Initial Environmental Examination

Project Number: 54425-001
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Republic of Indonesia: Asia Pacific Vaccine Access Facility - Responsive COVID-19 Vaccines For Recovery (APVAX RECOVER) Project

Prepared by PT Bio Farma for the Asian Development Bank.

CURRENCY EQUIVALENTS

(as of 10 November 2020)

Currency unit	–	Indonesian Rupiah (Rp)
Rp1.00	=	$0.0000688
$1.00	=	Rp.14,529

ABBREVIATIONS

ADB	-	Asian Development Bank
AMDAL	-	Analisis Mengenai Dampak Lingkungan (equivalent to environmental impact assessment)
ANDAL	-	Analisis Dampak Lingkungan (equivalent to environmental impact assessment report)
APVAX RECOVER	-	Asia Pacific Vaccine Access Facility - Responsive COVID-19 Vaccines for Recovery (APVAX RECOVER) Project
BCG	-	Bacillus Calmette-Guerin vaccine against tuberculosis
BPOM	-	*Badan Pengawas Obat & Makanan* (National Agency of Drug and Food Control of Indonesia)
COCP	-	Code of Construction Practice
DT	-	Diptheria
DTP	-	Diptheria-Tetanus-Pertussis
DTP-HB	-	Diptheria and tetanus toxoids and whole-cell pertussis and hepatitis B
EARF	-	Environmental assessment and review framework
EHS	-	Environment, health and safety
EMS	-	Environmental Management System
FDA	-	Food and Drug Agency
GAVI	-	Global Alliance of Vaccines and Immunization
GMP	-	Good Manufacturing Practice
HEP B	-	Hepatitis B
HiB	-	Haemiphilus influenzae type B
HPV	-	Human Papillomavirus
IEE	-	Initial environmental examination
MOEF	-	Ministry of Environment and Forestry
MOH	-	Ministry of Health
MSOE	-	Ministry of State-Owned Enterprises
NRA	-	National Regulatory Authorities
OHSaS	-	Occupational Health and Safety Accreditation System
PAHO	-	Pan American Health Organization
PIU	-	Project Implementation Unit
PMU	-	Project Management Unit
PROPER	-	Environmental Management Performance Assessment Program of MOEF
SPPL	-	Surat Pernyataan Pengelolaan Lingkungan (equivalent to an environmental commitment)
UKL/UPL	-	Upaya Pengelolaan Lingkungan Hidup dan Upaya Pemantauan Lingkungan Hidup (equivalent to an initial environmental examination)
UNICEF	-	United Nations Children's Fund
WHO	-	World Health Organization
WHO-EPI	-	Expanded Program on Immunization of WHO

NOTE

In this report, "$" refers to US dollars.

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I. EXECUTIVE SUMMARY

A. Project Rationale

1. COVID-19 continues to spread widely in Indonesia, having infected over 770,000 people with 22,000 fatalities as of 4 January 2021.[1] Indonesia's positivity rate of 20% is significantly higher than the 5% benchmark set by the World Health Organization (WHO).[2] Indonesia has implemented non-pharmaceutical interventions (NPIs),[3] collectively termed '3Ms',[4] to mitigate the spread of COVID-19. While 3Ms have the potential to control the spread of COVID-19,[5] compliance has been uneven.[6] 24% of the population does not have handwashing facilities available at home,[7] and over 10% of the population lives in slums and crowded informal settlements, making social distancing challenging.[8] NPIs have disrupted normal societal functioning and damaged the economy, triggering an economic contraction of 2.2% in 2020, down from an original growth estimate of 5.2%.[9] While the government has increased spending for social protection, health and other measures for relief and recovery,[10] this has led to a rise in public debt from 30.2% of gross domestic product (GDP) in September 2019 to 40.9% by 2021. The ongoing crisis has significantly impacted livelihoods, especially within the most vulnerable and remote communities. Close to 10 million people are at risk of falling below the national poverty line, with poverty incidence expected to increase from 9.4% in March 2019 to 11.9%–12.8% by the end of 2020.[11]

2. The rapid development of COVID-19 vaccines, some of which have already obtained Emergency Use Authorizations (EUA) in several countries, offers Indonesia the opportunity to strengthen its public health response and suppress COVID-19 through provision of safe and effective vaccines. As the world's fourth most populous country, Indonesia will simultaneously need to expand domestic vaccine manufacturing capacity to ensure sufficient supplies in order to avert future disease outbreaks.

3. The Committee for Handling COVID-19 and National Economic Recovery, headed by the Coordinating Minister for Economic Affairs, oversees COVID-19 response activities including the vaccination program. The executive chair of the Committee is the Minister of SOEs, who has been

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1 Government of Indonesia. COVID-19 Handling Committee and National Economic Recovery (accessed 30 December 2020).
2 World Health Organization (WHO). 2020. *Coronavirus disease 2019 (COVID-19): Situation Report – 38*. Geneva
3 European Centre for Disease Prevention and Control. 2020. *Guidelines for the implementation of non-pharmaceutical interventions against COVID-19*. Solna.
4 3Ms include: (i) 'Menjaga jarak' (large-scale social restrictions such as closure of schools and religious places, a ban on domestic travel, cancellation of public holidays and imposition of work from home policies), (ii) 'Mencuci tangan' (handwashing), and (iii) 'Masker' (mask wearing).
5 G. Castex et al. 2020. COVID-19: The impact of social distancing policies, cross-country analysis. *Economics of disasters and climate change*. pp. 1-25.
6 United Nations Children's Fund. 2020. *Indonesia COVID-19 Response Situation Report – Situation in Numbers (Oct 13, 2020)*. New York.
7 United Nations (UN) Women. 2020. *Counting the Costs of COVID-19: Assessing the Impact on Gender and the Achievement of the SDGs in Indonesia*. Bangkok.
8 World Bank. 2016. *Indonesia: Improving Infrastructure for Millions of Urban Poor*. Washington DC.
9 ADB. 2020. *Asian Development Outlook Supplement: December 2020—Paths Diverge in Recovery from Pandemic*. Manila.
10 Government of Indonesia, Ministry of Finance. 2020. *Report on the development of the implementation of COVID-19 handling and national economic recovery program 27 November 2020*. Jakarta.
11 ADB. Indonesia: COVID-19 Active Response and Expenditure Support Program.

coordinating closely the vaccine procurement efforts. Presidential Regulation No. 99/2020[12] sets out the implementation arrangement for vaccine procurement and distribution. It authorizes the Minister of Health to, among other things, assign Bio Farma and its subsidiaries PT Kimia Farma Tbk (Kimia Farma) and PT Indofarma Tbk (Indofarma)[13] to procure vaccines from various vaccine manufacturers and deliver to a location at provincial level as designated by the Ministry of Health (MOH). From there, responsibility for delivery to service points and eventual administration lies with provincial and district health offices in coordination with MOH.

4. Besides the Presidential Regulation No.99/2020, the government through MOH has issued decrees,[14] a plan[15] and technical guidelines[16] to support vaccine procurement and implementation (collectively termed vaccination strategy). The Health Minister Decree 84/2020 incorporates recommendations from the Indonesian Technical Advisory Group on Immunization[17] on the urgent need for vaccinations to reduce transmission, morbidity and mortality and restore economic productivity. The government has determined that, starting in the first quarter of 2021, 181.5 million[18] people should be vaccinated for free in two phases to reach herd immunity, estimated to require 426.8 million doses.

5. Government has mandated that all vaccines to be procured must (i) be listed under MOH decree 12758/2020[19]; and (ii) obtain EUA or distribution permit from the BPOM prior to administration. As of 29 December 2020, government requested binding commitments for 279.5 million doses and non-binding commitments for an additional 284 million doses. To ensure timely and sustainable supply for COVID-19 vaccine in 2023 and beyond, the government is promoting development of an indigenous vaccine called 'Merah Putih' in collaboration with Jakarta-based Eijkman Institute for Molecular Biology and Bio Farma.

6. In the longer term, the government aims to: (i) strengthen the independence of the national pharmaceutical industry, reduce dependency on imports and increase exports; (ii) boost research and development capability; and (iii) leverage economies of scale and increase productivity so pharmaceutical products – including vaccines - can be made available at affordable prices.[20] Bio Farma is central to realizing these goals. Established in 1890, and headquartered in Bandung,

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[12] Government of Indonesia. 2020. *Presidential Regulation 99/2020 on Vaccines procurement and implementation.* Jakarta.

[13] Bio Farma owns 90% stake in Kimia Farma and 80.6% stake in Indofarma, and these subsidiaries are engaged in the manufacture, distribution and retailing of pharmaceutical products.

[14] Government of Indonesia, MOH. 2020. *MOH decree 84/2020 on Implementation of vaccinations to control COVID-19 pandemic*. Jakarta; Government of Indonesia, MOH. 2020. *MOH decree 28/2020 on Implementation of vaccine procurement in the control of COVID-19*; Jakarta; Government of Indonesia, MOH. 2020. *MOH decree 6573/2020 on the COVID019 implementation team*. Jakarta*;* and Government of Indonesia, MOH. 2020. *MOH decree 12758/2020 on Determination of Vaccines for the Implementation of COVID-19 Vaccination.* Jakarta.

[15] Government of Indonesia, MOH. 2020. *Report of the Minister of Health Handling COVID-19.* Jakarta.

[16] Government of Indonesia, MOH. 2020. *Technical Guidelines for the implementation of vaccinations for management of COVID-19*. Jakarta.

[17] The group is composed of 18 vaccines experts from various prominent national (e.g. Indonesian Pediatrics Society, Indonesian Internal Medicine Society, Indonesian Medical Association) and international organizations (e.g., WHO, UNICEF).

[18] This figure is determined by taking the total population aged over 18 (188.7 million) and excluding 7.2 million people for whom vaccines are yet to be proven safe and efficacious such as pregnant women, those with certain comorbidities and those with previous exposure to COVID-19.

[19] At present, these vaccines are Astra Zeneca, Moderna, Novavax, Pfizer Inc and BioNTech, Sinovac Life Sciences, and Sinopharm, as well as vaccines to be produced by Bio Farma.

[20] Presidential Instruction no. 6/2016 was issued to increase the competitiveness of domestic pharmaceutical industries, encourage expertise in technology and innovation, and accelerate self-reliance in the domestic pharmaceutical market. Also included in Long Term Plan (RJPP) of Pharmaceutical Holding SOEs 2020-2024.

West Java province, Bio Farma is 100% state-owned producer of bacterial, viral and combination vaccines with annual production capacity of approximately two billion doses using four development platforms.[21] Bio Farma supports national self-sufficiency as sole supplier of vaccines to Indonesia's NIP and through the production of "New and Underutilized Vaccines" (NUVs) comprising: (i) new vaccines that MOH plans to introduce into the NIP or to control pandemics (e.g, COVID-19, dengue, rotavirus), and (ii) vaccines that are already part of NIP for which utilization needs to be expanded (e.g., inactivated polio, human papillomavirus (HPV), Japanese Encephalitis, pneumococcal vaccines).

7. Bio Farma also plays an instrumental role in bolstering regional and global vaccine security. With 12 WHO prequalified vaccines, it is one of UNICEF's key vaccine suppliers selling 569 million doses in 2019 (equaling approximately 23% of global dosage procured by UNICEF).[22] In 2019, more than half of Bio Farma's revenues of $170.6 million were derived from sales to international organizations or other countries. In November 2020, WHO listed Bio Farma's novel oral polio vaccine type 2 (nOPV2) as the world's first ever vaccine for emergency use, which also paves the way for potential emergency use listing of COVID-19 vaccines.[23] Bio Farma is one of the few suppliers of polio vaccine globally and a catalyst for boosting local vaccine manufacturing in other countries through the supply of bulk vaccines.[24] Increased export capacity of vaccines also supports the Association of Southeast Asian Nations (ASEAN) goal of strengthening regional vaccine security and self-reliance declared in 2019[25] and further emphasized in the ASEAN Comprehensive Recovery Framework in November 2020.[26]

8. The government, through the MSOE, as well as Bio Farma have requested ADB support under the APVAX facility, to help address Indonesia's urgent public health and economic challenges associated with COVID-19 and strengthen its production and institutional capacity.

B. Project Scope (Impact, Outcome, Outputs)

9. **Impact, Outcome.** The Project is aligned with the following impact: transmission of COVID-19 reduced, public health improved and economic productivity restored; priority populations safely vaccinated against COVID-19 in congruence with routine immunization services and other health services; and resilience and responsiveness of the health system to public health emergencies enhanced. The Project will have the following outcome: supply of COVID-19 and other NUVs to enhance domestic, regional and global health security increased. The Project outputs are described below.

10. **Output 1: COVID-19 vaccines procured and deployed to provinces.** The Project will provide financing for vaccine procurement by Bio Farma and/or its subsidiary Indofarma through the Rapid Response Component (RRC) of APVAX for delivery of minimum 50 million doses of COVID-19 vaccine to locations designated by MOH. The eligible expenditure items under the

[21] Bio Farma produces combination vaccine for Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus Influenzae type B; viral vaccines for seasonal influenza, Poliomyelitis types 1, 2 & 3, measles and Hepatitis B and bacterial vaccines for Tetanus and Neonatal Tetanus, Diphtheria, Tetanus and Pertussis, Tuberculosis. Vaccines are developed through live attenuated; inactivated whole cell; subunit toxoid; and conjugate platforms.

[22] Bio Farma. 2019. *Bio Farma Sales Data 2019*. Jakarta; and UNICEF. 2019. *Supply Annual Report 2019: Scaling Up for Impact*. New York.

[23] WHO. 2020. *First ever vaccine listed under WHO emergency use*. Geneva.

[24] Polio is still endemic in Afghanistan and Pakistan and outbreaks of new strains are circulating in Malaysia and the Philippines.

[25] ASEAN. 2019. *Leaders' Declaration on ASEAN Vaccine Security and Self Reliance (AVSSR)*. Jakarta.

[26] ASEAN. 2020. *ASEAN Comprehensive Recovery Framework.* Jakarta.

RRC will include: (i) vaccines that meet any of the eligibility requirements in Appendix 3 of APVAX, including advance payments, and (ii) international logistics and related services required for the transportation of vaccines from the place of purchase to designated delivery points in Indonesia.

11. **Output 2: Bio Farma's vaccine production capacity strengthened.** Under the project investment component (PIC) of APVAX, Bio Farma will increase its capacity to produce NUVs in bulk-form using the recombinant yeast-based technology platform from 20 million to 100 million doses per year. It initially plans to utilize the additional capacity to manufacture Merah Putih, recombinant Hepatitis B and HPV. The expansion in production capacity will be undertaken at two sites:

12. The first site will be Bio Farma's production complex in Bandung (Bandung facility) where construction will include interior and utility works to install additional capacity of 40 million doses per year. The newly established Building 43 facility will house the state of art vaccine production equipment for preparation (autoclaves, floor scale, media reactor); fermentation (incubator, fermentor); cell disruption (tangential flow filter (TFF) and homogenizer); separation (separator, mixing vessel, centrifuge); and purification (chromatography system and filtration system). Scope of civil works will be limited to interior works and utility works. The Bandung facility will be constructed and equipped to ensure compliance with good manufacturing practice (GMP) standards, which will in due course be subjected to regular BPOM and WHO audits. Facilities will also be equipped with electronic batch record software systems to enhance compliance with established processes, facilitate audits and decrease operating costs.

13. Due to space limitations at the Bandung facility, Bio Farma will also construct a new plant with gender-inclusive and accessibility features[27] and capacity of 40 million doses per year. The new plant will be located on a 2.3-hectare site at the Indotaisei industrial complex in West Java Province (Indotaisei facility). Construction of Indotaisei facility will include a production complex, offices and supporting facilities such as a water treatment plant, wastewater treatment plant, incinerator, and generator set. Both Bandung and Indotaisei facilities will house state of art vaccine production equipment for preparation, fermentation, cell disruption, separation, and purification in compliance with good manufacturing practice (GMP) standards, and be subjected to regular BPOM and WHO audits. Facilities will also be equipped with electronic batch record software systems to enhance compliance with established processes, facilitate audits and decrease operating costs.

14. The PIC will also support the installation of a new packaging line in the Bandung facility capable of packaging and cartoning 25 million vials per year and conducting automatic visual inspection, labelling serialization and cartoning serialization.

15. **Output 3: Bio Farma's institutional capacity enhanced and knowledge disseminated.** Under the PIC, the Project will support activities targeted at strengthening Bio Farma's institutional capacity in the medium to long term and promoting knowledge sharing among vaccine manufacturers in developing countries. First, Bio Farma will enter into partnership agreements with local universities to design and deliver a biochemical certification program for 90 employees (at least half of whom shall be female) over a 3-year period covering key topics including microbial biology, chemical engineering and pharmacy. Second, in order to strengthen

[27] Gender inclusive and accessibility features include provision of a lactation room on each level, separate female and male toilets with privacy and security. The buildings will also include accessible routes, toilets, curb ramp, ramp/lift/stair lift, parking, and signage.

its research and development capability, Bio Farma will sponsor up to 10 employees (at least half of whom shall be female) to obtain master's degrees at a reputable university overseas well known for its programs in infectious diseases, microbiology and immunology, and accompanying surveillance systems. Third, Bio Farma will roll-out a training program based on WHO's GMP training modules,[28] and attendance will be mandatory for new hires who will work in Bandung and Indotaisei facilities. Finally, knowledge gained by Bio Farma in construction and operation of these facilities will be shared through global platforms such as Developing Countries Vaccine Manufacturers' Network and Organization of Islamic Cooperation Vaccines Manufacturers Group.

C. Environment Safeguards Category, Due Diligence

16. **Screening and Categorization.** The project has been classified as category B for environment as per the ADB Safeguard Policy Statement (SPS 2009).[29] Each component of the project was screened for environmental safeguards. The RRC under output 1 classifies as category C. The availability of COVID-19 vaccines will result in a temporary increase of immunization waste at the point of vaccine use (i.e. health facilities). Improved immunization waste management is addressed in various government decrees and plans (discussed in section V.D) issued by MOH and MOEF. Construction of Indotaisei and Bandung vaccine production facilities under the PIC in output 2 have the potential for adverse temporary and site-specific environmental impacts and occupational risks. As a result, the PIC classifies as category B as per the ADB SPS. The vaccine production and packaging lines will adhere to national and international Good Manufacturing Practices (GMP)[30] and will be subject to certification and audits prior to and during commercial operation.[31] The capacity of Bio Farma's existing pollution control systems (including industrial wastewater treatment, and hazardous waste storage and treatment) will be increased to accommodate minor incremental waste production resulting from the project, and Bio Farma's current environment, health and safety (EHS) management systems will be extended to the new production lines, thus ensuring that Bio Farma's high level of compliance with relevant domestic and international EHS requirements can be maintained.[32]

[28] WHO. Good Manufacturing Practices (GMP) training modules (accessed 26 December 2020).
[29] ADB. 2009. *Safeguard Policy Statement*. Manila.
[30] Bio Farma implements the Indonesian Good Manufacturing Practices for pharmaceuticals as well as various WHO GMP, Good Laboratory Practices, Good Clinical Practices, and Good Distribution Practices.
[31] Bio Farma has a pharmaceutical quality assurance and control system managed and operated independently by the Quality Department and the Production Department. internal audits, external audits.
[32] Bio Farma applies various integrated systems such as fulfilling requirements of ISO 9001:2015 on quality management and quality assurance; ISO 14001:2015 on environmental management system; OHSAS 18001:2007 on occupational health and safety; ISO/IEC 17025:2016 on requirements for the competence of testing and calibration laboratories; ISO 26000 guidance for Corporate Social Responsibility (CSR).

Table 1: Environment safeguard categorization of project components

No	Project components	Environment safeguards categorization per ADB SPS 2009
1.	**COVID-19 vaccines procured and deployed to provinces (RRC window of APVAX facility)**	
a.	COVID-19 vaccines procured and deployed to provinces	**Cat. C -** Output does not involve works or equipment. The component will be subject to strict eligibility criteria for vaccine procurement as defined in the policy paper of the proposed APVAX facility. The availability of COVID-19 vaccines will result in a temporary increase of immunization waste at the point of vaccine use (i.e. health facilities). Improved immunization waste management is addressed in Minister Decrees 56/2015 and 18/2020, and technical guidelines (see footnotes 14 and 16, and discussion in Section V.D).
2.	**Bio Farma's vaccine production capacity strengthened (PIC window of APVAX facility)**	
a.	Equipment for producing an additional 40 million vaccine doses annually using recombinant yeast-based platform in Bio Farma's production complex in Bandung installed	**Cat. C for environment with minimal temporary impacts -** Equipment will be installed in existing production facilities of Bio Farma at its HQ in Bandung. No new facility construction required, but minor internal refurbishment works may be required. Facility and production line will be subject to validation and qualification by BPOM prior to production).
b.	Bio Farma's new plant with gender inclusive and accessibility features in Indotaisei industrial complex for producing 40 million vaccine doses annually using recombinant yeast-based platform constructed	**Category B for environment** – The new production facility with footprint of 2,000-3,000 m^2 will be established on a 2.6ha industrial compound owned by Bio Farma in Indo Taisei, Bukit Indah Industrial Area in Karawang Regency, West Java Province.
c.	1 new packaging line to package and carton 25 million vials per year operational	**Cat. C for environment** - One additional packaging line will be installed in existing facility in Building No. 43 of Bio Farma HQ in Bandung
3.	**Bio Farma's institutional capacity enhanced and knowledge disseminated (PIC window of APVAX facility)**	
a-d	Capacity Building, knowledge dissemination	**Cat. C for environment**

17. **Initial Environment Examination.** The preparation of the Initial Environmental Examination (IEE) is guided by the requirements outlined in ADB Safeguard Policy Statement (2009), Access to Information Policy (2018), and the International Finance Corporation's (IFC) Environmental, Health, and Safety Guidelines.

18. The IEE presents the: (i) description of the proposed activities to be financed under the RECOVER project; (ii) national and international laws, regulations and policies governing the project activities; (iii) environmental baseline condition at the proposed project sites; (iv) information disclosure and consultation activities; (v) potential environmental impacts of project components; (vi) environmental management, monitoring and reporting requirements; and (vii) institutional responsibilities and capacity building activities for the implementation of the environmental mitigation and monitoring measures.

19. The following methodologies and activities were undertaken in the conduct of the IEE:

a) Virtual site visit to the subproject sites to assess the areas of influence and identify any environmental and social issues.
b) Study of available assessments and planning documents, including but not limited to: feasibility studies for output 2b; ANDAL amendment (2019) for the Bandung production site (i.e. updated domestic environmental impact assessment); Bio Farma accreditations, permits, policies, procedures and monitoring reports related to environment management and occupational health and safety; national and international regulations and guidelines related to good manufacture practice (GMP) for pharmaceutical manufacturing and distribution.
c) Stakeholder meetings with the Ministry of Health (MOH) and Ministry of Environment and Forestry (MOEF), the World Health Organization (WHO) office in Jakarta, Dinas Lingkungan Hidup dan Kebersihan (DLHK) of Bandung City and Kerawang District, the health authorities of Kerawang District, and Dr. Hasan Sadikin hospital administration adjacent to the Bio Farma's site in Bandung City to ascertain the environmental issues that need to be considered in the design of the project.
d) Screening of project site using the Integrated Biodiversity Assessment Tool (IBAT) to determine presence of environmentally sensitive areas.
e) Environmental due diligence and audit of the existing Bio Farma facilities in Bandung and meetings with key staff involved in production and environment and social safeguards.
f) Discussions with Bio Farma on project impacts, mitigation measures, and institutional arrangements.
g) Preparation of the Environmental Management Plan and its Environmental Monitoring Plan.

D. Environmental Conditions

20. Bio Farma HQ Bandung and the new site in Indotaisei are located within the province of West Java on the island of Java. Bio Farma HQ is located in Jalan Pasteur, Bandung City. The entire complex covers a total land area of 9 hectares. The proposed COVID-19 vaccine production facility will be at Building #43 which occupies a land area of 2,200 m^2. The Bio Farma site in Bandung is located in a densely populated urban area. The land use is for commercial and residential use. The site adjacent to the west of the site is occupied by several health care facilities, including the Dr. Hasan Sadikin Central General Hospital, Rumah Sakit Pendidikan Universitas Padjadjaran University Hospital, Gedung Kemuning Hospital, and the RSHS and Bedah Policlinics.

21. The new site in Indotaisei Industrial Park is located within the jurisdiction of Kota Bukit Indah Kalihurip, Cikampek. The industrial park covers a total land area of 700 hectares. It was developed by the PT Indotaisei Indah Development (IID), a joint venture company between PT Besland Pertiwi and Taisei Corporation of Japan. The proposed site is in an area of 2.3 hectares

acquired by Bio Farma in 2018. In general, the Indotaisei industrial park is designed for a range of medium to heavy industries that are engaged in a various of manufacturing operations such as metal and plastic, glass, chemicals, resins, rubber, wood, metal, industrial gas, and automotive parts. The site is currently unoccupied and ready for civil works to start.

22. Air quality in the project's area of influence is generally good and compliant with the Indonesian ambient air quality standard (AQS). Monitoring results for 2019 indicate that noise levels are within the relevant national standard as well as the WHO noise guideline value for industrial and commercial areas (70 dBA). There are no surface water bodies in the proximity of the Bio Farma compound in Bandung. The nearest body of water to the Bio Farma site in Indotaisei is the Tarum Timur Canal which drains from the Jatiluhur Lake.

23. The sites of Bio Farma in Bandung and Indotaisei are in built up environments, with no- to minimal ecological values. Vegetation coverage in Indotaisei is limited to gras and shrubs of little ecological importance (natural re-growth after industrial park establishment, see **Figure 14**). There are no trees requiring relocation or felling. A rapid screening of legally protected sites between Bandung and Jakarta indicates that there are no legally protected sites that are in proximity to Bio Farma's sites in Indotaisei and Bandung. There are no physical cultural resources at the Bio Farma sites in Bandung and Indotaisei.

E. Environmental Impacts and Mitigation Measures

24. **During construction and/or refurbishment** of the facilities proposed under outputs 2a and 2b, the anticipated impacts will be confined within premises of Bio Farma. The new vaccine production facility in Indotaisei (output 2b) is expected to have a footprint of 2,000 m^2 and requires an RKL-RPL to be submitted to the local Department of Environment. Minor refurbishment works of the 4thfloor of building #43 at Bio Farma's HQ in Bandung will be required for output 2a. Output 2c (packaging line) will not require any works. Outputs 2a and 2c which are in the existing facilities of Bio Farma will require an amendment of the ANDAL and RKL-RPL due to proposed modifications on the use of the building floor, new equipment, and additional manpower. In general, the adverse impacts from these activities are anticipated to be localized, short-term and reversible. Mitigation measures are outlined in the Environmental Management Plan (EMP) in Section VIII of this IEE to manage the identified impacts and risks related to civil works. These measures include:

a) Control of air pollution from dust emissions from on-site excavation and emission from equipment and construction vehicles used for construction;
b) Management of water pollution from run-off or soil erosion from stockpiled construction materials, wastewater from domestic sewage of construction workers, and accidental spillage of oil and other lubricants from washing of construction equipment;
c) Limiting noise from construction activities that may disturb nearby communities;
d) Management of solid wastes from construction workers and construction and demolition wastes;
e) Management of occupational health and safety risks to construction workers, including COVID-19;
f) Adherence to ILO Core Labor Standards; and
g) Management of community health and safety impacts, primarily as a result of exposure to noise, smell of paints and solvents and excavated work areas.

25. **During the operational phase**, no significant environmental impacts and risks are anticipated. The vaccine production and packaging lines are required to comply with the GMP guidelines of WHO, PIC/S and BPOM. Bio Farma has a comprehensive pharmaceutical quality control and quality assurance system. The standards currently adopted for existing vaccine production processes will be expanded to the new production lines.

26. EHS is handled by the Safety and Environment Unit under Bio Farma's Environment and Social Management Division. This unit monitors the implementation of Bio Farma's EHS management system. In addition, Bio Farma has also established an Occupational Health and Safety Guidance Committee Team (P2K3), as well as Emergency Response Team (TTD). Internal audits of facilities and production lines are performed a minimum of three times per year in each facility, and are subject to unannounced inspections (usually on an annual basis) and regular formal audits (usually every three years) by BPOM, WHO, ISO and OHSAS accreditation inspectors.

27. **Waste generation.** Some incremental hazardous pharmaceutical waste generation during operation is anticipated. Inadequate handling and disposal of such hazardous waste could have adverse environmental and health impacts. Within Bio Farma's production facilities, risks are addressed through adherence to the INO, WHO and PIC/S GMP and in compliance with MOEF Regulation No. 12/2020 on Hazardous Waste Storage; MOEF Regulation 101/2014 Regarding the Management of Toxic and Hazardous Substances; MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Medical Service Facilities. Bio Farma has a comprehensive hazardous waste management procedure (236K-LIMB-B3) which also covers hazardous waste incineration (236K-INCI-M1). Recent independent audits conducted by ISO14001:2015 inspectors as well as by WHO concluded that procedures for decontamination and disposal of used contaminated materials and hazardous waste management were in place at Bio Farma.

28. **Pollution control.** Bio Farma operates several waste treatment facilities at Bandung HQ, including needle destroyer, autoclave for disinfection of wastes, two incinerators, two wastewater treatment plants (WWTP) for production wastewater and domestic sewage using disinfection/heat treatment, physical, biological and chemical treatment systems, and temporary hazardous waste storage facilities. A 3rd WWTP is under construction to treat wastewater from the Bandung facility, expected to be operational by December 2020. Stack emission monitoring is conducted on the incinerators on a quarterly basis and on the boiler and diesel generator sets on a semi-annual basis. The results are reported to the Department of Environment (DLH). Results confirm that all facilities comply with national wastewater and emission standards.

29. The new vaccine production site of Bio Farma in Indotaisei industrial park will be equipped with utilities such as WWTP, hazardous waste storage facility, incinerator, generator set, water treatment plant and underground water storge tank. The onsite WWTP will ensure that the effluent of the Bio Farma facility meets the discharge standard prior to discharge and treatment in the existing centralized WWTP of the Indotaisei industrial park. Hazardous solid waste will be temporarily stored at the new site in accordance with MOEF Regulation No. 12/2020 on Hazardous Waste Storage and BF procedure 236K-LIMB-B3 on Handling and Storage of Hazardous Waste, and will be treated in the new incinerator or handed over the a contracted licensed third party.

30. **Domestic safeguards requirements.** As a locator of the industrial park, the new production facility of Bio Farma will be required to prepare a UKL-UPL that will outline its

environmental management and monitoring measures. The UKL-UPL will be reviewed and approved by the DLH Karawang and forms part of the requirements in the issuance of the license to build the new facility. Bio Farma will secure the necessary permits for the incinerator and hazardous waste storage in accordance with the requirements of MOEF. Bio Farma will also secure the necessary environment permit for the new vaccine production facility (Bandung facility), which are not covered under the current environment permit.

31. **EHS accreditations.** Bio Farma applies various integrated systems such as fulfilling requirements of ISO 9001:2015 on quality management and quality assurance, ISO 14001:2015 on environmental management system, OHSAS 18001:2007 on occupational health and safety, ISO/IEC 17025:2016 on requirements for the competence of testing and calibration laboratories, ISO 26000 guidance for Corporate Social Responsibility (CSR), ISO 31000 Enterprise Risk Management, and International Finance Report Standard (IFRS). These accreditations will be expanded to the new production facilities in Bandung and Indotaisei.

