and corners from damage, and such items will be solid or sealed to prevent access and harborage of vermin.	
	not be housed in the same room nor, in the case of predator and prey, within sight, smell or sound of each other.	Floors will be moisture resistant, nonabsorbent, impact resistant and relatively smooth. Floors will be easy to repair and resistant to both the action of urine and other biologic materials and the adverse effects of hot water and cleaning agents. They will be capable of supporting racks, equipment, and stored items without becoming gouged, cracked or pitted. Depending on their use, floors will be monolithic or have a minimal number of joints.	
		Species that are incompatible or animals requiring different environmental conditions will be housed in different rooms. Thus, animals will be prevented from being affected by each other's sight, smell or sounds.	
1.3	B General and special purpose procedure rooms		
•	Establishments shall, where appropriate, have available laboratory facilities for the carrying out of simple diagnostic tests, post-mortem examinations, and/or the collection of samples that are to be subjected to more extensive laboratory investigations elsewhere. General and special purpose procedure rooms shall be available for situations where it is undesirable to carry out the procedures or observations in the holding rooms.	There will be general and special purpose processing rooms in the facility. Quarantine units for isolation of newly acquired animals and separate housing units for sick and injured animals will be constructed by taking into account the relevant EU Directive and national legislation.	
•	Facilities shall be provided to enable newly acquired animals to be isolated until their health status can be determined and the potential health risk to established animals assessed and minimized.		
•	There shall be accommodation for the separate housing of sick or injured animals.		
1.4	Service rooms		
•	Storerooms shall be designed, used and maintained to	The construction of the service rooms will be carried out by	

- safeguard the quality of food and bedding. These rooms shall be vermin and insect-proof, as far as possible. Other materials, which may be contaminated or present a hazard to animals or staff, shall be stored separately.
- The cleaning and washing areas shall be large enough to accommodate the installations necessary to decontaminate and clean used equipment. The cleaning process shall be arranged so as to separate the flow of clean and dirty equipment to prevent the contamination of newly cleaned equipment.

taking into account the relevant EU Directive and national legislation.

Adequate space will be available for storage of equipment, supplies, food, bedding, and refuse. It will be ample enough to accommodate storage of essential commodities to ensure the animals' uninterrupted husbandry and care (e.g. if delivery is delayed). Bedding and food will be stored in a separate area free from vermin and protected from the risk of contamination from toxic or hazardous substances. Areas used for food storage will not be subject to elevated temperatures or relative humidity for prolonged periods. Refuse storage areas will be separated from other storage areas. Refrigerated storage area

	^	-
Δ.	h	•
-	v	-

Applicable Design/Management Requirements		Measures to be Taken to Ensure Compliance of the Project	
•	Establishments shall provide for the hygienic storage and safe disposal of carcasses and animal waste. Where surgical procedures under aseptic conditions are required there shall be provision for one or more than one suitably equipped room, and facilities provided for postoperative recovery.	for dead animals and animal tissue waste will be kept below 7°C (44.6°F) to reduce putrefaction of wastes and animal carcasses and will be constructed in a manner that facilitates cleaning.	
2.	Environmental control		
2.1	Ventilation and temperature		
•	Insulation, heating and ventilation of the holding room shall ensure that the air circulation, dust levels and gas concentrations are kept within limits that are not harmful to the animals housed. Temperature and relative humidity in the holding rooms shall be adapted to the species and age groups housed. The temperature shall be measured and logged on a daily basis. Animals shall not be restricted to outdoor areas under climatic conditions which may cause them distress.	The building will consist of separate laboratories/rooms for experimental animals and transgenic organisms, with independent air conditioning and ventilation systems. The isolation, heating and ventilation systems of the sections will be established according to the biological requirements of animal species and age groups. Thus, the temperature and relative humidity will not disturb the animals. Air-conditioning will be provided with air handling units and will be kept under control with the automation system. In accordance with the instructions specified in the relevant regulations, the temperature and humidity values determined on the basis of species will not be exceeded during air- conditioning. Air-conditioning systems will be designed as redundant and will be monitored with a 24-hour automation system.	
2.2	! Lighting		
•	Where natural light does not provide an appropriate light/dark cycle, controlled lighting shall be provided to satisfy the biological requirements of the animals and to provide a satisfactory working environment	The lighting will be provided to meet the biological requirements of all animal species and to provide a satisfactory working environment.	
•	Illumination shall satisfy the needs for the performance of husbandry procedures and inspection of the animals.	sealed to prevent vermin access. A time-controlled lighting system will be used to ensure a uniform diurnal lighting cycle.	
•	Regular photoperiods and intensity of light adapted to the species shall be provided.	or a warning light to indicate the system is in override mode, and system performance and override functions will be	
•	When keeping albino animals, the lighting shall be adjusted to take into account their sensitivity to light.	regularly evaluated to ensure proper cycling. Dual-level lighting will be considered when housing species that are sensitive to	

2.3 Noise

Z.3			
•	Noise levels including ultrasound, shall not adversely affect animal welfare.	The noise level of the equipment, including ultrasound and alarm systems, to be used in the facility, will be at a level that will not affect animal welfare. A sound barrier system will be used on the walls in all animal rooms. In addition, sound absorbing panels will be added to the cages of animals when necessary. Thus, the transmission of sound from one cage to another will be prevented.	
•	Establishments shall have alarm systems that sound outside the sensitive hearing range of the animals, where this does not conflict with their audibility to human beings.		
•	Holding rooms shall where appropriate be provided with noise insulation and absorption materials.		

high light intensity, such as albino rodents; low-intensity lighting is provided during the light phase of the diurnal cycle, and higher-intensity lighting is provided as needed (e.g. when

Light bulbs or fixtures will be equipped with protective covers to ensure the safety of the animals and personnel. Moistureresistant switches and outlets and ground-fault interrupters will be used in areas with high water use, such as cage-washing

personnel require enhanced visibility).

areas and aquarium-maintenance areas.

2.3 Emergency and Alarm Systems

Applicable Design/Management Requirements		Measures to be Taken to Ensure Compliance of the Project	
•	Establishments relying on electrical or mechanical equipment for environmental control and protection, shall have a stand- by system to maintain essential services and emergency lighting systems as well as to ensure that alarm systems themselves do not fail to operate. Heating and ventilation systems shall be equipped with monitoring devices and alarms. Clear instructions on emergency procedures shall be prominently displayed.	The electrical system will be safe and provide appropriate lighting, a sufficient number of power outlets and suitable amperage for specialized equipment. In the event of power failure, an alternative or emergency power supply will be available to maintain critical services (e.g. the HVAC system, ventilated caging systems or life support systems for aquatic species) or support functions (e.g. freezers and isolators) in animal rooms, operating suites and other essential areas. Consideration will be given to outfitting movable equipment for which uninterrupted power is essential (e.g. ventilated racks) with twist-lock plugs to prevent accidental removal from the power supply. Heating and ventilation systems will be equipped with monitoring devices and alarms. Fire and environmental (HVAC) monitoring alarm and announcement systems will be selected and placed in such a way as to minimize possible animal disturbances. Since some species can hear such high frequencies, attention will be paid to the location of equipment capable of producing sound at ultrasonic frequencies. Clear instructions on emergency procedures will be	
_		prominently displayed.	
3.	Care of animals		
3.1	Health		
•	Establishments shall have a strategy in place to ensure that a health status of the animals is maintained that safeguards animal welfare and meets scientific requirements. This strategy shall include regular health monitoring, a microbiological surveillance program and plans for dealing with health breakdowns and shall define health parameters and procedures for the introduction of new animals. Animals shall be checked at least daily by a competent	The facility will have a strategy to maintain animal welfare and meet scientific requirements. The details of this strategy will be shared when the construction phase is completed.	
	animals are identified, and appropriate action is taken.		
3.2	2 Animals taken from the wild		
•	Transport containers and means of transport adapted to the species concerned shall be available at capture sites, in case animals need to be moved for examination or treatment. Special consideration shall be given, and appropriate measures taken for the acclimatization, quarantine, housing, husbandry, care of animals taken from the wild and, as appropriate, provisions for setting them free at the end of procedures.	Animal transportation may be intra-institutional, inter- institutional, or between a commercial or noncommercial source and a research facility. For wildlife, transportation may occur between the capture site and field holding facilities. Careful planning for all types of transportation is required to ensure animal safety and well-being. The process of transportation will provide an appropriate level of animal biosecurity while minimizing zoonotic risks, protecting against environmental extremes, avoiding overcrowding, providing for the animals' physical, physiologic or behavioral needs and comfort, and protecting the animals and personnel from physical trauma.	
3.3	B Housing and enrichment		
•	Animals, except those which are naturally solitary, shall be socially housed in stable groups of compatible individuals. In cases where single housing is allowed, the duration shall be limited to the minimum period necessary and visual, auditory, olfactory and/or tactile contact shall be maintained. The introduction or re-introduction of animals to established groups shall be carefully monitored to avoid problems of incompatibility and disrupted social relationships.	The species-specific housing conditions of the facility will be organized in accordance with the relevant EU Directive and national legislation. Environmental enrichment will be adapted to the species and individual needs of the animals concerned. The facility will have appropriate enrichment techniques in place, to extend the range of activities available to the animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the	

species.

Applicable Design/Management Requirements

Enrichment

All animals shall be provided with space of sufficient complexity to allow expression of a wide range of normal behavior. They shall be given a degree of control and choice over their environment to reduce stress-induced behavior. Establishments shall have appropriate enrichment techniques in place to extend the range of activities available to the animals and increase their coping activities including physical exercise, foraging, manipulative and cognitive activities, as appropriate to the species. Environmental enrichment in animal enclosures shall be adapted to the species and individual needs of the animals concerned. The enrichment strategies in establishments shall be regularly reviewed and updated.

Animal enclosures

Animal enclosures shall not be made out of materials detrimental to the health of the animals. Their design and construction shall be such that no injury to the animals is caused. Unless they are disposable, they shall be made from materials that will withstand cleaning and decontamination techniques. The design of animal enclosure floors shall be adapted to the species and age of the animals and be designed to facilitate the removal of excreta.

3.4 Feeding

- The form, content and presentation of the diet shall meet the nutritional and behavioral needs of the animal. The animals' diet shall be palatable and non-contaminated. In the selection of raw materials, production, preparation and
 - presentation of feed, establishments shall take measures to minimize chemical, physical and microbiological contamination.
 - Packing, transport and storage shall be such as to avoid contamination, deterioration or destruction. All feed hoppers, troughs or other utensils used for feeding shall be regularly cleaned and, if necessary, sterilized.
 - Each animal shall be able to access the food, with sufficient feeding space provided to limit competition.

3.5 Watering

- Uncontaminated drinking water shall always be available to all Water delivery methods will ensure that all animals are able to access food for a sufficient period of time while minimizing animals. water aggression.
- When automatic watering systems are used, they shall be regularly checked, serviced and flushed to avoid accidents. If solid-bottomed cages are used, care shall be taken to minimize the risk of flooding.
- Provision shall be made to adapt the water supply for aquaria and tanks to the needs and tolerance limits of the individual fish, amphibian and reptile species.

3.6 Resting and sleeping areas

- Bedding materials or sleeping structures adapted to the Bedding materials or sleeping structures adapted to the species will be provided. All sleeping areas will be kept clean species shall always be provided, including nesting materials or structures for breeding animals. and dry. Within the animal enclosure, as appropriate to the species, a
- solid, comfortable resting area for all animals shall be provided. All sleeping areas shall be kept clean and dry.

3.7 Handling

Animal enclosures will be adapted to the species and individual needs of the animals concerned and they will not be made out of materials detrimental to the health of the animals.

Food delivery methods will ensure that all animals are able to access food for a sufficient period of time while minimizing feeding aggression and nutrient loss.

The form, content and presentation of the diet will meet the nutritional and behavioral needs of each species. Hygiene conditions will be taken into account in all processes related to feedina.

Watering devices such as drinking tubes and automated water

delivery systems will be checked frequently to ensure

appropriate maintenance, cleanliness and operation.

prevent freezing of water sources.

Automated watering distribution systems will be flushed or

disinfected regularly. In cold weather, steps will be taken to

468

Applicable Design/Management Requirements		Measures to be Taken to Ensure Compliance of the Project	
•	Establishments shall set up habituation and training programs suitable for the animals, the procedures and length of the project.	Habituation and training programs will be set up suitable for the animals, the procedures and length of the project. For each research project, these conditions will be evaluated by the local ethics committee to be established at the facility.	

15.5 Residual Impacts

Residual effects are those effects that remain after mitigation has been implemented. Following effective mitigation of animal welfare impacts in line with the legislation and guidelines described above, residual effects regarding animal welfare in terms of ethical considerations as well as quality of scientific research are expected to be reduced to negligible to minor.

15.6 National and International Requirements

The Project will follow the applicable national and international standards and guidelines on animal welfare outlined in the subsections below. Specific design and management measures derived from the national and international requirements are presented in this section.

15.6.1 National Requirements

The legal framework related with animal welfare in Turkiye is largely aligned with the associated European Union (EU) Directives. Turkiye introduced several laws and regulations which are intended to protect animals used for experimental and other purposes. The key legislation relevant to the Project includes:

- Animal Protection Law No. 5199 (Official Gazette date/number: 01.07.2004/25509)
- Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes (Official Gazette date/number: 13.12.2011/28141)
- Regulation on the Welfare and Protection of Aquatic Vertebrates Used for Scientific Purposes (Official Gazette date/number: 20.04.2019/30751)
- Regulation on Working Procedures and Principles of Animal Testing Ethics Committees (Official Gazette date/number: 15.02.2014/28914)
- Law on Veterinary Services, Plant Health, Food and Feed No. 5996 (Official Gazette date/number: 13.06.2010/27610)

The Animal Protection Law No. 5199 was put into force tin 2004 to ensure that animals are afforded a comfortable life and receive good and proper treatment, to protect them to the extent possible from the infliction of pain, suffering and torture, and to prevent all types of cruel treatment. Pursuant to the article 9 of this law, animals cannot be used in non-scientific diagnosis, treatment and experiments. Institutions and organizations who carry out tests involving animals shall be permitted by ethics committees established in their institutions and organizations.

The legal structure for experimental animal use in Turkiye is primarily governed by the Regulation on Welfare and Protection of Animals Used for Experimental and Other Scientific Purposes established parallel to the EU Directive 2010/63/EU³²², as well as the Regulation on Working Procedures and Principles of Animal Testing Ethics Committees. The latter has introduced two types of ethics committees, namely the Central Ethics Committee for Animal Experiments (i.e. HADMEK) and the Local Ethics Committees for Animal Experiments (i.e. HADYEK). The main responsibilities of HADMEK are to determine ethical principles regarding the use of experimental animals, approve operating guidelines of local committees and monitor their legal compliance. In line with the provisions of this regulation, every

³²² European Commission: Animals used for scientific purposes (Last access on 28 July 2022, official website: https://ec.europa.eu/environment/chemicals/lab_animals/index_en.htm).
institution conducting animal experiments should establish a local ethics committee. In Turkiye, there are 119 local ethics committees whose guidelines had been approved by HADMEK as of February 2021.

The legal framework for experimental animal use also includes the Regulation on the Welfare and Protection of Aquatic Vertebrates Used for Scientific Purposes, which lays down rules and procedures for the use of aquatic vertebrate animals in experimental aquaculture practices, animal care and accommodation standards, as well as competence of personnel of breeders, suppliers and users.

In addition to the above, the Project will implement necessary procedures to ensure compliance with the Law on Veterinary Services, Plant Health, Food and Feed No. 5996, which defines the rules on protection from infectious animal diseases, identification and recording of animals, as well as the official controls and sanctions to be implemented at the entrance and exit of live animals and animal products to the country.

15.6.2 International Requirements and Guidelines

Since 1986, the EU has had specific legislation regarding the use of animals for scientific purposes, including development or production of new medicines, physiological studies, studying environmental effects and testing of chemicals or new food additives.

In 2010, the EU adopted the Directive 2010/63/EU on the protection of animals used for scientific purposes. The aim of the Directive is to strengthen legislation and improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the Three Rs (i.e. to Replace, Reduce and Refine the use of animals for scientific purposes) in the EU legislation. The Directive took effect in 2013 and was further amended in 2019 by the Regulation (EU) 2019/1010³²³. The amendments have been included in the consolidated text of Directive 2010/63/EU.¹

The scope of Directive 2010/63/EU is now wider and includes foetuses of mammalian species in their last trimester of development and cephalopods, as well as animals used for the purposes of basic research, higher education and training. It lays down minimum standards for housing and care, regulates the use of animals through a systematic project evaluation requiring inter alia assessment of pain, suffering distress and lasting harm caused to the animals. It requires regular risk-based inspections and improves transparency through measures such as publication of non-technical project summaries and retrospective assessment.

The key international guidelines applicable to animal welfare are listed below:

- WHO Laboratory Biosafety Manual, 3rd Edition, 2004 and 4th Edition, 2020
- CEN Workshop Agreement: Laboratory Biorisk Management Standard, 2008
- CDC-NIH Biosafety at Microbiological and Biomedical Laboratories (BMBL), 6th Edition, 2020
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019
- NIH Biosafety Level 3 Laboratory Certification Requirements, 2006
- World Organization for Animal Health (WOAH) Terrestrial Animal Health Code, 2022
- WOAH Guidelines on Disaster Management and Risk Reduction in Relation to Animal Health and Welfare and Veterinary Public Health, 2016
- Council for International Organizations of Medical Sciences (CIOMS) and International Council for Laboratory Animal Science (ICLAS) International Guiding Principles for Biomedical Research Involving Animals, 2012
- Universities Federation for Animal Welfare (UFAW) Handbook on the Care and Management of Laboratory and Other Research Animals 8th Ed., 2010

³²³ The Regulation (EU) 2019/1010. (Last access on 28 July 2022, official website: https://eur-lex.europa.eu/legalcontent/EN/ALL/?uri=celex:32019R1010)

- Animal Welfare Institute (AWI) Comfortable Quarters for Laboratory Animals 10th Ed., 2015
- Office of Laboratory Animal Welfare (OLAW) National Institutes of Health Guide for the Care and Use of Laboratory Animals, 8th Ed., 2011
- USDA Animal and Plant Health Inspection Service Animal Welfare Act and Animal Welfare Regulations, 2020

15.7 Proposed Monitoring and Reporting

Continuous monitoring will be undertaken in line with the Animal Welfare Management Plan developed for the Project, to determine the effectiveness of the mitigation and management measures that will be applied during animal production and animal testing. Therefore, the Project will establish a comprehensive review, monitoring and reporting system to be implemented by the Animal Welfare Unit to be established within the scope of the Project. Monitoring aspects will include:

- Continuous monitoring of animal housing requirements including bedding, lighting, noise and ventilation
- Continuous monitoring of feeding and watering requirements
- Continuous monitoring of animal health and vaccinations
- Continuous monitoring of behavioural indicators
- Continuous monitoring of proper implementation of relevant SOPs
- Continuous monitoring of staff training

Monitoring reports will summarize the compliance of the animal welfare management against the applicable standards/guidelines and details of any breaches, details of any investigation or remedial action taken as a result of a non-compliance, and a discussion of any relevant quality assurance issues. If applicable, any changes and improvements in animal welfare status will be reflected in the associated monitoring reports.

16 LABOUR AND WORKING CONDITIONS

16.1 Introduction

This chapter considers the potential impacts on labour and working conditions, including the occupational health and safety risks associated with the construction and operation labour of the Project including its subcontractors. It should be noted that information on the structure and qualifications of the workforce to be employed in the Project and the distribution of responsibilities of the Project Implementation Unit members is limited at the time of writing this report Therefore the assessment remained limited to general issues of labour and working conditions.

16.2 National and International Requirements

16.2.1 National Requirements

A comprehensive list of national laws and regulations regarding labour and working conditions is provided below, which is followed by a summary of related legislation together with their relevance with the Project.

Law/Regulation	Official Gazette (OG) date	OG number
Labour Law (4857)	10.06.2003	25134
Occupational Health and Safety Law (6331)	30.06.2012	28339
Law on Trade Union and Collective Bargaining (6356)	18.10.2012	28460
Law on Unions and Collective Bargaining for Public Servants (4688)	25.06.2001	24460
First Aid Regulation	29.07.2015	29429
Law on Social Insurance and General Health Insurance (5510)	16.06.2006	26200
Regulation on Working Duration Related to Labour Law	06.04.2004	25425
Regulation on Excess Work and Work in Excess Periods related to Labour Law	06.04.2004	25425
Regulation on Special Principles in Works Carried out by Employing Workers in Shifts	07.04.2004	25426
Regulation on Minimum Wage	01.08.2004	25540
Regulation on Working Procedures and Principles of Child and Young Workers	06.04.2004	25425
Regulation on Suspension of Work in Workplaces	01.08.2004	28603
Regulation on Annual Paid Leave	03.03.2004	25391
Regulation on Overwork and Overtime	06.04.2004	25425
Regulation on Working Procedures and Principles of Child and Young Workers	06.04.2004	25425
Occupational Health and Safety Services Regulation	29.12.2012	28512
Regulation on Occupational Health and Safety in Construction Works	05.10.2013	28786
Regulation on the Procedures and Principles of the Employee's Health and Safety Trainings	15.05.2013	28648
Regulation on Occupational Health and Safety Committees	18.01.2013	28532
Regulation on Occupational Health and Safety Risk Assessment	29.12.2012	28512
Regulation on Duties, Authority, Responsibilities and Trainings of Occupational Health and Safety Specialists	29.12.2012	28512
Regulation on Duties, Authority, Responsibilities and Trainings of On-site Doctor and Other Health Personnel	20.07.2013	28713
Regulation on Occupational Health and Safety in Temporary or Fixed Term Employment	23.08.2013	28744

Table 16-1: National Laws and International Conventions Regarding Labour and Working Conditions and Occupational Health and Safety

Law/Regulation	Official Gazette (OG) date	OG number
Regulation on the Health and Safety Measures to be taken in Workplace Buildings and Additions	17.07.2013	28710
Regulation on Ion Radiation Resources used in Health Services and Radiation Dose Limits of Working Staff and Work Principles	05.05.2012	28344
Regulation on Radiation Safety	24.03.2000	23999
Regulation on the Prevention of Exposure Risks from Biological Agents	15.06.2013	28678
Regulation on Manual Handling	24.07.2013	28717
Regulation on Safety and Health Signs	11.09.2013	28762
Regulation on the Works in Which Workers shall Work Maximum Seven and Half Hours or Less in a Day in Terms of Health Rules	16.07.2013	28709
Regulation on Use of Personal Protective Equipment in Workplaces	02.07.2013	28695
Regulation on Health and Safety Measures for Working with Carcinogenic and Mutagenic Substances	06.08.2013	28730
Regulation on Health and Safety Measures in Working with Chemical Substances	12.08.2013	28733
Regulation on the Emergency Situations in Workplaces	18.06.2013	28681
Regulation on the Protection of Workers from the Dangers of the Explosive Media	30.04.2013	28633
Regulation on the Control of Dust Emissions	05.11.2013	28812
Regulation on the Protection of the Workers against Vibration Risks	22.08.2013	28743
Regulation on the Protection of the Workers against Risks Relevant to Noise	28.07.2013	28721
Regulation on Protection of Buildings from Fire	19.12.2007	26735

Labour, health and safety issues are collectively ruled by the Labour Law No. 4857, Occupational Health and Safety Law No. 6331 and associated regulations. They aim to regulate the employer and the employee's duties, powers, responsibilities, work-related rights, working conditions, and obligations to provide occupational health and safety at work and improve the current health and safety conditions.

Details on the Legislation related to Labour and Working Conditions

The MoH estimates that there will be need for both contracted/subcontracted workers and public servants during the operation phase of the Project. As already known, there are contractors and subcontractors employed for the construction activities. In this regard, the workforce of the Project relies on the Turkish Labour Law No. 4857 and Law on Public Servants No. 657 together with the relevant regulations about labour and working conditions.

The Turkish Labour Law No. 4857 regulates as an umbrella law for labour-related practices at national context. Main objectives of this law include proper management of labour and working conditions, defining the roles, responsibilities and rights of workers as well as employers who reach an agreement about work through a mutual employment contract. Additionally, it embraces certain principles such as working hours, overtime hours, non-discrimination based on gender, race, political opinion, religion etc. and equal opportunity for all, minimum age for employment³²⁴, employment of disabled personnel, minimum wage, right to unionization and collective bargaining, termination and compensation benefits, annual leave and other leave opportunities (i.e. maternal leave).

Law on Public Servants No. 657 regulates all personnel affairs of the public servants including the required qualifications, appointments, duties, rights and obligations, salaries and allowances. The Law also includes articles on unionization, ways to raise grievance, retirement, annual leave and other leave opportunities (i.e. sickness leave).

³²⁴ Minimum age of employment is defined as 15 in the Turkish Labour Law No. 4857. Yet, it is stated in the law that children who have completed the age of fourteen and have completed the compulsory primary education can be employed in soft works as long as the work does not interfere with their physical, mental, social, educational and moral development.

Other laws and regulations that are in line with the Turkish Labour Law No. 4857 and Law on Public Servants No. 657 are listed and briefly defined as follows:

- Law on Trade Union and Collective Bargaining (6356): The objective of this Law is to make collective bargaining agreements between workers and employers in order to determine the mutual economic and social conditions and working conditions through decent and proper means.
- Law on People with Disabilities (5378): The purpose of this Law is to ensure that the disabled people benefit from their fundamental rights and freedoms through full and effective participation in social life including employment opportunities in the labour market on an equal basis with other individuals. The Law commits to preventing the discrimination based on disability in any aspect of employment (i.e. recruitment, proposed working hours and conditions, continuity of employment, career development, and healthy and safe working conditions).
- Regulation on Contractors and Subcontractors: The Regulation aims at managing the conditions for the establishment of the employer and subcontractor relationship, the notification and registration of the subcontractor's workplace, and the issues that should be included in the subcontractors' contracts within the scope of the Labour Law No. 4857.
- Regulation on Minimum Wage: The Regulation is based on the principles to be applied during the determination of the minimum wage as well as the duties and obligations of the employer. The provisions of this Regulation cover all workers within the scope of the Labour Law No. 4857 that have an employment contract. The Regulation commits to the principle of equality in wages.

Details on the Legislation related to Occupational Health and Safety

The scope of the Project requires certain occupational health and safety measures to be taken during both construction and operation phases. All measures will be in line with the Law on Occupational Health and Safety No. 6331, which is in place for all regulations related to health and safety of the workforce.

The purpose of the Law on Occupational Health and Safety No. 6331 is to regulate the duties, authorities, responsibilities, rights and obligations of employers and employees in order to ensure occupational health and safety at workplaces and to improve existing health and safety conditions.

In line with this Law, there is a variety of additional laws and regulations depending on the workplace and the scope of the work (i.e. noise, vibration, dust, chemical substances). Majority of these laws and regulations will be applied within the scope of the Project.

The Law also necessitates informing workers about the work-related health and safety risks together with providing them trainings to prevent such risks. The usage of personal protective equipment is one of the most significant requirements for workers in the context of occupational health and safety. Furthermore, the Law requires the employers to carry out regular health controls for their workers and report if any near misses, injuries, incidents or death occur at the workplace.

16.2.2 International Requirements

The following international documents have been taken into account to assess labour and working conditions during the ESIA process:

- The World Bank's Environmental and Social Framework (ESF), 2017
 - ESS 1: Assessment and Management of Environmental and Social Risks and Impacts
 - ESS 2: Labour and Working Conditions
 - ESS 4: Community Health and Safety
- The World Bank's ESF Guidance Notes for Borrowers
- The World Bank Group's Environment, Health and Safety (EHS) General Guidelines, 2007
- The World Bank Group's EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing, 2007
- The World Bank Group's EHS Guidelines for Health Care Facilities (2007)

- WHO Laboratory Biosafety Manual Fourth Edition and Associated Monographs, 2020
- OSHA Laboratory Safety Guidance, 2011
- International Labour Organisation (ILO) Conventions

The World Health Organization (WHO) published Laboratory Biosafety Manual (2020) to encourage countries to accept and implement basic concepts in biological safety and to develop national codes of practice for the safe handling of pathogenic microorganisms in laboratories within their geographical borders. The Project will ensure that the operation phase will be in compliance with the assigned biosafety level and that appropriate practices and procedures are observed by the WHO. BSL and ABSL laboratories will follow the guidelines of EN 12128 and if there are no rules under EN 12128, WHO guidelines will be applied.

The International Health Regulations (IHR) represents an obligation for all WHO Member States to work together for global health security. The IHR has a purpose to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

The International Labour Organisation (ILO) of the United Nations is responsible for overseeing compliance with international labour standards ('conventions' that national governments are signatories to). The ILO conventions reflect common values and principles on work-related issues and Member States can choose whether or not to ratify them. The ILO regularly monitors the implementation and the application of the conventions as well as developments in countries generally, whether or not they have chosen to ratify ILO conventions. International Labour Organization (ILO) Conventions that Turkiye has ratified are listed below³²⁵:

- C 2 Unemployment Convention, 1919
- C 11 Right of Association (Agriculture) Convention, 1921
- C 14 Weekly Rest (Industry) Convention, 1921
- C 15 Minimum Age (Trimmers and Stokers) Convention, 1921
- C 26 Minimum Wage-Fixing Machinery Convention, 1928
- C 29 Forced Labour Convention, 1930
- C 34 Fee-Charging Employment Agencies Convention, 1933
- C 42 Workmen's Compensation (Occupational Diseases) Convention (Revised), 1934
- C 45 Underground Work (Women) Convention, 1935
- C 53 Officers' Competency Certificates Convention, 1936
- C 55 Shipowners' Liability (Sick and Injured Seamen) Convention, 1936
- C 58 Minimum Age (Sea) Convention (Revised), 1936
- C 59 Minimum Age (Industry) Convention (Revised), 1937
- C 68 Food and Catering (Ships' Crews) Convention, 1946
- C 69 Certification of Ships' Cooks Convention, 1946
- C 73 Medical Examination (Seafarers Convention, 1946
- C 77 Medical Examination of Young Persons (Industry) Convention, 1946
- C 80 Final Articles Revision Convention, 1946
- C 81 Labour Inspection Convention, 1947
- C 87 Freedom of Association and Protection of the Right to Organise Convention, 1948
- C 88 Employment Service Convention, 1948

³²⁵ Accessed from <u>https://www.ilo.org/ankara/conventions-ratified-by-turkey/lang--en/index.htm</u> on 07 January 2023.

- C 92 Accommodation of Crews Convention (Revised), 1949
- C 94 Labour Clauses (Public Contracts) Convention, 1949
- C 95 Protection of Wages Convention, 1949
- C 96 Fee-Charging Employment Agencies Convention (Revised), 1949
- C 98 Right to Organise and Collective Bargaining Convention, 1949
- C 99 Minimum Wage Fixing Machinery (Agriculture) Convention, 1951
- C100 Equal Remuneration Convention, 1951
- C102 Social Security (Minimum Standards) Convention, 1952
- C105 Abolition of Forced Labour Convention, 1957
- C108 Seafarers' Identity Documents Convention, 1958
- C111 Discrimination (Employment and Occupation) Convention, 1958
- C115 Radiation Protection Convention, 1960
- C116 Final Articles Revision Convention, 1961
- C118 Equality of Treatment (Social Security Convention, 1962
- C119 Guarding of Machinery Convention, 1963
- C122 Employment Policy Convention, 1964
- C123 Minimum Age (Underground Work) Convention, 1965
- C127 Maximum Weight Convention, 1967
- C133 Accommodation of Crews (Supplementary Provisions) Convention, 1970
- C134 Prevention of Accidents (Seafarers) Convention, 1970
- C135 Workers' Representatives Convention, 1971
- C138 Minimum Age Convention, 1973
- C142 Human Resources Development Convention, 1975
- C144 Tripartite Consultation (International Labour Standards) Convention, 1976
- C146 Seafarers' Annual Leave with Pay Convention, 1976
- C151 Labour Relations (Public Service) Convention, 1978
- C152 Occupational Safety and Health (Dock Work) Convention, 1979
- C153 Hours of Work and Rest Periods (Road Transport) Convention, 1979
- C155 Occupational Safety and Health Convention, 1981
- C158 Termination of Employment Convention, 1982
- C159 Vocational Rehabilitation and Employment (Disabled Persons) Convention, 1983
- C161 Occupational Health Services Convention, 1985
- C164 Health Protection and Medical Care (Seafarers) Convention, 1987
- C166 Repatriation of Seafarers Convention (Revised), 1987
- C167 Safety and Health in Construction Convention, 1988
- C176 Safety and Health in Mines Convention, 1995
- C182 Worst Forms of Child Labour Convention, 1999
- C187 Promotional Framework for Occupational Safety and Health Convention, 2006

Out of 59 Conventions ratified by Turkey, 55 are in force, 3 Conventions have been denounced and one has been abrogated. These are C 15 Minimum Age (Trimmers and Stokers) Convention, C 34 Fee-Charging Employment Agencies Convention, C 58 Minimum Age (Sea) Convention (Revised), C 59 Minimum Age (Industry) Convention (Revised). None of these Conventions listed above have been ratified in the past 12 months.

Table 16-2 below presents the applicable International Labour Organization (ILO) Conventions on labour and working conditions.

Table 16-2: Applicable International Labour Organization Conventions on Labour and Working	J
Conditions	

Name	Date	Convention No
Unemployment Convention	1919	C-2
Weekly Rest (Industry) Convention	1921	C-14
Forced Labour Convention	1930	C-29
Minimum Age (Industry Convention)	1937	C-59
Freedom of Association and Protection of the Right to Organise Convention	1948	C-87
Protection of Wages Convention	1949	C-95
Right to Organize Collective Bargaining Convention	1949	C-98
Equal Remuneration Convention	1951	C-100
Abolition of Forced Labour Convention	1957	C-105
Workers' Representative Convention	1971	C-135
Minimum Age Convention	1973	C-138
Occupational Safety and Health Convention	1981	C-155
Termination of Employment Convention	1982	C-158
Worst Forms of Child Labour Convention	1999	C-182

16.2.3 Comparison of International Requirements and National Law in Labour and Working Conditions

A comparison of the above-mentioned national legislation on labour and working conditions and occupational health and safety with international requirements World Bank Environmental and Social Standard 2 (WB ESS 2) and International Labour Organization (ILO) standards is provided in Table 16-3.

As can be seen in the table, there are a number of gaps between national legislation, ILO standards and the World Bank ESS 2 requirements. The gaps will be addressed through the mitigation measures provided in Section 16.5.

477

Table 16-3: Comparison of International Requirements and National Law in Labour and Working Conditions

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
Terms and C	onditions of Employment				
Recruitment management	The Borrower will develop and implement written labour management procedures applicable to the project. These procedures will set out the way in which project workers will be managed, in accordance with the requirements of national law and this ESS. The procedures will address the way in which this ESS will apply to different categories of project workers including direct workers, and the way in which the Borrower will require third parties to manage their workers in accordance with this ESS. Decisions relating to the employment or treatment of project workers will not be made on the basis of personal characteristics unrelated to inherent job requirements. The labour management procedures will set out measures to prevent and address harassment, intimidation and/or exploitation. Special measures of protection and assistance to remedy discrimination or selection for a particular job based on the inherent requirements of the job or the objectives of the project will not be deemed as discrimination, provided they are consistent with national law.	Any discrimination, exclusion or preference made on the basis of race, colour, gender, religion, political opinion, nationality or social origin during recruitment process cannot be tolerated according to the ILO standards.	According to Labour Law No. 4857, there should be no discrimination based on language, race, colour, gender, disability, political thought, philosophical belief and religion within the workplace. In addition, it is obligatory to employ three percent disabled people in private sector workplaces employing 50 or more workers.	There is no requirement to prepare a labour management procedure or plan to Labour Law No. 4857 that requires direct workers and third party employees and includes measures to prevent and address harassment, intimidation and/or exploitation as well as discrimination and exclusion.	The Project preparedLabour Management Procedures for the Project in line with WB ESS2 that ensures full compliance to international standards. Contractors will prepare Labour Management Plans on the basis of these Labor Management Procedures.
Protecting the rights of the employees	Project workers will be provided with information and documentation that is clear and understandable regarding their terms and conditions of employment. The information and documentation will set out their rights under national labour and employment law (which will include any applicable collective agreements), including their rights related to hours of work, wages, overtime, compensation and benefits, as well as those arising from the requirements of this ESS. This information	Compliance with approved codes are compulsory and national laws should be compatible with ILO norms.	Compliance with Labour Law No. 4857, Occupational Health and Safety Law No. 6331 and Social Insurance Law No. 5510 is obligatory. The workers also have the right to unionization and collective bargaining through Law on Trade Union and Collective Bargaining No. 6356.	The national law is in line with WB ESS2 such that clear documentation and contracts are compulsory. The workers' right to unionize and collective agreement is protected.	No additional mitigations required.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	and documentation will be provided at the beginning of the working relationship and when any material changes to the terms or conditions of employment occur.				
Working hours and overtimes	Project workers will be provided with adequate periods of rest per week, annual holiday and sick, maternity and family leave, as required by national law and labour management procedures.	Excess working hours are forbidden above 45 hours a week.	As stated in the Labour Law No. 4857 Working Hours Code, working hours should not exceed 45 hours per week and 11 hours in a day. Also, the maximum allowed overtime duration is 270 hours per year.	There is no gap between international standards and national law. All holidays, sick and maternity leaves, public holidays are defined by Labour Law No. 4857.	No additional mitigations required.
Rests for shifts		One weekly rest day equals to 24 consecutive hours.	 Labour Law No. 4857 requires that: Employees working less than four hours should have a rest for 15 minutes, Those working between 4 and 7.5 hours should have a rest for 30 minutes, and Those working more than 7.5 hours should have a rest for one hour in a day. 	Rest periods are defined in Labour Law No. 4857 Article 68 and in line with international standards.	No additional mitigations required.
Working on national holidays		Working procedures of working on national holidays should be identified.	Compliance with Labour Law No. 4857 is compulsory.	No gaps identified.	No additional mitigations required.
Wages, benefits and conditions of work	Project workers will be paid on a regular basis as required by national law and labour management procedures. Deductions from payment of wages will only be made as allowed by national law or the labour management procedures, and project workers will be informed of the conditions under which such deductions will be made. Where required by national law or the labour management procedures, project workers will receive written notice of termination of employment and details of severance payments in a timely manner. All wages that have been earned, social security benefits, pension contributions and any other entitlements will be paid on or before termination of the working	Compliance with Equal Payment Convention and Convention for the Protection of Wages is compulsory.	Project workers will be paid on a regular basis as required by national law and labour management procedures. Deductions from payment of wages will only be made as allowed by national law or the labour management procedures, and project workers will be informed of the conditions under which such deductions will be made Project workers will be provided with adequate periods of rest per week, annual holiday and sick, maternity and family leave, as required by national law and labour management procedures. It is compulsory to comply with Law on Trade Union and Collective Bargaining No. 6356.	Project workers will be paid on a regular basis as required by national law and labour management procedures. Deductions from payment of wages will only be made as allowed by national law or the labour management procedures, and Project workers will be informed of the conditions under which such deductions will be made. Project workers will be provided with adequate periods of rest per week, annual holiday and sick, maternity and family leave, as required by national law and labour management procedures.	No additional mitigations required.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	relationship, either directly to the project workers or where appropriate, for the benefit of the project workers. Where payments are made for the benefit of project workers, project workers will be provided with evidence of such payments.				
Non-discrimi	nation and equal opportunity				
Non- discrimination and equal opportunity	The employment of project workers will be based on the principle of equal opportunity and fair treatment, and there will be no discrimination with respect to any aspects of the employment relationship, such as recruitment and hiring, compensation (including wages and benefits), working conditions and terms of employment, access to training, job assignment, promotion, termination of employment or retirement, or disciplinary practices. The Borrower will provide appropriate measures of protection and assistance to address the vulnerabilities of project workers, including specific groups of workers, such as women, people with disabilities, migrant workers and children (of working age in accordance with this ESS). Such measures may be necessary only for specific periods of time, depending on the circumstances of the project worker and the nature of the vulnerability.	Any discrimination, exclusion or preference made on the basis of race, colour, gender, religion, political opinion, nationality or social origin during recruitment process cannot be tolerated according to the ILO standards.	As stated in the Labour Law No. 4857, there should be no discrimination based on language, race, colour, gender, disability, political thought, philosophical belief and religion in the workplace. In Article 74 of the Labour Law No. 4857, a total of 16 weeks of maternity leave is defined for female employees to be used before and after giving birth. In principle, female employees must not be engaged in work for a total period of 16 weeks, eight weeks before due date and eight weeks after delivery. In case of multiple pregnancy, an extra two-week period shall be added to the eight weeks before delivery during which female employees must not work. However, a female employee, whose health condition is suitable based on the approval of a physician's certificate, may continue to work until the three weeks before delivery if she would like to do so. In this case, the time during which she has worked shall be added to the time period allowed to her after delivery.	There are no gaps identified.	No additional mitigations required.
Workers' orga	anizations				
Workers' organizations	In countries where national law recognizes workers' rights to form and to join workers' organizations of their choosing and to bargain collectively without interference, the project will be implemented in accordance with national law. In such circumstances, the role of legally established workers' organizations and	Under the Freedom of Association and Protection of the Right to Organize Convention of ILO, workers have the right to form or be involved in the workers' organizations.	The workers have the right to unionization and collective bargaining through Law on Trade Union and Collective Bargaining No. 6356.	Turkiye recognizes the right to form and join workers' organization, there is no restriction.	No additional mitigations required.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	legitimate workers' representatives will be respected, and they will be provided with information needed for meaningful negotiation in a timely manner. Where national law restricts workers' organizations, the project will not restrict project workers from developing alternative mechanisms to express their grievances and protect their rights regarding working conditions and terms of employment. The Borrower should not seek to influence or control these alternative mechanisms. The Borrower will not discriminate or retaliate against project workers who participate, or seek to participate, in such workers' organizations and collective bargaining or alternative mechanisms.				
Grievance n	nechanism				
Grievance mechanism	A grievance mechanism will be provided for all direct workers and contracted workers (and, where relevant, their organizations) to raise workplace concerns. Such workers will be informed of the grievance mechanism at the time of recruitment and the measures put in place to protect them against any reprisal for its use. Measures will be put in place to make the grievance mechanism easily accessible to all such project workers. The grievance mechanism will be proportionate to the nature and scale and the potential risks and impacts of the project. It will be designed to address concerns promptly, using an understandable and transparent process that provides timely feedback to those concerned in a language they understand, without any retribution, and will operate in an independent and objective manner. The grievance mechanism may utilize existing grievance mechanisms, providing that they are properly designed and	ILO conventions encourages the establishment of social dialogue mechanisms within the workplaces.	Law on Trade Union and Collective Bargaining No. 6356 defines the workers' representatives and workers' organizations as the channels of the grievance mechanism.	There is no Project specific grievance mechanism required by national law that includes direct workers and contracted workers.	The Project developed an internal grievance mechanism accessible to all workers (direct, contract) which is easily accessible, and ensures timely feedback.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	implemented, address concerns promptly, and are readily accessible to such project workers. Existing grievance mechanisms may be supplemented as needed with project-specific arrangements.				
Child labour					
Child labour	 A child under the minimum age established in accordance with this paragraph will not be employed or engaged in connection with the project. The labour management procedures will specify the minimum age for employment or engagement in connection with the project, which will be the age of 14 unless national law specifies a higher age. A child over the minimum age and under the age of 18 may be employed or engaged in connection with the project only under the following specific conditions: the work does not fall within hazardous work category or interfere with the child's education or be harmful to the child's health or physical, mental, spiritual, moral or social development, an appropriate risk assessment is conducted prior to the work commencing; and the Borrower conducts regular monitoring of health, working conditions, hours of work and the other requirement of this ESS. 	 According to ILO, people that are younger than 15 years old are considered as children. It is forbidden to employ a person who is below 15 years old. There should be risk assessment for worker who is above 15 and below 18 years old. Age distribution for child labour and young labour according to ILO are as follows: 0-12: It is forbidden to work. 13-14: They could be employed in soft works. 15-17: They could be employed in all types of works except the hazardous works. >18: They could work in all types of works. 	It is compulsory to comply with Regulation on Working Procedures and Principles of Child and Young Workers, Labour Law No. 4857 and Law on Occupational Health and Safety No. 6331. Age distribution for child labour and young labour according to national legislation are as follows: • 0-12: It is forbidden to work. • 13-14: They could be employed in soft works. • 15-17: They could be employed in the works that are defined as "the works that young workers can be employed" under Labour Law No. 4857. • >18: They could work in all types of works.	There are no gaps between international standards and national law.	No additional mitigations required.
Forced labou	r				

exacted from an individual under threat of force or penalty, will not be used in connection with the project. This prohibition covers any kind of involuntary or compulsory labour, such as indeptured	no one National law is in line with No additional mitigations international standards. required.
--	--

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	labour, bonded labour, or similar labour- contracting arrangements. No trafficked persons will be employed in connection with the project.				
Occupational	Health and Safety				
Occupational health and safety (OHS)	 Measures relating to occupational health and safety will be applied to the project. The OHS measures will include the requirements of this ESS, and will take into account the WBG General OHS guidelines and, as appropriate, the industry specific OHS guidelines and other good international industrial practices. The OHS measures applying to the project will be set out in the legal agreement and the ESCP. The OHS measures will be designed and implemented to address the following: Identification of potential hazards to project workers, particularly those that may be life threatening Provision of preventive and protective measures, including modification, substitution, or elimination of hazardous conditions or substances Training of project workers and maintenance of training records Documentation and reporting of occupational accidents, diseases and incidents Emergency prevention and preparedness and response arrangements to emergency situations, and Remedies for adverse impacts such as occupational injuries, deaths, disability and disease. All parties who employ or engage project workers will develop and implement procedures to establish and maintain a safe working environment, including that 	ILO has designed applicable conventions to provide for coherent and systematic treatment of OHS issues and to promote continuation of the preventative approach to OHS, with the aim of ensuring that OHS is prioritized at national agendas. In this regard, establishing and implementing coherent national policies on OHS through dialogue between government, workers' and employers' organizations and to promote a national preventive safety and health culture are among the objectives of the ILO conventions on OHS.	The purpose of the Law on Occupational Health and Safety No. 6331 is to regulate the duties, authorities, responsibilities, rights and obligations of employers and employees in order to ensure occupational health and safety at workplaces and to improve existing health and safety conditions. In line with this Law, there is a variety of additional laws and regulations depending on the workplace and the scope of the work (i.e. noise, vibration, dust, chemical substances). Majority of these laws and regulations will be applied within the scope of the Project. The Law also necessitates informing workers about the work-related health and safety risks together with providing them trainings to prevent such risks. The usage of personal protective equipment is one of the most significant requirements for workers in the context of occupational health and safety. Furthermore, the Law requires the employers to carry out regular health controls for their workers and report if any near misses, injuries, incidents or death occur at the workplace.	There are no gaps between international standards and national law.	No additional mitigations required.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	workplaces, machinery, equipment and processes under their control are safe and without risk to health, including by use of appropriate measures relating to chemical, physical and biological substances and agents. Such parties will actively collaborate and consult with project workers in promoting understanding, and methods for, implementation of OHS requirements, as well as in providing information to project workers, training on occupational safety and health, and provision of personal protective equipment without expense to the project workers. Workplace processes will be put in place for project workers to report work situations that they believe are not safe or healthy, and to remove themselves from a work situation which they have reasonable justification to believe presents an imminent and serious danger to their life or health. Project workers who remove themselves from such situations will not be required to return to work until necessary remedial action to correct the situation has been taken. Project workers will not be retaliated against or otherwise subject to reprisal or negative action for such reporting or removal.				
Non-employe	e workers				
Non-employee workers	The Borrower will make reasonable efforts to ascertain that third parties who engage contracted workers are legitimate and reliable entities and have in place labour management procedures applicable to the project that will allow them to operate in accordance with the applicable requirements of this ESS. The Borrower will establish procedures for managing and monitoring the performance of third parties in relation to the requirements of this ESS. In addition, the Borrower will incorporate the requirements	-	Turkish legislation does not have a specific law regarding the requirements of non- employee workers and supply chain. For the grievances of the non-employee workers, Law on Trade Union and Collective Bargaining No. 6356 defines the workers' representatives and workers' organizations as the channels of the grievance mechanism.	Turkish legislation does not have a specific law regarding the requirements of non- employee workers and supply chain.	The Project will follow WB ESS2 and other applicable international standards for labour management and implement Project specific Labour Management Procedures. Grievance mechanism will be available to all workers including contracted workers.

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	of this ESS into contractual agreements with third parties, together with appropriate noncompliance remedies. In the case of subcontracting, the Borrower will require third parties to include equivalent requirements and noncompliance remedies in their contractual agreements with subcontractors.				Supply chain labour risk assessment will be conducted to ensure there is no forced labour, child labour from the first tier suppliers.
	Contracted workers will have access to a grievance mechanism. In cases where the third party employing or engaging the workers is not able to provide a grievance mechanism to such workers, the Borrower will make the grievance mechanism available to the contracted workers.				
	will make the grievance mechanism available to the contracted workers. As part of the environmental and social assessment, the Borrower will identify potential risks of child labour, forced labour and serious safety issues which may arise in relation to primary suppliers. Where there is a significant risk of child labour or forced labour related to primary supply workers, the Borrower will require the primary supplier to identify those risks. The labour management procedures will set out roles and responsibilities for monitoring primary suppliers. If child labour or forced labour cases are identified, the Borrower will require the primary supplier to take appropriate steps to remedy them. Additionally, where there is a significant risk of serious safety issues related to primary supply workers, the Borrower will require the relevant primary supplier to introduce procedures and mitigation measures to address such safety issues.				
	Such procedures and mitigation measures will be reviewed periodically to ascertain their effectiveness. The ability of the Borrower to address these risks will depend upon the Borrower's level of control or influence over its primary suppliers. Where remedy is not possible,				

Торіс	WB ESF ESS 2	ILO	National Law	Gaps	Mitigation Measures
	the Borrower will, within a reasonable period, shift the project's primary suppliers				
	to suppliers that can demonstrate that they are meeting the relevant requirements of this ESS.				

16.3 Baseline Description

16.3.1 Labour and Working Conditions in Turkiye

There are approximately 3.5 million unemployed people in Turkiye according to the Labour Force Statistics Bulletin published by the TurkStat in June 2022. The reported national unemployment rate is 10.3%, while the employment rate is 47.8% and the labour force participation rate is 53.2%³²⁶. According to the most recent data published on provincial basis (2021), the labour force participation rate in Ankara is 50.3%. The number of registered unemployed people in Ankara was 198,681 as of October 2021. The rate of women among the unemployed was 52.7% and the rate of young population between the ages of 18 and 24 was 37.8%³²⁷.

As of July 2021, there are a total of 1,156,670 personnel employed in the health sector in Turkiye³²⁸. The distribution of the workforce by their profession is provided in Table 16-4 below.

Profession	Employed in the Ministry of Health	Employed in the University	Employed in the Private Sector	Total
Specialist physician	46,563	15,488	26,889	88,940
Doctor/Junior doctor	60,792	25,837	4,253	90,882
Dentist	11,647	2,608	19,243	33,498
Pharmacist	4,130	1,205	30,921	36,256
Nurse/Midwife	210,434	38,795	39,002	288,231
Other personnel	367,829	82,754	168,280	618,863
Total	701,395	166,687	288,588	1,156,670

Table 16-4: The distribution of the workforce in the health sector in Turkiye by their profession

Research and development (R&D) in health sector has been one of the focal points of the MoH. Accordingly, the need for development of infrastructure and competencies of the workforce in order to enhance R&D in the health sector was highlighted in the 2022 Performance Program⁴ of the MoH.

Occupational Health and Safety in Turkiye

Despite its extensive labour laws, Turkiye has a poor track record in terms of occupational safety and worker injuries/fatalities. Social Security Institution (SSI) annually publishes occupational health and safety statistics in Turkiye. According to the recent published report of 2021, 1,394 employees with social insurance lost their lives in fatal accidents. Of those fatalities, 1,362 were men and 32 were women³²⁹. The number of people who had an occupational accident was recorded as 511,084 in 2021 which increased by around 33% compared to the previous year.

In the annual report of SSI on Occupational Health and Safety Statistics in Turkiye, the statistical data regarding occupational health and safety among the workforce in human health services are also included. Accordingly, twelve fatalities occurred as a result of occupational accidents in 2021, four of which were women.

³²⁶ TurkStat, Labour Force Statistics June 2022. Accessed from ttps://data.tuik.gov.tr/Bulten/Index?p=Isgucu-Istatistikleri-Haziran-2022-45651 on 15 August 2022.

³²⁷ Turkish Employment Agency, Labour Market Research in 2021 – Ankara Report. Accessed from https://media.iskur.gov.tr/52046/ankara.pdf on 15 August 2022.

³²⁸ Turkish Ministry of Health, 2022 Performance Program. Accessed from <u>https://sgb.saglik.gov.tr/Eklenti/42482/0/2022-yili-performans-programi-31012022pdf.pdf?_tag1=9E7D668EA1139B97B47F3F9462006AA0DCE00A11</u> on 28 July 2022.

³²⁹ Social Security Institution, Occupational Health and Safety Statistics in Turkey, 2021. Accessed from https://www.sgk.gov.tr/lstatistik/Yillik/fcd5e59b-6af9-4d90-a451-ee7500eb1cb4/ on 16 January 2023.

In order to ensure a safe and secure working environment within the Project laboratories, a number of international standards by the World Bank and WHO have been defined which are mentioned in further sections of this report.

16.3.2 Project Employment and Labour Relations

The information on the Project's labour requirements was limited during preparation of the ESIA. However, it is likely that approximately 250 contractor and subcontractor workers will be on site at the peak of construction. It is expected that the employment will be based on unskilled and semi-skilled labour force during the construction phase.

Studies to determine the operational structure and employment profile in the operation phase of the Project are ongoing. A number of highly skilled personnel specialized in BSL3 laboratory processes will be required. The Project is expected to employ a total of approximately 200 operational staff most of whom will be civil servants of the MoH. The technical departments to be established within the Project will include biomedical, quality management, occupational health and safety, and information technology. Competent personnel profiles with respect to the Project's operational activities will be identified and staff will be recruited based on the minimum unit/department requirements. The personnel will be able to work after receiving and completing the necessary trainings including Good Labour Practice (GLP), Good Manufacturing Practice (GMP), emergency and Chemical, Biological, Radiological, and Nuclear (CBRN) incidents, as well as waste management.

Turkiye has the necessary capacity to build the facilities included in the Project with the help of external guidance (engineering, commissioning, etc.). However, the present human resources capacity to carry out daily activities for BSL3 laboratory processes within the scope of the Project is limited. The proposed Project will help increase the number of people specialized in this area. On the other hand, there is a sufficient volume of qualified and competent staff on attenuated and inactive viral vaccine studies in the veterinary field.

The required human resource for the facilities of the Project is anticipated as follows:

- Qualified and competent people to maintain security within the facilities,
- Qualified and competent people for transport works in and out the facilities,
- Qualified and competent transport company which meets international regulations at all applicable transportation activities,
- Qualified and competent human resources in various types of R&D and production aspects such as purification and BSL3 working experience including biosafety and biosecurity specialists,
- Qualified and competent people for the transgenic unit of the Project,
- Qualified and competent animal caretakers, supervisors and manipulators,
- Qualified and competent emergency response personnel, and
- Technical and maintenance staff for all units.

MoH Human Resources (HR) Policy

International requirements expect HR policies to be developed for projects describing how an organisation manages its employees. HR policies allow employers to communicate with employees, adopt a consistent approach to managing employees and demonstrate compliance with national laws. There will be an HR Policy and management systems or procedures specific to the Project that set out an approach to managing the workforce in accordance with the standards of the World Bank ESF and national law. These policies and procedures will be understandable and accessible to workers, and in the main language spoken by the workforce.

The MoH does not have an HR Policy. Rather, the MoH, as a public institution, follows the Turkish Labour Law No. 4857 and relevant ILO conventions for HR management. The responsibilities of the human

resource management have been shared among all the departments affiliated to the MoH. The MoH will establish a Project-specific HR Policy and ethical Code of Conduct (CoC) in compliance with the WB ESF ESS2, international standards and national legislation. The HR Policy will mainly cover the issues listed below:

- The roles and responsibilities of the personnel employed for human resource management,
- Corporate values of the MoH (i.e., non-discrimination and equal opportunity, child labour and forced labour),
- Worker rights under national labour and employment law,
- Collective agreements,
- Worker grievance mechanism,
- Training process of the workers, and
- Labour and working conditions (including but not limited to employment process, wages, working hours, annual leave, overtime arrangements, compensation benefits, unethical behaviours and disciplinary procedures).

It is necessary for the MoH to disclose the Project HR Policy and ethical CoC for all its workers (including subcontractors).

Gender

Turkiye has ratified a number of International Labour Organization (ILO) conventions, including the conventions on equal treatment of employees and gender equality. The Labour Law No. 4857 is in line with the international labour standards and conventions in most aspects such as child labour, forced labour, non-discrimination and equal opportunity, and right to join workers' organisations. However, there are no laws to support the gender equality at work in the Turkish legislation other than the maternity leave.

Establishment of a quota for the employment of women workers is a key principle to provide gender equality in the workplace. The Project will determine a quota and ensure both female and male employees have the same rights and benefits. The conditions of employment within the Project (including occupational trainings, wages, benefits and compensation) will be based on the workers' performances rather than their gender. There will be no pay gap stemming from gender among workers.

The Project will also ensure that the workers' Code of Conduct (annexed in the Human Resources Management Plan) includes appropriate and proportional security measures for women workers (i.e., lighting, alarms, separate toilets) and a confidential grievance process for the grievances related to sexual exploitation and abuse and sexual harassment (SEA/SH). Regular outreach will be enabled not only to workers, but also to the local community through trainings (including sensitization) in order to address SEA/SH risks around the site of the Project.

Terms and Conditions of Employment

In line with the World Bank ESF, Project workers will be provided with information and written contracts with documentation that is clear and understandable regarding their terms and conditions of employment. The information and documentation will set out their rights under national labour and employment law (which will include any applicable collective agreements) including their rights related to hours of work, wages, overtime, compensation and benefits. This information and documentation will be provided at the beginning of the working relationship and when any material changes to the terms or conditions of employment occur. The workers will have signed contracts that clearly describe terms of employment including the working rights. In addition to the written documentation, the contents of the contract will be explained to workers as they may difficulties in understanding the content of the contract. Terms and conditions of contract will be available at the Project site.

The Project workers will be paid on a regular basis as required by the Labour Law No. 4857.

There will be adequate periods for rest in a weekly manner for workers. The construction contractor of the Project may request employees to work overtime, which would not be exceeding 270 hours per year as stipulated in the Labour Law No. 4857. Further, the workers' consent shall be required for overtime work, in January each year, as specified in the law. Overtime work, work on weekends and public holidays will be compensated in accordance with requirements of this law. The contractor of the Project will prioritize local employment and employment from directly affected neighbourhoods of the Project to the extent possible. Local employment rates will be monitored by the Project on a regular basis.

Non-Discrimination and Equal Opportunity

The employment opportunities offered by the Project for all its potential and existing workforce will be based on the principles of non-discrimination and equal opportunity as per Turkish Labour Law No. 4857 and the standards described in the World Bank ESF. The personal characteristics of the workers that are unrelated to inherent job requirements will be disregarded to provide them a working environment with equal opportunity and no discrimination. There will be no discrimination with respect to any aspects of the employment relationship, such as recruitment, compensation, working conditions and terms of employment, access to training, promotion or termination of employment.

Worker's Organisations

Public servants have different union legislation in Turkiye. Public servants are covered under Law on Unions and Collective Bargaining for Public Servants No. 4688. Other workers are covered by the Law on Trade Union and Collective Bargaining No. 6356. There are four types of collective agreements regulated by this law:

- Workplace collective bargaining agreement,
- Enterprise collective agreements,
- Group collective agreements, and
- Framework agreements.

In line with these laws, Labour Law No. 4857 and the World Bank ESF, the Project will recognize workers' rights to form and join workers' organisations of their choosing and to bargain collectively without interference. The Project workers will be informed about their right to unionization.

Grievance Mechanism

A workers' grievance mechanism will be established for the Project accessible to all employees including Project Implementation Unit members, contractor and subcontractor workers, and any other type of workers working for the Project through which they can raise their concerns and suggestions. The MoH,contractors, and consultants will monitor workers' grievances and the actions taken to close the grievances through internal monitoring mechanism. A grievance log will be utilized in which grievances are categorized by their subjects and their closure time, as well as the current status and actions taken.

The Project will also provide a grievance mechanism for the workers and subcontractor workers through which they can submit confidential grievances related to SEA/SH. If there are any grievances reported regarding SEA/SH issues, necessary actions will be taken and preventive measures applied within and near the Project site immediately.

Workers' grievances can cover a broad range of concerns, from potentially illegal actions such as unethical recruitment, workplace discrimination, SEA/SH, to concerns about wages, how a poor relationship between two employees has been managed, a complaint about the quality of food in the canteen or a disagreement over holiday arrangements.

Child and Forced Labour

The Project will follow the Labour Law No. 4857, Turkish Constitution and the WB ESF ESS 2 in order to avoid forced labour³³⁰ and child labour. The Turkish legislation defines minimum age for employment as 15. Yet, it is stated in the legislation that children who have completed the age of fourteen and have completed the compulsory primary education can be employed in soft works as long as the work does not interfere with their physical, mental, social, educational and moral development. Regarding child labour, the ESS 2 requires complying with minimum age requirements set out in International Labour Organisation (ILO) Conventions and national legislation. The Project will keep records of the dates of birth of all employees verified by official documentation and will be very clear that no one under 18 years will be employed.

In line with the WB ESS 2, forced labour will not be used in connection with the Project. This prohibition covers any kind of involuntary or compulsory labour, such as indentured labour, bonded labour, or similar labour-contracting arrangements. No trafficked persons will be employed in connection with the Project. According to the Turkish legislation, no one can be forced to work.

The Project will also monitor records of workers of contractors and subcontractors on forced and child labour through regular monitoring and evaluation forms.

Retrenchment

The Project will comply with all legal and collectively agreed requirements relating to collective dismissal, including notification of public authorities, and provision of information to, and consultation with workers and their organisations. The employer, who is forced to collective dismissal as a result of the economic, technological, structural and similar business, workplace or the requirements of the job, must concretely reveal the reason for termination of the employment contracts and prove that termination is the last issue.

Non-Employee Workers and Supply Chains

For the non-employee workers to be engaged through contractors or other intermediaries, the Project will consider the risks associated with the recruitment, engagement, and demobilisation of the Project workers by third parties. Accordingly, the Project will establish commensurate policies and procedures for managing and monitoring the performance of third-party employers in relation to the Project. In addition, the Project will use reasonable efforts to incorporate these requirements in contractual agreements with such third-party employers and where relevant, will develop and implement a Contractor Management Plan. In the case of subcontracting, the Project will use reasonable efforts for third parties to include equivalent requirements in their contractual agreements with their subcontractors.

Security Forces

The security personnel will be employed in the scope of the Project. The process on the management of the security forces will in line with the requirements of the World Bank ESS 4 and as per ESS 4, The Project will be guided by the principles of proportionality and GIIP, as well as the applicable national law (i.e. the Law No 5188 on Private Security Services³³¹).

The personnel will provide security services in a manner that does not jeopardize the community's and workers' safety or relationship with them in line with the national requirements, World Bank ESS 4, and international best practices. The Project will ensure that security personnel have not been involved abuses in the past and are adequately trained as per the requirements.

³³⁰ Forced labour consists of work or service involuntarily performed that is exacted from an individual under threat of force or penalty, including through abusive and fraudulent recruitment practices.

³³¹ Official Gazette no/date: 25504/26.06.2004

The personnel will assess risks that are likely to occur within and outside the Project site and report to the senior management of the relevant Project parties (EPC Contractor during the construction phase and Project Implementation Unit during the operation phase).

16.3.3 Occupational Health and Safety

Operational planning and control of the processes need to be established and implemented as necessary to enhance occupational health and safety (OHS) by eliminating hazards or, if not practicable, by reducing the OHS risks to levels as low as reasonably practicable for all activities. Examples of operational control of the processes include:

- The use of procedures and systems of work,
- Ensuring the competence of workers,
- Establishing preventive or predictive maintenance and inspection programmes,
- Specifications for the procurement of goods and services,
- Application of legal requirements and other requirements, or manufacturers' instructions for equipment, and
- Engineering and administrative controls.

Turkiye has improved its occupational health and safety system by integrating international and regional standards to the national legislation. The objective is to prevent workplace accident risks specified in the ILO Occupational Health and Safety Convention.

Construction works are classified as 'very hazardous' according to the national Law on Occupational Health and Safety No. 6331. Therefore, necessary risk analyses will be prepared before the construction works of the Project start. It is required to train all personnel on occupational health and safety issues related to construction. An Occupational Health and Safety Management Plan has been prepared for the construction phase of the Project which will be implemented by the construction contractors. During the construction works, the occupational health and safety performance of the contractors will be monitored in line with this plan. Possible hazards related with construction works, that are also addressed in the Occupational Health and Safety Management Plan include the following:

- Working at height and fall hazards
- Rotating and moving equipment
- Vehicle driving and traffic safety
- Manual handling
- Electrical works, electrical equipment and hand-tools
- Working with hazardous materials
- Fire and explosion
- Noise and vibration
- Working environment temperature

Health and safety is also an essential aspect of the Project's operation phase since biosafety is central to the protection of human health from hazardous biological agents. The Project requires appropriate and sufficient measures since there are the risks of:

- Exposure of laboratory providers and personnel to infections/diseases during operation phase which may include pathogens and other potential infectious materials during laboratory/production activities and collection, handling, treatment and disposal of waste, and
- Exposure to hazardous materials and wastes including toxic chemicals, solvents and disinfectants.

Since there is limited information shared by the MoH, this section will define the general requirements to be applied in the Project regarding occupational health and safety measures. These general requirements

January 2024

will be enhanced by the MoH once the details of the Project are determined. As the very first step, the Occupational Health and Safety Management Plan prepared for the operation phase of the Project will be reviewed and enhanced in accordance with the Project specifics, to ensure compliance with the national and international requirements and monitor the occupational health and safety performance. The issues covered by the plan include but not limited to those listed below:

- Use of Personal Protective Equipment (PPE)
- Hazard and Operability Studies (HAZOP)
- Use of a formal Permit to Work (PTW) system
- Risk assessment
- Emergency preparedness and response
- Primary containment devices
- Process safety
- Personnel competence and training
- Routine health controls

Personal Protective Equipment (PPE)

The WHO defines the PPE within the biosafety laboratories as the equipment and/or clothing worn by personnel to provide a barrier against biological agents, thereby minimizing the likelihood of exposure³³². PPE includes, but is not limited to, laboratory coats, gowns, full-body suits, gloves, protective footwear, safety glasses, safety goggles, masks and respirators. The MoH will ensure that appropriate and sufficient PPE is provided to the employees within the Project. Also, it is necessary to regularly monitor if the employees use the PPE as per the requirements. Therefore, random and regular inspections will be conducted to monitor PPE usage.

Not only appropriate usage of PPE but also cleaning, maintenance, storage and disposal of them is significant for the health and safety of the personnel. The MoH will provide enough storage room for the PPE, which will be separate from personal lockers.

Routine, proactive monitoring and evaluation will highlight daily accounts of successful safety performance. Checklists and process maps are effective methods for achieving routine evaluation. A PPE checklist could include the specific PPE needed for that protocol, steps for checking the integrity of the PPE, steps for donning and doffing of the PPE, steps for decontaminating non-disposable, reusable PPE, and steps for discarding used PPE.

Hazard and Operability Studies (HAZOP)

Hazard and operability studies are a well-proven structured team-based method for hazard identification at process design completion or for planned modifications. The technique is a detailed examination of the process within the facility to assess the hazard potential of operation outside the design intention or malfunction of individual items of equipment and their consequential effects on the facility as a whole.

In order to identify the hazards and hazardous conditions that is possible to occur in the Project's operational activities, preparation of an appropriate management plan for hazard operational studies is necessary. Specialized equipment and processes with unique risk points require a Hazard Analysis of Critical Control Points and/or Hazard and Operability studies. Several benefits of HAZOP studies for operation phase of the Project are listed below:

- Potential deviations from intended design function are identified and corrected,
- OHS process and equipment hazards are revealed and eliminated, and

³³² World Health Organization, Biosafety Programme Management (Laboratory Biosafety Manual, Fourth Edition and Associated Monographs), 2020.

• Actions for necessary process or instrumentation improvements can be planned.

Permit to Work

Laboratory facilities must be designed to operate under safe circumstances in line with the national and international requirements. In addition, heightened control measures should be applied in accordance with the risk assessment³³³. For the facilities like the Project's components (i.e., BSL3 laboratory), it is required to apply appropriate design with maximum containment measures in order to control the highest risks within the laboratory. These high risks cover the investigations with biological agents that might create undesirable consequences (i.e. exposure to and/or release of these agents). As a part of the Occupational Health and Safety Management Plan, development and usage of a formal Permit to Work (PTW) system is necessary to ensure all potentially hazardous work is being carried out in a safe way. By this way, effective authorization of designated work, effective communication of the work to be carried out including hazards involved, and safe isolation procedures to be followed can be ensured, managed and monitored properly.

Risk Assessment

Risk assessments must be undertaken to identify the health and safety risks relating to specific hazards for the workers and communities. National occupational health and safety legislation, sector-specific standards, and international guidelines require a detailed risk assessment for workplaces. Conducting a risk assessment is an essential step to provide a safer workplace where occupational accidents, health and safety risks are prevented. It is necessary to conduct the risk assessment in order to:

- identify the hazardous conditions that exist in a workplace or that may come from outside,
- determine the main factors and root-causes which may lead the hazardous conditions to become risks,
- define the risks related to the hazardous conditions, and
- establish mitigation measures to be applied in the workplace.

Risk assessment is essential to ensure the safety of personnel working in laboratories. The Project is required to conduct a risk assessment, with the involvement of the competent laboratory personnel, in order to determine the risks and determine and implement a set of risk control measures to reduce those risks to an acceptable level. In the context of biosafety, risk is a combination of the likelihood of exposure to a biological agent (the hazard) and the consequences of that exposure (severity of infection and subsequent transmission potential). Risk assessment is conducted in five steps starting with gathering information, evaluation of the risks, development of a risk control category, selection and implementation of the risk control measures, reviewing risks and risk control measures.

Emergency Preparedness and Response

Emergency preparedness is another key to prevent and contain any risk of outbreaks within the laboratories. It includes early-warning surveillance, and local, national and international cooperation to ensure rapid and appropriate responses to the outbreaks. The national capacity for handling hazardous biological agents should be regularly assessed and appropriate levels of support and resources to help with outbreak response should be made available and secured³³⁴.

Furthermore, the WHO emphasizes that laboratory procedures should also be in place for reliable and rapid communication between other laboratories, hospitals, non-governmental organizations (NGOs), international and governmental organizations and the wider public. In order to fulfil this necessity, an

³³³ World Health Organization, Laboratory Design and Maintenance (Laboratory Biosafety Manual Fourth Edition and Associated Monographs), 2020.

³³⁴ World Health Organization, Outbreak Preparedness and Resilience (Laboratory Biosafety Manual Fourth Edition and Associated Monographs), 2020.

Emergency Preparedness and Response Plan specific to the Project will be developed and implemented in line with the Occupational Health and Safety Management Plan.

Primary Containment Devices (Biological Safety Cabinet, BSC)

For the protection of the laboratory personnel from pathogens, primary containment is utilized. Primary containment devices are found to be highly effective in reducing laboratory-associated infections when they are properly used and maintained. Biological safety cabinets (BSCs), screw-capped tubes, glove boxes, flexible-film isolators and local exhaust ventilators can be used in laboratories as primary containment devices. These devices protect the laboratory personnel, the laboratory environment and/or the work materials from exposure to infectious aerosols and splashes that may be generated when manipulating materials containing biological agents. The choice of a primary containment device depends on the risk assessment. Among these various types of primary containment devices, each of which uses different mechanisms to introduce an airflow into the device, treat the circulating air and exhaust it from the device and/or the laboratory, BSCs are the most commonly used primary containment devices³³⁵.

To ensure the biosafety and occupational health and safety within the Project, it is obligatory to establish BSCs in line with the international standards and requirements (i.e. WHO good microbiological practice and procedures). According to Centres for Disease Control and Prevention (CDC)³³⁶, primary containment devices that are not working properly are hazardous, especially when the user is unaware of the malfunction. Poor location, room air currents, decreased airflow, leaking filters, raised sashes, crowded work surfaces and poor user technique compromise the containment capability of a BSC. For a routine, proactive monitoring and evaluation of BSC performance, a BSC checklist could include checking the certification date of the cabinet, confirming the most recent BSC training date of the users, conducting an airflow check, and performing surface disinfection.

Process Safety Management

The aim of process safety management is to develop management systems and procedures to prevent unwanted releases, which may ignite and cause toxic impacts, local fires or explosions in facilities, affecting workers and nearby communities. Additionally, process safety management can also address issues related to the operability, productivity, stability, and quality output of processes, leading to the specification of safeguards against undesirable events.

Effective process safety management in biosafety laboratories is essential for reducing the risks of occurrence of accidents and ensuring the occupational health and safety within the facility³³⁷. There exist a variety of process safety hazards that must be managed within a biosafety laboratory. These hazards include chemical and physical hazards, other than the biohazards. Mitigation to possible risks associated with those hazards are covered in relevant sections of this ESIA report.

Personnel Competence and Training

It will be necessary to employ qualified research and production personnel with specific training in facility procedures, handling of equipment and infected animals, and manipulation of pathogenic agents. Personnel working in BSL3 laboratories should be also trained on sample and waste handling, transportation and storage, as well as management of biosafety risks. In this context, it is planned to establish a biosafety committee to take part in the operation of the Project and to assign several biosafety officers (please see *Chapter 14: Community Health and Safety* for more details on biosafety and biosecurity).

³³⁵ World Health Organization, Biological Safety Cabinets and Other Primary Containment Devices (Laboratory Biosafety Manual Fourth Edition and Associated Monographs), 2020

³³⁶Centers for Disease Control and Prevention (CDC), Biosafety in Microbiological and Biomedical Laboratories, Sixth Edition, 2020.

³³⁷ Center for Chemical Process Safety, Guidelines for Process Safety in Bioprocess Manufacturing Facilities, 2010.

Since laboratory risk control measures can be compromised by human error, it is critical to employ experienced, competent, well-trained and safety-conscious laboratory personnel who are well informed on how to recognize and control laboratory risks. By this way, it is possible to lower the potential risk of infection to the personnel and to produce accurate results in a safe laboratory environment. These personnel must be well informed of the biological and chemical hazards and the risk control measures in place to reduce the risks of working with those hazards^{338,339}. The involvement of the personnel to the risk assessment process is also preferable for regularly monitoring and updating the risks as well as determining the risk control measures. Also, specialized first aid providers need to exist in the laboratory to intervene the situations when required.

Routine Health Controls

Good labour practices and good manufacturing practices necessitates that health screenings, periodic health monitoring, and vaccinations of the personnel should be implemented and properly followed by the quality assurance unit within the laboratories. The Project is required to comply with the WHO requirements for routine health controls of the Project personnel within the BSL3 laboratory. In this context, occupational health of the personnel will be strictly monitored.

16.4 Assessment of Impacts

16.4.1 Methodology

The assessment of impacts is performed in accordance with to the national labour legislation and international requirements that are relevant to the Project activities. The assessment considered the impacts that might arise during the Project lifecycle, together with their possible risks on the employees, using the criteria provided in the next section for determining receptor sensitivity and impact magnitude and significance. Professional judgement has been used by appropriately qualified labour and occupational health and safety experts when assigning impact significance.

16.4.2 Determining Magnitude, Sensitivity, and Impact Significance

Sensitive or vulnerable receptors are generally considered to have less means to absorb adverse changes than non-sensitive or non-vulnerable receptors. Labour vulnerability is generally considered in relation to their capacity to cope with impacts and resilience to loss of livelihood or wellbeing. Table 16-5 below presents the guideline criteria that have been used to categorise the sensitivity of labour receptors.

Sensitivity	Definition
High	An already vulnerable receptor with minimal capacity and means to absorb proposed changes or with minimal opportunities for mitigation.
Medium	An already vulnerable receptor with limited capacity and means to absorb proposed changes or with limited opportunities for mitigation.
Low	A non-vulnerable receptor with some capacity and means to absorb proposed changes and some opportunities for mitigation.
Negligible	A non-vulnerable receptor with plentiful capacity and means to absorb proposed changes and good opportunities for mitigation.

Table 16-5: Criteria for Determining Sensitivity

The magnitude of an impact has been determined by consideration of the extent to which it results in a beneficial or adverse impact on individual and collective wellbeing. Wellbeing is considered as the financial, physical and emotional conditions and quality of life of people. For beneficial impacts, the extent

³³⁸ World Health Organization, Laboratory Biosafety Manual, Fourth Edition (Laboratory Biosafety Manual Fourth Edition and Associated Monographs), 2020.

³³⁹ World Health Organization, Outbreak Preparedness and Resilience (Laboratory Biosafety Manual Fourth Edition and Associated Monographs), 2020.

to which wellbeing is likely to be enhanced has been considered. Table 16-6 below summarises the typical varying degrees of impact magnitude.

Definition (considers likelihood, duration, number of people affected and spatial extent)
A highly likely impact that would have implications beyond the project life affecting the wellbeing of a large group of people and affecting various elements of the workers' resilience.
A likely impact that continues over a number of years throughout the project life and affects the wellbeing of specific groups of people and affecting specific elements of workers' resilience.
A potential impact that occurs periodically or over the short term throughout the life of the project affecting the wellbeing of a small number of people and with little effect on workers' resilience.
A potential impact that is very short lived so that the baseline conditions remain largely consistent and there is no detectable effect on the wellbeing of workers.

Table 16-6: Criteria for Determining Magnitude

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 16-7.

Magnitude of	Sensitivity of Receptors				
Impact	Negligible	Low	Medium	High	
Negligible	Insignificant	Insignificant	Insignificant	Insignificant	
Minor	Insignificant	Minor	Minor	Moderate	
Moderate	Insignificant	Minor	Moderate	Major	
Major	Insignificant	Moderate	Major	Critical	

Table 16-7: Impact Significant Matrix

16.4.3 Construction Phase

Potential impacts may occur during the construction phase related to labour and working conditions as listed below.

- Fair treatment, non-discrimination and equal opportunity of workers: Any discrimination on the basis of race, colour, gender, religion, political opinion, nationality or social origin should not be tolerated. The sensitivity of the employees in terms of this impact is medium. The magnitude of the impact is minor, which corresponds to an impact with minor significance level.
- Grievance mechanism and information disclosure to the workers on terms and conditions of employment: The Project workers might not be adequately informed about grievance mechanism as well as terms and conditions of their employment within the Project activities. Employees have medium sensitivity regarding this impact. The magnitude of the impact is minor, which leads to an impact with minor significance level.
- Contractor and subcontractor management (including child and forced labour): Construction works will
 be carried out by the main contractor and its subcontractors. The contractor or subcontractors may not
 have adequate knowledge about the World Bank standards and practices regarding contractor and
 subcontractor management. Workers of the contractors and/or subcontractors have medium sensitivity
 regarding this impact. Both the magnitude and the significance level of the impact is minor.
- Overtime working without workers' consent and/or compliance with national and international requirements: The Contractor may apply compulsory overtime for the completion of construction works on time. It also may not compensate the overtime work through payments. The overtime working may exceed the 270 hours per year. Employees have medium sensitivity regarding this impact. The magnitude of the impact is moderate, which corresponds to an impact with moderate significance level.

- Sexual Exploitation and Abuse and Sexual Harassment (SEA/SH) risks: Unless preventive measures are taken appropriately, the possibility of sexual harassment among employees may occur. Employees' sensitivity in regard to this impact is medium and the magnitude of the impact is moderate. Overall, this will lead to an impact with moderate significance level.
- Construction camp conditions: Workers' camps and accommodation conditions may not meet the World Bank standards (i.e. space per person, number of people staying in a room, hygiene of the rooms and other facilities within the camp). Employees have medium sensitivity regarding this impact. The magnitude of the impact is minor, which corresponds to an impact with minor significance level.

Potential positive impacts may include:

• Increase in the local employment rates through job opportunities created by the Project: The Project has the possibility to employ people from nearby settlements. People residing in the nearby settlements of the Project have medium sensitivity about this impact. The magnitude of the impact is moderate. Overall, this will lead to an impact with moderate significance level.

Human health impacts during site preparation and construction for the proposed Project would be the same as any construction project. The impacts would be localized and would affect only site workers or visitors on the site. However, construction activities have the potential for exposing workers or site visitors to a number of common hazards including physical hazards, electrical hazards, fire and explosion hazards and biological hazards. Potential impacts can occur related to:

- Personal protection use: Construction workers would be actively involved in potentially hazardous
 activities such as heavy equipment operations, soil excavations, and the handling and assembly of
 various building materials, and therefore personal protection measures will be a routine part of the
 construction activities (such as gloves, hard hats, steel toed boots, eye shields, and ear plugs or
 covers). Workers have high sensitivity regarding this impact. The magnitude of the impact could be
 minor to major, leading to impact significance of moderate to critical.
- Accidents/incidents: Potential impacts also include near misses, injuries or incidents due to the inadequate risk assessment, application of risk control measures and regular monitoring of the workplace incidents. Workers' sensitivity in regard to this impact is high. The magnitude of the impact could be moderate to major and the significance level of the impact could be major to critical.
- Dust, noise and vibration: Generation of dust, noise and vibration during construction activities (such as earthmoving, operation of equipment and vehicles, construction traffic) may also cause adverse effects on workers to be employed for the construction works unless sufficient measures are taken (i.e. health controls, usage of PPE). Construction workers have medium sensitivity regarding this impact. The magnitude of the impact is minor, which corresponds to an impact with minor significance level.

16.4.4 Operation Phase

In terms of labour and working conditions, potential negative impacts may occur during the Project operation related to:

- Fair treatment, non-discrimination and equal opportunity of workers: Any discrimination on the basis of race, colour, gender, religion, political opinion, nationality or social origin should not be tolerated. The sensitivity of the employees in terms of this impact is medium. The magnitude of the impact is minor, which corresponds to an impact with minor significance level.
- Grievance mechanism and information disclosure to the workers on terms and conditions of employment: The Project workers might not be adequately informed about grievance mechanism as well as terms and conditions of their employment within the Project activities. Employees have medium sensitivity regarding this impact. The magnitude of the impact is minor, which leads to an impact with minor significance level.
- Sexual Exploitation and Abuse and Sexual Harassment (SEA/SH) risks: Unless preventive measures are taken appropriately, the possibility of sexual harassment among employees may occur.

Employees' sensitivity in regard to this impact is medium and the magnitude of the impact is moderate. Overall, this will lead to an impact with moderate significance level.

Potential benefits may occur related to:

National contribution to number of personnel trained in vaccine research, development, production
and operation of BSL3 laboratories: The number of experienced and expert personnel is expected to
increase in line with the Project improvements. The Project will enhance human resource capacity in
vaccine production, and hence contribute to independent and sustainable vaccine production. In this
regard, the sensitivity of the people in Turkiye has medium sensitivity about this impact. The
magnitude of the impact is major. Overall, this will lead to an impact with major significance level.

Physical, chemical and biological risks may arise due to operation phase activities of the Project that might have impacts on health and safety of the employees. Potential impacts are listed as follows:

- Risks due to chemicals and hazardous substances:
 - Handling materials/chemicals is a typical part of the day-to-day routine laboratories. Chemical hazards represent potential for illness or injury due to single acute exposure or chronic repetitive exposure to toxic, corrosive, sensitizing or oxidative substances. They also represent a risk of uncontrolled reaction, including the risk of fire and explosion, if incompatible chemicals are inadvertently mixed. Workers' sensitivity in regard to this impact is high. The magnitude of the impact could be minor to major, leading to impact significance of moderate to critical.
 - Since laboratory activities use different sorts of chemicals and reagents, it can be predicted that different types of hazardous wastes will also be generated. Therefore, improper handling, treatment and disposal waste can cause serious health problem for workers, community (death, illness) and environment (i.e., impaired air quality, contamination of water courses). Duration of the impact would be long-term lasting through the entire life of the affected person or short-term depending on the hazard exposed to, therefore impact magnitude is considered to vary from minor to major. The sensitivity of the receptors will be high, therefore impact significance will be moderate to critical.
 - Non-biological hazards posed by chemical disinfectants should also be considered and appropriate non-biological risk control measures should be applied. Many chemical disinfectants may be harmful to humans, animals and/or the environment or pose a fire or explosion risk. Particular care is needed in the use and storage of such chemicals. Workers have medium sensitivity regarding this impact. The magnitude of the impact is major, corresponding to an impact with major significance level.
- Risks due to biosafety issues:
 - Biosafety risks from biological R&D and production activities: The Project personnel to be employed will be exposed to significant biosafety risks due to the laboratory activities unless relevant measures are taken under the light of international laboratory standards and requirements. Employees have high sensitivity regarding this impact. The magnitude of the impact is major, which corresponds to an impact with critical significance level.
 - Impact of wastes resulting from R&D, experimental animals building and production buildings (if not properly managed including spills): Wastes occurred as a result of the laboratory works can pose significant health risks to the Project personnel as well as the community including infectious diseases. Receptors' sensitivity is medium with regards to this impact that has moderate magnitude. Overall, this is an impact with moderate significance level.
 - Biosafety risks due to accidents, sabotage, terrorism and similar that occur unexpectedly: The Project may suffer from an unexpected disaster or sabotage and terrorism unless proper and highlevel safety and security measures are taken within the Project site. Receptors' sensitivity regarding this impact is high. The magnitude of the impact is major, which leads to this impact having critical significance level.
 - Security breach and improper management of safety zones and restricted access rules to the dedicated areas/units/zones: The Project personnel may face dangerous situations if there is a

security breach in access to restricted zones of the laboratory. The employees have medium sensitivity about this impact. The magnitude of the impact is moderate. Overall, this will lead to an impact with moderate significance level.

16.5 Mitigation Measures

To prevent, minimize or offset the adverse labour related impacts, mitigation measures were identified in accordance with the national regulations and laws, international best practices, the World Bank ESSs and WHO laboratory manual and monographs.

16.5.1 Construction Phase

Regarding the potential impacts of the Project on labour and working conditions during the construction phase, the following mitigation and enhancement measures will be applied, but not limited to:

- Development and implementation of a Project-specific Labor Management Procedure (addressing issues including non-discrimination and equal opportunity, workers' rights and benefits, right to unionization, grievance mechanism, child and forced labour) in line with the national and international requirements.
- Providing an accessible grievance mechanism to workers and contractor and sub-contractor workers through which they can raise their concerns and suggestions, that also includes a channel to receive and address confidential complaints related with SEA/SH with special measures in place.
- Development of a Code of Conduct for workers and ensuring that it includes appropriate and proportional security measures for women workers (i.e. lighting, alarms, separate toilets).
- Implementation of the Labour Management Procedure (including management of subcontractor labour).
- Ensuring that the main contractor and its subcontractors follow laws and regulations in the employment of construction workers.
- Ensuring security forces are employed and managed in line with the World Bank ESS 4, Good Internaitonal Industry practice (GIIP)and security measures are properly implemented in the Project site.
- Preparation of a SEA/SH Policy and ensuring its implementation by the contractors and subcontractors.
- Ensuring vulnerable workers as specified in the World Bank ESS2 and identified within the scope of the Project (i.e. women³⁴⁰, disabled, migrant workers) are protected and are not discriminated.
- Ensuring the use of all forms of child and forced labour is prevented in contractor/subcontractor companies as well as the supply chain.
- Development and implementation of a Construction Site Management Plan including a procedure for managing the construction camp for the accommodation of workers.
- Ensuring the construction camp and accommodation conditions are in compliance with the World Bank ESS 2 requirements.
- Development of an Employment and Procurement Strategy to ensure maximization of opportunities for local people and businesses.
- Implement procedures to confirm workers are fit for work before they start work.
- The contractor and its subcontractors will be required to follow the requirements of the Project. Contracts to be signed with subcontractors will include EHS requirements.

³⁴⁰ The World Bank Good Practice Note (GPN) on Addressing Sexual Exploitation and Abuse and Sexual Harassment (SEA/SH) in Investment Project Financing involving Major Civil Works (2020) states that SEA and SH are the types of GBV that are most likely to occur in a workplace and GBV disproportionately affects women and girls. Therefore, women and girls are particularly vulnerable at workplaces in which major civil works are practiced.

- Contractors will develop Labour Management Plans based on the Project Human Resources Management Plan/Labour Management Procedures (HRMP/LMP).
- All workers will be insured under Social Security Institution.

The mitigation measures that will be applied to reduce or avoid the potential occupational health and safety risks during the construction phase will include but not be limited to the following:

- Implementation of good site management practice (training and qualification of staff, appropriate work standards) to reduce occupational health and safety risks. The Contractor will ensure that all work will be carried out in a safe and disciplined manner and is designed to minimize the risks on neighbouring residents and environment.
- Ensuring that necessary fencing is installed around the Project site during construction.
- Implementation of the Occupational Health and Safety Management Plan.
- Conducting risk assessments.
- Development and implementation of a Construction Site Management Plan.
- Implementation of the Permit to Work procedure.
- Implementation of the Emergency Preparedness and Response Plan.
- Conducting regular drills.
- Ensuring supply and use of appropriate personnel protective equipment (PPE) in line with international best practice and national legislation.
- Providing regular trainings and toolbox talks to workers and subcontractor workers on the possible risks regarding the work site and works to be carried out (including key rules and regulations to follow), and keeping training records.
- Keeping accident records (fatalities, lost time incidents, near misses, any significant events including spills, fire, outbreak of pandemic or communicable diseases, social unrest, etc.).
- Regular inspection of equipment and vehicles.
- Definition of the relevant monitoring parameters and implementation of regular monitoring of the occupational health and safety performance of employees and subcontractors.
- The subcontractors will also be required to follow the requirements of the Project. Contracts to be signed with subcontractors will include EHS requirements.
- The Contractor will ensure a safe working environment for the workers and appropriate signposting of the sites will be provided.
- The Contractor will assign at least one full-time OHS specialist with relevant certification and experience in charge of OHS management on site.

16.5.2 Operation Phase

To address the potential impacts of the Project on labour and working conditions during operation phase, the following mitigation and enhancement measures will be applied:

- Development and implementation of a Human Resources Management Plan/Labour Management Procedures based on the Project's Labour Management Procedures (addressing issues including non-discrimination and equal opportunity, workers' rights and benefits, right to unionization, grievance mechanism, child and forced labour) in line with the national and international requirements.
- Providing an accessible grievance mechanism to workers and contractor workers with which they can
 raise their concerns and suggestions, that also includes a channel to receive and address confidential
 complaints related with SEA/SH with special measures in place.
- Development of a Code of Conduct for workers and ensuring that it includes appropriate and proportional security measures for women workers (i.e. lighting, alarms, separate toilets).

500

- Implementation of the Human Resources Management Plan/Labour Management Procedures (including management of subcontractor labour).
- Certification and human resource management for the laboratories, which are planned to be operated in accordance with the OECD Good Laboratory Practice (GLP).
- Ensuring that the subcontractors follow laws and regulations in the employment of workers.
- Ensuring fair treatment, non-discrimination and equal opportunity of all employees.
- Ensuring vulnerable workers as specified in the World Bank ESS2 and identified within the scope of the Project (i.e. women, disabled, migrant workers) are protected and are not discriminated.
- Ensuring the use of all forms of child and forced labour is prevented in subcontractor companies as well as the supply chain.
- Ensuring security forces are employed and managed in line with the World Bank ESS 4, GIIP, and security measures are properly implemented in the Project site.
- Preparation of a SEA/SH Policy.
- Establishing of a quota for the employment of women workers to provide gender equality.
- Implementation of a comprehensive labour training program that include biosafety, security, emergency response and waste management.

Regarding the potential occupational health and safety risks during the Project activities, risk assessments will be conducted to determine the complete set of measures required. At a minimum, it is necessary to apply the following mitigation measures:

- Implementation of the following as part of the ESMS: Occupational Health and Safety Management Plan, Emergency Preparedness and Response Plan, Community Health and Safety Management Plan, Hazardous Materials Management Plan, Waste and Wastewater Management Plan.
- Preparation of a laboratory-specific biosafety manual and associated standard operating procedures (SOPs). Adopt a biosafety policy.
- Establishment of a biosafety committee and appointment of biosafety officers.
- Application of good microbiological practices throughout the whole R&D and production activities.
- Checking laboratory equipment that should be routinely decontaminated, as well as repair, maintenance, or removal from the laboratory after spills, splashes, or other potential contamination.
- Regular monitoring and reporting of the occupational health and safety conditions within the Project including incidents and near misses.
- Providing a Self-Inspection Checklist for the Project personnel to fill the checklist on a regular basis and keeping the records of the checklist.
- PPE will be used to reduce the likelihood of exposure of personnel to both the chemical hazards and any biological agents present.
- Design and implement control measures and provide training on the appropriate usage, handling and storage of hazardous chemicals to prevent chemical hazards.
- Operation and maintenance of autoclaves must be assigned to trained, competent individuals. Operating instructions for the autoclave must be available.
 - Sterilization programmes with application area (for example, solids, liquids) and the parameters to be maintained (temperature, pressure, time) must be defined.
 - A loading plan (with information on the contents, number, volume and mass of the sterilized product) will also be available. Large and bulky material, large animal carcasses, sealed heatresistant containers and other waste that impedes the transfer of heat must be avoided.
 - A preventive maintenance programme must be developed, including regular visual inspection of the chamber, door seals, gauges and controls. This will be conducted by qualified personnel.

- A reliable steam source must be used to provide appropriately saturated steam, uncontaminated by water droplets or chemicals which inhibit the function of the autoclave or may damage the pipes or chamber of the autoclave.
- Waste or materials placed in the autoclave must be in containers that readily allow removal of air and permit good heat penetration.
- The chamber of the autoclave must be loosely packed so that steam can penetrate evenly.
- Hazardous chemical waste (for example, bleach), mercury or radioactive waste must not be treated in an autoclave.
- Operators must wear suitable thermally protective gloves, protective clothing and eye protection when opening the autoclave, even when the temperature has fallen to levels appropriate for opening the chamber.
- Care will be taken to ensure that the relief valves and drains of autoclaves do not become blocked by paper, plastic or other materials included in the waste or materials for decontamination.
- For the decontamination of volatile hazardous material (for example, spores of pathogens) the air relief of the autoclave must be equipped with an appropriate filter.
- Implementation of engineering and administrative control measures to avoid or minimize the release of hazardous substances into the work environment keeping the level of exposure below internationally established or recognized limits.
 - Chemical disinfectants must be selected, stored, handled, used and disposed of with care, following manufacturers' instructions.
 - Hazardous materials will be stored within secured and designated areas of the facility in containers or tanks located in bunded areas which can hold a minimum of 110% of the total storage volume.
 - Small amounts of chemicals necessary for daily use would be stored in the laboratory. Bulk stocks
 would be kept in specially designated rooms or buildings away from the main laboratory.
 - Replacement of the hazardous substances with less hazardous substitutes.
 - Where corrosive, oxidizing or reactive chemicals are used, handled, or stored, qualified first-aid would always be ensured. Appropriately equipped first-aid stations would be easily accessible throughout the place of work, and eye-wash stations and/or emergency showers would be provided close to all workstations where the recommended first-aid response is immediate flushing with water.
 - Keeping the number of employees exposed, or likely to become exposed to a minimum.
 - Communicating chemical hazards to workers through labelling and marking according to national and internationally recognized requirements and standards, including the Materials Safety Data Sheets (MSDS) or equivalent. Any means of written communication would be in an easily understood language and be readily available to exposed workers and first-aid personnel.
 - Training workers in the use of the available information (such as MSDSs), safe work practices, and appropriate use of PPE.

Assuring biosafety in the laboratory is essential for protecting the occupational health and safety. Specific mitigation measures to prevent any biosafety impacts on the Project employees will include:

- The facility will have and regularly review and update a biosafety manual and accompanying SOPs detailing safety practices and procedures in addition to standard practices (e.g., Occupational Safety and Health Administration (OSHA) blood borne pathogens, chemical and hazardous waste handling, emergency contact information). Computers may be made available in each laboratory which enable electronic access to these various SOPs and protocols.
- All researchers must be trained to follow the practices and procedures for biosafety and biosecurity as published by the laboratory, national authority guidelines, WHO, the CDC, and NIH. Spot-checking and post-training monitoring will be conducted to ensure full compliance with SOPs. Retraining is mandated for individuals who deviate from approved protocols.

- Laboratory personnel will be enrolled in a medical surveillance program commensurate with the risks involved in working with specific biological materials. These medical monitoring programs provide screening upon hire and ongoing surveillance to ensure that laboratory staff is immunized and maintain their health status to perform their duties within containment. Some pre-existing medical conditions preclude individuals from certain types of laboratory work.
- A primary containment unit such as a biological safety cabinet (BSC) will be used when handling certain biological agents to prevent the escape of aerosols into the environment and/or containment of certain equipment. The type of BSC used depends on the associated hazard in order to protect workers and the environment effectively. Other engineering controls that are in place in the BSL3 include high efficiency particulate air (HEPA) filtration and negative pressure, often with individual air purifying systems used to eliminate laboratory exposures of pathogens from infected animals. Specialized tubes with bio-seal closures and specialized housing will be used to avoid aerosol generation from centrifuges and other mechanical equipment.
- All employees wearing Personnel Protection Equipment (PPE) must be fit tested at least annually by an approved person prior to working in a biocontainment facility. Individuals who wear Powered Air Purifying Respirator (PAPR) must be trained initially on the use and care of the PAPR. Similarly, annual training may be required for this type of respirator. In addition to PPE required for the biological materials in use, engineering controls will be utilized whenever possible to protect workers and the community from biohazards.
- The MoH will assign full-time OHS specialist(s) with relevant certification and experience in charge of OHS management on site.

16.6 Residual Impacts

Residual impacts are defined as the impacts remaining after the implementation of the mitigation measures. For the potential impacts anticipated related to the labor and working conditions as well occupational health and safety aspects of the Project, it is expected that residual impacts will remain at minor level as long as the mitigation measures are properly applied throughout the lifetime of the Project.

16.7 Proposed Monitoring and Reporting

The Project is required to implement a monitoring system throughout the Project for the potential impacts regarding labour and working conditions as well as occupational health and safety. The monitoring system will determine the effectiveness of mitigation measures as detailed in the applicable management plans of the Project ESMS (including the Occupational Health and Safety Management Plan, Human Resources Management Plan/Labour Management Procedures, and Community Health and Safety Management Plan). The monitoring and reporting activities will include:

- Annual independent labour inspections
- Workers' grievances received and responded
- Routine biosafety and OHS monitoring and inspections
- Accident and incident reporting in line with applicable standards and regulatory requirements

Additionally, the MoH will: (i) promptly notify the World Bank of any incident or accident related to the Project which has, or is likely to have, a significant adverse effect on the environment, the affected communities, the public or workers (no later than 48 hours after learning of the incident or accident), (ii) provide sufficient detail regarding the scope, severity, and possible causes of the incident or accident, indicating immediate measures taken or that are planned to be taken to address it, and any information provided by any contractor and/or supervising firm, as appropriate, and (iii) subsequently, at the World Bank's request, prepare a report on the incident or accident and propose any measures to address it and prevent its recurrence (provide subsequent report to the World Bank within a timeframe acceptable to the World Bank). The above commitment will also be followed by the EPC Contractor (through the MoH) for incidents or accidents of similar nature related to the Project during the construction phase.

17 BIODIVERSITY

17.1 Introduction

This chapter addresses the protection and conservation of biodiversity and the ecosystem services within the Area of Influence (AoI) of the Project site. Baseline conditions on flora and fauna characteristics and resources of nature conservation are presented in Section 17.3.

The assessment presented in this chapter considers the potential impacts of construction and operational phases of the Project as well as measures and recommendations for the management and conservation of biological diversity.

17.1.1 Study Area and Area of Influence

The area of influence of the Project includes the areas directly within the land take for the proposed development as well as all ecological features which occurs within the areas likely to be affected by the Project:

- The parcel of 1555-4: The main project complex area (including mainly but not limited to experimental animal production/testing units, laboratory units and vaccine production units) will be built on the land registered with parcel number 1555-4 covering a 47,589 m² area. The green area covers approximately 34,700 m² surface (calculated by the biodiversity expert);
- The recreational area: The area adjacent to the parcel of 1555-4 which is planned to be used as a recreational area comprising of a total of 31,700 m²; and
- Surrounding habitats up to 1 km (circled area in Figure 17-1).



Figure 17-1: Area of Influence (Aol) for biodiversity assessment

Since it was neither possible nor practical to survey the entire AoI of the Project and as the Project is located within an urban setting, all ecological features within the Project footprint were reviewed through ecological walkover surveys which were supported by desktop studies. The ecological baseline within the
Aol was formulated from information obtained through various primary and secondary sources. Details on the methodologies used are provided in Section 17.2.

17.2 Methodology and Assessment Criteria

17.2.1 Methodology

Baseline information on terrestrial ecology has been collected through two different ecological walkover surveys conducted in December 2021 and May 2022 by flora and fauna experts. Information collected during the site visits were supported by desktop studies.

The first ecological walkover survey was conducted as part of the ESIA scoping study on 29 December 2021 (outside the flowering season and the breeding season of birds and other faunal species) by the biodiversity expert (Kerem Ali Boyla) with the objectives to:

- Have an appreciation of the general environmental and ecological value of the areas directly within the land take for the Project (general properties i.e., vegetation, soil, habitat connectivity and physical properties);
- Identify the main group of habitats and plants (e.g. tree species within the land take for the Project)
- Provide data for second ecological walkover survey.

A second ecological walkover survey was conducted on 24 May 2022 by the biodiversity expert (Kerem Ali Boyla) and flora expert (Dr. Mecit Vural) during the flowering season. The entire Project site was surveyed, and no habitat-based sampling was conducted. The objectives were to:

- Identify flora and fauna species within the AoI; and
- Identify areas regarded as being of biological importance and potentially more sensitive to impacts.

All ecological walkover surveys were undertaken by qualified local ecologists with regional knowledge and experience of flora and fauna.

No aquatic ecology studies were conducted in the Cubuk Stream as part of the baseline assessment, as it is heavily polluted as a result of historic discharges of untreated wastewater along the stream and the heavy pollution load and debris material on the stream bed were visually observed on both ecological walkover surveys. It was concluded that the stream is unlikely to host any significant population of native species.

17.2.1.1 Terrestrial Flora

All ecological walkover surveys included one-hour walks on land and identifying general ecological features and plant species. All plant species were recorded using survey transects.

During the first ecological walkover survey, general assemblages of plants, type of habitat and general properties of the vegetation were observed. The plant species identification could be partially completed as the survey was conducted outside of the flowering season. Tree species could be identified and counted.

During the second ecological walkover survey, it was aimed to identify individual species of plants with the expertise of flora expert. The species were categorized against national plant checklist³⁴¹. The standards of the International Union for the Conservation of Nature (IUCN) were also taken into consideration. IUCN maintains a List of Threatened Species (the IUCN Red List) which is a widely recognized, global

³⁴¹ Bizim Bitkiler official website (Last access on 22.07.2022; <u>https://www.bizimbitkiler.org.tr/list.html</u>). The database is based on Davis (1965-1985), Davis et al. (1988) and Güner et al. (2000):

[•] Davis P.H. (1965-1985), Flora of Turkey, V: 1-9, University of Edinburg, UK.

[•] Davis P.H. et al. (1988), Flora of Turkey, V:10, University of Edinburg, UK.

[•] Güner et al. (2000), Flora of Turkey, V 11, University of Edinburg, UK.

approach for evaluating the conservation status of plant and animal species. It provides information on taxonomy, conservation status and distribution information on taxa that are facing a high risk of global extinction. Red List criteria were used for plants.

17.2.1.2 Terrestrial Fauna

In biodiversity assessment, the target fauna groups included birds, mammals, amphibians, reptiles, and selected groups of insects, such as butterflies and dragonflies. The first ecological walkover survey focused mainly on birds, as other groups (most mammals, amphibians, reptiles and insects) were not active during winter.

Bird surveys included a 30-minute timed observation on a 500 m transect. Since the surface area of the Project site is relatively small, almost all individual birds were easily detected along the transect.

17.2.2 Determining Magnitude, Sensitivity, and Impact Significance

The conservation value (sensitivity) or weighting attributed to each ecological feature which occurs within the AoI of the Project needs to be undertaken, and these are defined in Table 17-1. The magnitude of the potential impacts upon each feature (Table 17-2) is then assessed for the construction and operation of the Project.

value (sensitivity)	Examples	Species Criteria	Habitat or Site Criteria		
Very High	Very high importance and rarity. International scale with limited potential for substitution	IUCN Critically endangered and endangered species	Internationally designated sites (or equal status). Critical habitats of significant international ecological importance.		
High	High importance and rarity, national scale, or regional scale with limited potential for substitution, species of international status but not within designated areas	IUCN Vulnerable species. European species and nationally protected species of significant population size and importance.	Nationally designated sites (or equal status). Areas of critical habitats of national ecological importance, and natural habitats of significant ecological importance and/or high biodiversity with limited potential for substitution.		
Medium	High or medium importance and rarity, local or regional scale, and limited potential for substitution, species of national status but not within designated areas	IUCN Near Threatened species. Nationally protected species or rare species, but not a significant population size and not of national importance.	Regionally important natural habitats. Natural habitats. Modified habitats with high biodiversity or under significant threat of loss within the region.		
Low	Very low or low importance and rarity, and local scale	IUCN Least Concern. Species of local national importance.	Undesignated sites and habitats of natural habitats of some local biodiversity and cultural heritage interest. Modified habitats with limited ecological value. Other sites with little or no local biodiversity and cultural interest. Modified habitats with limited biodiversity value.		
Negligible	Very limited ecological importance	IUCN Least Concern species. Species of no national importance.	Highly modified habitats of no biodiversity value.		

Table 17-1: Criteria for Determining Conservation Value (Sensitivity of the receiving environment)

Magnitude	Definition (considers duration of the impact, spatial extent, reversibility and ability to comply with legislation)
Major	Fundamental change to the specific environmental conditions assessed resulting in long term or permanent change, typically widespread in nature (regional national and international), would require significant intervention to return to baseline; exceed national standards and limits.
Moderate	Detectable change to the specific environmental conditions assessed resulting in non-fundamental temporary or permanent change.
Minor	Detectable but minor change to the specific environmental conditions assessed.
Negligible	No perceptible change to the specific environmental conditions assessed.

Table 17-2: Guidelines for Definition of Magnitude in the ESIA

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 17-3 below.

Sensitivity of Receptors							
Magnitude of Impact	Negligible	Low	Medium	High/Very High			
Negligible	Insignificant	Insignificant	Insignificant	Insignificant			
Minor	Insignificant	Minor	Minor	Moderate			
Moderate	Insignificant	Minor	Moderate	Major			
Major	Insignificant	Moderate	Major	Critical			

Table 17-3: Impact Significant Matrix

As part of the impact assessment, appropriate mitigation measures are reviewed and included to minimise any potential adverse impacts of the Project on biodiversity. The residual impacts are then determined.

17.2.3 Data Limitations

The ecological walkover surveys were conducted in two different seasons focusing on the typical habitats and areas of ecological interest.

Surveys were conducted in December 2021 and May 2022; and as such it was not possible to survey all seasons when species are active. Moreover, some early site preparation works, site stripping and excavation activities had been initiated and ongoing on parcel 1555-4, where the main project complex area will be built, at the time of the second ecological walkover survey. It was observed that the whole topsoil, including all vegetation on parcel 1555-4 had been removed. The biodiversity assessment for the parcel 1555-4 was undertaken with limited information from the remaining few plants on the edge of the boundaries of the parcel and outcomes of the first ecological walkover survey.

17.3 Overview of Baseline Conditions: Terrestrial Flora and Fauna

This section presents baseline conditions on terrestrial ecology and resources of nature conservation. The baseline includes information on protected areas, habitats and species gathered from primary and secondary data sources. Baseline information on terrestrial ecology has been collected through two different ecological walkover surveys; i) first ecological walkover survey conducted on 29 December 2021 by the biodiversity expert and ii) second ecological walkover survey conducted on 24 May 2022 by the biodiversity expert (Kerem Ali Boyla) and flora expert (Dr. Mecit Vural).

The Project site is located within the urban landscape of Ankara Metropolitan Municipality. The site is in an urban setting surrounded by factories and commercial enterprises. Çubuk stream flows along the site boundaries at a distance of 15 m to the northwest. There are a number of arable lands located to the west of the Çubuk Stream used for agricultural purposes. There is an existing road crossing through the Project site boundaries from north to south (between parcel 1555-4 and the recreational area).

There was a strip of native trees at the main project complex area (i.e. parcel 1555-4) observed during the first ecological walkover survey. The locations of the strip of native and planted trees are roughly indicated in Figure 17-2. During the second ecological walkover survey on 24 May 2022, it was observed that the trees had been removed. It was reported by the EPC Contractor for Phase I construction activities that the trees which were found suitable for relocation were transported to various tree plantation areas. Please refer to section 21.2.6.5 for detailed assessment on this topic.



Figure 17-2: The approximate location of the strip of trees within the Project site observed in December 2021

The historical changes of the land pattern in the Project area were reviewed using Google earth satellite imagery between 2002 and 2021 (Figure 12-3). In 2002, the whole parcel 1555-4 and recreational area were observed to be vacant land. As evident by Figure 12-3, the surrounding of the Project site has been developed between 2002 and 2018 by factories and commercial enterprises.



Figure 17-3: The historical changes of the land pattern in the Project site

In 2014, it was seen that the MoH General Directorate of Public Health storage warehouse was built in the adjacent parcel to the Project site (i.e. parcel no: 1555-5). As seen in Figure 12-3, the road crossing through the Project site boundaries from north to south (between parcel no: 1555-4 and the recreational area) was constructed in July 2015. A warehouse located on the Project site (i.e. parcel no: 1555-4) currently used for storage of vaccine equipment was constructed in 2018 near the south-eastern border of the parcel. As noted in *Chapter 2: Project Description*, the parcel 1555-4 for a period of time was used as a horse farm to support serum production. Aerial views indicate that the undeveloped part of parcel 1555-4 has been used for deposition of debris materials since 2014.

The "recreational area" primarily consisted originally of the flooded meadows of Çubuk stream. The meadow extended beyond its current borders further into the parcel of 1555-4 until the strip of trees. In 2014, the meadow was filled with approximately 2-3-meter-thick layer of earth to create a flat surface.

During the first ecological walkover survey in December 2021, soil piles; disposed debris and scrap materials and tracks of heavy vehicles were noted within the Project site. During the second ecological walkover survey in May 2022, it was observed that the whole vegetation within the parcel 1555-4 had been removed.

The parcel of 1555-4 and the "recreational area" could be regarded as "modified habitat" with limited ecological value³⁴². Photos taken during the first and second ecological walkover surveys are presented in Photo 17-1 and Photo 17-1: Views from the main project complex area (i.e. parcel 1555-4) (*Photos were taken during the first ecological walkover survey undertaken in December 2021*)



Photo 17-2.

³⁴² Habitat destruction is recognised as a major threat to maintenance of biodiversity and to assess likely significance of impacts, PS6 makes the following recommendations depending on habitat status:

[•] Modified Habitat: exercise care to minimise any conversion or degradation of such habitat, depending on scale of project, identify opportunities to enhance habitat and protect and conserve biodiversity as part of operations.

Natural Habitat: developer will not significantly convert or degrade such habitat unless no financial/technical feasible
alternatives exist, or overall benefits outweigh cost (including those to biodiversity), and conversion or degradation is suitably
mitigated. Mitigation measures need to achieve no net loss of biodiversity where feasible, this should be according to
mitigation hierarchy, with residual significant impacts addressed through offsetting and/or set asides of areas managed for
biodiversity.

[•] Critical Habitat: in areas of critical habitat the developer will not implement project activities unless there are no measurable adverse impacts on the ability of the critical habitat to support established populations of species described or on the functions of the critical habitat; no reduction in population of a recognised critically endangered or endangered species and lesser impacts mitigated as per natural habitats, developers must achieve net gain in biodiversity if critical habitats are affected.



Photo 17-1: Views from the main project complex area (i.e. parcel 1555-4) (Photos were taken during the first ecological walkover survey undertaken in December 2021)



Photo 17-2: Views from the main project complex area (i.e. parcel 1555-4) (Photos were taken during the second ecological walkover survey undertaken in May 2022)

17.3.1 Terrestrial Flora

The original flora within the Project site is generalist species that survive in the agricultural fields in the lowlands³⁴³.

It was observed during the first ecological walkover survey that the area had irregular surface due to soil deposition. This debris soil was dominated by successional and/or rudimentary plants such as *Atriplex sagittata* and *Rapistrum rugosum*. There was a strip of native trees (about 40-50 trees of 3-4 meters height), such as *Elaeagnus angustifolia* (Russian Oleander) and *Tamarix smyrnensis* (Tamarix) and planted *Pinus nigra* (Black Pine) trees (about 35-40 trees) at the main project complex area (i.e. parcel 1555-4). The locations of the strip of trees are roughly indicated in Figure 17-1. This strip could potentially host some native plant species.

The second ecological walkover survey (May 2022) was scheduled considering the peak flowering season for the flora species. Due to the initiation of early site preparation works, site stripping and excavation activities at the main project complex area (parcel 1555-4) at the time of this study, it was not possible to undertake a complete flora survey. It was observed that all vegetation and vegetative soil on the parcel 1555-4 had been almost completely removed. Hence, the edge plants that remained along the eastern border (wall separating the border of the parcel from the adjacent access road) were surveyed.

The "recreational area" was free of any vegetation during the first ecological walkover survey (in December 2021). Heavy machinery such as cylinders could have been flattened the area in the past. During second ecological walkover survey, some pioneer plant species, that were able to propagate on filled and compressed earth, were observed.

The riverbed of Çubuk Stream, which runs at an approximate 15 m distance parallel to the northwest boundary of the Project site, is largely damaged and lacks any significant riverine habitat except limited number of plant species. The scarcity of fauna and flora elements suggest that the water is heavily polluted and deoxygenated. In fact, an active discharge of untreated wastewater was observed to the Çubuk stream. However, some native plant species might be found along the river. The photos of the Çubuk stream are presented in Photo 17-3.



Photo 17-3: Views from Çubuk Stream

Threat Status and Endemism of Flora Species

As a result of ecological walkover surveys carried out in December 2021 and May 2022, a total of 30 flora taxa that belong to 15 families were identified (see Table 17-4). Photos of the flora species at the Project site are presented below in Photo 17-4.

³⁴³ Varol, Ö, Aydoğdu, M. 1999. The Flora of Steppe Surrounding Akyurt and Kalecik (Ankara). Commun. Fac. Sci. Univ. Ank. Series C V. 17; pp. 33-57.

All species identified in the Project site are categorized as Least Concern (LC) species in the IUCN Red List. There are no nationally or globally threatened species at the Project site.

Table 17-4: Identified flora species of the Project site

No	Taxon Name	Common Name	Family	BERN	CITES	IUCN ³⁴⁴	END	Local Name	Obse	rvation
									Parcel 1555-4	Recreational Area
1	Atriplex sagittata	Shining Orache	Amaranthaceae	-	-	LC	-	Dağ Ispanağı	x	
2	Conium maculatum	Poison Hemlock	Apiaceae	-	-	LC	-	Baldıran		x
3	Carduus pycnocephalus	Italian Thistle	Asteraceae	-	-	LC	-	Eşek Soymacı	х	
4	Lactuca serriola	Prickly Lettuce	Asteraceae	-	-	LC	-	Eşekhelvası	x	
5	Achillea nobilis	Noble Yarrow	Asteraceae	-	-	LC	-	Ayvananesi		х
6	Anchusa arvensis	Small Bugloss	Boraginaceae	-	-	LC	-	Ballık	х	
7	Noccaea perfoliata	Pepperweeds	Brassicaceae	-	-	LC	-	Çayır Akça Çiçeği		х
8	Sinapis arvensis	Wild Mustard	Brassicaceae	-	-	LC	-	Hardal		х
9	Sisymbrium altissimum	Tall Tumblemustard	Brassicaceae	-	-	LC	-	Ergelenotu		x
10	Descurainia sophia	Flixweed	Brassicaceae	-	-	LC	-	Has Sadırotu	х	
11	Lepidium draba	Heart-Podded Hoary Cress	Brassicaceae	-	-	LC	-	Diğnik	х	x
12	Rapistrum rugosum	Annual Bastard Cabbage	Brassicaceae	-	-	LC	-	Kedi Turpu		x
13	Sinapis alba	White Mustard	Brassicaceae	-	-	LC	-	Mamanık	х	
14	Scorzonera cana		Cichorieae	-	-	LC	-	Tekesakalı	х	
15	Astragalus	Milkvetches	Fabaceae	-	-	LC	-	Geven		х
16	Melilotus officinalis	Yellow Sweetclover	Fabaceae	-	-	LC	-	Kokulu Yonca		х
17	Astragalus hamosus	Southern Milkvetch	Fabaceae	-	-	LC	-	Koçboynuzu		х
18	Astragalus microcephalus		Fabaceae	-	-	LC	-	Anadolu Kitresi		х
19	Erodium cicutarium	Redstem Stork's-Bill	Geraniaceae	-	-	LC	-	Ebeiğnesi		х
20	Papaver hybridum	Rough Poppy	Papaveraceae	-	-	LC	-	Melez Gelincik		x
21	Plantago major	Greater Plantain	Plantaginaceae	-	-	LC	-	Yedidamarotu		x

³⁴⁴ The IUCN Red List Categories and Criteria are intended to classifying species at high risk of global extinction. It divides species into categories: Not Evaluated (NE), Data Deficient (DD), Least Concern (LC), Near Threatened (NT), Vulnerable (VU), Endangered (EN), Critically Endangered (CR), Extinct in the Wild (EW) and Extinct (EX).

Mott MacDonald | Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project Environmental and Social Impact Assessment Report

No	Taxon Name	Common Name	Family	BERN	CITES	IUCN ³⁴⁴	END	Local Name	Observation		
								_	Parcel 1555-4	Recreational Area	
22	Adonis aestivalis	Summer Pheasant's- Eye	Ranunculaceae	-	-	LC	-	Kandamlası	х		
23	Galium tricornutum	Corn Cleavers	Rubiaceae	-	-	LC	-	Havotu	х		
24	Urtica dioica	Great Stinging Nettle	Urticaceae	-	-	LC	-	Isırgan		x	
25	Hordeum murinum	Wall Barley	Poaceae	-	-	LC	-	Duvar Arpası	х		
26	Bromus sterilis	Barren Brome	Poaceae	-	-	LC	-	Sağır Ilcan	х		
27	Bromus tectorum	Cheatgrass	Poaceae	-	-	LC	-	Kır Bromu		х	
28	Phragmites australis	Common Reed	Poaceae	-	-	LC	-	Kamış	х		
29	Alopecurus arundinaceus	Creeping Foxtail	Poaceae	-	-	LC	-	Kamış Tilkikuyruğu	x		
30	Typha angustifolia	Narrow-Leaved Cattail	Typhaceae	-	-	LC	-	Saz		х	



Atriplex sagitata (Shining Orache) Conium

maculatum

(Poison Hemlock)

(Perfoliate Penny-

Rapistrum rugosum

(Annual Bastard

Cabbage)

Astragalus

Milkvetch)

hamosus (Southern

Cress



Anchusa arvensis (Small Bugloss)



Lepidium draba (Heart-podded Hoary Cress)



Melilotus officinalis (Yellow Sweetclover)



Plantago majör (Greater Plantain)



Bromus sterilis (Barren Brome)

January 2024



Adonis aestivalis

(Summer Pheasant's



(Cheatgrass)



Photo 17-4: Flora species in the Project site



Lactuca serriola Carduus pycnocephalus (Prickly Lettuce)

(Italian Thistle)



Sinapis arvensis Sisymbrium (Wild Mustard) altissimum (Tall Tumblemustard



Scorzonera cana

Erodium cicutarium

Urtica dioica (Great

Stinging Nettle)

(Redstem Stork's

. Bill



Genus Astragalus (Milkvetches)



Papaver hybridum (Rough Poppy)



Hordeum murinum (Wall Barley)



Typha angustifolia (Narrow-leaved Cattail)



516



Achillea nobilis

(Noble Yarrow)



Astragalus

microcephalus

Sinapis alba

(White Mustard)

Galium tricornutum (Corn Cleavers)



Alopecurus arundinaceus (Creeping Foxtail)

17.3.2 Terrestrial Fauna

During ecological walkover surveys, the faunal survey focused on birds as indicator species. Both parcels within the Project site are relatively small to possibly host any significant populations of mammal species. The Project site is completely isolated with roads from other modified habitats nearby. No mammal species were observed during the ecological walkover surveys and no important mammal species are expected to occur at the Project site. The only possible species are mobile mammals European Hare (*Lepus europaeus*) and Red Fox (*Vulpes vulpes*), both common larger mammals found and have adapted to the urban landscapes in Ankara. These species are listed as LC (Least Concern) by IUCN Red List.

During the ecological walkover surveys, common winter bird species of open landscape were observed (see Figure 17-4).





An evaluation of the threat status and endemism for species are presented using criteria from International Union for Conservation of Nature (IUCN), Bern Convention (BERN) and Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

Species	Observ	vation	Status	BERN ³⁴⁵	CITES	IUCN	
	December 2021	May 2022	-				
Feral Pigeon (Columba livia)	present	10	Resident	App. III	-	LC	
Eurasian Collared Dove (Streptopelia decaocto)	-	1	Resident	App. III	-	LC	
Magpie (<i>Pica pica</i>)	present	5	Resident	-	-	LC	

³⁴⁵ Appendix - II: Strictly Protected Fauna Species (SPFS); Appendix - III: Protected Fauna Species (PFS).