32. **Incremental waste generation at point of vaccine use.** The distribution and use of new vaccines will result in increased amounts of medical waste at the point of use (i.e. used vials and syringes at local health centers and hospitals). According to national regulations, every medical facility is required to segregate waste at the source, have its own medical waste treatment plants or use of licensed third-party waste management company.[33]

33. The draft Road Map for National COVID-19 Immunization[34] indicated that currently almost all government healthcare facilities have cooperation agreements with third party service providers in the management of medical wastes, including immunization waste. However, the road map acknowledges that the availability and capacity in waste management of third party service providers need to be reviewed and potentially increased. The limited number and uneven presence of licensed incinerators and cement kilns in Indonesia indicates areas of attention for the planning of additional facilities or alternatives for medical waste management.

34. To address this concern and further strengthen the national COVID-19 response, the MoEF released a circular note 2/2020 specific to the management of infectious waste from healthcare facilities.[35] Through this letter, MOEF advises healthcare facilities to do onsite treatment for its infectious waste using an onsite incinerator or autoclave before handing over the waste to a licensed hazardous waste management company.[36] In January 2021, MOH issued the Ministry of Health Decree HK.02.02/4/1/2021 about Technical Guidelines for the Implementation of Vaccinations in the Management of Corona Virus 2019 (COVID-19) Pandemic. The decree defines requirements for the collection, temporary storage, treatment and/or disposal, and documentation of immunization waste at health service facilities during implementation of the national COVID-19 vaccination program.

[33] Ministry of Health regulation 7/2019 on hospital environmental health; Ministry of Environment and Forestry regulation 56/2015 on the Technical Procedures and Requirements for Management of Hazardous and Toxic Waste Materials from Health Care Facilities; MOH Regulation No. 43/2013 on proper management of clinical laboratory; MOH Decree No. 1204/Menkes/SK/x/2004 on healthcare waste management.
[34] Ministry of Health. Road Map for National COVID-19 Immunization. Draft reviewed on 7 November 2020.
[35] Notice Letter No. SE.2/MENLHK/PSLB3/PLB.3/3/2020 on infectious (hazardous) and domestic waste management from COVID-19 response, dated March 24, 2020
[36] WHO Interim Guidance on water, sanitation, hygiene and waste management for the COVID-19 virus, dated March 19, 2020

35. As part of the MOH/MOEF medical waste management strategy[37], the MoEF plans to construct region-based healthcare waste management facilities – placing incinerators in five locations (Aceh, East Nusa Tenggara, West Nusa Tenggara, South Kalimantan and West Sumatra) in 2020/2021. This program will be continued until 2024, targeting a total of 32 locations of healthcare waste treatment facilities throughout the country as a national priority program to accelerate medical waste management, prevent illegal dumping, and ensure immediate treatment of waste due to COVID-19. MoEF also recommended that healthcare facilities, under the oversight of Province and District Health Offices, should coordinate with industries, such as the cement industry, to manage the disposal of their healthcare waste.

F. Environmental Management Plan, Monitoring, Reporting

36. The IEE includes an environmental management plan (EMP) which describes the environmental management measures that will be carried out to mitigate identified negative impacts or enhance the environment during implementation, and the environmental monitoring to be conducted to ensure that mitigation is provided and is effective in reducing impacts, or to determine the actual impacts of a project activity. The EMP outlines specific mitigation measures, environmental monitoring requirements, and related institutional arrangements for implementation.

37. Bio Farma will serve as the executing agency for the proposed project. To ensure smooth implementation, Bio Farma will appoint the Operations Directorate[38] as the project management unit (PMU) which will be responsible for overall project management, including project supervision, monitoring, accounting, and consolidated reporting, and the project management division[39] as the project implementing unit (PIU) which will be responsible for the implementation of all project components. Both PMU and PIU will be staffed with sufficient personnel to support different aspects of the project, including social and environmental safeguards, gender, procurement, financial management and technical issues. Bio Farma's Safety and Environment Unit will support the PMU and PIU in supervising compliance with the EMP during project implementation. Bio Farma will recruit consultants that will support the PMU/PIU in implementing the EMP, ensure financial management, and oversee construction.

38. The Bandung City environmental protection agency (DLH) will approve domestic assessments and monitoring plans (UKL/UPL or RKL/RPL) including issuance of environmental permits, and supervise compliance with approved plans and issued permits during project implementation.

39. Badan Pengawas Obat & Makanan (BPOM, the National Agency of Drug and Food Control of Indonesia), will conduct the evaluation of the new production facilities to determine the general conditions of the goods and their surroundings and evaluate the manufacturing process as part of product registration before any drug is circulated in the market. BPOM will oversee

[37] MOEF and MOH are partnering to improve the management of medical waste, including the availability of medical waste treatment, through an on-going medical waste management strategy. The strategy includes: (i) short-term solution to treat the cumulation of medical wastes by allowing the processing of waste in non-licensed facility-level waste incinerators or processing it through cement kilns, (ii) increasing the capacity of licensed third-party treatment facilities, (iii) developing a 10-year roadmap of medical waste management, (iv) developing an electronic instrument to monitor medical waste treatment from source to a disposal site, and (v) construction of a region-based medical waste treatment facilities (e.g. incinerator).

[38] Directorate/department responsible to manage and oversee the whole activities in Bio Farma.

[39] The division is under the coordination of the Operations Directorate.

product registration and issue distribution licenses for new vaccines. BPOM will implement laboratory examinations, certification of products, production and distribution facilities.

40. During the construction phase, the works contactor will be responsible for implementation of their construction EMP, to be developed based on the EMP defined in this IEE, under supervision of Bio Farma's PMU/PIU.

41. The works contractor will be required to prepare and submit monthly progress reports and submit these to the PMU/PIU. These reports will also include reporting on the contractor's environment management and supervision activities. Bio Farma's PMU/PIU (with support of the consultants) will prepare semi-annual environmental monitoring reports that covers all project activities classifying as category B, and submit these to ADB.

G. Information Disclosure, Meaningful Consultation, Grievance Redress Mechanism

42. Prior to and during preparation of this IEE, a series of information disclosure and consultation meetings were conducted. The consultations were conducted to collect project relevant information, present the proposed project to key agencies and elicit the environmental concerns/issues on the proposed project. Information about environmental clearance requirements was also gathered. Information disclosure and consultation activities are presented in the next sections.

43. Bio Farma's intention to import bulk COVID-19 vaccine and expand production capacities for COVID-19 vaccine in its new facility in Bandung facility of the Pasteur site was disclosed and disseminated to the public through printed and e-media as early as August 2020. Bio Farma also disclosed its intention to expand production capacities by establishing new vaccine production facilities in the Indotaisei industrial park through e-media. Bio Farma also maintains and regularly updates its website and facebook page to provide information on its ongoing clinical trials, and its intensions and progress towards the in-house production of the COVID-19 vaccine in Bandung.

44. Given travel restrictions during preparation of this IEE, consultation meetings were held online. The IEE authors met a series of key project stakeholders, including all relevant departments of Bio Farma, the Ministry of Health (MOH), the Ministry of Environment and Forestry (MOEF), BPOM, the Bandung City and the Kerawang District environment protection authorities (DLHK) in Bandung City and Karawang Regency, the Kerawang District health authorities, and WHO Indonesia country office. The meetings primarily aimed at understanding the project scope, clarifying Bio Farma's existing environment, health and safety policies, procedures and arrangements; seeking views of relevant government agencies on the project; and clarifying the country's current hospital waste management capacities and government's strategy and plans to address capacity gaps. Consultations confirmed broad support for the project and Bio Farma's and Indotaisei Industrial Park's compliance with relevant environment laws and regulations as well as conditions of environmental permit. No significant concerns were raised that relate to environment or safety.

45. No residential area is anticipated to be directly affected by the project interventions in Bio Farma's sites in Bandung and Indotaisei. As a result, no public consultation meetings were held. However, pre-construction consultations, primarily through information sharing, shall be conducted to inform relevant authorities and nearest institutions and communities about planned construction works and schedule, and the grievance redress mechanism (GRM, see Section VII).

Furthermore, Bio Farma will disclose the semi-annual environment monitoring reports on the project website in accordance with ADB's Access to Information Policy (2018).

H. Conclusion

46. This Initial Environmental Examination (IEE) together with the EMP is prepared in compliance with ADB SPS (2009) for category B projects. The IEE confirms that the project is not anticipated to result in significant impacts that unprecedented and irreversible. The RRC of the project classifies as category C, while category B for the PIC of the project is confirmed, primarily triggered by output 2b which will involve construction of a new vaccine production facility. Should there be any changes in the project components, scope and location during detailed engineering design, the environmental impacts resulting from the proposed modifications will be assessed to check if these changes will result to environmental impacts that would merit the updating of the IEE and the EMP.

II. PROJECT DESCRIPTION

A. Background Information and Project Rationale

47. COVID-19 continues to spread widely in Indonesia, having infected over 770,000 people with 22,000 fatalities as of 4 January 2021.[40] Indonesia's positivity rate of 20% is significantly higher than the 5% benchmark set by the World Health Organization (WHO).[41] Indonesia has implemented non-pharmaceutical interventions (NPIs),[42] collectively termed '3Ms',[43] to mitigate the spread of COVID-19. While 3Ms have the potential to control the spread of COVID-19,[44] compliance has been uneven.[45] 24% of the population does not have handwashing facilities available at home,[46] and over 10% of the population lives in slums and crowded informal settlements, making social distancing challenging.[47] NPIs have disrupted normal societal functioning and damaged the economy, triggering an economic contraction of 2.2% in 2020, down from an original growth estimate of 5.2%.[48] While the government has increased spending for social protection, health and other measures for relief and recovery,[49] this has led to a rise in public debt from 30.2% of gross domestic product (GDP) in September 2019 to 40.9% by 2021. The ongoing crisis has significantly impacted livelihoods, especially within the most vulnerable and remote communities. Close to 10 million people are at risk of falling below the national poverty line, with poverty incidence expected to increase from 9.4% in March 2019 to 11.9%–12.8% by the end of 2020.[50]

48. The rapid development of COVID-19 vaccines, some of which have already obtained Emergency Use Authorizations (EUA) in several countries, offers Indonesia the opportunity to strengthen its public health response and suppress COVID-19 through provision of safe and effective vaccines. As the world's fourth most populous country, Indonesia will simultaneously need to expand domestic vaccine manufacturing capacity to ensure sufficient supplies in order to avert future disease outbreaks.

49. The Committee for Handling COVID-19 and National Economic Recovery, headed by the Coordinating Minister for Economic Affairs, oversees COVID-19 response activities including the vaccination program. The executive chair of the Committee is the Minister of SOEs, who has been

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40 Government of Indonesia. COVID-19 Handling Committee and National Economic Recovery (accessed 30 December 2020).

41 World Health Organization (WHO). 2020. *Coronavirus disease 2019 (COVID-19): Situation Report – 38*. Geneva

42 European Centre for Disease Prevention and Control. 2020. *Guidelines for the implementation of non-pharmaceutical interventions against COVID-19*. Solna.

43 3Ms include: (i) 'Menjaga jarak' (large-scale social restrictions such as closure of schools and religious places, a ban on domestic travel, cancellation of public holidays and imposition of work from home policies), (ii) 'Mencuci tangan' (handwashing), and (iii) 'Masker' (mask wearing).

44 G. Castex et al. 2020. COVID-19: The impact of social distancing policies, cross-country analysis. *Economics of disasters and climate change*. pp. 1-25.

45 United Nations Children's Fund. 2020. *Indonesia COVID-19 Response Situation Report – Situation in Numbers (Oct 13, 2020)*. New York.

46 United Nations (UN) Women. 2020. *Counting the Costs of COVID-19: Assessing the Impact on Gender and the Achievement of the SDGs in Indonesia*. Bangkok.

47 World Bank. 2016. *Indonesia: Improving Infrastructure for Millions of Urban Poor*. Washington DC.

48 ADB. 2020. *Asian Development Outlook Supplement: December 2020—Paths Diverge in Recovery from Pandemic*. Manila.

49 Government of Indonesia, Ministry of Finance. 2020. *Report on the development of the implementation of COVID-19 handling and national economic recovery program 27 November 2020*. Jakarta.

50 ADB. Indonesia: COVID-19 Active Response and Expenditure Support Program.

coordinating closely the vaccine procurement efforts. Presidential Regulation No. 99/2020[51] sets out the implementation arrangement for vaccine procurement and distribution. It authorizes the Minister of Health to, among other things, assign Bio Farma and its subsidiaries PT Kimia Farma Tbk (Kimia Farma) and PT Indofarma Tbk (Indofarma)[52] to procure vaccines from various vaccine manufacturers and deliver to a location at provincial level as designated by the Ministry of Health (MOH). From there, responsibility for delivery to service points and eventual administration lies with provincial and district health offices in coordination with MOH.

50. Besides the Presidential Regulation No.99/2020, the government through MOH has issued decrees,[53] a plan[54] and technical guidelines[55] to support vaccine procurement and implementation (collectively termed vaccination strategy). The Health Minister Decree 84/2020 incorporates recommendations from the Indonesian Technical Advisory Group on Immunization[56] on the urgent need for vaccinations to reduce transmission, morbidity and mortality and restore economic productivity. The government has determined that, starting in the first quarter of 2021, 181.5 million[57] people should be vaccinated for free in two phases to reach herd immunity, estimated to require 426.8 million doses.

51. Government has mandated that all vaccines to be procured must (i) be listed under MOH decree 12758/2020[58]; and (ii) obtain EUA or distribution permit from the BPOM prior to administration. As of 29 December 2020, government requested binding commitments for 279.5 million doses and non-binding commitments for an additional 284 million doses. To ensure timely and sustainable supply for COVID-19 vaccine in 2023 and beyond, the government is promoting development of an indigenous vaccine called 'Merah Putih' in collaboration with Jakarta-based Eijkman Institute for Molecular Biology and Bio Farma.

52. In the longer term, the government aims to: (i) strengthen the independence of the national pharmaceutical industry, reduce dependency on imports and increase exports; (ii) boost research and development capability; and (iii) leverage economies of scale and increase productivity so pharmaceutical products – including vaccines - can be made available at affordable prices.[59] Bio Farma is central to realizing these goals. Established in 1890, and headquartered in Bandung,

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[51] Government of Indonesia. 2020. *Presidential Regulation 99/2020 on Vaccines procurement and implementation.* Jakarta.

[52] Bio Farma owns 90% stake in Kimia Farma and 80.6% stake in Indofarma, and these subsidiaries are engaged in the manufacture, distribution and retailing of pharmaceutical products.

[53] Government of Indonesia, MOH. 2020. *MOH decree 84/2020 on Implementation of vaccinations to control COVID-19 pandemic*. Jakarta; Government of Indonesia, MOH. 2020. *MOH decree 28/2020 on Implementation of vaccine procurement in the control of COVID-19*; Jakarta; Government of Indonesia, MOH. 2020. *MOH decree 6573/2020 on the COVID019 implementation team*. Jakarta*;* and Government of Indonesia, MOH. 2020. *MOH decree 12758/2020 on Determination of Vaccines for the Implementation of COVID-19 Vaccination.* Jakarta.

[54] Government of Indonesia, MOH. 2020. *Report of the Minister of Health Handling COVID-19.* Jakarta.

[55] Government of Indonesia, MOH. 2020. *Technical Guidelines for the implementation of vaccinations for management of COVID-19*. Jakarta.

[56] The group is composed of 18 vaccines experts from various prominent national (e.g. Indonesian Pediatrics Society, Indonesian Internal Medicine Society, Indonesian Medical Association) and international organizations (e.g., WHO, UNICEF).

[57] This figure is determined by taking the total population aged over 18 (188.7 million) and excluding 7.2 million people for whom vaccines are yet to be proven safe and efficacious such as pregnant women, those with certain comorbidities and those with previous exposure to COVID-19.

[58] At present, these vaccines are Astra Zeneca, Moderna, Novavax, Pfizer Inc and BioNTech, Sinovac Life Sciences, and Sinopharm, as well as vaccines to be produced by Bio Farma,

[59] Presidential Instruction no. 6/2016 was issued to increase the competitiveness of domestic pharmaceutical industries, encourage expertise in technology and innovation, and accelerate self-reliance in the domestic pharmaceutical market. Also included in Long Term Plan (RJPP) of Pharmaceutical Holding SOEs 2020-2024.

West Java province, Bio Farma is 100% state-owned producer of bacterial, viral and combination vaccines with annual production capacity of approximately two billion doses using four development platforms.[60] Bio Farma supports national self-sufficiency as sole supplier of vaccines to Indonesia's NIP and through the production of "New and Underutilized Vaccines" (NUVs) comprising: (i) new vaccines that MOH plans to introduce into the NIP or to control pandemics (e.g, COVID-19, dengue, rotavirus), and (ii) vaccines that are already part of NIP for which utilization needs to be expanded (e.g., inactivated polio, human papillomavirus (HPV), Japanese Encephalitis, pneumococcal vaccines).

53. Bio Farma also plays an instrumental role in bolstering regional and global vaccine security. With 12 WHO prequalified vaccines, it is one of UNICEF's key vaccine suppliers selling 569 million doses in 2019 (equaling approximately 23% of global dosage procured by UNICEF).[61] In 2019, more than half of Bio Farma's revenues of $170.6 million were derived from sales to international organizations or other countries. In November 2020, WHO listed Bio Farma's novel oral polio vaccine type 2 (nOPV2) as the world's first ever vaccine for emergency use, which also paves the way for potential emergency use listing of COVID-19 vaccines.[62] Bio Farma is one of the few suppliers of polio vaccine globally and a catalyst for boosting local vaccine manufacturing in other countries through the supply of bulk vaccines.[63] Increased export capacity of vaccines also supports the Association of Southeast Asian Nations (ASEAN) goal of strengthening regional vaccine security and self-reliance declared in 2019[64] and further emphasized in the ASEAN Comprehensive Recovery Framework in November 2020.[65]

54. The government, through the MSOE, as well as Bio Farma have requested ADB support under the APVAX facility, to help address Indonesia's urgent public health and economic challenges associated with COVID-19 and strengthen its production and institutional capacity. Bio Farma has requested two regular loans in the aggregate amount of $450 million from ADB's ordinary capital resources; of which $350 million will finance output 1, and a loan of $100 million will finance outputs 2 and 3.

55. The government, through the MSOE, as well as Bio Farma have requested ADB support under the APVAX facility, to help address Indonesia's urgent public health and economic challenges associated with COVID-19 and strengthen its production and institutional capacity.

B. Project Scope (Impact, Outcome, Outputs)

56. **Impact, Outcome.** The Project is aligned with the following impact: transmission of COVID-19 reduced, public health improved and economic productivity restored; priority populations safely vaccinated against COVID-19 in congruence with routine immunization services and other health services; and resilience and responsiveness of the health system to public health emergencies enhanced. The Project will have the following outcome: supply of

[60] Bio Farma produces combination vaccine for Diphtheria, Tetanus, Pertussis, Hepatitis B and Haemophilus Influenzae type B; viral vaccines for seasonal influenza, Poliomyelitis types 1, 2 & 3, measles and Hepatitis B and bacterial vaccines for Tetanus and Neonatal Tetanus, Diphtheria, Tetanus and Pertussis, Tuberculosis. Vaccines are developed through live attenuated; inactivated whole cell; subunit toxoid; and conjugate platforms.

[61] Bio Farma. 2019. *Bio Farma Sales Data 2019*. Jakarta; and UNICEF. 2019. *Supply Annual Report 2019: Scaling Up for Impact*. New York.

[62] WHO. 2020. *First ever vaccine listed under WHO emergency use*. Geneva.

[63] Polio is still endemic in Afghanistan and Pakistan and outbreaks of new strains are circulating in Malaysia and the Philippines.

[64] ASEAN. 2019. *Leaders' Declaration on ASEAN Vaccine Security and Self Reliance (AVSSR)*. Jakarta.

[65] ASEAN. 2020. *ASEAN Comprehensive Recovery Framework.* Jakarta.

COVID-19 and other NUVs to enhance domestic, regional and global health security increased. The Project outputs are described below.

1. Output 1: COVID-19 vaccines procured and deployed to provinces

57. The Project will provide financing for vaccine procurement by Bio Farma and/or its subsidiary Indofarma through the Rapid Response Component (RRC) of APVAX for delivery of minimum 50 million doses of COVID-19 vaccine to locations designated by MOH. The eligible expenditure items under the RRC will include: (i) vaccines that meet any of the eligibility requirements in Appendix 3 of APVAX, including advance payments, and (ii) international logistics and related services required for the transportation of vaccines from the place of purchase to designated delivery points in Indonesia.

2. Output 2: Bio Farma's vaccine production capacity strengthened

58. Under the project investment component (PIC) of APVAX, Bio Farma will increase its capacity to produce NUVs in bulk-form using the recombinant yeast-based technology platform from 20 million to 100 million doses per year. Output 2 includes three sub-outputs. These are presented below.

59. **Output 2a: Expansion of an existing vaccine production facility in Bio Farma Headquarters in Bandung (Bandung Facility).** Bio Farma existing vaccine production facilities on Bio Farma's site in Bandung will be scaled up to support production of 40 million doses per year of vaccines in 2024. The Bandung facility will house the state of art vaccine production equipment for preparation (autoclaves, floor scale, media reactor); fermentation (incubator, fermentor); cell disruption (tangential flow filtration (TFF) and homogenizer); separation (separator, mixing vessel, centrifuge); and purification (chromatography system and filtration system). Scope of civil works will include minor interior works and utility works. An additional wastewater treatment plant is currently under construction (250 m^3/d) to serve the Bandung facility. The vaccine production in the Bandung facility will be installed and equipped to ensure compliance with good manufacturing practice (GMP) standards, which will in due course be subjected to regular BPOM and WHO audits. The detail layout plan including required minor refurbishment works will be defined during detailed design.

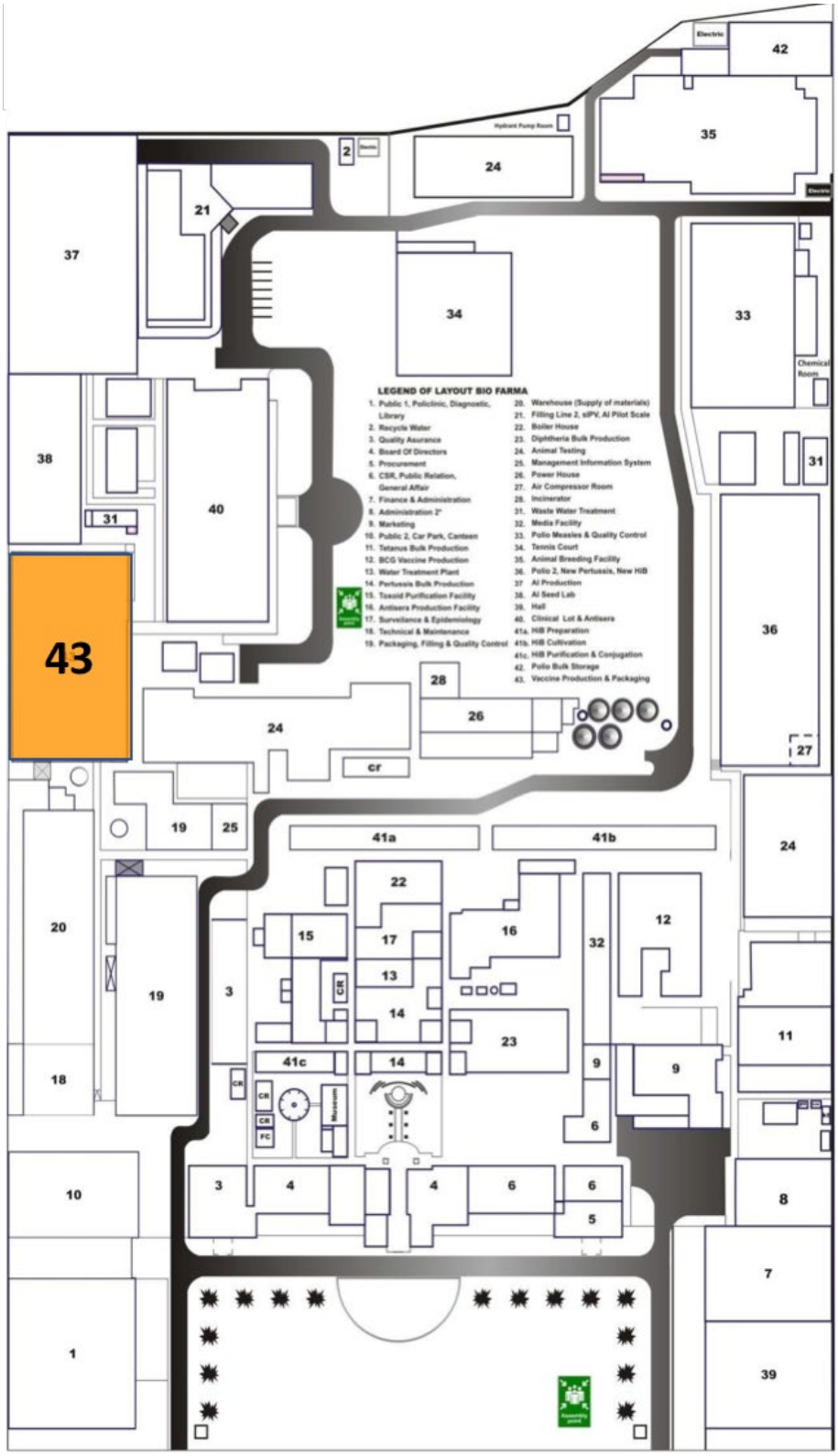


Figure 1: Plant Layout of Bio Farma's Bandung site, location of Building 43 (all buildings are existing)

Figure 2: Photography of Building No. 43, Pasteur site, Bandung

Table 2: Scope of subcomponents under output 2a

1. Minor works (Civil, Piping, HVAC, BPOM Qualification and Validation)
2. Equipment
+ Preparation
- Autoclave
- Floor Scale
- Media reactor
+ Fermentation
- Incubator
- Fermentor 2,5L
- Fermentor 25L
- Fermentor 250L
+ Cell Disruption
- TFF
- Homogenizer
+ Separation
- Separator
- Precipitation Vessel
- Buffer Vessel
- NaCl Vessel
- PEG Vessel

- Adsorption Vessel
- Aerosil Vessel
- Adsorption Wash Vessel
- Adsorption Buffer Vessel
- Desorption Vessel
- Desorption Buffer Vessel
- Desorbate Vessel
- Continuous centrifuge
- Supernatan vessel
+ Purification
- Chromatography System
- Feed vessel
- TFF
- Ultracentrifuge
- Chromatography System
+ Sterile Filtration
- Dilution Vessel
- Desalting Buffer Vessel
- Filtrate Vessel
- Filtration System
+ Supporting Equipment
- Biological Safety Cabinet
- Laminar Air Flow
- Autoclave Disinfection
+ Laboratory Equipment (small laboratory equipment e.g pH meter, particle counter, air sampler, integrity filter tester, garment washing & drying etc)
3. Utilities
- Waste Water Treatment Plant (under construction, not included in project scope)
- Generator Set (under installation, not included in project scope)
- Compressed Air
- UPS flywheel

60. **Output 2b: Construction of new plant at Indotaisei to manufacture vaccines.** Due to space limitations at the Bandung production complex, Bio Farma will construct a new plant on a 2.3-hectare site at the Indotaisei industrial complex in West Java Province (Indotaisei facility). Bio Farma has the block plan for the site which includes office building, vaccine production building and supporting facility buildings including on-site WWTP to treat the wastewater and ensure that the effluent of the Bio Farma facility meets the standard to be treated further by the existing WWTP (the WWTP that serve the whole Indotaisei industrial complex); one incinerator to manage the hazardous solid waste, a boiler house, a water storage tank, and other auxiliary facilities (**Figure 3**).

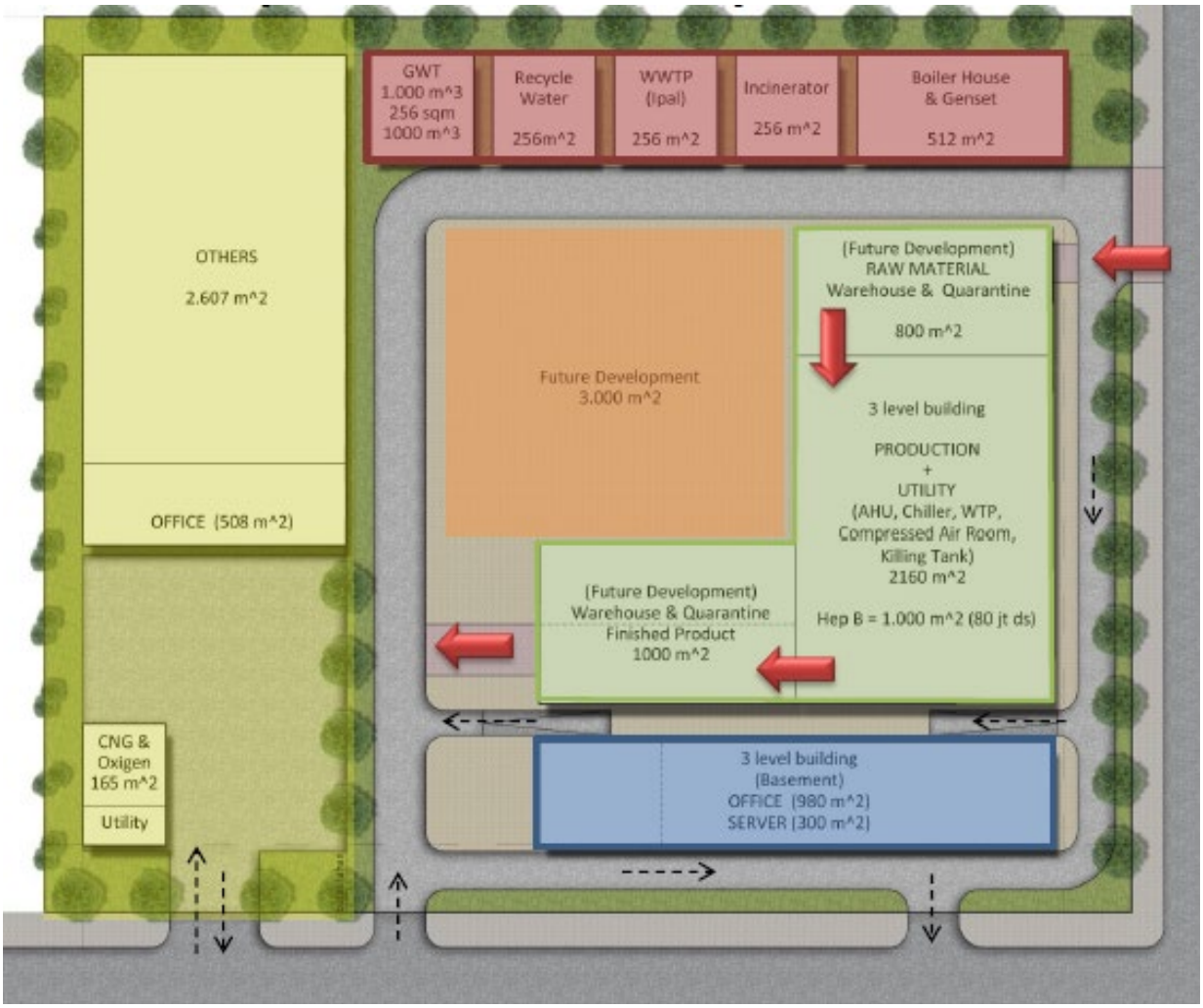


Figure 3: Site plan of Bio Farma's planned facility in Indotaisei, Karawang Regency

61. The Indotaisei facility will be designed to produce 40 million doses per year of vaccines including for hepatitis B and HPV, and depending on market needs, it could also prioritize the production of Merah Putih. The project will finance civil works and state of art vaccine production equipment for (i) preparation (autoclaves, floor scale, media reactor); fermentation (incubator, fermentor); cell disruption (TFF and homogenizer); separation (separator, mixing vessel, centrifuge); and purification (chromatography system and filtration system). The project will finance construction of the office building (3 story-building), the main vaccine production building (3 story-building) and supporting facilities (water storage, recycled water storage, wastewater pre-treatment plant, incinerator, boiler, genset). The Indotaisei facility will be designed, constructed and equipped to ensure compliance with GMP standards, and in due course be subjected to regular BPOM and WHO audits.

Table 3: Scope of subcomponents under output 2b

1. Main works (Civil, Piping, HVAC, Qualification and Validation)
2. Equipment
+ Preparation
- Autoclave

- Floor Scale
- Media reactor
+ Fermentation
- Incubator
- Fermentor 30L
- Fermentor 25L
- Fermentor 500L
+ Cell Disruption
- TFF
- Homogenizer
+ Separation
- Separator
- Precipitation Vessel
- Buffer Vessel
- NaCl Vessel
- PEG Vessel
- Adsorption Vessel
- Aerosil Vessel
- Adsorption Wash Vessel
- Adsorption Buffer Vessel
- Desorption Vessel
- Desorption Buffer Vessel
- Desorbate Vessel
- Continuous centrifuge
- Supernatan vessel
+ Purification
- Chromatography System
- Feed vessel
- TFF
- Ultracentrifuge
- Chromatography System
+ Sterile Filtration
- Dilution Vessel
- Desalting Buffer Vessel
- Filtrate Vessel
- Filtration System
+ Supporting Equipment
- Biological Safety Cabinet
- Laminar Air Flow
- Autoclave Disinfection

+ Laboratory Equipment (small laboratory equipment e.g pH meter, particle counter, air sampler, integrity filter tester, garment washing & drying etc)
3. Utilities
- Water Treatment Plant
- Air Compressor
- Boiler
- Neutralization Tank
- Genset
- Waste Water Treatment Plant
- Incinerator

62. **Output 2c: Installation of new packaging line.** The packaging line will be installed in Building 43 of Bio Farma's main site in Pasteur, Bandung. The packaging line will support the packaging and cartoning of 25 million vials per year from all Bio Farma facilities to be ready for distribution. It will require installation of equipment for automatic visual inspection and labelling serialization and cartoning serialization, which follow the specifications similar to the existing two packaging lines to ensure integrated operations.

3. Output 3: Bio Farma's institutional capacity enhanced and knowledge disseminated

63. Under the PIC, the Project will support activities targeted at strengthening Bio Farma's institutional capacity in the medium to long term and promoting knowledge sharing among vaccine manufacturers in developing countries. First, Bio Farma will enter into partnership agreements with local universities to design and deliver a biochemical certification program for 90 employees (at least half of whom shall be female) over a 3-year period covering key topics including microbial biology, chemical engineering and pharmacy. Second, in order to strengthen its research and development capability, Bio Farma will sponsor up to 10 employees (at least half of whom shall be female) to obtain master's degrees at a reputable university overseas well known for its programs in infectious diseases, microbiology and immunology, and accompanying surveillance systems. Third, Bio Farma will roll-out a training program based on WHO's GMP training modules,[66] and attendance will be mandatory for new hires who will work in Bandung and Indotaisei facilities. Finally, knowledge gained by Bio Farma in construction and operation of these facilities will be shared through global platforms such as Developing Countries Vaccine Manufacturers' Network and Organization of Islamic Cooperation Vaccines Manufacturers Group.

C. Description of Production Process

64. The following describes the production of vaccines. The steps are outlined in **Figure 4** and **Figure 5**.

1. Upstream Vaccine Production

65. The upstream vaccine production applies to the operation of the new plant under Output 2b to produce hepatitis B and HPV vaccines. The upstream production process involves: (i) inoculation, (ii) cultivation, (iii) harvest, (iv) inactivation, and (v) purification.

[66] WHO. Good Manufacturing Practices (GMP) training modules (accessed 26 December 2020).

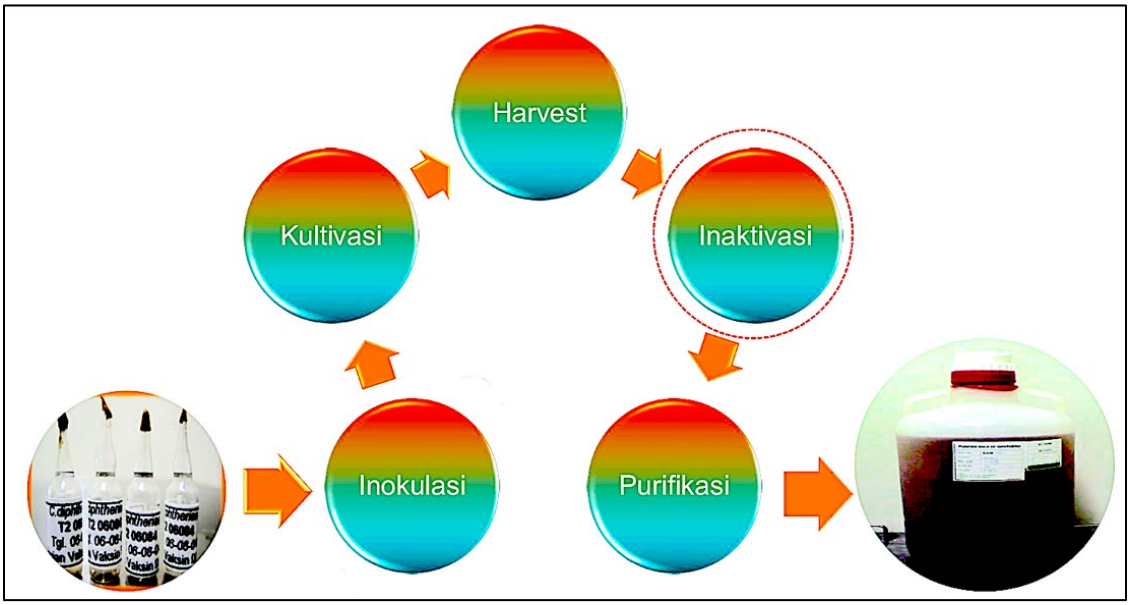


Figure 4: Upstream Vaccine Production Process

2. Downstream Vaccine Production

66. The downstream vaccine production will be for the COVID-19 vaccine under Output 1 and future production of Merah Putih under Output 2a. Downstream vaccine production involves: (I) validation tests, (ii) formulation, (iii) filling, (iv) freeze drying, (v) visual inspection, (vi) labelling, and (vii) packaging.

67. **Validation tests.** Bio Farma will conduct the validation tests on every bulk ready to fill (RTF). Quality assurance tests includes visual test, identity test, extractable volume, pH, aluminum content, osmotic pressure molar concentration, sterility, antigen content after dissociation, abnormal toxicity, endotoxin, and vaccine effectivity. The tests will be undertaken in conformity with the requirements of WHO and BPOM on GMP.

68. **Formulation.** This process involves mixing in vessels to achieve homogenized mixture.

69. **Filling.** The final bulk vaccine is charged into vials, ampoules, uniject, and/or pre-filled syringe. The filling process is carried out in separate areas within the clean area. Access to critical filling areas is restricted and unidirectional airflow systems are provided.

70. **Freeze drying.** The process of freeze drying is applied as a dehydration method to increase the stability and storage of live virus vaccines. The vaccine is completely frozen and then vacuumed significantly below the triple point of water and finally dried thru heat application to cause sublimation.

71. **Visual inspection.** The filled containers are inspected individually for extraneous contamination or other defects. The inspection process is done under suitable and controlled conditions of illumination and background. The operators doing the inspection are required to pass the regular eyesight checks, use personal corrective lenses (e.g. spectacles or contact lenses) as required.

72. **Labelling.** The labelling process is carried out so that each basket, tray or other carrier of products of components are clearly labelled with the name of the materials, its batch number and an indication of whether or not it has been sterilized. Indicators such as autoclave tape are used to indicate whether or not a batch (or sub-batch) has passed through a sterilization process.

73. **Packaging.** The vaccines are packed in boxes.

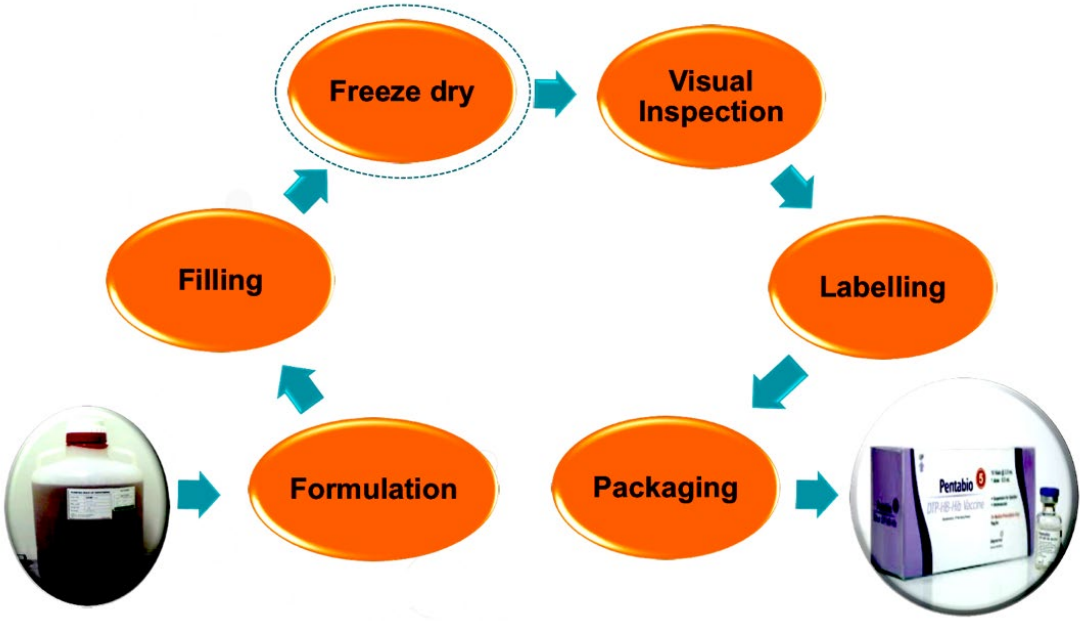


Figure 5: Downstream Vaccine Production Process

D. Institutional arrangements and project implementation schedule

74. **Project management.** Bio Farma will serve as the executing agency for the proposed project. To ensure smooth implementation, Bio Farma will appoint the Operations Directorate[67] as the project management unit (PMU) which will be responsible for overall project management, including project supervision, monitoring, accounting, and consolidated reporting. Bio Farma will appoint the project management division[68] as the project implementing unit (PIU) which will be responsible for the implementation of all project components. Both PMU and PIU will be staffed with sufficient personnel to support different aspects of the project, including environmental safeguards, GMP, gender, procurement, financial management and technical issues.

75. **Procurement and Consulting Services.** All procurement activities to be financed by ADB will follow the ADB Procurement Policy (2017, as amended from time to time) and Procurement Regulations for ADB Borrowers (2017, as amended from time to time). All procurement and recruitment of consultants will be supervised by Procurement Division of Bio Farma. The procurement plan is described in detail in the project administration manual (PAM), which is disclosed on the project website at www.adb.org.

[67] Directorate/department responsible to manage and oversee the whole activities in Bio Farma.
[68] The division is under the coordination of the Operations Directorate.

76. Bio Farma will (i) recruit a preliminary design consultant (PDC) to prepare conceptual and preliminary design of the new plant at Indotaisei site which shall be delivered under design-build modality, (ii) recruit a project management and supervision consultant (PMSC) to support Bio Farma in overall project management and construction supervision, (iii) recruit individual consultant(s) as needed to review the detailed engineering design (DED) for expansion of the existing facility that will require procurement of civil works, equipment and IT system contracts, and (iv) support the Procurement Committee as needed. The terms of reference of the PDC and PMSC are described in detail in the project administration manual (PAM), which is disclosed on the project website at www.adb.org.

77. **Implementation schedule.** The project will be implemented from February 2021 to March 2026. The implementation schedule is presented in **Figure 6** below.

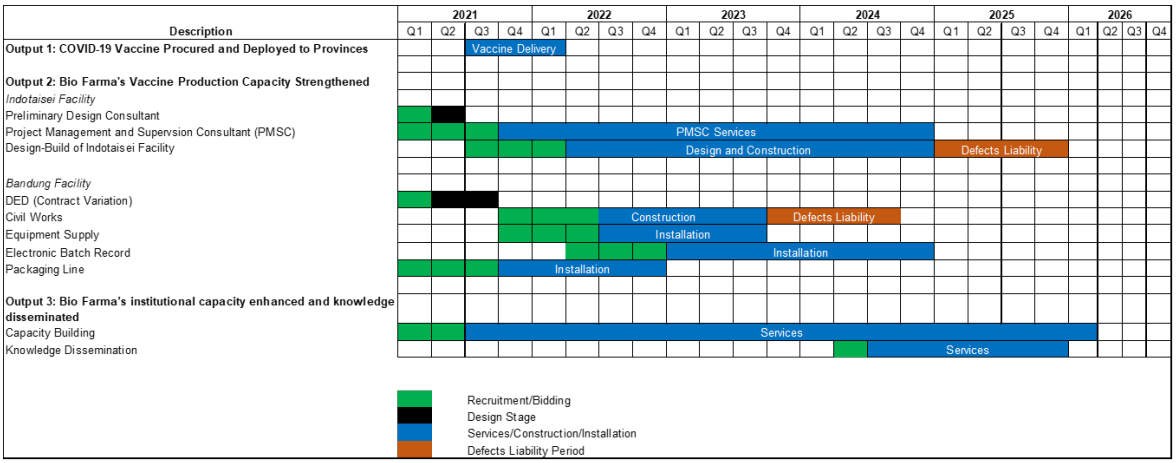


Figure 6: Project Implementation Schedule

78. The activities at the 4th level of Building 43 at Bio Farma site in Pasteur will only involve the construction of wall panels/partitions and the installation of equipment for the vaccine production. The area is currently empty and works can proceed immediately without need for major clearing or any demolition activities. The construction/installation activities may take 16 months to complete. The additional packaging line will also be installed in another section of Bandung facility and it will only take about 2-4 months.

79. Civil works will occur for the buildings and utilities at the new site in Indotaisei industrial park. Construction and equipment installation activities will take approximately 16-18 months.

III. POLICY, LEGAL, AND ADMINISTRATIVE FRAMEWORK

A. ADB Safeguard Policy Statement 2009

80. All projects supported by ADB must comply with ADB's Safeguard Policy Statement (SPS, 2009). ADB's SPS sets out the policy objectives, scope and triggers, and principles for Environmental safeguard areas to be followed across all aspects of its operations. ADB adopts a set of specific safeguard requirements that borrowers/clients are required to meet in addressing environmental impacts and risks. Borrowers/clients must comply with these requirements during the project preparation and implementation phases. ADB's environmental safeguard requirements are defined in ADB's SPS, Appendix 1 (Safeguard Requirements 1: Environment. Pages 30-40). All environmental safeguard principles and requirements of ADB's SPS are reflected in this IEE.

81. **International good practice.** ADB's SPS requires that during the design, construction, and operation of the project the borrower/client will apply pollution prevention and control technologies and practices consistent with international good practice, as reflected in internationally recognized standards such as the World Bank Group's *Environment, Health and Safety Guidelines* or the various WHO *Good Manufacturing Practice (GMP) guidelines.* These standards and guidelines contain performance levels and measures that are normally acceptable and applicable to projects of this nature. When host country regulations differ from these levels and measures, the borrower/client will achieve whichever is more stringent.

82. **Table 4** presents a list of IFC guidelines applicable to all activities supported under the RECOVER project and are referred to in this initial environmental examination (IEE) and environmental management plan (EMP) where appropriate.

Table 4: IFC guidelines applicable to all activities supported under RECOVER project

EHS Guideline	Description, Relevance to RECOVER project
EHS General Guidelines (2007)	Define general and GIIP that must be applied for facilities and activities to be supported under the RECOVER project. Key sections of the General Guidelines of relevance to RECOVER project include: − Environmental Guidelines (covering air emissions, wastewater and ambient water quality, hazardous materials management, waste management, noise) − Occupational health and safety − Community health and safety − Construction and decommissioning The General Guidelines are designed to be used together with the relevant Industry Sector EHS Guidelines which provide guidance to users on EHS issues in specific industry sectors (see below).
EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007)	The EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing include information relevant to pharmaceuticals and biotechnology manufacturing facilities. They cover the production of active pharmaceutical ingredients and secondary processing, including intermediates, formulation, blending, and packaging, and related activities research, including biotechnology research and production. Most importantly, the guidelines cover the following aspects that should

EHS Guideline	Description, Relevance to RECOVER project
	be considered in the design and operation of pharmaceutical manufacturing activities to be supported by the RECOVER project: − Management of environmental issues such as air emissions (volatile organic compounds, acid gases, and particulates), odors, industrial process wastewater, solid and hazardous wastes − Management of threats to biodiversity from the collection of genetic resources (bioprospecting), biosafety, and bioethics − Occupational health and safety − Process safety, pathogenic and biological hazards − Community health and safety
EHS Guidelines for Waste Management Facilities (2007)	Provide guidance for facilities or projects dedicated to the management of municipal solid waste and industrial waste, including waste collection and transport; waste receipt, unloading, processing, and storage; landfill disposal; physico-chemical and biological treatment; and incineration projects. Most importantly, the guidelines cover the following aspects that should be considered in the design and operation of solid waste management activities to be supported by the RECOVER project: − Municipal solid waste management (collection and transport, processing and storage, treatment, disposal) − Industrial non-hazardous waste management (such as sludge from water supply treatment plant, wastewater treatment plant, inert construction/demolition waste) − Occupational health and safety − Community health and safety

EHS = Environmental, Health, and Safety; GIIP = Good International Industry Practice.

83. The WHO established the World Health Organization Expanded Program on Immunization (WHO-EPI) more than 40 years ago to increase vaccine coverage rates around the world, reduce disease burden, and to increase smaller access inequities between low- and high-income countries. To ensure quality and safety, the WHO issues norms and standards on the production and control of biological products and technologies which are based on scientific consensus and consultations. The WHO assists member countries in ensuring the quality and safety of biological medicines and related in vitro biological tests worldwide. The WHO guidelines provide information on a range of topics for the National Regulatory Authorities (NRA) and manufacturers as well as recommendations to establish the technical specifications for manufacturing and quality control for specific products that meets international standards. The regulatory guidance documents produced by WHO aim to establish a harmonized regulatory framework for products moving in international markets.

84. WHO assesses the quality, safety and efficacy of vaccines for procurement to low- and middle-income countries. Vaccines that meet the WHO standards are prequalified and listed on the WHO website for information. The United Nations Children's Fund (UNICEF)[69], PAHO Revolving Fund, and GAVI (Vaccine Alliance)[70] refer to the WHO list of prequalified vaccines when purchasing. The WHO prequalification process includes WHO site audit and review of

[69] UNICEF is the global lead in vaccine procurement. The agency works in partnership with governments, global partners, and a large number of suppliers.

[70] The GAVI Alliance mainly ensures access to immunization in poor countries and provides support to routine vaccination programs.

clinical experience of a manufacturer with the candidate vaccine by external reviewers of WHO that also makes recommendations on available clinical evidence of efficacy, immunogenicity, and safety of the product. The recommendations from the WHO site audit and external reviewers are taken into account by WHO in the decision-making process for prequalification.

85. **Table 5** presents a list of key WHO guidelines applicable to all activities supported under the RECOVER project and should be used and referred to in environmental safeguard documents such as initial environmental examination (IEE) and environmental management plan (EMP). A more comprehensive list of WHO good manufacturing practice (GMP) and guidelines are presented in Appendix 5.

Table 5: WHO Good Manufacturing Practice (GMP) guidelines applicable to all activities supported under RECOVER project

WHO Guideline	Description, Relevance to RECOVER project
WHO GMP for pharmaceutical products: main principles[71]	Provides good practices in production and quality control and is used as a standard to justify GMP status, which constitutes one of the elements of the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. The certification is granted through the assessment of applications for manufacturing authorizations and as a basis for the inspection of manufacturing facilities. The basic elements of quality management are: - an appropriate infrastructure or pharmaceutical quality system, encompassing the organizational structure, procedures, processes and resources; - systematic actions necessary to ensure adequate confidence that a product (or service) will satisfy given requirements for quality.
WHO GMP for biological products[72]	Serves as a basis for establishing national guidelines and the application of risk-based approaches to GMP. The guidance applies manufacturing procedures related to growth of strains of microorganisms and eukaryotic cells, extraction of substances from biological tissues, including human, animal and plant tissues, and fungi, recombinant DNA (rDNR) techniques, hybridoma techniques, and propagation of microorganisms in embryos or animals.
WHO GMP for sterile pharmaceutical products[73]	Provides the guidelines for the production of sterile preparations in various operations (such as those involving containers and closures, product preparation, filling and sterilization), quality control, sanitation, levels of environmental cleanliness in accordance to ISO 14644, sterilization methods, and personnel and premises requirements.
WHO Technical Report Series TRS[74]	The WHO TRS guidelines cover all the pharmaceutical topics as: Process validation; Cleaning validation; Analytical method validation; Qualification of equipment; Water system validation; HVAC validation; Computer system

[71] WHO good manufacturing practices (GMP) for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report. Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
[72] WHO good manufacturing practices (GMP) for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report. Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3.
[73] WHO good manufacturing practices (GMP) for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report. Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6.
[74] https://www.who.int/biologicals/WHO_TRS_980_WEB.pdf

WHO Guideline	Description, Relevance to RECOVER project
	validation; Market complaint handling; Product recalls, and others. Most relevant TRS guidelines for the project include: WHO-TRS 902/2002, WHO-TRS 908/2003, WHO-TRS 929/2005, WHO-TRS 980-2014, WHO TRS 937-2006.
PIC/S Guide to Good Manufacturing Practice for Medical Products (PE 009-14, 2018)	International guidance from the Pharmaceutical Inspection Convention, Pharmaceutical Inspection Cooperation Scheme (PIC/S) to ensure harmonized GMP standards. Originally derives from the WHO GMP Guides and has been further developed in order to comply with stringent manufacturing and health requirements, to cover new areas (e.g. biologicals) and to adapt to scientific and industrial technology (e.g. biotech).
WHO GMP for water for pharmaceutical use[75]	Provides information on available specifications for water for pharmaceutical use (WPU), guidance about which quality of water to use for specific applications, such as the manufacture of active pharmaceutical ingredients (APIs) and dosage forms, and good manufacturing practices regarding the design, installation and operation of pharmaceutical water systems.
WHO GMP for Pharmaceutical Products Containing Hazardous Substances[76]	Sets out good practices applicable to facilities handling pharmaceutical products including APIs that contain hazardous substances such as certain hormones, steroids or cytotoxins. The guidelines also sets additional workers' safety criteria, standards for air-conditioning and ventilation systems of the facility, and procedures in all zones where the handling of products could lead to cross-contamination, exposure of personnel or discharge to the environment. The production of certain products containing hazardous substances should generally be conducted in separate, dedicated, self-contained facilities.
WHO guidelines on quality risk management[77]	Covers activities such as research and development, sourcing of materials, manufacturing, packaging, testing, storage and distribution. The guidelines define the following: - Quality risk management (QRM) process - QRM application for pharmaceuticals - QRM considerations for medicines regulatory authorities - risk management tools.

B. Government of Indonesia's Environmental Policy and Regulatory Framework

86. Besides ADB's SPS, the RECOVER project and all its components must also comply with the Government of Indonesia's environmental laws, standards, rules, and requirements which impose restrictions on activities to avoid, minimize, or mitigate likely impact on the environment. It is the responsibility of the Bio Farma to ensure that all activities under the RECOVER project

[75] WHO Good Manufacturing Practices (GMP): water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2.
[76] WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2.
[77] WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2.

are in accordance with the legal framework, whether national or local. Compliance is required in all stages of project implementation, including design, construction, and operation and maintenance. Key laws and regulations that apply to the RECOVER project are presented below.

C. National environmental regulatory framework

87. **Law No 32 of 2009.** The main Indonesian law on environmental management is Law No. 32 of 2009 on Protection and Management of Environment. The Law established the principles of environmental impact assessment (EIA) and includes the requirements on: (I) detailed EIA/ *Analisis mengenai dampak lingkungan hidup* (AMDAL) and environmental management and monitoring plans (EMP) / *Rencana pengelolaan lingkungan hidup-rencana permantauan lingkungan hidup* (RKL-RPL); (ii) systematic planning for environmental protection and management; (iii) clear distribution of responsibilities between central and local authorities for environmental supervision; (iv) use of an "ecoregion" or ecosystem approach; and (v) expanded provisions for civil, administrative, and criminal enforcement. The law enabled the development of implementing regulations on hazardous waste, water pollution, air pollution, environmental monitoring and reporting, information disclosure, and community involvement.

88. Article 22 of the Law states that any business and activity that has significant impact[78] on the environment shall have an environmental impact assessment (AMDAL), and Article 34 specifies that any business and activity that does not require an AMDAL, shall undertake *Upaya Pengelolaan Lingkungan Hidup dan Upaya Pemantauan Lingkungan Hidup* (UKL-UPL), whereas for micro and small businesses and activities that do not require an UKL-UPL, a statement of ability to undertake environmental management and monitoring of their activity, *Surat Pernyataan Pengelolaan Lingkungan* (SPPL), is required. Further, Article 36 specifies that all activities shall have environment permit that will be given by concerned government agency after the environmental assessment document has been approved. MOEF Regulation No. 25/2018 sets out the procedure for provincial and local government authorities to screen proposed businesses and activities that require an UKL-UPL or SPPL.

89. Minister of Environment and Forestry (MOEF) Regulation No. 38/2019 on Types of Business and/or Activities Plan requiring Environmental Impact Analysis. This regulation began implementation in September 2019 and supersedes Decree No. 5 of 2012. The new regulation introduces the gradation of AMDAL (A, B, and C) based on complexity and scale of the project, impacts, and sensitivity and carrying capacity of location. AMDAL A is for business/activities that are highly complex and located in very sensitive area (with cumulative values >9); AMDAL B is for activities which are moderately complex and located in moderately sensitive areas (with cumulative values 6 – 9); and AMDAL C are neither complex nor in sensitive areas (with cumulative values <6)) . Appendix III and IV of the regulation specify that the location of the project shall comply with the spatial plan.

90. For manufacturing activities generating hazardous wastes and involving contaminated equipment such as pharmaceutical manufacturing operations, the regulation prescribes that those with building area greater or equal to 10,000 square meters or land area greater than or equal to 5,000 hectares will require AMDAL but those less than these thresholds will require UKL/UPL. For existing projects that are operational but will require some modification or expansion, the MOEF requires the preparation of the Addendum AMDAL or new UKL/UPL. For an existing project that is operational without environmental document, the project should prepare an

[78] Criteria of significant impact is also provided in Article 32 of the Law.

environmental evaluation document (*Dokumen Evaluasi Lingkungan Hidup/DELH*) or environmental management document (*Dokumen Pengelolaan Lingkungan Hidup/*DPLH).

91. **Environmental assessment procedure.** The environmental assessment procedure is described in MOEF Regulation No. 38/2019, MOEF Regulation No. 25/2018, and Government Regulation No. 27/2017. All projects or business proposals will undergo screening to classify whether a project proposal would need AMDAL, UKL-UPL, DELH or SPPL.

92. MOEF Regulation No. 23/2018 outlines the criteria and procedures for businesses or activities where there are proposed changes or modifications and would require amendment of the Environmental Permit. In accordance with Article 4 of MOEF Regulation No. 23/2018, the permit holder is required to request for a revision of the Environmental Permit to the authorized Minister, governor, or regent/mayor together with the environmental information report outlining the proposed changes. The proposed changes are evaluated by a technical team of the AMDAL Assessment Committee and/or experts. If the changes of business activities may result to significant impacts on the environment, the permit holder is required to prepare a new AMDAL or Addendum of the AMDAL document. For business and/or activity wherein the UKL-UPL is mandatory, a new UKL-UPL needs to be prepared. If the proposed changes will not result to significant impacts on the environment, them the revision of the Environmental Permit can be done without revision of the environmental feasibility decision or UKL-UPL recommendation.

93. **MOEF Regulation No. 22/2018** sets out the procedures for online single submission (OSS) for environmental assessment and permitting processes in accordance with the requirements of Government Regulation No. 24/2018 on introducing the electronic integrated business licensing through an OSS system to process applications for business and project licenses. Under Article 35(1), the Environmental Permit is not required if: (I) the location of the business and/or activity is within the special economic zone, industrial zone, or free trade zone and in a free port or; (ii) the business and/or activity is classified as a micro and small business, a business and/or activity that is not required to have an AMDAL or UKL-UPL. However, any business that is located in a special economic zone, industrial zone or free trade zone and free port is required to develop a detailed RKL-RPL based on the RKL-RPL of its relevant zone. The RKL-RPL shall be approved by the management of the relevant zone.

94. **Other laws and regulations** of relevance for the environment assessment procedure include the following:

- Law No.1/1970 on Workers' Safety and Ministry of Workforce Decree Kep-51/MEN/1999 on Reference Standard for Activities in Working Area.
- Law No. 26/2007 on Spatial Planning;
- Law No. 14/2008 on Public Information Disclosure;
- Government Regulation 12 of 2010 on Living Environment Management and Monitoring Efforts and Statement of Capability to Manage and Monitor the Living Environment;
- Government Regulation 17 of 2012 on Guidelines for Community Participation and Environment Disclosure in Environmental Impact Assessment and Environmental Permitting;
- Government Regulation 27 of 2012 on Environment License/Permit;
- Government Regulation No. 101 of 2020 on hazardous Waste Management
- Government Regulation No. 27 of 2020 on Specific Waste Management

- Decree of Minister of Environmental Affairs 45 of 2005 on Guidelines for the Formulation of Reports on the Realization of Environmental Management Plans (RKL) and Environmental Monitoring Plans (RPL);
- Minister of Environment Decree 9 of 2010 on Guidelines on Community Grievances and Handling of Grievances Caused by Pollution and/or Degradation;
- Minister of Environmental and Forestry Regulation No. 12 of 2020 on Hazardous Waste Storage.