Species	Observ	vation	Status	BERN ³⁴⁵	CITES	IUCN
	December 2021	May 2022	-			
Jackdaw (Corvus monedula)	present	2	Resident	-	-	LC
Hooded Crow (Corvus cornix)	4	-	Resident	-	-	LC
Crested Lark (Galerida cristata)	1	-	Resident	App. II	-	LC
Great Tit (Parus major)	2	-	Resident	App. II	-	LC
Penduline Tit (Remiz pendulinus)	-	1	Along Çubuk stream	App. II	-	LC
Cetti's Warbler (Cettia cetti)	-	1	Along Çubuk stream	App. II	-	LC
Common Chiffchaff (Phylloscopus collybita)	1	-	Winter Migrant	App. II	-	LC
Robin (Erithacus rubecula)	2	-	Winter Migrant	App. II	-	LC
Blackbird (Turdus merula)	1	-	Winter Migrant	App. III	-	LC
Chaffinch (Fringilla coelebs)	20	-	Winter Migrant	-	-	LC
Brambling (Fringilla montifringilla)	1	-	Winter Migrant	-	-	LC
Goldfinch (Carduelis carduelis)	2	-	Resident	App. II	-	LC
Starling (Sturnus vulgaris)	10	5	Resident	App. II	-	LC
House Sparrow (Passer domesticus)	2	10	Resident	App. II	-	LC
Tree Sparrow (Passer montanus)	5	-	Resident	App. II	-	LC

All bird species observed are listed as LC (Least Concern) by IUCN Red List. None of the observed bird species are endemic and/or listed in threatened categories of IUCN.

The probable faunal species within the Project site are described below. Note that no amphibian and reptile species observations were made during the first ecological walkover survey (in December 2021) in the Project site as these fauna species become dormant in winter in Ankara province. During the second ecological walkover survey (in May 2022), no observations were made in parcel 1555-4 as some early site preparation works, site stripping and excavation activities had been initiated and ongoing on this parcel.

- *Amphibian species:* Although not directly observed in the Project site, amphibians might occur along Çubuk stream.
- *Reptile Species:* Some common reptile species (particularly wall lizards) might occur at the Project site and recolonise after the construction phase.
- Mammal Species: During both ecological walkover surveys, no mammal species or mammal tracks were observed in the Project site. Only possible large-bodied mammal species include European Hare (*Lepus europaeus*) and Red Fox (*Vulpes vulpes*), which are regularly occurring species in urban/rural environments around Ankara. In addition, rodent species such as *Microtus* sp., *Nannospalax xanthodon* are likely to exist in the region due to the agricultural lands around the project site. However, by reason of the Çubuk Stream located between the agricultural lands and the Project area, the probability of their existence in the study area is very low.

17.3.3 Protected Sites and Other Sites in the Vicinity of the Project Site

The Project site is not located within any nationally or internationally protected areas. Also, it is not located within any internationally recognised areas of high biodiversity value, such as Key Biodiversity Areas (KBAs), World Heritage Natural Sites, Biosphere Reserves, Ramsar Wetlands of International Importance, Important Bird Areas and Alliance for Zero Extinction Sites. The nearest legally protected area is Kızılcahamam National Park, 49 km northwest of the Project site and Mogan Lake Wetland, 35 km south of the Project site. The nearest important site for biodiversity is Kazan Tepeleri, located 3.5 km

away from the site, which houses some important plant species including *Asperula bornmuelleri*, *Astragalus densifolius ssp. ayashensis*, *Campanula damboldtiana*, *Cephalaria paphlagonica* ve *Sideritis galatica*.



Figure 17-5: The Project site and the nearest Key Biodiversity Sites

17.4 Assessment of Impacts

All floral species identified in the Project site are field-edge species (those common along edges and in unforested areas). In general, the original flora within the Project site is generalist species that survive in the agricultural fields in the lowlands³⁴⁶ and is probably comparable to the edge plants of arable fields on the other side of the Çubuk stream. No globally and/or nationally threatened floral species were encountered.

The parcel of 1555-4 and the "recreational area" could be regarded as "modified habitat" with limited ecological value. The removal of modified habitats in parcel 1555-4 has already caused the loss of habitat for various fauna species.

During the construction phase of the Project, the potential impacts could include:

- Permanent habitat loss within the Project footprint,
- Noise and light disturbance from construction activities affecting fauna species,
- The use of herbicides and pesticides in the recreational area to maintain landscaping might have negative impact on the birds,
- Disturbance to riverine habitat (the area between the stream and the borders of the recreational area), due to deposition and storage of excess soil material along the stream and construction of walls and other structures to channel the water,
- Introduction or spread of non-native invasive species accidently is a risk that can occur during construction activities which may cause impact with minor,

³⁴⁶ Varol, Ö, Aydoğdu, M. 1999. The Flora of Steppe Surrounding Akyurt and Kalecik (Ankara). Commun. Fac. Sci. Univ. Ank. Series C V. 17; pp. 33-57.

 Indirect impacts on biodiversity are expected to include waste disposal, without directly impacting species' populations and habitats, and when mitigated in line with environmental management plans could be avoided.

During operational phase of the Project, the potential adverse impacts on habitat, flora and fauna may include:

- Increased noise and disturbance to fauna due to Project activities and traffic increase,
- Disturbance affecting fauna from light and human presence from operation activities,
- Low pollution risk arising from accidental spills due to mismanagement of materials and wastes.

The Project is not likely to create any impacts on the protected sites.

Flora and fauna species present within the Project site are of low conservation value and the magnitude of the impacts during construction and operation are considered moderate as a result of loss of modified habitats due to the Project activities. Therefore, the overall impact significance will be minor adverse.

17.5 Mitigation Measures

17.5.1 Construction Phase

The general mitigation measures to ensure that there are no further impacts on the habitat and associated species are as follows:

- All construction and operational working areas will be kept to a minimum to reduce habitat loss and degradation. Off-road access will be prohibited. Plans will be implemented to minimize all construction traffic activities. Dust suppression measures will be implemented during the working periods.
- Soil removed from construction sites will be stored and used in the restoration.
- Select the location of the stockpiles with consideration of environmental safeguards.
- Habitats affected temporarily during construction will be restored/reinstated on a 'like-for-like or better principle', using the species only native.
- The Project activities will be limited with the boundaries of the construction area, including traffic routes to avoid impact on the adjacent vegetation.
- Where restoration is not possible on site (e.g. under the footprint of the permanent structures), similar habitat will be created off-site. Çubuk Stream can be considered as restoration area.
- Ensure proper waste disposal avoiding natural habitats.
- Construction work will adhere to the best practice pollution prevention guidance outlined by the Construction Industry Research and Information Association guidance³⁴⁷.
- Specific measures to avoid disturbance of habitat are not limited to, but must include the following:
 - Construction materials will be stored and maintained away from watercourses. Silt fences or similar will be placed around exposed ground and stockpiles, and early revegetation of the completed elements of the scheme will be undertaken to reduce further erosion.
 - Surface water runoff from the construction sites into the watercourses will be avoided and a system of cut-off ditches, silt fencing and/or bunds will be installed if required.
 - Chemicals and fuels will be stored in secure containers located away from watercourses or water bodies. No refueling of plant of machinery will take place near the watercourse.
 - Appropriate native trees, such as willow and poplar, will be propagated for habitat restoration.
 - The borders of the recreational area will be fenced to mark the extent of the natural riverine habitat along the stream.

³⁴⁷ CIRIA (2015). Environmental good practice on site (fourth edition) (C741). Charles, P., Edwards, P. (eds). CIRIA, London

- Biosecurity measures will be implemented during the construction phase to prevent the spread of invasive alien species (IAS). Biosecurity is defined as a set of precautions that aim to minimize the risk of moving non-native species, parasites and diseases. Measures must include:
 - The briefing and training of workers on good biosecurity practices appropriate to their role.
 - Equipping workers with the necessary equipment, Personal Protective Equipment (PPE) and materials to implement biosecurity control measures. This will most frequently comprise disinfectant tablets, sprayers and brushes to clean and disinfect equipment and PPE prior to leaving site.
 - Minimize traffic and the distance it has travelled
 - Source goods/materials locally where possible
 - Contain any IAS and report their presence
 - Train and raise awareness regarding IAS
 - Pressure wash vehicle tires in a contained area
 - Record and report the presence of any IAS
 - Use native plants for reinstatement and landscaping
- A ban on hunting by construction and operation staff will be implemented to reduce pressure on species protected species in the Project areas and surroundings. All construction and operation staff living at the Project area will be required to follow company rules and code of conduct.
- Removal of topsoil and vegetation will be implemented to ensure no individuals are killed or no galleries are destructed, and populations of the species continue to survive in the area.
- Within the scope of the project, existing roads will be used as much as possible and new roads will not be opened unless it is necessary.
- Although not directly in the field of activity, nearby water resources and streams with seasonal flows, biotopes are the most advantageous habitat for many amphibians and reptiles. In addition, these areas in the region are very important in the thermoregulation of nocturnal wild animals. Therefore, it is essential to protect these resources and areas at every stage of the activity.
- Arrange induction meeting for newcomers in order to provide information about environmental and social policies, responsibilities, and management system in line with the ESMS.
- Hold regular trainings in order to raise awareness associated with the natural assets & importance of the site and protection of the natural structure including legislative framework, related conventions and their requirements as in line with the ESMS.
- Avoidance of unnecessary revving of engines and switch off equipment when not in use.
- Vehicles and equipment will be properly maintained to meet the manufacturers' noise rating levels.
- Dust management will be applied.
- Application of herbicides and insecticides will not be allowed for the riverine habitat.
- Artificial lighting used on construction sites and camps at night will be shaded and directed downwards to avoid light spillage and disturbance to birds or other wildlife.
- The lighting of the Project area will be kept to a minimum, and sensory lighting systems will be considered instead of night-long active lighting. Lights will be directed downwards.

17.5.2 Operation Phase

The Project site is mostly composed of modified habitats, the habitat loss to occur within the Project site will be mitigated to the extent possible, through implementation of mitigation measures to ensure that the Project-related impacts are minimized.

It is essential to restore the riverine habitats along Çubuk stream, at least on the borders of the recreational area. Any part of the riverine habitat that has been intentionally or unintentionally modified is

subject to habitat restoration. For habitat restoration it is possible to propagate some riverine plant species, including herbs, scrubs and trees, using native plants from the other side of the bank.

A landscaping study has been undertaken by the MoH including proposed number of trees and shrubs to be planted, amount of vegetable soil to be laid down as well as the type and details related with plant species. Considering the total surface area of the Project site, it is proposed that total of 2005 trees (including leaved and coniferous trees), 1510 shrubs, 6950 seasonal plants and 123 volubilate plants will be planted in the Project site (including parcel 1555-4 and recreational area) forming a total planted area of approximately 20,000 m². The current landscape study is mainly comprised of ornamental and exotic species, and should be modified to include use of native species and seed or fruit bearing plants that might attract some birds. For example, thistles species in the family *Asteraceae (Carduus, Cirsium, and Onopordum)* provide seeds for Goldfinch (*Carduelis carduelis*) and Greenfinch (*Chloris chloris*). Blackberries and brambles (*Rubus*) can attract Blackbird (*Turdus merula*) and Cetties Warbler (*Cettia cetti*). Some riverine trees, such as Willows (*Salix*) or poplars (*Populus*) provide home for migrant songbirds, such as Chiffchaff (*Phylloscopus collybita*), Penduline Tit (*Remiz pendulinus*) and many other species. In order to prevent alien species from affecting the natural flora of the region and to prevent the possibility of invasion, it is recommended to not use exotic species as much as possible in landscape studies.

The landscape study will be revised and a 'Landscape Management/Repair/Rehabilitation Plan' will be developed within the scope of the Project to restore the vegetation of the area including landscape analyses, methodology to be applied for repairing, assessment and determination of landscape characteristics, management, control and monitoring of the plan. Landscape repairing will be started following completion of the construction works and a monitoring program will be established to be applied during post construction works.

For night-lighting of the facility, night-lighting systems that focus on target lighting will be preferred as much as possible. This will also minimize energy consumption.

17.6 Residual Impacts

Residual effects are those effects that remain after mitigation has been implemented. It is expected that residual impacts will be insignificant when the mitigation measures that are described above are fully implemented throughout the lifetime of the Project.

17.7 Compliance against National and International Requirements

The Project is required to meet the international standards of the World Bank ESS6: Biodiversity Conservation and Sustainable Management of Living Natural Resources which recognizes protecting and conserving biodiversity and sustainably managing living natural resources are fundamental to sustainable development. World Bank ESS6 defines biodiversity as the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species, and of ecosystems. The ESS6 objectives are:

- To protect and conserve biodiversity and habitats,
- To apply the mitigation hierarchy and the precautionary approach in the design and implementation of projects that could have an impact on biodiversity,
- To promote the sustainable management of living natural resources,
- To support livelihoods of local communities, including Indigenous Peoples, and inclusive economic development, through the adoption of practices that integrate conservation needs and development priorities.

The following international conventions and conservation lists will be abided by the Project in regard to biodiversity issues:

- Convention on Biological Diversity (CBD) which represents a dramatic step forward in the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of genetic resources (ratified in 1996),
- Bern Convention on Protection of Europe's Wildlife and Living Environment (acceded by the Decision
 of the Council of Ministers dated 9 January 1984 and published in the Turkish Official Gazette dated
 20 February 1984 and no. 18318),
- CITES Convention on Trade in Endangered Species of Wild Flora and Fauna (ratified in 1996),
- International Union for the Conservation of Nature (IUCN) list of threatened species (the IUCN Red List).

The Red List by the International Union for the Conservation of Nature (IUCN) is used as a standard tool to assess the threat status of the species. The Red List is a List of Threatened Species (the IUCN Red List) which is a widely recognized, global approach for evaluating the conservation status of plant and animal species. It provides information on taxonomy, conservation status and distribution information on taxa facing a high risk of global extinction.

The Key Biodiversity Areas (KBA), also maintained by IUCN, is a list of sites identified with standard global criteria and with high biodiversity value. Some KBAs might not have been included within the national systems of protected areas. However, still, all KBAs are recognized as priority sites for global conservation, along with nationally recognized protected areas.

Turkiye is a signatory of the CBD, whereby the CBD defines biodiversity as "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems". As a signatory, Turkiye has a responsibility to:

- Safeguard its biodiversity,
- Introduce procedures requiring environmental impact assessment for projects likely to have significant impacts on biological diversity,
- Introduce legislative provisions that ensure environmental policies and procedures are duly taken into account.

17.8 Proposed Monitoring and Reporting

Further to the mitigation measures described above, a Biodiversity Management Plan will be implemented during the construction and operation phases of the Project, to ensure that the flora (and the associated fauna to be formed) within the Project areas are maintained and enhanced to the extent possible. The ecological monitoring and reporting responsibilities are detailed in this plan. The ecological monitoring and reporting :

- continuous monitoring of fauna disturbance, nest of birds and other species
- continuous monitoring of growing vegetation at project site/rehabilitation area
- continuous monitoring of staff training
- reporting on the process of landscaping activities with vegetation achievement records
- reporting of compliance of the biodiversity management against the applicable standards/guidelines and detail of any breaches and non-compliances

Additionally, during the operation phase, a Landscaping Management Plan will be developed and implemented, which lays out the landscaping management procedures, as well as the vegetation success criteria.

18 CULTURAL HERITAGE

18.1 Introduction

This chapter describes the known and potential cultural heritage sites and archaeological assets (including status and geographical distribution) within and surroundings of the proposed Project site that may be affected by the construction and operation activities of the Project. Potential tangible and intangible cultural heritage within the Cultural Heritage Impact Assessment (CHIA) border of the Project are identified to evaluate the possible effects of the Project activities on these assets. The results of the desk-based study findings (desktop study phase) and archaeological walkover surveys (field research phase) were used to establish the baseline information.

An initial baseline assessment of all available data was conducted for the Project site during the scoping phase of the ESIA process included desk-based research, literature survey (academic publications and historic maps were used), followed by an archaeological walkover survey. 1st (first) archaeological walkover survey was undertaken at the Project site on 28 December 2021 by two archaeologists from the Cultural Heritage Assessment Team³⁴⁸, which was also supported through desk-based research by a Senior Archaeologist.

Following the scoping phase and initial baseline assessment, academic publications, previous cultural heritage studies and surface survey results reports, UNESCO List of Tangible and Intangible Cultural Heritage, inventory records of the Ministry of Culture and Tourism and historic maps were reviewed. 2nd (second) archaeological walkover survey was conducted within the Project site and its vicinity on 11-12 April 2022 by the Cultural Heritage Assessment Team and consisted of the following:

- The entire Project site was screened for tangible cultural heritage during the 2nd archaeological walkover survey. The Project site was divided into grids by using GIS to enable structured data collection and documentation during archaeological walkover survey through assigning codes to cultural remains to be identified in the field, if any. Rectangles with a width of approximately 50m were created in the direction of "Northeast-Southwest". The obtained data during 2nd archaeological walkover survey were processed in a mapping and analysis platform³⁴⁹ for determining the possible impacts of the Project.
- Regarding the intangible cultural heritage, the "qualitative interview technique" was carried out within the scope of the 2nd archaeological walkover survey; with individuals i) who has knowledge about the history and geography of the region; ii) to whom those areas are valuable; and iii) who know, live, sustain and transfer the intangible cultural elements in those areas. Additionally, face-to-face interviews have been conducted with representatives of the local community and data on intangible cultural heritage elements have been collected during interviews. Details and findings of the study are provided in Section 18.2.

18.1.1 Study Area and Area of Influence

The area of influence for tangible cultural heritage is limited to the area where the Project activities are to be conducted. The area of influence for the intangible cultural heritage study is determined in accordance with the outcome of desktop studies undertaken by the intangible cultural heritage key expert, through

³⁴⁸ The Cultural Heritage Assessment Team for the Project consists of cultural heritage experts from REGIO Danışmanlık Inc. including Tangible Cultural Heritage / Key Expert: A.Halim ÖZATAY; Tangible Cultural Heritage Expert / Visual Documentation: Serkan AKDEMİR; Tangible Cultural Heritage Expert / Ancient Historian: Yunus EKİM; Intangible Cultural Heritage Expert: Seray AYAZ.

taking into consideration settlements where cultural elements are likely to be found around the Project site. These settlements were included in the geographical scope of the impact assessment study.

The geographical boundaries of the AoI with regards to tangible and intangible cultural heritage are presented and shown in Table 18-1 and



Figure 18-1.

Table 18-1: Area of influence for tangible and intangible cultural heritage

Province	District	Neighbourhood	Study Area	Approximate Distance to the Project Site (km) ³⁵⁰
Tangible C	Cultural He	eritage		
Ankara	Akyurt	Balikhisar	1555 Block 4 Parcel (where the Project components will be built/positioned)	0
Ankara	Akyurt	Balikhisar	Recreation Area (where the recreational area to be established within the scope of the Project)	0
Intangible	Cultural H	leritage		
Ankara	Akyurt	Balikhisar	-	3.3
Ankara	Akyurt	Saracalar	-	0.9
Ankara	Akyurt	Guzelhisar	-	4.1
Ankara	Cubuk	Dumlupinar	-	4.5

³⁵⁰ Includes Parcel No. 1555-4 and the recreational area.



Figure 18-1: Illustration of area of influence for tangible and intangible cultural heritage (*Please refer to Table 18-1*)

18.1.2 Data Limitations

The limitations set for identification of cultural assets are as follows:

- For desktop study phase, lack of previous scientific field surveys and publications about the Project area and its surroundings,
- Unavailability of registration information from authorities responsible for cultural assets (Ankara Regional Council for the Conservation of Cultural Property) in the AOI, and
- Since Cubuk Stream flows at an approximate distance of 15 m along the northwest boundary of the Project site; depending on the professional judgement of Cultural Heritage Assessment Team, some cultural assets may have possibly remained under alluvial accumulation.

18.2 Baseline Description

18.2.1 Site Location

Çubuk Plateau (including the area where the Project will be realized) is a large rift plateau of graben formed as a result of tectonic movements. It is surrounded by mountains and hills formed due to horst depression. Idris Mountain is located to the east of the plateau while Elma Mountain and Hüseyin Gazi Hill are located to the south, Çiçek Mountain, Mire Mountain and Sedlik Hill are located to the west and Aydos Mountain is located to the north of the plateau. This geologic formation surrounded by mountains enables the climate in the plateau to be more temperate compared to its surroundings. The geographical, topographical and climatic conditions of the Project site are in parallel with the settlement preferences of humanity since prehistoric times.

18.2.2 Archaeological and Historical Background

18.2.2.1 Tangible Cultural Heritage

The basement rocks in Çubuk Plateau were formed during sub-Triassic period, over which Neogene aged volcanics and sedimentary units came with disharmony, and quaternary alluviums sat on these Neogene units with disharmony. Many fossil beds were identified at Çubuk Plateau and its surroundings, which is considered within Sinap Formation geologically, during the paleontological studies. Identified fossil beds include small and large mammals' fossils from Neogene Period.

Convenient climate conditions were created by the surrounding mountains at Çubuk Plateau which, in turn, led to dense human settlements in the area since prehistoric ages up until today. The history of the area goes as far back as the Middle Palaeolithic period. The most important finding area for palaeolithic (gathering and hunting) period is Etiyokuşu³⁵¹ located to the south of Çubuk Plateau. Later, the area was dominated by Phrygians³⁵² and Galatians³⁵³. Balıkhisar Mound (Höyüktepe), Aktepe and Kara Höyük are important finding sites in the area for Phrygian Period. Although it is known that Ankara and its surroundings were dominated by Galatians for a long period of time, no tangible finding exists in the Project site and its vicinity with regard to Galatian domination.

Çubuk Plateau and its surroundings as well have seen dense habitation in Roman and Byzantine Periods³⁵⁴. With the Roman domination, city of Ancyra (Ankara) has become one the most important centres for military, commercial, industrial and intellectual life³⁵⁵. Galatia's becoming a commerce centre thanks to its wide road networks has a big contribution in this. The route that connects the city of Ancyra to Gangra (Çankırı) located to the northeast is one of these large road networks. This route is located on Çubuk Plateau on the natural passageway that opens to the Black Sea. The number of settlements in the region has seen a significant increase thanks to the commercial richness provided by this route. The roadmap created by David French³⁵⁶ for the region shows that the Ancyra - Gangra Roman Road passes about 500 m southeast of the Project site³⁵⁷. The "Altinova Historical Stone Bridge", located on this road, which preserved its importance during the Byzantine, Seljuk and Ottoman periods, was observed during archaeological walkover survey (Figure 18-2).

³⁵¹ Reference: Harmankaya, S., & Erdoğu, B. (2002). Türkiye İlk Tunç Çağı Araştırmaları Üzerine Bir Değerlendirme: İlk Tunç Çağı. TAY- Türkiye Arkeolojik Yerleşmeleri (4a- 4b, page 7-41). içinde İstanbul: TASK Vakfı Yayınları; Çınar, H., & Gümüşçü, O. (30.08.2002). Osmanlıdan Cumhuriyete Çubuk Kazası. Ankara: Bilge Yayınevi; Buluç, S. (1991). İlkçağda Ankara. Ankara Dergisi, (1(1), 13-28).

³⁵² Reference: Sevin, V. (1982a). Frygler. Anadolu Uygarlıkları Görsel Anadolu Tarihi Ansiklopedisi, (2, s. 247-274).

³⁵³ Reference: Lequenne, F. (1991). Galatlar. Ankara: Türk Tarih Kurumu Yayınları / Buluç, S. (1991). İlkçağda Ankara. Ankara Dergisi, (1(1), 13-28).

³⁵⁴Reference: Buluç, S. (1991). İlkçağda Ankara. Ankara Dergisi, (1(1), 13-28).

³⁵⁵ Reference: Buluç, S. (1991). İlkçağda Ankara. Ankara Dergisi, (1(1), 13-28); Sargon, E. (1991). Ankara (İslam Öncesi). (DİA, III). İstanbul.

³⁵⁶ Reference: He was the director of the Ankara branch of the British Archaeological Institute between the years of 1968 and 1993. David French was also a scientist having works on Anatolian Archaeology.

³⁵⁷ Reference: Archaeological Atlas of Antiquity (Web source: <u>https://vici.org/about-vici.php.</u>; Access date: 09 March 2022)



Figure 18-2: General View from Altinova Historic Stone Bridge

With the division of Roman empire into two in 395 A.D., Ankara and its surroundings remained inside the borders of Byzantine Empire³⁵⁸. Various remains from the Roman and Byzantine Periods are observed within Çubuk Plateau, such as milestones, inscriptions, columns and architectural blocks etc. Elecik, Cücük, Büğdüz, Balıkhisar, Camili, Güldarpı, Güzelhisar (Kızılhisar), Çatköy Fortress, Yakup Derviş Necropolis and Kızıleşik Tumulus are important sites for findings from Roman and Byzantine Periods. Ankara and its surroundings were occupied by Arabs in the year of 654³⁵⁹, however this domination did not last long.

Seljukian Period was a period in which reconstruction works were conducted for Ankara as well as its vicinity. Many public buildings such as mosques, prayer rooms, public baths, madrasahs, hermitages, fountains, bridges and inns were constructed during this period³⁶⁰. There are many architectural examples such as public baths, caravansary and tombs belonging to this period in Çubuk Plateau. Seyyid Kalender Veli and Gül Baba tomb (hermitage) are among the important tombs that belong to this period.

After the year of 1300, a constant domination struggle was experienced around Ankara between Ottoman-Karamanian-Eretna people and Ahi Order from Ankara³⁶¹.

The historical background knowledge as the result of the desktop research is important in terms of demonstrating the potential of tangible cultural assets within the borders of Ankara province, including the Project location. The lists and locations of tangible cultural assets having national³⁶² and international³⁶³ recognition in the close vicinity of the Project site are presented in Table 18-2/Figure 18-3 and Table 18-3/Figure 18-4, respectively.

³⁵⁸ Reference: Sargon, E. (1991). Ankara (İslam Öncesi). (DİA, III).

³⁵⁹ Reference: Kaegi, W. E. (2000). Bizans ve İlk İslam Fetihleri. (M. Özay, Çev.) İstanbul: Kaknüs Yayınları.

³⁶⁰ Reference: Kuban, D. (1968). Anadolu - Türk Şehri: Tarihî Gelişmesi, Sosyal ve Fizikî Özellikleri Üzerinde Bazı Gelişmeler. Vakıflar Dergisi(7), 53-73.

³⁶¹ Reference: Göde, K. (1994). Eratnalılar 1327 - 1381. Ankara: Türk Tarih Kurumu Basımevi.

³⁶² Reference: Identified as the result of the literature survey over an area having 14km diameter centered on Parcel No. 1555-4 (see Table 18-1), i.e., Project impact area.

³⁶³Reference:UNESCO, World Heritage Convention Official Website: <u>https://whc.unesco.org/en/list/;</u> <u>https://whc.unesco.org/en/tentativelists/state=tr</u>

Table 18-2: International Tangible Cultural Heritage Areas³⁶⁴

No	Site name	Province	District	Distance to Project (km)
World	Heritage List of UNESCO			
N/A	N/A	N/A	N/A	N/A
World	Heritage Tentative List of UNESCO			
1	Haci Bayram Mosque and its Surrounding Area (the Haci Bayram District)	Ankara	Altindag	18
2	Historic Town of Beypazarı	Ankara	Beypazari	89
3	Gordion	Ankara	Polatli	97



Figure 18-3: International Tangible Cultural Heritage Areas

³⁶⁴ UNESCO, World Heritage Convention Official Website: <u>https://whc.unesco.org/en/list/;</u> <u>https://whc.unesco.org/en/tentativelists/state=tr</u>

Table 18-3: National Tangible Cultural Heritage Areas

No	Name of Tangible Cultural Heritage Asset	Province	District	Distance to Project site (km)	Paleolithic	Neolithic	Chalcolithic	Early Bronze	Middle Bronze	Late Bronze	Hittite	Iron	Hellenistic	Roman	Byzantine	Ottoman
1	Baba Sultan Shrine ³⁶⁵	Ankara	Akyurt	10												
2	Bugduz Archaeological Remains ³⁶⁶	Ankara	Akyurt	7												
3	Balikhisar (Hoyuktepe) Hoyuk ³⁶⁷	Ankara	Akyurt	4												
4	Esenboga Flat Settlement ³⁶⁸	Ankara	Cubuk	3												
5	Akyurt Central Mosque ³⁶⁹	Ankara	Akyurt	11												
6	Balikhisar Archaeological Remains ³⁷⁰	Ankara	Akyurt	3.4												
7	Guzelhisar Archaeological Remains ³⁷¹	Ankara	Akyurt	4												
8	Kalaba Tumuli ³⁷²	Ankara	Akyurt	11												

PERIODS/ AGES

³⁶⁵ Reference: <u>https://www.turbeler.org/detay/178-baba-sultan-hz-taberi-sultan</u>)

³⁶⁶ Reference: <u>https://www.akyurt.bel.tr/uploads/pages/ilcemiz-bugduz-mahallesi-muhtelif-parsellere-ilisk/bugduz.pdf</u>

³⁶⁷ Reference: <u>https://akyurt.meb.gov.tr/www/akyurtun-tarihi/icerik/892</u>

³⁶⁸ Reference: <u>https://www.resmigazete.gov.tr/ilanlar/eskiilanlar/2018/01/20180128-4-1.pdf</u>

³⁶⁹ Reference: <u>https://issuu.com/taylankoken/docs/ankara_-akyurt_tarihi_ve_arkeolojis_2c30c1a1b8c208</u>

³⁷⁰ Reference: <u>http://akyurt.gov.tr/tarihce</u>

³⁷¹ Reference: <u>https://issuu.com/taylankoken/docs/ankara_-akyurt_tarihi_ve_arkeolojis_2c30c1a1b8c208</u>

³⁷² Reference: <u>https://ankaradergisi.org/jvi.aspx?pdir=jas&plng=tur&un=JAS-73644&look4=#:~:text=Ankara'n%C4%B1n%20Akyurt%20il%C3%A7esinde%20bulunan,mezar%20odas%C4%B1%20g%C3%BCn%20%C4%B1%C5%9F%C4%B1%C4%9F %C4%B1na%20%C3%A7%C4%B1kar%C4%B1lm%C4%B1%C5%9Ft%C4%B1r.</u>



³⁷³ Reference: http://sosyodenemeler.blogspot.com/2014/05/hac-veli-dede-turbesi-ankara-akyurt.html

³⁷⁴ Reference: Harmankaya, S., & Erdoğu, B. (2002). Türkiye İlk Tunç Çağı Araştırmaları Üzerine Bir Değerlendirme: İlk Tunç Çağı. TAY- Türkiye Arkeolojik Yerleşmeleri (Vol.. 4a-4b, p. 7-41). İstanbul: TASK Vakfı Yayınları.

³⁷⁵ Reference: <u>http://arkeodenemeler.blogspot.com/2015/01/</u>

³⁷⁶ Reference: <u>https://www.cubuk.bel.tr/mesire-yerleri/meliksah/</u>

³⁷⁷ Reference: <u>http://arkeodenemeler.blogspot.com/2015/01/taspnar-kalntlar-ankara-galatia-cubuk.html</u>

³⁷⁸ Reference: Decision Number 4670 (dated 28.08.2017) of the Ankara Regional Council for the Conservation of Cultural Property Number I

³⁷⁹ Reference: Harmankaya, S., & Erdoğu, B. (2002). Türkiye İlk Tunç Çağı Araştırmaları Üzerine Bir Değerlendirme: İlk Tunç Çağı. TAY- Türkiye Arkeolojik Yerleşmeleri (Vol. 4a-4b, p. 7-41). İstanbul: TASK Vakfı Yayınları.

³⁸⁰ Reference: <u>https://www.akyurt.bel.tr/uploads/pages/ilcemiz-bugduz-mahallesi-muhtelif-parsellere-ilisk/bugduz.pdf</u>

³⁸¹ Reference: French, D. H. (2012). Roman Roads and Milestones of Asia Minor :3 Milestones (Vol. 3). London: BIAA.

³⁸² Reference: http://www.zulfikarhalifeoglu.com.tr/proje-Etlik Altindag Tas Altinova Kopruleri-35.htm



Figure 18-4: National Tangible Cultural Heritage Areas³⁸³

18.2.2.2 Intangible Cultural Heritage

The region which is at an important location from a geographical perspective, was preferred by people as a settlement location since the early periods of history due to its arable fields and natural riches such as water resources. The region witnessed various settlements in various periods from Palaeolithic Age until the end of the 20th century as well as occasional migration movements. This has greatly contributed to tangible and intangible cultural heritage values in the region. Being located on the routes of King and Silk roads as of antiquity and Middle Ages, the region has seen various habitations in different periods in history.

The Turkic tribes which settled first in Çubuk and its vicinity generally habited in the ruins and uplands. Therefore, traces of Roman and Byzantine periods are encountered in the area. It is accepted that Turkic tribes settled in the area during Seljukian Period. Turkish soldiers arriving in the area also brought with them their families, traditions, rituals, beliefs and all the tangible and intangible cultural values they acquired on the road. This folk was of Bektashi faith. Bektashi folk has been the leading factor in Turkifying Ankara and its vicinity and making this area yurt for Turks. Çubuk Plateau and its vicinity entered under the domination of Ottomans in 1354. In fact, Ottoman sources refer to Çubuk Bazaar, Çubukabad as a settlement.

The historical background is important in terms of demonstrating the potential of intangible cultural assets within the borders of Ankara province, including the location where the Project will be developed. Intangible cultural assets having international and national recognition are given in Table 18-4 and Table 18-5, respectively.

³⁸³ The approximate route for Ancyra-Gangra Roman Road is marked in green line based on data such as ancient historical knowledge, historical maps and milestones of ancient roads (Reference: https://vici.org/vici/38153/?lang=en)

No	UNESCO List Ref. No.	Intangible Cultural Heritage Element	Year of Admission to the UNESCO List
1	(3)	Âşıklık (Minstrelsy) Tradition	2009
2	(6)	Traditional Sohbet Meetings	2010
3	(5)	Semah, Alevi-Bektaşi ritual	2010
4	(11)	Turkish Coffee Culture and Tradition	2013
5	(13)	Flatbread Making and Sharing Culture: Lavash, Katyrma, Jupka, Yufka Katrıma, Jupka, Yufka	2016
6	(15)	Spring Celebration– Hidrellez	2017
7	(18)	Art of Miniature	2020

Table 18-4: International Intangible Cultural Heritage Elements^{384 and 385}

Table 18-5: National Intangible Cultural Heritage Elements³⁸⁶

No	Inventory / Local Applications	Element Group Titles	
1	Copper Craftsmanship	Traditional Handleraft and Craftamanahin	
2	Saddlers		
3	Cloth Weaving Tradition: Angora Weaving	Weaving Art and Traditions	
4	Knitting Traditions: Sock Knitting	Oya/Embroidery Processing, Sewing and Knitting Traditions	
5	Traditional Sohbet Meetings: Ferfene		
6	Seymen Tradition	Traditional Meetings and Organizations	
7	Village Guest Houses		
8	Hacı Bayram-i Veli Visits and Traditions	Social Practices Related to Cultural Sites	
9	Midwifery Culture	Prenatal /Postnatal and Childhood Traditions	
10	"Bush Seeing" as part of Rain Prayer	Traditions and Practices Based on Beliefs	
11	Âşıklık (Minstrelsy) Tradition	Folk Music and The Tradition of Singing Song	
12	Village Theatre Performers: Sinsin	Traditional Theatrical Arts and Games	
13	Bathhouse Traditions in Historic Baths	Traditional Healing and Cleaning Practices, Production of Care Products	
14	Ankara Simidi/ Local Dish		
15	Offering Cheese Pudding to Guests, Especially to Groom before Wedding Arrangement	Turkish Culinary Culture/ Traditional Food	
16	Ankara Tava/ Local Dish	and Beverage Making and Social Practices	
17	Ankara Yaprak Döneri/ Local Dish		
18	Pickle Culture and Traditions: Cubuk Pickles		

³⁸⁴ Reference:<u>https://ich.unesco.org/en/state/turkey-TR?info=elements-on-the-lists</u>

³⁸⁵ Total of 21 intangible cultural heritage elements of Turkiye have been registered in the UNESCO list. However, seven (7) intangible cultural heritage elements among them which are presented in the Table 18-4 are found to be related with Ankara province.

³⁸⁶ Prepared based on the results of literature review on the districts (see Table 18-1) where the neighbourhoods are located within the project are of influence. The presence of 18 elements identified by desktop research in neighbourhoods within the boundaries of the Project impact area have been confirmed during field survey studies.

18.2.3 Observations of Archaeological Walkover Surveys at the Project Site

18.2.3.1 Tangible Cultural Heritage

There are rich natural resources (such as water resources, mineral resources, transportation opportunities, proximity to agricultural areas) suitable for human settlement around the geographical area where the Project is located. However, no archaeological or historical settlement traces have been found in the Project site (Parcel No. 1555-4 where the Project components will be built/positioned) and recreational area to be established within the scope of the Project) during both 1st and 2nd archaeological walkover surveys. On the other hand, there may be tangible cultural heritage assets (chance finds) that have been buried in the geographical area of the Project site or its close vicinity and whose existence will be determined by advanced research techniques or that will be unearthed during the construction works.

The geographical area of the Project site is located on fertile agricultural land. Important water resources and mineral resources are located in and around the region. The region is also located at the crossroad enabling access to different regions; and thereby, the region has created suitable conditions for human settlement from past to present. Therefore, some archaeological assets may still be buried under the earth in the region. National tangible cultural assets (see Table 18-3) identified in the vicinity the Project site support this idea regarding this potential.

18.2.3.2 Intangible Cultural Heritage

Within the scope of the cultural heritage impact assessment study on intangible cultural heritage assets, a total of 17 people from four (4) pre-selected settlements were interviewed. The details of face-to-face interviews held in pre-selected settlements are presented in Table 18-6. The majority of the participants' ages are between 45-75³⁸⁷.

Neighbourhood	Interview Topics	Number of Interviewed People	Photos from the Interviews
Balikhisar	Introduction Briefing participants about the purpose of the interview Questioning whether International Intangible Cultural Heritage Elements exist in the participant's neighbourhood Questioning whether National Intangible Cultural Heritage	6	

Table 18-6: Details of face-to-face interviews on Intangible Cultural Heritage Elements³⁸⁸

³⁸⁷ All interviewees speak Turkish.

³⁸⁸ Prepared based on the results of literature review on the districts (see Table 18-1) where the neighbourhoods are located within the project are of influence. The presence of 18 elements identified by desktop research in neighbourhoods within the boundaries of the Project impact area have been confirmed during field survey studies.

Neighbourhood	Interview Topics	Number of Interviewed People	Photos from the Interviews
	Elements exist in the participant's neighbourhood		NR WELL
Saracalar	Questioning whether Local Intangible Cultural Heritage Elements exist in the participant's neighbourhood	5	
Güzelhisar		3	
Dumlupinar		3	

All settlements consist of Sunnite Muslims, except the people of Saracalar who are followers of Bektashi religion. It was observed that major transition points of life such as birth, circumcision, military service, wedding and death, are continued by blending traditional and modern methods in all surveyed neighbourhoods although there are some minor differences in practice. Agricultural production (agricultural products such as wheat, barley, sunflower and corn) is carried out with modern methods in all surveyed neighbourhoods. There is no agricultural production based on traditional methods. Interviews were conducted to determine whether there are intangible cultural heritage assets that are known at the international and national levels in the surveyed neighbourhoods. It was observed that a large part of these assets still exists in the neighbourhoods. As an outcome of the face-to-face interviews held during the 2nd archaeological walkover survey, it has been determined that intangible cultural elements such as blacksmithing- iron craftsmanship (in Dumlupınar), embroidery (Guzelhisar) and traditional illness treatment methods (Balıkhisar, Dumlupınar) are still being used (see Table 18-7).

And the second second second

The list of intangible cultural heritage assets found within the project area of influence (see Table 18-1) are presented in Table 18-6.

Table 18-7: Intangible Cultural Heritage	e Elements in the Project Aol
--	-------------------------------

	Local applications presented in the	Neighbourhoods within the Scope of the CHIA Study			
No	international data (confirmed during 2 nd archaeological walkover survey)	Balikhisar	Guzelhisar	Saracalar	Dumlupinar
1	Âşıklık (Minstrelsy) Tradition		√		
2	Traditional Sohbet Meetings				√
3	Semah, Alevi-Bektaşi Ritual			√	
4	Turkish Coffee Culture and Tradition	\checkmark	√	\checkmark	√
5	Flatbread Making and Sharing Culture: Lavash, Katyrma, Jupka, Yufka Katrıma, Jupka, Yufka	√	√	√	\checkmark
6	Spring Celebration– Hidrellez	\checkmark	√	\checkmark	√
	Local applications presented in the	Neighborhoods	within the Scope o	f the CHIA Study	
No	national data (confirmed during 2 nd archaeological walkover survey)	Balikhisar	Guzelhisar	Saracalar	Dumlupinar
1	Knitting Traditions: Sock Knitting		√	√	
2	Traditional Sohbet Meetings: Ferfene				\checkmark
3	Seymen Tradition		√		√
4	Village Guest Houses	√	√	√	√
5	Hacı Bayram-i Veli Visits and Traditions	√	\checkmark	\checkmark	\checkmark
6	"Bush Seeing" as part of Rain Prayer	√	√	√	√
7	Âşıklık (Minstrelsy) Tradition		√		
8	Village Theatre Performers: Sinsin	√	√		
9	Bathhouse Traditions in Historic Baths	√	√	√	√
10	Offering Cheese Pudding to Guests, Especially to Groom before Wedding Arrangement	√	\checkmark		\checkmark
11	Ankara Tava/ Local Dish		√		√
12	Pickle Culture and Traditions: Cubuk Pickles	√	√	√	√
No	Local applications observed during	Neighborhoods	within the Scope o	f the CHIA Study	
NU	2 nd archaeological walkover survey	Balikhisar	Guzelhisar	Saracalar	Dumlupinar
1	Iron Craftsmanship				√
2	Needlework		✓		
3	Traditional Treatment Methods	✓			√

18.3 Assessment of Impacts

18.3.1 Overview

Potential tangible and intangible cultural heritage within the Cultural Heritage Impact Assessment (CHIA) border of the Project were identified to evaluate the possible effects of the Project activities on these assets. An initial baseline assessment of all available data was conducted for the Project site during the scoping phase of the ESIA process, which included desk-based research, literature survey and an archaeological walkover survey. The 1st (first) archaeological walkover survey was undertaken at the

Project site on 28 December 2021. Following the scoping phase and initial baseline assessment, academic publications, previous cultural heritage studies and surface survey results reports, UNESCO List of Tangible and Intangible Cultural Heritage, inventory records of the Ministry of Culture and Tourism and historic maps were reviewed. 2nd (second) archaeological walkover survey was conducted within Project site and its vicinity on 11-12 April 2022 by the Cultural Heritage Assessment Team. The gathered baseline information which constitutes the basis of the impact assessment on cultural heritage is presented in Section 18.2.

The impact of Project activities on the cultural assets are evaluated based on "Guidance on Heritage Impact Assessments for Cultural World Heritage Properties" document prepared by ICOMOS and adopted by the Ministry of Culture and Tourism for its use to properly assess the impact of construction activities on cultural sites.

18.3.2 Methodology and Assessment Criteria

The cultural heritage assets within the scope of Project identified in the AoI are classified based on their level of importance. Table 18-8 presents example guidance for assessing value of heritage assets (Annex 3A of the International Council on Monuments and Sites (ICOMOS) CHIA Guidance).

Table 18-8: Guidance for	assessing value of heritage	assets (Annex 3A of	the ICOMOS CHIA
Guidance ³⁸⁹)			

Grading	Archaeology	Built heritage or Historic Urban Landscape	Historic Landscape	Intangible Cultural Heritage or Associations
	Sites of acknowledged international importance inscribed as World Heritage (WH) property.	Sites or structures of acknowledged international importance inscribed as of universal importance as WH property.	Landscapes of acknowledged international importance inscribed as WH property.	Areas associated with intangible cultural heritage activities as evidenced by the national register.
Very High	Individual attributes that convey Outstanding Universal Value (OUV) of the WH property.	Individual attributes that convey OUV of the WH property	Individual attributes that convey OUV of the WH property.	Associations with particular innovations, technical or scientific developments or movements of global significance.
	Assets that can contribute significantly to acknowledged international research objectives.	Other buildings or urban landscapes of recognised international importance.	Historic landscapes of international value, whether designated or not	Associations with particular individuals of global importance.
			Extremely well-preserved historic landscapes with exceptional coherence, time- depth, or other critical factors.	
	Nationally designated Archaeological Monuments protected by the State Party's laws	Nationally designated structures with standing remains.	Nationally designated historic landscape of outstanding interest.	Nationally - designated areas or activities associated with globally - important Intangible cultural heritage activities.
High	Undesignated sites of the quality and importance to be designated.	Other buildings that can be shown to have exceptional qualities in their fabric or historical associations not adequately reflected in the listing grade.	Undesignated landscapes of outstanding interest.	Associations with particular innovations, technical or scientific developments or movements of national significance.

³⁸⁹ Reference: <u>http://openarchive.icomos.org/id/eprint/266/1/ICOMOS_Heritage_Impact_Assessment_2010.pdf</u>

Grading	Archaeology	Built heritage or Historic Urban Landscape	Historic Landscape	Intangible Cultural Heritage or Associations
	Assets that can contribute significantly to acknowledged national research objectives.	Conservation Areas containing very Important buildings.	Undesignated landscapes of high quality and importance, and of demonstrable national value	Associations with particular individuals of national importance.
		Undesignated structures of clear national importance.	Well preserved historic landscapes, exhibiting considerable coherence, time- depth or other critical factors.	
	Designated or undesignated assets that can contribute significantly to regional research objectives.	Designated buildings. Historic (unlisted) buildings that can be shown to have exceptional qualities or historical associations.	Designated special historic landscapes.	Areas associated with Intangible cultural heritage activities as evidenced by local registers.
Medium		Conservation Areas containing buildings that contribute significantly to its historic character.	Undesignated historic landscapes that would justify special historic landscape designation.	Associations with particular innovations or developments of regional or local significance.
		Historic townscapes or built-up areas with important historic integrity in their buildings or built settings.	Landscapes of regional value.	Associations with particular individuals of regional importance.
			Averagely well-preserved historic landscapes with reasonable coherence, time- depth or other critical factors.	
	Designated or undesignated assets of local importance.	"Locally Listed" buildings.	Robust undesignated historic landscapes.	Intangible cultural heritage activities of local significance.
Low	Assets compromised by poor preservation and/or poor survival of contextual associations.	Historic (unlisted) buildings of modest quality in their fabric or historical associations	Historic landscapes with importance to local interest groups	Associations with particular individuals of local importance.
	Assets of limited value, but with potential to contribute to local research objectives.	Historic Townscape or built-up areas of limited historic integrity in their buildings or built settings.	Historic landscapes whose value is limited by poor preservation and/or poor survival of contextual associations.	Poor survival of physical areas in which activities occur or are associated.
Negligible	Assets with little or no surviving archaeological interest.	Buildings or urban landscapes of no architectural or historical merit; buildings of an intrusive character.	Landscapes little or no significant historical interest.	Few associations or intangible cultural heritage vestiges surviving.
Unknown potential	The importance of the asset has not been ascertained.	Buildings with some hidden (i.e. inaccessible) potential for historic significance.	N/A	Little is known or recorded about intangible cultural heritage of the area.

Table 18-9 sets out the definition used to determine the magnitude of impacts.

Impact Grading	Archaeological Attributes	Built Heritage or Historic Urban Landscape Attributes	Historic Landscape Attributes	Intangible Cultural Heritage Attributes or Associations
Major	Changes to attributes that convey OUV of WH properties.	Change to key historic building elements that contribute to OUV, such that the resource is totally altered.	Change to most or all key historic landscape elements, parcels or components; extreme visual effects; gross change of noise or change to sound quality; fundamental changes to use or access; resulting in total change to historic landscape character unit and loss of OUV.	Major changes to area that affect the intangible cultural heritage activities or associations or visual links and cultural appreciation.
	Most or all key archaeological materials, including those that contribute to OUV such that the resource is totally altered.	Comprehensive changes to the setting.		
	Comprehensive changes to setting.			
Moderate	Changes to many key archaeological materials, such that the resource is clearly modified.	Changes to many key historic building elements, such that the resource is significantly modified.	Change to many key historic landscape elements, parcels or components; visual change to many key aspects of the historic landscape; noticeable differences in noise or sound quality; considerable changes to use or access; resulting in moderate changes to historic landscape character.	Considerable changes to area that affect the intangible cultural heritage activities or associations or visual links and cultural appreciation.
	Considerable changes to setting that affect the character of the asset.	Changes to the setting of an historic building, such that it is significantly modified.		
Minor	Changes to key archaeological materials, such that the resource is slightly altered.	Change to key historic building elements, such that the asset is slightly different.	Change to few key historic landscape elements, parcels or components; slight visual changes to few key aspects of historic landscape; limited changes to noise levels or sound quality; slight changes to use or access; resulting in limited change to historic landscape character.	Changes to area that affect the intangible cultural heritage activities or associations or visual links and cultural appreciation.
	Slight changes to setting.	Change to setting of an historic building, such that it is noticeably changed.		
Negligible	Very minor changes to key archaeological materials, or setting	Slight changes to historic building elements or setting that hardly affect it.	Very minor changes to key historic landscape elements, parcels or components; virtually unchanged visual effects; very slight changes in noise levels or sound quality; very slight changes to use or access; resulting in a very	Very minor changes to area that affect the intangible cultural heritage activities or associations or visual links and cultural appreciation.

Table 18-9: Criteria for Determining Magnitude (Annex 3B of the ICOMOS CHIA Guidance³⁹⁰)

³⁹⁰ Reference: <u>http://openarchive.icomos.org/id/eprint/266/1/ICOMOS_Heritage_Impact_Assessment_2010.pdf</u>

Impact Grading	Archaeological Attributes	Built Heritage or Historic Urban Landscape Attributes	Historic Landscape Attributes	Intangible Cultural Heritage Attributes or Associations
			small change to historic landscape character.	
No change	No change.	No change to fabric or setting.	No change to elements, parcels or components; no visual or audible changes; no changes in amenity or community factors.	No change

The significance has been determined by the interaction between the magnitude of impacts and the sensitivity of receptors affected, as depicted in the significance matrix shown in Table 18-10.

Table 18-10: Scale and Severity of Change/Impact Matrix³⁹¹

Value for Cultural	Scale and Severity of Change/Impact						
Heritage Assets	No change	Minor	Low	Moderate	Major		
For World Heritage List	Significance of effe	ct or overall impact		-	-		
Properties VERY HIGH – Attributes Which Convey Outstanding Universal Value	Neutral	Slight	Moderate/Large	Large/Very Large	Very Large		
For other heritage assets or attributes	Significance of effe	ct or overall impact					
Very High	Neutral	Slight	Moderate/Large	Large/Very Large	Very Large		
High	Neutral	Slight	Moderate/ Slight	Moderate/Large	Large/Very Large		
Medium	Neutral	Neutral/ Slight	Slight	Moderate	Moderate/Large		
Low	Neutral	Neutral/ Slight	Neutral/ Slight	Slight	Slight/Moderate		
Negligible	Neutral	Neutral	Neutral/ Slight	Neutral/ Slight	Slight		

18.3.3 Construction Phase

The majority of impacts to cultural heritage assets occur during the construction phase of the projects. Potential activities to be undertaken during the construction phase of the Project that can have an impact on tangible and intangible cultural heritage, are presented in Table 18-11.

Table 18-11: Potential Construction Activities

Tangible Cultural Heritage	Intangible Cultural Heritage
 Removal of vegetation and/or dismantling of building(s) 	Human movements
Installation of fencing	Traffic
Topsoil stripping	
Excavation of foundations, etc.	
Siting of construction sites and other Project/associated facilities	
Landscaping/ earth-mounding	
 Waste disposal including excess excavated materials 	

- Presence of workforce
- Fresence of workio
 Leaks and spills

There is no known tangible cultural asset in the Project impact area; therefore, proposed construction activities presented in Table 18-11 are not expected to have any effect on known cultural assets.

³⁹¹ Reference: <u>http://openarchive.icomos.org/id/eprint/266/1/ICOMOS_Heritage_Impact_Assessment_2010.pdf</u>
However, these elements can have a potential impact on tangible cultural assets that may have been undiscovered and buried under the soil.

Unlike tangible cultural heritage, there are intangible cultural heritage elements in the Project impact area. Based on guidance for assessing value of heritage assets (Table 18-8); "Value of Heritage Asset" of 6 internationally recognised elements are defined as "Very High", 12 nationally recognised elements are defined as "High" and 3 elements detected in field studies are defined as "Low" (Table 18-12).

			ICOMOS Impact Assessment (Either Adverse or Beneficial)		
Intangible Cultural Heritage Data Source	No	Name	Value of Heritage Asset	Scale & Severity of Change/Impact	Significance
Local Applications Presented in the	1	Âşıklık (Minstrelsy) Tradition	Very High	No Change	Insignificant
International Data (Confirmed During	2	Traditional Sohbet Meetings	Very High	No Change	Insignificant
Walkover Survey)	3	Semah, Alevi-Bektaşi Ritual	Very High	No Change	Insignificant
	4	Turkish Coffee Culture and Tradition	Very High	No Change	Insignificant
	5	Flatbread Making and Sharing Culture: Lavash, Katyrma, Jupka, Yufka Katrıma, Jupka, Yufka	Very High	No Change	Insignificant
	6	Spring Celebration– Hıdrellez	Very High	No Change	Insignificant
	1	Knitting Traditions: Sock Knitting	High	No Change	Insignificant
	2	Traditional Sohbet Meetings: Ferfene	High	No Change	Insignificant
	3	Seymen Tradition	High	No Change	Insignificant
	4	Village Guest Houses	High	No Change	Insignificant
	5	Hacı Bayram-i Veli Visits and Traditions	High	No Change	Insignificant
Local Applications	6	"Bush Seeing" as part of Rain Prayer	High	No Change	Insignificant
National Data (Confirmed During	7	Âşıklık (Minstrelsy) Tradition	High	No Change	Insignificant
2n ^d Archaeological Walkover Survey)	8	Village Theatre Performers: Sinsin	High	No Change	Insignificant
	9	Bathhouse Traditions in Historic Baths	High	No Change	Insignificant
	10	Offering Cheese Pudding to Guests, Especially to Groom before Wedding Arrangement	High	No Change	Insignificant
	11	Ankara Tava/ Local Dish	High	No Change	Insignificant
	12	Pickle Culture and Traditions: Cubuk Pickles	High	No Change	Insignificant
Local Applications	1	Iron Craftsmanship	Low	No Change	Insignificant
Observed During	2	Needlework	Low	No Change	Insignificant
Walkover Survey/ Field Study	3	Traditional Treatment Methods	Low	No Change	Insignificant

Table 18-12: Intangible Cultural Heritage	Impact Assessment
---	-------------------

Some intangible cultural heritage elements which were determined during the desktop studies using the academic and literature sources could not be identified during the field interviews. These are art of miniature, copper craftsmanship, saddlers, cloth weaving tradition: angora weaving, midwifery culture, local cuisine. Therefore, these elements are not included in the list presented in Table 18-11.

The Value of Heritage Asset was determined as "Very High" for international data while it was determined as "High" for national data and "Low" for the data collected during the walkover survey. Despite these differences, "Scale & Severity of Change/Impact" is defined as "No Change" for all of intangible cultural heritage elements and "Significance of Impact" (Either Adverse or Beneficial) is identified as "Insignificant" (presented in Table 18-11).

18.3.4 Operation Phase

The Project has no potential to impact tangible cultural assets during the operating phase. The activities associated with the operation phase to be undertaken within the facility premises will be confined to areas previously impacted during the construction phase of the Project (Parcel no. 1555-4 and recreational area). With the implementation of the mitigation measures to be taken during the construction phase of the Project (see Section 18.4.1), there will be no related impact on cultural heritage during the operation phase.

Operation phase activities have no potential to create any negative impacts on intangible cultural heritage elements present in the Project AoI.

18.3.5 Summary of Outcomes

No tangible cultural heritage, archaeological and historical settlement traces have been found in the Project site premises during archaeological walkover surveys. On the other hand, there may be tangible cultural heritage assets (chance finds) that have been buried in the geographical area of the Project site or its close vicinity, whose existence will be determined by advanced research techniques or that will be unearthed during the construction works.

Unlike tangible cultural heritage, there are intangible cultural heritage elements in the Project area of influence (AoI). The Value of Heritage Asset was determined as "Very High" for international data while it was determined as "High" for national data and "Low" for the data collected during the walkover survey. Despite these differences, "Scale & Severity of Change/Impact" is defined as "No Change" for all of intangible cultural heritage elements and "Significance of Impact" (Either Adverse or Beneficial) is identified as "Insignificant". In conclusion, no effect on intangible cultural assets is identified in the Project AoI.

18.4 Mitigation Measures

18.4.1 Construction phase

A Cultural Heritage Management Plan and its sub-procedure, namely the Chance Find Procedure, have been developed for the Project to eliminate, minimize and prevent the effects of the construction phase of the Project on cultural assets. The provisions of the Chance Find Procedure include notification of relevant competent bodies for found objects or sites (if any); delivering training to the Project personnel, including contractor as well as sub-contractor employees, on the procedures to follow in case any chance finds are discovered; and securing the area of chance finds to avoid any further disturbance or destruction.

The Cultural Heritage Monitoring Expert/s of the EPC Contractor(s) will visually monitor all construction or other ground disturbance activities for evidence of presence of cultural heritage items. If chance finds of archaeological asset objects are discovered during Project construction activities, the relevant museum directory will be informed of chance finds pursuant to Law No: 2863 using a "Chance Find Report Form" by construction site responsible to record the date and time of discovery, coordinates of the location of

the chance find, description of the chance find, contacts made with the authorities and decisions taken, and the date of recommencement of work. Chance Finds will be recorded in the Chance Find Register which will be kept up to date by Cultural Heritage Monitoring Expert/s. It will be reviewed in regular environmental and social meetings (weekly or monthly).

18.4.2 Operation phase

Since the mitigation measures defined against impacts that the Project may have on cultural assets will be eliminated by the implementation of Cultural Heritage Management Plan and Chance Find Procedure during the construction phase, there will be no cultural assets to be intervened during the operation phase, hence no further mitigation measures are defined for the operation phase. Nevertheless, the MoH will ensure that the abovementioned plan/procedure will be applied during the Project lifetime.

18.5 Compliance with National and International Requirements

18.5.1 National Regulatory Framework for Tangible and Intangible Cultural Heritage

Movable and immovable cultural and natural assets in Turkiye are protected and preserved by the Law on Preservation of Cultural and Natural Assets (Law No. 2863) (amended by law numbered 3386), published in the Official Gazette (O.G.) numbered 18113 and dated 23 July 1983. The law defines the movable and immovable cultural and natural assets to be protected, arranges the related actions to be taken, determines the establishment and duties of the relevant organizations that will take implementation decisions. Law on Preservation of Cultural and Natural Assets (Law No. 2863) establishes legal protection for the following:

- Any immovable cultural asset from after the end of the 19th century, identified by the Ministry of Culture and Tourism (MoCT) as an important asset worthy of preservation,
- All natural assets and immovable cultural assets constructed up until the end of the 19th century,
- All immoveable cultural assets located within archaeological sites,
- Buildings/areas that have witnessed significant historical events during the National War and the foundation of the Turkish Republic and dwellings that have been used by Mustafa Kemal ATATÜRK, regardless of time and registration.

MoCT is the responsible body for protection of cultural heritage in Turkiye at the national level. As part of the Ministry, the High Commission for the Protection of Cultural Assets is responsible for protecting and restoring the immovable cultural and natural assets. Related to natural assets, the responsible body is the Ministry of Environment, Urbanization and Climate Change (MoEUCC) (General Directorate of Natural Assets Protection) for the works, processes, and decisions foreseen in Law 2863 about natural assets except movable ones, natural archaeological sites, and the related protection areas. There are also Cultural Assets Protection Regional Boards at regions defined by the MoCT, which are responsible for the protection of cultural heritage within their respective jurisdictions.

In addition to Law 2863, there are principal decisions related with the protection and preservation of cultural and natural assets, among which Principal Decision No.658 (dated 05.11.1999) defines the evaluation and classification criteria for archaeological sites in three levels as given below:

- 1st Degree Archaeological Sites: Highest level of protection. Areas to be preserved as they are, except for scientific studies with preservation purpose. In these areas any kind of excavation, other than scientific excavations, and construction are prohibited;
- 2nd Degree Archaeological Sites: Moderate level of protection. Areas to be preserved as they are, except for scientific studies with preservation purpose. The preservation and utilization requirements for these areas are set by Regional Preservation Boards. Additional construction is prohibited. At the 1st Degree Sites, for exceptional cases such as necessity for infrastructure construction among others, Regional Preservation Boards may permit such activities based on the approval of the relevant museum and the head of the scientific excavation team;

• **3rd Degree Archaeological Sites:** Lowest level of protection. Construction is permitted based on the decisions of Regional Preservation Boards.

In addition to the laws and regulations described above, UNESCO put into force the "Convention for the Safeguarding of the Intangible Cultural Heritage" in the 32nd General Conference held in Paris between September 29th and October 17th, 2003. The ratification accession to the convention was officially made by the Republic of Turkiye with the "Law No. 5448 Regarding the Approval of the Convention of Safeguarding of Intangible Cultural Heritage on March 27th, 2006". The intangible cultural heritage legally safeguarded by the relevant law was defined as "*Cultural products and production processes such as oral narratives and oral traditions created by the folk in oral culture environments and included in folklore studies, performance arts, social practices, rituals and festivals, folklore, practices related to the universe and nature, handcraft traditions*".

18.5.2 International Regulatory Framework for Tangible and Intangible Cultural Heritage

The following the guiding principles of international organizations have been taken into consideration during the work carried out:

- The World Bank Environmental and Social Framework (ESF), ESS 8: Cultural Heritage; and
- Guidance on Heritage Impact Assessments for Cultural World Heritage Properties, ICOMOS 2011.

ESS 8 aims to i) protect cultural heritage from the adverse impacts of project activities and support its preservation; ii) address cultural heritage as an integral aspect of sustainable development; iii) promote meaningful consultation with stakeholders regarding cultural heritage; and iv) promote the equitable sharing of benefits from the use of cultural heritage.

Turkiye has ratified the following key international conventions regarding the cultural heritage, which are applicable to the Project:

- United Nations Educational, Scientific, and Cultural Organisation (UNESCO), Convention on the Protection and Promotion of the Diversity of Cultural Expressions (Turkiye made the ratification accession on 02 November 2017).
- United Nations Educational, Scientific, and Cultural Organisation (UNESCO), Convention for the Safeguarding of the Intangible Cultural Heritage (Turkiye made the ratification accession on 27 March 2006).
- United Nations Educational, Scientific, and Cultural Organisation (UNESCO), Convention on the Protection of World Cultural and Natural Heritage (Turkiye made the ratification accession on 16 March 1983).
- United Nations Educational, Scientific, and Cultural Organisation (UNESCO), Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (Turkiye made the ratification accession on 21 April 1981).

18.6 Residual Impacts

The residual impact as a result of Project activities on the archaeological remains is estimated insignificant when the "Cultural Heritage Management Plan" and "Chance Find Procedure" developed specifically for the Project and the mitigation measures that are described above are fully implemented throughout the lifetime of the Project.

18.7 Proposed Monitoring and Reporting

The Cultural Heritage Management Plan and the Chance Find Procedure (annexed to the plan) that have been developed for the Project will be shared with all parties involved and the MoH will ensure that the abovementioned plan/procedure will be applied during the Project lifetime. The function of the monitoring process will be as follows:

- Provide advice to define the areas where the Project activities may continue or shall be stopped due to cultural heritage findings
- To record cultural heritage features observed on, and close to the existing project related areas
- To record cultural heritage's features discovered during project activities
- To provide advice in the form of a 'preliminary assessment' to the relevant department on the significance and implications of new discoveries on the Project impact area

All ground disturbance activities will be monitored by cultural heritage expert/s during the Project activities. In case of encountering any cultural heritage findings, the Chance Find Procedure will be initiated.

19 CUMULATIVE IMPACT ASSESSMENT

19.1 Introduction

This chapter presents the outputs of the Cumulative Impact Assessment (CIA) performed for the Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project (the Project). The CIA covers cumulative impacts determined for the Project in combination with risks and impacts from other relevant past, present and reasonably foreseeable developments as well as unplanned but predictable activities enabled by the Project that may occur in the future or at a different location.

Cumulative impacts are impacts that may result from the combination of past, present or future actions of existing or planned activities in the Project's area of influence (AoI). Cumulative impacts can result from individually minor but collectively significant activities taking place over a period of time. While a single activity may itself result in an insignificant impact, it may, when combined with other impacts (significant or insignificant) in the same geographical area and occurring at the same time, result in a cumulative impact that is significant. Therefore, determination of cumulative risks and impacts of the Project is considered as a significant step for ensuring a reliable and sustainable project management.

The relevant sections of this chapter include an assessment of the cumulative impacts related to the construction and operation activities of the Project, considering the scheme as a whole, as well as with any other known present and planned developments within the AoI. The assessment will consider cumulative impacts that are recognized as significant on the basis of scientific concerns and/or reflect the concerns of project-affected persons (PAPs).

19.2 National and International Guidance and Requirements

The following guidance and requirements have been taken into consideration in the CIA performed:

- World Bank Environmental and Social Standard 1: Assessment and Management of Environmental and Social Risks and Impacts: ESS1 sets out the responsibilities for assessing, managing and monitoring environmental and social risks and impacts associated with each stage of the project in order to achieve environmental and social outcomes consistent with the WB ESSs. ESS1 calls for the assessment of potential environmental and social risks and impacts of the project in an integrated way by considering all relevant direct, indirect and cumulative impacts throughout the project lifecycle.
- International Finance Organization (IFC) Performance Standard 1: Assessment and Management of Environmental and Social Risks and Impacts: PS1 recognizes that; because of the increasing significance of systemwide risk factors such as climate change, water availability, decline of species biodiversity, degradation of ecosystem services, and modification of socioeconomic and population dynamics, among others, cumulative impact assessment and management is an essential framework for risk management.
- Turkish Environmental Impact Assessment Regulation³⁹² defines the cumulative impact assessment as: "identifying and analysing the environmental risks and impacts of a project on the defined project area and other areas or resources that will be directly affected by the project, together with other present, future and foreseen activities that may be directly related to the project".
- In addition to WB standards and national legislation, IFC's Rapid Cumulative Impact Assessment (RCIA) methodology was taken into consideration during the preparation of this chapter. The IFC Good Practice Handbook on Cumulative Impact Assessment and Management: Guidance for the Private Sector in Emerging Markets (August 2013) reports that every environmental and social aspect that can be subject to cumulative impacts cannot be appropriately factored into a CIA, therefore it is

³⁹² Published in the Official Gazette Date/No: 29.07.2022/31907

considered as good practice to focus on the assessment and management strategies on Valued Environmental and Social Components (VECs). VECs are environmental and social attributes that are considered as important in assessing risks, such as:

- Physical features, habitats, wildlife populations (e.g., biodiversity),
- Ecosystem services,
- Natural processes (e.g., water and nutrient cycles, microclimate),
- Social conditions (e.g., health, economics), or
- Cultural aspects (e.g., traditional spiritual ceremonies).

19.3 Methodology

The methodology of the cumulative impact assessment is adapted from the Rapid Cumulative Impact Assessment (RCIA) approach outlined in the IFC Good Practice Handbook on Cumulative Impact Assessment and Management: Guidance for the Private Sector in Emerging Markets. The CIA approach of the IFC aims to analyse the magnitude and significance of the potential impacts and risks of proposed developments by focusing on the potential effects of other human activities and natural environmental and social external drivers on the defined VECs over a defined temporal scale.

IFC Good Practice Handbook outlines the following steps when undertaking an RCIA (please also see Figure 19-1Hata! Başvuru kaynağı bulunamadı.):

- Step 1: Determine spatial and temporal boundaries
- Step 2: Identify VECs in consultation with effected communities and stakeholders
- Step 3: Identify all developments affecting VECs
- Step 4: Determine present condition of VECs
- Step 5: Assess cumulative impacts and evaluate their significance over predicted future conditions
- Step 6: Design and implement: (a) adequate strategies, plans, and procedures to manage cumulative impacts, (b) appropriate monitoring indicators, (c) effective supervision mechanisms



Figure 19-1: Rapid Cumulative Impact Assessment (RCIA) approach of the IFC

19.3.1 Assumptions and Limitations

For the purpose of this assessment, it has been assumed that other developments considered in the inter-project assessment are developed at similar timeframes to the Project, given that exact construction and operation timeframes are unknown. This assumption represents a worst-case scenario, and the conclusions of the assessment may be conservative on this basis.

Where detail on other developments is limited, detailed assessment on inter-project cumulative impacts has not been possible. In this situation, a conservative approach has been taken to consider a worst-case scenario.

19.3.2 Identification of Boundaries and VECs

The study area for the consideration of cumulative impacts incorporates the area that features other developments which are considered in this chapter. The temporal scale of the assessment is the construction and operation phase durations of the Project.

Valued Environmental and Social Components (VECs) are the main objects of the cumulative impact assessment process. VECs are defined as any part of the environment that is considered significant by the proponent, public, scientists and government involved in the assessment process. Importance may be determined on the basis of cultural values or scientific concern.

While VECs may be directly or indirectly affected by a specific development, they often are also affected by the cumulative impacts of several developments. VECs are the ultimate recipient of impacts because they tend to be at the ends of ecological pathways.

The Turkish EIA Regulation addresses this issue to some extent without necessarily specifying VECs. Annex V of the EIA Regulation includes a list of sensitive areas or regions. This list includes the areas that must be protected in accordance with relevant Turkish legislation and due to international agreements to which Turkiye is a signatory. It also lists those areas that must be protected in general (including areas protected by regional environmental plans, agricultural areas of certain types, wetlands, water resources such as lakes, rivers, groundwater, and areas of ecological importance).

In this chapter, VECs have been identified based on assessments undertaken in the ESIA study, drawing attention on identification of critical receptors that may be potentially affected by the Project. The VECs have been identified based on the available information obtained for the activities/developments in the vicinity of the Project site and considering the environmental and social conditions of the study area.

The VECs that have been identified for this Project are identified as follows:

- Workers of the Project,
- Local communities and livelihoods (including agricultural land users),
- Local and regional businesses/facilities,
- Air and water quality,
- Traffic safety,
- Community health, and
- Social well-being.

19.4 Developments in the vicinity of the Project site

A search has been undertaken to identify local projects that could have the potential to result in cumulative impacts with the Project, based upon their scale and location. In that context, Ankara Metropolitan Municipality's Master Development Plan for 2023 and Ankara Province 2022 Investment Program were reviewed for identifying the developments in the vicinity of the Project site. The projects listed below in Table 19-1 were identified.

No.	Authority	Project Name	Sector	Description	Status
1	Private Sector – Söğüt İnşaat	Otonomi Outlet Shopping Mall and Wellness Centre Project	Commercial	Within the scope of the project, it is planned to build a shopping mall with a total of 200,000 m^2 closed area and 657 offices within the boundaries of project area. Project covers construction and operation activities.	At pre-construction stage, current status unknown
				An EIA report dated 2017 was prepared for the project.	
2	Ankara International Exhibition and Convention Corporation	Ankara International Exhibition and Convention Center Project	Commercial	The project covers construction of a fair area in Akyurt district. The fair area is expected to include an exhibition area, administrative buildings, a conference hall with a capacity of 1,800 people, an open car park with a capacity of 7,500 vehicles and a total of 20 meeting offices with an area of 120 m ² .	At construction stage, current status unknown
3	Ministry of Transport and Infrastructure	Ankara Esenboğa Airport Metro Line Project	Transportation	Project includes purchase of subway cars (102 subway cars), consultancy services and construction & electromechanical activities	At planning stage, current status unknown

Table 19-1: Details of developments in the vicinity of Project site 393

The projects were evaluated based on their scale and distance to the Project site. The projects that were identified to result in cumulative impacts in the vicinity of the Project site (within approximately 5 km radius) are discussed below.

19.4.1 Otonomi Outlet Shopping Mall and Wellness Centre Project

Otonomi Outlet Shopping Mall and Wellness Centre Project (hereinafter referred to as 'Shopping Mall Project') is a wellness centre project which includes a shopping centre and office spaces. The project is planned to include a shopping centre with a total of 200,000 m² closed area and 657 offices on a total area of 80,814 m² in Akyurt district, Block 1555 Lot 23. The current zoning status of this area is shown as "Urban Study Area" (KÇ5) in Ankara Metropolitan Municipality's Master Development Plan. The project site is located in the same block with the Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project. The Figure 19-2 below shows the two project sites.

³⁹³ Information has been obtained from 2022 Investment Program for Ankara Province

⁽http://ankara.gov.tr/kurumlar/ankara.gov.tr/Ankara2022/Duyurular/2022_yatirim_programi.pdf) and 2021 Investment Program of Ministry of Transportation and Infrastructure (https://www.uab.gov.tr/uploads/pages/yatirim-performansprogramlari/yatirim-programi-2021.pdf).



Figure 19-2: The location of Otonomi Outlet Shopping Mall and Wellness Centre project near the Project site

Within the scope of the project, one shopping mall and four office buildings are planned to be built as main units: including stores, a supermarket, a technology market, a cinema, entertainment areas, children's playgrounds, office areas, landscape areas, technical and administrative areas, emergency shelters, parking lots, heating and cooling area, water storage, generator, electrical room, fire escapes, and mechanical units. The general site plan is presented in Figure 19-3 below.



Figure 19-3: Otonomi Outlet Shopping Mall and Wellness Centre project site plan

According to information provided in the EIA Report prepared for the project, the construction of the Project is expected to start after the completion of the EIA process as well as the application projects and last for four years. The EIA positive decision has been obtained in July 2017; however, it is known that the construction activities have not started yet. The current status of the project is unknown at this stage.

The following information were highlighted from the EIA Report, dated 2017:

- In the project area, there are structures that previously belonging to the Ministry of Health. These structures have no use at the current situation. Existing buildings are planned to be used as construction site facilities. After the completion of the construction processes, these structures will be demolished and removed from the project area within the framework of the national legislation.
- It is planned that 1100 people will be employed during the construction phase and the construction will take 36 months. After the completion of the construction works and the commissioning of the project, a total of 700 people are expected to work at the operation phase.
- The need for potable water is calculated as 185 m³/day for the construction phase and 673 m³/day for the operation phase.
- Wastewater generation due to project activities is calculated as 185 m³/day for the construction phase and 673 m³/day for the operation phase. It is planned that necessary wastewater discharge and connection permits will be obtained for discharge of generated wastewater to the municipality sewer system.
- First, basic excavation works will be carried out for land preparation. The amount of excavation
 material in the project area is estimated to be approximately 160,000 m³ (including vegetative soil) and
 the amount of filling material is calculated as 40,000 m³.
- Some portion of the materials to be obtained from the excavation activities will be used in the filling, and the portion that is not used in as filling will be disposed of by transferring to the designated area of Ankara Metropolitan Municipality, without being stored in the project area.
- It is anticipated that approximately 10% (16,000 m³) of the excavation material will be vegetative soil. The vegetative soil is planned to be stored within the designated area of 995 m² at the project site. The vegetative soils will be used in landscaping at the project site after the completion of the construction works.
- Following the EIA Process, a Waste Management Plan will be prepared under the coordination of the Shopping Mall Management and will be submitted to the approval of the Ankara Provincial Directorate of Environment, Urbanization and Climate Change (PDoEUCC). Waste management activities will continue in line with the approved waste management plan and necessary notifications and statements will be made to the PDoEUCC.

19.4.2 Ankara International Exhibition and Convention Centre Project

The Ankara International Exhibition and Convention Centre (hereinafter referred to as 'Exhibition Centre Project" is a project developed by the Ankara International Exhibition and Convention Corporation in partnership with the Ankara Metropolitan Municipality, the Turkish Union of Chambers and Commodity Exchanges, the Ankara Chamber of Commerce, the Ankara Chamber of Industry, the Ankara Commodity Exchange, the Akyurt Municipality, and the Ankara Union of Chambers of Artisans and Craftsmen.

The subject exhibition and convention centre is planned to be located in the Northern Ankara Akyurt development area. The Esenboğa Airport metro line (please refer to section 19.4.3 for detailed information) connection to the city centre is expected to make the new convention centre easily accessible.

According to the information gathered from the official website of the project³⁹⁴, the first stage of the project consists of 50,000 m² of exhibition and activity areas and 50,000 m² of conference, food and beverage, and service spaces. The second stage of modular expansion will contain 100,000 m² of closed exhibition space. The proposed project is expected to include a separate exhibition area designated for Air Expos in conjunction with the planned third runway of the airport.

³⁹⁴ http://ankarafair.com/index_en.html



Figure 19-4: Ankara International Exhibition and Convention Centre Layout

The proposed Ankara International Exhibition and Convention Centre Project area is in an approximately 1.4 km distance to the Project site (also see Figure 19-4). It is known that the proposed project is still at the construction stage, however it is not known whether the construction activities are currently ongoing or not. Therefore, a more detailed assessment could not be performed at the time of this assessment.



Figure 19-5: The location of Akyurt International Fair Area near the Project site

19.4.3 Ankara Esenboğa Airport Metro Line Project

There is a planning of construction of a metro line that will connect Ankara Esenboğa Airport to the city centre of Ankara. It is reported that the metro line will be approximately 26 km long and is expected to be connected to the underground and aboveground railway network in the city centre from Keçiören Kuyubaşı station. The project budget is outlined in the Ankara Province 2022 Investment Program and 2021 Investment Program of Ministry of Transport and Infrastructure.

The metro line is expected to pass near the Project area as shown in Figure 19-5. However, no further and accurate information was available regarding the Ankara Esenboğa Airport Metro Line Project at the time of this assessment, therefore a more detailed assessment could not be performed.



Figure 19-6: The expected route of Ankara Esenboğa Airport Metro Line near the Project site

19.5 Cumulative Impact Analysis of the Developments

Identified developments within the close vicinity to the Project site have been reviewed to determine if any combination might result in potential cumulative effects. The potential cumulative impacts that might be a result of addition of the Project to the current situation at the AoI of the Project were also assessed within this study.

The assessment of inter-project cumulative impacts is not intended to provide a detailed assessment of the effects of future developments; it has been undertaken at a high-level in the context of broad development parameters sufficient to provide an understanding of the likely cumulative environmental and social effects. Other developments are limited in nature and relevant information is not always readily available, which prevents a more detailed assessment being undertaken.

19.5.1 Air Quality

Construction Phase

There is possibility that some portion of the construction activities of the Shopping Mall Project, Exhibition Centre Project and the Project being performed at similar timeframes. Construction phase activities are expected to have emissions to air such as dust and emissions associated with on-site vehicles (particulate matter (PM), sulphur dioxide (SO₂) and nitrogen oxides (NO_x)). Considering that these three projects are in close vicinity of each other, the dust levels and other emission levels such as PM, SO₂ and NO_x must be closely monitored to prevent uncontrolled cumulative emission releases into the atmosphere.

Operation Phase

For the operation phase of the Project, the potential air emissions that may occur are anticipated to result from ventilation shafts, pure steam generator and steam boilers. For all three projects, it is anticipated that there will be no activity that will generate significant dust emissions during the operation phase. During the operation phase of the Shopping Mall Project and the Exhibition Centre Project, it is expected

that gas emissions will occur from heating and cooling of the facilities to be established in the project areas and from the vehicles using the parking lot.

19.5.2 Noise

Construction Phase

There is possibility that some portion of the construction activities of Shopping Mall Project, Exhibition Centre Project and the Project will take place at similar timeframes. The main sources of noise are expected to be engines of construction vehicles and excavation activities for all three projects. Construction activities will inevitably create some degree of noise emissions at locations in close vicinity of the construction site of these three projects, however, it will be a temporary source of impact to the surroundings.

According to the EIA report of the Shopping Mall Project, noise emission calculations have been performed based on the worst case scenario, assuming that all construction machinery will work simultaneously and continuously. For this reason, the noise levels that will occur in reality are expected to be much lower than the noise level calculated within the EIA report. According to the report, the closest sensitive receptor to the project area was detected as the residential area located at a distance of approximately 70 m to the shopping mall project site. The calculation results indicate that the noise level at 70 m was 69.3 dBA. According to the EIA report, it is not expected that the nearest settlements will be adversely affected by the noise to be generated during the construction works of the Shopping Mall Project.

All things considered, it is expected that the cumulative noise impacts associated with construction phase of the Shopping Mall Project, Exhibition Centre Project and the Project are not expected to have a major significance level on the surrounding environment. Also to add, considering that these three projects are in the close vicinity of each other, activities that cause noise and vibration must be spread over time so that multiple activities that generate noise and vibration do not occur at the same time and their cumulative impacts are mitigated during the construction phases.

Operation Phase

The main sources of noise during the operation phase of the three projects will be the equipment related to energy generation and heating/ cooling systems such as pumps, compressors, steam generators, fans, variable refrigerant volume systems, air handling units or cooling towers. Additionally, there will be vehicle movements within the area where these three projects are located, including loading/unloading and car parking areas. Considering that there is already an airport and several production facilities in the vicinity of project sites, the cumulative noise impact due to the operation activities of Shopping Mall Project, Exhibition Center Project and the Project is not expected to have a major significance level on the surrounding environment.

19.5.3 Traffic

Construction Phase

The known developments in close vicinity of the Project site that will potentially generate additional traffic in the future are anticipated to be the Shopping Mall Project and the Exhibition Centre Project. It is known that the Shopping Mall Project is still at the pre-construction stage and the Exhibition Centre Project is at the construction stage. According to the local press, it is understood that the construction of Exhibition Centre Project has been suspended for a certain length of time and the latest news indicate that the construction is planned to be continued. However, no accurate information is available at the time of this assessment.

It is reported in the EIA report of the Shopping Mall Project that during the construction phase, the number of existing buses is expected to increase by 4.57%, number of existing cars is expected to

increase by 1.32%, and the number of existing trucks is expected to increase by 2.44%. Also reported in the EIA report, no negative impact is expected in terms of traffic on the highway located in the vicinity of the shopping mall project area during the construction phase according to the traffic increase percentages.

Details of traffic volume to be generated by the cumulative effect of proposed Shopping Mall Project and Exhibition Centre Project are currently limited and further information is required with regard to the details on construction phasing of these developments before a robust assessment of the likely cumulative impacts can be undertaken. However, based on the close proximity to the two projects, it is considered that the Shopping Mall Project and Exhibition Centre Project could potentially have impacts on the local road network, such as the increase of traffic, especially during construction activities. The cumulative impacts could be especially pronounced if the construction programmes of these developments overlap with the Project peak construction traffic generation. However, these will be of limited duration and vary according to the construction programmes.

Operation Phase

It is reported in the EIA report of the Shopping Mall Project that during the operation phase, the number of existing buses is expected to increase by 26.6%, number of existing cars is expected to increase by 10.4%, and the number of existing trucks is expected to increase by 1.56%. Also reported in the EIA report, no negative individual impact is expected in terms of traffic on the highway to be located in the vicinity of the shopping mall project area during the operation phase according to the traffic increase percentages.

The gathered information from EIA report of the Shopping Mall Project regarding employment that could have potential impacts on the traffic around the Project site during the operation phase are presented below:

- It is anticipated that 700 personnel will be employed for the operation phase, and an average of 6,000 visitors will visit the shopping mall and office areas daily.
- It is planned to employ an average of 3,285 people in the Office Area during the operation phase.
- During the operation phase, approximately 500 shopping mall personnel are expected to arrive at the project area with shuttles. It is foreseen that the remaining 200 personnel will arrive at the shopping mall and office area with their personal vehicles.
- In the office area, when it is considered that approximately 3000 personnel will arrive with services and the remaining personnel will be transported by personal vehicles, it is expected that 60 buses and 285 cars will arrive in the project area daily.
- It is also foreseen that the people who will use the shopping mall and office area will arrive at the project area with their personal vehicles. According to the calculations made for traffic management, it is predicted that every four people will arrive with one vehicle, and therefore it is expected that 1,500 cars will arrive in the project area daily.
- It is anticipated that an average of 25 trucks will arrive at the project site daily for the supply of goods to the project area.

Considering that the Exhibition Centre Project will not be actively used by the end users as the shopping mall for daily purposes, it is expected that additional cumulative traffic load on the existing road network during the operation phase of the projects will be lower than those associated with construction phase of the projects.

Once operational, approximately 200 staff are expected to be employed within the Project, most of whom will be civil servants or contracted workers. Most personnel are expected to live in various neighborhoods and districts of Ankara and arrive to the Project site by using the shuttle service. It is likely that some personnel might use their private cars to commute to the facility. On the other hand, it is anticipated that almost 4,000 personnel will be employed during the operation phase of the Shopping Mall Project, of

which 3,000 are expected to use the shuttle service to arrive at the shopping mall. All things considered, the projects might have additional cumulative load to the existing traffic in the area, especially during the start and end of shifts due to shuttle services.

19.5.4 Waste

The Ankara province manages waste by the existing third-party and municipality owned licensed and permitted waste management (i.e. recycling and disposal) and wastewater treatment facilities. Cumulative impacts in relation to waste and wastewater arising from the Project are likely to be the extra demand placed on these disposal, recycling and treatment facilities. The availability of waste and wastewater facilities for future developments in the region will need to be assessed by planning authorities, as the area of influence is open to further development in the future.

Construction Phase

During the construction activities of the three projects, the listed types of waste are expected to be generated:

- Packaging waste generated by the workers (e.g., paper and cardboard, glass, plastics, metals),
- Organic solid wastes generated due to catering services provided for the employees,
- Construction wastes,
- Empty drums, cans, containers, etc. (if used to contain hazardous chemicals, then the containers are considered as hazardous waste according to the national legislation),
- Scrap metal, packing material and card boxes, wood and timber scraps,
- Medical waste from the infirmary unit within the construction sites,
- Wastes such as oily rags resulting from the maintenance of machine and equipment and various thinners, solvents and paints,
- Waste battery and accumulators, and
- Domestic wastewater generated by the workers at the construction sites.

These wastes are expected to be collected, stored and transported to the designated and appropriate waste management sites through licensed waste contractors according to the relevant Turkish regulations. Therefore, it is not expected that cumulative impacts due to construction phase waste handling, storage, transport and disposal activities will have a major significance level, if managed properly.

Operation Phase

Types of waste to be generated due to operation activities of the Shopping Mall Project, Exhibition Centre Project and the Project are listed below:

- Packaging waste (e.g., paper and cardboard, glass, plastics, metals),
- Organic solid wastes,
- Waste vegetable oils,
- Waste oils due to mechanical equipment maintenance activities (empty drums and containers containing hazardous chemicals are considered as hazardous waste according to the national legislation),
- Waste batteries,
- Medical waste from infirmary units and the Project, and
- Domestic wastewater

It is not anticipated that waste management activities during the operation of proposed projects will create any adverse impacts on the local environment if handling, storage, transport and disposal of the waste comply with the requirements of the national regulations and international standards.

19.5.5 Socio-economy

Construction Phase

Potential negative impacts on surrounding receptors (i.e., agricultural lands, neighbouring business facilities) and vulnerable groups (especially women) during construction activities may increase as a result of the project developments in the vicinity of the Project site. The negative impacts may include dust, traffic, loss of income, health, safety and security.

Positive impacts include local benefits during construction related to creation of employment opportunities and benefits to the local economy through supply of goods and materials.

Operation Phase

When the timelines of project developments in the vicinity of the Project are considered, it is anticipated that employment opportunities and income generation will increase for individuals living in the neighbourhoods. The positive impacts of these developments will also be on local procurement of goods and services.

19.6 Cumulative Impact Mitigation

Effective communication will be sought by the Project with the other development projects in close vicinity to coordinate the mitigation measures and management strategies being applied to minimise and monitor the impacts on air quality, noise, traffic, and waste management.

19.6.1 Air Quality

Although no significant cumulative air quality impact is expected during the construction phase of the projects, the following best practices are recommended to be implemented during the construction activities:

- Implementation of air quality management plans
- Application of dust suppression methods to keep airborne dust at acceptable levels, such as water spraying at dust generating areas especially during dry weather conditions
- All vehicles, machines and equipment will be used and maintained by routine checks in accordance with the manufacturer guidelines and they will not be left idling for long periods if not in use
- Deteriorating vehicles and equipment will be replaced with the new ones
- Attention will be paid to the driver acts to ensure compliance with the regulatory speed limits and loading standards
- Investigation of the grievances reported by stakeholders through the public grievance mechanisms of project

Although no significant cumulative air quality impacts are anticipated to occur due to operation phase activities of the proposed projects, several mitigation measures have been identified as listed below:

- Uniform and homogeneous air distribution will be made through fans within the entire indoor parking areas
- There shall be CO (carbon monoxide) detection systems for measurement, adjustment and warning in heavily loaded indoor parking areas. There shall also be sensors to monitor the level of CO and CH₄ explosive fuel gases such as CO and CH₄ (methane) in the parking areas.

19.6.2 Noise

Although no significant cumulative noise impact is expected to occur due to the proposed projects, the following best practices are recommended to be implemented during construction and/or operation phases of the projects:

- High efficiency mufflers shall be used on all construction equipment
- Equipment will be maintained and controlled on a regular basis
- · Vehicles, machinery and equipment will not be left idling for long periods if they are not in use
- Noise abatement equipment shall be used where appropriate
- Complaints from nearby settlements related with noise emission caused by construction activities shall be investigated following the provisions of the grievance mechanisms developed for the projects
- Continuous noise monitoring will be undertaken to confirm and record noise levels and to identify if further mitigation is required

19.6.3 Traffic

There is a need to provide ongoing consultations with key stakeholders in the vicinity of the Project site to coordinate the construction and operation of the proposed projects and identify suitable physical and traffic management measures to mitigate the impacts of cumulative traffic on the capacity of the local road network and the amenity of local residents as well as employees/workers of the nearby facilities.

Considering the potential overlap of the construction schedules of three projects (i.e., Shopping Mall Project, Exhibition Centre Project and the Project), necessary consultations shall be undertaken to discuss alternative routes and access with the local authority representatives during the construction activities. This will aim to minimise scheduling intense works concurrently or consecutively that could adversely affect local communities.

As mentioned in section 19.5.3, the projects might have additional cumulative load to the existing traffic in the area, especially during the start and end of shifts due to shuttle services. The potential cumulative impacts on the local roads and communities can be minimized by coordinated traffic management within these three projects once operational activities are initiated, such as maximising use of public transport for journeys to and from the city centre and other residential areas where workers are accommodating and communicating the shift hours between these three projects.

19.6.4 Waste

As mentioned in section 19.5.4 of this chapter, anticipated cumulative impacts are not expected to be major if mitigated properly. The following mitigation measures are proposed to eliminate the potential impacts regarding waste management:

- To prevent increase in traffic load due to waste transportation: Wastes shall be transferred outside rush hours if the waste management facility waste acceptance procedures are suitable
- To prevent increase of waste load in waste management facilities: Waste hierarchy techniques shall be applied to reduce amount of waste generated
- Secure on-site waste storage areas shall be established in the project sites, away from watercourses
- Excavated soils from construction activities shall be used for backfilling
- Solid wastes shall be managed according to relevant Turkish legislation and disposed to the licensed facilities of the municipality

19.6.5 Socio-economy

Regarding potential cumulative impacts on socio-economy, the following mitigation and enhancement measures will be applied:

- Development of an employment and procurement strategy to ensure maximization of opportunities for local people and businesses
- Procurement of goods from local suppliers to the extent possible
- The project development activities including construction activities and related project works (such as rehabilitation of Cubuk Stream bed within the scope of the Project) shall be timed such that the projects will not affect activities of the agricultural land users. Income and production losses, if any, of the users of the agricultural land shall be compensated in compliance with the requirements of the World Bank's ESF.
- Regular consultations with the projects' parties, neighbouring communities, business facilities and other stakeholders for ensuring that health and safety measures are implemented and regularly monitored
- Ensuring that the projects' parties take effective measures to prevent health, safety and security risks (including SEA/SH risks) in line with the Project's SEA/SH policy to be developed

19.7 Conclusion

In conclusion, it is expected that the cumulative impacts associated with the abovementioned developments and the Project are not expected to have a major significance level on the surrounding environment and local communities provided that necessary mitigation measures are taken. It is to be noted that communication with the neighboring facilities regarding the occurrence of any disturbances are continuously undertaken by MoH and the Phase I construction contractor. Communication will be continued during Phase II construction works. In addition, although MoH is not present at Project site during Phase I construction works, there is a vaccine storage centre of MoH located near the Project area, therefore any concerns regarding the Project can also be raised through the existing facility.

20 ENVIRONMENTAL AND SOCIAL MANAGEMENT

20.1 Introduction

This chapter demonstrates a systematic framework that aims at ensuring transparent and effective monitoring, prevention, minimisation, mitigation, off-setting and enhancement measures to address the environmental, health, safety and social impacts associated with the Project. In accordance with this aim, an Environmental and Social Management System (ESMS) will be developed and established by the MoH to be implemented during construction and operation phases of the Project. The mitigation measures identified during the ESIA study in order to avoid, mitigate or enhance project impacts are captured under the ESMS. The main objective of the ESMS is to describe the way environmental and social risks and impacts, including all community-related, labour-related and environment-related issues, will be managed during both construction and operation phases of the Project. The ESMS involves Project-specific management plans developed by the MoH to implement the mitigation measures. Planning, implementation, control and review of the processes in terms of environmental and social risks and impacts are also within the scope of the ESMS.

The proposed ESMS will be compatible with Environmental and Social Management Plan (ESMP) prepared within the scope this ESIA study. Additionally, it will be in line with the relevant Turkish laws and regulations, World Bank requirements, international standards, good practice notes and guidelines which are listed, but not limited to, as below:

- The World Bank's Environmental and Social Framework (ESF), 2017
- The World Bank Group's Environment, Health and Safety (EHS) General Guidelines, 2007
- The World Bank Group's EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing, 2007
- The World Bank Group's EHS Guidelines for Healthcare Facilities, 2007
- World Health Organization (WHO) Laboratory Biosafety Manual, 2020
- WHO Biorisk Management: Laboratory Biosecurity Guidance, 2006
- United Nations (UN) Model Regulations on the Transport of Dangerous Goods, 2021
- European Union (EU) directives that are relevant to scope of the Project
- International Labour Organization (ILO) Conventions on Labour and Working Conditions

The ESMS will also be established in line with the following international good practice and standards:

- ISO 9001:2015 Quality Management System
- ISO 14001:2015 Environmental Management System
- ISO 45001:2018 Occupational Health and Safety Management System
- ISO 39001:2012 Road Traffic Safety Management System

20.1.1 Potential Project Impacts and Risks

The Project will result in environmental and social impacts and risks on various receptors due to the construction and operation phase activities. These impacts and risks must be assessed and mitigated for the effective and safe operation of the Project. The identified impacts and risks that will arise from Project activities and the associated management and mitigation measures to be taken are described in detail in the relevant chapters of this ESIA report. The Project-specific management plans that are prepared within the ESMS will also cover the specific measures relevant to each topic assessed within this ESIA report.

20.1.2 Summary of Commitments

The Project commits to prevent any arising impacts regarding the construction and operation phase activities by taking necessary mitigation measures to ensure an environmentally and socially sustainable Project lifecycle. In this regard, it is committed that an ESMS will be established, and this system will ensure compliance with national and international laws, regulations and standards relevant to the Project regarding the environmental and social aspects.

20.2 ESMS Planning

20.2.1 Scope of the ESMS Planning

The scope of the ESMS will involve the issues listed below:

- Stakeholder Engagement and Grievance Mechanism
- Plans: Detailed plans prepared by contractors related to specific aspects and areas which are impacted by their scope of works
- Procedures: More specific work instructions developed by the Project Owner, in collaboration with construction contractors, to support the implementation of the plans.

20.2.1.1 Human Resources Management

The MoH does not have an publicly shared HR Policy. Rather, the MoH, as a public institution, follows the Turkish Labour Law No. 4857 and relevant ILO conventions for HR management. The responsibilities of the human resource management have been shared among all the departments affiliated to the MoH. An HR Management Plan/Labour Management Procedures (HRMP/LMP) document will be developed under the Project ESMP specific to the Project that set out an approach to managing the workforce in accordance with the standards of the World Bank ESF and national law. Therefore, the MoH will establish or revise (if there is already one) the Project-specific HRMP/LMP and ethical Code of Conduct (CoC) in compliance with the WB ESF ESS2, international standards and national legislation. The HRMP/LMP will mainly cover the issues listed below:

- The roles and responsibilities of the personnel employed for human resource management,
- Corporate values of the MoH (including non-discrimination and equal opportunity, child labour and forced labour),
- Worker rights under national labour and employment law,
- Collective agreements,
- Worker grievance mechanism,
- Training process of the workers, and
- Labour and working conditions (including but not limited to employment process, wages, working hours, annual leave, overtime arrangements, compensation benefits, unethical behaviours and disciplinary procedures).

The MoH will disclose the prepared/updated HRMP/LMP and its annex ethical CoC for all its workers (including subcontractors). These policies and procedures will be understandable and accessible to workers, and in the main language spoken by the workforce.

20.2.1.2 Stakeholder Engagement and Grievance Mechanism

Open and transparent stakeholder engagement is critical for the sustainability, ownership and implementation of the Project. The objective of the stakeholder engagement is to provide opportunity for affected and/or interested individuals, groups, communities and organizations to express their opinions and concerns about the Project, so that these opinions/concerns can be considered and addressed during assessment of impacts and identification of mitigation measures covered under the ESMS. The

preparation and disclosure of ESIA abides by WB ESF ESS1 and ESS10 and adheres to the principle of effective stakeholder engagement throughout the Project lifecycle.

Prior to the ESIA study, the PMSU of the MoH conducted an online disclosure meeting to inform stakeholders about potential environmental and social impacts of the "Component 4: Strengthening Capacity of MoH to respond to COVID-19" of HSSSP (including the Project). The stakeholder engagement process of the Project has continued during the ESIA scoping phase through engagement with the key project stakeholders. Scoping consultations were undertaken with key public institutions to determine potential Project Affected Persons (PAPs)/stakeholders, to gain a deeper understanding of the Project area and potential Project impacts, and to understand their perception of the Project in order to reflect their views and recommendations to Project design and respond to any concerns they may have on the Project. Consultations were also held with non-governmental entities and neighbouring facilities and communities that may be prone to direct Project construction and operation impacts. Please refer to *Chapter 5: Stakeholder Engagement* for further details.

The stakeholder engagement and consultation activities will continue during the construction and operation phases of the Project in order to maintain decent and constructive relations with the neighbouring communities and other stakeholders. Additionally, a Stakeholder Engagement Plan (SEP) has been prepared for the development of clear targets, successful reach out to the stakeholders, and effective implementation of the stakeholder engagement activities. The activities to be undertaken during the construction and operation phases of the Project are provided in the SEP.

A Grievance Mechanism (GM) has been established by the MoH to assist resolve complaints and grievances in a timely, proactively, unbiased, effective and efficient manner that is responsive for all related parties (including external stakeholders through the community GM and internal stakeholders through the workers' GM) involved during both construction and operation phases of the Project. A well-functioning GM provides a transparent and credible process for fair, effective and lasting outcomes. It also builds trust and cooperation as an integral component of broader community consultation that facilitates corrective actions. It aims at continuously improving the Project performance through regular assessments of the grievances and identifying structural adjustments by conducting root cause analysis.

All plans and reports about the Project together with the information on the Project's Grievance Mechanism channels established at national, ministerial, contractor and consultant level will be published on the Project website³⁹⁵. The Project website will be updated regularly to include information on operation activities and any changes in environmental and social policy, plans and procedures that are followed.

20.2.2 Plans, Policies and Procedures

The following plans are described within the ESMP and are developed to achieve environmental, health and safety and social (EHSS) objectives for the construction and operation phases of the Project: (note that two separate plans for each topic are available for construction and operation phases, unless indicated otherwise)

- Chemicals and Hazardous Materials Management Plan
- Air Quality Management Plan
- Noise Management Plan
- Waste and Wastewater Management Plan (including Medical Waste Management Plan for the operation phase)
- Pollution Prevention Plan
- Traffic Management Plan
- Human Resources Management Plan/Labour Management Procedures (including Code of Conduct)

³⁹⁵ https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html

- Community Health and Safety Plan
- Occupational Health and Safety Plan
- Resource Efficiency Management Plan
- Biodiversity Management Plan (single management plan for both construction and operation phases)
- Emergency Preparedness and Response Plan
- Animal Welfare Management Plan (for the operation phase only)
- Security Management Plan
- Cultural Heritage Management Plan (including Chance Find Procedure) (single management plan for both construction and operation phases)

These plans will be supported with operational procedures and related instructions as necessary as part of the ESMS. The ESMS procedures and plans will be periodically (or when necessary) reviewed and revised. Additional procedures and plans will be developed as the Project progresses, as necessary. The development and implementation of the supporting operational procedures, related instructions and additional procedures and plans will be under the responsibility of General Directorate of Public Health (GDPH) of MoH.

Furthermore, the Contractor will establish its own ESMS and implement Contractor ESMP and its submanagement plans that will be prepared in line with the ESMP and its sub-management plans during construction phase.

In addition to Project ESMS plans and procedures, a comprehensive biosafety and biosecurity program specific to the Project will be adopted to be able to keep track of biological risks that may arise during the operation phase. A Biosafety Manual specific to the facility and Standard Operating Procedures (SOPs) will be implemented throughout the operation activities.

Furthermore, a Landscaping Management Plan will be developed by the Project Owner during the operation phase and implemented, which will lay out the landscaping management procedures, as well as the vegetation success criteria.

20.2.3 Environmental, Health, Safety and Social Impact and Risk Assessment

The identification of the significant environmental, health and safety and social risks and impacts of the Project is considered as the principal stage of the planning of an effective ESMS. Significant impacts of the Project have been identified within this ESIA report and an ESMP is developed for the Project in order to manage these significant impacts. The EHSS impact assessment study defines the:

- Mitigation measures and required actions for the identified risks and impacts of the Project,
- Source of the action (e.g., applicable legislation, Project ESIA commitments, Lender's requirements), and
- Timeframes and responsible parties.

The impact assessment is performed considering the legal and other requirements, type, scale and location of the Project, environmental and social baseline data, frequency, duration, possibility of the impact, opinion of relevant internal and external parties, affected receptors (e.g., workers, community, environment), and emergency situations and security.

20.2.4 Legal and Other Requirements

The applicable legislation and standards for the Project are identified for each topic (e.g., air quality control and monitoring, waste management, traffic management) in the related chapters of this ESIA report. This provides an understanding of the legal requirements such as permitting, as well as the implementation of international guidelines during the design, construction and operation of the Project.

20.2.5 Targets, Objectives and Programs

EHSS objectives and targets will be set out in Project-specific management plans for the Project to comply with legal requirements and obligations for assuring continuous improvement of the environmental and social quality targets and objectives. Targets and objectives will cover issues such as efficient use of raw materials, management of waste materials and hazardous substances, natural resources/energy consumption and reduction, community and occupational health and safety, and improvement of awareness of employees to any emerging risks within the Project site. Targets and objectives will be specific, measurable and applicable. Deadlines and responsible party for each program established to achieve desired results will be assigned. Environmental and social targets and programs will be documented and monitored continuously during the Project lifecycle.

20.3 Implementation of the ESMS

20.3.1 Responsibilities, Resources and Training

The roles and responsibilities of related parties are defined in the environmental and social submanagement plans for construction and operation developed within the ESMS in detail.

Personnel with direct responsibility for the Project's environmental and social performance such as health and safety specialist, environmental officer, social specialist, biosafety specialist, emergency team members are required to be present in the organisational structure of both EPC Contractor for construction phase and MoH when providing construction supervision and also when performing operation phase activities. The mentioned staff will be adequately qualified, trained and experienced to perform their work. Competencies of these employees will be consistent with national legal requirements and relevant international standards. External experts and/or consultancy services, if legally or technically necessary, will also be obtained during the Project phases. Determination and providing of the training needs, informing and increasing the awareness of the employees, subcontractors and suppliers regarding the ESMS Policy, significant environmental and social risks and impacts, and procedures will be defined.

Providing required trainings to all Project personnel is critical for effectively performing the assigned roles responsibilities, especially during operation since the operation phase will include consideration of biosafety measures for laboratory personnel. The necessary staff will be assigned for the operation process in accordance with the World Health Organization (WHO) standards and technical trainings will be provided by the Project Owner for relevant personnel prior to the operation. As for the construction phase, the EPC Contractor is required to provide necessary environment, OHS, social, safety and security related trainings as well as job-specific trainings which are required to be taken to perform specific construction activities. Furthermore, the training requirements during construction and operation phases are defined in the E&S sub-management plans developed under the Project ESMS, in detail.

The institutional arrangements regarding the ESMS and monitoring implementation of its requirements during the construction and operation phases of the Project are provided in Table 20-1 and Table 20-2 below, respectively. The key roles and responsibilities for implementation of the ESMS are identified based on the World Bank environmental and social requirements and international best practice.

Roles	Responsibilities
EPC Contractor Project Manager	 Overall responsibility for environmental, health, safety and social performance of Project contracted works, including subcontractors
	 Ensure adequate resources are provided for implementation of ESMS
	 Ensure the ESMS documentation are distributed to all subcontractors
	Participate in site inspections to plan and confirm the detailed design of E&S site measures
	Review and approve detailed site plans and method statements incorporating E&S measures
	 Ensure that all personnel involved in construction activities, including subcontractors and service providers, are adequately trained and informed on the requirements of the ESMS
	 Participate in site inspections in the early stages of works with the EHS Manager and subcontractors
	 Audit subcontractor performance and ensure all subcontractors implement the mitigation measures described in the ESMS
EPC Contractor EHS	Ensure the ESMS is implemented by all personnel and subcontractors
Manager	Review and update the ESMS documentation as required
	Conduct internal audits and record identified incompliances
	 Develop necessary monitoring and reporting forms and establish appropriate document control procedures.
	 Ensure related trainings are provided to personnel and subcontractors
	Oversee subcontractors' EHS compliance through the subcontractor monitoring program
	 Implement monitoring programs under the ESMS
	 Review monitoring results against the requirements of national regulations and international standards, investigate non-compliances and ensure that immediate corrective actions are taken.
	Provide support for resolution of grievances
EPC Contractor EHS Specialists	 Undertake field inspections to monitor implementation of ESMS requirements, reporting any issues directly to the EHS Manager on a daily basis
	 Contribute to weekly and incident EHS reports prepared by the EHS Manager
Biosafety Specialist	 Providing advice and guidance for Phase II construction works of the Project, such as during the construction of technical buildings
All EPC Contractor and Subcontractors Personnel	Understand the ESMS requirements associated with their work and comply with them in the course of their duties

Table 20-1: The key roles and responsibilities for implementation of the ESMS during construction

Table 20-2: The key roles and responsibilities for implementation of the ESMS during operation

Roles	Responsibilities		
Project General Manager	 Overall responsibility for environmental, health, safety and social performance of Project including subcontractors 		
	 Ensure adequate resources are provided for implementation of ESMS 		
	Ensure the ESMS documentation is distributed to all subcontractors.		
Project EHS Manager	Overall responsibility in occupational heath and safety and environmental compliance		
	Ensure the ESMS documentation is implemented by all personnel and subcontractors		
	 Review and update the ESMS documentation as required 		
	 Conduct internal audits and record identified incompliances 		
	 Develop necessary monitoring and reporting forms and establish appropriate document control procedures 		
	Ensure related trainings are provided to personnel and subcontractors		
	 Ensure the E&S team conducts all monitoring and reporting as set out in the ESMPs 		
	Oversee subcontractors' EHS compliance through the subcontractor monitoring program		
	 Implement monitoring programs under the ESMS 		
	 Review monitoring results against the requirements of national regulations and international standards, investigate non-compliances and ensure that immediate corrective actions are taken. 		
	 Determining necessary resources for proper implementation of the ESMS and reporting them to the General Manager 		

Roles	Responsibilities
Environmental Chief	 Ensuring the Project compliance with the environmental requirements of the ESMS Having responsibility for forming and training (including toolbox talks) of the Project personnel regarding environmental management issues Coordinating environmental management during the lifetime of the Project Reporting all hazards, non-conformances and incidents Ensuring all personnel including management level be aware of environmental requirements Undertaking periodic audits and inspections of the facility to monitor performance against the environmental requirements Ensuring that all provisions in the contractor engagements regarding environmental requirements as per the Project standards during the operation phase and auditing the performance of the contractors on those requirements Working in coordination with CLO to address any off-site environmental issues and/or grievances Supporting CLO to find solutions to the answers of grievances raised by employees, the local community and local institutions regarding environmental issues
EHS Staff	 Supporting the EHS Manager and Environmental Chief Undertaking the tasks given by the EHS Manager and Environmental Chief Reporting the hazards, incidents and non-conformances to EHS Manager and Environmental Chief
Project Biosafety Officer	 Providing advice and guidance to personnel and management on biological safety issues Developing, implementing, maintaining and continually improving a biosafety and biosecurity programme Ensuring that all personnel are properly trained in the use of personal protective equipment (PPE) and other safety procedures. Ensuring that the laboratory is properly equipped with the necessary safety equipment, such as biosafety cabinets, and that all equipment is properly maintained and inspected. Ensuring that the laboratory is operating safely and in compliance with all relevant regulations and guidelines.
Project Animal Welfare Manager	 Ensure the Animal Welfare Management Plan is implemented by all personnel and subcontractors, review and update the plan as required Oversee compliance through the animal welfare monitoring program Develop necessary monitoring and reporting forms and establish appropriate document control procedures Conduct internal audits and record identified incompliances Ensure related trainings are provided to personnel and subcontractors Review the outcomes of the animal welfare program monitoring against the requirements of national regulations and international standards. If non-compliances against the requirements are detected, investigate the non-compliance and ensure that immediate corrective actions are taken.
Project Security Manager	 Ensure the Security Management Plan is implemented by all personnel and subcontractors, review and update the plan as required Implement a monitoring program to verify the effectiveness of security measures Develop necessary monitoring and reporting forms and establish appropriate document control procedures Conduct internal audits and record identified incompliances Ensure related trainings are provided to personnel and subcontractors Oversee subcontractors' security compliance through the subcontractor monitoring program If monitoring indicates any non-compliances, investigate the non-compliance and ensure that immediate corrective actions are taken Review and assess any incidents to prevent their reoccurrence

Roles	Responsibilities
Human Resources (HR) Manager	Overall responsibility of recruitment and employment, performance management, and strategy management of all Project employees
	Oversee the conditions of employment, contractual terms, pay negotiations and issues relating to equality and diversity
	Ensure the contracts with the contractors are developed in line with the provisions of the Human Resources Management Plan/Labour Management Procedures (HRMP/LMP)
	 Ensure the HRMP/LMP is implemented by all employees including subcontractors and supply chain companies, monitor implementation of the Code of Conduct
	Review and update the HRMP/LMP as required
	 Develop necessary monitoring and reporting forms and establish appropriate document control procedures
	Conduct internal audits and record identified incompliances
	Ensure related trainings are provided to civil servants and contractors
	Ensure that the grievance mechanism for the Project employees is established and implemented and that all employees are informed of its purpose and how to use it
	 If monitoring indicates any non-compliances, investigate the non-compliance and ensure that immediate corrective actions are taken
Community Liaison Officer (CLO)	 Maintaining engagement and liaison with the local communities during the lifetime of the Project
	 Reporting all hazards, non-conformances and grievances related to the EHS management of Project to the EHS Manager
All Project Personnel including Subcontractors	 Understand the ESMS requirements associated with their work and comply with them in the course of their duties
	 Reporting any activities which are causing risks and non-compliances

20.3.2 Operational Control

An ESMP and associated management plans are developed for the Project in order to manage the adverse impacts on humans and the environment during the construction and operation phases. The ESMP is prepared based on the international standards and national legislation requirements, as well as the international best practice. The ESMP considers the outcomes of the ESIA study and is a plan that describes the necessary mitigation measures to avoid, minimize or compensate the adverse impacts during the construction and operation phases of the Project, responsible parties for the implementation of the mitigation measures, the timing of implementation, and monitoring and audit requirements. The ESMP focuses on the avoidance of impacts, and where this is not possible, presents technically and financially feasible and cost-effective mitigation measures to minimize possible impacts to acceptable levels. The ESMP will be kept up to date with any required additional mitigation throughout the Project lifecycle and to reflect the requirements of new and/or amended laws and regulations.

20.3.3 Environmental and Social Emergency Preparedness and Response

An Emergency Preparedness and Response Plan has been developed as part of the ESMS for emergency cases such as accidents, explosions, fires, gas leakages, hazardous chemical/biological and liquid waste spills, disease outbreaks and similar incidents that occur unexpectedly due to equipment/infrastructure failures, employee errors, natural disasters (flooding, landslides, earthquakes, storms), sabotage and similar.

The following focus areas shall be detailed within the procedure:

- Emergency response team information and personnel responsibilities,
- Emergency response activities, emergency drills, internal trainings,
- Emergency response resources,
- Maintenance and control of emergency response equipment (e.g., fire emergency equipment, pollution prevention equipment, first aid cabinets, material safety data sheets, personal protective equipment, warning and guiding signs),

 Measures to be taken in case of any incident or emergency, biological or chemical release, or natural disaster.

20.4 ESMS Control, Monitoring and Reporting

20.4.1 Monitoring

It is required to establish a monitoring system throughout the Project lifecycle for the review and control of the ESMS. The monitoring system will determine the effectiveness of the ESMS within the scope of the Project. In line with this requirement, monitoring activities will be regularly applied by the MoH in order to monitor the following:

- The compliance of the ESMS with the Turkish legislation, World Bank ESF ESSs, and international requirements related to environmental and social aspects of the Project,
- The compliance of the ESMS with commitments described in the ESMP,
- Implementation of the ESMP and other plans and procedures developed within the scope of the Project, and
- Improvements achieved as the Project progresses.

20.4.2 Reporting

An effective and consistent reporting system is essential for implementation of the ESMS. Routine internal reporting and external auditing provides the necessary inputs for ensuring continuous improvement of the Project. Performance monitoring, auditing and reporting will be carried out during the Project phases to ensure compliance with the requirements of the ESMP, commitments in this ESIA report, and the overall ESMS.

The EPC Contractor will provide Monthly E&S Performance Reports to the MoH. The reporting requirements during construction phase are defined in the E&S sub-management plans developed within the ESMP in detail.

The MoH will provide quarterly reporting to the World Bank based on monitoring results as a Project requirement during the construction phase. The final scope and format of all reports will be agreed with the MoH and the World Bank prior to them being required and produced.

20.4.3 Non-conformities and Corrective, Preventive and Improving Actions

Any non-conformities, weaknesses, deficiencies, deviations and improvement opportunities within the Project activities will be identified by means of audits, checks, measurements and collected grievances. The identified non-conformities will be analysed in order to define their root cause, and appropriate corrective/preventive/improving actions will be determined, initiated and tracked through the process. Required amendments will be reflected to the management programs, Project-specific procedures and plans, including the ESMP.

21 ENVIRONMENTAL AND SOCIAL AUDIT OF THE CONSTRUCTION WORKS

21.1 Introduction

21.1.1 Background

This chapter presents findings of the construction site audit for the Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project (the Project) on the basis of the site visit observations and meetings held on 22 December 2022 within the scope of the Environmental and Social Impact Assessment (ESIA) study. The study covers assessment of the compliance of the basic construction works for Phase I construction of the Project (please refer to Section 2.6.1 for description of the Phase I and Phase II planning for the Project) against relevant Turkish environmental and social legislation and international standards including the World Bank (WB) Environmental and Social Framework (ESF).

As a result of the audit and assessment, a number of gaps in compliance with the national and international requirements were identified. An environmental and social action register which includes recommendations on how to close the identified gaps and actions that are required to be taken for the Project to meet the applicable standards is presented in section 21.3 of this chapter.

21.1.2 Overview of the Construction Works

The basic construction works for Phase I construction activities of the Project are presently continued by the Engineering, Procurement and Construction (EPC) Contractor and its subcontractors. YDA Construction (a subsidiary of YDA Group) has become the EPC Contractor of the Phase I construction works through an agreement signed with the MoH in February 2022. These construction works include the construction of three Phase I buildings as shown in Figure 21-1 inside the red-lined area, namely, the administrative building, the research & development (R&D) building, and the experimental animals production/test building. Phase I construction activities do not include any mechanical or electrical works to be performed within the buildings.



Figure 21-1: Extent of Phase I Construction Works

The components of the Phase I construction works and their footprint and operational areas are provided in Table 2-2 below. Road constructions and landscaping are not included in the Phase I construction activities.

Building		Footprint area (m²)	Operational area (m²)
Administrative Building (Basement + Ground Floor + 3 floors + Attic)	The building will have a basement floor, ground floor and three floors. The basement floor will consist of technical areas, parking garage, laundry rooms and kitchen. The ground floor will have dining hall, cafeteria, meeting rooms, service areas and offices. The 1st and 2nd floors will comprise of offices, meeting rooms and service areas. The 3rd floor will have temporary guest accommodation rooms (approximately 17 rooms) for academic visitors. In the attic, there will be a maintenance room where technical units will be placed.	2142.00	10714.09
Glass Cafeteria (Ground floor)	There will be a glass cafeteria positioned between the administrative building and the R&D building. The glass cafeteria can be directly reached from the ground floor of the administrative building.	206.92	206.92
Research and Development Building (Basement + Ground Floor+ 2 floors + Attic)	The R&D building will have a basement floor, ground floor and two floors. The basement floor will consist of technical areas (UPS room, storage room, maintenance room, etc.) and parking garage, and the entrance in the basement floor will be also used as service entrance. The ground floor will have registration and admissions unit and laboratory area. The 1st and 2nd floors will comprise of offices, laboratory areas, wet and technical volumes. There will also be a biobank unit on the 2nd floor. In the attic, there will be a maintenance room where technical units will be placed.	1941.95	5968.63
Parking Garage (Basement)	There will be a basement level parking garage.	171.72	171.72

Table 21-1: Phase I construction components and footprint/operational a	areas ³⁹⁶

³⁹⁶ The construction footprint areas are retrieved from Project document presenting layouts, building details, surface areas and floor plans prepared by Mesart Mimarlık ve İnşaat A.Ş.

Building		Footprint area (m ²)	Operational area (m ²)
Experimental Animals Production/Test Building (Basement + Ground Floor+ 2 floors + Attic)	The building will have a basement floor, ground floor and two floors. The basement floor will consist of laboratory and wet volumes as well as transfer and asepsis areas for experimental animals coming to the facility. The ground floor will have laboratory area, wet volumes and offices. The 1st and 2nd floors will comprise of laboratory area, maintenance room and wet volumes. In the attic, there will be a maintenance room where technical units will be placed.	1842.98	7231.40

21.1.3 Description of Audit Process

The Consultant has undertaken an audit in order to provide a gap analysis to assess compliance of the existing construction works with the applicable standards which comprised of a comprehensive document review, site visit and discussions held during the site visit with the MoH and EPC Contractor representatives.

A site visit was performed with the participation of a MoH representative and EPC Contractor representatives including the construction chief, a health, safety and environment (HSE) manager from YDA Construction corporate office, human resources (HR) chief, and several other construction site personnel. The OHS chief of the construction site was not available for an interview at the time of the site visit. The site visit included review of the current situation at multiple locations within the construction site, such as the constructed buildings and worker facilities. Worker facilities included the resting areas, toilets, refectories, offices, intern office, site entrance office, OHS office, and the infirmary.

21.1.4 Limitations

This chapter provides an overview of the Project construction works based on documentation and information made available by the MoH and EPC Contractor together with the discussions made during the site visit. Please note that environmental and social documentation and information received until 6 February 2023 have been considered in this chapter.

21.2 Environmental and Social Management

21.2.1 General

21.2.1.1 Environmental and Social Management System (ESMS)

As reported by the EPC Contractor, YDA Group has Human Resources, Environment, Occupational Health and Safety Policies in place and holds ISO 9001:2015 Quality Management System and ISO 14001:2015 Environmental Management System certifications. The EPC Contractor also has a partially established Environmental and Social Management System (ESMS) in place that it uses to manage and monitor environmental, social and occupational health and safety performance of the Project. The ESMS plans and procedures shared by the EPC Contractor for the Consultant's review are listed below:

- Natural Resources Conservation Procedure: Published in September 2017 and revised in February 2020. The procedure briefly describes actions for environmental protection, water management and soil management. However, it is observed that these actions are not project-specific, and the procedure was prepared in a broader approach instead of a project-specific approach. Natural resource use is reportedly tracked with the 'Natural Resource Use Tracking Form' covering energy and fuel use.
- Cultural Heritage Protection Procedure: Published in September 2017 and revised in February 2020. This procedure aims to set out the principles for protection of immovable or movable cultural heritage that may arise during excavation and construction activities, notifying the relevant

authorities, and the management of the process of delivering such assets to the state without any harm. The procedure was prepared to be used in all construction projects of the EPC Contractor.

- Waste and Emission Management Procedure: Published in September 2017 and revised in February 2020. The procedure covers the management procedures of waste and emissions that will occur as a result of construction activities in line with the national environmental legislation and international standards and requirements.
- Occupational Health and Safety Emergency Response Plan: The plan was published in May 2022 specifically for the Project. The plan covers emergency scenarios including fire, explosion and natural disasters. It includes lists and contact information of emergency teams (i.e., first aider, rescue, security, fire extinguishing and transport teams).
- Health and Safety Plan: The plan was published in April 2022 specifically for the Project. The Consultant has reviewed the document and concluded that the training plan and emergency teams list that were provided within the plan are not up-to-date and must be revised in accordance with the Project requirements and organisational capacity.
- Subcontractor and Supplier Management Procedure: Published in September 2017 and revised in February 2020. The procedure defines steps of the selection and evaluation process and performance assessment criteria for subcontractor and supplier companies. Accordingly, the Consultant understands that the performance assessments are conducted annually with the use of Subcontractor Performance Assessment Form and Supplier Performance Assessment Form of the EPC Contractor.
- Satisfaction Analysis and Grievance Management Procedure: Published in September 2017 and revised in February 2020. The procedure determines the actions, methods and responsibilities for evaluating, resolving and concluding complaints, suggestions and other grievances from stakeholders and internal and external persons or organizations that are connected to the Project activities.

It has been concluded that, a project-specific Environmental and Social Management System (ESMS) has not been fully established for the ongoing construction activities. The development of the ESMS should be completed by revising the existing ESMS documentation according to the requirements of WB ESSs and also by adopting necessary additional ESMS documentation prepared for the construction phase within the scope of the ESIA upon their approval by the World Bank, including the Environmental and Social Management Plan (ESMP) and associated plans and procedures. These would include:-

- Stakeholder engagement plan (including a public grievance management procedure)
- Human Resources Management Plan/Labour Management Procedures
- Community health and safety management plan
- Security management plan
- Chemicals and hazardous materials management plan
- Air quality management plan
- Noise management plan
- Pollution prevention management plan
- Resource efficiency management plan
- Biodiversity management plan
- Traffic management plan
- Waste and wastewater management plan
- Cultural heritage management plan (including chance find procedure)
- Occupational health and safety management plan
- Emergency preparedness and response plan

21.2.1.2 Organizational Capacity

The EPC Contractor has shared its general organisational chart for review (see Figure 21-2). According to this organisation chart, there are five technical units under the Project Manager, i.e., façade works, construction site unit, design office, electrical unit, and mechanical unit. Each of the units has their own chief personnel. In addition, OHS unit and the accounting unit also operate under the Project Manager.