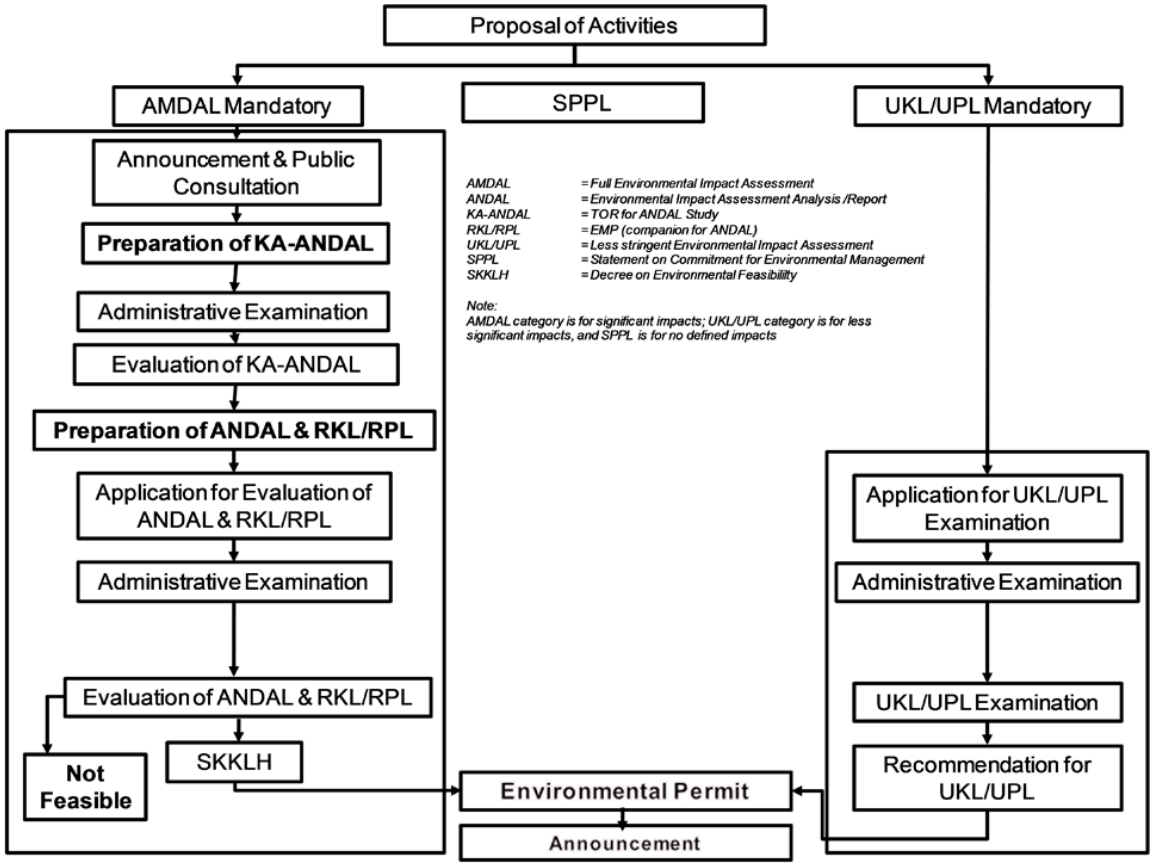


Figure 7: Flowchart of Indonesian Environmental Screening and Clearance

95. The Indonesia AMDAL system generally conforms to the intent of ADB's environmental policy principles, requirements and management guidelines. **Table 6** shows the relationship between the ADB environmental categorization and those under Indonesia's regulations/policies. Essentially, an AMDAL study corresponds to an EIA, and an UKL-UPL corresponds to an IEE. The Statement of Environmental Management and Monitoring undertaking (*Surat Pernyataan Kesanggupan Pengelolaan dan Pemantauan Lingkungan Hidup* -SPPL) generally corresponds to the environmental implication review of Category C projects as per the ADB SPS 2009.

Table 6: ADB and Indonesia Project Categorization Systems

ADB Project Categories	AMDAL GoI Project Categories
Category A: A proposed project (or project component) is classified as category A if it is likely to have significant adverse environmental impacts that are irreversible, diverse, or unprecedented. These impacts may affect an area larger than the sites or facilities subject to physical works. An environmental impact assessment is required.	**AMDAL**: Projects that according to law require an Environmental Impact Assessment (AMDAL). The detailed criteria that trigger an AMDAL defined in the MOEF Regulation No. 38/2019 on Types of Activities requiring Environmental Impact Assessment.
Category B: A proposed project (or project component) is classified as category B if its potential adverse environmental impacts are less adverse than those of category A projects. These impacts are site-specific, few if any of them are irreversible, and in most cases mitigation measures can be designed more readily than for category A projects. An initial environmental examination is required.	**UKL-UPL**: Projects that according to law requires Environmental Management Effort (UKL) and Environmental Monitoring Effort (UPL). However, special discretion and judgment of environmental agencies at local and national level (based on particular consideration) may override the category, and UKL-UPL Category may be "upgraded" to AMDAL Category.
Category C: A proposed project (or project component) is classified as category C if it is likely to have minimal or no adverse environmental impacts. No environmental assessment is required although environmental implications need to be reviewed	**SPPL**: Projects that do not require AMDAL or UKL-UPL are obliged to submit a 'statement of management and environmental monitoring ability' or SPPL**.**

96. Prior to project component implementation, Bio Farma should consult *Dinas Lingkungan Hidup* (DLH, Provincial and District Environmental Office) to ensure compliance with environmental law and regulation.

D. Regulations and guidelines related to pharmaceutical manufacturing

97. The production of new vaccines and their market entry is highly regulated. New vaccines must pass numerous regulatory hurdles before reaching markets. The manufacture of drugs, vaccines, and other pharmaceuticals in Indonesia is regulated by the National Agency of Drug and Food Control (*Badan Pengawas Obat & Makanan*, BPOM) under Article 68 of Presidential Decree No. 103/2001. The BPOM works alongside the Ministry of Health (MOH) and the National Narcotics Agency in developing and implementing policies, standards, procedures and criteria for food and drug control. BPOM has been audited by WHO to meet the criteria as a National Regulatory Authority (NRA) capable of supervising PT. Bio Farma. In 2018, BPOM received a nearly perfect score of 98 out of a maximum score of 100. The BPOM also issues product registration and certifications for production facilities and distribution facilities.

98. BPOM conducts pre-market (during the production process until before the product is distributed) and post-market (during circulation of the product) surveillance. BPOM oversees registration and issues distribution licenses. After registration, a scientific review is completed by the Clinical Committees under the Pharmacy Directorate (BINFAR), MOH, who decide if the product should be listed on National Formulary.

99. Under Article 3 of BPOM Regulation No. 14/2014, the BPOM Technical Implementation Unit implements laboratory examinations, testing and assessment of pharmaceutical products and microbiological quality of the product, and implements certification of products, production and distribution facilities.

100. For new facilities, the BPOM conducts the evaluation of the main production facility to determine the general conditions of the goods and their surroundings and evaluate the manufacturing process as part of product registration before any drug is circulated in the market. The drug must meet the requirements of efficacy, safety, and quality.

101. In January 2006, Decree No. HK.00.06.0511 was issued that revised HK.00.05.3.02152/2001 on the implementation of the guidelines for good manufacturing practices (GMP). The requirements of BPOM are defined in the Good Manufacturing Practice (GMP) guidelines and Operational Manual for Implementation of GMP (*Pedoman Cara Pembuatan Obat Yang Baik*) which was revised in 2006.[79] The revised guidelines include updated requirements on qualification and validation, contract manufacture and analysis, manufacturing of sterile pharmaceutical products, manufacture of blood products, manufacture of investigational product for clinical trial, and computerized system and the Quality Management System. Indonesia's GMP refers to the GMP Guidelines from WHO, i.e. WHO-TRS 902/2002, WHO-TRS 908/2003, WHO-TRS 929/2005, WHO TRS 937-2006, PIC/S PE 009-14 Guide to GMP for Medicinal Products (2018) and other international GMP codes and guidelines (see **Table 5**).

102. The BPOM GMP guidelines include principles and requirements related to the following:

a) quality management and assurance
b) identification of key personnel, organization, qualification, responsibilities and training
c) standards for facility premises such as weighing areas, production areas, storage areas, quality control areas, and ancillary areas
d) standards for the design and construction of facility and equipment, installation and location, and maintenance
e) maintenance and validation of sanitation and hygiene of personnel and premises
f) standards on the production process from raw materials handling, process validation, prevention of cross-contamination in production, batch and lot numbering system, weighing and dispensing, process for handling returns, rejects, recovered and returned materials, in-process control, finished product quarantine, storage, packaging, and delivery
g) principles and standards for good quality control laboratory
h) self-inspection and quality audits
i) handling of complaints
j) procedures for documentation from specifications of starting materials, packaging materials, intermediate and bulk products, and finished products
k) contract manufacture and analysis
l) standards for qualification and validation.

[79] Indonesian Good Manufacturing Practice Guidelines for pharmaceuticals was first developed in 1988 and enforced in 1989. An Operational Manual for GMP implementation was then developed in 1989. Due to rapid development in science and technology in the field of pharmaceuticals, the guidelines was revised in 2001 and again in 2006.

103. The GMP Guidelines also prescribe the principles and standards for the manufacture of sterile products to minimize risks of microbiological contamination. The standards are outlined in Annex 1 of the GMP Guidelines.

104. Other laws and regulations in Indonesia related to pharmaceuticals, health, and consumer protection are:

a) Law No. 8/1999 on Consumer Protection (State Gazette/1999 No. 42, Addendum No. 3821
b) Law No. 36/2009 concerning Health (State Gazette/2009 No. 144, Addendum No. 5063)
c) Government Regulation No. 72/1998 concerning Securing Pharmaceutical Preparation and Health Devices (State Gazette of the Republic of Indonesia 1998, No. 138, Addendum No. 3781)
d) Government Regulation No. 69/1999 concerning Food Label and Advertisement (State Gazette of the Republic of Indonesia 1999, No. 131, Addendum No. 3867)
e) Government Regulation No. 28/2004 concerning Food Safety, Quality and Nutrition (State Gazette of the Republic of Indonesia 2004 No. 107, Addendum No. 4244)
f) Regulation of the Minister of Health No. 1010/Menkes/Per/XI/2008 concerning Drug Registration as amended by Regulation of the MOH No. 1120/Menkes/Per/XII/2008
g) Regulation of the MOH No. 1799/Menkes/Per/XII/2010 concerning Pharmaceutical Industry
h) Regulation of the MOH No. 1148/Menkes/Per/VI/2011 concerning Pharmaceutical Wholesaler
i) Decree of the Head of the Agency of Drug and Food Control Number HK.00.05.23.4415 Year 2008 concerning The Enactment of Electronic System in the Context of Indonesia National Single Window in the Agency of Drug and Food Control Environment
j) Regulation HK.03.1.23.10.11.08481/2011 concerning Criteria and Managing of Drug Registration.

105. In addition, **Ministry of Health Regulation No. 42/2013** regulates vaccines and vaccinations.[80] This regulation oversees vaccination programs' implementation, delivery, monitoring and evaluation, surveillance, research and development. Under the regulation, the Minister may assign a State-Owned Enterprise (SOE) to engage in vaccine production, and in cases where domestic production cannot match need, the Minister can appoint a pharmaceutical wholesaler to top up supply.

106. With regard to COVID-19 vaccines, **BPOM has the regulatory mandate** for the following: (1) approval for the implementation of clinical trials; (2) approval of special entry mechanisms and import approvals of raw materials required for development and use of the COVID-19 vaccine; (3) issuing certificates for the proper manufacturing and distribution of vaccines; (4) granting approval for emergency use authorization or issuing a product license number for the COVID-19 vaccine; (5) approval for the release of lots; (6) quality control and product safety along the COVID-19 vaccine supply chain.

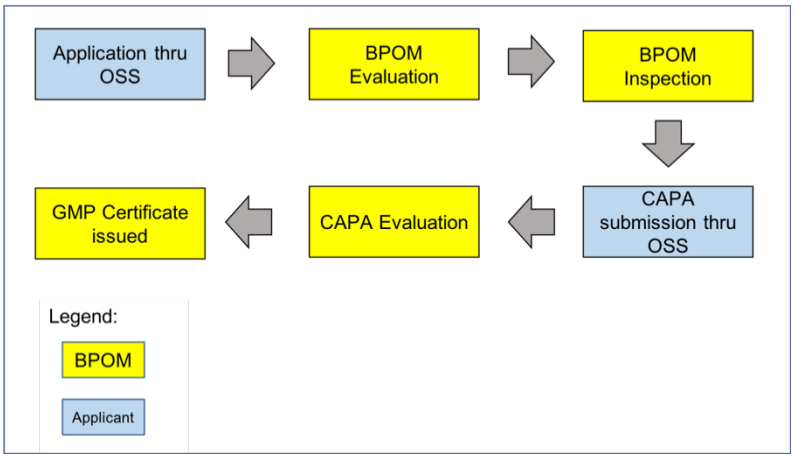
107. The regulation and requirements regarding approval of **clinical trials** is outlined in BPOM No. 21/2015. Based on Article 14, clinical trials require approval for the pre-marketing clinical test and post-marketing clinical trials. The trials should adhere to the Good Clinical Test Method

[80] https://peraturan.bkpm.go.id/jdih/userfiles/batang/PMK%20No.%2042%20ttg%20Penyelenggaraan%20Imunisasi.pdf

(CUKB) standard for the design, implementation, monitoring, audit, recording, analysis, and reporting of the test. The standard provides assurance that the data and reported results are accurate and reliable, and that the rights, integrity and confidential of the clinical test subjects are protected. Before the pre-marketing clinical test is carried out, it is mandatory to obtain approval from the Head of the BPOM and from the Ethics Commission, an independent institution consisting of medical/scientific professionals and non-medical/non-scientific members in the field of clinical testing.

108. The BPOM also requires the implementation of **bioequivalence (BE) tests** for drugs that will be used to prevent the spread of COVID-19. The bioequivalence test is intended to obtain data on the therapeutic equivalence of drugs to their innovative drugs. The BE Test Protocol Approval (PPUB) can be submitted online at https://newaero.pom.go.id.

109. The online **Certification of Good Manufacturing Practices** (CPOB) process is through the OSS at https://e-sertifikasi.pom.go.id/page. Requirements of the certification process includes information on the facility (layout, flow of personnel, flow of materials, design of HVAC system, commissioning and qualification report of facility, water treatment plant, compressed air system, and other utility systems), quality management system, protocols and standard operating procedures for aseptic process validation, production process, and cleaning validation, laboratory test methods and calibration, equipment operation and maintenance, and personnel qualification, health and medical records. If an applicant meets the requirements of CPOB, a conditional approval is issued to enable the drug registration process and the drug manufacturing process. The CPOB certificate is issued after the CPOB inspection is carried out. The CPOB certificate issued by BPOM is renewable every five years and is subject to a minimum of annual inspection and surveillance by BPOM.



Note: BPOM = National Agency of Drug and Food Control (Badan Pengawas Obat & Makanan); OSS = online submission system; CAPA = corrective action plan; GMP = good manufacture practice.

Figure 8: Simplified Illustration of the GMP (CPOB) Certification Process for Marketed Pharmaceutical Products

110. For **imported drugs**, the CPOB assessment process involves the screening of required documents, assessment of risk study, and inspection of overseas drug manufacturing facility by BPOM. Conditional approval of the CPOB certificate can be issued while waiting for the results of overseas inspection.

111. A **Certification of Good Drug Distribution Method** (CPOB) is required to be carried out online via https://sertifikasicdob.pom. During the COVID-19 pandemic, the inspection of facilities is carried using desktop / online inspection mechanism such as video calls, WhatsApp, or email communication technical where documents can be submitted via email and discussed during calls.

112. The entry of drugs and medicinal ingredients into Indonesia during the COVID-19 pandemic is facilitated through service timelines on issuance of **Import Certificate (SKI)** by BPOM. The SKI issuance service is carried out online with SKI issued in electronic form. The BPOM conducts risk-based evaluation, particularly of critical points for the entry requirements of drugs, medicinal ingredients, and vaccines to ensure safety, quality, and efficacy of drugs and medicinal substances that enter Indonesia territory. Prior to importation, the product is registered first with BPOM through the submission of the complete dossier, collection of data quality, efficacy, and safety from clinical trials. The vaccine undergoes sampling and testing by the National Testing Center of Drug and Food (PPOMN) at BPOM. Vaccines are evaluated against the batch/lot release certificate from the country of origin where the vaccine was released for every importation. Vaccine that has obtained the SKI can be circulated after results of sampling and testing and document evaluation confirm compliance with the requirements of BPOM.

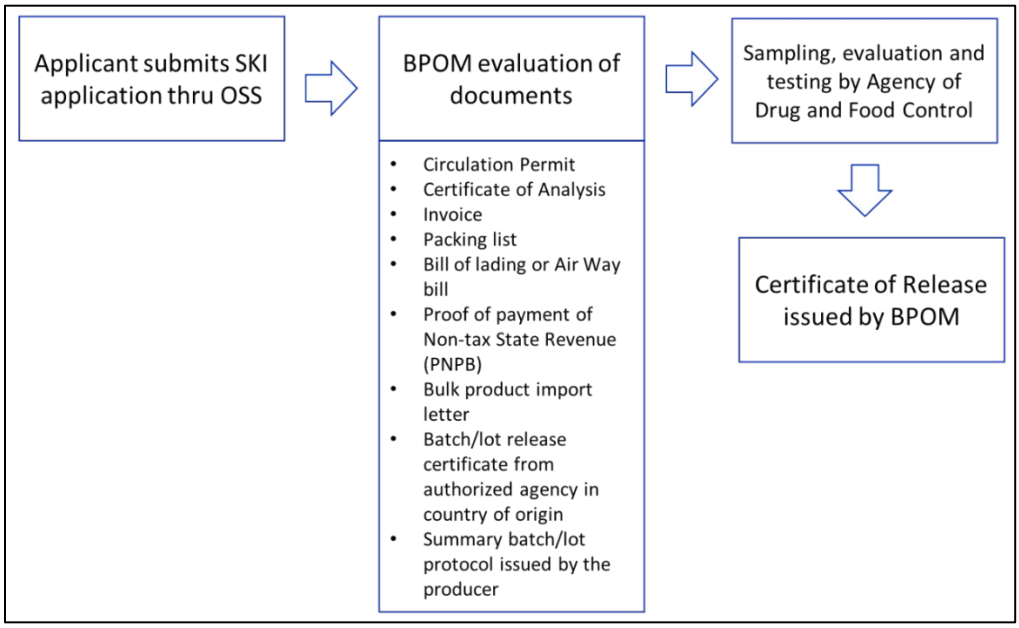


Figure 9: Simplified Illustration of the Certification Process for Imported Vaccines

113. Under BPOM Regulation No. 26/2008 on Integrated Business Licensing Services in the Drug and Food Sector, a pharmaceutical industry is required to obtain a **Drug Circulation Permit and a Drug Distribution Permit** for domestic production by fulfilling the CPOB certificate for registered dosage forms and active substance producer CPOB certificate.

E. Regulations on Pollution Prevention and Waste Management

114. Pharmaceutical manufacturing operations are required to comply with the regulations governing the management of generated wastes such as hazardous materials and wastes,

wastewater, and air emissions. Spent vaccines generated by end users in provinces and districts are also regulated by the MOEF.

115. The country's main framework on **hazardous waste management** is cast in Government Regulations No.101/2014 regarding hazardous waste management, whereas the specific regulations on hazardous waste management in health care settings are prescribed in MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Healthcare Facilities (this regulation applies for hospitals as well as clinical laboratories). Similar requirements on hazardous waste management are also part of the hospital accreditation criteria, in which MOH makes it mandatory for all hospitals to get accredited by an independent accreditation body every three years, as well as the requirements for Bio-safety level-2 (BSL-2) laboratory accreditation requirements.

116. The new MOEF Regulation No. 12/2020 specifies the requirements on licensing of hazardous waste storage, including location, emergency response equipment, first-aid facilities, spill handling, loading and unloading facilities, and the allowable hazardous waste storage period.

117. The requirements on the management of air emissions from hazardous waste incinerators are outlined in MOEF regulation No. 56/2015, which defines the technical specifications of the incinerator and the allowed emissions threshold. The threshold set in the regulation is comparable with the performance standard set in the IFC EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007). Government Regulation No. 101/2014 and MOEF Regulation No. 56/2015 require all incinerators and autoclaves that are used to treat hazardous waste to obtain treatment permit/license from MOEF. There are strict requirements on the management of medical incinerator ash (e.g. bottom ash, fly ash). MOEF regulation No. 56/2015 required all incinerator residue from hazardous waste treatment to be disposed to i) sanitary landfill, ii) controlled landfill, or iii) licensed hazardous waste landfill. For the disposal to sanitary and controlled landfill, the regulation requires the conduct of pre-treatment to the wastes by encapsulation or inertization, or to engage licensed third-party to manage it.

118. Standards on **wastewater** effluent from healthcare and pharmaceutical facilities in Indonesia is comparable with the good international practice.[81] MOH Regulation No.7/2019 outlines the requirement to manage the wastewater from such facilities, this includes the requirement to have a wastewater pre-treatment plant, conduct routine effluent monitoring, meet the effluent threshold requirements and report the monitoring to relevant government agencies. The effluent standard from the wastewater treatment plant is prescribed in the MOEF Regulation No. 5/2014 on the wastewater effluent standard. The threshold set in the regulation is comparable with the performance standard set in the IFC EHS Guidelines for Pharmaceuticals and Biotechnology Manufacturing (2007). MOEF Regulation No. 56/2015 requires wastewater from incinerators to comply with MOEF Regulation No. 5/2014.

119. The COVID-19 vaccination program is required to follow the waste management procedures as outlined in the MOH Decree 84/2020 and the Technical Guidelines for the Implementation of Vaccinations in the Management of COVID-19 Pandemic (HK.02.02/4/1/2021). Under the decree and technical guidelines, used syringes are to be placed in safety boxes. Once the safety box is fully filled, the safety box must be labeled. Other wastes such as vaccine vials, alcohol cotton swabs, medical masks and gloves must be disposed in plastic bags specifically for

[81] WHO guidelines on safe management of waste from healthcare activities (section 9 – collection and disposal of wastewater) and WBG EHS guidelines for healthcare facilities.

medical waste or ordinary plastic bags properly marked as “medical waste”. The collected medical waste are to be properly stored at the health center and then destroyed together with other vaccination wastes for proper treatment in incinerators that has permit from MOEF or through a third-party licensed waste treatment facility with cooperation agreement with the regency/city. Another option for managing used syringes in safety boxes is to bury in concrete pits following the specifications in the technical guidelines.

120. Relevant regulations on pollution control and waste management as applicable to the project are in **Table 7**.

Table 7: Government Regulations on Pollution Control and Waste Management

Government Regulation	Description, Relevance to RECOVER Project
Hazardous Waste	
MOEF Regulation 101/2014 Regarding the Management of Toxic and Hazardous Substances	Outlines the procedures for the management and disposal of toxic and hazardous wastes (B3) and substances, including the implementation of waste monitoring or manifest system. The regulation builds upon the “cradle to grave” principle, with rigid manifest system to track the flow of waste from generator to disposal facility. Any activities to store, transport, utilize, treat or dispose hazardous waste require valid permit/license from the government. All permitting, except for temporary storage, are mandated to MOEF, while the temporary storage permit is in the jurisdiction of sub-national environmental agency (DLH). The regulation also prescribes the technical requirement for incinerator as well as the requirement for the disposal of combustion residue from incinerators, fly ash and bottom ash to licensed hazardous waste landfill.
MOEF Regulation No. 12/2020 on Hazardous Waste Storage and Management	Provides detailed guideline for the preparation and implementation of B3 Waste storage as stipulated on MOEF Regulation 101/2014. Specifies the requirements on licensing of hazardous waste storage, including location, emergency response equipment, first-aid facilities, spill handling, loading and unloading facilities, and the allowable hazardous waste storage period.
MOEF Notice Letter No. 2/2020 on infectious (hazardous) and domestic waste management from COVID-19 response	Through this letter, MOEF advises healthcare facilities to do onsite treatment for its infectious waste using an onsite incinerator or autoclave before handing over the waste to a licensed hazardous waste management company.
MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Healthcare Facilities	Provides the guideline and requirements in managing hazardous heath care wastes, including the requirement on reduction, segregation, packaging, storage, transportation, treatment and disposal. Defines permitting/licensing requirements for incinerators and autoclaves that are used to treat hazardous waste, including stack emission standard for incinerators. Defines disposal requirements for incinerator residue from hazardous waste treatment. Supersedes MOEF Regulation No. 18 of 2009 on Obtaining Permits for Storage, Treatment and Disposal of Hazardous Waste.
MOH Regulation 18/2020 About Region-Based Medical Waste Management from Health Facilities	Aims at addressing identified gaps and disparities in healthcare waste management services, and which provides guidelines to carry out the establishment of the region-based healthcare waste management systems. It clarifies the roles and responsibilities of central government, regional government, and health facilities and requirements for healthcare waste monitoring, recording and reporting.

Government Regulation	Description, Relevance to RECOVER Project
MOH Decree HK.02.02/4/1/2021 about Technical Guidelines for the Implementation of Vaccinations in the Management of Corona Virus 2019 (COVID-19) Pandemic	Defines requirements for the collection, temporary storage, treatment and/or disposal, and documentation of immunization waste at health service facilities for COVID-19 vaccination program.
Water Pollution	
Minister of Environment Regulation No. 68/2016	Requires an environmental permit/license for a business or activity that discharges wastewater.
Government Regulation No. 82/2001 on Water Quality Management and Water Pollution Control	Article 37 requires that every business or activity that discharges wastewater shall prevent the occurrence of water pollution. Article 38 requires that the entity discharging wastewater shall comply with the conditions stipulated in the license.
Minister of Environment Regulation No. 1/2010 on Water Pollution Control Procedure	Outlines the water quality standards to be achieved within a certain period through implementation of a work program to control water pollution. The regent/mayor can reject the location permit application submitted by a part responsible for the business/activity is based on the analysis the water pollution load from the business/activity will cause exceedance of the load capacity of the receiving water body.
MOEF Decree No. 5/2014 and MOEF Decree No. 16/2019 on industrial effluent standard.	Defines wastewater effluent standards for industry-specific activities.
Air Emissions	
Government Regulation No. 41/1999 Regarding Air Pollution Control	Outlines the allowable air emission standards for stationary sources of air pollution.
Noise	
Minister of Environment Decree No. 48/1996 on Noise Level Ranges	Annex I of the decree presents the allowable noise levels (dBA) based on area/activity/environment. For industrial sites, the maximum allowable noise level is 70 dBA. In areas near hospitals, schools, places of worship or similar facilities, the maximum allowable noise level is 55 dBA. Article 4 prescribes that the Governor may establish a more stringent standard for noise level than the provisions outlined in Annex I of the decree.

F. Regulations on Labor Management

121. The regulation protecting the safety and welfare of workers is outlined in Law No. 13/2003. Under Article 87 of the Law, every industry is required to implement a work health and safety management system that is integrated into its industrial management system.

G. International Agreements, Conventions and Programs

122. Indonesia has ratified several international conventions, including some of potential relevance to the project, among others:

- The **Pharmaceutical Inspection Convention (1970)** and **Pharmaceutical Inspection Co-operation Scheme (PIC/S, 1995)** are two international instruments between countries and pharmaceutical inspection authorities. The PIC/S is meant as an instrument to improve co-operation in the field of Good Manufacturing Practices between regulatory authorities and the pharmaceutical industry. The PIC Scheme is an informal agreement

between health authorities instead of a formal treaty between countries. PIC and the PIC Scheme, which operate together in parallel, are jointly referred to as PIC/S. PIC/S became operational in November 1995. Indonesia become member in 2012.

- The **International Pharmaceutical Regulators Programme (IPRP)** was created in 2018 to promote convergence of regulatory approaches for pharmaceutical medicinal products for human use. Through its Management Committee and various working groups, IPRP facilitates discussions on global regulatory issues and on emerging technologies. IPRP also provides a venue to support the implementation of ICH guidelines and other standards, and for inter-agency information sharing and collaboration.
- **Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989).** Indonesia has ratified the international agreement to reduce cross-country movement of waste in accordance with the minimum limit of the Convention to create an environmentally friendly waste management and efficient; reducing toxicity of waste generated and to ensure that environmental management is the basis for resource development.
- **Convention on Biological Diversity**, for parties to require the environmental assessment of their proposed projects that are likely to have significant adverse impacts on biological diversity with a view of avoiding or minimizing such impacts. Indonesia is obliged to respect and protect traditional knowledge related to sustainable utilization of biodiversity, including promote fair benefit sharing of the use of traditional knowledge. Based on this convention, the Nagoya Protocol was established, which was also ratified by the Government of Indonesia.
- **Convention on the Prevention of Marine Pollution by Dumping Wastes and Other Matter (1972).** Indonesia follows an international agreement to control marine pollution due to accumulation of waste and other materials and to encourage regional agreements to complement the Convention; the London Convention came into effect in 1996.
- **Vienna Convention for the Protection of the Ozone Layer**, in 1998, and subsequent protocol and amendments, for parties to take appropriate measures to protect human health and the environment against adverse impacts likely to arise from human activities that will/likely modify the ozone layer.
- **United Nations Framework Convention on Climate Change (1992).** Indonesia has ratified the international agreement to achieve stabilization of greenhouse gas concentrations in the atmosphere as low as possible to prevent dangerous anthropogenic interference with the climate.
- Indonesia has ratified the **Paris Agreement** within the United Nations Framework Convention on Climate Change (UNFCCC) dealing with greenhouse gases emissions mitigation, adaptation and finance in October 2016.

IV. DESCRIPTION OF THE ENVIRONMENT

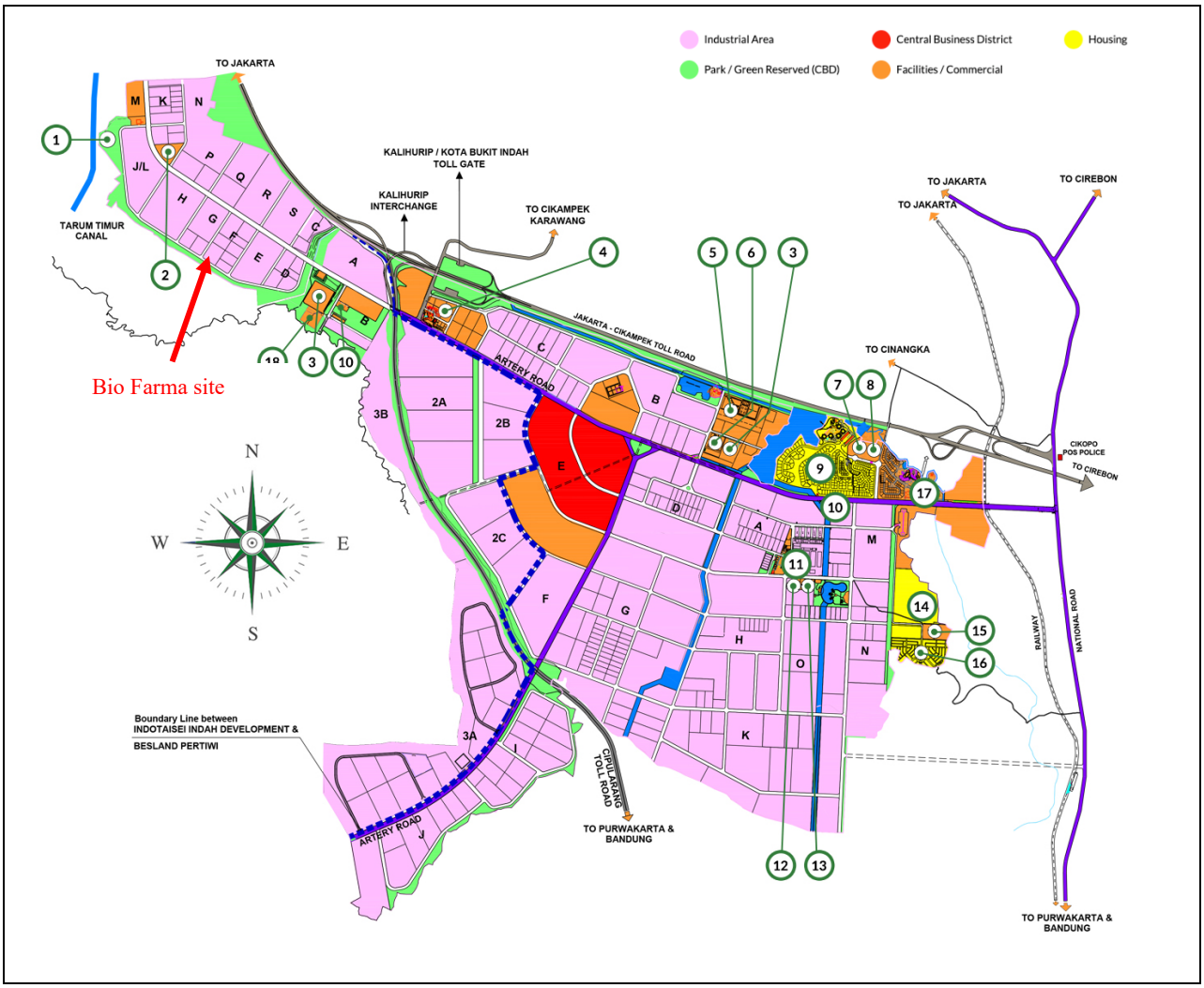
A. Physical

1. Geography, Location

123. Bio Farma HQ Bandung and the new site in Indotaisei are located within the province of West Java on the island of Java. The province is bounded by the province of Banten and Jakarta on the west, the Java Sea to the north, the province of Central Java to the east, and the Indian Ocean to the south. The provincial capital is Bandung.