Source: Organisational Chart of the EPC Contractor, February 2023

Figure 21-2: Construction Site Organisational Chart of the EPC Contractor

For human resource management, the EPC Contractor employs a Human Resources (HR) Chief and a timekeeper. The HR Chief is responsible for managing labour and working conditions of both contractors and subcontractors, and reports to the Chief of Construction Site.

Pursuant to the Communique on Workplace Hazard Classes Related to Occupational Health and Safety³⁹⁷ Annex-1, construction works and site preparation activities related with the Project are regarded as 'very dangerous'. As per the Regulation on Duties, Authority, Responsibilities and Trainings of Occupational Health and Safety Specialists³⁹⁸ and Regulation on Duties, Authority, Responsibilities and Trainings of Workplace Doctor and Other Health Personnel³⁹⁹, in workplaces defined as 'very dangerous', OHS specialists and workplace doctors should be assigned and work minimum 40 minutes/month and 15 minutes/month per employee, respectively.

According to the OHS organisational chart of EPC Contractor within its Health and Safety Plan, a full-time OHS Chief, an OHS specialist, a workplace doctor and other health personnel are employed at the construction site. The OHS specialist, the workplace doctor and other health personnel are appointed based on the legal hourly requirements by a Joint Health and Safety Unit (JHSU)⁴⁰⁰ which provides external OHS services to the EPC Contractor. The official assignment records of OHS professionals were provided for the Consultant's review and it is concluded that the EPC Contractor complies with the national legislation requirements on assignment of OHS professionals. In addition, according to the reviewed documentation, all subcontractors on site also have assigned OHS specialists and workplace

³⁹⁷ Published in the Official Gazette No/Date: 28509/26.12.2012

³⁹⁸ Published in the Official Gazette No/Date: 28512/29.12.2012

³⁹⁹ Published in the Official Gazette No/Date: 28713/20.07.2013

⁴⁰⁰ According to the Regulation on Occupational Safety and Health Services (Official Gazette No/Date: 28512/29.12.2012), an occupational safety and health unit should be established in workplaces, or otherwise, these services can be provided in collaboration with a Joint Occupational Safety and Health Unit (JSHU).

doctors in line with the national legislation. The OHS Chief is tasked with oversight of environmental compliance onsite.

In addition to the abovementioned documents and the organisational charts, the Consultant has also reviewed the assignment records for OHS Chief, workers' representatives and emergency support staff of the EPC Contractor.

21.2.1.3 Subcontractor and Supply Chain Management

As reported by the EPC Contractor, there are seven subcontractor companies which are listed in Table 21-2 by their duties within the Project and approximate number of workers (as of November 2022).

Name of the subcontractor company	Duty at the construction site	Approximate number of workers (as of November 2022)
Akpinar Construction	Rough construction works	40
Tamkoçlar Steel Engineering	Anchor manufacturing	1
Fe-Ka Engineering Construction	Insulation works	1
Şahin Crane	Crane	1
Mep Installation Design	Installation works	2
Ata Sav Security Services and Systems	Security	4
Taner Catering	Catering	3
Total		52

Table 21-2: Subcontractor Companies by Their Duties and Approximate Number of Workers⁴⁰¹

As noted above, the EPC Contractor has a Subcontractor and Supplier Management Procedure in place, which complies with the national legislation as well as international labour requirements. The procedure covers certain principles on work-related permits, workers' human rights, their right to be unionized, prohibition of forced and child labour, protection of the workers' rights on payments and benefits, ensuring occupational health and safety standards at the worksite, emergency preparedness, workers' accommodation, and workers' grievance mechanism. The Subcontractor and Supplier Management Procedure also explains the selection and evaluation process applied to subcontractor and supplier companies within the labour management system of the EPC Contractor.

All seven companies listed in Table 21-2 had previously been subcontracted by the EPC Contractor in various other construction projects, and therefore, selection and evaluation process had been previously applied to these companies. As reported by the HR Chief, within the scope of the Project, performances of subcontracted companies are reviewed during and after the completion of their works. The evaluation criteria includes whether the works are completed in a timely manner, whether the business and human relations comply with the corporate policies of the EPC Contractor, and whether the behaviour/approach of the workers or the company properly meet the national legislation related to labour management. The performance is evaluated over 100 points and if a subcontracted company scores below 60 points based on the evaluation criteria, the EPC Contractor ends contract with that company.

The contracts made with subcontractors include clauses related to payments, working hours, overtime working, required trainings, disciplinary actions and penalty procedures. If a subcontractor company fails to comply with any of the clauses specified in the contract, the EPC Contractor penalizes the company in line with the contract requirements. On 14 July 2022, in one of the regular site inspections with the participation of the HR Chief and the timekeeper, a subcontracted worker whose personnel files and contract were not registered in the EPC Contractor's labour management system was detected. HR Chief

⁴⁰¹ The information is obtained from the HR Chief of the EPC Contractor during the site visit.

recorded this issue and officially reported it to the relevant authorities. The subcontractor company was penalized with a monetary fine which was deduced from the progress payment of the company.

In addition to work contracts, the EPC Contractor also signs an OHS and Environment Contract with its subcontractors. The template of this contract was shared with the Consultant for review. With the OHS and Environment Contract, the subcontractors commit to ensure compliance with the quality, OHS, environmental, and human resources policies, together with ethics, personnel behaviour and zero tolerance rules of the EPC Contractor. Furthermore, lifesaving OHS rules are defined within the contract template as listed below:

- Do not work without a Work Permit in conditions where a working permit is required. Follow the work instructions.
- Observe the suitability of the working environment. Check the industrial hygiene conditions.
- Make use of necessary personal protective equipment (PPE), especially during working at height.
- Do not disable equipment/systems that provide security.
- Do not enter restricted areas without permission of relevant unit/chief personnel.
- Do not start work without energy isolation, avoid contact.
- Do not get under any suspended load or between any mechanical systems.
- Learn and be aware of the emergency situations and measures before starting to work.
- Wear seat belt while driving, do not exceed speed and control limits. Do not talk on the phone while driving.
- Report dangerous situations and near-misses.

At the time of the site visit, Akpınar Construction had the highest number of subcontracted workers in the construction site. The workers of the EPC Contractor and Akpınar Construction have assigned workers' representatives. Accordingly, there were three workers' representatives at the time of the site visit, two of them were the representatives of contracted workers and one was of the workers of Akpınar Construction.

EPC Contractor has two main suppliers based on the scope of construction activities. These are Kocalar Construction for concrete supply and Dofer Construction Services for iron supply. The labour management of the companies is provided through the Subcontractor and Supplier Management Procedure, including the selection and evaluation process of the supply chain companies in compliance with national legislation and requirements of WB ESS2: Labour and Working Conditions.

21.2.1.4 Construction Supervision

Supervision of the construction works is performed by MoH General Directorate of Health Investments. The General Directorate supervises construction works performed under health investments in Türkiye and holds sufficient capacity.

Regular reporting mechanism is established between the contractor and the MoH as a supervisor, which includes daily and/or weekly site visits to the construction site and regular notifications.

21.2.1.5 Environmental Permitting

Connection of the generated wastewater within the construction site to the municipality sewer system is currently done through the vaccine storage building of the General Directorate of Public Health (GDPH) of the MoH which is next to the Project site. It is understood that a Wastewater Connection Permit has not yet been secured for the Project site. However, it is required both by the Water Pollution Control Regulation⁴⁰² and ASKI's Regulation on Wastewater Discharge to Sewers that a separate and

⁴⁰² Published in the Official Gazette No/Date: 25687/31.12.2004

independent connection point should be provided for each parcel, and wastewater connection permit must be obtained for domestic wastewater discharges.

As discussed in section 3.2.1, the Project is 'exempted' under the Regulation on Environmental Impact Assessment (EIA)⁴⁰³.

21.2.2 Occupational Health and Safety (OHS)

21.2.2.1 Observations

Several non-compliances were detected during the site visit performed on 22 December 2022 regarding occupational health and safety practices at the construction works, as listed below.

- There are locations on site that are not precautioned for fall incidents. Construction railings and safety nets were not in place at several locations inside the buildings that are under construction.
- Some of the scaffolds inside the constructed buildings were not appropriate for use since they did not have any periodic control labels or safety rails.
- It was observed that the staircase railings that were installed inside the buildings might not be able to prevent falls since they were poorly mounted.
- Periodic control labels of the fire extinguishers on site were missing.
- Missing safety harnesses and helmets were noted for several workers.

The EPC Contractor should ensure that the observed non-compliances and similar situations are addressed by the OHS management and satisfactory occupational health and safety conditions are established across the construction site in line with the requirements of WB ESS2: Labour and Working Conditions.

21.2.2.2 Site Inspections and Audits

According to the Health and Safety Plan of the Project, the OHS Chief is responsible of conducting internal audits and reporting of the audit findings to the Chief of Construction Site on a regular basis. Although it was reported that periodic audits are performed across the construction area by the OHS Chief and the OHS specialists of the subcontractors, no documentation or records of these audits were available for review. It is also unclear how the OHS performance of the subcontractor companies are monitored by the EPC Contractor. OHS site inspections and audits of worker and subcontractor works should be regularly performed and properly documented by the EPC Contractor to ensure compliance with the WB ESS2- as well as the WBG Environment, Health and Safety Guidelines.

The Ministry of Labour and Social Security (MoLSS) performed two OHS audits at the Project site by on 3 November 2022 and on 5 December 2022. The associated audit finding reports prepared by the Ministry were provided to the Consultant for detailed assessment and review. The Consultant has reviewed two letters; the first audit letter included information regarding the initial OHS audit findings and non-compliances, while the second audit letter confirmed that all non-compliances were addressed and closed.

According to the first audit finding report of the MoLSS, fifteen non-compliances and nine noncompliances were identified for the EPC Contractor and its subcontractors respectively. The noncompliances reported regarding the EPC Contractor are listed below:

- Fall from height risks were detected across the construction area,
- There was risk of falling objects at the entrance of the construction area due to the walkway shed not being wide enough,
- Work platforms inside the construction area were not equipped with safety rails,

⁴⁰³ Published in the Official Gazette No/Date: 31907/29.07.2022
- Staircase railings did not have mid-rails between the top rail and the walking surface,
- Lack of construction railings in several stair landings,
- Entrances to areas where with risks of falling objects were not restricted,
- Access to facades of the construction area were not restricted against the risk of falling objects,
- The stairs constructed for reaching the tower crane were found to be noncompliant,
- Several electrical cables were present on the ground without protection from mechanical or physical impacts,
- No fire extinguishers were present in the prefabricated worker resting areas,
- Insufficient number of cabinets in the prefabricated changing rooms where clean and dirty clothing are kept separately,
- No smoke detectors were present in the prefabricated worker resting areas and the refectory,
- Appointment time for the workplace doctor was insufficient, and
- No 'other health personnel' staff was employed in the workplace.

In addition, the following non-compliances were identified regarding the sub-contractor Akpınar Construction:

- The use of full body belts or similar safety systems by the employees was not ensured in places where the protective barriers need to be temporarily removed during the construction works,
- Work platforms inside the construction area were not equipped with safety rails,
- · Fall from height risks were detected at exterior working platforms,
- Safety risks to the workers were noted due to exposed iron in the moulding area,
- No statical calculation report was provided for the scaffolding system,
- Appointment time for the workplace doctor was insufficient,
- Appointment time for the OHS specialist was insufficient,
- No 'other health personnel' staff was employed in the workplace, and
- No OHS board has been formed in the workplace.

The second audit report indicated that the previously listed non-compliances were resolved. Although the non-compliances were closed at the time of the second audit, the Consultant has once more observed several non-compliant situations such as fall from height risks and lack of safety rails. The Consultant is of the opinion that these health and safety risks must be strictly monitored and mitigated by the OHS site personnel.

21.2.2.3 Accidents

The Consultant was informed that an accident and near miss tracking system is in place to record the accidents that occur within the workers of the EPC Contractor and the subcontractors in the scope of the Health and Safety Plan. According to the plan, an accident file is opened in case of occurrence of any accident in the construction site. The file would include the following documents: job entry notice of the worker, job entry health report, worker contract, training certificates, PPE delivery forms, risk assessment, OHS committee decisions made for the accident, job description document, OHS and other instruction documents, occupational competency certificates, and accident investigation report. The template of accident investigation report is included in the Health and Safety Plan of the EPC Contractor, which includes information regarding the accident/incident and the worker, root cause analysis and defined corrective measures.

A total of five occupational accidents (one by the EPC Contractor, four by the subcontractor company Akpinar Construction) have occurred within the construction site since the beginning of the construction works. The Consultant was provided with the accident notifications made to the Social Security Institution of Turkiye under the Ministry of Labour and Social Security. According to the accident notifications, three

of the accidents have resulted in lost time injuries and no fatalities have occurred. However, no further information were shared with the Consultant for review. To ensure compliance with the WB ESS2, the EPC Contractor should develop accident monitoring logs in which accident investigation details are fully recorded including root cause analysis, lost time for the injuries and the identified corrective and/or preventive actions. Accident monitoring logs also need to include near misses that occur during the construction works.

21.2.2.4 Risk Assessment

As required by the Occupational Health and Safety Risk Assessment Regulation⁴⁰⁴ and the WBG Environment, Health and Safety Guidelines, risk assessments should be conducted and regularly updated to identify possible hazards at workplaces, the likelihood and severity and associated risks and relevant mitigation measures. As reported by the site representatives, the EPC Contractor and its subcontractors have risk assessments in place for the site operations.

The EPC Contractor has a comprehensive risk assessment document available dated May 2022, as noted by the Consultant during the site visit containing detailed assessment of the identified risks across the construction site and associated measures. In line with the regulatory requirements, the EPC Contractor has a risk assessment team in place including the Chief of Construction, OHS Chief, workplace doctor, an employee representative and support personnel as indicated by the risk assessment team assignment record (dated May 2022) that was shared for review.

The EPC Contractor should update the existing risk assessment based on the specific construction works ongoing across the site within the scope of the Project, and ensure that workers are informed regarding the actions to be taken for the identified risks.

21.2.2.5 Equipment Periodic Inspections

The Regulation on Health and Safety Conditions in the Use of Work Equipment⁴⁰⁵ defines the work equipment that are subject to periodic controls, the control criteria and the necessary control periods. Accordingly, the work equipment subject to periodic control include: pressure vessels and fittings, lifting and conveying equipment, installations (including electrical, fire, ventilation and heating), workbenches, industrial shelves and doors, and work machinery. The Consultant was provided with periodic control reports for all work equipment present at the construction site, i.e. tower crane, heating boiler, booster tanks, boiler tanks, work machinery, and workbenches.

The periodic controls were performed in October 2022 by an external company (Tekkim Engineering). Review of the periodical control reports indicate that measurement results are compliant with the abovementioned regulation and the relevant standards. The next controls are planned to be performed in October 2023 as per the subject regulation.

It is also required by the Regulation on Health and Safety Conditions in the Use of Work Equipment that periodic controls of electrical installations, grounding installations and lightning conductors are performed annually according to the specifications set out by the relevant electrical regulatory framework. Accordingly, the Consultant was provided with periodical grounding measurements for electrical installations and mechanical panels within the construction site that were performed in October 2022 by Tekkim Engineering on behalf of the EPC Contractor. Assessment of the measurement results indicated no regulatory non-compliances related to electrical and grounding installations.

Apart from the legally required annual inspections described above, the EPC Contractor has periodic OHS inspection control forms where findings of the safety and maintenance checks of the tower crane are recorded. To ensure compliance with the requirements of the WBG Environment, Health and Safety Guidelines, such forms, checklists and tracking lists should be established and used for safety monitoring

⁴⁰⁴ Published in the Official Gazette No/Date: 28512/29.12.2012

⁴⁰⁵ Published in the Official Gazette No/Date: 28628/25.04.2013

of all equipment, tools and installations within the construction site, including lifting equipment such as internal and external scaffolds.

21.2.2.6 OHS Meetings

In accordance with the Regulation on Health and Safety Committees⁴⁰⁶, a health and safety committee should be established if there are fifty employees or more in an entity and monthly committee meetings should be held where health and safety conditions of the workplace are reviewed and evaluated. The reports of the monthly health and safety committee meetings held by the EPC Contractor for the Project from June to November 2022 were made available to the Consultant. It is documented that meetings are regularly conducted and all necessary parties (i.e., Chief of Construction Site as chair of the board, board secretary, OHS Chief, workplace doctor, EPC Contractor worker representative, and EPC Contractor support personnel) have attended these meetings.

21.2.2.7 OHS Trainings

It was reported that the site management holds weekly OHS trainings, in addition to induction trainings provided to each employee upon start of employment. Sample OHS training forms were provided to the Consultant. Accordingly, the OHS training includes general topics, health topics, technical topics and other topics including high-risk works.

In accordance with the Regulation on Vocational Trainings of the Workers to be Employed in Works Classified as Dangerous and Very Dangerous⁴⁰⁷, workers at construction works should receive vocational competency certificates specific to their work. Vocational competency certificates are available and were shared with the Consultant for slinger-pointer trainings and heavy equipment operator trainings of workers. However, the vocational competency certificate for the steam boiler operator was not available although it is listed in the 'list of professions with certification obligation' of the subject regulation. Additionally, the personnel working in the refectory of the workplace do not hold and should obtain hygiene training certifications in accordance with the Regulation on Hygiene Training⁴⁰⁸.

21.2.2.8 Periodic Health Inspections

The Consultant was informed during the site visit meeting that the initial and periodic health inspections of the direct and subcontracted workers are being performed by the externally contracted Joint Health and Safety Unit (JHSU). The Consultant was provided with two sample initial health inspection reports prepared by the workplace doctor. No non-compliances were observed.

To ensure compliance with the requirements of the WBG Environment, Health and Safety Guidelines, tracking lists should be established and used for monitoring of all periodic health inspections.

21.2.2.9 Permit-to-Work

As reported by the site representatives, a permit-to-work system is implemented for the Project, as evidenced by the template forms for night works and shaft construction works that were shared with the Consultant. The work permit forms include information regarding the worker, employer and the work to be performed and the defined timeframes. Reportedly, work permits are also utilized for other high risk works including hot works, working at height, working in confined space and electrical works, however samples were not available for review. Additionally, no work permit track lists or work permit procedures for employees and sub-contractors were available onsite.

During the site visit, the Consultant observed that several subcontractor personnel were performing hot work onsite, however, the personnel were not able to verify that they have obtained a work permit prior to

⁴⁰⁶ Published in the Official Gazette No/Date: 28532/18.01.2013

⁴⁰⁷ Published in the Official Gazette No/Date: 28706/13.07.2013

⁴⁰⁸ Published in the Official Gazette No/Date: 28698/05.07.2013

performing the works. The implementation of the permit-to-work system should be improved by the EPC Contractor and it should be ensured that required work permits are taken in a timely manner in accordance with the construction work programme. It is also recommended that a permit track list is kept by all the subcontractors in order to provide effective coordination of ongoing works on construction site.

21.2.2.10 Emergency Preparedness and Response

In line with the Regulation on Emergency Situations at the Workplaces⁴⁰⁹, the EPC Contractor has a project-specific Occupational Health and Safety Emergency Response Plan in place that was published in May 2022. The plan covers emergency scenarios including fire, explosion and natural disasters and defines the emergency equipment and emergency teams including first aider, rescue, security, fire extinguishing and transport teams. However, it was observed that several sections of the plan need to be revised and updated to reflect the existing conditions for the Project (such as the training plan and emergency response team lists).

An emergency support staff training was performed by the EPC Contractor on 10 May 2022. According to the training records, the training included topics including emergency scenarios, emergency response planning, emergency teams and their duties, and first aider duties.

The Regulation on Protection of Buildings from Fire⁴¹⁰requires that at least one fire and evacuation drill is conducted at workplaces annually. Accordingly, an emergency response drill was performed at the construction site on 15 May 2022 with the participation of the construction site employees, OHS specialist, workplace doctor, and the emergency teams. An action list was provided within the Emergency Drill Form for measuring the effectiveness of the drill. The outcomes of the drill were mostly reported as "good", however there was one action (related with the personnel gathering and counting at the emergency assembly areas) that was reported as "to be improved". However, there was no statement attached to this form that the defined action was improved following the drill.

There are sufficient number of fire extinguishers across the construction site including locations where hot works and electrical works are carried out, however, it was observed that periodic control labels were missing for the fire extinguishers. Timely periodic controls of the fire extinguishers should be completed by the OHS management.

According to the First Aid Regulation⁴¹¹, at least one first aider must be assigned for 10 people for very dangerous workplaces. The Consultant was provided with the first aider certificates of ten first aid personnel for review. Although it is understood that the number of first aider personnel is in line with the regulatory requirements, the validity dates of first aider licences have expired. The certificates must be renewed as soon as possible.

21.2.3 Labour and Working Conditions

21.2.3.1 Overview

At the time of the site visit, construction workforce that was present onsite consisted of approximately 80 employees, of which nearly 30 were subcontractors' workers. On the technical and management side of the EPC Contractor, there were two female personnel and three disabled personnel.

The number of workers varies by the workload and the progress of the construction works each month. The exact number was determined based on the payroll records of November 2022. At peak times, there were 127 workers (including technical, management and construction workers of the EPC Contractor, and

⁴⁰⁹ Published in the Official Gazette No/Date: 28681/18.06.2013

⁴¹⁰ Published in the Official Gazette No/Date: 26735/19.12.2007

⁴¹¹ Published in the Official Gazette No/Date: 29429/29.07.2015

subcontracted workers) on the site. The highest number of workers on the construction site was recorded on 15 November 2022.

The working hours at the construction site are 8:00-17:00 and workers' transportation is enabled by shuttle buses serving various neighbourhoods across Ankara.

The EPC Contractor has been utilizing the Human Resources (HR) Procedure of another project of the YDA Group for labour management, which is not specific to the labour management practices of the Phase I construction activities of the Project. Furthermore, it does not comply with the labour management requirements of the WB ESS2: Labour and Working Conditions. The EPC Contractor should adopt an HR plan/procedure for the Project in line with the WB ESS2 requirements.

As noted above, the EPC Contractor has a Subcontractor and Supplier Management Procedure, which complies with the national and international labour requirements. The EPC Contractor should also adopt a Labour Management Plan that covers all workers including direct workers, subcontractors and suppliers in accordance with the prepared HR procedure in order to comply with the WB ESS2 requirements.

21.2.3.2 Terms and Conditions of Employment

It was reported by the representatives of the EPC Contractor that employment opportunities for the Phase I construction works are announced through the career websites and the posters displayed around the construction site. As explained by the HR Chief, the employment process occurs in two ways:

- Workers from other construction sites of YDA Construction: If the required workforce can be obtained through the existing workers of other construction sites where YDA Construction is the EPC Contractor, the employment process involves the relocation of the personnel files to the construction site of the Project, the revision of the necessary documentation as per the requirements of the job and the Project, signing the worker contract prepared for the construction activities of the Project, and the provision of the required on-the-job training within the scope of the Project. This process is applied for both contracted and subcontracted workers of YDA Construction, who are working in other construction sites and employed for the construction activities of the Project. The consent of the workers for relocation from one construction site to another is obtained in the beginning of the process.
- Newly employed workers: The employment process for the newly employed workers starts with an initial screening of eligible candidates. It is followed by the CV review of the candidates and job interview. Prior experiences, place of residence, expectations from the work and the EPC Contractor, working conditions, wages and benefits, trainings, non-discrimination and equal opportunity, working hours and overtime working are covered during the interview. After the interview, if the candidate is found to be appropriate for the job in terms of competency, s/he is offered the position. The process is completed once the worker contract prepared for the construction activities of the Project is signed, and all necessary documentation is provided by the worker and included in the personnel files. As reported by the HR Chief, the worker obtains and completes on-the-job trainings within the first week of her/his employment.

The following observations were made regarding personnel files and worker contracts:

- The worker contracts include clear and understandable information regarding the terms and conditions of employment. Workers are also informed about their rights under the Labour Law⁴¹², the working hours, overtime working, wages, compensation, and benefits through the contract clauses. Minimum wage requirements of the law are met in the worker contracts. Each contract is signed by the worker and the authorized personnel of the EPC Contractor on the starting date of the worker.
- All reviewed personnel files contained the required documentation (i.e. employment approval form, indefinite term employment contract, copy of identity card, on-the-job training form, employee

⁴¹² Official Gazette Number/Date: 4857/22.05.2003

recruitment tracking form, identity register copy, medical report, emergency contact, the written consent to work overtime, criminal record, certificate of residence). However, it was noted that the signature of the authorized personnel of the EPC Contractor was missing in the on-the-job training and employee recruitment tracking forms. The EPC Contractor was informed that these forms should be filled and signed as appropriate.

- The tracking form in fact stands as a good practice of the EPC Contractor because it provides a systematic way to track work-related issues such as medical conditions as well as occupational health and safety records of the worker, and trainings provided to the worker.
- As reported by the HR Chief, all personnel files are stored in lockers located in the HR Chief's office. Only HR has access to the personnel files and if any other authorized personnel from the management side is required to review the personnel files, s/he needs to acknowledge and get approval of the HR Chief.
- The personnel files and worker contracts were found to be partially compliant with the national legislation. After the signatures are completed, they will be fully compliant. Regarding the WB ESS2 requirements, the worker contracts should include clauses regarding the workers' grievance mechanism, non-discrimination and equal opportunity principle, and commitment of the workers to prevent sexual exploitation and abuse (SEA) and sexual harassment (SH). The EPC Contractor should revise the worker contracts accordingly.

The following observations were made regarding working hours and overtime:

- The monitoring system for recording the attendance of all workers (based on their companies) is managed through the timekeeper employed by the EPC Contractor. The timekeeper visits the construction site once daily in the beginning of the day. The workers on the construction site sign the attendance list and the list is provided to the HR Chief after each recording.
- It was observed during the site visit that some subcontractors sometimes leave the construction site early when they finish their daily tasks. It was reported by the representatives of the EPC Contractor that these subcontractors leave the construction site under the supervision of the Chief of Construction Site. However, a list regarding those who leave the construction site was not available.
- For timekeeping, it is recommended for the EPC Contractor to adopt a turnstile system as soon as possible for better management of working hours and attendance. If utilizing the turnstile system is not possible in the near future, the timekeeper should visit the site twice or three times a day in order to take attendance appropriately.
- Workers have a lunch break between 11:30 and 13:00. Also, they have a break at 15:00 for 15 minutes. Weekly resting day is Sunday for all workers.
- All workers are informed regarding overtime working through the clauses in their contracts and
 provide written consents for overtime work which are included in their personnel files together with
 signed contracts. Overtime works are followed through the overtime tracker, which is controlled by
 the timekeeper and monitored by the HR Chief. If a worker works on Sunday, s/he is paid double
 daily salary in the upcoming payment period as required by the national legislation. In addition to
 double daily salary, the worker is allowed to have a rest on a weekday. It was reported by the EPC
 Contractor representatives that overtime work is rarely required (e.g. after 17:00 for concrete works)
 and do not exceed the legislative requirements set out by the Labour Law which limit daytime
 working hours to 11, night-time working hours to 7.5 and annual overtime hours to 270.

The following observations were made regarding payments:

- Payroll slips and worker contracts were reviewed during the site visit. All salary payments are made through bank transfers on a monthly basis as confirmed by both the EPC Contractor representatives and the workers.
- The following information was provided by the HR Chief regarding salary payments of workers of the EPC Contractor and subcontracted workers:

- Workers of the EPC Contractor: The overtime tracker is checked prior to the payment. If the worker worked overtime during that month, the overtime payment is added to the regular salary. The EPC Contractor directly transfers the salaries to the bank accounts of the workers within the first five days of each month. The payroll slips of November 2022 were reviewed onsite with the HR Chief and no non-compliances were identified. Workers sign their payroll every month.
- Subcontracted workers: The overtime tracker is checked prior to the payment. If the worker worked overtime during that month, the overtime payment is added to the regular salary. Salaries of the subcontracted workers are transferred to the bank accounts of the subcontractor company within the first five days of the month. The EPC Contractor requests the bank receipts of all workers to crosscheck if the workers are properly paid as specified in their contracts (for both regular and overtime work payments). If the amount paid to the worker is higher than the amount paid by the EPC Contractor, it is not questioned since the subcontracted companies have varying rewarding systems/motivational bonuses or other kinds of additional support for holidays, birthdays etc. If a lower amount is paid to the worker, EPC Contractor requests further information about the reason of this deduction. If the reason is legally acceptable (e.g. worker received an advance payment in the previous month), the EPC Contractor approves the payment. Subcontracted workers sign their payroll every month.
- Even though salaries of subcontracted workers are transferred to the bank accounts of the subcontractor companies within the first five days of the month, the security personnel stated that they receive their payments on the 15th day of the month and sometimes even later. The security personnel added that they raised their concerns to both their employer and the EPC Contractor. However, the salaries remain to be paid with delays. The EPC Contractor should ensure that such delays are prevented.
- A number of uncertainties (e.g. late payments, higher or lower salary amounts) were identified with the relevant clauses of the contracts, regarding the salary payments of subcontracted companies. The EPC Contractor should closely monitor the payment records of the subcontractors in line with the WB ESS2 requirements. A checklist should be utilized in which the dates as well as the amounts of payments are recorded and followed properly. The EPC Contractor should apply effective measures towards subcontractor companies by considering the benefit of the subcontracted workers based on the grievances related to payments. Effective measures may involve verbal warning, written notice and monetary fines in case of repetition.

21.2.3.3 Non-Discrimination and Equal Opportunity

For the Phase I construction works of the Project, the EPC Contractor has adopted the Non-Discrimination and Equal Opportunity Policy prepared for another project of the YDA Group. The policy includes generic clauses which clearly state that no discrimination based on the workers' ethnicity, gender, sexual orientation, marital status, political view, disability, religion or any other personal characteristics will be allowed or tolerated. The policy also covers the issues of ensuring equal opportunity for all workers in access to trainings and fringe benefits provided by the company, and fair treatment to all individuals in employment processes.

As stated by the HR Chief, the Non-Discrimination and Equal Opportunity Policy is practiced and applied in the construction site, and working conditions and work-related benefits are provided to all workers (including subcontractors) according to the policy. Also, all workers are informed about the policy as part of the induction process. As agreed by the HR Chief, the existing policy should be revised to cover all Project workers including subcontracted workers and to include the credentials of the Project.

It was reported by the HR Chief that there are no migrant workers employed for the construction activities including subcontractors. Review of the personnel files during the site visit also confirmed that all contracted and subcontracted workers are Turkish citizens.

The following observations were made regarding prevention of sexual exploitation and abuse (SEA) and sexual harassment (SH):

- At the time of the site visit, there were four women employed within the scope of the Phase I construction activities of the Project. Two of them were subcontracted workers, employed in Taner Catering, and two were the technical personnel of the EPC Contractor.
- Two subcontracted women workers were interviewed during the site visit. No grievances, concerns
 or requests were reported by the interviewees related to SEA/SH. They did not experience any
 discrimination and risks related to SEA/SH either in and around the construction site or in the
 shuttle. They had separate toilets and resting areas. They pointed out that they feel really secure
 and do not have any concerns in communicating with management personnel. In general, they were
 satisfied with the working conditions.
- The EPC Contractor built a barrier/wall that divides the access roads of construction workers and female workers to the toilets and refectories (Please see Annex J.20).
- In the OHS and Environment Contract of the EPC Contractor that is signed with contractors, there is
 a specific clause on combating violence, harassment and abuse at the workplace. The clause states
 that the security personnel will receive training on incident response approaches. Additionally, to
 fight against harassment and abuse risks, working environment will be kept transparent. Confidential
 reporting of harassment and abuse incidents will be provided to the EPC Contractor.
- By considering the Contract mentioned above, the EPC Contractor should establish a written policy covering all workers (including contracted, subcontracted and supplier workers) showing their commitment to prevent any risks related to SEA/SH at the workplace.
- Also, the workers' grievance mechanism of the EPC Contractor should ensure the opportunity of anonymous application in accordance with confidentiality principle as specified in the Contract.
- An item concerning the commitment to prevent SEA/SH should be included in all workers' contracts. Preventive measures and sanctions should be clearly mentioned in the contracts.
- A specific training focusing on the prevention SEA/SH and the grievance mechanism should be given to all workers as part of the induction training. Refresher trainings should be provided on a monthly basis.

21.2.3.4 Child and Forced Labour

The EPC Contractor monitors the existence of child labour among workers and subcontractors' workers through personnel files. No child labour practices were identified at the time of the site visit. All workers employed for the Phase I construction activities of the Project were older than 18 based on the personnel files that were reviewed. Although the EPC Contractor performs well in child labour control, there was no written action plan or policy to embrace in case of child labour employment in the construction works.

The practice of the EPC Contractor for monitoring the existence of child labour does not cover supply chain companies. Therefore, the EPC Contractor should include in their labour management procedure an item questioning the existence of child labour not only among subcontractors but also in supply chain companies.

It was stated by the representatives of the EPC Contractor that there were no forms of forced labour in the construction activities among workers and subcontractors. This was confirmed through on-the-spot interviews conducted with construction workers. All workers were working with their consent and there was no indication that any of the workers was forcefully working.

21.2.3.5 Trainings

The trainings provided by the EPC Contractor as part of the on-the-job training includes the following:

- General information about the company
- General description
- Organizational structure
- Corporate culture, principles and values

- Physical location and layout of the construction site
- Information about the company operations
- Legal rights and responsibilities of the workers
- Use of tools, equipment and materials
- Signing the payrolls and confidentiality
- Working and resting times
- Annual leaves and national holidays
- Quality policies
- Job descriptions
- General responsibilities of departments and personnel
- Information about the working conditions and occupational health and safety
- Working discipline and general rules
- Awareness on the occupational health and safety
- Hygiene at the workplace
- Use of the personal protective equipment
- Emergency response and prevention methods
- Risks and protection measures specific to the job to be performed by the worker
- Job orientation (to be provided by the authorized personnel in the department)
- The description of the department/project
- The documents to be used in the department/project
- Detailed information about the job to be performed by the worker

The OHS and Environment Contract was shared with the Consultant, which provides a detailed list of the trainings that all workers need to obtain as per the regulatory requirements. The training list should be updated to include trainings on non-discrimination and equal opportunity policy, workers' grievance mechanism and prevention of SEA/SH to ensure compliance with the WB requirements.

There were no additional documents available onsite about the trainings (e.g. training materials, attendee tracking lists) at the time of the site visit. As reported by the site representatives, all trainings are provided to the workers before they start working on the construction site, and the trainings are refreshed on a regular basis (weekly, bi-weekly or monthly depending on the type of the training).

The EPC Contractor should keep the records of the provided trainings appropriately. The records should include training materials and participant lists. Also, the frequency of each training provided to the workers should be specified in the on-the-job training form.

21.2.3.6 Workers' Facilities

The facilities in the Project construction site include resting areas, toilets, refectories, intern office, OHS office, and the infirmary. There is no canteen within the construction site. The EPC Contractor provides workers tea, coffee and sugar every week. Workers bring their other needs (e.g. food, cigarette etc.) from home or buy from a store that is located in close proximity to the construction site.

There was no labour accommodation on the construction site at the time of the site visit. The EPC Contractor indicated that labour accommodation was not required for Phase I construction activities. There are shuttles for access to the construction site, many workers use the shuttles and few use public transportation or personal cars.

Toilets and resting areas were at a reasonable distance from the construction area. There were separate toilets for women and men in the Project site; and the doors can be locked. Toilets were found to be hygienic. No grievances about toilets and resting areas were noted during the interviews with workers.

There were separate resting areas for each subcontracted company and two of them were visited during the site tour. Based on the observations, it was concluded that these areas need improvement. The number of resting areas for workers is not adequate and there is no sufficient space for dressing and resting. Also, there were limited resources in the resting areas. Lockers, chairs, tables and glasses/cups were observed as insufficient to serve workers' needs. Additionally, there were no air conditioners and water dispensers in the resting areas. Resting areas did not seem be aired and cleaned regularly. Workers did not report any issues related to resting areas during the interviews.

There was no assigned place for workers who pray. The representatives of the EPC Contractor stated that workers allocate a clean space in their resting areas and pray there. When asked about the praying area needs, none of the workers reported a request or a grievance. The representatives of the EPC Contractor added that the workers who would like to pray are carried to the nearest mosque to the construction site (Otonomi Mosque) via a shuttle on Fridays.

There are two refectories in the construction site; one is for technical and management personnel of the EPC Contractor and the other is for construction workers. The meals are not prepared in the construction site, but procured from a subcontracted catering company. The meals are heated in the kitchen within the refectories located in the construction site. Both refectories were visited during the site tour. The weekly meal plan was reviewed and three workers of Taner Catering were interviewed. Nutritional values of each meal are regularly checked by the responsible personnel in the catering company. There were no grievances from workers' side related to nutritional values or portions of the meals. However, the representatives of the EPC Contractor reported that there were a few verbal grievances regarding the taste. Immediate actions were taken and the meal plans were revised in line with the requests and grievances of the workers.

Both refectories and kitchens were found to be clean at the time of the site visit. Toilets and refectories were found to be compliant with the national legislation and the WB ESS2 requirements. However, the conditions within the resting areas should be improved through the provision of sufficient resources as follows:

- The number of resting areas should be increased to provide adequate space for each worker to dress and rest.
- Each resting area should be equipped with air conditioner and water dispenser.
- The number of lockers, chairs, tables, and glasses/cups should be increased in line with the number of workers.
- Resting areas should be aired and cleaned on a daily basis.

21.2.3.7 Security

The Project construction site is fenced with concrete walls and barbed wires. The site is under surveillance 24/7 by the contracted security personnel. Four security personnel from Ata Sav Security Services and Systems are employed to secure the Project site.

Personnel files of the security personnel were reviewed and one was interviewed during the site tour. Accordingly, the worker was found to be compliant in terms of receiving necessary trainings and certification and did not have any criminal records. The worker is authorized to use armed weapons, however he is not armed in the construction site since the risk assessment of the EPC Contractor concluded that this was not necessary.

The security personnel stated that there were no grievances reported by neighbouring business facilities, agricultural land users, or other external stakeholders.

There are no security cameras in or around the Project site. It is recommended that the EPC Contractor procures appropriate number of cameras to place in the relevant areas within and around the Project construction site. The Security Plan that has been developed within the scope of the ESIA process that

describes the EPC Contractor's approach and procedures for managing the security of Project facilities should also be adopted and security measures should be implemented in line with applicable national law, WB ESS4: Community Health and Safety and GIIP.

21.2.3.8 Workers' Grievance Mechanism

The Satisfaction Analysis and Grievance Management Procedure developed for the Project was shared by the EPC Contractor, which includes information regarding the workers' grievance mechanism. The procedure provides information on available grievance channels (i.e. e-mail, telephone, grievance boxes) to Project workers.

A brief summary of the grievance mechanism of the EPC Contractor is given below as per the procedure:

- A 'Grievance Officer' is appointed by the Project Manager to receive, evaluate and finalize all grievances reported by workers as well as communities and other external stakeholders.
- There is a sufficient number of pens and grievance forms next to the grievance boxes.
- All grievances are allowed to be reported confidentially/anonymously.
- Necessary resources to resolve grievances are provided.
- Grievances are evaluated according to the timeline specified in the priority definitions. High priority grievances are resolved within one day. Medium priority grievances are resolved in 30 working days whereas low priority ones are resolved in one year at most.
- Received grievances and their results are recorded in and followed up through the 'Grievance Register and Follow-up Form'.
- All grievance records and resolutions are reviewed during senior management meetings.

Project workers are informed about the Satisfaction Analysis and Grievance Management Procedure through the induction trainings and additional planned and unplanned trainings. Other than the grievance mechanism, the procedure also describes the satisfaction surveys that are applied to the Project workers and the clients of the EPC Contractor. The EPC Contractor should revise the existing grievance mechanism procedure in line with the WB ESS2 to enable anonymous applications and include information on the management of SEA/SH related grievances from receipt to the resolution.

The site representatives stated that the grievance boxes are rarely used by the workers. Workers usually report their requests and grievances to the workers' representatives or the managers/chiefs of the EPC Contractor. The representatives added that since the construction site is small-scaled and all workers are familiar with each other, grievances are mostly raised verbally and they are resolved immediately unless it requires further support from external sources.

Two grievance boxes are located in the construction site, one in the management building and the other at the site entrance. However, there were no empty grievance forms or pens available next to the boxes. When workers need to use the grievance boxes, they write their grievance on an empty paper away from the grievance box, and they put that paper in the box. The workers are free to submit grievance notes anonymously. Yet, the representatives mentioned that they prefer to include their names or the name of their company. The grievance boxes are not locked and secured.

The HR Chief informed the Consultant that grievance boxes are checked weekly and grievances are reviewed immediately. However, there is no grievance log where the received grievances through both boxes and oral statements are recorded.

As reported by the HR Chief, grievances received from workers to date were related to taste of the meals and the quality of the roads used to access the construction site. The longest resolution process of the grievances was seven days, and it was about the quality of the access roads which required external support. Other than this, grievances were resolved in a day.

21.2.3.9 Local Employment/Procurement

The EPC Contractor does not have a specific plan for local employment or local procurement. However, it was stated that the majority of workers are from closer neighbourhoods in Pursaklar, Çubuk and Akyurt districts. For local procurement, the HR Chief pointed out that they prefer to supply goods and materials from the companies that are in close proximity to the Project construction site as long as such companies meet the selection and evaluation criteria of the EPC Contractor in terms of quality of service, contractual requirements and other terms and conditions of work. As discussed in *Chapter 16: Labour and Working Conditions*, the Project should develop and implement an Employment and Procurement Strategy to ensure maximization of opportunities for local people and businesses.

21.2.4 Community Health and Safety

A Community Health and Safety Plan is currently not in place for the Project and no associated monitoring and reporting are being undertaken. To ensure compliance with WB ESS4: Community Health and Safety, the EPC Contractor should put in place and implement the Community Health and Safety Plan which has been developed within the scope of the ESIA process, that outlines measures to avoid health, safety and security risks to the communities nearby the construction site, with particular attention to vulnerable people.

As part of the audit process, interviews were undertaken with representatives from neighbouring businesses and facilities. Işbir Yatak Mattress Factory and the vaccine storage warehouse of the GDPH were contacted via phone call on 23 December 2022 and three car dealers in Otonomi were visited in person during the site visit. Işbir Yatak Mattress Factory and General Directorate did not report any concerns or grievances related to construction activities of the Project. Issues related to dust and community health and safety were noted by the interviewees in Otonomi. In general, no impacts related to traffic density were identified.

The interviewees in Otonomi emphasized that the dust had impacted their facilities during all summer and they needed to wash the displayed cars twice a day due to intensive dust exposure. However, the impact was not observed during the site visit as the construction works were not that severe as it was in the summer season.

Two interviewees in Otonomi also had concerns about the directions of the tower crane that was actively used for the construction activities. They reported that the crane sometimes passed over the lands of Otonomi, and small stones fell from the crane from a significant height on the lands of Otonomi. However, they did not report these grievances to any person or institution (e.g. EPC Contractor, CIMER) for resolution. This situation creates a major safety risk on communities as well as the workers, therefore the EPC Contractor should take immediate and effective actions to mitigate this risk.

21.2.5 Stakeholder Engagement and Public Grievance Mechanism

As reported by the EPC Contractor representatives, a Stakeholder Engagement Plan (SEP) is presently not in place for the Phase I construction activities of the Project. As noted above, there is a Satisfaction Analysis and Grievance Management Procedure in place which identifies the actions, methods and responsibilities for evaluation, resolution and closing of grievances received from the Project's stakeholders. The procedure covers grievances raised by both internal stakeholders (all Project workers) and external stakeholders (i.e. public institutions, communities, NGOs). The grievance mechanism for the external stakeholders is similar to the internal grievance mechanism outlined above in section 21.2.3.8.

There is no supporting evidence of implementation of the external grievance mechanism for the construction activities of the Project, such as grievance logs or established grievance channels (i.e. website, email, phone). The EPC Contractor representatives stated that they have not received any grievances regarding the Project activities through national grievance channels (i.e. CIMER) or their own grievance mechanism.

The external grievance mechanism of the EPC Contractor should be updated to ensure compliance with the requirements of the WB ESS10: Stakeholder Engagement and Information Disclosure in line with the requirements set out in Section 5.7 of this report. The revised grievance mechanism should enable anonymous applications as well as reporting of SEA/SH related grievances. The external grievance mechanism should also be integrated to the existing grievance mechanism developed for the Project by the MoH and official grievance logs should be established for recording and tracking the grievances received from public.

Furthermore, the EPC Contractor should adopt the SEP developed within the scope of the ESIA, for identification and engagement planning of the Project stakeholders, and implement it within the scope of the ESMS in line with the WB requirements. The SEP should also be disclosed at the Project website.

The Consultant recommends that a Community Liaison Officer is appointed by the EPC Contractor in line with Project requirements outlined in *Chapter 5: Stakeholder Engagement*, who will develop and manage the public grievance mechanism to be established within the SEP.

21.2.6 Environment

21.2.6.1 Air Quality and Noise

The construction works have been ongoing without any monitoring of the air quality (particularly emitted dust levels) and noise impacts. In order to ensure alignment with WB requirements, the EPC Contractor should put in place and implement an Air Quality Management Plan and a Noise Management Plan developed within the scope of the Project ESMS that outline monitoring requirements and measures to mitigate potential impacts from construction activities. As discussed in 21.2.4 above, businesses nearby the Project area have reported adverse conditions that have occurred due to occasional elevated dust levels generated at the site.

21.2.6.2 Soil Management

It was reported by the EPC Contractor that the excavation material generated during the construction works has been transported to the excavation waste landfill operated by the Akyurt District Municipality. However, records of excavated material transfer and disposal were not available onsite.

It was also reported that none of the removed material qualified as vegetative topsoil. If any additional excavation works are to be performed, any vegetative topsoil should be carefully removed from the areas to be impacted by construction activities and preserved for eventual use for landscaping and revegetating purposes in line with the Regulation on Control of Excavated Soil, Construction and Demolition Wastes⁴¹³. Also, the segregated and stockpiled topsoil should be covered to prevent windborne dust emissions and the slope of the stockpiling area should not exceed 5%.

The EPC Contractor has shared its Natural Resources Conservation Procedure with the Consultant for review. The procedure sets out the procedures for environmental protection, water management and soil management to be implemented by its workers and subcontractors. Starting from the site delivery, issues such as stripping of the vegetative soil, opening of roads, management of the excavation soil, debris and construction waste, area filling and levelling, land rehabilitation and arrangement studies are managed and monitored by the EPC Contractor in accordance with this procedure. However, the procedure does not cover management of potentially encountered contaminated soils during excavation works. During the site visit, the Consultant did not observe any soil contamination that could occur due to accidental oil/fuel leakages or inappropriate chemical/hazardous material management, waste management or housekeeping practices, etc.

For management of site soils and any contaminated material, the EPC Contractor should put in place and implement site specific procedures/plans developed within the scope of the ESIA including the Waste and

⁴¹³ Official Gazette date/no: 18.03.2004/25406

Wastewater Management Plan and Pollution Prevention Management Plan in line with WB ESS3: Resource Efficiency and Pollution Prevention and Management.

21.2.6.3 Water Supply and Wastewater Management

It was reported by the site representatives that potable water is supplied through the city water network operated by the Ankara Water and Sewerage Administration (ASKI) of the Ankara Metropolitan Municipality. It is understood from the site visit meeting discussions that the potable water connection to the site was made in October 2022. No water analysis has been performed to date for the potable water used within the construction site. Bottled water is used for drinking water purposes.

A Wastewater Connection Permit which is a requirement as per the Water Pollution Control Regulation⁴¹⁴ as well as the ASKI's Regulation on Wastewater Discharge to Sewers (2011) has not been secured for the construction site. It is understood that the generated wastewater within the site is currently discharged to the municipality's sewer system through the vaccine storage building of the General Directorate of Public Health (GDPH) building of the MoH which is next to the Project site. However, the legislation requires that a separate and independent connection point should be provided for each parcel, and relevant permit should be obtained for domestic wastewater discharges.

It was unclear how the contaminated water from washing, cleaning equipment, construction tools and vehicles are managed at the Project site. Such wastewaters should be collected and treated with oil separators before discharging to the sewerage system in line with the WBG Environment, Health and Safety Guidelines.

In the Natural Resources Conservation Procedure of the EPC Contractor discussed above, basic principles of water use and wastewater management practices are defined. The procedure briefly describes actions for water and wastewater management for all projects of EPC Contractor, however, the defined practices are not project-specific. Within the scope of the ESMS, the Waste and Wastewater Management Plan and Resource Efficiency Management Plan developed as part of the ESIA process need to be put in place by the EPC Contractor outlining the Project's approach for managing its water resources and wastewater, identifying measures to minimize the impacts of the Project on the water environment and providing guidelines for implementation of a water and wastewater quality monitoring program in line with the requirements of the WB ESS3.

21.2.6.4 Waste Management

The EPC Contractor manages the wastes generated during the construction activities according to the generic Waste and Emission Management Procedure that is in place. The types of wastes that are generated within the construction site include domestic waste, metal scrap, excavation waste and construction waste (including packaging waste) and hazardous waste (due to the use of hydraulic oils and fuels for the construction equipment and machinery). There is a temporary waste storage area within the site where various waste materials are stored including paper and cardboard, plastic, glass, metals, etc. It was observed that the designated area is sufficient for the amount of waste stored, however should be equipped with a drainage system, spill response kits and trays for secondary containment of hazardous wastes.

The Consultant was informed that metal scrap is sold to an external company, and the excavation waste is transferred to the designated landfill area of the Akyurt Municipality. The amount of metal scrap sold was recorded as 18.4 tons in December 2022. Although no further documentation regarding waste disposal was provided to the Consultant, it is understood that the mixed municipal waste is collected from Project site by Ankara Metropolitan Municipality's relevant unit within certain intervals regularly. It is to be noted that recyclable and non-recyclable waste have separated areas for temporary collection at

⁴¹⁴ Published in the Official Gazette No/Date: 25687/31.12.2004

construction site. Although no cooking activities are performed at site, food waste is expected to be generated in the refectories. According to the Regulation on Waste Management⁴¹⁵, the waste producer is obliged to fill in and keep a copy of the waste declaration form by using the online system of the MoEUCC (namely MoTAT), starting from January every year, until the end of March at the latest, including the waste information of the previous year. It should be ensured by the EPC Contractor that MoTAT waste declarations are made to the Ministry's system every year in accordance with the relevant national legislation.

Additionally, the Project-specific Waste and Wastewater Management Plan developed as part of the ESIA process needs to be put in place by the EPC Contractor within the scope of the ESMS, outlining the Project's approach for managing and monitoring the Project's waste generation during construction works including subcontractor activities in line with the WB ESS3 requirements.

21.2.6.5 Chemicals and Hazardous Materials Management

In relation to the chemicals and hazardous materials use and management, it was reported that several chemicals are utilized in the construction works, including hydraulic fluids, paints and construction adhesives, and sample Safety Data Sheet (SDS) documents for the synthetic protective primer and water-based paint were shared with the Consultant for review. It is understood that the protective primer is used for protecting the external and internal metal surfaces from rusting, and the paint is used as a topcoat for wood, metal or mineral surfaces after surface preparation. In general, hazardous materials are stored in labelled containers in designated storage areas with fire extinguisher equipment available in line with applicable regulatory requirements; however, spill trays, spill response kits and secondary containment are also required in these areas. Additionally, it was observed that pressurized cylinders containing liquified petroleum gas (LPG) in front of the kitchen area were not supported through wall mounting creating risk of release of flammable material. The LPG cylinders should be appropriately secured to the wall.

A Chemicals and Hazardous Materials Management Plan documenting hazardous material handling and storage practices is currently not in place for the construction works of the Project. The EPC Contractor needs to put in place and implement the Chemicals and Hazardous Materials Management Plan developed within the scope of the ESIA process in line with the WB ESS3: Resource Efficiency and Pollution Prevention and Management, including quantities stored onsite and records of use of all hazardous materials (including subcontractors).

21.2.6.6 Biodiversity

During the first ecological walkover survey conducted within the scope of the ESIA in December 2021, it was observed that there was a strip of native trees (about 40-50 trees of 3-4 meters height) such as *Elaeagnus angustifolia* (Russian Oleander) and *Tamarix smyrnensis* (Tamarix) and planted *Pinus nigra* (Black Pine) trees (about 35-40 trees) at the main project complex area (i.e. parcel 1555-4). The Consultant was informed that the trees suitable for relocation were transported to various tree plantation areas and others were cut. No further information or records were available onsite regarding where the removed trees were transferred for further management. In Turkey, tree removal and transplantation must be performed in accordance with the Regulation Concerning Exploitation of Trees and Shrubs on Private-registered Immovables not Regarded as Forest⁴¹⁶ and as per the regulation, for trees species that grow in the State forests, a petition process must be followed for removing and transporting these trees as required and detailed in the subject regulation. The Project is currently not compliant with the abovementioned requirement.

The Biodiversity Management Plan developed within the scope of the ESIA should be implemented by the EPC Contractor to ensure adequate management and control of the activities that may pose

⁴¹⁵ Published in the Official Gazette No/Date: 29314/02.04.2015

⁴¹⁶ Official Gazette No/Date: 31330/10.12.2020

biodiversity-related risks associated with the construction of the Project and to ensure compliance with international good practice on biodiversity and WB ESS6: Biodiversity Conservation and Sustainable Management of Living Natural Resources.

21.2.6.7 Cultural Heritage

A Chance Find Procedure is not currently available as part of the Project ESMS. The EPC Contractor has a generic Cultural Heritage Protection Procedure in place dated February 2020 that was shared with the Consultant. The procedure defines the principles of protection of immovable or movable cultural heritage that may arise during site preparation or excavation activities, informing the relevant government authorities, and the management of the process of delivering them to the relevant authorities without any occurring damage. Reportedly, to date, no cultural heritage resources have been identified on site.

21.2.7 Environmental and Social Action Plan for Phase 1 Construction Activities

Table 21-3 below presents an environmental and social action plan that sets out the necessary mitigations and actions to address the gaps identified during the audit study conducted for Phase 1 construction activities of the Project. The plan should be implemented for the remaining construction activities of Phase 1.

Table 21-3: Environmental and Social	Action Plan for	Construction Activities
--------------------------------------	-----------------	--------------------------------

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
ESS1	Assessment and I	Management of Environmental and Social	Risks and Impacts		
1.	Environmental and Social Management System (ESMS)	 Definition of Project-specific ESMS documents (e.g., plans, policies, procedures) Establish an organizational structure for the implementation of the ESMS Appoint a full time qualified Environmental and Social Manager Prepare and put in place site specific procedures/plans for construction phase (and improve existing procedures/plans as necessary), including the following: Chemicals and Hazardous Materials Management Plan Air Quality Management Plan Noise Management Plan Noise Management Plan Vaste and Wastewater Management Plan Pollution Prevention Management Plan Construction Traffic Management Plan Human Resources Management Plan (including Code of Conduct) Community Health and Safety Management Plan Occupational Health and Safety Management Plan Human Resources Management Plan Human Resources Management Plan Gesource Efficiency Management Plan Human Resources Management Plan Gesource Plan Human Resources Management Plan Human Resources Management Plan Human Resources Management Plan Human Resources Management Plan Human Resources Management Plan/Labour Management Plan Emergency Preparedness and Response Plan Security Management Plan Construction Site Management Plan Cultural Heritage Management Plan (including Chance Find Procedure) 	WB ESS1 Best practice	 An established and implemented ESMS and relevant documentation (e.g., risk assessments, plans, procedures, control forms) An established organizational structure and defined roles for ESMS Appoint a full time Environmental and Social Manager Written and approved site specific environmental and social plans/procedures ESMS system records (e.g., audit records, measurement records, training records) Implement monitoring activities in line with the ESMS 	MoH (for establishing and implementing Project ESMS) EPC Contractor (for establishing its own ESMS and implementing Project ESMS as well as its own ESMS)

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Provide training for designated staff on environment, health, safety and social topics. 			
2.	Environmental and Social Management System (ESMS)	 Implementation of ESMS, ESMP and the following plans: Chemicals and Hazardous Materials Management Plan Air Quality Management Plan Noise Management Plan Waste and Wastewater Management Plan Vaste and Wastewater Management Plan Pollution Prevention Plan Construction Traffic Management Plan Community Health and Safety Management Plan Occupational Health and Safety Management Plan Occupational Health and Safety Management Plan Resource Efficiency Management Plan Human Resources Management Plan Human Resources Management Plan Emergency Preparedness and Response Plan Security Management Plan Construction Site Management Plan Construction Site Management Plan Cultural Heritage Management Plan Cultural Heritage Management Plan, including Wanagement Plan Audit the organization of works for implementation of the system and relevant plans, including works carried out by the subcontractors 	WB ESS1 Best practice	 Required documentation as per ESMS, ESMP and specific plans (e.g., permits, consents, official correspondence, monitoring reports, construction site audit reports and similar) Training records of workers Audit and inspection reports 	EPC Contractor
3.	ESMS/ESMP Compliance	 Quarterly progress reporting to World Bank Monthly E&S performance reporting to MoH 	WB ESS1	Quarterly progress reportsMonthly E&S performance reports	MoH (for quarterly progress reports) EPC Contractor (for monthly
4.	Permitting	Obtain all necessary permits/consents/approvals:	WB ESS1	 Records of permits, official letters, licenses, approvals, documents etc. 	MoH

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Wastewater Connection Permit 	National Legislation		
ESS 2	: Labour and Work	ing Conditions			
5.	Human Resources	 Implement the Human Resources Management Plan Develop and implement a Gender-Based Violence and Harassment (GBVH) Policy Issue contracts to workers upon recruitment Keep personnel files of all workers that include their work contracts, training records, medical surveillance records, next of kin contact details and similar relevant documents Develop a database of employees and subcontractor employees that includes information on the age, social security number, identity card number, gender, ethnicity, nationality and hometown. Payroll checks by EPC contractor against issues such as subcontractor wage rates, payment of benefits and timely payments. 	WB ESS 2	 GBVH Policy Worker contracts Personnel files Database of employees Short quarterly reports available for review by external monitors 	EPC Contractor
6.	Workers' Grievances	 Publicize the Workers' Grievance Mechanism to workers Implement the Workers' Grievance Mechanism with the opportunity to apply anonymously Respond to grievances in a timely manner Undertake necessary corrective actions if needed 	WB ESS 2	 Workers' grievance log including records of grievances, response to grievances and corrective actions 	EPC Contractor
7.	Occupational Health and Safety	 Implement the Occupational Health and Safety Management Plan in line with WBG requirements and national legislation Record all accidents, incidents and near- misses Comply with health and safety legislation applicable to the construction phase of the Project and eliminate the non-compliances identified in 21.2.2 above including safety 	WB ESS 2 WBG EHS Guidelines National Legislation	 Occupational Health and Safety Plan Records of audit reports, regular inspections, and similar documentation Accident, incident and near-miss logs and accident reports Records of corrective actions Training records 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		measures, use of PPE and periodic controls of equipment.			
8.	Subcontractors	 Implement the HRMP/LMP which includes checking of subcontractors to verify they are reputable and legitimate enterprises Prepare a subcontractor list Require subcontractors to manage their workers in line with the Project's HR Management Plan and adopt grievance mechanism through contract clauses Require subcontractors to adhere to the Project's ESMS plans through contract clauses Require subcontractors to report accidents, incidents and safety non-compliances through contract clauses 	WB ESS 2	 Contracts with subcontractors Subcontractor list Records of subcontractor's accidents, incidents and non-compliances Subcontractor personnel files Subcontractor training records for EHS topics Evidence on how workers are informed about the grievance mechanism Grievance log and records of grievances 	EPC Contractor
9.	Sexual Exploitation and Abuse/Sexual Harassment	 Implement sufficient security measures to reduce SEA/SH risks at the construction site (i.e. security cameras, anonymous grievance mechanism, separate toilets, dressing and resting areas available to lock) Publicize the Workers' Grievance Mechanism to workers Implement the Workers' Grievance Mechanism with the opportunity to apply anonymously Approach SEA/SH grievances in a more sensitive way and in an immediate timeframe 	WB ESS 2	 Workers' grievance log including records of grievances, response to grievances and corrective actions Evidence documentation from the construction site facilities (i.e. photos from separate toilets, dressing and resting areas) 	EPC Contractor
10.	Supply of Materials	 Supply materials as close as possible to the Project site Prepare a supplier list Supply materials from licensed/certificated/permitted suppliers/facilities Prefer to the extent possible recycled materials and environmentally friendly materials that are certified as "green" or "low carbon" by accredited agencies 	WB ESS 2	 Records of supply sources Supplier list Licenses/certificates/permits of the suppliers and supplied materials 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
11.	Labour Audit	 Carry out annual third-party labour audit for assessment of compliance of the site 	WB ESS 2	Annual third-party audit report	EPC Contractor
ESS 3	: Resource Efficier	ncy and Pollution Prevention and Managen	nent		
12.	Resource Efficiency	 Implement the following plans: Resource Efficiency Management Plan Water and Wastewater Management Plan Chemicals and Hazardous Materials Management Plan Water use: Assess, identify and adopt good operation practices for water saving and water efficiency measures and provide training to site workers on good operation practices. Perform regular measurement and recording of principal flows within the site, define and regularly review performance targets, and regularly compare water flows with performance targets. Raw material use: Ensure minimization of construction materials and optimizing the use of resources to avoid potential wastage. Maximize reuse of excavated soil material in the construction works. Establish systems and verification practices for the assessment of environmental and social performance of material suppliers and products to ensure that materials are sourced with sustainability principles. Seek to reduce or eliminate the use of toxic or hazardous raw materials. 	WB ESS 3 Best Practice	 Periodic maintenance records Measurement and recordings of energy and water flows Chemical/Hazardous Material Risk Assessment Forms/Checklists Supplier Evaluation Forms Training records 	EPC Contractor
13.	Pollution Prevention	 Adopt good construction site practices for the protection of soil, surface water and groundwater (e.g., storage areas, spillage control, spill kits) 	WB ESS 3 Best Practice National Legislation	 Records of periodic site inspections Presence of spill response kits and their manuals on construction site Records of monitoring of the implementation of the relevant plans 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Keep spill response kits at designated areas with specific instructions for their use and train site staff on the use of spill kits. Implement the following plans: Chemicals and Hazardous Materials Management Plan Emergency Preparedness and Response Plan Waste and Wastewater Management Plan Train construction workers 		 Audit and control reports, spillage incident records, measurement results, contaminated soil disposal records, training records and similar documentation 	
14.	Chemicals and Hazardous Materials	 Implement the Chemicals and Hazardous Materials Management Plan Prepare an inventory of hazardous materials Obtain Safety Data Sheets (SDSs, formerly known as MSDS) and provide in relevant locations in in both English and Turkish Make Personal Protective Equipment (PPE) available for relevant personnel Train relevant personnel Take required on-site measures Keep hazardous materials at designated areas Locate suitable fire-fighting equipment close to hazardous material storage/usage areas 	WB ESS 3 Best Practice National Legislation	 Records of audits Hazardous material inventory Site inspection records Incident records Training records 	EPC Contractor
15.	Waste management	 Implement the following plans: Waste and Wastewater Management Plan Emergency Preparedness and Response Plan Chemicals and Hazardous Materials Management Plan Obtain necessary permits related with the disposal of excavated soil Collect, segregate, label and store, transport, and dispose/recycle the wastes in line with the Waste and Wastewater Management Plan 	WB ESS 3 National Legislation	 Records of periodic site inspections performed to check all wastes are separately collected, segregated, labelled and stored in designated areas Disposal records of all types of wastes Disposal records of excavated soil Check waste disposal contracts Licenses of haulers' and disposal facilities' Declaration records made to the Ministry of Environment, Urbanization and Climate Change (MoEUCC) Training records of workers 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Design and construct a designated waste storage area to ensure that hazardous wastes are properly stored at the construction site Dispose wastes at licensed facilities according to their waste categories in accordance with regulatory requirements Perform periodic inspections in the waste recycling/ disposal facilities to ensure proper disposal practices are implemented Keep records of waste generation, storage and disposal Use licensed haulers for the transport of wastes and keep waste transfer certificates Ensure disposal/recycling of wastes at licensed facilities Train site workers for waste management, minimization and zero waste practices Obtain compulsory liability insurance for hazardous materials and wastes, if applicable Implement procedures for identifying and dealing with contaminated soils and materials if encountered during construction, including appropriate storage and disposal. Contaminated soils will be disposed of in an appropriately licensed disposal site by ensuring relevant transport procedures. Ensure transfer of construction and demolition waste including excavation soil to licenced disposal facilities of the municipality line with national requirements. 		 Hazardous Materials and Hazardous Waste Compulsory Liability Insurance Policy 	
16.	Wastewater	 Discharge domestic wastewater to the municipality infrastructure in accordance with the permits and protocols for connection to the municipal sewer system Monitor effluent regularly as required by Ankara Water and Sewage Administration (ASKI) 	WB ESS 3 National/Local Legislation	 Municipal sewer system connection certificate obtained from the relevant authority Regular wastewater analysis results 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
17.	Air Emissions (dust, exhaust emissions)	 Implement the Air Quality Management Plan Implement the Construction Traffic Management Plan Undertake quarterly air quality measurements for PM10 and PM2.5 Perform daily site inspections for the observation of significant dust 	WB ESS 3 National Legislation	 Records of site inspections Records of quarterly air quality monitoring undertaken by a third-party Equipment and vehicle maintenance records and emission certificates Training records of workers and drivers 	EPC Contractor
18.	Noise	 Implement the Noise Management Plan Obtain consent from Provincial Directorate of Environment, Urbanisation and Climate Change (PDoEUCC) in case construction activities are conducted during evening and night-time Undertake noise measurements at the closest sensitive receptors (locations as identified in the ESIA report) for 24 hours. Install noise barriers if needed 	WB ESS 3 National Legislation	 Records of site inspections Records of noise monitoring Training records of workers 	EPC Contractor
19.	Environmental Accidents	 Record keeping on environmental accidents and actions taken 	WB ESS 3	 Environmental accident records and the actions log 	EPC Contractor
ESS 4	: Community Heal	th and Safety			
20.	Community Health and Safety	 Implement the Community Health and Safety Management Plan Implement the Construction Traffic Management Plan Prepare and implement Construction Site Management Plan Undertake measures for air and noise as identified in the ESMP Implement Emergency Preparedness and Response Plan (EPRP) and disclose the plan to communities Update local authorities and communities if there are changes in the EPRP Undertake regular drills/exercises regarding the emergency measures Train the workers regarding health and safety risks for the communities 	WB ESS 4	 Records of audits and regular inspections Sufficient number of traffic signs Training records Evidence of disclosure and updates Records of drills Records of meeting with the communities 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Document discussion of any identified impacts, risk and mitigation measures with communities during construction (at least annually) in the scope of Environmental and Social Performance Annual Monitoring Report (AMR) 			
21.	Security	 Implement the Security Management Plan Hire adequate, trained security staff who have not been involved in past abuses Train the security personnel 	WB ESS 4	 Records of audits and inspections Records of credentials of security staff Training records 	EPC Contractor
ESS 5	: Land Acquisition	, Restrictions on Land Use and Involuntar	y Resettlement		
22.	Agricultural land users on the northwest of the Project site	 Closely follow-up the timeline of the construction activities of the Project as well as rehabilitation works of Çubuk Stream in order not to affect the agricultural land users Consultation on the Project and related activities in order to avoid any adverse impacts Implement Public Grievance Mechanism including information on contact details of responsible staff to handle grievances 	WB ESS 5	 Records of the consultations (i.e. minutes, photos) Community grievance log including records of grievances, response to grievances and corrective actions Stakeholder engagement and consultation activity log 	EPC Contractor
23.	Assignment of the unregistered land to the MoH	• Ensure that the construction is proceeding in line with the permissions including the assignment of the unregistered land as per the national legislation	WB ESS 5	Official letter	EPC Contractor
ESS 6	ESS 6: Biodiversity Conservation and Sustainable Management of Living Natural Resource				
24.	Biodiversity Conservation	 Implement the Biodiversity Management Plan Collect vegetative topsoil separately from the subsoil and stockpile for reuse. The separately collected topsoil shall be preserved for eventual use for landscaping and revegetating purposes. Slope of the stockpiles shall not exceed 5% and the stockpiles will be covered. Provide records for transplantation of native trees in line with national legislation 	WB ESS 6 National legislation	 Records of audits and inspections, records of topsoil reuse Records of tree transplantation 	EPC Contractor

No	Subject	Action	Legal Framework	Reporting requirement/ Indicator for successful implementation	Responsibility
		 Prevent introduction of alien species on purpose or by accident 			
ESS	8: Cultural Heritage				
25.	Chance Finds	 Develop and implement a Chance Find Procedure to be applied in the event of an archaeological discovery during construction activities 	WB ESS 8	 Records of chance finds documentation Copies of correspondence with authorities 	
ESS	10: Stakeholder Eng	agement and Information Disclosure			
26.	Information Disclosure/ Stakeholder Engagement/ Community Grievances	 Implement the Stakeholder Engagement Plan (SEP) and update the plan in case of any significant changes in the Project Publicize SEP and Public Grievance Mechanism including information on contact details of responsible staff to handle grievances Implement Public Grievance Mechanism Respond to grievances in a timely manner Undertake necessary corrective actions if needed Document records of consultation and information disclosure Annual reporting to WB on the implementation of the ESMP and any new impacts/risks identified to affected communities 	WB ESS 10	 The Stakeholder Engagement Plan Community grievance log including records of grievances, response to grievances and corrective actions Stakeholder engagement and consultation activity log Minutes of meetings Annual reports 	EPC Contractor

ANNEXES



Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Environmental and Social Impact Assessment Report

ANNEX C - Stakeholder Engagement Activities

March 2023 Confidential

Mott MacDonald Restricted

Mott MacDonald Mesa Koz Sahrayıcedit District Atatürk Street No. 69 / 255 34734 Kadıköy Istanbul Turkey

T +90 (0) 216 766 3118 mottmac.com

Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Environmental and Social Impact Assessment Report

ANNEX C - Stakeholder Engagement Activities

March 2023 Confidential

Mott MacDonald T Danışmanlık Mühendislik Ltd Şti. is a member of the Mott MacDonald Group registered in England and Wales no 1110949. Registered office: Mott MacDonald House, 8-10 Sydenham Road, Croydon CR0 2EE, United Kingdom Mott MacDonald | Confidential | Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project Environmental and Social Impact Assessment Draft Report ANNEX C – Stakeholder Engagement Activities

Information class: Secure

This Report has been prepared solely for use by the party which commissioned it (the 'Client') in connection with the captioned project. It should not be used for any other purpose. No person other than the Client or any party who has expressly agreed terms of reliance with us (the 'Recipient(s)') may rely on the content, information or any views expressed in the Report. This Report is confidential and contains proprietary intellectual property and we accept no duty of care, responsibility or liability to any other recipient of this Report. No representation, warranty or undertaking, express or implied, is made and no responsibility or liability is accepted by us to any party other than the Client or any Recipient(s), as to the accuracy or completeness of the information contained in this Report. For the avoidance of doubt this Report does not in any way purport to include any legal, insurance or financial advice or opinion.

We disclaim all and any liability whether arising in tort, contract or otherwise which we might otherwise have to any party other than the Client or the Recipient(s), in respect of this Report, or any information contained in it. We accept no responsibility for any error or omission in the Report which is due to an error or omission in data, information or statements supplied to us by other parties including the Client (the 'Data'). We have not independently verified the Data or otherwise examined it to determine the accuracy, completeness, sufficiency for any purpose or feasibility for any particular outcome including financial.

Forecasts presented in this document were prepared using the Data and the Report is dependent or based on the Data. Inevitably, some of the assumptions used to develop the forecasts will not be realised and unanticipated events and circumstances may occur. Consequently, we do not guarantee or warrant the conclusions contained in the Report as there are likely to be differences between the forecasts and the actual results and those differences may be material. While we consider that the information and opinions given in this Report are sound all parties must rely on their own skill and judgement when making use of it.

Information and opinions are current only as of the date of the Report and we accept no responsibility for updating such information or opinion. It should, therefore, not be assumed that any such information or opinion continues to be accurate subsequent to the date of the Report. Under no circumstances may this Report or any extract or summary thereof be used in connection with any public or private securities offering including any related memorandum or prospectus for any securities offering or stock exchange listing or announcement.

By acceptance of this Report you agree to be bound by this disclaimer. This disclaimer and any issues, disputes or claims arising out of or in connection with it (whether contractual or non-contractual in nature such as claims in tort, from breach of statute or regulation or otherwise) shall be governed by, and construed in accordance with, the laws of England and Wales to the exclusion of all conflict of laws principles and rules. All disputes or claims arising out of or relating to this disclaimer shall be subject to the exclusive jurisdiction of the English and Welsh courts to which the parties irrevocably submit.

1

Annex C: Stakeholder Engagement Activities

Annex C-1: Scoping Phase Stakeholder Meetings Minutes, Notes and Photos

Annex C-2: ESIA Phase Site Visit Notes and Photos

Annex C-1: Scoping Phase Stakeholder Meetings Minutes, Notes and Photos

Annex C-1: Scoping Phase Stakeholder Meetings Minutes, Notes and PhotosDuring ESIA Disclosure

Annex C-1: Scoping Phase Stakeholder Meetings Minutes, Notes and Photos

The issues, comments and evaluations noted during the stakeholder meetings conducted as part of the scoping phase of the Environmental and Social Impact Assessment (ESIA) study carried out for the Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project are listed in the tables below.

Date/Location:	28.12.2021/ Akyurt Municipality Building
Stakeholder(s):	Akyurt District Governorship, Akyurt Municipality, Akyurt District Health Directorate
Participants:	District Governor of Akyurt, Metin Selçuk Mayor of Akyurt Municipality, Hilal Ayık Deputy Mayors of Akyurt Municipality Hüseyin Demirel, Cemalettin Sarp MoH Akyurt District Health Director, Dr. Asuman Tezelkahraman Social experts from SRM Team: Ece Kılıçözlü (Land Acquisition and Resettlement Expert), Sadık Avcı (Stakeholder Engagement Expert) Ministry of Health, Project Management Support Unit, Environment and Social (E&S) Team: Zeynep Buyan Kop (Social Expert) E&S consultant from Mott MacDonald Team: Ecenur Alper (Social Consultant)
Subject	Comments and Evaluations
General information about Akyurt	 The Mayor provided general information about the socioeconomic and demographic conditions in Akyurt. Akyurt consists of 26 neighbourhoods including six central neighbourhoods and 20 villages. The local population is around 38,000. The main means of living of the people in Akyurt are agriculture, animal husbandry and industry. Akyurt receives an average of 5% immigration every year. In this context, it is one of the two peripheral districts in Ankara in which the residents do not emigrate. Akyurt has a young population. Studies on population projections for the next few years are carried out by the Municipality. The Municipality aims at being prepared in case the demand for basic needs such as education increases. Akyurt is a district of Ankara with a developed and still developing industrial zone. The facilities of some military industries (Aselsan, Havelsan) are also located in Akyurt. The Mayor stated that Akyurt has an industrial zone that affects approximately one million people living in Ankara. This impact stems from the production chain, employment potentialities and investment opportunities in Akyurt. Otonomi (road vehicles sales point), YDS (a footwear manufacturing company focused on health and safety sector), lşbir Yatak Mattress Factory and General Directorate, Borusan Automotive and Man Turkey are also important facilities in Akyurt. These facilities are close to the project area. With employees traveling to these facilities during the day, the population in Akyurt can reach up to 80,000. One of the ÖSYM (student selection and placement centre) exam centres is located in Akyurt district. Currently, the Ministry of Health has a vaccine depot in Akyurt adjacent to the project site (parcel no: 1555-5). Industrial organizations such as Türktpsan and Türk laç ve Serum Sanayi are also located in Akyurt. Akyurt is a leading region especially in serum production (It was stated that 2/3 of overall serum production of Turkey is undertake

	 It was mentioned that Akyurt district is easy to access via means of transportation, the roads are regularly maintained, and the probability of road closings in difficult conditions (e.g., heavy snowfall) is low. An international fairground and a shopping centre (Otonomi Outlet Shopping Mall and Wellness Centre) are planned to be built in the district in the near future. The communication network and interaction between the Municipality and Akyurt Industrialists' and Businesspeople's Association (AKSIAD) is strong. Within the scope of the stakeholder participation activities of the project, the Mayor stated that they can provide automatic with AKSIAD.
General information about the Project	Abovementioned/ Interviewed participants were recently informed about the project. Our project team provided general information to the participants about the project and the ESIA studies. Stakeholder engagement, public consultation meeting, meaningful consultation and grievance mechanism were also explained. Stakeholder engagement activities and consultations will continue to be undertaken through the Project.
Alternative Locations for the Project	In case the current project area becomes insufficient in the future, Akyurt Municipality representatives suggested that alternative lands can be proposed for the project.
Concerns about Odour Safety	One of the concerns raised by the participants was odour control/odour safety due to manure. Previously, there was an odour problem in Akyurt deriving from animals. Some regulations (limitations on husbandry within the district1) were made to prevent odour. Concerns about public health on how to manage manure and waste were conveyed to our project team.
Concerns about Çubuk Stream	Another concern conveyed by the representatives of the Municipality was the risk of chemical leakage from laboratories to the soil and mix of this leakage into Çubuk Stream. This situation poses a serious risk to public health. Our project team informed the participants about the security measures to be taken to prevent the risk of leakage from the laboratories in and out directions to the extent possible in the light of the information made available to the ESIA team at this stage. In addition, considering the risk of flooding in Çubuk Stream, it was decided to obtain a report on flood calculations from the State Hydraulic Works together with their opinions/views about the project.
The Advantages of the Project	The proximity of the project area to Esenboğa Airport is considered as one of the advantages of the project in terms of access and transportation. It was observed that the general views of the participants towards the project are quite positive. Authorities think that this project will be a good opportunity for Akyurt to develop and become recognised. It was also stated that it would be a good investment for the benefit of Turkey.

¹ Municipality representatives stated that a presidential decree was published regarding the issue. However, it was not provided, and the decree is not available on the official websites.

4

Date/Location:	28.12.2021/ Near the exit of the Project Site
Stakeholder(s):	The Residents of Balıkhisar Neighbourhood
Participants:	The Mukhtar of Balıkhisar Neighbourhood, Ahmet Böcekçi Social experts from SRM Team: Ece Kılıçözlü (Land Acquisition and Resettlement Expert), Gökhan Metin (Senior Social Impact Assessment Expert), Sadık Avcı (Stakeholder Engagement Expert) E&S consultant from Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General Information about Balıkhisar Neighbourhood	 The mukhtar of Balıkhisar neighbourhood provided general information about Balıkhisar, which encompasses the area that the project facilities are planned to be built. There are several factories and industrial sites in the area where the neighbourhood is located. It was stated that more than half of the factories in Akyurt district are located in Balıkhisar Neighbourhood. There are also households in the neighbourhood whose livelihoods depend on agricultural activities. Consolidation was carried out in the agricultural lands in the neighbourhood. (Our project team believes that this transaction can be considered as a cumulative impact). There has been a tendency to emigrate in Balıkhisar Neighbourhood. While the population was 4,600 in 2002, it was mentioned that approximately 1,500 people have been residing in the neighbourhood in 2021. The mukhtar reported that the unemployment rate (including youth unemployment) is not high in the neighbourhood.
General Information about the Project	The mukhtar stated that he was briefly informed about the project recently. A document related to the project (about the public consultation meeting within the scope of the "Component 4: Strengthening Capacity of MoH to respond to COVID-19" of the HSSSP project conducted on 20.12.2021) was sent to the mukhtar, but he could not attend the meeting due to the late receipt of the document. Our project team provided general information about the project and ESIA studies. Stakeholder engagement activities to be carried out within the scope of the Project, public consultation meeting, meaningful consultation and grievance mechanism were mentioned. The mukhtar stated that he can provide support to our project team during these processes. The village mansion of the neighbourhood was proposed by him for conducting survey and meetings.
Possible Impacts Stemming from the Project	The mukhtar did not mention any negative impacts that may arise from the project. He confirmed that during the construction of the vaccine depot, which was built before the Project and located on the land adjacent to the project area (parcel no: 1555-5), the neighbourhood and its residents were not affected by the construction vehicles and that there were no problems. He stated that protocol roads were/will be used for construction rather than village roads. It was verified that the students going to school in the neighbourhood do not use the roads around the Project site. The mukhtar stated that the roads around the Project site are mostly used by people working in factories/business areas and by employee shuttles.

5

Date/Location:	28.12.2021/ Cafenomi, Akyurt
Stakeholder(s):	The Residents in Saracalar Neighbourhood
Participants:	The Mukhtar of Saracalar Neighbourhood, İrfan Çalışkan Social experts from SRM Team: Ece Kılıçözlü, Gökhan Metin, Sadık Avcı E&S consultant from Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General Information about Saracalar Neighbourhood	Saracalar neighbourhood is the closest neighbourhood to the project site. Its population is approximately 1,350-1,400. The mukhtar has been residing in Saracalar neighbourhood for 32 years. He noted that animal husbandry was restricted in the region and near the airport with the presidential decree due to odour of animals and manure.
General Information about the Project	The mukhtar stated that he was informed about the Project recently. He added that a brief information about the Project was given when a noise measuring device was installed at the beginning of the same week within the scope of the Project's ESIA baseline studies. Our project team also provided general information about the project and ESIA studies. Stakeholder engagement activities to be carried out within the scope of the project, public consultation meeting, meaningful consultation and grievance mechanism were also explained.
Possible Impacts Stemming from the Project	The mukhtar stated that his primary concern about the impacts that may arise from the Project is the odour. He mentioned that the odour of animals and manure used to be felt in the neighbourhood previously, especially in windy weather. Apart from this issue, the mukhtar did not mention any potential negative impacts that may occur. The mukhtar believes that business areas such as Otonomi and YDS, which are closer to the Project site, may be affected more by the project than the residents of Saracalar Neighbourhood.

Mott MacDonald Restricted
Date/Location:	29.12.2021/ YDS
Stakeholder(s):	The Workforce of YDS
Participants:	CEO of YDS, Vedat Yakupoğlu Board Member of YDS, İsmail Harmandar Social experts from SRM Team: Gökhan Metin, Sadık Avcı E&S consultant from Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General Information about YDS	<text><text><image/><text><text></text></text></text></text>
	departments work in three shifts.
General Information about the Project	They stated that they knew about the Project as much as they saw in the news. Our project team provided general information about the Project and ESIA studies. Stakeholder engagement activities to be carried out within the scope of the Project, public consultation meeting, meaningful consultation and grievance mechanism were also explained. In addition, it was explained that gender equality and violence issues against women will be addressed within the framework of the ESIA. In this context, safety of female employees in the factory and the possibility of being exposed to harassment or violence during the construction phase of the Project were also evaluated. Participants reported that female employees spend time mostly inside the factory and rarely leave the factory during work hours. They added that employees rarely leave the factory for lunch break and other breaks.
Possible Impacts Stemming from the Project	The possibility of the reoccurrence of the manure odour from the breeders in the vicinity before, was conveyed as a concern. Participants did not express any concerns about the roads that may be used jointly by the factory and the Project site during the construction phase. It was stated that there are alternative shuttle roads and additional roads for the use of factory employee shuttles and other vehicles in case of traffic congestion that may occur due to construction. The participants stated that there are infrastructure problems in the region and that the sewerage and waste management is poor. Their concern is whether the existing infrastructure

problems will increase with the proposed Project (Our project team believes that this situation can be considered as a cumulative impact).

Date/Location:	29.12.2021/ Işbir Yatak Mattress Factory and General Directorate
Stakeholder(s):	The Workforce of Işbir Yatak General Directorate, Işbir Yatak Fabrikası (Mattress Factory), Işbir Sünger Sanayi A.Ş. (Mattress Foam Industry)
Participants:	lşbir Yatak Mattress Factory Business Development Manager, Ünal Akmeşe Işbir Yatak Mattress Factory Quality Control Management Director, Nazmiye Ünal Social experts from SRM Team: Gökhan Metin, Sadık Avcı E&S consultant from Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General Information about Işbir Yatak Mattress Factory and General Directorate, Işbir Sünger Mattress Foam Industry	<text><text><text><image/></text></text></text>
General Information about the Project	Participants stated that they were not previously informed about the Project. Our project team provided general information about the Project and ESIA studies. Stakeholder engagement activities to be carried out within the scope of the project, public consultation meeting, meaningful consultation and grievance mechanism were explained. In addition, it was explained that gender equality and violence issues against women will be addressed within the framework of the ESIA. In this context, the safety of female employees in the factory and the possibility of being exposed to harassment or violence during the construction phase of the Project were also evaluated. Participants confirmed that employees rarely leave the factory during work hours, they stay inside the factory for lunch breaks and other breaks.
Possible Impacts Stemming from the Project	Dust and noise pollution that may occur during the construction phase of the project were reported as the main concerns for the factory. Since the factory also produces medical mattresses, it is of great importance to prevent dust pollution.

Regarding the roads that are likely to be used jointly between the factory and the Project site during the construction phase, the participants stated that the probability of any negative impact is low. It was stated that there are alternative roads for the use of factory employee shuttles and other vehicles in case of traffic congestion that may occur due to construction. It was also mentioned that the construction of the previously built vaccine depot on the land adjacent to the Project site did not have any significant impacts on the factory and the employees during the construction.

Date/Location:	29.12.2021/ Otonomi
Stakeholder(s):	The Workforce and the Visitors of Otonomi
Participants:	Operations/ Business Manager of Otonomi, Seyit Coşkun Social experts from SRM Team: Gökhan Metin, Sadık Avcı E&S consultant from Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General Information about Otonomi	Otonomi is a road vehicles sales point that includes 663 independent businesses, and it has been in operation since 2016. It is planned by the management to increase the number of enterprises to over 750. There are over 2,000 employees working in Otonomi in total. The locations of Otonomi and the project site are shown below:
General Information about the Project	The manager stated that he has little knowledge about the Project. Our project team provided general information about the Project and ESIA studies. Stakeholder engagement activities to be carried out within the scope of the project, public consultation meeting, meaningful consultation and grievance mechanism were explained. The manager mentioned that there is an e-mail group and SMS system that includes the businesses and employees of Otonomi, and that he can support our team during the stakeholder engagement process through these communication channels.
Possible Impacts Stemming from the Project	The manager did not report any concerns that may arise from the Project. He mentioned that the construction of Otonomi Outlet Shopping Mall and Wellness Centre will begin soon (approximately in a few months) on a land that belongs to Otonomi. It is estimated that the shopping centre will be in operation in 2023 (Our project team believes that this situation can be considered as a cumulative impact and further information will be obtained in the following phases of the Project).

Date/Location:	28.12.2021/ MoH GDPH Vaccine and Pharmaceuticals Storage Warehouse
Stakeholder(s):	The Workforce of the MoH GDPH Vaccine and Pharmaceuticals Storage Warehouse
Participants:	Unit Manager of MoH GDPH Vaccine and Pharmaceuticals Storage Warehouse, Fatih Şekerci Ministry of Health, Project Management Support Unit, Environment and Social (E&S) Team: Mahmut Alkan (Departmental Manager), Emre Tanrıverdi (Environmental Expert), Kenan Polat (Technologist), Sinem Otlu (Equipment Consultant), Semra Şahin (Midwife) E&S consultants from Mott MacDonald Team: Pelin Karakaya (Senior Environmental Engineer and Project Manager), Dilan Laçin (Environmental Consultant)
Subject	Comments and Evaluations
General Information about the MoH GDPH Vaccine and Pharmaceuticals Storage Warehouse	Vaccine and pharmaceutical distribution to all provinces of Turkey is regulated within the depot.
General	The Unit Manager reported the following:
Information about	The weather in the region is windy and foggy.
the Region and the Project Site	 In the past, the hotels around Esenboğa Airport reported some complaints about the odour caused by the serum farm formerly located in the Project site and by the husbandry activities in the region. Therefore, the experimental animals in the depot were transferred to the facility of the Ankara Veterinary Faculty in Kazan.
	 Horses used for serum production were kept freely in the current Project site in the past. Animal carcasses may have been buried at the site.
	 The parcel of the depot and the Project site has been fenced for 15 years. A door was constructed between 1555-4 and 1555-5 parcels to create a connection point between these two parcels.
	• The Project site has not been used for residential or commercial purposes in the past.
	 Intersection arrangements around the Project site would be useful.
	 There is no treatment plant in the region. Wastewater is discharged to the sewer system and discharges to the Çubuk Stream are currently prevented.

12

Photos from the Stakeholder Meetings



13



Mott MacDonald Restricted

1

Annex C-2: ESIA Phase Site Visit Notes and Photos

The issues, comments and evaluations noted during stakeholder meetings (household surveys, mukhtar surveys, women focus group interviews, business/factory surveys, interviews with authorities) conducted as part of the stakeholder engagement activities of Environmental and Social Impact Assessment (ESIA) study carried out for the Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project are listed in the tables below.

1. HOUSEHOLD / MUKHTAR SURVEYS

Date/Location:	06.06.2022 / Balıkhisar, Saracalar and Güzelhisar neighbourhoods
Stakeholder(s):	The residents of Balıkhisar, Saracalar and Güzelhisar neighbourhoods
Participants:	Mukhtars of Balıkhisar, Saracalar and Güzelhisar neighbourhoods Households residing in Balıkhisar and Saracalar neighbourhoods SRM Team: Gökhan Metin Interviewers: Ekin Kula, Tuğçe Kaban, Burçak Sel Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information	Balıkhisar and Saracalar are the closest neighbourhoods to the Project site. Household surveys in Balıkhisar and Saracalar were conducted. Additionally, the team conducted surveys with mukhtars of Balıkhisar, Saracalar and Güzelhisar.
Household surveys	26 household surveys in Balıkhisar and 32 household surveys in Saracalar were successfully completed. Project information document has been distributed to the participants. Further information about the surveys will be provided in the ESIA report after the analysis.
Mukhtar surveys	Surveys with mukhtars of Balıkhisar, Saracalar and Güzelhisar neighbourhoods were conducted. Project information document has been distributed to the mukhtars. Further information about the surveys will be provided in the ESIA report after the analysis.

Date/Location:	07.06.2022 / Saray Gümüşoluk, Altınova, Saray Cumhuriyet, Dumlupınar and Yenice neighbourhoods
Stakeholder(s):	The residents of Saray Gümüşoluk, Altınova, Saray Cumhuriyet, Dumlupınar and Yenice neighbourhoods
Participants:	Mukhtars of Saray Gümüşoluk, Altınova, Saray Cumhuriyet, Dumlupınar and Yenice neighbourhoods
	Households residing in Saray Gümüşoluk and Altınova neighbourhoods
	Women residing in Saray Gümüşoluk and Altınova neighbourhoods
	SRM Team: Gökhan Metin
	Interviewers: Ekin Kula, Tuğçe Kaban, Burçak Sel
	Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information	On the second day of the site visit, household surveys in Saray Gümüşoluk and Altınova, which are also close to the Project site, were conducted. Additionally, the team conducted surveys with mukhtars of Saray Gümüşoluk, Altınova, Saray Cumhuriyet, Dumlupınar and Yenice.
Household surveys	32 household surveys in Saray Gümüşoluk and 14 household surveys in Altınova were successfully completed. Project information document has been distributed to the participants. Further information about the surveys will be provided in the ESIA report after the analysis.
Mukhtar surveys	Surveys with mukhtars of Saray Gümüşoluk, Altınova, Saray Cumhuriyet, Dumlupınar and Yenice neighbourhoods were conducted. Project information document has been distributed to the mukhtars. Further information about the surveys will be provided in the ESIA report after the analysis.

2. WOMEN FOCUS GROUP INTERVIEWS

Date/Location:	06.06.2022 / Balıkhisar neighbourhood
Stakeholder(s):	Women residing in Balıkhisar neighbourhood
Participants:	Five women residing in Balıkhisar neighbourhood Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the interview	A focus group interview with women from Balıkhisar neighbourhood was conducted. Project information document has been distributed to the interviewees. Five women participated in the focus group interview. Their ages range between 23 and 65. The average age is 36. Two of the participants are working in the public health centre in Balıkhisar and the others are housewives. Three of the participants are married and have children. Two of them are single. Female safety is of great consideration within the Project. Balıkhisar is a significant neighbourhood for the Project since it is in close proximity to the Project area. Main findings of the focus group interview in Balıkhisar are described below.
Daily life of women	 Women are mostly responsible for cooking, cleaning, taking care of children, and growing fruits and vegetables in their own garden. Few women work as cleaning ladies or work in factories as workers. Some women participate in activities that are organized in the neighbourhood such as baking bread in the village bakery, needlework courses, the Quran courses. Usually, they do not leave the neighbourhood unless there are health problems that necessitate going to the hospital.
Problems that women face	The biggest problem for women in Balıkhisar is public transportation. There are very few minibuses operating between the centre and Balıkhisar. The lack of means of public transportation hinders them to go outside of the neighbourhood for bazaars, hospitals, shopping malls etc. Also, children have difficulties accessing schools outside the neighbourhood. They stated that Balıkhisar residents tend to emigrate to other neighbourhoods due to this transportation problem. Women would like to have more courses in their neighbourhood especially about agricultural and husbandry activities, awareness raising trainings regarding certain diseases that especially women suffer from (i.e., regular breast self-examinations for early detection of breast cancer).
Health problems that women suffer from	Main health problems of women are kidney dysfunctionalities, breast cancer and colorectal cancer.
About the Project	They have not heard about the Project before. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project) for anything. They believe the Project will create positive impacts both for Turkey and for their neighbourhood. They hope the transportation systems around Balıkhisar will be improved together with the Project. They did not report any concerns related to the Project and its impacts.

Date/Location:	06.06.2022 / Saracalar neighbourhood
Stakeholder(s):	Women residing in Saracalar neighbourhood
Participants:	Five women residing in Saracalar neighbourhood Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the interview	A focus group interview with women from Saracalar neighbourhood was conducted. Project information document has been distributed to the interviewees. Five women participated in the focus group interview. Their ages range between 34 and 67. The average age is 47. One of the participants knits dolls/toys and sell them online. Others are housewives. All participants are married and have children. Saracalar is also a significant neighbourhood for the Project since it is in close proximity to the
	Project area. Main findings of the focus group interview in Saracalar are described below.
Daily life of women	Majority of the women in Saracalar are housewives. They are busy with domestic works such as taking care of children/grandchildren/the elder members of their family, cooking and cleaning. Also, women grow various vegetables in their own garden. As participants reported, the number of women going to universities has recently increased in Saracalar and those graduating from universities have started working in nearby factories.
Problems that	There is not a public place for women where they can come together.
women face	The lack of a bazaar, pharmacy and the inadequacy of public health centre are other problems that participants mentioned.
	There are a number of residents in Saracalar who need patient care. The burden of taking care of them is on women. Therefore, they pointed out the necessity of a patient care and rehabilitation centre.
	Additionally, they stated the high rates of unemployment especially among the youth in Saracalar.
Health problems that women suffer from	Main health problems of women are allergies, high blood pressure and breast cancer.
About the Project	They have not heard about the Project before. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project). They sometimes visit Otonomi for the grocery store in it. They usually use Gate 1 or Gate 2 for their visits to Otonomi.
	employment opportunities and improve the neighbourhood.
	Their concerns about the Project are the waste and pollution. Also, they stated that the existence of workers coming outside the neighbourhood during construction may make them feel insecure.

Date/Location:	07.06.2022 / Saray Gümüşoluk neighbourhood
Stakeholder(s):	Women residing in Saray Gümüşoluk neighbourhood
Participants:	Five women residing in Saray Gümüşoluk neighbourhood Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the interview	A focus group interview with women from Saray Gümüşoluk neighbourhood was conducted. Project information document has been distributed to the interviewees. Five women participated in the focus group interview. Their ages range between 38 and 66. The average age is 50. Two of the participants work in the kindergarten/Quran course within Saray Gümüşoluk. Others are housewives. All participants are married and four of them have children. Main findings of the focus group interview in Saray Gümüşoluk are described below.
Daily life of women	 Women are expected to be responsible for cooking, cleaning the house, taking care of children, ovine breeding, and growing fruits and vegetables in their own garden. There are not many social activities among women except for the sewing embroidery courses in Saray Gümüşoluk. They are usually staying in their own houses. As participants reported, husbands/fathers of women in Saray Gümüşoluk are not very supportive of women's working. The neighbourhood is very close to a busy traffic road. Women stated that they bake bread and sell them on the road on weekends.
Problems that women face	Main problems that women in Saray Gümüşoluk are listed as the lack of public health centre, schools, playground, bazaar and public transportation. For health issues, they have to go to Pursaklar, Saray or the city hospital, all of which are not close to Saray Gümüşoluk. Only municipal buses operate between the neighbourhood and the centre. However, there is not any card loading mechanism in Saray Gümüşoluk. Establishing a card loading machine and providing minibuses to operate could solve these problems. Also, there are some problems related to infrastructure. Participants mentioned that the frequency of power cuts increases in bad weather conditions.
Health problems that women suffer from	They did not specify any health problems that women suffer from.
About the Project	They have not heard about the Project before. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project). They think that the Project will be beneficial for the country and the neighbourhood. They expect the Project to increase employment opportunities and improve the neighbourhood. They did not report any concerns related to the Project and its impacts.

Date/Location:	07.06.2022 / Altınova neighbourhood
Stakeholder(s):	Women residing in Altınova neighbourhood
Participants:	Six women residing in Altınova neighbourhood Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the interview	A focus group interview with women from Altınova neighbourhood was conducted. Project information document has been distributed to the interviewees. Six women participated in the focus group interview. Their ages range between 31 and 55. The average age is 38. Two of the participants are teachers in the primary school located in Altınova. Others are housewives. All participants are married and have children. Main findings of the focus group interview in Altınova are described below.
Daily life of women	Similar to other neighbourhoods, majority of the women in Altınova are housewives. They are responsible for taking care of children/grandchildren/the elder members of their family, cooking and cleaning. Some women grow fruits and vegetables in their own garden together with their husbands. Women do not prefer to go outside of the neighbourhood except for social activities such as picnic with family, shopping for the needs of children and the house.
Problems that women face	The insufficiency of public transportation, banks, public health centres was mentioned by participants as the greatest problems. Also, they mentioned that the population has been increasing in the neighbourhood and the infrastructure remains incapable to serve needs. The capacity of the classes are full and exceeding. Participants emphasized the urgency of establishing another school for children.
Health problems that women suffer from	Other than back and waist pains, participants did not specify any health problems that women suffer from.
About the Project	They have not heard about the Project before. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project). They hope the Project will be beneficial for the development of the neighbourhood. They did not report any concerns related to the Project and its impacts.

7

3. BUSINESS/FACTORY SURVEYS

Date/Location:	08.06.2022 / Student Selection and Placement Centre (ÖSYM) E-exam Centre
Stakeholder(s):	Workers and users of Student Selection and Placement Centre (ÖSYM) E-exam Centre
Participants:	Security personnel of Student Selection and Placement Centre (ÖSYM) E-exam Centre SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	The exam centre is open only at the weekends when there are exams. During the weekdays, only the security personnel is working within the facility. There are four shifts and 17 security personnel work in each shift. Project information document has been distributed to the security personnel.
Transportation and usage of roads	There is not a service/bus of the centre for workers. All workers arrive in and leave from the exam centre by themselves (by either their personal car or public transportation). They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project). They use Özal Boulevard, then they exit the boulevard to turn left through the Ankara-Çubuk Road and reach the exam centre. The entrance of the centre is also on the Ankara-Çubuk Road.
Grievances/ concerns	No grievances or problems were reported. No potential negative impact was assessed.

Date/Location:	08.06.2022 / Halkbank Warehouse and Social Facilities
Stakeholder(s):	Workers of Halkbank Warehouse and Social Facilities
Participants:	Manager of Halkbank Warehouse and Social Facilities
	SRM Team: Gökhan Metin
	Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about	Halkbank Warehouse and Social Facilities is next to the exam centre. 29 employees are working in the facility.
the facility	Project information document has been distributed to the manager.
Transportation and usage of roads	There is one service/bus for worker transportation. Most of the workers use this service/bus. They usually arrive at 9:00 and leave at 18:00. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project). They use Özal Boulevard, then they exit the boulevard to turn left through the Ankara-Çubuk Road and reach the facility. The entrance is also on the Ankara-Çubuk Road.
Grievances/ concerns	No grievances or problems were reported. No potential negative impact was assessed.

Date/Location: 08.06.2022 / Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.) Stakeholder(s): Workers of Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.) Participants: Human Resources Manager of Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.) SRM Team: Gökhan Metin Mott MacDonald Team: Econur Alper Subject Comments and Evaluations General information about the facility Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7.45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Figure 1: Current access roads to the Project site The representative reported some concerns and grievances. First of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incinaration. In addition, he stated that if there will be a process involving the incinaration of wastes, the smoke will affect their operations ton the facility negatively. He would like to be informed about e		
Stakeholder(s): Workers of lşbir Sünger Mattress Foam Industry (lşbir Sünger Sanayi Ticaret A.Ş.) Participants: Human Resources Manager of lşbir Sünger Mattress Foam Industry (lşbir Sünger Sanayi Ticaret A.Ş.) Status SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper Subject Comments and Evaluations General information about her salitiv Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7.45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Figure 1: Current access roads to the Project site Figure 1: Current access roads to the Project site Grievances/ concerns The representative reported some concerns and girevances. First of all, he tod that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project as already started without consultation or providing the incineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about ervinonmental risks (biological waste, the smoke will affect their operations in the facility negatively. He would like to be informed about per ation phases of the Project.	Date/Location:	08.06.2022 / Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.)
Participants: Human Resources Manager of Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.S.) SRM Team: Gökhan Metin Mott MacDonald Team: Econur Alper Subject Comments and Evaluations General information about Information about and the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: transportation and usage of roads Figure 1: Current access roads to the Project site Figure 1: Current access roads to the Project site Crievances/ concerns Crievances / concerns MacHink their consultation in the scalitation is just a formality and he does not think their consultation or providing information. In addition, he stated that if there will be a process involving the inclineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about environmental risks (biological waste, toes) the safe dy started without consultation or providing the construction and operation phases of the Project.	Stakeholder(s):	Workers of Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.)
SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper Subject Comments and Evaluations General information about the facility Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Figure 1: Current access roads to the Project site Figure 1: Current access roads to the Project site Crievances/ concerns The regreentative reported some concerns and grievances. First of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about environmental risks (biological waste, chemical waste, dust) during the construction and operation phases of the Project.	Participants:	Human Resources Manager of Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.)
Subject Comments and Evaluations General information about the facility Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 service/buses and 20 cars within the facility. Worker service/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Figure 1: Current access roads to the Project site Figure 1: Current access roads to the Project site Crievances/ concerns The representative reported some concerns and grievances. Fist of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incineration of wastes, the smoke will affect their operations in the facility. He would like to be informed about environmental risks (biological waste, chemical waste, dust) during the construction phase of the Project.		SRM Team: Gökhan Metin
Subject Comments and Evaluations General information about the facility Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: the facility of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: the facility of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: the facility of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: the facility of the trucks use the route marked with red project integration of the trucks use the route marked with red project integration of the truck use the route marked with red project integration of the truck use the route marked with red project integration of the truck use the route the approximate the route truck use the route the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use the route truck use truck use the route truck use troute truck use the route truck use the route truck		Mott MacDonald Team: Ecenur Alper
General information about the facility Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager. Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: the truck of the truck use the route marked with red arrow. The facility meets to be consulted about the road closure as a part of the Project. Image: the truck use the route marked with red arrow. The facility meets to be consulted about the road closure as a part of the Project. Image: the truck use the route marked with red arrow. The facility meets to be consulted about the road closure as a part of the Project. Image: the truck use the route marked with red arrow. The facility meets to be consulted about the road closure as a part of the Project. Image: the truck use the route marked with red arrow. The facility reduction the truck use the route marked with red arrow. The facility reduction the truck use the route marked with reducting interviews with neighbour truck. Image: the truck use the route marked with reducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incineration of wastes, the	Subject	Comments and Evaluations
Transportation and usage of roads There are 12 services/buses and 20 cars within the facility. Worker services/buses and some of the trucks use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: transportation of the truck use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: transportation of the truck use the route marked with red arrow. The facility needs to be consulted about the road closure as a part of the Project. Image: transport transport transport to the transp	General information about the facility	Approximately 150 employees are working in the mattress foam industry. There are two shifts. Most of the workers use this service/bus. They usually arrive at 7:45 and leave at 18:15. Project information document has been distributed to the manager.
Grievances/ concernsThe representative reported some concerns and grievances.First of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information.In addition, he stated that if there will be a process involving the incineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about environmental risks (biological waste, chemical waste, dust) during the construction and operation phases of the Project.Also, the number of workers to be employed for both construction and operation was also	Transportation and usage of roads	<form></form>
concerns First of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about environmental risks (biological waste, chemical waste, dust) during the construction and operation was also Also, the number of workers to be employed for both construction and operation was also	Grievances/	The representative reported some concerns and grievances
requested in order to take precautions against vehicle traffic, transportation and population	concerns	First of all, he told that conducting interviews with neighbour facilities is just a formality and he does not think their concerns will be considered since the construction phase of the Project has already started without consultation or providing information. In addition, he stated that if there will be a process involving the incineration of wastes, the smoke will affect their operations in the facility negatively. He would like to be informed about environmental risks (biological waste, chemical waste, dust) during the construction and operation phases of the Project. Also, the number of workers to be employed for both construction and operation was also requested in order to take precautions against vehicle traffic, transportation and population

Date/Location:	08.06.2022 / İşbir Optik
Stakeholder(s):	Workers of İşbir Optik
Participants:	Quality Manager of İşbir Optik SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	İşbir Optik is located on the other side of the Özal Boulevard. There are three shifts. Project information document has been distributed to the manager.
Transportation and usage of roads	Most of the workers use this service/bus. They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project).
Grievances/ concerns	The representative reported two concerns. The first one is about the location of the Project site. He mentioned that there is a high population density around the Project site due to many industrial business areas and factories. An unforeseen incident during vaccine production process may lead to negative results. He said that a less populated area could be selected. The other concern is about dust pollution. Dust may affect their work negatively.

Date/Location:	08.06.2022 / Otonomi - Özkan Automotive
Stakeholder(s):	Workers and visitors of Otonomi
Participants:	Manager of Özkan Automotive Two security personnel of Otonomi SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	There are around 700-750 independent enterprises in Otonomi with more than 2,000 employees working in total. Project information document has been distributed to the manager and the security personnel.
Transportation and usage of roads	There is not a service/bus for Otonomi workers. All workers arrive in and leave from Otonomi by themselves (by either their personal car or public transportation). There are four entrances of Otonomi. The busiest ones are Gate 1 and Gate 3. Approximately 2,000 vehicles enter into Otonomi from each of these two gates. Gate 3 stands on the same route with the recreational area of the Project. Also, the road that will be closed as a part of the Project is used for test drives by enterprises and clients.
Grievances/ concerns	Their concerns are mostly related to dust and noise. They need to clean the vehicles on sale more frequently due to dust. They are worried about the risk of spread of disease because of some biological materials and waste. They would like to be informed about these issues.

Date/Location:	08.06.2022 / İşbir Yatak Mattress Factory and General Directorate
Stakeholder(s):	Workers of İşbir Yatak Mattress Factory and General Directorate
Participants:	Quality Manager of İşbir Yatak Mattress Factory and General Directorate SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	İşbir Yatak Mattress Factory and General Directorate is a significant business area since it is located just across the Project site and the entrances of İşbir Yatak and the Project site are facing each other. They had been informed during the previous site visit. They stated that they are regularly following the construction stage of the Project. Project information document has been distributed to the manager.
Transportation and usage of roads	They actively use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project) for transportation of workers and materials. The worker services/buses are located on the General Özkan Özgün Street after the workers get off in the morning until they get on again after work. They are open to creating alternative routes for the transportation purposes. They need to be consulted about the road closure as a part of the Project.
Grievances/	No grievances or problems were reported. Potential impacts regarding roads were assessed
concerns	

Date/Location:	08.06.2022 / MAN Turkey
Stakeholder(s):	Workers of MAN Turkey
Participants:	Occupational Health and Safety Management Systems Manager of MAN Turkey SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	MAN Turkey is located on the other side of the Özal Boulevard. They had been informed prior to the site visit since one of the noise measurement devices was located there. Project information document has been distributed to the manager.
Transportation and usage of roads	They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project).
Grievances/ concerns	No grievances or problems were reported. No potential negative impact was assessed. However, the representative would like to be informed in detail about the traffic load of the Project both in construction and in operation, vaccines to be produced within the facility and management of the medical waste.

Date/Location:	08.06.2022 / Borusan Automotive
Stakeholder(s):	Workers and visitors of Borusan Automotive
Participants:	Administrative Affairs Responsible of Borusan Automotive SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	Borusan Automotive is located on the other side of the Özal Boulevard. Project information document has been distributed to the representative.
Transportation and usage of roads	They do not use the roads next to the Project site (General Özkan Özgün Street and the road on recreational area of the Project).
Grievances/ concerns	No grievances or problems were reported. No potential negative impact was assessed. However, the representative would like to be informed about the characteristics of the facility in terms of the vaccines to be produced, capacity of the facility etc.

Date/Location:	09.06.2022 / Turkish Medicine and Serum Industry (Türk İlaç ve Serum Sanayi) & TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)
Stakeholder(s):	Workers of Turkish Medicine and Serum Industry & TURKplast
Participants:	Human Resources Manager of Turkish Medicine and Serum Industry & TURKplast Four Quality Assurance Chiefs of Turkish Medicine and Serum Industry & TURKplast Deputy Production Manager of Turkish Medicine and Serum Industry & TURKplast SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	Turkish Medicine and Serum Industry and TURKplast are not in close proximity to the Project site. However, they use the General Directorate of Public Health (GDPH) warehouse building next to the Project site time to time. Project information document has been distributed to the representatives.
Transportation and usage of roads	<text></text>
Grievances/	Their concerns are about the competitive market conditions and their risk of personnel loss.
- concerns	animal groups to be tested on experiments, organizational capacity of the facility and employment processes. Also, they wonder the way the vaccines will be filled and packaged.

Date/Location:	09.06.2022 / Project Site
Stakeholder(s):	Workers of the Project during construction phase
Participants:	Responsible personnel of the construction contractor (YDA) of the Project Security personnel of the Project SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the facility	There are less than 10 workers in the Project site for existing construction works. Currently, workers are working on only the construction of administration building as the first phase of the construction. When other phases of the construction stage start, it is estimated that there will be around 250 workers at most. Two dormitories/wards are under construction for the accommodation of approximately 50 workers. Local employment opportunities are not available since the construction contractor has its own subcontractors. They do not have a plan on employment of Community Liaison Officer (CLO). Rather, they plan to employ a chief who will be responsible for the organizations about accommodation, cafeteria and worksite, and a human resources chief/personnel.
Transportation and usage of roads	They plan to have a worker service/bus for the rest of the workers who will not stay in domitories/wards. The roads surrounding the Project site (General Özkan Özgün Street and the road to be closed and included in recreational area) are paved. The continuation of the General Özkan Özgün Street after the Project site (on the other side of Çubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Çubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Çubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Qubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Qubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Qubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the other side of Qubuk Stream, located in Pursaklar district) is also paved. Image: Street after the Project site (On the Other side of General Özkan Özgün Street, located in Pursaklar district)
Grievances/	They have not received any complaints or grievances when they are working on the Project
concerns	site.

> Traffic-related problems (congestion etc) has not occurred. The construction area is regularly irrigated with a sprinkler and tractor to prevent dust spread.

Date/Location:	09.06.2022 / Agricultural lands near the Project site
Stakeholder(s):	Users of agricultural lands
Participants:	Two agricultural labourers Security personnel of the Project SRM Team: Gökhan Metin Mott MacDonald Team: Ecenur Alper
Subject	Comments and Evaluations
General information about the agricultural lands	The agricultural labourers stated that the agricultural lands near the Project area have many shareholders (around 72 different shareholders) and all lands are rented/leased for agricultural activities. They are from Esenboğa neighbourhood, and they are not staying in agricultural lands permanently. Rather, they occasionally start coming to the lands from March to June and they visit the lands daily between June and October for cultivation. Labourers mostly cultivate barley, parsley, tomato and mint. Project information document has been distributed to the labourers. They had vegetable racks piled up on the recreational area of the Project. They reported that they relocated the racks after having been informed by a Project team member. During the site visit, majority of the racks (approximately 80-85 % of all racks) were located near the agricultural land. As it can be interpreted from the picture below, the rest of the racks were still on the recreational area. Labourers said that they could not relocate all racks because of the economic burden of transportation.
	Photo 3: The rest of the racks that are still on the recreational area
	They had been informed about the Project through the communication for relocation of the racks. However, they had some mistaken knowledge about the Project. For instance, they thought the Project will expand through the other side of the Çubuk Stream, and the agricultural lands will also be a part of the Project area. We made relevant corrections and provided information about the Project. The cultivation starts in June and continue until the end of October. For the harvest process, they employ 6-8 seasonal workers coming from surrounding neighbourhoods.
Transportation and usage of roads	A truck is used once a day for the transportation of agricultural products through both routes marked with red and black arrows. They need to be consulted about the road closure as a part of the Project.



20

4. INTERVIEWS WITH AUTHORITIES

Date/Location:	06.06.2022 / Akyurt District
Stakeholder(s)	Akyurt District Municipality, Mayor, Hilal Ayık Akyurt District Municipality, Deputy Mayor, Hüseyin Demirel Akyurt District Municipality, Deputy Mayor, Cemalettin Sarp Akyurt District Municipality, Chief of the Planning and Projects Directorate, Bünyamin Akyurt Akyurt District Governorship, District Governor, Metin Selçuk Akyurt District Health Directorate, Director, Asuman Tezel Kahraman Akyurt District Directorate of Agriculture & Forestry, Director, M. Beşir Sungur Akyurt District Social Assistance and Solidarity Foundation, Civil Servant
Participants:	SRM Team: Sadık Avcı, Aysima Çalışan Mott MacDonald Team: Pelin Karakaya
Institutions	Comments and Evaluations
Akyurt District Governorship & Akyurt District Municipality	The health industry is currently developing in Akyurt. Many pharmaceutical warehouses, vaccine warehouses of the Ministry of Health, and companies producing medical products are already located in the district. While Akyurt's daytime population is 70,000, its night-time population is 35,000. Employees come from neighbouring provinces to work in Otonomi, MAN Turkey and other factories in the Industrial Zone. There were cattle breeding farms with capacities ranging from 500 to 5000, particularly in rural neighborhoods of Akyurt, before they were restricted in order to reduce nuisance and odour complaints in the vicinity of Esenboğa Airport. According to this restriction, new livestock facilities are not allowed to be established in the forbidden zone for livestock, while the existing livestock facilities are limited to a maximum of 5 cattle and 10 small cattle. Over the years, the number of people engaged in agriculture has significantly decreased, and some of the young people started to prefer to work in industrial establishments in Akyurt or in the surrounding districts. No adverse impact is expected due to the Project. For example, the possibility of an odour safety problem due to experimental animals would not be an issue considering that the Project will be designed and built according to international standards. No traffic congestion problems are expected during the construction and operation phases. In regard to the access road closing due to the Project, no adverse effects to traffic flow are anticipated. Otonomi, MAN Turkey and the surrounding factories use the main road in general. it was stated that construction of an alternative access road is not in the planning of Akyurt Municipality and is under the responsibility of the Ankara Metropolitan Municipality. After the Project starts operating, locals of Akyurt should be prioritized for employment. The Project should offer job and internship opportunities for the students and graduates of the Health Vocational High School in the district. Solid wastes c
Akyurt District Health Directorate	Since Çubuk Stream, which is at risk of flooding, is very close to the Project, it should be ensured that the Project will not get any damage in case of any natural disaster. Odour safety must be ensured and waste management should be strictly controlled. An emergency action plan must be created for any kind of unexpected event.

21

Akyurt District The economic worth of the lands in Akyurt are high. Therefore, farmers who usually plant Directorate of barley and wheat do not want to engage in agriculture. They sell their lands because they Agriculture & cannot obtain enough profit for a decent livelihood. Forestry There are two biogas plants in Akyurt which convert animal waste into energy. One produces 4 megabytes and the other 3.2 megabytes of energy. There are a total of 1059 registered farmers in Akyurt District, of which 29 are registered in Balıkhisar. There is a total of 19,574 hectares of registered agricultural land in Akyurt district. Registered agricultural land in Balıkhisar covers an area of 725 hectares and mainly consists of cereal farms. Akyurt District There are a total of 178 people receiving old-age pension in Akyurt district and 3 of these Social Assistance reside in Balıkhisar. It was also reported that 203 people receive disability benefits in and Solidarity Akyurt district, of which 3 reside in Balıkhisar. Foundation

Date/Location:	06.06.2022 / Pursaklar District
Stakeholder(s):	Pursaklar District Governorship, District Governor, Mehmet Yıldız Pursaklar District Municipality, Deputy Mayor, Ahmet Öztürk Pursaklar District Directorate of Agriculture & Forestry, Director, Bilal Karabiber Pursaklar District Social Assistance and Solidarity Foundation, Director, Songül Başaran
Participants:	SRM Team: Sadık Avcı, Aysima Çalışan Mott MacDonald Team: Pelin Karakaya
Institutions	Comments and Evaluations
Pursaklar District Governorship	The district governor, Mehmet Yıldız, had not been informed about the Project before the interview. Mr. Yıldız stated that he could not foresee any adverse impacts. Instead, he expressed that the Project might create new job opportunities for locals who have suffered from the problem of increasing unemployment rates as a result of the decrease in agriculture and animal husbandry in the district.
Pursaklar District Municipality	The deputy mayor, Ahmet Öztürk, was not informed about the Project either. Mr. Öztürk believed that the Project is likely to increase the socio-economic development of the northern region of Ankara by creating employment opportunities and developing health industry. No adverse impact is expected.
Pursaklar District Directorate of Agriculture & Forestry	It was reported that there are a total of 245 registered farmers and a total of 2537 hectares of registered agricultural land in Pursaklar district. Registered agricultural land in Pursaklar mainly consists of cereal farms.
Pursaklar District Social Assistance and Solidarity Foundation	In Pursaklar district, there are a total of 358 people receiving old-age pension and 522 people receiving disability benefits.

Date:	07.06.2022
Stakeholder(s):	DSI (Directorate General for State Water Works), Regional Director, Tolga Gökhan Diri DSI (Directorate General for State Water Works), Watershed Management, Monitoring and Allocations Branch Manager, Seher Varol Directorate of Esenboğa Airport Veterinary Border Control, Director, Fazıl Karabulut
Participants:	SRM Team: Sadık Avcı, Aysima Çalışan Mott MacDonald Team: Pelin Karakaya
Subject	Comments and Evaluations
Directorate- General for State Hydraulic Works	No rehabilitation works have been done or are planned by DSI on the adjacent section of Çubuk Stream. A flood study and stream rehabilitation works (including a flood protection wall) are highly needed for this region. According to the Regional Director, this flood study should be carried out by the Project owner and approved by DSI. This issue is extremely crucial because Çubuk Stream carries a high risk of flooding. Moreover, the Project should not have a basement or, if it has, should be well protected because the groundwater in this area is elevated. In a separate meeting, the Watershed Management, Monitoring and Allocations Branch Manager stated that DSI has already performed a flood study for the Project area, no further flood studies are necessary and that DSI has notified MoH of their findings including the necessary flood level for the Project with their letter dated 28.02.2022.
Directorate of Esenboğa Airport Veterinary Border Control	The directorate regulates the air transport of animals to the region. This region was previously the livestock production centre of Ankara. However, livestock production is banned here due to the odour problem. There are already three animal vaccine production centres in Ankara which are located in the city centre. One of them has BSL-3 level laboratories. Since the necessary precautions have been taken, no problems have been encountered so far. Similarly, since international standards will be maintained both during the construction phase and the operation phase, no adverse effects are expected regarding this Project.

Date:	09.06.2022 / 10.06.2022
Stakeholder(s):	Ankara Metropolitan Municipality Waste Coordination Branch Office, Branch Manager, Duygu Soytürk
	Ankara Metropolitan Municipality Waste Coordination Branch Office, Civil Servant, Salih Demir
	Ankara Metropolitan Municipality Waste Management Branch Office, Branch Manager, Mücahit Başıbüyük
	Ankara Metropolitan Municipality Infrastructure Coordination Centre, Director, Aziz Murat Seyrek
	Ankara Water and Sewerage Administration (ASKI), Deputy General Manager, Oktay Başkaya
Participants:	SRM Team: Sadık Avcı, Aysima Çalışan
	Mott MacDonald Team: Pelin Karakaya
Institution	Comments and Evaluations
Ankara Metropolitan Municipality	Waste Management Regulation is pursued for waste disposal. Ankara Metropolitan Municipality operates a facility in Mamak where collected wastes are separated and disposed of based on their types. The Municipality also operates a waste incineration plant. Different types of wastes from many provinces are disposed of or incinerated in these facilities of AMM. The Project is likely to produce domestic waste, recyclable waste vegetable oils, medical waste and hazardous waste. Ankara Metropolitan Municipality has the capacity to dispose of all waste types produced by the Project. The medical wastes to be produced by the Project will be collected and disposed of by ITC, which is a medical waste disposal company contracted by AMM. It was reported by the Waste Management Branch Manager that the Project has already obtained a license for construction and holds a permit for disposal of the excavation waste at the excavation waste disposal facility located in Akyurt.
Ankara Water and Sewerage Administration (ASKI)	The Project needs to obtain wastewater connection certificates from ASKI for construction and operation phase wastewater disposals. It was reported by the ASKI Deputy General Manager that there are wastewater infrastructure deficiencies in the area where the Project will be developed. It was noted that an official letter should be submitted to ASKI by the MoH Health Investments General Directorate to inquire about the infrastructure requirements of the Project. It was also reported that there are no issues regarding the potable water supply infrastructure. Necessary mitigations should be applied to minimize the risk of flooding in the Project area.