124. Bio Farma HQ is located in Jalan Pasteur, Bandung City. The entire complex covers a total land area of 9 hectares. The proposed COVID-19 vaccine production will be at Building #43 which occupies a land area of 2,200 m^2 (see section below, **Figure 1 and Figure 2**).

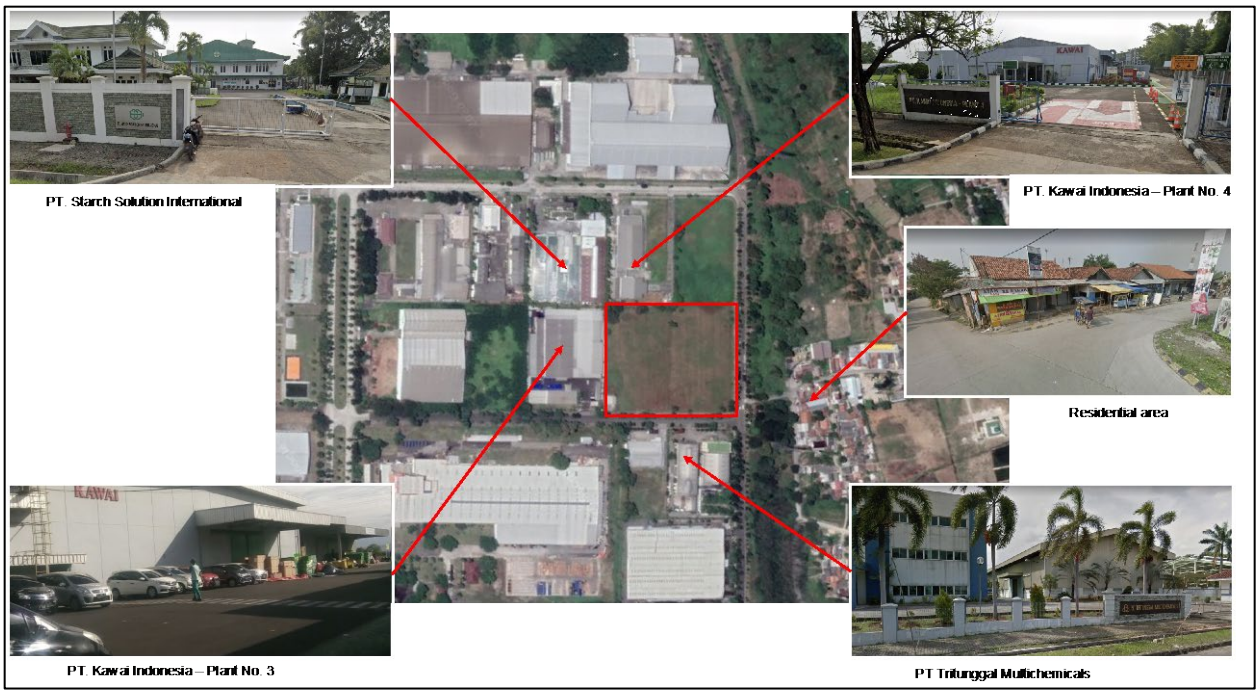
125. The new site in Indotaisei Industrial Park is located within the jurisdiction of Kota Bukit Indah Kalihurip, Cikampek in West Java. The industrial park covers a total land area of 700 hectares. It was developed by the PT Indotaisei Indah Development (IID), a joint venture company between PT Besland Pertiwi and Taisei Corporation of Japan (**Figure 10**). The industrial park is designed for locators engaged in the medium to heavy manufacturing operations.



Source: https://www.kotabukitindah.com/masterplan

Figure 10: Map of Indotaisei industrial complex

126. The proposed site of the Bio Farma in Indotaisei is in an area of 2.3 hectares. The land was acquired by Bio Farma from PT Vuteq Trading Indonesia in 2018. The site is adjacent to Kawai Plant 3 on the north, by Kawai Plant 4 on the east, by the park arterial road and landscaped/green area on the south, and by the Tritungga Multi-Chemicals plant on the west. The industrial park and the plant site is accessible through the Jakarta-Cikapek Toll Road (**Figure 11**).



Source: Google Earth (accessed on 12 November 2020)

Figure 11: Aerial view of Bio Farma's site in Indotaisei industrial complex

View of the project site (vacant lot). Further to the north is the building of Kawai Plant 3.

View of the project site (vacant lot). Further to the west, across the road is the Tritungga Multi-Chemicals Plant and other manufacturing facilities at Indotaisei Industrial Park

Figure 12: View of the project site and immediate vicinity

2. Topography, Geology, Soils

127. The existing Bio Farma site in Bandung is located at an altitude of 690-730 above sea level. Based on the Geological Map of the Bandung Basin (Soedjatmiko, 1972) soil in the area consists of tuff clay, tuff sand, and tuff gravel.

128. The new site of Bio Farma in Indotaisei is located on a low stretch of mountainous area at elevation of 50 – 70 meters above sea level. Soil at the site in Indotasei is sandy clay. At depths of -5 m below ground surface, soil is clay and silt, characterized with medium to stiff density. At -10 m to -20 m, soil is clayish with some silt. The bedrock can be encountered at depths of -20.21 m which is characterized as very stiff to hard rock.

3. Air Quality

129. Air quality in the project's area of influence is generally good and compliant with the Indonesian ambient air quality standard (AQS). Ambient air quality monitoring is conducted by an independent licensed monitoring agency on a semi-annual basis at various points within the Bio Farma compound in Bandung. Monitoring results at various points within the site for 2019 are presented in **Table 8** below.

Table 8: Ambient air quality monitoring results in Bio Farma's Bandung site, 2019

			April 2019		October 2019	
Parameter	**Unit**	***INO AQS***	**Front yard**	**Backyard**	**Front yard**	**Security office**
SO_2***	ug/Nm^3	*365*	16.56	25.92	21.27	23.22
CO***	ug/Nm^3	*10,000*	<1,145	<1,145	<1,145	2,782
NO_2***	ug/Nm^3	*150*	<8.10	<8.10	<8.10	12.83
O_3*	ug/Nm^3	*235*	13.76	26.17	20.51	31.62
HC**	ug/Nm^3	*160*	3.7	4.1	8.35	8.15
PM_{10}***	ug/Nm^3	*150*	50.25	67.2	88.4	86.28
$PM_{2.5}$***	ug/Nm^3	*65*	41.9	47.26	9.56	9.26
TSP***	ug/Nm^3	*230*	72.2	88.5	100.46	112.12
Pb***	ug/Nm^3	*2*	0.02	0.03	0.03	0.03
NH_3***	ug/Nm^3	*2*	0.0067	0.0083	0.0137	0.0093
H_2S***	ug/Nm^3	*0.02*	0.0002	0.0002	0.0004	0.0003

Notes: * sampling duration = 1 hour; ** sampling duration = 3 hours; *** sampling duration = 24 hours

130. Ambient air quality data at the Bio Farma's site in the Indotaisei industrial park was not available at IEE preparation stage. Air quality monitoring will be conducted during construction and facility operation in accordance with the monitoring plan defined in the EMP.

4. Noise

131. Ambient noise levels within Bio Farma's site in Bandung are monitored on a semi-annual basis by a licensed independent monitoring agency. Monitoring points cover the front yard and back yard areas (where no production activities occur), the site access area (access gate) as well as production areas including the waste incinerator, the mechanics and engineering area, and

the wastewater treatment plants. Monitoring results for 2019 (**Table 9**) indicate that noise levels are within the relevant national standard as well as the WHO noise guideline value for industrial and commercial areas (70 dBA). Results further indicate that traffic noise emissions from road Jl. Layang Pasupati Road is an important contributor to ambient noise levels within the Pasteur site.

Table 9: Noise monitoring results in Bio Farma's Bandung site, October 2019

Unit	*INO Noise standard*	Monitoring Location (October 2019)					
		Engineering room	Entrance Gate	Back Yard	Incinerator area	WWTP No. 1	WWTP No. 2
dBA	*70*	56.77	64.07	53.35	61.69	53.28	53.35

Note: sampling duration = 24 hours

132. Noise levels at the Bio Farma's site in the Indotaisei industrial park was not available at IEE preparation stage. Noise monitoring will be conducted during construction and facility operation in accordance with the monitoring plan defined in the EMP.

5. Water Resources

133. There are no surface water bodies in the proximity of the Bio Farma compound in Bandung. The nearest body of water to the Bio Farma site in Indotaisei is the Tarum Timur Canal which drains from the Jatiluhur Lake. The industrial park sources its raw water for industrial purposes from the Jatiluhur Lake through the Tarum Timur canal. Raw water is treated and distributed by the PT Bukit Indah Tirta Alam.

6. Climate

134. The climate in Indonesia is largely hot and humid, with rainfall occurring mostly in low-lying areas and mountainous regions experiencing cooler temperatures (**Figure 13**). The wet season occurs from November and April while the dry season happens from May through October. There is little season-by-season variation in temperature, which ranges from 25 – 26°C. In lowland areas, the average annual rainfall is in the range of 1800 – 3200mm while the mountainous regions can experience rainfall of up to 6000 mm. The lowest rainfall during the dry season averages around 160 – 180 mm. The island of Java which is in the northwest climate region that experiences more consistent rainfall, with peaks in April and October.

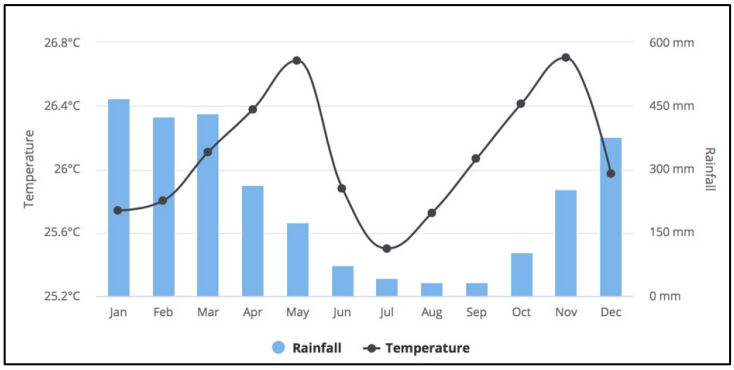


Figure 13: Average monthly temperature and rainfall in West Java (1901-2016)[82]

[82] World Bank Climate Change Knowledge Portal (2018). Climate Data: Historical URL: https://climateknowledgeportal.worldbank.org/country/indonesia/climate-data-historical

7. Natural Hazards and Disaster

135. The eastern and western portion of the island of Java are highly vulnerable to multiple climate hazards, including drought, floods, landslides, and sea-level rise. Between 2001 and 2007, 4,000 disasters occurred such as floods (37%), drought (24%), landslides (11%), and windstorms (9%). The two sites in Bandung and Indotaisei are on elevated flat terrain and are not vulnerable to floods or landslides.

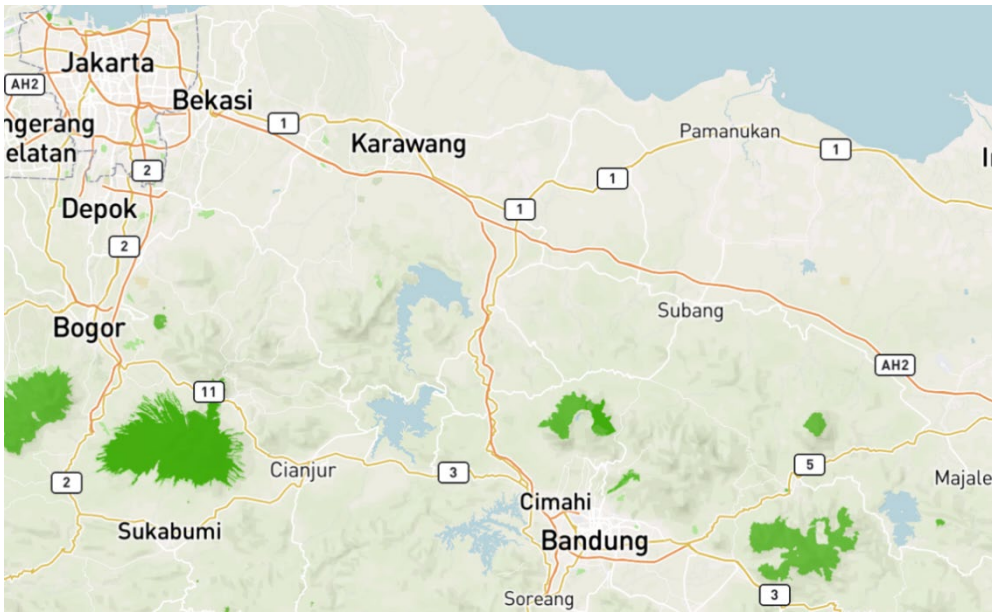
B. Ecology

136. The sites of Bio Farma in Bandung and Indotaisei are in built up environments, with no- to minimal ecological values. Vegetation coverage in Indotaisei is limited to gras and shrubs of little ecological importance (natural re-growth after industrial park establishment, see **Figure 14**). There are no trees requiring relocation or felling. The habitat screening tool provided as layer in ADB's SPADE GIS platform indicates that the site classifies as modified habitat, and that there are no sites classifying as potentially critical habitat in the project's area of influence.[83]

137. A rapid screening of legally protected sites between Bandung and Jakarta indicates that there are no legally protected sites that are in proximity to Bio Farma's sites in Indotaisei and Bandung (**Figure 15**). The nearest legally protected area (which is also a designated Key Biodiversity Area) is the Gunung Burangrang Nature Reserve, North of Bandung but outside the project's area of influence.

Figure 14: Current land cover at Bio Farma's site in Indotaisei industrial park

[83] https://adb-spade.org/maps/2646/view



Source: https://www.protectedplanet.net/country/ID (accessed on 12 November 2020)

Figure 15: Legally protected areas in Bandung and Karawang

C. Socioeconomic Conditions

1. Population, economy, socio-economic resources

138. In 2005, the population of Bandung was 2.2 million people with a density of 13,693/km^2.The May 2010 census enumerated 2.3 million people. Based on data from Statistics Indonesia, the population of Bandung in 2014 was 2.4 million, making Bandung the third most populous city in Indonesia.

139. The city administration is divided into 30 districts and 153 villages. For development purposes, the 30 districts are grouped into eight sub-city regions. The sub-city regions of Bandung are Arcamanik, Cibeunying, Kerees, Kordon, Gedebage, Ujungberung, Bojonagara and Tegalega. Bio Farma's site in Bandung is located in Pasteur urban village, Sukajadi district, Bojonagara region.

140. According to 2010 census data, the total population in Pasteur urban village was 16,724 people and 4,189 households. A signicant portion of the population are private company employees (2198), government employees (605),

141. The economy in Bandung comes from tourism, business, manufacturing industries, education institutions, retail services, financial services, pharmaceutical companies, and food production. There are seven industrial and trade areas in Bandung. These include Binong Jati Knitting Industrial and Trade Center, Cigondewah Textile Trade Center, Cihampelas Jeans Trade Center, Suci (T and Oblong), Shirt Industrial Center, Cibaduyut Shoes Industrial Center, Cibuntu Tofu and Tempeh Industrial Center, and Sukamulya Sukajadi Doll Industrial Center.

142. The Indotaisei production facility will be located in Karawang Regency. Key socio-economic indicators including population, age structure, education background, key industries and health and community facilities are described in **Figure 16** below.

Communities	Workforce	Local Business & Industry Procurement	Health & Community Well-Being

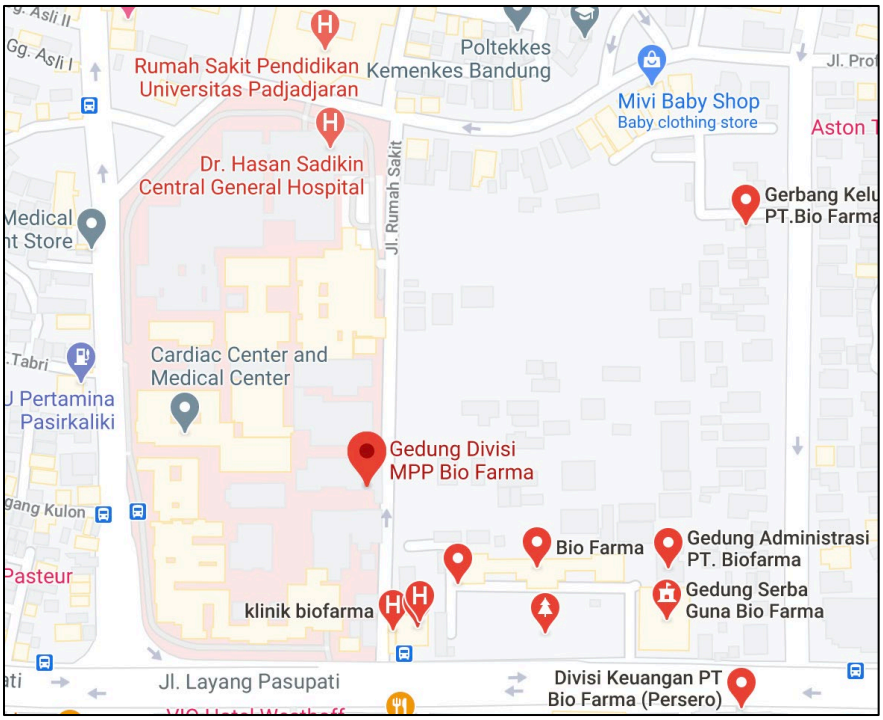
• **Total population**: 2.3M people
• **Poverty Rate**: 8%
• **Age Structure**:
  • Productive age is more dominant than older age
  • Every 100 productive people support 46 non-productive people
	• **Economically Active** Population: 1.1M (64% employed)
	• **Education Background**:
	  • No education: 40%
	  • Primary school: 15%
	  • Junior high school: 18%
	  • High school: 20%
	  • University: 7%
	• **Labor Union:** TBC
		• **Main Industries**:
		1. Trade, Restaurants, Hotels
		2. Manufacturing
		3. Agriculture, Forestry, Hunting, Fisheries
		4. Community, Social, Personal Services
			• **No. of Healthcare Facilities**:
			  • Hospital: 19
			  • Maternity hospital: 3
			  • Puskesmas: 50
			  • Policlinic: 143
			  • Pharmacy: 121
			• **No. of Schools**:
			  • Primary school: 1,044
			  • Junior high school: 223
			  • High school: 176
			• **Human Development Index** (Education, Health, Welfare): 70%

Source: Feasibility Study Service for PT Bio Farma (Persero)'s Yeast Based Project Land Facility in the Region of Indotaisei. Final Report. July 2020.

Figure 16: Baseline socio-economic conditions in Karawang Regency

2. Land Uses

143. The Bio Farma site in Bandung is located in a densely populated urban area. The land use is for commercial and residential use. The site adjacent to the west of the site is occupied by several health care facilities, including the Dr. Hasan Sadikin Central General Hospital, Rumah Sakit Pendidikan Universitas Padjadjaran University Hospital, Gedung Kemuning Hospital, and the RSHS and Bedah Policlinics.



Source: Google maps (accessed on 13 November 2020)

Figure 17: Healthcare facilities located west of Bio Farma's site in Bandung

Building 43 and the Jl Rumah Sakit (road)

The adjacent Dr. Hasan Sadikin Central General Hospital and Jl Rumah Sakit (road) which are across the Bio Farma property.

Figure 18: Photos of the adjacent road and hospital across Building 43

144. In general, the Indotaisei industrial park is designed for a range of medium to heavy industries that are engaged in a various of manufacturing operations such as metal and plastic, glass, chemicals, resins, rubber, wood, metal, industrial gas, and automotive parts (**Figure 10**). The site is currently unoccupied and ready for civil works to start (**Figure 14**).

3. Physical Cultural Resources

145. There are no physical cultural resources at the Bio Farma sites in Bandung and Indotaisei. The Bio Farma site in Bandung includes a mosque (Figure 1, Building No. 1) which is administered by Bio Farma. The Indotaisei industrial park includes a mosque and a church (Figure 10, Buildings No. 10 and No. 17), which are under the administration of the industrial park management. There is no risk of chance-finds at Bio Farma's site in Indotaisei industrial park.

D. Environmental Due Diligence (Audit) of Existing Bio Farma Facilities

146. An environmental due diligence of the existing Bio Farma facilities was conducted to determine the safeguard compliance status, identify past or present safeguards concerns, and determine corrective measures to bring the project into compliance.

147. The existing Bio Farma facilities are located in Jalan Pasteur No. 28, Sukajadi District, Bandung. The property covers a total land area of 91,058 m^2. In addition, there are support facilities in Cisarua, Lembang, West Bandung Regency on an area of 282,441 m^2. The company also has a representative office in Pakarti Center Building, Jl. Tanah Abang III No. 23-27, Jakarta. The production, research and development, marketing and administration facilities of Bio Farma operate at the Jalan Pasteur site.

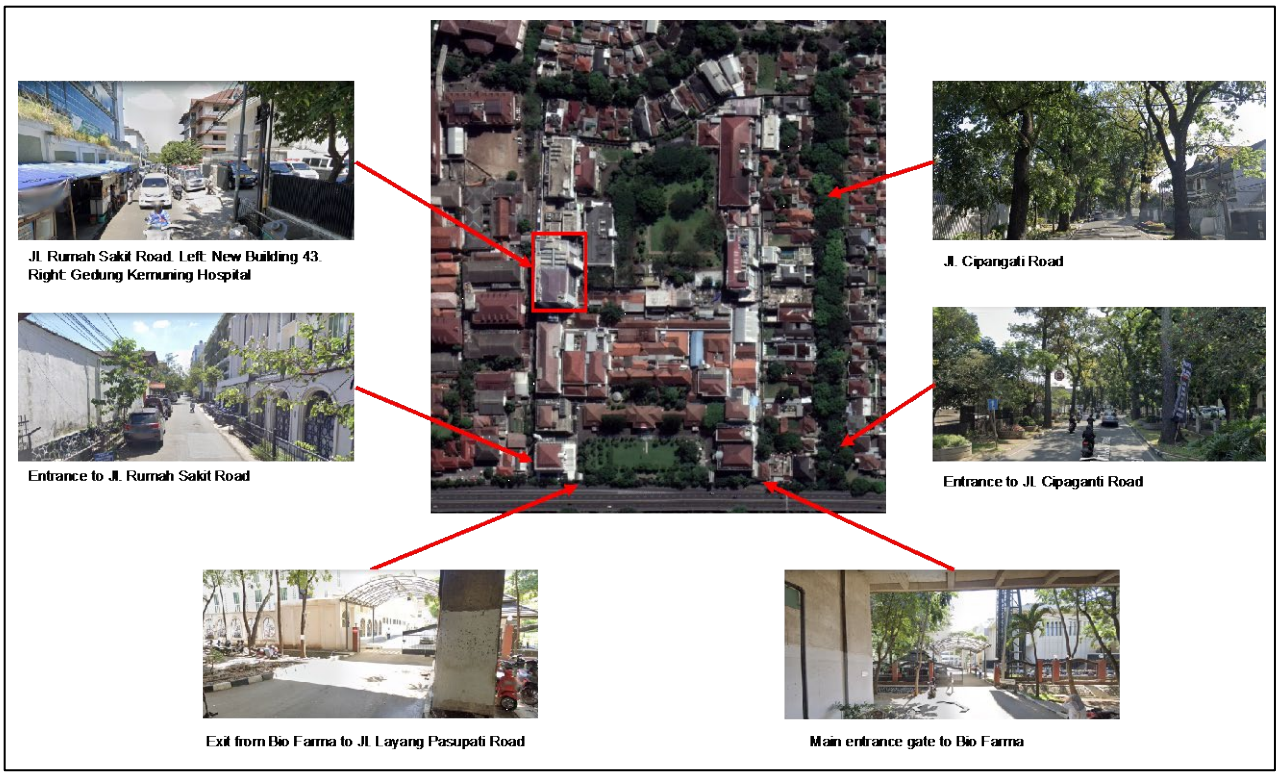


Figure 19: Aerial view of Bio Farma's Pasteur Site, Bandung

148. There are a total 43 buildings within the Bio Farma headquarters in Bandung. Building 43 where the equipment for COVID-19 production (Merah Putih) and the additional packaging line will be installed is located at western section of the property. Building 43 is adjacent to the Jalan Rumah Sakit on the west, by Building 38 for AI seed laboratory on the north, by Building 40 for clinical lot and antisera and Building 24 for animal testing on the east, and by Building 20 for warehouse (supply of materials) on the south (Figure 20).

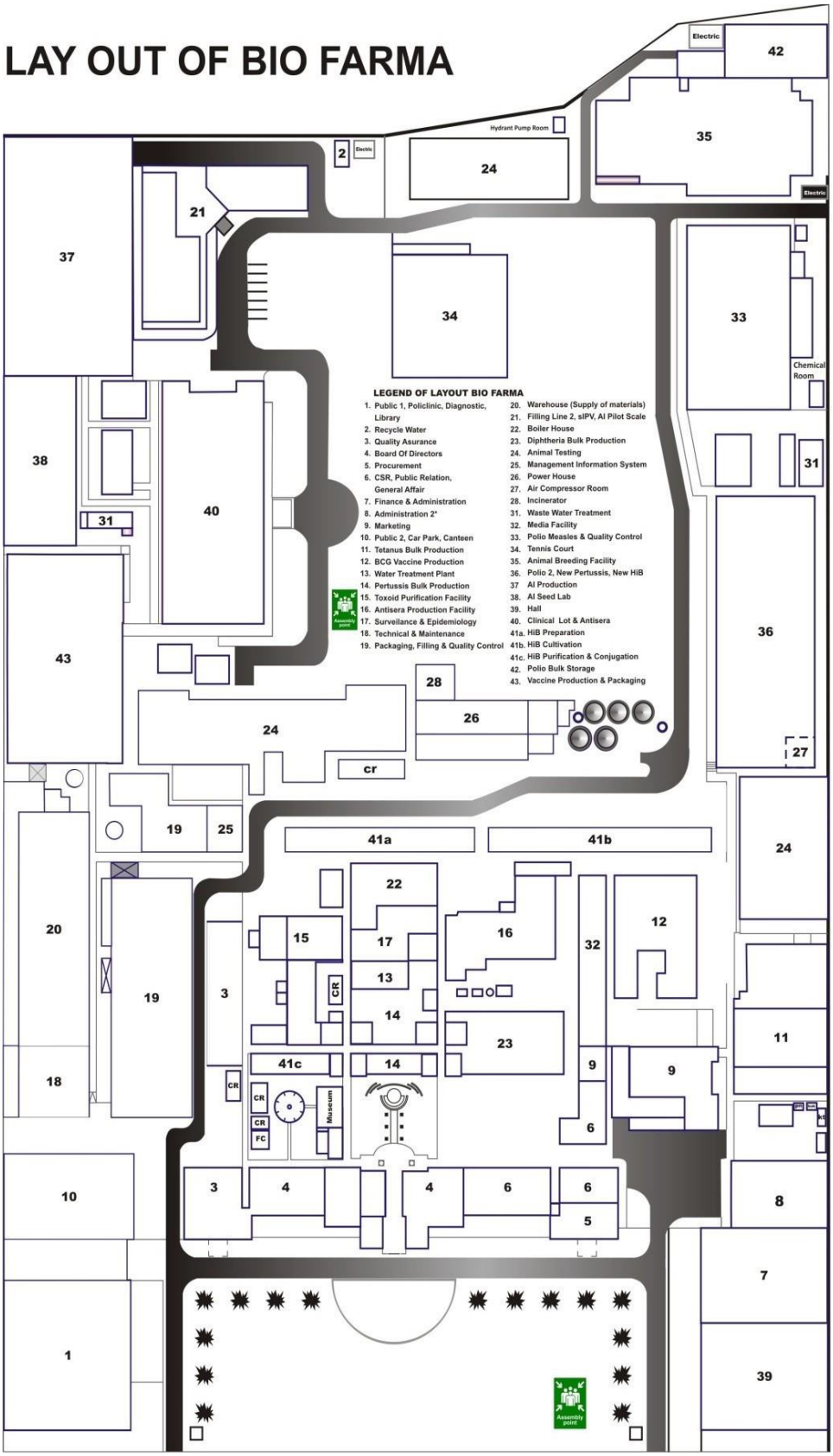


Figure 20: Layout plan of Bio Farma's Pasteur Site

149. **Building No. 43** is the newest building within Bio Farma's site in Bandung City. It was completed in 2019. Building 43 consists of six floors with mezzanine and one basement. The building is primarily designed for vaccine production and packaging. The building occupies a land area of 3,000 m^2 and has a floor area of about 16,902 m^2. Each level has a floor area of about 2,493 m^2. The project will utilize the 1st floor for the packaging and the 4th floor for Merah Putih vaccine production. Currently, the 4th floor is still empty while some packaging equipment are already present in the 1st floor. **Table 10** presents the current uses of each floor of the building.

Table 10: Current Uses and Activities of Each Floor of Building 43

Floor	Amenities	Function	Remarks
Basement	Storage area (cold room)	Final product storage	Temperature - 5±3oC, 25 million containers Temperature - 20±5oC, 4 million vials Temperature - 26±4oC, 9 million containers
Ground Floor	Filling Line 1	Preparation of vaccine solutions Bulk formula vaccine (D,T, P, HB, Hib) Filling and capping bacterial vaccine products (D, T, P, HB, Hib)	28 million vials/year
First Floor	Packaging Line	3 Packaging lines for vaccine in vial 1 packaging line for vaccine in syringe Each consisting of: process visual inspection, labeling, blistering and packaging	3 packaging lines: 55 million containers
	Offices and control room	Offices and training rooms Control rooms	-
2nd Floor (to be used for Output 2c)	Filling Line 2 and Filling Line 3	Filling line 2 – formulation and filling siPV vaccine Filling line 3 – formulation and filling frozen vaccine dry	20 million doses/year
3rd Floor	Amenities Bulk Production	SiPV bulk production facility which includes facilities to process	20 million doses/year

	SiPV	cultivation, harvest, concentration, purification, inactivation	
4th Floor (to be used for Output 2a)	Amenities Bulk Production Filling Line 4	Bulk production facility Filling Line 4 for formulations and filling vaccine products in syringe	Bulk production facilities Filling Line 4 – 12 million syringe/year
5th Floor	Amenities Bulk Production Tetanus toxoid	Bulk Production Facility for tetanus includes process of cultivation, harvest, toxin, concentration, detoxification, purification	400 million doses/year

150. The 4th floor will be retrofitted for use in the vaccine production for Merah Putih vaccine production. The new packaging line to support packaging and cartoning of finished products will be installed on the 2nd floor.