5. INTERVIEWS WITH NGOs

Date:	08.06.2022
Stakeholder(s):	Akyurt Industrialists' and Businessmen's Association – AKSİAD, General Coordinator, Serkan Özşölen
	Association of Public Health Specialists – HASUDER, Member, Prof. Dr. Tuğrul Erbaydar
	Association of Public Health Specialists – HASUDER, Member, Emin Erkal
Participants:	SRM Team: Sadık Avcı, Aysima Çalışan Mott MacDonald Team: Pelin Karakaya
Institution	Comments and Evaluations
AKSIAD	The board of AKSİAD had not been officially informed about the location, structure, and scope of the Project. Having 65 members, AKSİAD has partnered with many projects such as developing natural gas infrastructure, opening Gazi Vocational School, making road works, supporting the Gendarmerie Station, and creating accessible areas for persons with disabilities. Although Akyurt is the closest periphery district to the city centre, public transportation between Akyurt and the central districts is very limited and most employees use service vehicles for transportation. Metro infrastructure is highly needed for this region. Another important problem in Akyurt is the frequent power outages because the infrastructure is insufficient. Power outages cause financial damage to businesses.
	In addition to Esenboğa Airport, Otonomi, Akyurt Fair (under construction) and Industrial Zones, and many other factories, the Project is considered to make a positive contribution to the socio-economic development of Akyurt.
HASUDER	HASUDER is an association with 600-700 members, most of whom are academics. According to the association, the Project is very necessary and important for Turkey. However, this process should be guided by transparency. Since it is a strategic facility, security precautions should be at a high level, and hazards and dangers such as pandemic, epidemic, and bioterror should be considered. This Project is extremely crucial for national security. International standards should be followed in the design, and all types of waste should be disposed of in a way that does not cause any health or environmental problems. This Project must be operated and governed by the state; any company should not be authorized in this regard. The association also noted that as a result of the mismanagement of the COVID-19 pandemic in Turkey, vaccine hesitancy and anti-vaccination have increased among the citizens.
	Comprenensive governmental policies should be adapted and regulated to reduce vaccine hesitancy.

26

Photos from surveys and interviews






29

Surveys and Interviews

İşbir Yatak Mattress Factory and General Directorate



Turkish Medicine and Serum Industry (Türk İlaç ve Serum Sanayi) & TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)





Directorate General for State Hydraulic Works

Mott MacDonald Restricted

30

Surveys and Photo Interviews Akyurt Industrialists' and **Businessmen's** Association – AKSIAD **Association Of** Public Health Specialists -HASUDER **Akyurt District** Directorate of Agriculture & Forestry, Director

31



Mott MacDonald Restricted

32

Annex C-3: ESIA Public Consultation Meeting Minutes

Date/Location:	20 May 2024 (14:00-15:30) / Virtual
Stakeholder(s):	Public and stakeholders
Participants: ²	Project Management Support Unit of MoH General Directorate of Public Health of MoH General Directorate of Health Investments of MoH Ankara Provincial Health Directorate Ministry of Agriculture and Forestry Ministry of Environment, Urbanization, and Climate Change Ministry of Industry and Technology Ankara Metropolitan Municipality General Directorate of State Hydraulic Works District Governorship of Akyurt Akyurt District Health Directorate Mott Macdonald (ESIA Consultant)
Subject	Comments and Evaluations
Türkiye Preparedness for Public Health Emergencies Project (TPPHEP) Introductory Meeting and Ankara Vaccine Production Center (VPC) Environmental and Social Impact Assessment (ESIA) Presentation	 <u>Agenda of the Meeting:</u> The agenda items of the meeting were Ankara VPC Project objective, components of the Project, proposed activities, potential environmental and social (E&S) impacts, proposed mitigation measures, and information about the framework E&S plans Ankara VPC project description, project importance, potential E&S impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. Topics: The role of the Project Management Support Unit (PMSU) of the Ministry of Health (MoH) in the Project, as well as the roles and responsibilities of other project executive units, were explained at the beginning of the project, and the meeting's content was communicated to the participants. A presentation was provided by PMSU, outlining the agenda items for the TPPHEP Project meeting. The first part of the presentation explained the Project background, scope, duration, application area and objectives. At the end of the first part, participants were asked if they had any questions or requested additional information about the Project. No additional questions or opinions were received from the participants. The aims and objectives of the project's stakeholder participants in detail in the presentation. Following this presentation, the ESIA consultant Mott MacDonald experts provided details about the Ankara VPC ESIA Report. At the end of the second presentation, participants were asked to express their opinions, suggestions or questions including the Project's complaint mechanism and stakeholder participation approach.

² Since the kindergarten will be used by the children of health workers to be employed in the VPC who have not been selected yet, it is not possible to consult with the parents at this stage. However, future consultations regarding the ESIA will include these parents.

11. At the end of the presentation, it was explained through which communication channels the Project complaint mechanism could be reached, and the relevant telephone lines, e-mail addresses and correspondence addresses, including PMSU social and environmental specialist contact e-mails, were conveyed to the participants.

34

Annex C-4: Public Consultation During ESIA Disclosure

Date/Location:	12 June 2024 (Various)
Stakeholder(s):	Nearby facilities and neighbourhoods
Participants:	Emre Tanrıverdi (Project Management Support Unit of MoH)
Stakeholder	Comments and Evaluations
Nearby neighbourhoods (Balıkhisar and Saracalar)	PMSU conducted additional on-site engagement activities after the virtual public consultation meeting. On 12 June 2024, mukhtars of Balıkhisar and Saracalar neighborhoods were met at their offices. They were informed about the ESIA disclosure process, project schedule, technical details, potential environmental and social impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. Following the introduction to the mukhtars, details about the Project were presented to the local people at the Balıkhisar neighborhood tea house. Approximately 15 local residents attended the meeting, and participants indicated that there were no grievances related to the Project due to the location of the project area. Participants stated that there is no interaction between the settlements and the project area, and that the Ankara-Esenboğa Airport road acts as a natural barrier. The website link to the ESIA report and information on the grievance mechanism were provided to the participants.
Nearby facilities (İşbir Yatak, Otonomi)	In addition, İşbir Yatak and Otonomi representatives were visited as part of the on-site engagement activities, which had been consulted at the beginning of the ESIA studies. YDS representatives were attempted to be reached, however, no response was received and they could not be contacted for a meeting. The Deputy General Director of İşbir Yatak and the operations manager of Otonomi were informed about the ESIA process and technical details of the Project. Information about the stakeholder engagement processes and grievance mechanism tools was presented to the stakeholders. It was learned that no external grievances from the workers of İşbir Yatak and enterprises of Otonomi had been sent to the management, and there were no grievances about the Project activities.

35

Photos from interviews



36





mottmac.com



Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Stakeholder Engagement Plan

January 2024

J

Mott MacDonald Mesa Koz Sahrayıcedit District Atatürk Street No. 69 / 255 34734 Kadıköy Istanbul Turkey

T +90 (0) 216 766 3118 mottmac.com

Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Stakeholder Engagement Plan

January 2024

Mott MacDonald T Danışmanlık Mühendislik Ltd Şiti, is a member of the Mott MacDonald Group registered in England and Wales no 1110949. Registered office: Mott MacDonald House, 8-10 Sydenham Road, Croydon CR0 2EE, United Kingdom

Issue and Revision Record

Revision	Date	Originator	Checker	Approver	Description
A	28.11.22	Gokhan Metin Aysima Calisan Ecenur Alper	Ece Kilicozlu	Pelin Karakaya	Draft Plan
В	13.03.2023	Ecenur Alper	Pelin Karakaya	Neslihan Ayvaz	Revised Draft Plan
С	23.10.2023	Ecenur Alper Mustafa Islek	Pelin Karakaya	Neslihan Ayvaz	Revised Draft Plan
D	20.12.2023	Ecenur Alper Mustafa Islek	Pelin Karakaya	Neslihan Ayvaz	Final Draft Plan
E	14.06.2024	Ecenur Alper Mustafa Islek	Pelin Karakaya	Neslihan Ayvaz	Final Draft Plan

Document reference:

Information class: Standard

This document is issued for the party which commissioned it and for specific purposes connected with the abovecaptioned project only. It should not be relied upon by any other party or used for any other purpose.

We accept no responsibility for the consequences of this document being relied upon by any other party, or being used for any other purpose, or containing any error or omission which is due to an error or omission in data supplied to us by other parties.

This document contains confidential information and proprietary intellectual property. It should not be shown to other parties without consent from us and from the party which commissioned it.

i

Contents

Abbr	eviatio	ons and Acronyms	4
1	Introc	duction and Project Summary	6
	1.1	Overview	6
	1.2	Objectives, Structure and Scope of the Stakeholder Engagement Plan	6
	1.3	Project Information and Location	7
2	Sumr	mary of Previous Stakeholder Engagement Activities	9
	2.1	Before The ESIA Study	9
	2.2	During The ESIA Process	9
		2.2.1 Scoping Phase Site Visit and Consultation (December 2021)	9
		2.2.2 ESIA Study Phase Site Visit and Consultation (June 2022)	10
3	Natio	nal Regulatory and International Requirements	16
	3.1	Overview	16
	3.2	National Legislation and Requirements	16
	3.3	World Bank Stakeholder Engagement and Consultation Requirements	16
4	Stake	eholder Identification and Analysis	18
	4.1	Overview	18
	4.2	Project Stakeholders	18
		4.2.1 Internal Stakeholders	18
		4.2.2 External Stakeholders	18
5	Stake	eholder Engagement Programme	25
	5.1	Overview	25
	5.2	Vulnerable Groups Considerations	25
	5.3	Pandemic Mitigations	26
	5.4	Stakeholder Engagement Approach and Future Stakeholder Engagement	27
6	Disclo	osure and Consultation Process	31
7	Griev	vance Mechanism	33
	7.1	Public Grievance Mechanism	33
		7.1.1 SABIM: Communication Centre of Ministry of Health "Alo 184"	33
		7.1.2 CIMER: Turkish Presidential Communication Centre	37
		7.1.3 YIMER: Foreigners Communication Centre	37

		7.1.4	Contractor and Supervision Consultant Level Public Grievance Mechanism	37
		7.1.5	Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)	38
	7.2	Workers	s' Grievance Mechanism	38
		7.2.1	SBN: Health Meeting Point of Ministry of Health "Alo 182"	38
		7.2.2	CIMER: Turkish Presidential Communication Centre	39
		7.2.3	Contractor and Supervision Consultant Level Workers' Grievance Mechanism	39
		7.2.4	Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)	40
	7.3	Project	Grievance Resolution Process	41
	7.4	World E	ank's Grievance Redress Service	42
	7.5	Commu	inity Liaison Officer	43
	7.6	Project	Contact Information	43
8	Reso	ources a	nd Responsibilities	44
9	Moni	itoring a	nd Reporting	45
	9.1	Monitor	ing	45
	9.2	Reporti	ng	45
10	Anne	exes		47
	10.1	The app	blication form on the website of the PMSU (in Turkish)	47
	10.2	Grievan	ice form	48
	10.3	Grievan	ice log	49
	10.4	Stakeho	older engagement tracker	50
	10.5	The Fire Social T	st Stakeholder List for the Project (Created by the Environmental and Feam of the PMSU)	51
	10.6	PMSU (Online Meeting Agenda Details	53
	10.7	Institutio	ons and Organizations Participating in The PMSU Online Meeting	56
	10.8	The Pro	pject's Information Document	57
	10.9	Organis	ational Chart of the PMSU affiliated to the MoH	62

Contents

Tables

Table 2-1: Engagement Methods and Number of Stakeholders Reached	12
Table 3-1: The ESSs of the World Bank that are relevant to the stakeholder engagement	16
Table 4-1: Directly Affected Stakeholders	20
Table 4-2: Other Interested Parties	21
Table 5-1: Stakeholder Engagement Approach and Future Stakeholder Engagement	27

Figures

Figure 1-1: The Project Location	8
Figure 1-2: The Project Site and its Parcel Division	8
Figure 4-1: Identification of Stakeholders and Engagement Scheme	19
Figure 7-1: The Flowchart of SABIM	35
Figure 7-2: Steps of the Grievance Mechanism of the Project ⁴	41

Abbreviations and Acronyms

ABSL	Animal Biosafety Level	ICAO	International Civil Aviation Organisation
AFAD	Ministry of Interior, Disaster and Emergency Management Presidency	ICLAS	International Council for Laboratory Animal Science
AIFD	Researcher Pharmaceutical Companies Association	IDEA	Istanbul Experimental Research Centre
АММ	Ankara Metropolitan Municipality	IHR	International Health Regulations
ASKI	Ankara Water and Sewerage Administration	ISO	International Standards Organization
AWI	Animal Welfare Institute	IUCN	International Union for the Conservation of Nature
BAS	Building automation system	KLİMİK	Turkish Clinical Microbiology and Infectious Diseases Association
BMBL	Biosafety at Microbiological and Biomedical Laboratories	KUTTAM	Koc University Research Centre for Translational Medicine
BSC	Biological safety cabinet	KUISCID	Koc University İşbank Centre for Infectious Diseases
BSL	Biosafety Level	MoAF	Ministry of Agriculture and Forestry
BUHASDER	Prevention of Communicable Diseases Association	МоСТ	Ministry of Culture and Tourism
САВ	Community Advisory Board	MoEUCC	Ministry of Environment, Urbanization and Climate Change
CBRN	Chemical, Biological, Radiological and Nuclear	МоН	Ministry of Health
ССТУ	Closed-circuit television	MoIT	Ministry of Industry and Technology
CDC	Centres for Disease Control	MoLSS	Ministry of Labour and Social Security
CEN	European Committee for Standardization	ΜοΤΙ	Ministry of Transport and Infrastructure
CFR	Code of Federal Regulations	NGOs	Non-governmental organizations
cGMP	Current Good Manufacturing Practice	NIH	National Institute of Health
CIMER	Turkish Presidential Communication Centre	OIE	World Organisation for Animal Health
CIOMS	Council for International Organizations of Medical Sciences	OLAW	Office of Laboratory Animal Welfare
CITES	Convention on Trade in Endangered Species	ÖSYM	Student Selection and Placement Centre
СМС	Chemistry, Manufacturing, and Controls	PAPs	Project Affected Persons
CWA	CEN Workshop Agreement	PDoEUCC	Provincial Directorate of Environment, Urbanization and Climate Change
DIN	German Institute for Standardisation	PID	Project Information Document
DRM	Design Requirements Manual	PMSU	Project Management Support Unit
DSI	State Hydraulic Works	PPE	Personal protective equipment
EHD	Infectious Diseases Association	PPP	Public Private Partnership
EHS	Environment, Health and Safety	R&D	Research and Development
EHSS	Environmental, Health and Safety and Social	SABIM	MoH Communication Centre

EKMUD	Turkish Infectious Diseases and Clinical Microbiology Specialization Association	SBN	Meeting Point at Health
ESMF	Environmental and Social Management Framework	SEA/SH	Sexual Exploitation and Abuse/Sexual Harassment
EGO	Ankara Electricity, Gas and Bus Operations Organization	SEP	Stakeholder Engagement Plan
EIA	Environmental Impact Assessment	SES	Trade Union of Public Employees in Health and Social
ERAGEM	Erciyes University Vaccine Research Development Centre	SOP	Standard Operational Procedure
ESCP	Environmental and Social Commitment Plan	SWOT	Strengths, weaknesses, opportunities, threats
ESF	Environmental and Social Framework	THKD	Turkish Protection of Animals Association
ESIA	Environmental and Social Impact Assessment	Three Rs	Replacement, Reduction, Refinement
ESMP	Environmental and Social Management Plan	ТМС	Turkish Microbiology Society
ESSs	Environmental and Social Standards	TPHA	Turkish Public Health Agency
EU	European Union	TPMDA	Turkish Pharmaceutical and Medical Devices Agency
EUROVENT	A provider of third-party performance certification programmes for HVAC industry	TS	Turkish Standards
FDA	U.S. Food and Drug Administration	TUBITAK	The Scientific and Technological Research Council of Turkiye
GDPH	General Directorate of Public Health	TUÇEV	Environmental Protection Foundation
GLP	Good Laboratory Practice	TUSEB	Health Institutes of Turkiye
GM	Grievance Mechanism	UFAW	Universities Federation for Animal Welfare
GMP	Good Manufacturing Practice	UN	United Nations
GMT	Good microbiological techniques	UNECE	United Nations Economic Commission for Europe
HASUDER	Public Health Specialist Association	UNESCO	United Nations Educational, Scientific, and Cultural Organisation
HAYTAP	Animal Right's Federation	UPS	Uninterruptible power supply
HEPA	High efficiency particulate air [filter]	USDA	United States Department of Agriculture
HIDER	Turkish Hospital Infections and Control Association	WB	World Bank
HVAC	Heating, ventilation and air	WHO	World Health Organization
	conditioning		

1 Introduction and Project Summary

1.1 Overview

This is the Stakeholder Engagement Plan (SEP) for "Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project" (the Project), which is planned to be developed in Akyurt district of Ankara province in the Central Anatolian region of Turkiye.

The SEP identifies the Project stakeholders, defines their roles and engagement capacities, describes the ways of interactions them and draws the route map in order to reach the Project targets through a transparent, inclusive and collaborative manner.

This SEP provides a framework for stakeholder engagement; it has been designed so that the Project Management Support Unit (PMSU) can demonstrate engagement that is effective, meaningful, consistent, comprehensive, coordinated and culturally appropriate in line with all the relevant legal and regulatory commitments at national context and good international industry practice. It encompasses the stakeholder engagement activities and consultations conducted/to be conducted during pre-construction, construction and operation phases of the Project. The SEP will be continuously updated throughout the Project implementation period, as required.

1.2 Objectives, Structure and Scope of the Stakeholder Engagement Plan

Open and transparent stakeholder engagement is critical for a project's sustainability, ownership and implementation. The objective of the stakeholder engagement is to provide opportunity for affected and/or relevant individuals, groups, communities, and organizations to express their opinions and concerns about the Project in order to consider them when assessing impacts and determining mitigation measures. As the World Bank ESS10 necessitates, stakeholder engagement involves the following aspects:

- Identification and analysis of all potentially affected individuals, groups, communities, and organizations that will be considered as stakeholders,
- Planning the steps for the way stakeholder engagement, information disclosure and meaningful consultation with stakeholders will be held,
- Formation of a good understanding of the Project for stakeholders,
- Identification of the issues that may be risky for the Project or the stakeholders,
- Addressing a grievance system/mechanism for long-term communication between the Project and the stakeholders,
- Responding to grievances through the grievance mechanism, and
- Reporting to stakeholders.

Initiating the stakeholder engagement in an earlier phase of the Project contributes the stakeholder engagement processes to be successful and effective. In line with the World Bank ESS10 and international best practice, stakeholder engagement was started during the scoping phase of the Project through the engagement of key Project stakeholders. Stakeholder engagement continued throughout the ESIA process of the Project and will continue during post-ESIA phases.

The SEP includes the following sections:

- 1. Introduction and Project Summary
- 2. Summary of Previous Stakeholder Engagement Activities

- 3. National Regulatory and International Requirements
- 4. Stakeholder Identification and Analysis
- 5. Stakeholder Engagement Programme
- 6. Disclosure and Consultation Process
- 7. Grievance Mechanism
- 8. Resources and Responsibilities
- 9. Monitoring and Reporting
- 10.Annexes

1.3 Project Information and Location

The World Bank assists governments in formulating a preparedness plan to provide the highest level of medical care, maintain primary healthcare, and minimize risks to both staff and patients. In Turkiye, inequalities deriving from different socioeconomic variables had been affecting the accessibility to healthcare services. For that matter, the Turkish Government has taken some significant steps to reduce unequal access to health systems and to strengthen the health system. The Health System Strengthening and Support Project (HSSSP), which is financed by the World Bank, was one of these steps. The details on the HSSSP are provided in the Section 2.1 of the ESIA report.

The HSSSP was approved on September 21, 2015, and became effective on November 26, 2015. The Project Development Objective (PDO) of the HSSSP is to improve primary and secondary prevention of selected non-communicable diseases (NCDs), increase the efficiency of hospital management, and enhance the capacity of the Ministry of Health (MoH) for evidence-based policymaking. Subsequently, the Environmental and Social Management Framework (ESMF) was updated in February 2022, and aligned with the Environmental and Social Framework (ESF) of the World Bank, replacing the OPs in 2018.

One of the components within the scope of the HSSSP (Component 4) concerns strengthening capacity of the MoH and relevant national systems to respond to COVID-19 as well as public health preparedness. MoH will undertake two projects under this component, one of which will be newly established in Ankara (the Project).

The main objective of the Project is to establish a national vaccine production centre, which will provide benefits through:

- increasing the mechanisms that would improve the research capacity,
- strengthening the capacity to combat pandemics/epidemics that are risky at national or international level, and
- improving the infrastructure by experimental animal production to support vaccine-related studies.

The Project site is located in Balıkhisar neighbourhood of Akyurt district of Ankara. The Project site has been allocated to the MoH by the Ministry of Treasury and Finance.

The location of the Project site and its parcel division are shown in

Figure 1-1 and Figure 1-2, respectively.



Figure 1-1: The Project Location



Figure 1-2: The Project Site and its Parcel Division

2 Summary of Previous Stakeholder Engagement Activities

2.1 Before The ESIA Study

In line with the World Bank requirements, an online consultation meeting was conducted on December 20, 2021, between 2 p.m. and 3 p.m. in order to reach all related Project stakeholders and to inform them about the updated ESMF for HSSP and activities included in the Project together with the new component (Component 4). Based on the feedback received during the meeting, the ESMF was revised and finalized. The final version of the ESMF has been disclosed on the website of the PMSU in February 2022¹.

A stakeholder list was first created by the PMSU Environmental and Social Team for the online meeting held on December 20, 2021, which is given in Annex 10.5. The text in Annex 10.6 was sent by PMSU to all these stakeholders through official channels. NGOs and universities were also contacted by phone. The institutions and organizations participating in the meeting are presented in Annex 10.7.

The invitation link to the online meeting was sent to the representatives of the institutions and organizations who shared their information to participate after conveying the information letters and phone calls. The meeting agenda was also shared with the participants via the same e-mail which the meeting link was sent. In the meeting agenda, it was stated that opinions and suggestions regarding the Project's ESMF document could be provided until 29 December 2021.

During the meeting, a presentation was made that included the information about the Project and the PMSU. The presentation also acknowledged the participants about the establishment and organizational structure of the PMSU. Finally, the information about stakeholder relations, grievance mechanism and the steps of the mechanism was provided in the presentation. The meetings ended after the question-answer session.

2.2 During The ESIA Process

2.2.1 Scoping Phase Site Visit and Consultation (December 2021)

Social experts (a senior social impact assessment expert, a land acquisition and resettlement expert, a stakeholder engagement expert and a social consultant) of the ESIA team conducted a field study on 28 and 29 December 2021 for the scoping study to identify the potential social impacts and risks of the Project. Scoping consultations were undertaken with key public institutions, to determine potential Project Affected Persons (PAPs)/stakeholders, to gain a deeper understanding of the Project area and potential Project impacts, and to understand their perception of the Project in order to reflect their views and recommendations to Project design and respond to any concerns they may have on the Project. Consultations were also held with neighbouring facilities that may be prone to direct Project construction and operation impacts. The external stakeholders interviewed within the scope of field studies are listed below.

- Mayor of Akyurt,
- Deputy Mayors of Akyurt,
- District Governor of Akyurt,
- Akyurt District Health Director,

¹ https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html

- Mukhtar of Balıkhisar neighbourhood,
- Mukhtar of Saracalar neighbourhood,
- CEO of YDS,
- Board Member of YDS,
- Business Development Manager of Işbir Yatak Mattress Factory and General Directorate,
- Quality Control Management Director of Işbir Yatak Mattress Factory and General Directorate,
- Operations Manager of Otonomi, and
- Representative of Mesart Architecture Company.

The initial findings of the consultations are as follows:

- The Mayor and the District Governor's approach towards the Project is positive and supportive. It has been observed that Akyurt Municipality supports the Project and is willing to take part in the Community Advisory Board² as an active participant and effective board member. Flood risk and reclamation requirements associated with the Çubuk stream was an issue of concern noted by the Akyurt Municipality which should be consulted with the General Directorate of State Water Works (DSI).
- The Project is located in Balıkhisar neighbourhood (within 5 km distance to the Project site) and Saracalar is the closest neighbourhood (within 1 km distance) to the Project site. Therefore, the mukhtars of these neighbourhoods were interviewed during the scoping phase field study of the Project. Mukhtars' information level on the Project was limited to the news shared on media, however they welcomed the Project. Even though the mukhtar of Balıkhisar had received an invitation to the online disclosure meeting held on 20 December 2021, he could not attend it. The ESIA team informed the Mukhtars regarding the planned stakeholder engagement activities to be carried out within the scope of the Project.
- During the consultations with neighbouring facilities, dust and odour safety were reported as main concerns requiring measures. Other issues of concern reported by the neighbouring facilities included the infrastructural (i.e. sewerage and waste management) inadequacies in the area and whether the existing infrastructure issues will be elevated as a result of the proposed Project.
- During the meetings, participants from the neighbouring factories were briefly informed that gender equality and violence issues against women would be addressed within the framework of the ESIA. In this context, safety of female employees in the nearby factories and the risk of being exposed to harassment or violence during the Project construction were also addressed in the meetings. Accordingly, stakeholders confirmed that employees rarely leave the factory during work hours, they stay inside the factory for lunch breaks and other breaks. Mitigation measures have been defined within the ESIA in order to maintain safety of female workers around the Project site.

2.2.2 ESIA Study Phase Site Visit and Consultation (June 2022)

The ESIA consultations aimed to gather baseline data, understand Project-related concerns and requests of PAPs, reflect opinions of key stakeholders and identify vulnerable groups. The consultations involved meetings with district and province level governmental institutions, meetings with non-governmental organizations, interviews with the representatives of neighbouring facilities, business enterprises and factories, socio-economic household surveys with PAPs in the area of influence, mukhtar interviews and focus group meetings with women

² A Community Advisory Board (CAB) will be established for the Project. The roles and responsibilities of the CAB, membership structure, frequency of meetings and disclosure activities are defined in the SEP. Please see Section 8 and Section 9 of the SEP for more detailed information about the CAB.

residing in the neighbourhoods directly affected and/or the closest surroundings. The content and sections of the questionnaires for household surveys, mukhtar interviews, business enterprise/factory interviews, and focus group interviews with women were determined by taking into account the scope of the Project and ESIA requirements of World Bank. All questionnaires were approved by the Project Team within the PMSU of the MoH in 30 May 2022. The content and sections of the questionnaires are briefly listed below:

- Household surveys
- Information about the interviewee (i.e. age, gender, vulnerability category (if applicable)
- Information about the household (i.e. number of people living in the house, students, elderly, disabled, age and gender distribution within the household, infrastructural conditions of the house)
- The major problems within the neighbourhood
- Information about the Project
- Grievance mechanism
- Business/enterprise interviews
 - Information about the interviewee (i.e. age, gender)
 - Information about the workplace (i.e. name, address, number of male and female workers, working hours, number of workers using shuttles to commute, number of vehicles that the facility has (by type), infrastructural conditions of the neighbourhood)
 - Information about the Project
 - Grievance mechanism
- Mukhtar interviews
 - Information about the mukhtar
 - Information about the neighbourhood and residents (i.e. population, vulnerable groups, educational services, health services, security, infrastructural conditions, transportation, economy, agriculture and livestock, organizations)
 - The major problems within the neighbourhood
 - The information about the Project
 - Grievance mechanism
- Focus group meetings:
- Daily life of the women in the neighbourhood (i.e. working, farming, childcare, elderly care, cooking)
- The major problems that women face within the neighbourhood (i.e. access to education, lack of health services, lack of transportation infrastructure, poverty, unemployment)
- Leisure time activities of women
- The information about the Project
- The approach of women in case people move to the neighbourhood to work in the Project activities
- Discussion about the risks related to SEA/SH
- Grievance mechanism

For more details, the questionnaires are provided in Annex G of the ESIA report.

Accordingly, 109 household surveys and focus group interviews with 21 women in four neighbourhoods, eight mukhtar interviews (within mukhtars of neighbourhoods within a distance of 5 km to the Project site), nine workplace surveys, interviews with two users of agricultural lands near the Project site, interviews with 20 representatives of public institutions, local

governments and two NGO representatives have been carried out during the ESIA preparation, which are outlined below in Table 2-1. During the consultations, the Project Information Document (PID)³ which was prepared by the ESIA team was distributed to all consulted stakeholders and PAPs, additional PIDs were also given to the mukhtars for distribution to the PAPs. The PID describes the key elements of the Project, including its rationale, composition, potential benefits and risks, environmental and social aspects.

Consultation Methods	Number of Stakeholders
Household Surveys	 109 Household Surveys 26 household surveys in Balıkhisar 32 household surveys in Saracalar 37 household surveys in Saray Gümüşoluk 14 household surveys in Altınova
Mukhtar Interviews	 8 Mukhtar Interviews Balıkhisar Saracalar Güzelhisar Saray Gümüşoluk Altınova Saray Cumhuriyet Dumlupınar Yenice
Women Focus Group Interviews	 4 Meetings, 21 Participants Balıkhisar (5 participants) Saracalar (5 participants) Saray Gümüşoluk (5 participants) Altınova (6 participants)
Business Interviews	 9 Business Interviews Student Selection and Placement Centre (ÖSYM) E-exam Centre Halkbank Warehouse and Social Facilities Işbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.) İşbir Optik Otonomi - Özkan Automotive İşbir Yatak Mattress Factory and General Directorate MAN Turkiye Borusan Automotive Turkish Medicine and Serum Industry (Türk İlaç ve Serum Sanayi) & TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)
Interviews with users of agricultural lands	 Two Users of Agricultural Lands Users of private lands located to the west of the Çubuk Stream used for agricultural purposes

Table 2-1: Engagemen	t Methods and	Number of	Stakeholders	Reached
----------------------	---------------	-----------	--------------	---------

³ Please see Annex 10.8 for the content of the Project Information Document.

Consultation Methods	Number of Stakeholders
	Regional and Local Authorities, 20 Stakeholders
	Akyurt District Municipality, Mayor
	 Akyurt District Municipality, Deputy Mayor
	 Akyurt District Municipality, Deputy Mayor
	Akyurt District Municipality, Chief of the Planning and Projects Directorate
	Akyurt District Governorship, District Governor
	Akyurt District Health Directorate, Director
	 Akyurt District Directorate of Agriculture & Forestry, Director
	Akyurt District Social Assistance and Solidarity Foundation, Civil Servant
	 Pursaklar District Governorship, District Governor
	 Pursaklar District Municipality, Deputy Mayor
	 Pursaklar District Directorate of Agriculture & Forestry, Director
	 Pursaklar District Social Assistance and Solidarity Foundation, Director
	 DSI (Directorate General for State Water Works), Regional Director
Meetings	• DSI (Directorate General for State Water Works), Watershed Management,
C C	Monitoring and Allocations Branch Manager
	 Directorate of Esenboğa Airport Veterinary Border Control, Director
	Ankara Metropolitan Municipality Waste Coordination Branch Office, Branch Manager
	Ankara Metropolitan Municipality Waste Coordination Branch Office, Civil Servant
	Ankara Metropolitan Municipality Waste Management Branch Office, Branch Manager
	Ankara Metropolitan Municipality Infrastructure Coordination Centre, Director
	 Ankara Water and Sewerage Administration (ASKI), Deputy General Manager
	NGOs, Three stakeholders
	 Akyurt Industrialists' and Businessmen's Association – AKSİAD, General Coordinator
	 Association of Public Health Specialists – HASUDER, Members

The initial findings of the consultations are as follows:

- The findings of the interviews conducted with eight mukhtars within the scope of the stakeholder engagement activities in June 2022 indicate that the mukhtars do not expect any adverse impacts to arise from the proposed development. The most important positive impact of the Project at the national level is perceived as the improvement of vaccine production and health services, while at local level it is expected that the Project will contribute to local employment opportunities as well as regional growth and development. The topics that the mukhtars would like to be informed the most are as follows:
 - The commencement and the end date of the Project construction,
 - The vaccination production process, how the vaccines will be produced and which vaccines will be produced,
 - As animal production will be performed within the scope of the proposed activities, will there be generation of odour emissions? What will be the measures to prevent this?
 - Local employment
- During the meetings with nine representatives of various neighbouring facilities, business enterprises and factories, two of the representatives expressed that the Project would not negatively affect corporate activities while three stated that they did not have adequate knowledge about the Project and the remaining told that their activities might get impacted. Potential adverse impacts voiced by the representatives are as follows:
 - During the construction phase, dust and noise might affect their work-related activities.
 - Any kind of changes in the employee shuttle and truck service routes due to Project traffic during the construction phase might increase the travel times. However, representatives stated that the new service route would be two or three kilometres longer

when compared to previous route and this would not be a major impact for facilities. Therefore, no request was raised by representatives on this issue. Mitigation measures to be taken on managing traffic impact are provided in Section 13.4.2 of the ESIA report.

- Possible closure of the section of the unnamed road (between parcel 1555-4 and the recreational area) as a result of the Project might adversely affect the enterprises and clients of Otonomi who currently unofficially use that road for test drives. Interviewed car dealers stated that Otonomi is placed on a very large land in which alternative roads for test drives could be created in case the existing unnamed road is closed.
- Possibility of labour loss to the Project by local private sector biotechnology facilities during the operation period due to competitive labour market.
- The topics that the workplace representatives would like to be informed the most are as follows:
- The commencement and the end date of the Project construction,
- Dust, noise and traffic impacts,
- Health measures to be taken.
- As mentioned earlier, a total of 109 household surveys were conducted within the scope of the stakeholder engagement activities in June 2022. Based on the results of the surveys, 64% of the participants stated that the Project is likely to cause positive impacts while 8% thought that the impacts of the Project might be adverse. 26% did not have an opinion about the impacts of the Project and 2% thought the Project will create both positive and negative impacts. The topics that the participants would like to be informed the most are as follows:
 - The commencement and end date of the Project construction,
 - Local employment,
 - Dust, noise and traffic impacts,
 - Health measures to be taken.
- Focus group interviews were held with women in Balıkhisar, Saracalar, Saray Gümüşoluk and Altınova neighbourhoods.
 - They believe the Project will create positive impacts both for Turkiye and for their neighbourhood. They hope the transportation systems around Balikhisar will be improved together with the Project.
 - They expect the Project to increase employment opportunities and improve the neighbourhood.
 - Women residing in Balıkhisar, Saray Gümüşoluk and Altınova neighbourhoods did not report any concerns related to the Project and its impacts.
 - Women residing in Saracalar neighbourhood have concerns about the waste and pollution related to the Project. Also, they stated that the existence of workers from outside the neighbourhood during construction may make them feel insecure.
- According to the interviews conducted with key governmental stakeholders, the Project is expected to have positive impacts on national and local levels. The interviewed stakeholders believe that the most significant benefits of the Project will be vaccine production, improvements in the health sector, regional development and support for local employment. Even though in general the stakeholders do not believe that the Project would have negative impacts, they would like to be informed further about the Project including the measures to be taken against possible impacts as well as the operation practices. The important issues raised during of the consultations are summarized below:
 - As per the consultations held with Akyurt Municipality, when the Project starts operating, locals of Akyurt should be prioritized for employment. The Project should offer internship opportunities for the students and graduates of the Health Vocational High School in the district. Akyurt Municipality also once again noted the flood risk and reclamation

requirements associated with the Çubuk stream and that the issue needs to be consulted with the General Directorate of State Water Works (DSI).

- According to the consultations held with DSI, no rehabilitation works have been performed or are planned by DSI on the adjacent section of Çubuk Stream. A flood study and stream rehabilitation works (including a flood protection wall) are highly needed for this region. The Watershed Management, Monitoring and Allocations Branch Manager of DSI stated that the authority has already performed a flood study for the Project area and notified MoH (with their letter dated 28 February 2022) of their findings including the flood level to be taken into consideration for the design of structures.
- According to the consultations held with the Ankara Metropolitan Municipality (AMM) and Ankara Water and Sewerage Administration (ASKI), there are wastewater infrastructure deficiencies in the area where the Project will be developed. It was noted by the ASKI Deputy General Manager that an official letter should be submitted to ASKI to inquire about the infrastructure requirements of the Project. It was also reported that the AMM has facilities in place with the capacity to dispose of all wastes likely to be produced by the Project and operates a waste incineration plant for disposal of the pathogenic wastes. The medical wastes to be produced by the Project will be collected by ITC, which is a licensed medical waste disposal company contracted by AMM.

3 National Regulatory and International Requirements

3.1 Overview

The SEP itself has been prepared in compliance with, and stakeholder engagement activities identified in this SEP will conform to the following legislation and standards:

- Relevant Turkish national legislation
- Environmental and Social Framework of the World Bank

Further details of the relevant Turkish legislation and applicable international requirements are provided in the Chapter 3 of the ESIA report.

3.2 National Legislation and Requirements

Under the scope of the current Turkish EIA Regulation (published in the Official Gazette dated 29 July 2022 and numbered 31907), several references are made to information disclosure and stakeholder participation.

The legal obligation to organise a public consultation meeting at the beginning of the national EIA process in Turkiye is defined within this Regulation on EIA. This Regulation refers to informing and consulting the public about the Project, holding the meeting at the Project site, prior approval of the place and date of the meeting by the Governor and announcement in a local and national newspaper at least 10 days before the meeting.

3.3 World Bank Stakeholder Engagement and Consultation Requirements

The World Bank's Environmental and Social Framework (ESF) (effective as of October 2018) has been primarily taken into account during the stakeholder engagement and SEP development processes of the ESIA study. In addition, the consultation principles on openness, access to information, accountability, transparency, visibility and accessibility that are defined in the World Bank Group Consultation Guidelines (effective as of June 2019) have been taken into consideration during the stakeholder engagement and SEP preparation processes.

The Environmental and Social Standards (ESSs) of the World Bank ESF that are relevant to the stakeholder engagement are listed in Table 3-1 below.

ESS	Key Policies and Objectives
ESS 1: Assessment and Management of Environmental and Social Risks and Impacts	ESS1 sets out the Borrower's responsibilities for assessing, managing and monitoring environmental and social risks and impacts associated with each stage of a project supported by the Bank through Investment Project Financing, in order to achieve environmental and social outcomes consistent with the ESSs.
	Accordingly, the Borrower will continue to engage with, and provide sufficient information to stakeholders throughout the life cycle of the project, in a manner appropriate to the nature of their interests and the potential environmental and social risks and impacts of the project. For High Risk and Substantial Risk projects, the Borrower will provide to the Bank and disclose documentation, as agreed with the Bank, relating to the environmental and social risks and impacts of the project prior to project appraisal. The documentation will address, in an adequate manner, the key risks and impacts of the project, and will provide sufficient detail to inform stakeholder engagement and Bank decision making.
ESS 10: Stakeholder Engagement and Information Disclosure	This ESS recognizes the importance of open and transparent engagement between the Borrower and project stakeholders as an essential element of good international practice. Effective stakeholder engagement can improve the

Table 3-1: The ESSs of the World Bank that are relevant to the stakeholder engagement

ESS	Key Policies and Objectives	
	environmental and social sustainability of projects, enhance project acceptance, and make a significant contribution to successful project design and implementation. This ESS ensures that the process of stakeholder engagement will involve the following: stakeholder identification and analysis; planning how the engagement with stakeholders will take place; disclosure of information; consultation with stakeholders; addressing and responding to grievances; and reporting to stakeholders.	

4 Stakeholder Identification and Analysis

4.1 Overview

Project stakeholders are defined as individuals, groups or other entities who:

- are impacted or likely to be impacted directly or indirectly, positively or adversely, by the Project (also known as 'affected parties'); and
- may have an interest in the Project ('interested parties'). They include individuals or groups whose interests may be affected by the Project and who have the potential to influence the Project outcomes in any way.

Cooperation and negotiation with the stakeholders throughout the Project development often also require the identification of persons within the groups who act as legitimate representatives of their respective stakeholder group (i.e. the individuals who have been entrusted by their fellow group members with advocating the groups' interests in the process of engagement with the Project). Community representatives may provide helpful insight into the local settings and act as main conduits for dissemination of the Project-related information and as a primary communication/liaison link between the Project and targeted communities and their established networks that are identified as the Project stakeholders. Verification of the stakeholder representatives (i.e. the process of confirming that they are legitimate and genuine advocates of the community they represent) remains as an important task in establishing contact with the community stakeholders. Depending on the different needs of the identified stakeholders, the legitimacy of the community representatives can be verified through a random sampling of community members by using techniques that would be appropriate and effective when the necessity to prevent coronavirus (COVID-19) transmission is considered.

4.2 **Project Stakeholders**

The Project stakeholders are categorized under two subjects as external stakeholders and internal stakeholders. In the stakeholder analysis, the roles of the internal stakeholders in the Project, institutional stakeholder participation and their involvement are described. In the analysis of external stakeholders, the role of stakeholders, methods and activities to consult and engage with them, and the frequency and subject of the of the engagement activities to be conducted with stakeholders during the Project's lifecycle are discussed.

4.2.1 Internal Stakeholders

Internal stakeholders are direct workers of the Project, contractors/ subcontractors and their workers, and Project-related consultants as well as experts of the Project's construction and operation phases. Project workers are significant stakeholders for technical, environmental and social performance of the Project.

4.2.2 External Stakeholders

External stakeholders in the Project represent the stakeholders affected by the Project or affecting the Project in some way. Identified external stakeholders for the Project are public institutions/ governmental bodies, non-governmental bodies, universities and research laboratories, neighbouring and nearby facilities, media, and the households, settlements, vulnerable/disadvantaged groups, community members that have a potential to be affected by the Project. In Figure 4-1, the external stakeholders in the Project are summarized.



Figure 4-1: Identification of Stakeholders and Engagement Scheme

These stakeholders are the stakeholders who directly or indirectly affected by the Project and are likely to be affected from other activities of the Project.

Directly Affected Stakeholders (Affected Parties)

These stakeholders are the stakeholders who are directly affected by the construction and operation activities of the Project. These activities and possible negative impacts are traffic, dust and noise during construction phase of the Project.

Directly affected stakeholders and their settlements are determined as following:

- Mukhtars and residents of Balıkhisar, Saracalar, Saray Gümüşoluk and Altınova neighbourhoods
- Users of agricultural lands near the Project site
- Workers and customers of business enterprises and factories near the Project site (Ministry of Health General Directorate of Public Health (GDPH) Vaccine and Pharmaceuticals Storage Warehouse, Otonomi, Otonomi Outlet Shopping Mall and Wellness Centre (to be constructed), YDS Yakupoğlu A.Ş., Işbir Yatak Mattress Factory and General Directorate, Işbir Sünger Mattress Foam Industry Factory, Student Selection and Placement Center (ÖSYM) Exam Centre, Halkbank Warehouse and Social Facilities, Man Turkiye, İşbir Optik, Borusan Automotive, Vilsan Veterinary and Medicine Industry (Vilsan Veteriner ve İlaç Sanayi), Turkish Medicine and Serum Industry, TTS Türktıpsan A.Ş, TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)
- Municipalities and district governorates of Akyurt and Pursaklar districts

Some groups within the directly affected stakeholders (i.e. users of agricultural lands near the Project site) might be affected from dust during construction phase. Additionally, the crops and irrigation system in the agricultural lands might be damaged due to Project-related activities. A stream remediation on the Çubuk Stream will be conducted as a part of the Project. Especially, the timing of stream remediation works is very critical for the agricultural workers since they draw water from the stream for their agricultural activities.

Transportation services (i.e. workers' shuttles, trucks, automobiles) of some business enterprises and factories may be affected by the Project's construction phase activities. They may need to change to transportation routes due to changes in roads., Also, excessive dust 19

deriving from construction activities may interfere with their factory production and preservation of the products.

Considering the potential impacts, it is important to be in a regular, open and transparent communication with these stakeholders.

Among project-affected there may be individuals or groups who, because of their particular circumstances, may be disadvantaged or vulnerable. They may be more likely to be adversely affected by the project impacts, and/or more limited than others in their ability to take advantage of the Project's benefits, and/or more limited to participate fully in the consultation process. They may require specific measures to overcome these limitations.

Other interested parties

The related stakeholders in this group are as follows:

- All public institutions operating on national, regional, and local levels and being able to affect the Project activities,
- Educational institutions, universities, and research institutes interested in the Project purpose, objective, and outcomes,
- All media organizations making news on and promoting the Project
- NGOs interested in the Project's outcomes and activities
- Mukhtars of the neighbourhoods adjacent to the Project-affected neighbourhoods (Güzelhisar, Saray Cumhuriyet, Yenice and Dumlupinar)
- All health institutions that are interested in the Project

4.2.2.1 List of External Stakeholder Groups

Identified key stakeholders are given in the tables below.

Table 4-1: Directly Affected Stakeholders

Level	Organization	Relation to the Project	
Neighbouring Facilities	YDS Yakupoğlu A.Ş.	Facilities, centres and lands/parcels, neighbouring to the Project site, are key stakeholders, who may be subject to impacts from both construction and operational phase of the Project.	
	Işbir Yatak Mattress Factory and General Directorate		
	Otonomi (highway vehicles sales point)		
	GDPH Vaccine and Pharmaceuticals Storage Warehouse of MoH		
	Private parcel owners (agricultural lands/parcels located to the northwest of the Project site- northern side of the Çubuk stream)		
	Project representatives of Otonomi Outlet Shopping Mall and Wellness Centre		
	Student Selection and Placement Center (ÖSYM) Exam Centre		
	Halkbank Warehouse and Social Facilities		
	lşbir Sünger Mattress Foam Industry (İşbir Sünger Sanayi Ticaret A.Ş.)		
	Man Turkiye	 Facilities, located in close proximity to the Project site, are key stakeholders who may be subject to impacts from both construction and operational phase of the Project. 	
Nearby	İşbir Optik		
Facilities	Borusan Automotive		
	Vilsan Veterinary and Medicine Industry (Vilsan Veteriner ve İlaç Sanayi)		
	Turkish Medicine and Serum Industry (Türk İlaç ve Serum Sanayi)	_	
	TTS Türktıpsan A.Ş		
	TURKplast (Türkiye Plastik Medikal Ürünler A.Ş.)		

Level	Organization	Relation to the Project
Settlements	Neighbourhoods within a radius of approximately 5 km to the Project site include Saracalar, Balıkhisar, Saray Gümüşoluk, Altınova, Yenice, Saray Cumhuriyet and Dumlupınar	Neighbourhoods are key stakeholders who may be subbject to potential impacts of the Project.
Vulnerable/ Disadvantaged Groups	Female workers of the closest businesses near the Project site	Vulnerable groups are key stakeholders who may be subject to potential impacts of the Project.
	Elderly, disabled, women headed households in Balıkhisar, Saray Gümüşoluk, Saracalar and Altınova neighbourhoods	
	Women groups in Balıkhisar and Saracalar neighbourhoods	
	People with disabilities	
	The elderly	
Community Members	Individuals and groups residing in the neighbourhoods within a radius of approximately 5 km to the Project site	Community members are key stakeholders who may be subject to potential impacts of the Project.
	Community workers employed or to be employed for the construction activities (including contractors and subcontractors)	
	Workers of neighbouring facilities	

Table 4-2: Other Interested Parties

Level	Organization	Relation to the Project	
	Ministry of Health (MoH)		
· ·	MoH, General Directorate of Health Investments	-	
	MoH, General Directorate of Public Health	•	
	MoH, General Directorate of Public Hospitals	- - - The Project has been proposed by MoH. MoH will be responsible for	
	MoH, General Directorate of Administrative Services		
	MoH, General Directorate of Health Information Systems		
	MoH, General Directorate of Health Services	operation of the Project.	
	MoH, General Directorate of Health Improvement		
	MoH, General Directorate of Emergency Health Services		
	MoH, Office of Press and Public Relations		
	MoH, Health Institutes of Turkiye (TUSEB)	_	
	MoH, Turkish Medicine and Medical Devices Agency		
	Ministry of Agriculture and Forestry (MoAF)	_	
	MoAF, General Directorate of Food and Control	_	
	MoAF, General Directorate of Livestock	 MoAF may have specific views about the operation of the Project related to R&D, laboratories and production units. 	
	MoAF, General Directorate of Fisheries and Aquaculture		
	MoAF, General Directorate of State Hydraulic Works		
National	MoAF, General Directorate of Water Management		
Governmental	MoAF, Veterinary Control Central Research Institute		
Bodies	MoAF, Foot and Mouth Disease Institute (\$AP Institute)		
	Ministry of Environment, Urbanization and Climate Change (MoEUCC)	_	
	MoEUCC, General Directorate of EIA, Permit and Audit	-	
	MoEUCC, General Directorate of Environmental	MoELICC has regulatory functions in	
	Management	 relation to the Project such as environmental impact assessment permits and environmental permitting. 	
	MoEUCC, General Directorate of Intrastructure and Urban		
	I ransformation		
	MoEUCC, General Directorate of Spatial Planning		
- - - - -	Ministry of Transport and Infrastructure (MoTI)	MoTI may have specific views	
	MoTI General Directorate of State Airports Authority	regarding evaluation of the Project	
	MoTI Civil Aviation General Directorate	which is approximately 2,000 m away	
	MoTI General Directorate of Infrastructure Investments	 from Esenboğa Airport, according to the obstacle plan and other relevant legislation as well as existing and planned structures and legislation in the region. 	
	MoTI General Directorate of Highways		
	Ministry of Labour and Social Security (MoLSS)		
	MoLSS, General Directorate of Labor	-	

Level	Organization	Relation to the Project	
	MoLSS, General Directorate of Occupational Health and Safety	MoLSS may have specific views on labour and working conditions, and health and safety of facility personnel.	
	Ministry of Interior, Disaster and Emergency Management Presidency (DEMP- AFAD in Turkish)	AFAD has a function to respond to emergency situations and cooperate with various government agencies.	
	Ministry of Industry and Technology (MoIT)		
	MolT, General Directorate of Research and Development Incentives MolT, General Directorate for Strategic Research and	MoIT may have views on technology development.	
	Productivity		
	Scientific and Technological Research Council of Turkiye (TUBITAK) Marmara Research Center- Institute of Genetic Engineering and Biotechnology	TUBITAK may have specific views on the Project on R&D aspects.	
	Ministry of Culture and Tourism (MoCT)	MoCT may have views in terms of	
	MoCT General Directorate of Cultural Heritage and Museums	legislation.	
	5 th Regional Directorate of DSI (State Hydraulic Works)	This organization may have specific views about water courses running close to the Project site.	
	9 th Regional Directorate of Ministry of Agriculture and Forestry	This organization may have specific views on the potential protected areas close to the Project site and the status of the trees in the Project site.	
Regional Governmental	4 th Regional Directorate of General Directorate of Highways	The organization may provide opinion regarding road crossing within the Project site.	
Bodies	Ankara Regional Board Directorate of Cultural Assets Protection	This organization is an important stakeholder to identify and clarify the archaeological potential of the Project site.	
	The Governorship of Ankara	The governorship representing the national government is the highest authority in the province.	
	Ankara Metropolitan Municipality		
	Ankara Metropolitan Municipality, Directorate of		
	Ankara Metropolitan Municipality. Directorate of Zoning and		
	City Planning	The metropolitan municipality and its relevant departments will have responsibilities in relation to the Project.	
	Ankara Metropolitan Municipality, Directorate of		
	Transportation		
	Ankara Metropolitan Municipality, Ankara Electricity, Gas and Bus Operations Organization (EGO Concred Directorate)		
	Ankara Metropolitan Municipality Directorate of Health		
	Services		
	Ankara Governorship Provincial Directorate of Health	T he second state of the second state of the	
Provincial	Ankara Provincial Directorate of Health, Pharmacy and	the provision of health services and healthcare workforce in the province.	
Governmental	Medical Devices Branch		
Bodies -	Ankara Governorship Provincial Directorate of Social Security Institution	This organization may provide specific views on labour and working conditions, and health and safety of facility personnel.	
	Ankara Governorship Provincial Directorate of Environment, Urbanization and Climate Change (PDoEUCC)	PDoEUCC has regulatory functions related to the Project such as environmental impact assessment permits and environmental permitting.	
	Ankara Provincial Directorate of Agriculture and Forestry	These organizations may provide	
	Esenboğa Airport Veterinary Border Control Directorate (under MoAF)	provincial-specific and/or site-specific views on the Project.	
	Ankara Provincial Directorate of Disaster and Emergency Management	These organizations have a function	
	Ankara Provincial Command of Gendarmerie	to manage and respond to	
	Ankara Water and Sewer Administration (ASKI)	These organizations may provide an	
	ASKİ Akyurt Regional Directorate	opinion related to water/wastewater	
	The Local Governorship of Akyurt, The Municipality of Akyurt		

Level	Organization	Relation to the Project	
	Directorate of Zoning and Urbanisation	The Project site is located in Akyurt	
District Level	Directorate of Civil Works	 district and the local governorship, the central municipality and their related 	
	Directorate of Plan and Project		
Governmental	Directorate of Cleaning Works	 departments are stakeholders regarding obtaining relevant permits 	
Bodies	Directorate of Municipal Police	approvals during planning and	
	Akyurt District Directorate of Health	construction and operation phases of	
	The Local Governorship of Pursaklar, The Municipality of Pursaklar	the Project.	
	Turkish Medical Association	It is important to engage this association to understand their concerns.	
	Turkiye Trade Union of Health Workers (Sağlık-İş)		
	Trade Union of Public Employees in Health and Social Services (SES)	_	
	Trade Union of Revolutionary Health Workers (Dev-Sağlık İş)	_	
	Trade Union of Employees of Health and Social Services (Sağlık-sen)		
	Trade Union of Turkish Health (Türk Sağlık-sen)	_	
	Independent Trade Union of Public Workers in Health and Social		
	United Trade Union of Public Workers in Health and Social Services	-	
	(Genel Sağlık İs)		
	Turkish Microbiology Society (TMC)	- The demotion of the second second station is the second	
	Turkish Clinical Microbiology and Infectious Diseases Association	 I rade unions and associations are important stakeholders representing 	
	(KLİMİK)	the labour rights of health sector	
	Turkish Infectious Diseases and Clinical Microbiology Specialization Association (EKMUD)	personnel and research and development laboratories.	
	Prevention of Communicable Diseases Association (BUHASDER)	-	
National Non-	Pediatric Infectious Diseases and Immunization Association		
Governmental	Clinical Research Association		
Bodies	Infectious Diseases Association (EHD)	-	
	Turkish Hospital Infections and Control Association (HIDER)	-	
	Researcher Pharmaceutical Companies Association (AIFD)	- - -	
	Public Health Specialist Association (HASUDER)		
	Turkish Thoracic Society		
	Turkish Red Crescent (Kızılay)		
	Turkiye Confederation of Disabled	Requesting opinion of this federation is important to understand their expectations.	
	Animal Right's Federation (HAYTAP)	These are important stakeholders	
	Turkish Protection of Animals Association (THKD)	representing the animal rights.	
	World Health Organization (WHO) - Turkiye	Requesting opinion of this organization is important to understand their views and requirements.	
	Chamber of Environmental Engineers	·	
	Chamber of Forests Engineers	_	
	Chamber of City Planners	_	
		These chambers and associations	
		_ may provide provincial-specific and or	
Provincial	Environmental Protection Foundation (TUÇEV)	site-specific views related to the	
and District	Ankara City Council	_ Project.	
Level Non-	Ankara Chamber of Industry	_	
Governmental	Ankara Chamber of Trade	_	
Bodies	Akyurt Industrial and Business People Association	It's formation the second second second	
Media	Local, regional and social media (including newspapers, TV stations, social media channels)	It is important to engage with local and regional media organizations for effective public disclosure and consultation.	
	Ankara University- Faculty of Veterinary		
Universities,	Koc University (Istanbul)-Research Centre for Translational Medicine	 Universities and research laboratories 	
Research	(KUTTAM)	are among the interested parties in terms of conducting research and other partnerships in laboratory studies.	
Laboratories Centres and	Koc University (Istanbul)-İşbank Centre for Infectious Diseases (KUISCID)		
Companies	Erciyes University-Vaccine Research Development Centre (ERAGEM)		
	Istanbul University- Faculty of Veterinary Medicine		
Level	Organization	Relation to the Project	
-------	---	-------------------------	
	TUBITAK Marmara Research Centre (MAM) - Genetic Engineering and		
	Biotechnology Institute	_	
	Dollvet Biotechnology Inc.	-	
	Vetal Animal Health Products Inc.	-	

4.2.2.2 Disadvantaged/ vulnerable individuals or groups

According to the data provided by Akyurt and Pursaklar District Social Assistance and Solidarity Foundation, there are a total of 178 people receiving elderly pension in Akyurt district and three of these reside in Balıkhisar neighbourhood. It was also reported that 203 people receive disability benefits in Akyurt district, of which three reside in Balıkhisar. In Pursaklar district, there are a total of 358 people receiving elderly pension and 522 people receiving disability benefits. Of those receiving elderly pension in Pursaklar, three, two and 19 of them are living in Altınova, Saray Gümüşoluk and Saray Cumhuriyet neighbourhoods respectively. 16 residents from Altınova neighbourhood, one resident from Saray Gümüşoluk neighbourhood and 65 residents from Saray Cumhuriyet neighbourhood receive disability benefits for themselves or their relatives.

According to the results of household surveys, of the total number of the household head surveyed,

- 29% are women,
- 14% are persons with disabilities, and
- 48% are over 65 years of age.

As of 2021, the total female population of Balıkhisar and Saracalar neighbourhoods, which are the closest settlements to the Project area, is 1,010. It is observed during the site visit conducted in June 2022, the number of female employees in the ten workplaces surveyed varies between 500 and 999.

5 Stakeholder Engagement Programme

5.1 Overview

The stakeholder engagement programme outlines a systematic approach to inform and communicate with stakeholders throughout the Project lifecycle. This section provides a plan for the main stakeholder engagement activities that will be undertaken during the construction and operation phases of the Project. In order to meet best practice approaches, the Project will apply the following principles for stakeholder engagement programme:

- Openness and life-cycle approach: public consultations for the Project will be arranged during the whole Project lifecycle, carried out in an open manner, free of external manipulation, interference, coercion or intimidation,
- Informed participation and feedback: information will be provided to and widely distributed among all stakeholders in an appropriate format; opportunities are provided for communicating stakeholders' feedback, for analysing and addressing comments and concerns, and
- Inclusiveness and sensitivity: stakeholder identification is undertaken to support better communications and build effective relationships. The participation process for the Project is inclusive. All stakeholders are encouraged to be involved in the consultation process, to the extent the current circumstances permit. Equal access to information is provided to all stakeholders. Sensitivity to stakeholders' needs is the key principle underlying the selection of engagement methods.

5.2 Vulnerable Groups Considerations

The vulnerable groups relevant to the Project are identified as women, poor, elderly, and persons with disabilities. On the basis of the vulnerable group identification, the SEP will follow a gender sensitive approach through all phases of the Project and stakeholder engagement activities. Women living in the neighbourhoods in close proximity to the Project site, women working in nearby business enterprises and factories, women to be employed for the Project activities, and other women stakeholders will be informed on the Project and its impacts, actions to be taken, the Environmental and Social Action Plan (ESAP), employee relationships, labour management, and grievance mechanism.

The same sensitive approach will be adopted for the poor, elderly, and disabled during the stakeholder engagement activities. These vulnerable people will be regularly consulted throughout the construction and operation phases by the Project's community liaison officers.

During the consultations with the disabled, audio devices and accessible platforms will be applied. Special education coordinators as well as sign language translators will take part in the consultation meetings when necessary. For the elderly, the consultation areas will be ensured to be accessible.

They will receive the information about the Project including the impacts, mitigation measures, and grievance mechanism. Their grievances will be registered to the grievance log as specified in the SEP.

Even though no risk of sexual exploitation and abuse/sexual harassment (SEA/SH) was identified and assessed during the site visits and consultations (including focus group meetings with women), mitigation measures to prevent the risk of SEA/SH will be taken throughout the Project lifecycle. The received grievances will be categorized by considering the subject of the grievance and the gender of the grievance applicant.

5.3 Pandemic Mitigations

In case of new pandemic conditions, measures will be in place to undertake virtual consultations rather than face-to-face meetings.