View of Building 43 from Jl. Hasan Sadikin

Front side view of the building (main entrance)

Front view of the building

Figure 21: Building No. 43 in Bandung

Figure 22: 2nd floor in Building No. 43 in Bandung where packaging line (output 2c) will be installed

151. **Water Supply.** Water is sourced from a mix of city water and bore well water, with additional WFI loops depending on the water quality requirements of production lines. The company utilizes a water treatment plant using an electro de-ionization system and optimizes water use by implementing programs on efficiency of blow down boiler, drainage water recycling for use as raw water, and washing machine wastewater management. Bio Farma uses two infiltration wells for soil water recovery as part of water conservation efforts. The company reported in 2017 that through the implementation of the 3R program (reduce, reuse, recycle) on water conservation, water savings of about 35,000 m^3or 17.26% of total water utilization was achieved which is comparably higher than the 2016 water efficiency rate of 16.43%.[84] The water conservation efforts subsequently resulted in the reduction in the volume of wastewater generated by the facility from 30,428 m^3 per month in 2018 to 11,430 m^3 per month in 2019.[85] Bio Farma has a procedure in place for water monitoring to ensure strict quality standards for pharmaceutical use. An additional water treatment plant is currently under construction at Bio Farma's HQ in Bandung.

152. **Power Supply.** The facility secures its power supply from the grid through PLN distribution lines. There are also standby diesel engine generator sets to provide power in case of outages. The company implements the Energy Efficiency Program to reduce energy use as well as reduce

[84] Quantitative impact of saving energy and water. Bio Farma Corporate Social Responsibility Report. 2017.
[85] PT Bio Farma Sustainability Report. 2019.

greenhouse gas emissions (GHG). Energy efficiency activities include a number of cleaner production processes in the production lines such as the use of time control on the air handling unit (AHU), use of inverters on chiller pump, use of hydrocarbon cooling media, recovery of condensate water, installation of selective control system on elevator, installation of LED lights and solar cell at Administration 2 Building, and modifications in the compressed air drainage system.

153. **Wastewater Treatment.** The operation of the Bio Farma facilities are served by two wastewater treatment plants with capacities of 50 m^3/day and 150 m^3/day for production wastewater and domestic sewage using disinfection/heat treatment, physical, biological and chemical treatment systems (Figure 23). A third wastewater treatment plant with capacity of 250 m^3/day in now under construction to treat the wastewater from Building #43 (Figure 24). The new wastewater treatment facility is expected to be operational by December 2020.

Disinfection/Killing Tank

WWTP No. 1

WWTP No. 2

Figure 23: Existing wastewater treatment facilities in Bio Farma's Pasteur Site

Figure 24: Third wastewater treatment facility under construction/installation in Bio Farma's Pasteur Site

154. Wastewater effluent quality monitoring is conducted monthly by a licensed external monitoring agency. Results confirm that both existing wastewater treatment plants operate in compliance with MOEF Decree No. 05/2014 on effluent standard as indicated in **Table 11** and **Table 12** below.

Table 11: Wastewater treatment plant No. 1 effluent monitoring results, 2019

Parameter	Location	Unit	*MOEF 05/2014*	Jan-2019	Apr-2019	Jul-2019	Oct-2019
BOD	Inlet	mg/L	-	59.24	79.56	20.12	53.41
	Outlet	mg/L	*100*	21.05	46.22	4.9	19.84
COD	Inlet	mg/L	-	168.77	251.12	69.4	172.35
	Outlet	mg/L	*300*	58.75	146.93	16.9	64.01
TSS	Inlet	mg/L	-	126.00	122.00	18.00	268.00
	Outlet	mg/L	*100*	10.00	30.00	8.00	44.00
TN	Inlet	mg/L	-	9.72	7.56	8.16	39.71
	Outlet	mg/L	*30*	2.59	7.35	3.71	29.34
Fenol	Inlet	mg/L	-	<0.00046	0.0061	<0.00046	0.0044
	Outlet	mg/L	*1.0*	<0.00046	0.0011	<0.00046	<0.00046
pH	Inlet	mg/L	-	7.65	7.85	7.62	6.1
	Outlet	mg/L	*6.0-9.0*	7.23	7.91	7.21	6.19

Table 12: Wastewater treatment plant No. 2 effluent monitoring results, 2019

Parameter	Location	Unit	*INO standard*	Jan-2019	Apr-2019	Jul-2019	Oct-2019
BOD	Inlet	mg/L	-	51.06	119.7	253.61	104.41
	Outlet	mg/L	*100*	26.64	56.81	8.31	16.12
COD	Inlet	mg/L	-	138.22	375.57	874.51	336.79
	Outlet	mg/L	*300*	71.52	178.76	28.3	52.02

TSS	Inlet	mg/L	-	122.00	240.00	216.00	85.00
	Outlet	mg/L	*100*	32	30.00	18.00	56.00
TN	Inlet	mg/L	-	12.78	8.51	37.01	5.68
	Outlet	mg/L	*30*	11.37	0.92	8.1	4.65
Fenol	Inlet	mg/L	-	0.0042	0.0067	<0.00046	0.0032
	Outlet	mg/L	*1.0*	<0.00046	0.0006	<0.00046	0.0008
pH	Inlet	mg/L	-	7.42	6.53	7.4	6.86
	Outlet	mg/L	*6.0-9.0*	7.14	7.68	7.11	7.47

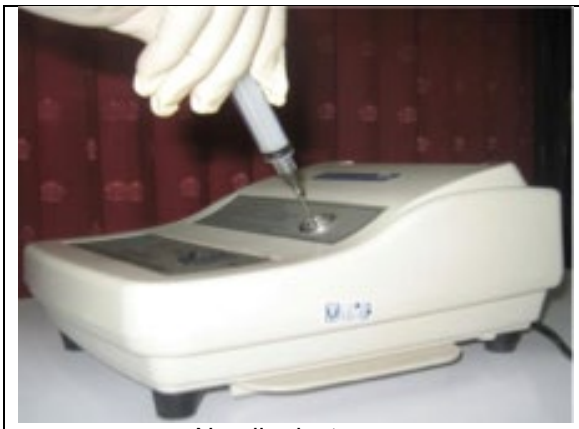
155. **Waste management.** Bio Farma has a comprehensive waste management system in place at its Bandung site. The system adheres to MOEF Regulation No. 12/2020 on Hazardous Waste Storage; MOEF Regulation 101/2014 Regarding the Management of Toxic and Hazardous Substances; MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Medical Service Facilities. Bio Farma has a comprehensive hazardous waste management procedure (236K-LIMB-B3) which also covers hazardous waste incineration (236K-INCI-M1). Recent independent audits conducted by ISO14001:2015 inspectors as well as by WHO concluded that procedures for decontamination and disposal of used contaminated materials and hazardous waste management were in place.

156. Bio Farma operates several waste storage and treatment facilities at its Bandung HQ, including needle destroyers, autoclaves for disinfection of wastes, two incinerators (MDWS-300, capacity 270 kg/day and SW-320, capacity 288 kg/day), and temporary hazardous waste storage facilities. The necessary licenses for the incinerators and the temporary hazardous waste storage facilities have been secured from MOEF.[86] In addition, Bio Farma relies on PT. Prasadha Pamunah Limbah Industri (PPLI), a licensed hazardous waste management company for the collection, transport and treatment of hazardous waste.[87] PPLI has valid permits from MoEF and the Director General of Land Transportation for the collection, transportation and treatment of hazardous waste.[88]

[86] Including (i) Incinerator permit 1. Decree of the Minister of Environment and Forestry No. SK.12 / Menlhk / Setjen / PSLB.1 / 1/2016 concerning the Extension of Permit for Hazardous and Toxic Waste Management for Hazardous and Toxic Waste Treatment Activities on behalf of PT. Bio Farma, January 11, 2016; (ii) Incinerator permit 2. Decree of the Minister of Environment and Forestry No. SK.519 / Menlhk / Setjen / PSLB.1 / 9/2017 concerning Extension of Permit for Hazardous and Toxic Waste Management for Hazardous and Toxic Waste Treatment Activities on behalf of PT. Bio Farma, 28 September 2017; and (iii) Permit from the Head of the Investment Service and One Stop Integrated Services for Bandung City No. 0003 / PNB3 / VIII / 2017 / DPMPTSP dated 28 August 2017 concerning Temporary Storage Permit for Hazardous and Toxic Waste (B3).

[87] Agreement for the procurement of B3 waste transportation, delivery and final treatment services between PT. Bio Farma and PT. PPLI, No. 4497 / PGD / IV / 2020, dated 13 April 2020.

[88] Including: (i) Hazardous waste (B3) waste processing permit PT. PRASADHA PAMUNAH LIMBAH INDUSTRI (PPLI Company). Minister of Environment and Forestry Decree No. Sk. 76 / Menlhk / Setjen / PLB.3 / 2/2017, dated 16 February 2017; and (ii) Decree of the Director General of Land Transportation No. SK.00202 / AJ.309 / 1 / DJPD / 2018 concerning the license to carry out special goods transportation to transport dangerous goods (B3), dated May 28 2018.



Needle destroyer

Autoclave

Figure 25: Needle destroyer and autoclave in Bio Farma's Pasteur Site

Figure 26: Existing hazardous waste storage facility in Bio Farma's Pasteur Site

Figure 27: Existing hazardous waste incinerator, ash storage area in Bio Farma's Pasteur Site

157. Incinerator stack emission monitoring is conducted on a quarterly basis by a licensed independent monitoring agency. Results for the four 2019 monitoring campaigns confirm that the incinerators are fully compliant with Kep-03/BAPEDAL/09/1995 regarding Technical Requirements of Hazardous Waste Management) (**Table 13**).

Table 13: Incinerator stack emission monitoring results in Bio Farma's Bandung site

Parameter	Unit	INO Emission standard (Kep-01/BAPEDAL/09/1995)	Monitoring results for 2019 monitoring campaigns			
			Feb-19	Jun-19	Sep-19	Dec-19
Particles	mg/Nm^3	50	46.01	24.61	34.8	22.3
SO2	mg/Nm^3	250	74.7	23.6	27.8	3.8
NO2	mg/Nm^3	300	72.3	26.3	31.7	14.6
HF	mg/Nm^3	10	<0.1	<0.1	<0.1	<0.1
CO	mg/Nm^3	100	95.6	35.2	47.6	23.4
HCL	mg/Nm^3	70	<3	<3	<3	<3
CH4	mg/Nm^3	35	33.88	17.8	8.5	19.5
Metals						
As	mg/Nm^3	1	<0.001	<0.001	<0.001	<0.001
Cd	mg/Nm^3	0.2	<0.006	<0.006	<0.006	<0.006
Cr	mg/Nm^3	1	<0.005	0.113	<0.005	<0.005
Pb	mg/Nm^3	5	<0..01	<0..01	<0..01	<0..01
Hg	mg/Nm^3	0.2	<0.001	<0.001	<0.001	<0.001
Ti	mg/Nm^3	0.2	<0.02	<0.02	<0.02	<0.02

Notes: Stack height = 15m; stack diameter = 0.38m

158. **Environmental Compliance.** Bio Farma has approved environmental permits from the Department of Environment (DLHK) of Bandung City Government including amendments to ANDAL and RKL-RPL due to changes in operation. The latest amendment of ANDAL and RKL-RPL was granted on 20 March 2019 based on the evaluation of the AMDAL Commission Team for the changes in the vaccine production activities of the facility in Jalan Pasteur No. 28, Sukajadi District Bandung due to the following: (i) use of the former diphtheria room at Building 43 as a PFS packaging (prefilled syringe); and (ii) employment of additional 100 workers. The amendment included the expansion plan of Bio Farma and can also accommodate the COVID-19 packaging. Bio Farma is now discussing with DLH whether the 2019 amendment of the ANDAL and RKL-RPL is enough since there will be no increase in capacity. The company also has approved permits for industrial wastewater disposal, permit for hazardous waste temporary storage, contracts with licensed waste collectors, and permit of groundwater extraction.

159. Bio Farma achieved the Green PROPER rating from Government for its performance from 2017 – 2018 and the Gold PROPER rating in 2015 – 2017. The rating evaluation of the MOEF shows that the company is performing beyond compliance in terms of environmental management.

160. **Environment protection policy.** Bio Farma has an environment protection policy which is divided into 5 main areas: (i) Green Process, which applies green principles to all business processes, ranging from raw material selection through the selection of vendors who commit to

environment protection in the production, filling, and packaging of products; (ii) Efficient energy use; (iii) Water efficiency and water conservation through implementation of 4R principle (reduce, reuse, recycle, recovery); (iv) Waste management and segregating waste into five categories; and (v) Effort in involving employees and their families, to adapt a pro-environment work culture and attitude.

161. **EHS audit.** Recent audits conducted by WHO Prequalification Team in March 2019 and by the joint WHO and BPOM team in February 2020 confirm that Bio Farma has adequate systems and capacities in place to ensure compliance with very stringent EHS requirements for pharmaceutical production.[89,90] The WHO and BPOM audits and ADB's rapid assessment confirms the following:

162. **Occupational health and safety (OHS), environment management.** Bio Farma adheres to the Occupational Health and Safety Management Systems (OHSAS) 18001:2007 standard. OHS Management is handled by the Safety and Environment Unit under PT Bio Farma (Persero)'s Environment and Social Management Division, which in turn in under the SEVP Human Capital and Compliance Department (**Figure 28** and **Figure 29**). This Safety and Environment Unit monitors the implementation of Bio Farma's OHS management system and the environment within Bio Farma.

163. There are also designated Bio Safety Officers and a Biosafety Committee (under the Risk Management and Compliance Division) that ensure compliance of all products and production activities with the WHO, BPOM and Ministry of Health regulations.

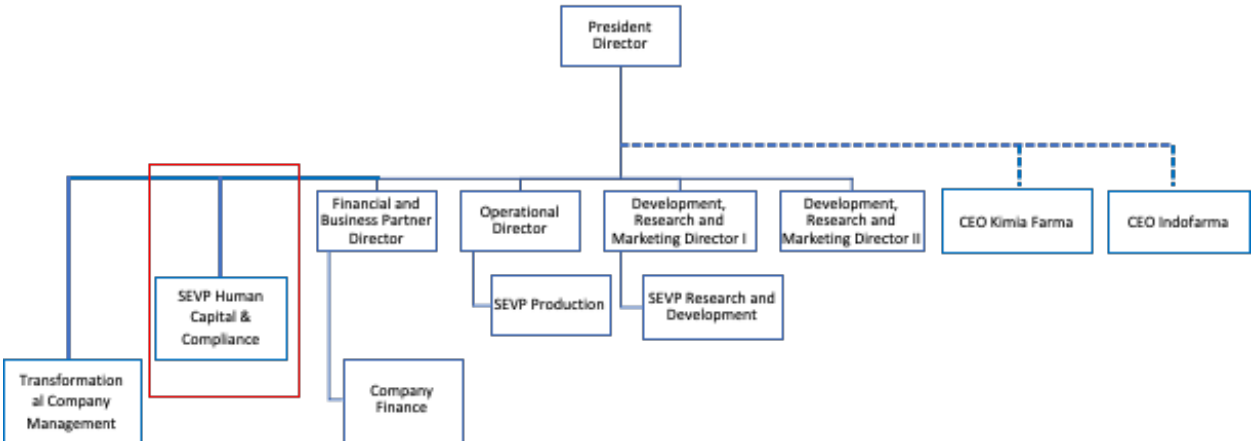


Figure 28: Bio Farma's Corporate structure
Source: Decree of the Directors of PT. Bio Farma (Persero) KEP-00021/DIR/VII/2020, dated 7 July 2020.

[89] WHO Public Inspection Report of the Vaccine Manufacturer. Prequalification Team Inspection Services. PT Bio Farma (Persero). 18 to 22 March 2019.
[90] WHO Prequalification Team – Inspection Services Closing of Inspection. PT Bio Farma, Bandung. 15 October 2020.

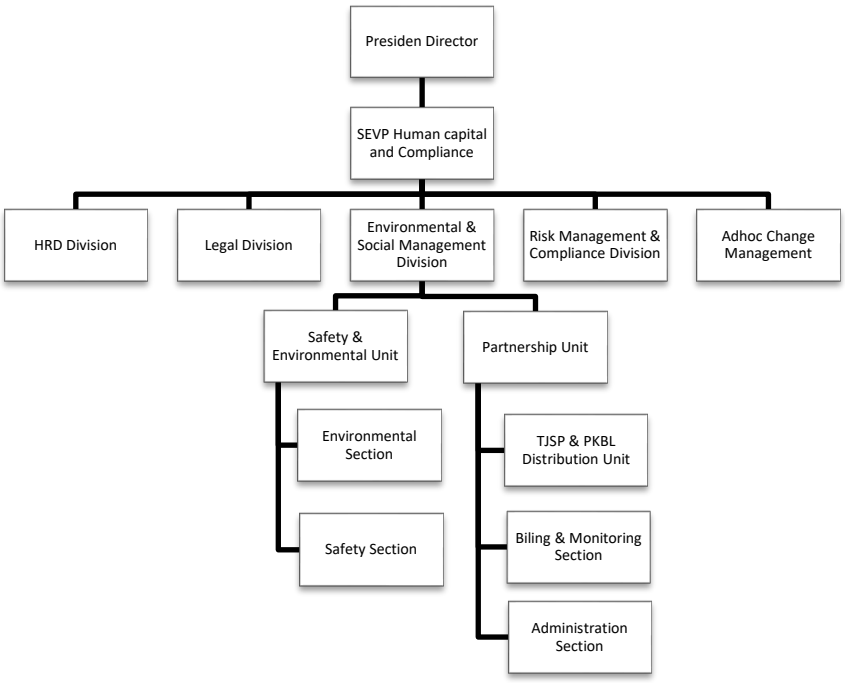


Figure 29: Bio Farma's Environment, Health and Safety institutional organization
Note: PKBL = Program Kemitraan dan Bina Lingkungan (*Partnership and Community Development Program*); TJSP = Tanggung Jawab Sosial Perusahan (*Corporate Social Responsibility*).

164. In addition, Bio Farma has also established an Occupational Health and Safety Guidance Committee Team (P2K3), as well as Emergency Response Team (TTD). To ensure the effectiveness of the emergency response system, the emergency response procedures are periodically tested with the intention of assuring they are clearly understood and that all employees are capable of implementing these responses in the event of an emergency. Emergency drills and simulations are conducted once every two years involving all of Bio Farma's personnel and the communities in the company's vicinity. Throughout 2017-2019, Bio Farma recorded zero accidents in its operational activities both at HQ and in Regional Offices. Bio Farma also has a pharmaceutical quality control and quality assurance system that is managed and operated independently by the Quality Department and the Production Department.

165. All Bio Farma departments at the site have sufficient number of personnel with appropriate qualifications with respect to education, experience and training to perform their functions. There is clear organizational separation of responsibilities for production and quality matters.

166. **EHS accreditations.** Bio Farma applies various integrated systems such as fulfilling requirements of ISO 9001:2015 on quality management and quality assurance (certificate identity number 1025988 valid until 26 June 2022), ISO 14001:2015 on environmental management system (certificate identity number 10132913 valid until 12 July 2021), OHSAS 18001:2007 on occupational health and safety (certificate identity number 10183325 valid until 11 March 2021), ISO/IEC 17025:2016 on requirements for the competence of testing and calibration laboratories, ISO 26000 guidance for Corporate Social Responsibility (CSR), ISO 31000 Enterprise Risk Management, and International Finance Report Standard (IFRS), The company implements the INO CPOB (Pedoman Cara Pembuatan Obat yang Baik; Indonesian Good Manufacturing Practice guidelines for pharmaceuticals), WHO Good Manufacturing Practice (GMP) guidelines,

Good Laboratory Practices (GLP), Good Clinical Practices (GCP, and Good Distribution Practices (GDP). In 2017, Bio Farma was trusted as the Center of Excellence Research Vaccine Organization Islamic Cooperation (OKI).

167. **Standard Operating Procedures on Environmental Protection and Safety.** Bio Farma has operating procedures related to the following:

- Handling and storage of hazardous wastes (236K-LIMB-B3, Penanganan dan Penyimpanan B3)
- Operation and maintenance of incinerator (236-INCI-M1, Pengeopeasian dan Pemeliharaan Insinerator
- Operation of wastewater treatment system (236K-LIMB-01, Pengoperasian Sistem Pengolahan Air Limbah)
- Management of Non Hazardous Garbage (214-PS-01, Penanganan Sampah Non B3)
- Management of domestic wastewater (214K-PLD-01, Penanganan Air Limbah Domestik)
- Operation and Maintenance of Glass Grinder Machine ((236K-GlassG-01, Pengoperasian dan Pemeliharaan Mesin Glass Grinder)
- Fire Fighting and Security (236K-APK-DKD, Alat Pemadam & Deteksi Kebakaran)
- Emergency Preparedness and Response (236K-KTD-01, Kesiagaan dan Tanggap Darurat)
- Safety Patrol (236K-SP-01)
- Evaluation of Compliance with Environmental Laws and Regulations (236K-SIS-EK, Evaluasi Kepatuhan terhadap Hukum dan Peratuan Perundangan Lingkungan & K3)
- Identification of Aspects or Hazards and Impacts or Risks (236K-SIS-IAP, Identifikasi Aspek atau Bahaya & Dampak atau Resiko)
- Work Safety Analysis (236K-SIS-JSA, Analisis Keselamata Kerja)
- Provision of Safety and Environmental Signs (236-PRKL-01, Penyediaan Rambu K3 & Lingkungan)
- Management and Controlling of Resources (236K-PP-SDA, Penanganan dan Pengendalian Sumber Daya)
- Handling of Public Complaints related to Environment and Safety Aspects (236K-PKM-K3L, Penanganan Keluhan Masyarakat terkait Aspek Lingkungan & K3)
- Work Permit (236K-IKER-01, Ijin Kerja)

V. ANTICIPATED ENVIRONMENTAL IMPACTS AND MITIGATION MEASURES

A. Impact Screening and Scoping

168. **Project benefits.** The project will have positive social benefits as the project will bring improvements to health and indirectly reduce poverty, particularly for Indonesians. Specifically, activities under the project will increase availability of vaccines and the chance for populations to be immunized. Vulnerable populations such as health care workers, those who directly serve communities, older people and care workers, will be prioritized for vaccination, in line with the MOH's vaccination implementation strategy. Within Bio Farma, employees will benefit from institutional capacity building.

169. **Environment safeguards screening and categorization.** Each component of the project was screened for environmental safeguards at project conceptualization stage (**Table 14**). The procurement of COVID-19 vaccines under output 1 is not anticipated to result in any significant adverse environmental impacts or significant health and safety risks. The COVID-19 vaccines to be procured under output 1 will be subject to BPOM issuance of a distribution permit. Immunization waste generated at the point of vaccine use (hospitals and healthcare facilities) will increase during the vaccination campaign. MOH and MoEF are taking actions to address the incremental healthcare waste generated by the COVID-19 pandemic. This also covers immunization waste generation at point of vaccine use (see Section V.D). Outputs 2a (equipment for COVID-19 vaccine production), 2c (equipment for packaging line) will involve procurement of new equipment to be installed in existing facilities of Bio Farma's headquarter (HQ) in Bandung, and are not anticipated to result in significant adverse impacts. Minor internal refurbishment works may be required on the floors that will house the new COVID-19 vaccine production and packaging facilities in Bandung (4th floor and 2nd floor of building #43, respectively). These works could result in temporary and highly localized adverse impacts and occupational safety concerns. Output 2b, the yeast-based vaccine production facility for Hep B and HPV vaccines to be established on Bio Farma's compound in Indotaisei industrial park) will involve major civil works to construct the production facility, office building and auxiliary facilities. Such works have the potential for adverse temporary and site-specific environmental impacts.

170. The new vaccine production and packaging lines will adhere to INO and WHO Good Manufacturing Practice (GMP) guidelines and will be subject to facility, utilities, equipment and process validation and qualification prior to production in accordance with GMP guidelines, and regular internal and external audits during production.

171. As a result, the overall RECOVER project was classified overall as category B for environmental safeguards per ADB's SPS (2009), with the RRC (output 1) and output 3 classifying as category C and PIC (output 2) classifying as category B.

Table 14: Screening and classification of project components per the ADB Safeguard Policy Statement (2009)

No	Project components	Environment safeguards categorization per ADB SPS 2009
1.	COVID-19 vaccines procured and deployed to provinces (RRC window of APVAX facility)	

a.	COVID-19 vaccines procured and deployed to provinces	**Cat. C -** Output does not involve works or equipment. The component will be subject to strict eligibility criteria for vaccine procurement as defined in the policy paper of the proposed APVAX facility. The availability of COVID-19 vaccines will result in a temporary increase of immunization waste at the point of vaccine use (i.e. health facilities). Improved immunization waste management is addressed in Minister Decrees 56/2015 and 18/2020, and technical guidelines (see footnotes 14 and 16, and discussion in Section D).
2.	**Bio Farma's vaccine production capacity strengthened (PIC window of APVAX facility)**	
a.	Equipment for producing an additional 40 million vaccine doses annually using recombinant yeast-based platform in Bio Farma's production complex in Bandung installed	**Cat. C for environment with minimal temporary impacts -** Equipment will be installed in existing production facilities of Bio Farma at its HQ in Bandung. No new facility construction required, but minor internal refurbishment works may be required. Facility and production line will be subject to validation and qualification by BPOM prior to production).
b.	Bio Farma's new plant with gender inclusive and accessibility features in Indotaisei industrial complex for producing 40 million vaccine doses annually using recombinant yeast-based platform constructed	**Category B for environment** – The new production facility with footprint of 2,000-3,000 m^2 will be established on a 2.6ha industrial compound owned by Bio Farma in Indo Taisei, Bukit Indah Industrial Area in Karawang Regency, West Java Province.
c.	1 new packaging line to package and carton 25 million vials per year operational	**Cat. C for environment** - One additional packaging line will be installed in existing facility in Building No. 43 of Bio Farma at its HQ in Bandung.
3.	**Bio Farma's institutional capacity enhanced and knowledge disseminated (PIC window of APVAX facility)**	
a-d	Capacity Building, knowledge dissemination	**Cat. C for environment**

172. **Involuntary resettlement.** The project (both RRC and PIC) is classified as category C for involuntary resettlement, as there are no anticipated relocations of any persons on the project sites, and no resettlement plan is required. The new plant and its facilities will be built on land owned by Bio Farma, which was purchased from PT. Indotaisei, an Industrial Area Developer, in 2017 with the status of in 2017 with the status of Right to Build. Land rights are valid until September 2042. The land is located in Indotaisei Industrial Estate, Bukit Indah City in Karawang Regency, West Java Province. No one uses or occupies the land. The refurbishment of Building 43 facility and installation of new packaging line will take place in Bio Farma's existing building on the Bio Farma site in Pasteur, Bandung City, West Java Province. Given the land availability for the plant in Kerawang Regency and the use of existing building, no land acquisition and involuntary resettlement is required.

173. **Impacts on indigenous peoples.** The project (RRC and PIC) is classified as category C for indigenous people safeguards, as there are no negative impacts arising. Both the new plant

and expansion of capacity of existing plant under output 2 will be carried out on land already available and owned by Bio Farma, in West Java Province. While some indigenous peoples groups live in West Java Province, they live far from the project sites and have integrated with the majority of non-indigenous peoples. Capacity development for Bio Farma staff (output 3) will not affect the indigenous peoples' socio culture, beliefs, and livelihood system.

174. **Gender**. The Project is categorized effective gender mainstreaming (EGM), taking into account Bio Farma's existing activities and commitment to undertake activities that benefit women, children and people with disabilities. A gender equality and social inclusion action plan has been drafted, which includes the following actions: development of gender-inclusive and accessible facilities for vaccine production, ensuring women's proportional representation in new recruitment to be conducted to operate Bandung and Indotaisei facilities, establishment of feasible targets for representation of people with disabilities in the company's workforce, and the development of a corporate gender equality and social inclusion strategy and action plan.

175. Based on the rapid screening of potential adverse impacts on the environment and risks to occupational health and safety caused by the project, the following environmental issues associated with pharmaceuticals manufacturing have been considered as part of the assessment and management plan:

176. Construction-related environment issues and occupational risks, including:
- Impacts on air quality due to generation of dust, noise
- Discharge of domestic sewage and construction wastewater with impact on water quality
- Stormwater runoff containing sediments
- Occupational health and safety

177. During facility operation:
- Air emissions
- Wastewater generation
- Solid and hazardous wastes
- Occupational risks
- Product safety

178. These aspects are discussed in detail in the following sections.

B. Anticipated impacts during construction

179. The construction activities will be confined within the premises of Bio Farma. Construction activities include the renovation of the 4th floor at Building 43 for the installation of equipment for Merah Puth vaccine production and installation of new packaging line at the 2nd floor. Construction works of the new site in Indotaisei industrial park will include the construction of the production building and the office building as well as the site development works on the property of Bio Farma within the industrial park. The following presents the potential impacts that may occur from the renovation works and equipment installation at Building 43 and construction activities at the new plant site.

180. **Impacts on water quality.** During the installation of equipment and minor works at the existing Bio Farma site, there will be minimal impact on surface water quality since minor construction/refurbishment activities such as installation of wall panels and equipment are

confined within Building 43. However, for the construction activities at the new site, the site clearing, foundation works and other related earthworks can potentially cause soil erosion. This could lead to runoff of mud and silt into drainage canals and cause clogging of canals and sedimentation of receiving surface water. Appropriate mitigation measures are necessary through employment of silt traps or sediment control devices to avoid runoff. Likewise, materials such as cement, sand, and gravel are to be covered with tarpaulin and provided with bunds. Other erosion control measures are:

a) Limiting construction and material handling during periods of rains and high winds;
b) Stabilizing all cut slopes, embankments and other erosion-prone working areas while works are ongoing;
c) Stabilizing all earthwork disturbance areas within 30 days after completion of earthworks;
d) Cement mixer washing will be prohibited at the site to prevent clogging of drains.

181. The construction activities will also generate domestic sewage due to the presence of workers at the site. Bio Farma requires its contractors to provide their own temporary toilet facilities at the working area of Building 43 for workers to maintain sanitation in the area. The contractor will be required to conduct daily cleaning and instruct workers to properly use and maintain the temporary toilets during the construction. For the new site in Indotaisei, the staging area within the property will also have temporary toilet facilities with septic tanks for use of contractors and workers.

182. There may also be leakage of spills of fuel and lubricants that may contaminate soil, surface water and groundwater. To manage spills of fuel and lubricants, the contractor will be required to ensure the following:

a) Soil surfaces where chemicals are stored shall be made impermeable and provided with bunds. The bunds should be able to hold 110% of the maximum capacity of the largest tank or drum.
b) Vehicle and other heavy equipment maintenance and re-fueling activities of contractor will be prohibited at the project site.

183. **Impacts on air quality.** Air quality may be affected by earthmoving activities, operation of machinery, and from movement of construction hauling vehicles. Dust and gases from fuel combustion may be generated and result in nuisance and localized impacts on air quality. To manage dust and air emissions, equipment to be utilized by the contractor should be well-maintained to a high standard to ensure efficient running and fuel burning to ensure compliance with the emission standards. Equipment and machineries that will run on high horsepower will be provided with tail gas purifiers.

184. Dust from earthmoving activities can be avoided by:

a) Equipping material stockpiles and concrete mixing equipment with dust shrouds.
b) Regular water spraying on construction area, roads, and stockpiled material.
c) Deployment of workers assigned to clean the work area particularly driving surfaces and gutters as standard site management practice.
d) Materials with soil, sand and other fine materials will be covered with tarpaulin sheets particularly during hauling.

e) Limit the speed of vehicles delivering equipment and materials to the site, e.g. not exceeding 20 km/hour when entering the premises or passing through unpaved roads and populated areas.