5.4 Stakeholder Engagement Approach and Future Stakeholder Engagement

Table 5-1: Stakeholder Engagement Approach and Future Stakeholder Engagement

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Cor Met	nmunication hods	Period	Re	esponsible
Local	Communities							
	Neighbouring facilities, nearby facilities, factories and businesses		 Consultation about the Project stages, informing on possible effects of the Project and communication mechanism with stakeholders, informing about grievance mechanism of the project 	•	Visit Face-to-face consultation		•	PMSU
1	Residents in the closest neighbourhoods	Local	 Project Environmental and social impacts of the Project Mitigation measures defined within the ESIA report 		meeting Website	Construction and Operation	•	Community Advisory
	lisers of the closest agricultural	_			Social media			Board (CAB)
	lands		 ENALTY Control and Social Management Plans ESIA report, SEP, PID and other Project related documents 	•	Posters, billboards Online meetings			
			 Consultation about Project stages, informing about possible effects of the Project and communication mechanisms with 	•	Visit			
	Mukhtars of the Project Impacted Neighbourhoods (Balıkhisar, Saracalar, Saray		 stakeholders, informing about grievance mechanism of the Project Mitigation measures defined within the ESIA report 	•	Consultation meeting		•	PMSU
2	Gümüşoluk, Altınova) and their neighbour settlements	Local	 Environmental and social impacts of the Project 	•	Web site	Construction		САВ
	(Güzelhisar, Saray Cumhuriyet, Dumlupınar and Yenice)		Environmental and Social Management Plans	•	Social media			
			 Local employment ESIA report, SEP, PID and other Project related documents 	•	Posters Online meetings			
3	Vulnerable Groups		Consultation about Project stages, informing about possible	•	Visit			
	Elderly	-	effects of the Project and communication mechanisms with stakeholders, informing about grievance mechanism of the	•	Consultation			514011
	People with disabilities	Local	Project, provisions to prevent the risks of sexual	•	Web site	Construction and Operation	•	PMSU
	Women	-	(SEA/SH)	•	Social media			
	Children		 Mitigation measures defined within the ESIA report 	•	Posters			

27

Νο	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
	Female workers of the closest businesses and factories		 Environmental and social impacts of the Project Environmental and Social Management Plans Local employment ESIA report, SEP, PID and other Project related documents 	 Accessible platforms with audio devices, special education coordinators and sign language translators when necessary 		
Public	Institutions					
4	Public institutions/ stakeholders at national level Public institutions/ stakeholders at	National	 Consultation about Project stages, informing about possible effects of the Project as well as grievance mechanism of the Project, Permissions, consultation about Project stages; informing about grievance mechanism of the Project Environmental and social impacts of the Project 	 Visit Correspondence Website Online meetings Visit 	Construction and Operation Construction and	PMSUMoH
U	provincial and district level	incial and district	 Mitigation measures defined within the ESIA report Environmental and Social Management Plans 	Correspondence	Operation	• FM30
6	District Municipalities	Regional	 Consultation about the Project, informing about grievance mechanism of the Project, interviewing for grievances, receiving opinions and recommendations Environmental and social impacts of the Project Mitigation measures defined within the ESIA report Environmental and Social Management Plans 	VisitCorrespondence	Construction and Operation	• PMSU
Educat	tional Institutions					

Mott MacDonald | Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project Stakeholder Engagement Plan

No	Stakeholders	Activity Level	Issues to be consulted/discussed	Communication Methods	Period	Responsible
7	Universities and Research Laboratories	Regional	 Consultation about Project stages, informing about possi effects of the Project and communication mechanisms w stakeholders, informing about grievance mechanism of th Project ESIA report, SEP, PID and other Project related docume 	ble Visit ith he Consultation meeting ents Website	Construction and Operation	• PMSU
Prima	ary Health Care Institutions					
8	Hospitals, Health Centres and Pharmacies	Regional	 Consultation about Project stages, informing about possi effects of the Project and communication mechanisms w stakeholders, informing about grievance mechanism of th Project 	 Visit Consultation meeting Website 	Construction and Operation	PMSUMoH
			 ESIA report, SEP, PID and other Project related docume 	nts Social media		
NGO	8			Posters		
	-	National	 Consultation about general stages of the Project and construction activities Consultation about expected positive and negative effect the Project, informing about grievance mechanism of the Project 	 Visit Consultation meeting 	Construction and	• PMSU
9	NGOs	and Regional	 Environmental and social impacts of the Project 	Website	Operation	 CAB
		0	Mitigation measures defined within the ESIA report	 Social media 		
			 Environmental and Social Management Plans 	 Posters 		
			ESIA report, SEP, PID and other Project related docume	nts		
Medi	а					
10	Media Associations and Agencies	National and Regional	 Sharing information on general stages of the Project and construction activities Consultation about expected positive and negative effects 	 Press release Visit S of Consultation meeting 	Construction	PMSUCAB
		the Project, informing about grievance mechanism of the Project	Website		-	

• ESIA report, SEP, PID and other Project related documents • Social media

Inter	nal Stakeholders									
11	MoH Units	National and	• tional and	Project updates and changes in operations information on labour rights, contract information, code of conduct including provisions for SEA/SH, workers' grievance mechanism of the Project etc.		Trainings Face to face meetings	rainings ace to face meetings Construction			
••	suppliers, construction workers	Regional	•	Workers' grievance mechanism	•	Visit	and Operation	•	MoH	
			•	Environmental and Social Management Plans	•	Correspondence				
			•	ESIA report, SEP, PID and other Project related documents						

6 Disclosure and Consultation Process

Public disclosure and engagement activities of the Project are managed by PMSU of the MoH and have been carried out with the support of the ESIA team. A virtual public consultation meeting was held on 20 May 2024 (at 14:00) following the approval of the draft ESIA report by the WB and the disclosure of the report on the MoH website. The meeting was undertaken virtually to allow for wider participation of public and stakeholders. The public consultation meeting was announced to the Project stakeholders by invitations through e-mail and telephone. Links to the Project documents (including draft final SEP and ESIA) published on the PMSU website (https://pydb.saglik.gov.tr/TR-103390/turkiye-halk-sagligi-acil-durumlarina-hazirlikli-olma-projesi.html) were also delivered to stakeholders.

The MoH invited public institutions via official letters which included the link to the virtual meeting. Mukhtars, being the primary contact persons for reaching out to community members, were specifically contacted by phone. The mukhtars of the Balıkhisar and Saracalar neighbourhoods were invited to the meeting and were requested to announce the meeting to the local communities through appropriate methods. Additionally, nearby industrial facilities (İşbir Yatak, Otonomi, and YDS) were contacted prior to the meeting. An official invitation letter was sent to YDS, whose KEP (registered e-mail) address was available.

The virtual public consultation meeting was conducted with 30 participants representing the Project stakeholders. However, no representatives from the companies, mukhtars, or residents from the neighborhoods attended the meeting. The participants of the meeting are listed below:

- Project Management Support Unit of MoH
- General Directorate of Public Health of MoH
- General Directorate of Health Investments of MoH
- Ankara Provincial Health Directorate
- Ministry of Agriculture and Forestry
- Ministry of Environment, Urbanization, and Climate Change
- Ministry of Industry and Technology
- Ankara Metropolitan Municipality
- General Directorate of State Hydraulic Works
- District Governorship of Akyurt
- Akyurt District Health Directorate
- Mott Macdonald (ESIA Consultant)

The new project of MoH, which will be financed by the WB (Türkiye Preparedness for Public Health Emergencies Project) and includes financing of the Project was presented to the participants by PMSU at the beginning of the meeting. The objective and components of the Project, proposed activities, potential environmental and social impacts, proposed mitigation measures, and information about the framework E&S plans were presented by PMSU to the participants. Following the PMSU presentation, the ESIA consultant Mott MacDonald's experts provided details about the ESIA Report, which was finalized prior to the meeting and disclosed on the PMSU website. This presentation covered the project description, project significance, its potential environmental and social impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. The presentation was supported with figures, photographs and maps, and the impacts of the construction and operation phases of the project were presented separately.

Participants were invited to ask questions and provide comments after the presentations during the question-and-answer section. However, no positive or negative feedback was received from the stakeholders. The contact information for PMSU environmental and social experts was

provided to the participants, allowing project stakeholders to reach out with any potential questions or comments.

Given that no representatives from the companies, mukhtars, or neighborhood residents attended the virtual meeting, PMSU conducted additional on-site engagement activities after the virtual consultation meeting. On 12 June 2024, mukhtars of Balıkhisar and Saracalar neighborhoods were met at their offices. They were informed about the ESIA disclosure process, project schedule, technical details, potential environmental and social impacts, proposed mitigation measures, stakeholder consultation process, and grievance mechanism. Following the introduction to the mukhtars, details about the Project were presented to the local people at the Balıkhisar neighborhood tea house. Approximately 15 local residents attended the meeting, and participants indicated that there were no grievances related to the Project due to the location of the project area. Participants stated that there is no interaction between the settlements and the project area, and that the Ankara-Esenboğa Airport road acts as a natural barrier. The website link to the ESIA report and information on the grievance mechanism were provided to the participants.

In addition, İşbir Yatak and Otonomi representatives were visited as part of the on-site engagement activities, which had been consulted at the beginning of the ESIA studies. YDS representatives were attempted to be reached, however, no response was received and they could not be contacted for a meeting. The Deputy General Director of İşbir Yatak and the operations manager of Otonomi were informed about the ESIA process and technical details of the Project. Information about the stakeholder engagement processes and grievance mechanism tools was presented to the stakeholders. It was learned that no external grievances from the workers of İşbir Yatak and enterprises of Otonomi had been sent to the management, and there were no grievances about the Project activities.

Since the kindergarten will be used by the children of health workers to be employed in the VPC who have not been selected yet, it is not possible to consult with the parents at this stage. However, future consultations regarding the ESIA will include these parents.

7 Grievance Mechanism

The main objective of a Grievance Mechanism (GM) is to assist resolve complaints and grievances in a timely, proactively, unbiased, effective and efficient manner that satisfies all parties involved. Specifically, it provides a transparent and credible process for fair, effective and lasting outcomes. It also builds trust and cooperation as an integral component of broader community consultation that facilitates corrective actions. It aims at continuously improving the Project performance through regular assessments of the grievances and identifying structural adjustments by conducting root cause analysis. It is necessary to disclose the grievance mechanism to all stakeholders in a clear and understandable way. As defined in the Environmental and Social Management Framework (ESMF)⁴ developed by the PMSU, the GM of the Project:

- Provides affected people with avenues for making a complaint or resolving any dispute that may arise during the course of the implementation of projects,
- Ensures that appropriate and mutually acceptable redress actions are identified and implemented to the satisfaction of complainants,
- Supports accessibility, anonymity, confidentiality and transparency in handling complaints and grievances, and
- Avoids the need to resort to judicial proceedings (unless as a last resort).

The Project parties involve the MoH (including PMSU and the Project Implementation Unit), EPC (Engineering, Procurement and Construction) Contractor of the construction activities of the Project, and the supervision consultant during the operation phase. To ensure the successful implementation and management of the Project GM, each party will assign community liaison officers for managing grievances as well as implementing stakeholder engagement and disclosure activities in general.

7.1 Public Grievance Mechanism

Public grievance mechanism of the Project is in place in order to ensure that all public stakeholders identified within the scope of the Project can raise their grievances, concerns, suggestions or requests through defined grievance channels.

The public grievance mechanism is established in line with the ESMF prepared for the HSSSP. Accordingly, suggestions and complaints can be directed through the website of the PMSU⁵. Applications can also be directed by telephone and/or mail of PMSU contact addresses. Annex 10.1 of the SEP shows the Turkish version of the application form that is provided on the website of the PMSU. The public grievance mechanism channel of the PMSU is suitable for raising anonymous grievances.

As the Project concerns the whole country, national mechanisms that are already in use will also be available in accordance with the newly established grievance mechanism. These mechanisms are as follows:

7.1.1 SABIM: Communication Centre of Ministry of Health "Alo 184"

The Ministry of Health founded a Communication Centre (SABIM) in 2004 to receive complaints, problems and suggestions from employees, health workers and patients with the possibility of reporting anonymously. The following channels are involved in the SABIM:

⁴ Accessed from <u>https://pydb.saglik.gov.tr/Eklenti/42794/0/cevrevesosyalyonetimnihaitrpdf.pdf</u> on 28 January 2023.

⁵ https://pydb.saglik.gov.tr/TR-76672/talep-oneri-ve-sikayet-formu.html

- Hotline by phone "Alo 184" line, which is accessible 24/7,
- Website via https://sabim.gov.tr/,
- WhatsApp communication line via 0541 888 0184, or
- In person from the Patient Communication Unit

SABIM serves as a ministerial level grievance mechanism for its employees, health workers, patients and citizens at large. Inquiries, demands and complaints about all health services provided by the MoH are responded by professionally managed call centre personnel with 260 operators, 187 analysts and 69 other staff. SABIN has been also resolving issues related to COVID-19 pandemic. The hotline provides translation support in six languages English, German, French, Arabic and Russian.

Specialized services are provided for the disabled people under the "Unimpeded Health Communication Centre (ESIM)". The ESIM provides services 24/7 in sign language in order to ensure access of the disabled citizens to the health services. ESIM offers live interpreting services for the persons with hearing disorder while calling 112 ambulance centre, getting appointments from the Central Appointment System and during medical examinations.

Responsibilities and services given by SABIM are listed below:

- To conduct engagement and communication processes between complainant and the MoH via phone, e-mail, website, and WhatsApp,
- To process any data and grievance that is directed from CIMER, and
- To carry out processes related to the grievances from other public institutions and organizations regarding health services in Turkiye for both Turkish and non-Turkish citizens.

Applications to the Alo 184 are replied to and recorded by operators using a special software. The recorded applications are assessed by SABIM officials and transferred to related administrators. Firstly, the analyst examines the application. In the cases that need urgent solutions, the analyst conducts necessary research and coordination works by intervening immediately. For the cases that do not need urgent solutions, the analyst manages the resolution process by making an importance list among the cases during resolution process. After reaching a decision and resolution, citizens are informed in line with the legislation. If the applications require further investigation, they send the applications to the dispatch team. The dispatch team examines the applications, finalizes the applications when necessary, or sends them to the analyst of the Central or Provincial Health Directorates at the relevant unit depending on the content of the applications.

The Central or Provincial analyst examines all the details of the submitted application and takes the necessary actions. After these processes are completed, the citizen is informed as soon as any feedback is obtained in defined time frames. Transactions made and results entered into the system are evaluated by SABIM unit officers. The application whose review has been completed is closed by the Unit Responsible.



Figure 7-1: The Flowchart of SABIM

Analysts working at the headquarter and/or field units of the MoH have access to the system on the Internet, view duties assigned to them, take required actions, and report the results through the system. Administrators are able to monitor transactions of analysts, which were taken against applications concurrently through the system.

Grievances received by SABIM are resolved **no later than 15 business days** that is dictated under the Law of Right to Information No. 4982. Institutions and organizations provide access to information or document requested upon application **within 15 business days**. However, number of days will raise to **30 business days** in cases the application concerns more than one institution and organization such as:

- The requested information or document is provided from another unit within the institution and organization applied for, and
- The opinion of another institution and organization is demanded.

According to statistics, 80% of the calls are resolved within 24 hours. Number of grievances received per month was close to 40,000 in 2019. With the COVID-19 pandemic, this number has surpassed 40,000. The MoH has increased its capacity by establishing "COVID-19 Team" consisting of analysts, psychologists, physicians, general practitioners and other health care staff such as nurse, healthcare officer, etc. in the communication centre due to the increase in calls and demand to get online medical counselling.

7.1.1.1 Principles of SABIM

Anonymity: With the "Hide My Personal Information" button on the application registration screen in SABIM, the information of the citizens can be hidden in accordance with the demands of the individuals and depending on the sensitive content of the application. However, in applications involving harassment allegations, it is informed that the information of the person

35

will be exposed due to the fact that the subject is being moved to the judicial authorities, and it is communicated that the application cannot be examined if the personal information is hidden. If the citizen gives consent to create applications without hiding their personal information, applications are directed to the relevant institutions. If the person has any statement of violence/ threat against the healthcare worker, there is also no confidentiality of personal information in these applications. Because the person's statements and information are notified to the institution's superiors by searching the relevant institution and by sending the application. However, if there is a grievance of the citizen in the meantime, the grievances are written in the application content in detail and the application is sent to the relevant institutions in order to evaluate the application.

Accessibility: Disabled people, asylum seekers, refugees and those with temporary protection (Syrians) registered in Turkiye can also reach SABIM. For those who are not native in Turkish, an Interpreter Line is available communication can be held simultaneously. Communication is provided by conducting teleconferences.

Objectivity, fairness, transparency: All grievances and feedbacks are handled with a fair and objective approach. Transparency is another main principle of the grievance mechanism.

Other than the principles mentioned above, the mechanism will be revised as follows:

Handling Sexual Exploitation and Sexual Harassment and Gender-Based Violence and Harassment (SEA/SH/GBVH) issues: The operators will be trained on how to handle grievances related to SEA/SH/GBVH. Health workers who are part of the outbreak response will be trained with the basic skills to respond to disclosures of SEA/SH/GBVH that could be associated with or exacerbated by the epidemic, in a compassionate and non-judgmental manner and know to whom they can make referrals for further care or bring into treatment centres to provide care on the spot.

Turkiye has already a national referral system for GBVH, not only domestic violence but also workplace related harassment, bullying, violence as well as SEA/SH at workplace, which all institutions and healthcare facilities are following⁶. These are under the auspices of Ministry of Labour and Social Security and already detailed in both the Turkish Labour Code No. 4857 and Turkish Penal Code No. 5237, where unacceptable behaviours are explained and relevant penalties are detailed. Psychosocial support is already provided for women and girls who may be affected by the outbreak and are also GBVH survivors.

The grievance mechanism that will be in place for the Project will also be used for addressing SEA/SH/GBVH issues at workplace and will have mechanisms for confidential reporting with safe and ethical documenting of SEA/SH/GBVH issues. Further, the grievance mechanism will also have processes to immediately notify both the MoH and the World Bank of any SEA/SH/GBVH cases and grievances, with the consent of the survivor. Therefore, the existing grievance mechanism will also be strengthened with procedures to handle allegations of SEA/SH/GBVH violations. The grievances related to exploitation of female workers, including sexual harassment and abuse at the workplace and unfair treatment will be prioritized to take actions. The Project Director, Deputy Project Director and Social Expert shall be responsible for taking appropriate action in cases in which there is reason to believe that any right has been violated. The appropriate designated authorities will be informed about investigations into cases of SEA/SH/GBVH, and of the action taken as a result of such investigations.

The number, frequency and the topics of the received grievances and feedbacks are analysed and reported periodically to the related units and administrative level. Based on these detailed

⁶ KADES – Women Support Application

reports, the most frequently addressed issues are identified and improvement activities are initiated.

7.1.2 CIMER: Turkish Presidential Communication Centre

The third national grievance mechanism is CIMER (Turkish Presidential Communication Centre). Grievances can be raised through:

- Hotline by phone "Alo 150" line,
- Petition and post to T.C Cumhurbaşkanlığı Külliyesi 06560 Beştepe, Ankara, TURKIYE, and
- Website via <u>CİMER T.C. Cumhurbaşkanlığı İletişim Merkezi (cimer.gov.tr)</u>.

CIMER delivers 99% of received grievances to the related governmental institutions in a timely and appropriate manner. Each grievance received for health sector via CIMER is already being conveyed to SABIM. Therefore, CIMER and SABIM systems are integrated.

7.1.3 YIMER: Foreigners Communication Centre

The "Foreigners Communication Centre" (YIMER) provides an opportunity for foreigners to convey grievances. YIMER will be available for foreign Project stakeholders to report their Project-related grievances through the following communication channels:

- Website: http://www.yimer.gov.tr,
- Call Centre: 157, or
- Phone number: +90 312 157 11 22.

7.1.4 Contractor and Supervision Consultant Level Public Grievance Mechanism

By integrating national grievance channels to the Project-specific grievance mechanism, all public grievances reported by the stakeholders in the scope of the Project will be recorded and addressed. Nevertheless, the Public Grievance Mechanism of the Project will not be limited to communication channels at national or ministerial level. Rather, public grievances will be received and managed at contractor and supervision consultant level. The main contractors of the Project to be employed for both construction and operation phases will establish their own public grievance mechanism specific for the Project and assign a community liaison officer for management of the Project-related grievances. These grievance mechanisms to be established by the contractors will be integrated to the existing system within the Project Grievance Mechanism.

If a grievance is received about the construction activities by the national/ministerial level grievance channels, the community liaison officer within the MoH will get in contact with the community liaison officer of the EPC Contractor who will be in charge of managing grievances received from both public and the Project workers (including subcontractors).

The community liaison officers of the contractors are responsible for reporting to the MoH about the closure of the grievances received via national/ministerial channels as well as the grievances received via the grievance channels of the contractors. The MoH will monitor all grievances through the reports provided by the contractors and the central grievance log.

After the grievances are successfully closed and the corrective actions are taken, the results of the grievances including anonymous grievances will be announced on the Project website (https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html).

7.1.5 Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)

The Project will have security measures (i.e. security personnel, surveillance system through security cameras) to minimise the risk of SEA/SH cases. In addition to the security measures, the public grievance mechanism channel of the PMSU is available and accessible by stakeholders to report their any grievances, suggestions or requests related to SEA/SH issues. The grievance mechanism allows for anonymous applications, which is especially critical for reporting any SEA/SH related issue. The privacy, health and safety of the grievance applicant will be the key principles in handling SEA/SH cases. The identity of the grievance applicant will be fully maintained to ensure confidentiality and hinder the risks of retaliation.

SEA/SH cases will be recorded and analysed as a part of the current grievance mechanism of Project. However, they will be approached in a more sensitive way and in an immediate timeframe.

The public grievance mechanism of the Project will be disclosed to the Project's external stakeholders through stakeholder engagement activities and consultation meetings as described above .

7.2 Workers' Grievance Mechanism

Workers' grievance mechanism covers all grievances, requests and suggestions reported by the Project employees (including Project Implementation Unit members, contractor and subcontractor workers) and the employees of the supplier companies within the scope of the Project.

A Project-specific Workers' Grievance Mechanism Procedure for both construction phase and operation phase will be prepared in line with the WB ESS2 requirements. The procedure will define the ways to report grievances, ways to address these grievances received from all Project employees, and community liaison officers for management of the workers' grievances.

The Procedure will be prepared and applied by the contractors throughout the life of the Project. While the MoH is responsible for the entire grievance mechanism of the Project, the contractors are responsible for establishing their own Workers' Grievance Mechanism Procedure and reporting the grievances as well as the outcomes of the mechanism to the MoH. The MoH will monitor the worker grievances through the reports provided by the contractors and the central grievance log.

Similar to the public grievance mechanism, the Project will embrace and integrate relevant national grievance mechanisms to the Project Grievance Mechanism. SBN (Health Meeting Point of Ministry of Health) is one of these grievance mechanisms that is in place for health workers. It is possible to raise anonymous grievances through SBN, which is explained in detail below:

7.2.1 SBN: Health Meeting Point of Ministry of Health "Alo 182"

Until the establishment of "Health Meeting Point of Ministry of Health (SBN)" website in 2011, workers in the health sectors used this system to raise their voices and submit grievances. However, the establishment of SBN generated a new platform for the health service personnel to raise their voices in addition to SABIM.

SBN is established for health service workers or graduates of any departments providing health education and all personnel of the MoH not only to gather up-to-date information about appointment rules, compassionate leave, permutation requests, promotion exams but also to submit grievances and any suggestions. To benefit from SBN services, members of

mentioned worker groups need to register to the system. As of July 2020, there are over 58,000 members registered to SBN.

After registration, they can convey their inquiries, demands and complaints through the following channels:

- Hotline by phone "Alo 182" line, which is accessible 24/7 and
- Website via <u>https://sbn.saglik.gov.tr/.</u>

There are six sections in SBN portal that are:

- 1. Ask us,
- 2. I have an idea,
- 3. Looking for solution,
- 4. Billboard,
- 5. Permutation, and
- 6. Frequently asked questions.

Inquiries, demands, complaints about all health services provided by SBN are responded by a team composed of 133 personnel.

Workers shall quickly inform management of labour issues, such as a lack of PPE, unreasonable overtime, stress and any harassment (i.e. physical, psychological and sexual abuse and exploitation) related issues at workplace via the grievance channels of the MoH (SBN, SABIM, Provincial Health Directorates). These grievance channels allow anonymous grievances and have an appeal process in place.

7.2.2 CIMER: Turkish Presidential Communication Centre

The Project employees can also report grievances via CIMER, which is already explained in the previous section. The channels to access CIMER are as follows:

- Website: http://www.cimer.gov.tr,
- Call Centre: 150, or
- Phone number: +90 312 525 55 55.

7.2.3 Contractor and Supervision Consultant Level Workers' Grievance Mechanism

Apart from national grievance mechanism channels, the Project will establish additional tools (i.e. grievance boxes, raising grievances through reporting to the workers' representatives, separate meetings with female workers) in the Project site and facilities to enable the Project employees report grievances. The tools to be established by the contractors will be integrated to the existing system within the Project Grievance Mechanism.

The following will be applied for successful implementation and management of workers' grievance mechanism through grievance boxes:

- There will be at least three grievance boxes at the Project facilities (i.e., cafeteria, main entrance-exit points, administrative building); and, there will be available and empty grievance forms as well as pens next to the boxes.
- The grievance boxes will be locked and secured. Only the community liaison officer of the contractors during construction phase and operation phase will have the keys of the boxes. Only these personnel will have the authority to open and check boxes.
- The workers will have the opportunity to apply anonymously.

- The grievance form provided in Annex 10.2 of the SEP will be used within the scope of the workers' grievance mechanisms of the contractors throughout the life of the Project.
- The location of the boxes will be specifically selected as out of sight from bystanders and cameras (i.e. resting areas) in order to preserve the anonymity of the grievance applicant.
- The grievance boxes will be checked daily and grievances will be registered to the grievance log immediately.
- Grievances will be classified depending on their subjects while registering to the grievance log.

There will be workers' representatives who will be assigned by the Project workers. Reporting grievances to the workers' representatives will also be a part of the workers' grievance mechanism. Workers' representatives will be responsible for informing the community liaison officers that manage grievances about all grievances that s/he received either verbally or in written way. The community liaison officers will register those grievances into the grievance log.

The workers (including subcontractors) will be informed about the grievance mechanism as a part of the induction process. The information provided during the induction will involve that the workers will not be retaliated or fired just because they raise grievances.

The workers of the supplier companies will be informed about the grievance mechanism prior to receiving the goods and services. The information provided during the induction will involve that the workers will not be retaliated or fired just because they raise grievances.

Community liaison officers assigned for managing grievances will investigate the grievances reported by the Project workers together with a workers' representative and the personnel from senior management team such as the Human Resources Manager of contractor companies employed for the Project's phases.

After the grievances are successfully closed and the corrective actions are taken, the results of the grievances including anonymous grievances will be displayed on the notice boards within the Project site.

7.2.4 Receiving Grievances related to Sexual Exploitation and Abuse (SEA) and Sexual Harassment (SH)

There will be sufficient security measures (i.e. security personnel, surveillance system through security cameras) to prevent the risk of SEA/SH cases in the Project site. In addition to the security measures, workers will have the opportunity to raise grievances related to SEA/SH through grievance boxes with the possibility of anonymous application.

SEA/SH cases will be recorded and analysed as a part of the current grievance mechanism of Project. However, when a SEA/SH grievance is reported, it will be approached in a more sensitive way and in an immediate timeframe in comparison with other grievances.

The privacy, health and safety of the complainant will be the key principles in handling SEA/SH cases. The identity of the grievance applicant will be kept strictly confidential to hinder the risks of retaliation.

As a good practice, the Project parties are recommended to organize separate meetings with female workers on a regular basis (i.e. quarterly) to learn if they have any concerns or grievances related to SEA/SH risks and to improve the existing security measures if they are not adequate. Such meetings can be managed by the community liaison officers managing grievances or the Human Resources Manager with active participation of female workers to the extent possible.

Within the scope of the Project, a Labour Management Plan and a Human Resources Management Plan will be prepared. Both plans will include:

- The way to announce the grievance mechanism to the workers,
- The number and locations of the grievance boxes within the Project site,
- The units responsible for opening and recording the grievances, and
- The way the grievances will be managed in a timely manner.

7.3 **Project Grievance Resolution Process**

The flow of operation of the Project Grievance Mechanism (both community and workers' grievance mechanisms), which is visualized in Figure 7-2 below, will be in line with the resolution process defined in the ESMF developed by the PMSU.

As visualized in Figure 7-2, the main steps for handling grievances within the scope of the Project are receive, register, approval, define, inform, obtain and close⁷.



Figure 7-2: Steps of the Grievance Mechanism of the Project⁴

<u>Receive and Register the Grievance</u>: Grievance/complaint applications are registered by the community liaison officers of the Project parties (MoH including PMSU and the Project Implementation Unit, EPC Contractor of the construction activities of the Project, and the supervision consultant during the operation phase). All applications are registered in a central log.

<u>Acknowledgment of the Grievance by the MoH:</u> Following the registration, the grievance will be received and acknowledged by the MoH. The community liaison officers of the MoH will inform the complainant that grievance is registered.

<u>Define Related Departments and Actions:</u> The community liaison officers of the MoH will conduct classification and initial assessment in order to define the related department(s) and actions for timely and accurate resolution of the grievance.

⁷ Environmental and Social Management Framework developed by the PMSU, February 2022

⁽https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html)

<u>Inform Complainant:</u> After the experts in the related department(s) review the grievance and take relevant action(s) about it, the response is sent to complainant.

<u>Obtain Information about Action Taken to Avoid/Reduce the Issue:</u> Information regarding the action(s) taken in order to avoid or reduce the issue are forwarded to the MoH by the experts in the related department(s). Where the grievance requires further investigations, root cause analysis or actions, the MoH may request the assistance of outside authorities as appropriate.

<u>Close the Complaint:</u> After all these steps are followed, the grievance/complaint is closed and marked as resolved. Announcements regarding the results and corrective actions taken will be properly displayed through the Project website and notice boards within the Project site.

The grievance mechanism of the Project should respond to the complainant within 15 days after the grievance is received. If the resolution period of the grievances will take longer due to further investigation (i.e. to receive official letters, opinions), then it can expand to 30 days. However, the complainant (if not anonym) should be informed about the prolonged resolution process.

While the MoH is responsible for implementation and managements of the entire grievance mechanism of the Project, other Project parties are also responsible for establishing their own Grievance Mechanism Procedures for both workers and communities and reporting the grievances and outcomes of the mechanism to the MoH. These grievance mechanisms and procedures developed by other parties will be integrated to the Project Grievance Mechanism. The MoH will monitor the Project grievances through regular reports provided by the Project parties.

7.4 World Bank's Grievance Redress Service

Communities and individuals who believe that a World Bank-supported project has or is likely to have adverse effects on them, their community, or their environment have the opportunity to submit their grievances through existing project-level grievance redress mechanisms or the World Bank's Grievance Redress Service (GRS).

GRS ensures the World Bank's responsiveness and accountability to project-affected communities by ensuring that grievances are promptly reviewed and addressed.

All grievances must be in writing and addressed to the GRS through the following ways:

- Online, access the online form
- By email to grievances@worldbank.org
- By letter or by hand delivery to the World Bank Headquarters in Washington D.C., United States or any World Bank Country Office print and use this form (DOCX)

Grievances must:

- Identify the project subject of the grievance
- Clearly state the project's adverse impact(s)
- Identify the individual(s) submitting the complaint
- Specify if the complaint is submitted by a representative of the person(s) or community affected by the project
- If the complaint is submitted by a representative, include the name, signature, contact details, and written proof of authority of the representative.

Supporting evidence is not necessary but helpful in reviewing and resolving the complaint. The complaint may also include suggestions on how the individuals believe the complaint could be resolved. All complaints will be treated as confidential. The GRS will not disclose any personal data that may reveal the identity of complainants without their consent.

More information on how to raise grievances to the World Bank's GRS is provided in the World Bank website⁸.

7.5 Community Liaison Officer

The Project parties involve the MoH (including PMSU and the Project Implementation Unit), EPC Contractor of the construction activities of the Project, and the supervision consultant during the operation phase. To ensure the successful implementation and management of the Project GM, each party will assign community liaison officer for managing grievances. Resolving the incoming complaints, informing the stakeholders, and communicating with the stakeholders will be carried out by these community liaison officers.

7.6 Project Contact Information

All the Project plans, reports and the results of the public grievances together with the corrective actions taken will be published on the Project website (<u>https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html</u>).

Additionally, suggestions and complaints related to the Project can be directed through the following:

Contact Information

Project: Ankara Akyurt Vaccine Production Centre, Experimental Animal Production Centre and ABSL3 Level Laboratory Project

Main Responsible Party of the Project: The Turkish Republic Ministry of Health Project Management Support Unit

Address: Bilkent Yerleşkesi, Üniversiteler Mahallesi Dumlupınar Bulvarı 6001. Cadde No:9 06800 Çankaya/Ankara-TURKIYE

E-mail: trhealth@saglik.gov.tr

Project website:

https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesiprojesi.html

Grievance form: https://pydb.saglik.gov.tr/TR-76672/talep-oneri-ve-sikayet-formu.html

The public grievance mechanism of the Project and grievance channels will be disclosed to the Project's external stakeholders through stakeholder engagement activities and consultation meetings as defined in the Section 5.6.

The Project employees will be informed about the workers' grievance mechanism and channels through induction trainings.

⁸ The website can be accessed through <u>https://www.worldbank.org/en/projects-operations/products-and-services/grievance-redress-service</u>.

8 Resources and Responsibilities

The PMSU will have an overall responsibility for undertaking and supervising engagement with all stakeholders in relation to the Project and will use available resources to ensure that the relevant activities are conducted effectively and to the appropriate standard. Received grievances and response status with actions taken/ to be taken and the results will be summarized in monthly reports. These reports will include a section detailing the number and nature of grievances received and performance in addressing the grievances. The organizational chart of PMSU is shown in Annex 10.9.

The parties of interest for the pre-construction, construction, and operation phases of the Project are listed below with the explanation of their roles and responsibilities.

The PMSU will be responsible for;

- Ensuring coordination between international parties and implementing units of the MoH within the scope of carrying out the Project,
- Providing technical support to the implementing units of the MoH during the process of the Project being carried out,
- Ensuring the Project to be completed on time and within the budget allocated,
- Monitoring the Project process regularly and evaluating it,
- Managing and regulating the relationships between the Project implementing units,
- Noticing issues that might hinder the Project from being accomplished timely and taking measures to prevent them, and
- Supervising the compliance of the unit activities with the Project objectives.

MoH has the authority to;

- Carry out public health services within the country level and for this purpose to establish, build, operate, or to allow operation the necessary facilities,
- Develop and implement the tendering process for the planning, design, construction and operation of the facilities within the Project, and
- Operate national level grievance mechanism channels (SABIM, CIMER, SBN).

EPC Contractor of the Phase I EPC Contractor, its workers (including subcontractors) will be committed to the Labour Management Plan and will be responsible for the identified roles and responsibilities within the Labour Management Plan.

Main Contractor for other phases of construction works: The main contractor for the next phases of construction works within the Project will be determined by the MoH through the utilization of tender process. It will be involved in the Labour Management Plan.

Community Liaison Officers of the MoH (including PMSU and the Project Implementation Unit), **Contractors and Supervision Consultant:** The Community Liaison Officers assigned within the scope of the Project will be responsible for the preparation of monthly, quarterly and annual social reports, following the grievances, and conducting stakeholder engagement and disclosure activities with stakeholders.

Community Advisory Board (CAB): A CAB will be established under the scope of the Project. It is responsible for monitoring the activities, impacts and measures taken as of the beginning of the construction period of the Project until the first year of the operation, informing communities, mukhtars, workplaces and NGOs, and conveying their views to the PMSU. The CAB will consist of members affiliated to Akyurt Municipality, Pursaklar Municipality, Akyurt District Governorate, Pursaklar District Governorate and Akyurt District Health Directorate.

9 Monitoring and Reporting

9.1 Monitoring

The PMSU will be responsible for monitoring, evaluation and reporting activities, overseeing progress related to the Project activities, outcomes, and results. Through the PMSU, the MoH will be responsible for:

- collecting and consolidating all data related to their specific suite of indicators,
- evaluating results, and
- reporting results to the World Bank regularly and before each implementation support mission.

The SEP monitoring and evaluation reports will be submitted to the World Bank periodically by the PMSU. The PMSU will also inform the Community Advisory Board to be established as part of the Project every three months through organizing meetings.

An Environmental and Social Management Plan (ESMP) has been prepared within the scope of the ESIA study of the Project. The ESMP identifies monitoring objectives and specifies the type of monitoring, with linkages to the impacts assessed in the environmental and social assessment and the mitigation measures described in the ESMP. Specifically, the monitoring section of the ESMP provides;

- a specific description, and technical details, of monitoring measures, including the parameters to be measured, methods to be used, sampling locations, frequency of measurements, detection limits (where appropriate), and definition of thresholds that will signal the need for corrective actions; and
- monitoring and reporting procedures to ensure early detection of conditions that necessitate particular mitigation measures and furnish information on the progress and results of mitigation.

Therefore, monitoring of the Project together with the SEP will be carried out in line with the ESMP.

9.2 Reporting

The SEP will be periodically revised and updated as necessary in the course of Project implementation in order to ensure that the information presented herein the SEP is consistent and is the most recent, and that the identified methods of engagement remain appropriate and effective in relation to the Project context and specific phases of the development. Any major changes to the Project related activities and to its schedule will be duly reflected in the SEP.

Quarterly summaries and monthly internal reports on public grievances, enquiries and related incidents, together with the status of implementation of associated corrective/preventative actions, will be collated by the designated grievance mechanism officer of the Project, and referred to the senior management of the Project. Monthly internal reports and quarterly summaries will be used to assess both the number and nature of grievances (if any), along with the ability of both PMSU and the Contractors to address grievances in a timely and effective manner.

Information on stakeholder engagement activities undertaken by the Project during the year can be conveyed to the World Bank and to the stakeholders in two ways, which are listed below:

Quarterly Reports: The PMSU will submit an overall report of the Project implementation to the World Bank. These reports will include environmental, social, health and safety performance of

the Project, including but not limited to a summary of activities for each beneficiary healthcare facility, stakeholder engagement activities and grievances log.

Annual Reports: PMSU will publicly report on its environmental and social performance on an annual basis including a summary of any grievances raised and how they have been resolved. To inform the external stakeholders Annual Environmental and Social Report (brief summary of the Annual Environmental and Social Monitoring Report (AESMR)) will be developed and published on the PMSU's website. Additionally, a standalone report on Project's interaction with the stakeholders as part of the communication campaign of the MoH will be published annually.

These reports will include the following aspects of the Project:

- The number of Project-related grievances received within a reporting period (i.e. quarterly/six monthly) and the number of those resolved within the prescribed timeline.
- Monthly summaries of grievances raised by internal and external stakeholders, queries and related incidents together with the implementation status of corrective/preventive actions
- Consultations and the disclosure activities, which will be referred the PMSU in all phases of the Project and to Contractor in the construction phase.

10 Annexes

10.1 The application form on the website of the PMSU (in Turkish)

	Anasayfa	PYDB	Kurumsal	Projeler	Mevzuat	Dökümanlar	İletişim	
			B	aşvuru Fo	ormu			
Başvuru Türü *			Başvurunun k	(onusu *				
Seçiniz		Ŧ	Seçiniz			*		
Seçiniz			-					
Şikayet			Başvurunun A	Alınaigi liçe *		Başvuru	Başvuruya Konu Kurum *	
Öneri			Seçiniz			▼ Seçini	Ľ	*
Bilgi Talebi								
	1							li
3asvuran Bilailer				Te	elefon/Mail			
Başvuran Bilgiler ^{Ad Soyad}								
Başvuran Bilgiler Ad Soyad								
Başvuran Bilgiler Ad Soyad 1/IIce/Köy				Ci	nsivet			

10.2 Grievance form

Application Form	
Type of Application	Grievance
	Suggestion
	Information
	Request
	Other (Please specify with a few words)
Province of Application	
Institution/Organization of the Application	
Subject of the Application	
Name and Surname (For anonymous applications, please leave this section empty)	
Contact Information and Desfamed Magna of	Phone:
Communication to Contact (Please choose at least one means of communication)	E-Mail
	Mail:
	Fax:
Date of Application	Day/Month/Year

10.3 Grievance log

Registr	Date of	Location	How is the	Name of the	Information	about th	e grieva	nce holder		Grievance	Description of	Grievance	Responsible	Action	Due date of the	Date of	Supporting
ation number	the grievance received and registered	of the grievance received	grievance received? (via Grievance Form, community meeting, telephone etc.)	responsible staff receiving grievance	Name and surname	Gender	ID number	Telephone and/or e- mail	District	category	the grievance	status (open, closed, pending)	person/ department for follow-up	planned	addressing the grievance	action taken	documents for grievance closeout and resolution

10.4 Stakeholder engagement tracker

No	Date	Location/ Engagement Channel	Authorized Person Conducting the Activity	The Name of the Engagement Activity	Type of Stakeholder Engaged (Community/Public, Mukhtar, etc.)	Number of Stakeholders Engaged	Meeting Place and Time	Discussion Subject	To do list, thoughts and comments
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									

10.5 The First Stakeholder List for the Project (Created by the Environmental and Social Team of the PMSU)

Key Stakeholder Groups	Stakeholders in the Group						
	Ministry of Health						
	General Directorate of Public Hospitals						
	Turkish Medicines and Medical Devices Agency						
	General Directorate of Public Health						
	General Directorate of Health Services						
	General Directorate of Emergency Health Services						
	General Directorate of Health Promotion						
	General Directorate of Health Information Systems						
	General Directorate of Administrative Services						
	General Directorate of Press and Public Relations						
Public Institutions at	Ministry of Environment, Urbanization and Climate Change						
National Level	Directorate General of Environmental Impact Assessment, Permit and						
	Inspection						
	Directorate General of Environmental Management						
	Ministry of Energy and Natural Resources						
	Ministry of Industry and Technology						
	Ministry of Agriculture and Forestry						
	General Directorate of Nature Conservation and National Parks						
	Health Institutes of Turkiye (TUSEB) (Vaccination Institute, Health Policies, Health						
	Services Quality and Accreditation, Biotechnology institutes)						
	I UBI I AK Marmara Research Center (MAM) - Genetic Engineering and						
	Governorates						
	Ankara Governorate						
	Dravinaid Directorate of Agriculture and Exector						
	Ankara						
Public Institutions at	Istanbul						
Provincial Level	Provincial Directorate of Environment and Urbanization						
	Ankara						
	İstanbul						
	Ankara Regional Directorate of Highways						
	Provincial Health Directorate						
	Ankara						
	İstanbul						
	District Municipalities						
	Küçükçekmeçe Municipality						
	Akvurt Municipality						
	Kijoilkeekmeen District Covernorate						
	Alexet District Course arets						
Dublic Institutions of District							
Public Institutions at District	Project Beneficiary Hospitals and their related units						
Level	Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and						
	Research Hospital (MAESH)						
	Headman's Onices						
	Istasyon Quarter Headman's Office (Istanbul)						
	Atakent Quarter Headman's Office (Istanbul)						
	Balıkhisar Quarter Headman's Office (Ankara)						
Crowno Donnocontin -	Chambers of Industry						
Groups Representing	İstanbul Chamber of Industry						
Commercial Stakeholders	Ankara Chamber of Industry						
Commercial Glakeholders	Chambers of Commerce						

Key Stakeholder Groups	Stakeholders in the Group						
	İstanbul Chamber of Commerce						
	Ankara Chamber of Commerce						
	Infectious Diseases and Clinical Microbiology Specialty Society of Turkiye (EKMUD)						
	Pediatric Infectious Diseases and Immunization Association						
Non-governmental	Turkish Society of Microbiology (TSM)						
Organizations	Infectious Diseases Association (EHD)						
-	Turkish Society of Hospital Infection and Control (HIDER)						
	Infectious Diseases Prevention Association (BUHASDER)						
	Association of Research-Based Pharmaceutical Companies (AİFD)						
	Ankara University Faculty of Veterinary Medicine						
Universities	İstanbul University Faculty of Veterinary Medicine						

10.6 PMSU Online Meeting Agenda Details



T.C. SAĞLIK BAKANLIĞI Proje Ydactim Destek Birimi

SAYI : 35227628-KONU: Faeliyet Bilgilendirme Topiantisa

DAOLTIM VERLERINE

Sağlık Bakanlığı Proje Yönetim Destek Birimi (PYDB) tarafından yürünileri ve Dünya Bankası tarafından desteklerini "Sağlık Sisteminin Göçlendinilmesi Ve Desteklerinesi Projesi (SSGDP) (LN:\$531-TR)ne iki yeni fasiliyet eklerimiştir. Bunlardan iki "Ankara Akyun Aşı Öretim Merkezi, Deney Hayvan Üretim Merkezi ve ABSL3 Seviye Laboratovan", diğer fasiliyet ist "İstanbul Mehmet Akif Ersoy Deneşsel Araştınını Geliştirme ve Eğitim Merkezi (IDEA) bünyesinde Hayvan Biyoğüvenlik Seviyesi (ABSL) 2 ve 3 Laboratovar Tesisi için eklipman alamı ve kurulumundan oluşmaktadır.

PYDB olarak yukanda baheedilen faaliyetler, bu faaliyetleris ilgili degörtilen çevresel ve sosyol riskler ile bu riskleri ortadan kaktamak için atruaçak önlemler hakkanda daha detaylı bilgi vermek amacıyla 20 Arabk 2021 Panartesi günü sont 14:00-15:00 arasında online bir bilgilendirme toplantısı düsanlışnecektir. Toplantı somanda ayrıca socu-cevaptan olaşan bir otanım gerçekleştirilecektir.

Kutumunuzu tatatilen toplantiya katilacak kişi veya kişilerin İsim-Soyisim ve iletişim bilgiletini aşağıda yer alan tablo formatışda 16 Aralık Persentbe 16:00'ya kadar revnen buvunkop'disaglik göyetr e-posta adresine gönderilmesi gerekmektedir. Toplantı linki, bilgileri gönderilen kutumuşlara 79 Aralık 2021 tarihinde gönderilecektir.

Corregini bilgilerinize anz/nca edecim.

			(
W	KATILIA	ICI BILGILER]	
KURUM VE BİRİM	ADI SOYADI	TELEPON NO	E-POSTA ADRESI
	phile and when the		10 State 10 State 10 State

EK: Dağılım Listesi (2 sayfa)

Proje Vinetim Dattak Briteri Idan Isler Recollentistiga Oriversitelet Mak. Durnispear Balvari 6901. Old. No.9 Kat. 2 Çushaya ANKARA

Bögi için: Senna ŞAHIN Telefun Na: (UH2) 471 85-14 E-posta:senna.cahin@exglik.gov.w

Zahide SENALP Proje Direktoro

Distantia state model from the

T.C. SAGLIN BAKANLIĞI Proje Yönttim Destek Birimi EK: Sogjek Bokanleg 1. Kana Hastanelen GM 2. Türkiye Baç ve Tibbi Cibar Kanana 3. Halk Sagjeg GM Sagisk Hizmetleri GM Acit Saglik Hizmetleri GM 4 5 Sagligin Geliştirilmesi GM Saglılı Yatınmları GM Sağlılı Bilgi Sistemleri GM 6. 73 4 Yonetim Hizmetleri GM Basar ve Hafkla flightler GM 9 10. Cevre, Schirciffa ve İldim Değişitliği Bakanlığı I. Cevresel Etki Değerleridamesi, İzin ve Denetim GM 2. Cevre Yunzlimi GM 2. Enerji ve Tabii Kayaaklar Bakanlığı Hazine ve Maliye Bakanlığı Sanayi va Teknoloji Bakaulığı Tarsor ve Oracan Bakaabğı I. Doğa Kuruma ve MRSi Parklar GM Türkiye Sağlık Eostitüleri Başkındığı (TÜSEB) (Aşı Esstinisii, Sağlık Politikaları, Sağlık Hizmetleri Kalite ve Akreditasyen, İliyeteknoloji onstitikleri) TÜBİTAK MAM – Gen Mühendirliği ve Biyeteknoloji Enstitüsk Valillader Ankara Valiligi 2 Istanbol Vability I Tarrin ve Orman Müdürlüğü I Ankora Tarın ve Orman İl Müdürlüğü 2 İstinbel Tarın ve Orman İl Müdürlüğü Çevre ve Şebircilik İl Müdürbiğü Ankora Istanizul 2. Karayoflari Ankara Bilgo Miiduringii Il Sugisk Miiduringu Anicera 1 Industel 2 Peoje Ydnesim Destek Sicini Idari Idar Koonfinatio kiga Daivenidelei Mak Durikgenar Batver 9001. Cad. Sor9 Kat. 2 Qaokaya/ANKARA Dilgi icio: Serra SAHIN Telefro No: (0312) 471 85 14 E-gestametara sabie@seglik.gov.tr



SAĞLIK SİSTEMİNİN GÜÇLENDIRILMESİ VE DESTEKLENMESİ PROJESİ

Saat: 14:00 - 15:00

Değerli Katılımcılar,

2015 yılında Dünya Bankası tarafından onaylanarak yürürlüğe giren "Sağlık Sisteminin Güçlendirilmesi ve Desteklenmesi Projesi", COVID-19 salgınıyla birlikte 2021 yılında yeniden yapılandırılarak iki yeni faaliyeti bünyesine eklemiştir. "Ankara Akyurt Aşı Üretim Merkezi, Deney Hayvanı Üretim Merkezi ve ABSL3 Seviye Laboratuvarı" ve "İstanbul Mehmet Akif Ersoy Deneysel Araştırma Geliştirme ve Eğitim Merkezi (IDEA) Hayvan Biyogüvenlik Seviyesi (ABSL) 2 ve 3 Laboratuvarları" için donanım alımı ve kurulumu Proje'ye dâhil edilmiştir.

Proje'ye eklenen iki yeni faaliyetle, Dünya Bankası'nın Çevresel ve Sosyal gereklilikleri ile ilgili risk değerlendirmesi yapılmış; konuyla ilgili alınacak önlemlerin de yer aldığı "Çevresel ve Sosyal Yönetim Çerçevesi (ÇSYÇ)" dokümanı Sağlık Bakanlığı Proje Yönetim ve Destek Birimi tarafından oluşturulmuştur.

https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-

desteklenmesi-projesi.html bağlantısından ÇSYÇ dokümanına erişebilir; bu dokümanla Ilgili öneri ve görüşlerinizi **29 Aralık 2021**'e tarihine kadar birimimize iletebilirsiniz.

Zaman	Açıklama
14:00-14:25	Projenin ve ekibin tanıtılması
14:25-14:40	Proje faaliyetleri ile çevre-sosyal risk değerlendirme çalışmaları
14:40-15:00	Soru/Cevap

10.7 Institutions and Organizations Participating in The PMSU Online Meeting

The institutions and organizations participating in the meeting are presented below:

- The Ministry of Health and its departments: General Directorate of Health Promotion, General Directorate of Public Health, Office of Press Counsellor, Project Management and Support Unit
- Ministry of Energy and Natural Resources
- Ministry of Industry and Technology: General Directorate of Strategic Research and Efficiency, General Directorate of Industry, General Directorate of National Technology
- Ministry of Treasury and Finance: Department of Support Services
- The World Bank
- Ankara Provincial Directorate of Health
- İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery
- Akyurt Municipality
- Akyurt District Governorate
- Akyurt District Directorate of Health
- ESIA Consultancy Company and its Experts
- Turkish Society of Microbiology
- Infectious Diseases and Clinical Microbiology Specialty Society of Turkiye (EKMUD)
- University of Health Sciences, Institute of Defensive Health Sciences, Department of Chemical, Biological, Radiological and Nuclear Defense (CBRN Defense)
- University of Health Sciences Hamidiye Faculty of Medicine, Department of Medical Microbiology
- Ankara Yıldırım Beyazıt University Faculty of Health Sciences
- Ankara University Faculty of Veterinary Medicine

10.8 The Project's Information Document



Haziran 2022



Giriş

MOTT

Bu doküman, "Aşı Üretim Merkezi, Deney Hayvanı Üretim Merkezi ve ABSL-3 Seviye Laboratuvarı Projesi" (dokümanın devamında "Proje" olarak anılacaktır) hakkında sizleri bilgilendirmeyi ve sizlere Proje'yi tanıtmayı amaçlayan Proje Bilgilendirme Dokümanı'dır. Proje Bilgilendirme Dokümanı'nda, paydaşların (Proje'den etkilenebilecek ya da Proje ve etkileri ile ilgilenen bireyler, gruplar, topluluklar, kurum ve kuruluşlar) Proje'nin Çevresel ve Sosyal Etki Değerlendirmesi (ÇSED) sürecinde dikkate alınacak olan fikir ve görüşlerini ifade etme yolları açıklanmaktadır.

Dünya Bankası, en üst düzey tibbi bakım sağlamak, temel sağlık hizmetlerini sürdürmek ve hem personele hem de hastalara yönelik riskleri en aza indirmek için hazırlık planının oluşturulmasında hükümetlere destek sağlamaktadır. Bu bağlamda, Türkiye Cumhuriyeti Hükümeti sağlık sistemlerine erişimdeki eşitsizliği azaltma ve sağlık sistemini güçlendirme hedefleriyle bazı önemli adımlar atmıştır. Dünya Bankası'nın desteklediği Sağlık Sisteminin Güçlendirilmesi ve Desteklenmesi Projesi (SSGDP) atılan bu önemli adımlardan biridir.

Proje, SSGDP'nin dördüncü bölümü kapsamında yer alan iki alt projeden biridir. Proje ile ulusal düzeyde bir aşı üretim merkezinin kurulması hedeflenmiş olup yanda listelenen atılacak adımlar yoluyla da bu hedefe ulaşmak amaçlanmaktadır.

Proje'nin Hedefleri:

pilot/endüstriyel düzeyde üretilmesi

Üretim için proses geliştirmenin yapılabileceği, ulusal ve uluslararası standartlara uygun temiz alanların ve çeşitli biyogüvenlik düzeyi (BSL1-2-3) koşullarının tasarımı

Üretim için gerekli olan farklı ölçeklerde biyoreaktör ve laboratuvar ekipmanlarının kurulması

Bu çalışmaların in vivo testleri için gerekli deney hayvanı ünitesinin oluşturulması

İyi Laboratuvar Uygulamaları ve İyi Öretim Uygulamaları kurallarına göre çalışacak bir yapı oluşturulması

Üniversitelerin ve özel sektörün eğitim ve Ar-Ge çalışmaları yapabilmesi için son teknoloji ve ihtiyaçlara uygun bir merkez kurulması

Alt Projeler: https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sisteminin-guclendirilmesi-ve-desteklenmesi-projesi.html



Şekil 1: Proje sahası ve parsel sınırları

Proje Sahasının Özellikleri

Proje sahası konumu: Ankara ili Akyurt ilçesi Balıkhisar mahallesi

Proje sahasının Ankara şehir merkezine uzaklığı: 20 kilometre

Ankara Esenboğa Havalimanı'nın Proje sahasına göre konumu: Yaklaşık 3 kilometre kuzeydoğu

Proje sahasına en yakın mahalleler: Saracalar, Balıkhisar, Altınova ve Saray Gümüşoluk.

Proje'nin inşa edileceği alan, Şekil 1'de gösterildiği gibi ana proje kompleksi ve rekreasyon alanı olarak iki bölümden oluşmakta olup toplam 79,324 m² alanı kaplamaktadır.

- Ana Proje Kompleksi (1555-4 parsel): Ana proje kompleksi (deney hayvanı üretim/deney üniteleri, laboratuvar üniteleri ve aşı üretim üniteleri başta olmak üzere) 47,602 m²lik 1/1000 ölçekli uygulama imar planında "Refik Saydam Hıfzısıhha Serum Çiftliği Alanı" olarak belirlenen alan üzerine inşa edilecektir. Alan, Sağlık Bakanlığı'na aittir.
- Rekreasyon Alanı: Proje kapsamındaki rekreasyon alanı, ana proje kompleksine bitişik ve yaklaşık 31,722 m²'lik 1/1000 ölçekli uygulama imar planında "Yeşil Alan" olarak gösterilen alan üzerinde oluşturulması planlanmaktadır. Bitişik iki parselin (1555-4 numaralı parsel ile rekreasyon alanı yapılması planlanan parsel) birleştirilmesi için Bakanlık tarafından gerekli başvurular yapılmıştır.

Proje alanı çevresindeki arazi kullanımı (mevcut tesisler, inşaat süreci başlayacak olan alışveriş merkezi ve tarım alanları dahil olmak üzere) Şekil 2'de gösterilmektedir.



Şekil 2: Proje sahası çevresinde arazi kullanımı

- Proje sahasına bitişik parselde Sağlık Bakanlığı Halk Sağlığı Genel Müdürlüğü'ne (HSGM) tahsis edilen bir aşı depolama tesisi bulunmaktadır. Proje sahasında aşı ekipmanının depolanması için kullanılan bir ilave depo da işletilmektedir. Proje inşaatına başlanmadan önce Proje sahasında yer alan bu depo yıkılacak ve saha temizlenecektir.
- Çubuk Çayı, Proje sahasının kuzeybatı sınırı boyunca uzanmaktadır. Çubuk Çayı ile ana proje kompleksinin en yakın noktası (Deney Hayvanları Üretim/Test Binası) arasındaki mesafe yaklaşık 90 metredir.

Proje'nin Ana Bileşenleri

Ana proje kompleksinin aşağıdaki bina ve birimlerden oluşması planlanmaktadır:

- İdari Bina (depolar, güvenlik, yemekhane, idari ofis, misafirhane),
- Ar-Ge Binası,
- Deney Hayvanları ve Transgenik Organizmalar Üretimi/Test Binası,
- Aşı Üretim ve Depolama Binaları (bakteriyel ve viral pilot üretim alanları, inaktif viral aşı üretim alanları, rekombinant aşı üretim alanları, kalite kontrol laboratuvarları dahil),
- Yükleme/Boşaltma Alanı (üretim binalarının kuzeyinde yer alır),
- Atık Merkezi,
- Teknik Bina,
- Güvenlik Binası,
- Gözetleme Kuleleri (Beş noktanın konumlandırılması planlanmaktadır).

"Proje kapsamında inşa edilecek tesisler ile Sağlık Bakanlığı, birçok aşıyı (SARS-CoV 2, difteri, botülizm, tetanoz antitoksini ve kuduz dahil) ve ilgili ürünleri (serum/ immunoserum, antikor/antijen vb.) araştırmak ve üretmek için yeterli kapasiteye sahip olacaktır."

Proje kapsamında inşa edilecek tüm binaların çatılarında enerji üretimi için güneş enerjisi panelleri yerleştirilmesi planlanmaktadır.

Olası bir deprem anında biyogüvenlik risklerini en aza indirmek için üretim binası olarak inşa edilecek üç bloğa sismik izolasyon yöntemi uygulanacaktır.



Proje alanının tamamını, jiletli tel bariyerler ve CCTV kameraları ile donatılmış güvenlik duvarları çevreleyecektir. Alan, farklı güvenlik seviyelerine sahip iki bölgeden oluşacaktır:

- Bölge I: İdari, Ar-Ge ve Deney Hayvanları ve Transgenik Organizmalar Üretim/Test Binalarını içerecektir.
- Bölge II: Üretim Binası, Atık Binası, Teknik Bina, Yükleme/Boşaltma Alanı ve rekreasyon alanını içerecektir. Bölge II, daha yüksek bir güvenlik seviyesinde korunacak ve hem araçlar hem de yayalar tarafından Bölge I'den Bölge II'ye geçiş için ayrı bir güvenlik kontrolü daha yapılacaktır.

Rekreasyon alanı içerisinde sadece işletme personelinin kullanacağı bir anaokulu yapılması öngörülmektedir. Rekreasyon alanının kalan bölümleri peyzaj ve dinlenme alanlarından oluşacaktır.
Proje'nin Mevcut Durumu ve Önerilen Faaliyetler

Proje, mevcut durumda planlama aşamasındadır. İnşaatın, 2023 yılının sonlarında tamamlanması beklenmektedir. Üretimin ise 2023 yılının son aylarında veya 2024 yılının ilk aylarında başlaması hedeflenmektedir. Proje için aşağıdaki ana faaliyetlerin gerçekleştirilmesi planlanmaktadır:



Çevresel ve Sosyal Etki Değerlendirmesi (ÇSED) Süreci



- Sağlık Bakanlığı, Proje'nin inşaatından ve işletmesinden sorumlu olacaktır.
- Proje'nin inşaatı hazine bütçesinden yararlanılarak finanse edilecektir. Ekipman tedariği ve kurulumu için Dünya Bankası tarafından kredi desteği sağlanacaktır. Bu nedenle, Dünya Bankası Çevresel ve Sosyal Cercevesi (CSC) ve Türkiye Cumhuriyeti mevzuatı hükümlerine göre Proje'nin inşa edilmesi ve işletilmesine ilişkin çevresel ve sosyal rişkler, ÇSED kapsamında ele alınacaktır.
- Proje için Türk mevzuatı uyarınca ÇED (Çevresel Etki Değerlendirmesi) çalışması gerekliliğine ilişkin Çevre ve Şehircilik İl Müdürlüğü ile ilgili yazışmalar ve görüşmeler devam etmektedir.

Paydaşlar ile İletişim

CSED calışmasının bir parçası olan bu Proje Bilgilendirme Dokümanı, Proje ile ilgili tüm çevresel ve sosyal konuların göz önünde bulundurulmasını sağlamak ve ilgili paydaşlardan görüş alabilmek amacıyla çeşitli kuruluşlara gönderilmekte ve halka ulaştırılmaktadır.

Proje'nin farklı aşamalarında, ilgili paydaş grupları ile çeşitli paydaş katılım faaliyetleri gerçekleştirilecektir. Proje'nin paydaşlarını; ülke, bölge, il, ilçe ve mahalle düzeyindeki kamu kurumları, üniversiteler ve araştırma laboratuvarları, sivil toplum kuruluşları, Proje sahasına yakın ve komşu tesisler, ve yerel halk oluşturmaktadır.





Görüs Bildirme Fırsatı

Sizleri, Proje'nin çevresel ve sosyal konularını değerlendirmeye ve alınması gereken önlemler ile ilgili görüşlerinizi sunmaya davet ediyoruz.



Proje: Ankara Akyurt Aşı Üretim Merkezi, Deney Hayvanı Üretim Merkezi ve ABSL-3 Seviye Laboratuvarı Projesi

Proje Sorumlusu: Sağlık Bakanlığı Proje Yönetim Destek Birimi

Adres: Bilkent Yerleşkesi, Üniversiteler Mahallesi Dumlupinar Bulvari 6001. Cadde No:9 06800 Çankaya/ Ankara

E-posta: trhealth@saglik.gov.tr

Proje internet sitesine aşağıdaki "Link'e" tıklayarak ya da yandaki "QR Kodu" okutarak ulaşabilirsiniz:

https://pydb.saglik.gov.tr/TR-76671/8531-saglik-sistemininguclendirilmesi-ve-desteklenmesi-projesi.html

"QR Kodu"



10.9 Organisational Chart of the PMSU affiliated to the MoH⁹



PMSU ORGANISATIONAL CHART

⁹ The organisational chart has been prepared on the basis of the information given in Proje Yönetim Destek Birimi (saglik.gov.tr), which was accessed on 20 October 2022.