185. **Noise.** Although the construction activities at Building 43 is across a hospital, the renovation works and equipment installation activities are confined within the building itself. Intensity of noise can reach 80 – 90 dBA at 15 m (50ft) distance from the source. However, activities are not anticipated to cause noise that may cause nuisance to the hospital occupants because noise will be dissipated by the walls of the building. The potential impact of noise from construction activities may come from movement of haulage vehicles to and from the site. Measures to manage noise from vehicles will be to strictly prohibit construction after 10pm. Construction activities at the new site will comply with the time restrictions of Indotaisei industrial park.

186. **Generation of construction wastes.** Solid wastes that will be generated during the construction of the buildings and from equipment installation includes debris, wooden planks, steel bars, cement bags, wires, and other related construction materials. There will also be excavated materials that may be generated during the foundation works at the new site. The recoverable/recyclable materials can be segregated and could be used in other projects of the contractor or sold to recycling shops. Construction waste are to be stored in secure containers or areas to prevent uncontrolled disposal. The final disposal site of the waste and spoils will only be in approved sites by the local authorities.

187. Biodegradable wastes such as food wastes, leftovers, and other similar wastes generated by the construction workforce may cause unsanitary conditions at the site. These wastes will be collected in bins and will be disposed in permitted disposal site in compliance with the requirements of the Indotaisei industrial park. The contractor will be required to provide sufficient waste bins with cover at strategic locations within the construction site. The waste bins should be emptied regularly to prevent overflow that can lead to infestation of vermins and birds.

188. Any hazardous wastes such as oil and grease, solvents and empty paint containers used during the construction activities will be collected separately from the regular garbage and will be collected through MOEF-licensed third-party hazardous waste treatment and disposal facility.

189. **Impacts on worker health and safety.** Potential risks to workers are related to the construction of the new site and renovation of Building 43 are on physical hazards from lifting and moving of heavy loads and operation of machineries, fall hazards, electrocution during installation of equipment, fire, dust and noise. Measures will be undertaken to avoid causing hazards to workers and the environment such as:

a) Use of barricade/fence to cover the construction area;
b) Implementation of a systematic program of works that will avoid disrupting operations, particularly at Building 43;
c) Use of existing sanitary facilities for workers and regular cleaning of these facilities;
d) Strict requirement on wearing of personal protective equipment (PPE) in order to minimize or eliminate work-related accidents;
e) Posting of safety signages in strategic locations within the construction site;
f) Use of only certified and tested machineries and equipment;
g) Provision of adequate training or instruction for occupational health and safety;
h) Adequate supervision of safe work systems;

i) Ensure that means of access to and exit from the site are without risk to health and safety;
j) Ensure that a first aid kit is available at the construction site at all times and that all staff members are responsible for first aid and are aware of local health care facilities;
k) Promptly report any incident or accident to Bio Farma and relevant local authorities.

190. In compliance with the core labor standards, Bio Farma and its contractor will strictly prohibit employment of workers under the age of 16. Persons between age 16-18 can only be allowed to work in non-hazardous environment. In addition, there shall be no discrimination regarding recruitment, wages, and compensation.

191. **COVID-19 Protocols During Construction.** The spread of COVID-19 virus and other infectious diseases may occur in the workplace. Bio Farma will adhere to guidelines imposed by the Government on the prevention of spread of the virus as well as the recommendations of the WHO to manage risks. The following are recommended measures to prevent the spread of COVID-19 virus during the construction phase:

a) Physical distancing will be observed in all work-related situations;
b) Temperature checks will be conducted on workers and visitors;
c) Implement work shifts or staggered schedule to avoid concentration and crowding of workers;
d) Organize one-way movement systems;
e) Natural ventilation will be ensured in the workplace;
f) Increase frequency of cleaning and disinfection;
g) Monitoring health status of workers, develop protocols for cases of suspected and confirmed cases.

192. In addition, the following clauses will be included in the bidding documents for the works contractor:

a) Require the submission of a COVID-19 Health and Safety Management Plan in the technical bid. Consequently, include this element as part of the technical bid evaluation; and
b) Highlight the safeguard compliance requirement in the Particular Conditions of Contract in relation to the contractor's Environmental Management Plan. This must include a Site-Specific Health and Safety Management Plan which incorporates the HS COVID-19 Plan for the Employer's approval prior to mobilization of site work.

193. **Community health and safety.** Construction activities may pose safety hazards and threats to nearby residents and passersby, including staff, patients, and guests of adjacent hospital at the Bio Farma site in Pasteur. It may also cause temporary traffic disruption at the adjacent road during unloading of equipment.

194. At the new site in Indotaisei industrial park, there are no settlers that may be directly affected by the construction activities except for the movement of construction vehicles to the site. To safeguard community health and safety, the following measures to be implemented by the contractor:

a) Planning construction activities to minimize disturbances to residents and passersby;

b) Providing warning signs, barriers, and security personnel to prevent entry of unauthorized persons to the construction site;
c) Ensuring that drivers of all vehicles strictly follow road rules and maintain good road safety standards while driving;
d) Properly supervise deliveries of construction materials to the site by deploying traffic marshals;

195. During site hand-over, there may be hazardous waste materials, unprotected latrines, and organic wastes remaining after construction that may pose risk to health and safety. Prior to acceptance of works, Bio Farma will ensure that the contractor has undertaken the following:

a) Remove all unused or discarded construction materials from the site before hand-over;
b) Landscape surrounding to reinstate original site conditions;
c) Remove all temporary dwelling, cook houses, and latrines upon completion of the site;
d) Turn-over a clean and sanitary site;
e) Submit all as-built drawings and complete report to Bio Farma.

C. Anticipated impacts during operation

196. The operation of the facilities should conform to the standards and requirements of BPOM, PIC/S and WHO on Good Manufacturing Practices and will be subject to BPOM and WHO certifications and audits. These standards are outlined in the following: (i) CPOB 2018 (Guideline for Good Drug Manufacturing (PP BPOM No. 34 Year 2018); (ii) WHO TRS 980 (WHO Expert Committee on Biological Standardization, Biological product-standards, vaccine standards); (iii) WHO Good Laboratory Practices (GLP); (iv) WHO Guideline on Biosafety; (v) ISO 14644 (clean rooms and associated controlled environments); (vi) ISO 9001 (quality assurance system); (vii) ISO14001 (environmental management system); and (viii) OHSAS 18001 (occupational health and safety). To ensure compliance with the international and national standards, Bio Farma will provide measures of its quality risk management, validation of master plan, master formulation, protocols on sanitation, cleaning and fumigation, and environmental and safety management measures.

197. During the operational phase, wastes from the production consists of the following:

a) Air emission from the production and from operation of the incinerator, boiler, and generator sets;
b) Production wastewater;
c) Domestic wastewater;
d) Solid and hazardous wastes.

198. Other anticipated impacts of the production of vaccines are related to occupational risks and product safety. Discussed in the succeeding sections are the impacts of vaccine production and mitigation measures to address these adverse impacts.

199. **Air emission.** The vaccine production process may generate volatile organic compounds, acid gases and particulates from the mixing, formulation, fermentation and filling processes and in the operation of reactor vents, vessels, centrifuges, and filtering systems. Fermentation processes may also cause odor nuisance.

200. Bio Farma facilities will be provided with the following for control of point and emissions:

a. Exhaust ventilation hoods;
b. Venting of emissions from sterilization chambers into control devices such as catalytic converters or carbon adsorption;
c. Installation of dedicated filtration systems;
d. Installation of high efficiency particulate air (HEPA) filters in the heating, ventilating and air conditioning (HVAC) systems to control particulate matter emissions internally and externally as well as to prevent indoor cross-contamination. Air ducts will be segregated to prevent air cross-contamination from different processes and to ease the air stream treatment;
e. Use of closed-loop liquid and gas collection equipment for cleaning of reactors and other equipment.

201. Another source of air emission is the operation of the incinerator for the disposal of disinfected wastes from autoclave, material and product rejects, and other hazardous wastes. Polluting emissions may include carbon dioxide (CO_2), CO, NOx, sulfur dioxide (SO_2), particulate matter, ammonia, amines, acids (HCL, HF), VOCs, dioxins/furans, polyaromatic hydrocarbons (PAHs), etc. Based on the plan of the new facility, the incinerator will be designed and built with temperature and oxygen control system and exit gas quenching at combustion chambers to ensure compliance with national emission standards.

202. During start-up and shut-down, auxiliary burners are to be provided to maintain required operational combustion temperatures at all times when unburned wastes is in the combustion chamber. Emissions from the incinerator will be monitored on quarterly basis to ensure that it is operated and maintained in strict conformity with BF procedure 236K-INCI-M1 on Incinerator Operation and Maintenance.

203. The new facility will also require a boiler and standby generator set which are sources of air emission from fuel combustion. The operation of these equipment may generate CO_2, CO, SO_X, NO_X, and particulate matter. Similar to the current plant operation in Pasteur, stack emissions of the incinerator, boiler and generator set will be monitored and reported to MOEF/DLH.

204. **Generation of ash from incinerator.** The combustion of solid wastes generates ash and other material remaining after incineration. To avoid the generation of excessive amounts of ash, the design of the incinerator furnace will have narrow grate bar spacing with a waste throughput rate that provides sufficient agitation and residence time of waste in the furnace at sufficiently high temperatures. Each incinerator has two combustion chambers, with chamber 1 operating at a temperature of 800^{o}C and chamber 2 at a higher temperature of 1000oC for complete combustion. The operation of each incinerator is automated through a control panel that monitors temperature and other combustion parameters.

205. The design and operation of the incinerator at the new site will be similar to the existing incinerators at the Pasteur site. Generated ash (fly ash and bottom ash) are collected in drums and collected by a MOEF-licensed hazardous waste transporter and treater.

Figure 30: Existing incinerator at Bio Farma Pasteur site

206. **Generation of wastewater.** The operation of the production facilities is expected to generate production wastewater from the washing of equipment and media/solutions used in the bulk vaccine manufacturing process, condensed steam from sterilization, and facility washing. Domestic wastewater is also generated from toilets and canteen. The main conventional pollutants in the production wastewater streams are biochemical oxygen demand (BOD), chemical oxygen demand (COD), total suspended solids (TSS), ammonia, toxicity, biodegradability, and pH.

207. The 3rd wastewater treatment plant (WWTP) currently under construction at Bio Farma's Bandung production site will accommodate the wastewater from Building 43. This 3rd WWTP at Bio Farma will serve the production of vaccines and other support facilities at Building 43 such as packaging, quality control and media production, as well as the adjacent surveillance/clinical testing building, validation and calibration laboratory (No. 3), administration building, Hepatitis B building, laboratory animal support production buildings/SHL, pilot scale building No. 34, marketing building, and other support facilities.

208. The wastewater from production, testing and processing processes containing microorganisms is processed in the tub waste tank by heating at 121°C using steam (killing tank) before it is channeled through closed pipelines to the WWTP. The process of disinfection/heat treatment will remove microorganisms in the wastewater before it goes to subsequent treatment process. Once pre-treated in the killing tank, the wastewater is channeled into the WWTP where it is mixed with the domestic wastewater. The combined wastewater is then further treated in the aeration tank using the activated sludge system to increase decomposition of the wastewater and then into the sedimentation tank to settle impurities and separate foam and particles. The final effluent is disinfected with NaOCl.

209. Bio Farma's current practice of reusing its treated effluent for use as boiler feed water will be sustained to reduce water consumption. This will also reduce the pollution load that will be discharged into the drain leading to Cikapundung River.

210. The new plant site in Indotaisei will also have its own WWTP that is designed similar to the treatment process at Pasteur site. About 40% of the treated effluent will be reused as boiler feed water and the residual effluent from the plant will be channeled into the sewer lines leading the centralized WWTP of Indotaisei (**Figure 31**). This existing centralized WWTP of Indotaisei industrial park applies a biological treatment with cyclic sequential activated sludge (CSAS)

process and has a current capacity of 15,800 m^3/d, with plans for extension to 28,000m^3/d once the current capacity is reached. Currently, the centralized WWTP only receives about 6,000 m^3/day of wastewater, hence, the expected wastewater effluent from the new plant site of Bio Farma can be adequately accommodated by the centralized WWTP.

Figure 31: Wastewater treatment plant in Indotaisei Industrial Park

211. **Hazardous waste.** The sources of hazardous wastes or potentially hazardous wastes include packaging waste, used air filter media, rejects and expired products, laboratory wastes, and sludge from the wastewater treatment process. Bio Farma will implement its standard operating procedure on handling and storage of hazardous waste (236K-LIMB-B3) that includes procedures for segregation, decontamination and disposal of contaminated materials using autoclaves, needle destroyer, incinerator for the final destruction of hazardous wastes.

212. A temporary hazardous waste storage area will be provided at the new site in accordance with MOEF Regulation No. 12/2020 on Hazardous Waste Storage. The hazardous wastes will be treated in a new incinerator. The temporary waste storage facility and the incinerator will be subject to permits by MOEF.

213. All hazardous wastes will be managed in strict compliance with MOEF Regulation 101/2014 regarding the Management of Toxic and Hazardous Substances, MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Medical Service Facilities, and BF procedure 236K-LIMB-B3 on Handling and Storage of Hazardous Waste.

214. **Solid waste.** Non-hazardous solid waste such as food wastes and other similar garbage will be generated by workers and staff. There are also non-biodegradable wastes such as paper, cartons, plastics, and containers. Solid waste segregation bins with labels are to be provided in several areas within the plant premises. Trash containers have 5 different colors, i.e., yellow (cans and glasses), green (organic), red (B3/hazardous waste), orange (plastic and rubber), and gray/black (paper). The non-hazardous wastes will be managed in strict compliance with BF procedure 214K-PS-01 (Handling of Non-B3 Waste). Disposal of non-hazardous solid waste at Building 43 will be integrated with the solid waste management system of Bio Farma while the

non-hazardous solid waste generated at the new site will be disposed through the solid waste disposal facility of Indotaisei industrial park.

215. **Occupational health and safety risks.** The design of the production facilities in Building No. 43 and Indotaisei will ensure that health and safety measures and safety devices are in place to avert risks following the EHS management system under BF Director Regulation No. PER-00013-DIR-III-2020 on Occupational Safety and Health and BF procedure 236K-SIS-EK on Evaluation of Compliance with Environmental and K3 laws and regulations. Proper control measures will be implemented to avoid workers from being exposed to hazards in the workplace. These hazards include exposure to hazardous materials during handling and accidental releases of substances that can cause serious harm to health and safety of workers and the environment.

216. Bio Farma will implement its biosafety procedures and hazardous material management plan. The plan includes an assessment of hazards, process safety, training, incident investigation, contractor training, and supervision.

217. Autoclaves will be provided to decontaminate material from virus culture facilities. In addition, there will be autoclaves for aseptic filling rooms.

D. Indirect, cumulative impacts

218. The project is not anticipated to result in significant adverse induced, indirect or cumulative impacts, with exception of incremental immunization waste generation at the point of vaccine use as a result of increased vaccine production by Bio Farma. This aspect is discussed below.

219. **Immunization waste generation at point of vaccine use.** The scope of waste management required transcends the boundary and premises of Bio Farma and to the agencies that will undertake distribution and use of the vaccines. The distribution and use of new vaccines will result in increased amounts of medical waste at the point of use (i.e. used vials and syringes at local health centers and hospitals). MOH estimates that the implementation of the Road Map for National COVID-19 Immunization will result in a temporary but significant increase in immunization waste generation. With a target population of 160 million people (those aged above 18 years) and each receiving two doses (320 million injections) in a year, immunization waste is expected to increase by 1,400% during the immunization campaign.[91]

220. The road map indicates that currently almost all government healthcare facilities have cooperation with third-party service providers in the management of medical wastes, including immunization waste. The road map instructs that if private healthcare facilities will provide COVID-19 immunization, they shall coordinate with the local government healthcare facilities, the Province and District Health Offices or cooperate with licensed third parties to manage immunization waste, but acknowledges that the availability and capacity in waste management of third party service providers need to be reviewed and potentially increased.

221. A recent review conducted by the World Bank concludes that Indonesia's medical waste management system is diverse in quality, with better services concentrated in Java.[92] According to the latest data from the MOH in December 2019, there are 82 licensed incinerators and three

[91] Ministry of Health. Road Map for National COVID-19 Immunization. Draft reviewed on 7 November 2020.
[92] http://documents1.worldbank.org/curated/en/892831589576862772/pdf/Draft-Environmental-and-Social-Systems-Assessment-ESSA-Indonesia-Emergency-Response-to-COVID19-P173843.pdf

licensed centralized autoclaves across 20 out of 34 provinces, with the treatment capacity of around 73 tons/day (Figure 32). Almost 55% of the incinerators and autoclaves are on the island of Java. Beside licensed incinerators and autoclaves, licensed cement kilns with a capacity of up to 249 tons of hazardous waste per day are available to process medical waste. However, these kilns are located only in seven provinces, again, most of which are situated in Java. The limited number and uneven presence of licensed incinerators and cement kilns in Indonesia indicate areas of attention for the planning of additional facilities or alternatives for medical waste management.

222. Immunization waste management is primarily regulated through standards in MOH Regulation 12/ 2017 on Conduct of Immunization, and MoEF Regulation 56/2015 on the Technical Procedures and Requirements for Management of Hazardous and Toxic Waste Materials from Health Care Facilities. According to these and other relevant national regulations, every medical facility is required to segregate waste at the source, have its own licensed medical waste treatment plants or use of licensed third-party waste management company.[93]

223. MOEF and MOH have worked together for several years to improve the management of medical waste, including the availability of medical waste treatment, through a series of short- to long-term strategic actions: (i) developing a 10-year roadmap of medical waste management (para 223); (ii) short-term solution to treat the cumulation of medical wastes by allowing the processing of waste in non-licensed facility-level waste incinerators or processing it through cement kilns (paragraph 227); (iii) developing an electronic instrument to monitor medical waste collection from source to treatment and disposal site (paragraph 245); (iv) training and capacity building to regional offices and health facilities (paragraph 225); and (v) construction of region-based medical waste treatment facilities (e.g. autoclaves and incinerators, see paragraph 231).

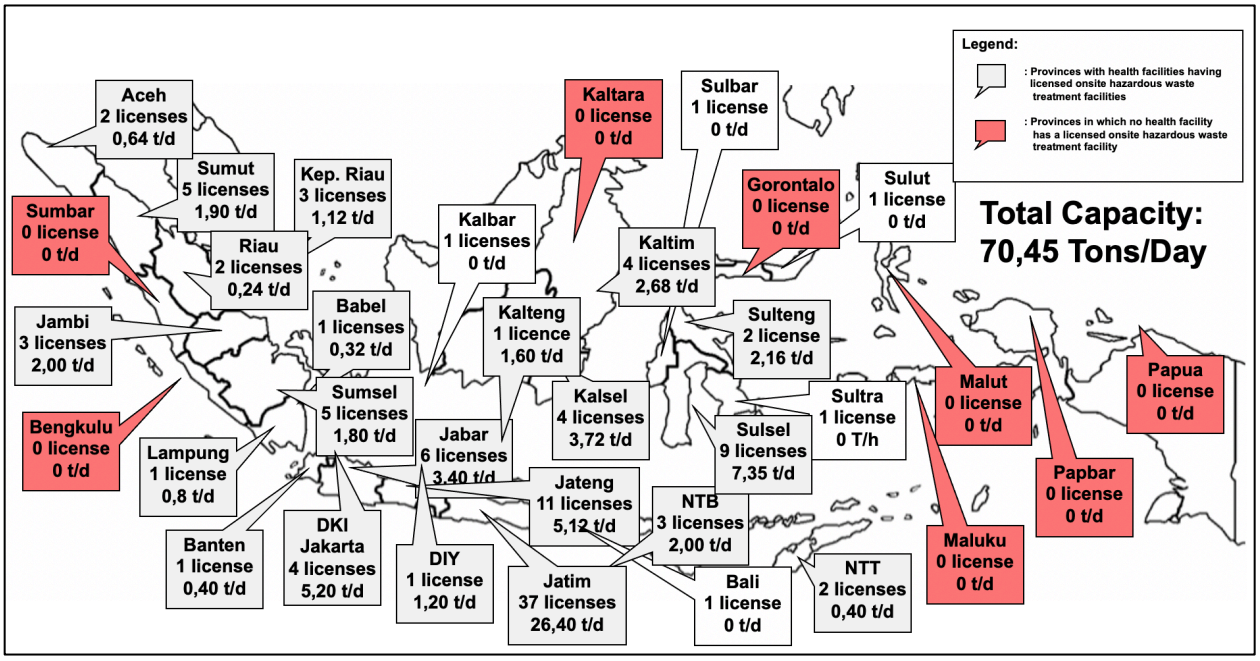
224. **Road Map 2019-2028 on the Management of Hazardous and Toxic Waste from Health Service Facilities.** The Government of Indonesia has issued a road map up to Year 2028 to improve the capacity and system to manage hazardous healthcare wastes. The road map takes cognizance of the needs of hospitals and clinics throughout the country on proper medical waste disposal and the current capacity and availability of medical waste treatment facilities. The road map outlines the short-term, medium-term, and long-term strategies that the Government will implement to prevent medical waste disposal directly into the environment and also to ensure that the operation of hazardous waste treatment facilities meet the standards or are operating with valid permits. Through special allocated budget from the national government, budget support for local government / provinces through the regional health agency will be provided for the infrastructure development such as temporary hazardous waste storage, freezer, autoclave, incinerator and other similar types of healthcare waste treatment technologies. Local government can enter into cost-sharing agreement or collaborate with enterprises to operate the facilities. A technical implementing unit which includes representatives from MOH and the MOEF will oversee the implementation of the road map.

225. The road map is designed to provide all 34 provinces with at least one treatment facility up to Year 2028. In this way, healthcare waste treatment becomes accessible and there will be reduced cost for transporting wastes. In 2020, the MOH has established five facilities out of the 34 target treatment facilities. These are located in Aceh, West Sumatra, South Kalimantan, West Nusa Tenggara, and East Nusa Tenggara.

[93] Ministry of Health Regulation 7/2019 on hospital environmental health; MOH Decree No. 1204/ 2004 on healthcare waste management.

226. MOH conducts annual trainings and capacity building events on medical waste management for regional centers and health facilities. In response to the COVID-19 pandemic, throughout June-July 2020, MoEF, MOH and WHO hosted a series of webinars to share the current policies and national protocols on medical waste management in healthcare facilities as well as the safe use of incinerators and autoclaves in the context of COVID-19. More than ten thousand participants from all 34 provinces across Indonesia have participated in the webinar series.[94]

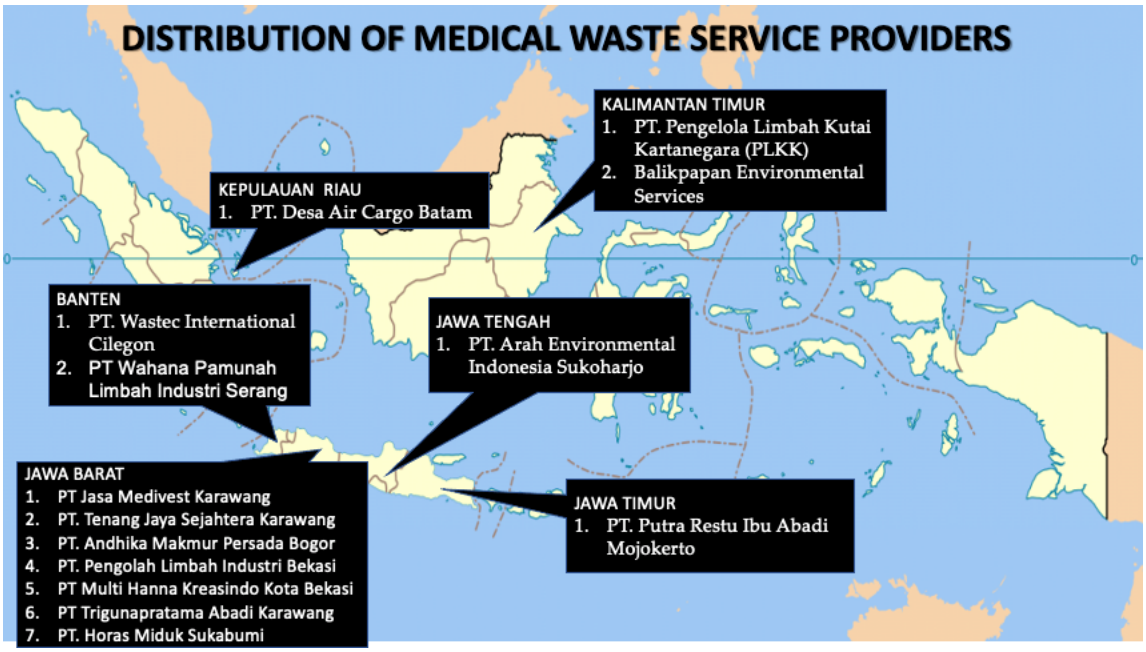
227. During the webinar series, some challenges in waste management were highlighted by the MOH and MOEF and discussed by the participants, including the availability and use of waste treatment amenities in healthcare facilities. While some hospitals have an incinerator to dispose of the medical waste generated, many do not have the necessary license to operate it. Of a total 2,889 hospitals, 130 hospitals have licensed incinerators on their premises (with a total treatment capacity of 70 tons per day, Figure 32). Hospitals that do not have their own incinerators contract private healthcare waste management providers. As of November 2020, the country had 140 licensed companies for medical waste transport, and 16 licensed companies for centralized medical waste treatment (located in 7 provinces, with a total treatment capacity of 731 tons per day, Figure 33 and 34).



Source: MOEF presentation on "Policy of Hazardous Waste Management from Health Service Facilities; Decree 56/2015" dated 31 June 2020.

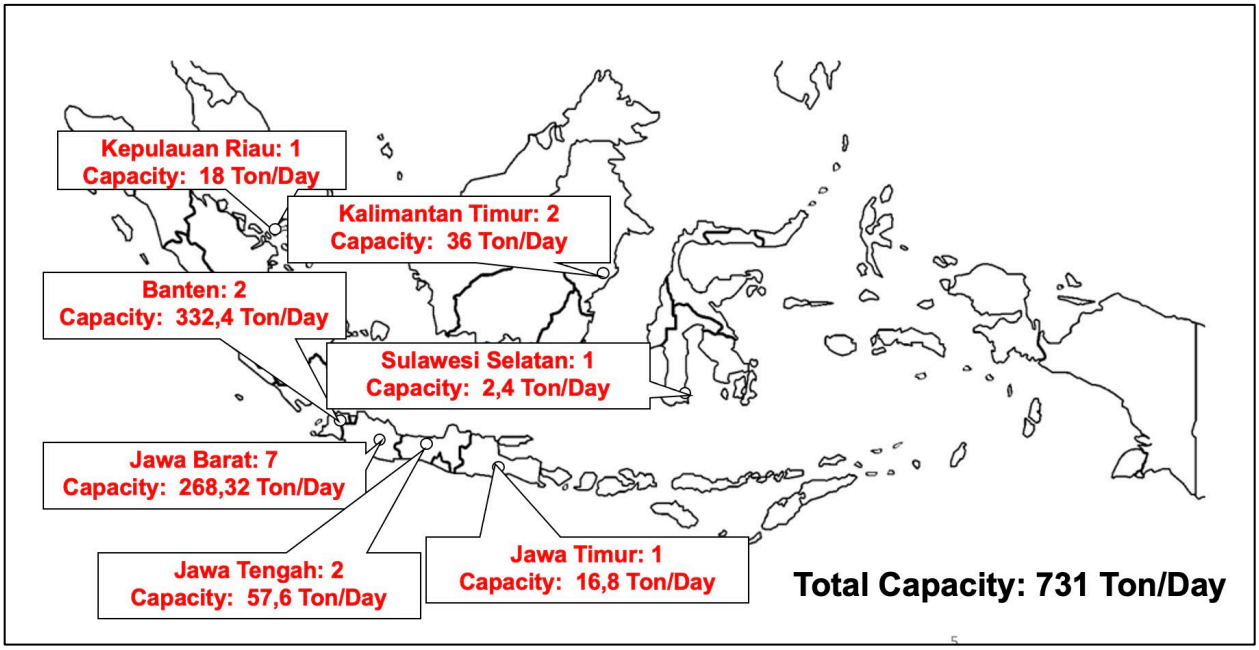
Figure 32: National distribution of licensed onsite incinerators at health facilities

[94] https://www.who.int/indonesia/news/detail/21-07-2020-safe-waste-management-during-covid-19-response



Source: Presentation of the Environmental Health Directorate, MoH on "Medical Waste Management Policy During Covid-19 Pandemic), dated 31 June 2020

Figure 33: Distribution of licensed medical waste treatment facilities (privately operated)



Source: MOEF presentation on "Policy of Hazardous Waste Management from Health Service Facilities; Decree 56/2015" dated 31 June 2020.

Figure 34: Treatment capacity and distribution of centralized licensed hazardous waste treatment facilities

228. To address this concern and further strengthen the national COVID-19 response, the MoEF released a circular note 2/2020 specific to the management of infectious waste from

healthcare facilities.[95] Through this letter, MOEF advises healthcare facilities, which treat COVID-19 patients and people who may have COVID-19, to do onsite treatment for its infectious waste using installed, but not yet licensed incinerators or autoclaves before handing over the waste to a licensed hazardous waste management company. This implies that such hospitals, with or without valid hazardous waste treatment license/permit[96], can treat their infectious waste onsite during COVID-19 pandemic, provided such facilities comply with national emission control requirements and that treated waste is handed over to licensed disposal site afterwards. Requirements on the management of air emissions from the medical incinerator are outlined in MOEF regulation No. 56/2019, in which the regulation set the technical specifications of the incinerator and the allowed emissions threshold. MOEF's directive does not apply to facilities without existing treatment facilities, but to those that have systems in place during the finalization stage of the permit attainment process. This means that 115 additional incinerators can be used for treating medical waste during COVID19 pandemic. Onsite treatment for COVID-19 infectious waste is also recommended by WHO.[97] Among others, the WHO recognizes that small-scale incineration can be a transitional response to an immediate requirement, but that the burning of PVC plastics and other chlorinated waste should be avoided to prevent the generation of dioxins and furans.

229. Upon further consultations with MOEF, MOH received a verbal recommendation that allows the burial of COVID-19 infectious waste, provided that these wastes have been previously disinfected, the burial site meets the requirement prescribed in relevant regulation and coordination with the local environmental agency is conducted. The practice for the onsite burial of infectious wastes during an emergency is in line with MOEF regulation No. 56/2015 and also listed as one of the alternatives from WHO to manage healthcare wastes during emergencies.[98] Based on MOEF Regulation No. 56/2015, there are several required criteria for the location of the onsite burial, i.e., it should: (i) be safe from flooding risk, (ii) have a minimum of 20 meters distance to the nearest well or residential area, (iii) be equipped with fences and warning sign. The regulation also outlines the technical requirements on the burial cell, such as (i) the depth should be more than 1.8 meters, (ii) the bottom layer of the cell should be coated with clay with minimum 20 cm in thickness, among others.

230. MOH (through the Directorate General of Public Health, Directorate of Environmental Health), issued in April 2020 a guidance document (MOH Decree HK.01.07/MENKES/537/2020) on waste management for hospitals and local health facilities that handle COVID-19 patients. The decree specifies medical waste management requirements in health facilities. Among others, the guidance recommends local storage of medical waste in refrigerated and sealed containers when direct waste treatment is not possible, and provides technical guidance on local burial of pathological and sharp waste after initial disinfection and destruction.

231. Subsequently, MOH issued MOH Regulation 18/2020 About Region-Based Medical Waste Management from Health Facilities, which aims at addressing identified gaps and disparities in medical waste management services. The implementation of the road map is

[95] Notice Letter No. SE.2/MENLHK/PSLB3/PLB.3/3/2020 on infectious (hazardous) and domestic waste management from COVID-19 response, dated March 24, 2020

[96] Under normal circumstances, Government Regulation No. 101/2014 and MOEF Regulation No. 56/2015 require all incinerators and autoclaves that are used to treat medical waste to obtain treatment permit/license from MOEF.

[97] WHO Interim Guidance on water, sanitation, hygiene and waste management for the COVID-19 virus, dated March 19, 2020.

[98] WHO guideline on safe management of wastes from healthcare activities, Chapter 14 – healthcare waste management in emergencies.

supported by the issuance of the MOH Regulation No. 18/2020 on the Region-Based Medical Waste Management. The new regulation outlines the guidelines to carry out the establishment of the region-based medical waste management systems, roles/responsibilities of central government, regional government, and healthcare facilities, requirements for recording and reporting, guidance and supervision by the district/provincial/city health offices and MOH, and the monitoring and evaluation instruments.

232. As part of the MOEF National Program for Incinerators 2020-2024, the MoEF is in the process of installing region-based healthcare waste incineration facilities. A total of 32 incinerators are planned to be operational by 2024. The first one was established in Makassar in 2019 (capacity: 2.4 tons per day). MOH advised in December 2020 that five incinerators are currently being installed (Aceh, East Nusa Tenggara, West Nusa Tenggara, South Kalimantan and West Sumatra) and are expected to be operational in Q1 2021. This program will be continued until 2024, targeting a total of 32 locations of healthcare waste treatment facilities throughout the country as part of the national priority program to accelerate medical waste management to increase medical waste treatment capacity, prevent illegal dumping, and ensure immediate treatment of waste due to outbreak of COVID-19.[99] MoEF also recommended that healthcare facilities, under the oversight of Province and District Health Offices, should coordinate with industries, such as the cement industry, to manage the disposal of their healthcare waste.

233. In January 2021, MOH issued the Ministry of Health Decree HK.02.02/4/1/2021 about Technical Guidelines for the Implementation of Vaccinations in the Management of Corona Virus 2019 (COVID-19) Pandemic. The decree defines requirements for the collection, temporary storage, treatment and/or disposal, and documentation of immunization waste at health service facilities during implementation of the national COVID-19 vaccination program.

234. MOH, in collaboration with and support of WHO and UNDP, is in the process of procuring and installing four autoclaves and four incinerators to reduce the accumulation of medical waste from COVID-19 healthcare activities. These will be installed in regions where current waste treatment capacities are low, including Maluku, Riau Islands, South Sulawesi, South and West Sumatra, and Bali. WHO and UNDP regional offices in Jakarta advised in December 2020 that the following facilities were being installed, and will be operational by Q1 2021:

Incinerators:
- BBTKL Ambon - Maluku Province
- BBTKL Batam - Riau Island Province
- BBTKL Makassar - South Sulawesi Province
- M. Hoesin Hospital in Palembang- South Sumatra

Autoclaves:
- Sardjito Hospital - DI Yogyakarta;
- M. Djamil Hospital Padang - West Sumatra
- Sanglah Hospital Denpasar - Bali
- Soeradji Hospital Klaten - Central Java

[99] National Priority Program: B3 Waste Treatment Health Service Facilities. National Program 2020-2024.al MOEF Presentation on Hazardous Waste Management Policy from Health Service Facilities. June 30, 2020.

VI. INFORMATION DISCLOSURE, CONSULTATION, AND PARTICIPATION

A. Introduction

235. The Safeguard Policy Statement 2009 (SPS) requires project proponents to (i) carry out meaningful consultation that begins early and carried out throughout the project cycle, and (ii) provide timely disclosure of relevant information that potentially affected people can understand and can be easily accessed. Moreover, SPS also requires that consultations be free from coercion, be gender inclusive and caters to the needs of disadvantaged and vulnerable people, and that all relevant views of affected people are considered.

236. Prior to and during preparation of this IEE, a series of information disclosure and consultation meetings were conducted. The consultations were conducted to present the proposed project to key agencies and elicit the environmental concerns/issues on the proposed project. Information about environmental clearance requirements was also gathered. Information disclosure and consultation activities are presented in the next sections.

B. Information disclosure

237. Bio Farma has been active in disclosing information related to COVID-19 vaccine import, trials and production. Bio Farma's intention to important bulk COVID-19 vaccine and expand production capacities for COVID-19 vaccine in its new facility in Building 43 of the Pasteur site was disclosed and disseminated to the public through printed and e-media as early as August 2020. Bio Farma also disclosed its intention to expand production capacities by establishing new vaccine production facilities in the Indotaisei industrial park through e-media. Examples include:

- Article in Republika.co.id dated 6 August 2020 (https://republika.co.id/berita/qen8wz380/bio-farma-investasi-rp-13-triliun-tambah-kapasitas-produksi)
- Article in CNBC Indonesia dated 28 September 2020 (https://www.cnbcindonesia.com/tech/20200928124813-37-189951/diam-diam-tim-sinovac-ke-pabrik-bio-farma-bandung-ada-apa)
- Article in detikfinance dated 4 August 2020 (https://finance.detik.com/industri/d-5120296/ri-produksi-vaksin-corona-pabrik-bio-farma-mau-ditambah)
- Article in Tribunternate.com dated 28 September 2020 (https://ternate.tribunnews.com/2020/09/28/pemerintah-klaim-uji-klinis-vaksin-covid-19-dari-sinovac-berjalan-lancar-dan-hasilnya-baik)
- Article in Kontan.co.id dated 10 December 2019 (https://industri.kontan.co.id/news/bio-farma-bakal-bangun-pabrik-vaksin-baru)

238. Bio Farma also regularly updates its website (http://www.biofarma.co.id/id/) and facebook page (https://www.facebook.com/biofarmaID) to provide information on its ongoing clinical trials, and its intensions and progress towards the in-house production of the COVID-19 vaccine in Bandung.

239. **Future information disclosure.** During project implementation, Bio Farma will ensure that planned construction activities are disclosed to the public through information signboards at the Bandung and Indotaisei production sites. The signboards will include contact information of the PMU and the relevant contractor(s). Furthermore, Bio Farma will disclose the semi-annual

environment monitoring reports on the project website. Project activities will also be disclosed through Bio Farma's annual reports, which will be disclosed on their company website.

C. Consultation

240. In view of the corona virus disease (COVID 19) pandemic in Indonesia and the rest of the World, resulting in travel and physical meeting restrictions to and within Indonesia, consultation meetings were held online. The IEE authors met a series of key project stakeholders (**Table 15**). Such meetings primarily aimed at understanding the project scope, clarifying Bio Farma's existing environment, health and safety policies, procedures and arrangements; seeking views of relevant health and environment protection agencies.

241. A meeting was held on 19 November 2020 with the environment protection authorities (DLHK) of Bandung City, including the Head of the AMDAL Division and the Head of the Waste Management Division. DLH confirmed that Bio Farma had conducted all the necessary environmental assessments and secured all the necessary permits for existing facilities and production lines, and that Bio Farma's EHS performance was fully satisfactory, as demonstrated in their Gold and Green PROPER rating in the past 6-7 years. DLH Bandung further advised that the environmental audit requested by DLH Bandung City in 2018 also confirmed Bio Farma's full compliance with regulatory requirements. With regard to the proposed new vaccine production lines in Building 43, DLH advised that these were not yet covered in the environment license and that Bio Farma should seek clarification and confirmation from DLH Bandung on due diligence requirements as per Government Decree 27/2012 once the scope is confirmed.

242. A meeting was also held with health and environment protection authorities of Kerawang District on 25 November 2020 to clarify the status and capacity of infectious waste management at this time of COVID-19 pandemic and to identify whether there are programs in place or proposed to manage the increase in volume of medical wastes. Also discussed during the meeting were the environmental requirements for the proposed new facility of Bio Farma at Indotaisei industrial park and the environmental performance of the industrial park..

243. DLH Kerawang District confirmed that the Indotaisei industrial park fully complies with environmental safeguards requirements; that the park has secured approval of the AMDAL and the necessary permits to establish and operate the industrial park, and that it was fully compliant with environment monitoring and reporting requirements as per the approved RKL/RPL (monitoring plan). The DLH advised that the Indotaisei industrial park had applied for participation in the national PROPER program of MOEF in 2020. The DLH further confirmed that the facility to be established by Bio Farma in Indotaisei industrial park would be subject to UKL/UPL, to be approved by the DLH Kerawang District, provided that the AMDAL of Indotaisei industrial park already includes pharmaceutical facilities. If the Indotaisei AMDAL did not mention pharmaceutical facilities, then Indotaisei is required to submit an addendum of its AMDAL.

244. The Kerawang district health authorities confirmed that medical waste transport, temporary storage and treatment capacities in Kerawang District were currently sufficient to cope with increased COVID-19 waste, with several licensed companies operating medical waste incinerators in the district. However, the health authorities identified budget constraints at small health facilities (puskemas) to avail of private medical waste service providers as possible bottleneck in ensuring full compliance with regulatory requirements for infectious waste management. From the period March to September 2020, the hospitals in Kerawang generated about 18 tons while the small clinics generated about 738 kg. All healthcare facilities follow the

DLH guidelines on hazardous waste management. However, the small clinics (puskemas) are having difficulty to cope due to the increase in expenses for treatment of infectious wastes. The health office suggested to increase the budget from the local government for the puskesmas so these small clinics may be able to properly manage the increase in volume infectious wastes.

245. The Dr. Hasan Sadikin hospital administration was consulted prior to construction of Building 43, and during preparation of this IEE (19 November 2020). Concerns raised at the time related to potential restricted access for ambulances and other vehicles to the hospital during machinery and equipment delivery. Bio Farma advised that all heavy equipment and machinery was delivered on Saturdays and Sundays to minimize traffic disturbance. Such an approach will also be applied for delivery of equipment for the vaccine production and the packaging line in Building 43.

246. A meeting was held on 10 December 2020 with UNDP Indonesia to discuss UNDP's support for medical waste management during the COVID-19 pandemic. UNDP confirmed that new equipment for waste treatment facilities, including 4 medical waste incinerators and 4 autoclaves, were ready for installation and that these would likely be operational in Q1 2021 (see paragraph 233 above). UNDP also advised that the SMILE project implemented by MOH with support of UNDP[100], which enables real-time visibility of vaccine cold chain logistics by digitizing stock supplies and storage temperature across vaccine cold chain points, is in the process of being expanded to track COVID-19 vaccine distribution from provincial health centers to point of use. In addition, UNDP is providing technical assistance to MOH to develop an e-monitoring system for medical waste. The system will allow the tracking of waste streams from the point of generation to the point of treatment, where the system will link to MOEF's waste monitoring system. UNDP's system will allow the tracking of healthcare waste types, quantities, and flows. UNDP advised that the system would first be piloted in Jakarta, and if successful would be scaled up to national level.

247. A meeting was held on 15 December 2020 with MOH and MOEF to discuss plans, programs and strategies of the Government from the point of view of the central government regarding the improvement of capacities to manage medical waste in view of the increase in hazardous healthcare wastes with the COVID-19 pandemic. Representatives from the Directorate of Performance Assessment of Hazardous and Non-Hazardous Waste Management of MOEF and from the Directorate of Environmental Health of MOH. Information was shared regarding the road map of the establishment of region-based healthcare waste management and treatment infrastructures in all regions/provinces throughout Indonesia from 2019-2028 and the recently issued MOH regulation no. 18/2020 to support the implementation of the road map. Information was also shared about future plans to improve the healthcare waste tracking system of MOH through an electronic monitoring (E-monitoring) that is linked to the existing electronic waste tracking system (SILACAK) of the MOEF.

Table 15: Offices and agencies consulted during project and IEE preparation

Office	Name, Designation	Matters discussed (of relevance to IEE)
Bio Farma – Management	Suharta Wijaya, Director of Finance and Corporate Business	Project scope, project financing plan, procurement plan, capacity building.

[100] https://www.id.undp.org/content/indonesia/en/home/operations/projects/democratic_governance/the-access-and-delivery-partnership1.html

Office	Name, Designation	Matters discussed (of relevance to IEE)
	Iin Susanti, Head of Division, Strategic Planning Agus Sularno, Head of Sub-Division, Project Management Budi Sulistyadi, Head of Division, Treasury	SPS safeguards requirements, institutional arrangements for safeguards implementation. Virtual site visits of Bandung and Indotaisei sites through drones. Existing pollution control systems and their performance
Bio Farma - Quality Assurance and Legal	Poppy Patricia, Manager, Quality Assurance Widya Artiana, Head of Section, Legal	Vaccine registration process Vaccine import procedures WHO and PIC/S GMP guidelines, BPOM certification procedures
Bio Farma Safety and Environment Unit	Zaki Zakaria Ash Sholih Zain, Safety and Environment Unit	BF environment, health and safety (EHS) organization structure BF EHS supervision and monitoring procedures, risk register and management BF's grievance redress procedure Pollution control – infrastructure, equipment and monitoring arrangements Institutional arrangements for EMP implementation during project implementation Domestic environmental safeguards requirements, status of compliance
DLH Kerawang District	Agus Mustaqin, Head of Environmental Administration Application Section Wendy Firmansyah, Head of Environmental Impact Assessment Section	Indotaisei industrial park's compliance with Government decree 27/2017 in terms of environment assessments and permits; environment performance Environment due diligence and permit requirements for Bio Farma's proposed vaccine production facility in Indotaisei Hazardous waste treatment capacities in Kerawang District
DOH Kerawang District	Dwi Teguh Wibisono, Head of the Environmental Health Section	Medical waste management in Kerawang District – current practices, capacities and bottlenecks at health care facilities and private service providers (collection, treatment)
MOH	Nadia Wiweko, Director for Vector Communicable Diseases	Vaccines rollout policies (knowledge work)
MOEF	Aristin Apriani, Head of Section for Service, Performance Assessment of Hazardous and Non-Hazardous Waste Management Directorate Randi Aditia Wiguna, Verification of Hazardous and	Policy context, MOEF strategy, plans and past and future activities with regard to health care waste management in Indonesia

Office	Name, Designation	Matters discussed (of relevance to IEE)
	Non-Hazardous Waste Management Directorate	
MOH	Lora Agustina, Head of Section for Waste Handling, Environmental Health Directorate Adhy Prasetyo Widodo, Environmental Health Directorate	Policy context, MOH strategy, plans and past and future activities with regard to health care waste management in Indonesia
BPOM	Lucia Rizka Andalucia, Director Registration	Vaccines regulatory issues including registration processes and audits of Bio Farma
UNDP Indonesia	Fiqhi Rizky Zahib R Dengo, National Project Manager Arry Lesmana Putra, Project Manager for Health Governance Initiative Cluster	COVID-19 waste management at health facilities UNDP medical waste management program with MOH, including SMILE vaccine tracking system and medical waste e-monitoring and tracking system (under development) Status of installation of additional autoclaves and incinerators in health facilities
WHO Indonesia	Dr. Paranietharan, WHO Representative in Indonesia Inga Williams, Planning officer, Indonesia office Indah Deviyanti, Environment Health Specialist, Indonesia office	Vaccines landscape in Indonesia COVAX and vaccine readiness assessment tool Medical waste management, including policies and initiatives of MOH and MOEF
Dr. Hasan Sadikin Central General Hospital	Maudy Dirgahayu Hussein, Head of Environmental Health Facilities	There are no concerns related to Building 43 construction. Possible concerns related to building 43 construction, equipment installation, waste management; Current hospital waste management practices adhere to the requirements of MOEF on segregation of infectious waste. Each container of healthcare wastes from various sources/departments at the hospital is properly labelled and then disposed through a licensed waste transporter and treater.

248. **Future consultation.** No residential area is anticipated to be directly affected by the project interventions in Bio Farma's sites in Bandung and Indotaisei. Pre-construction consultations (primarily through information sharing) shall be conducted to inform relevant authorities and nearest communities about planned construction works and schedule, and the grievance redress mechanism (GRM, see Section VII).

249. In addition, people who may in the future be adversely affected by the project may submit complaints to ADB's Accountability Mechanism. The Accountability Mechanism provides an independent forum and process whereby people adversely affected by ADB-assisted projects can

voice, and seek a resolution of their problems, as well as report alleged violations of ADB's operational policies and procedures. Before submitting a complaint to the Accountability Mechanism, affected people should make an effort in good faith to solve their problems by working with the concerned ADB operations department. Only after doing that, and if they are still dissatisfied, should they approach the Accountability Mechanism.[101]

[101] Accountability Mechanism. http://www.adb.org/Accountability-Mechanism/default.asp.

VII. GRIEVANCE REDRESS MECHANISM

250. ADB's SPS requires the borrower to establish a grievance redress mechanism (GRM) to receive and facilitate the resolution of safeguards-related issues and concerns affecting the project. PT. Bio Farma has established a standard procedure for complaints handling called Handling of Public Complaints related to Environment and Safety Aspects (236K-PKM-K3L, Penanganan Keluhan Masyarakat terkait Aspek Lingkungan & K3). The guidelines refers to the following documents: Standard ISO 14001 (2015 clause 6.1), ISO 45001 standard (2018 clause 5.4), SOP 236K-SIS-IAP (Identification of hazard and impact / risk aspects), SOP 100K-SIS-19 (handling change), SOP 100K -SIS-20 (handling deviation and investigations).

251. This procedure is used as a reference for complaint handling from the community regarding Environmental and Occupational Health and Safety (OHS), which is a social control in the context of realizing the concept of "green industry" and a form of community involvement and supervision that needs to be handled/managed effectively and efficiently, and can be accounted for.

252. This procedure applies to handling complaints that occur as a result of an activity or process at Bio Farma which potentially can cause an adverse impact on the environment as well as irregularities in the implementation of OHS requirements. The complaint handling process includes receiving, reviewing, distributing, confirming, clarifying or investigating, examining, delivering response, reporting, follow-up and record.

253. **Authority and Responsibilities.** Recipients of complaints from external parties are responsible to inform the Safety and Environment Unit by filling the complaint form (Appendix 3), while complaints from internal parties regarding work activities can be informed to the Head of Division and/or the Health and Safety Advisory Committee (P2K3 team) to be assigned in identifying important aspects. If the complaint has the potential to disrupt security, such as resulting in violent conflicts, threats, riots etc. in the company area, then the receiving unit must immediately coordinate with the Security Section. The head of the relevant division is responsible for coordinating complaints in his/her division. If a follow-up is needed, this is communicated to the Safety and Environment Unit.

254. The Head of Safety and Environment Unit or the Command Centre is responsible for coordinating the follow-up of complaints received and filling out the Complaint Handling Form. The Head of Corporate Communication together with the Head of Safety and Environment Unit is responsible for providing an explanation of follow-up on complaints. The Head of the Environmental and Social Management Division is overall responsible for the handling complaints.

255. The steps to be followed in filing complaints and the procedures for redress during construction phase are the following:

256. Internal Complaint Handling

(i) Workers/employees can submit suggestions/complaints related to OHS and environmental management system to the head of their division or the P2K3 team either verbally or in writing.
(ii) Complaints from workers/employees related to the OHS risks and hazards and the environment in production and working areas are carried out in the relevant Section/Unit

and filled in the identification document for important aspects according to the 236-SIS-IAP standard procedure.

(iii) If the complaint is a suggestion for improvement of the OHS and environmental management system, it can be submitted to the P2K3 team and/or the Safety and Environment Unit.

(iv) Complaints that require further adjustments in existing procedures are followed up in accordance with established Change Handling Procedures.

(v) Complaints received by the Safety and Environment Unit and/or the P2K3 team are recorded and documented.

257. Handling external complaints

(i) Public complaints can be submitted directly orally (face to face or telephone) or in writing (letter, fax, electronic media and printed media) – contact information is provided through the facebook page and Bio Farma website.

(ii) Community complaints received by the Safety and Environment Unit and/or the P2K3 team are recorded and documented.

(iii) Complaints submitted orally are recorded in the complaint form (Appendix 3).

(iv) Such recording should at least contain information on the date it was received, identity of the complainant, and the main / topic of the complaint.

(v) Complaints in writing with clear identities, will be responded in writing no later than 10 (ten) working days after being received.

(vi) Complaints that have been recorded will be reviewed in order to identify problems, clarify information, and follow-up steps.

(vii) If it is a suggestion / idea for improvement - go to point (ix)a.

(viii) The reviews are carried out as follows:

a. Examine the documents and/or information received
b. Formulate the core of the complaint and the root of the problem (with reference to the 100K-SIS-20 document)
c. Linking the content of the complaint with the relevant regulations/procedures
d. Complete the required data/information
e. Determine whether it has an element of increase and/ or deviation
f. Determine the results of the review and subsequent handling.

(ix) The results of the review:

a. Complaints that advocate for improvements of the OHS and environmental management system will be discussed in the Quality Health & Safety and Environment (QHSE) meeting and/or safety committee meeting so that they can be followed up in accordance with applicable procedures through Change Handling Procedures.
b. Complaints that indicate irregularities with logical and adequate substance and supported by evidence are immediately followed up with corrective actions and preventive actions. If necessary, perform an audit with a specific purpose/ investigative audit.
c. Complaints whose substance is inadequate and do not indicate irregularities with a clear identity of the reporter, will be clarified.
d. Follow-up complaints in the form of answering questions, providing information and clarification carried out by the Corporate Communication Department if needed accompanied by the Environmental and Safety Unit.

(viii) Follow-up is considered complete if there is no more response within 10 (ten) working days after the last response.

(ix) Monitoring of follow-up complaints can be done directly through monitoring in the work unit, coordination meetings and others.
(x) Follow-up monitoring is grouped into status in process, completed status accompanied by evidence.

258. **Reporting.** Public complaint handling reports and other documents are properly archived in accordance with the applicable filing procedures. Follow-up reports on community complaints are discussed at Safety Committee Meetings and OHSE Meetings.

VIII. ENVIRONMENTAL MANAGEMENT PLAN

A. Environmental Management and Mitigation

259. This Environmental Management Plan describes the environmental management measures that will be carried out to mitigate identified negative impacts or enhance the environment during implementation, and the environmental monitoring to be conducted to ensure that mitigation is provided and is effective in reducing impacts, or to determine the actual impacts of a project activity. The EMP outlines specific mitigation measures, environmental monitoring requirements, and related institutional arrangements for implementation. Where impacts and risks cannot be avoided or prevented, mitigation measures and actions will be identified so that the project activity is designed, constructed, and operated in compliance with applicable laws and regulations of Indonesia and meets the requirements specified in this document and the ADB SPS (2009). All applicable Government of Indonesia environmental permits/ approvals/ concurrences and ADB clearances must be obtained prior to contract award and commencement of civil works.

260. During the construction phase, the works contactor will be responsible for implementation of the contract-specific EMP, to be developed based on this EMP, under supervision of Bio Farma. Bio Farma will be responsible for implementation of any pre-contract award and/or pre-construction measures in the EMP, and measures related to project operation.

261. In the event of any design changes or unanticipated impacts, the IEE or EMP will have to be updated as per ADB SPS (2009) requirements.

262. Table 16 presents the project environment management and mitigation plan.

Table 16: Environmental Management Plan

Potential impacts and issues	Nature of impacts/Issues	Environmental Action /Prevention Measures	Location	Responsibility	Source of Fund
Design and pre-construction phase					
Facility design	Failure to comply with BPOM and WHO requirements for facility design	- Ensure compliance with relevant design standards for pharmaceutical production facilities based on the GMP requirements of WHO, PIC/S and BPOM.	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Environmental compliance	Failure to comply with the EIA requirements of MOEF P.38/2019	- Coordinate with DLH to present proposed modifications at Building 43 and secure the environmental clearance from provincial environmental authority (DLH)	Pasteur site	Bio Farma	Bio Farma
		- Prepare the UKL-UPL and secure the environmental clearance from DLH	Indotaisei site	Bio Farma	Bio Farma
Permits	Failure to secure necessary permits and clearances prior to construction	- Secure the necessary approvals and construction permit from the Indotaisei industrial park and from local government prior to start of construction works	Indotaisei site	Bio Farma	Bio Farma
Construction phase					
Environmental and social Issues	Complaints and concerns from community	- Establish and disseminate effective GRM - Share contractor contact details with local authority leaders - Disclose such information at construction site	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
EHS capacity of contractor	Inadequate EHS management capacity of contractor	- Assign qualified EHS staff at the construction site to supervise and monitor EHS aspects of construction works and report to Bio Farma PMU/PIU	Pasteur site and Indotaisei site	Works contractor	Works contractor
Monitoring and Reporting	Failure to comply with BPOM and WHO requirements Failure to adequately implement the EHS measures	- Submit monthly progress reports/status of construction and EHS to Bio Farma PMU/PIU	Pasteur site and Indotaisei site	Works contractor	Works contractor
Erosion impacts	Facility construction may require earthworks which	- Ensure that erosion control includes:	Indotaisei site	Works contractor	Works contractor

	will leave surfaces liable to erosion, especially in heavy rain periods. This could lead to runoff of mud and silt into canals and cause clogging of canals and sedimentation of receiving surface water.	- provision of silt traps or sediment control devices - materials such as cement, sand and gravel are to covered with tarpaulin and provided with bunds - limiting construction and material handling during periods of rains and high winds; - stabilizing all cut slopes, embankments and other erosion-prone working areas while works are going on; - stabilizing all earthwork disturbance areas within 30 days after completion of earthworks. - cement mixer washing will be prohibited at the site to prevent clogging of drains.			
Generation of domestic wastewater	Indiscriminate disposal of domestic wastewater/sewage by workers can lead to unsanitary conditions at the site	- Require contractor to provide temporary toilet facilities for workers at the working area/floor level of Building 43 - conduct daily cleaning of the toilet facilities and maintain sanitation in the work area.	Pasteur site	Bio Farma Works contractor	Works contractor
		- Provide temporary toilets with septic tanks for use of workers at the construction camp	Indotaisei site	Works contractor	Works contractor
Water and soil pollution	Leakage of spills of fuel and lubricants that may contaminate soil, surface water and groundwater	- Prevent pollution of soil, surface water/ groundwater by ensuring the following: - soil surfaces where chemicals are stored shall be made impermeable and provided with bunds. Bunds should be sized to hold 110% of the maximum capacity of the largest tank or drum; - Vehicles/ heavy equipment maintenance and re-fuelling area shall prevent spillage of fuel, oil and hazardous materials to seep into soil; - oil traps shall be provided in the maintenance and service areas; and - fuel refilling areas must be located > 50 m from water sources and	Pasteur site and Indotaisei site	Works contractor	Works contractor

			protected by temporary bunds to contain spills. A spill clean-up kit must be present on site.			
Air quality	Concentration of machinery working in one area plus haulage vehicle traffic may result in local areas of poor air quality	-	Maintain equipment to a high standard to ensure efficient running and fuel-burning; Provide high-horsepower equipment with tail gas purifiers - Ensure that all vehicle emissions comply with relevant emission standards	Pasteur site and Indotaisei site	Works contractor	Works contractor
Dust	Earthmoving and construction haulage traffic can cause poor air quality and nuisance to nearby communities	-	Equip material stockpiles and concrete mixing equipment with dust shrouds - Conduct regular water spraying on construction sites, construction roads, and stockpiled material - Deployment of workers assigned to clean the work area particularly driving surfaces and gutters as standard site management practice - Cover with tarpaulin sheets vehicles carrying soil, sand, or other fine materials to and from the construction sites - Limit speed of vehicles delivering equipment materials to the site, e.g. not exceeding 20 km/hour when entering the premises or passing through unpaved roads and populated areas	Pasteur site and Indotaisei site	Works contractor	Works contractor
Noise impacts on sensitive receptor	Noise caused by the concentration of machinery working in one area, plus haulage vehicles, can cause a range of impacts from nuisance to health problems.	-	Strictly prohibit construction after 10pm - During construction, ensure installation of temporary anti-noise barriers to shield sensitive receptors	Indotaisei site	Works contractor	Works contractor
Water Quality	Pollution of local water courses through sediment	-	Construct site drainage to ensure that any rainfall will be diverted to a holding pond, or suitable land to prevent localised flooding and sedimentation of surface water	Pasteur site and Indotaisei site	Works contractor	Works contractor
Construction waste and spoil	Unauthorized or careless storage and disposal of	-	Segregate recoverable/recyclable materials which could be used in other	Pasteur site and Indotaisei site	Works contractor	Works contractor

	waste can damage property and block natural drainage.	projects of the contractor or sold to recyclers. - Store construction waste securely in containers to prevent uncontrolled disposal - Ensure that final disposal site of waste and spoil will be in a site approved by the local authorities			
Hazardous waste	Oil and grease, solvents, empty paint containers and other similar hazardous wastes will be generated which can contaminate soil, surface water and groundwater.	- Provide temporary hazardous waste storage area within the construction site, separate from regular garbage - Commission the services of MOEF-licensed third-party hazardous waste treatment and disposal facility to collect the hazardous waste	Pasteur site and Indotaisei site	Works contractor	Works contractor
Waste from workers	The construction workforce will generate domestic garbage (food wastes, paper, and other solid waste including food-laden wash water) which causes impacts if poorly disposed	- Provide sufficient waste bins with cover for biodegradable wastes at strategic locations and ensure that they are: - protected from birds and vermin; - emptied regularly to prevent overflow; and - disposed of in local disposal site as approved by local authorities	Pasteur site and Indotaisei site	Works contractor	Works contractor
Occupational health and safety	Workers are subject to safety hazards while operating and/or moving around machinery, as well as dust and noise impacts from extended exposures at the work site.	- Ensure that all reasonable steps are taken to protect any person on the site from health and safety risks - Use of barricade/fence to cover the construction area - Strict requirement on wearing of personal protective equipment (PPE) in order to minimize or eliminate work-related accidents. - Provision sanitary facilities for workers and regular cleaning of these facilities - Posting of safety signages in strategic locations within the construction site - Use of only certified and tested machineries and equipment - Provision of adequate training or instruction for occupational health and safety - Adequate supervision of safe work systems	Pasteur site and Indotaisei site	Works contractor	Works contractor

		- Ensure that means of access to and exit from the site are without risk to health and safety - Ensure that a first aid kit is available at the construction site at all times and that all staff members are responsible for first aid and aware of local health care facilities - Promptly report any incident or accident to Bio Farma and relevant local authorities			
		- Implement a systematic program of works that will avoid disruption of operations of other areas at Building 43 - Only authorized workers with proper identification will be allowed to enter the premises of Building 43.	Pasteur site	Works contractor	Works contractor
Core labor standards (CLS)	Works contractor does not adhere to CLS	- Contractor to ensure adherence to CLS. The following activities are strictly prohibited: - employment of workers under the age of 16; persons between age 16-18 can only work in non-hazardous environment - discrimination regarding recruitment, wages and compensation	Pasteur site and Indotaisei site	Works contractor	Works contractor
COVID-19	Inadequate risk management protocols expose workers, Bio Farma staff and nearby communities to COVID-19 risk.	- Contractor to formulate (as part of the EHS plan) and maintain COVID-19 risk management protocol in accordance with relevant INO regulations and guidelines, and international good practice guidelines as issued by WHO.	Pasteur site and Indotaisei site	Works contractor	Works contractor
Community health and safety	Construction work poses safety hazards and threats to nearby residents and passers-by, including staff, patients and guests of adjacent hospital. Excavations, loss of access and movements of large machinery and vehicles	- Ensure that community health and safety will be safeguarded by: - planning construction activities to minimize disturbances to residents, passers-by, and utilities; - reinstating land to its original condition after construction; and - implementing safety measures around the construction sites to protect Bio Farma staff, visitors, the general	Pasteur site and Indotaisei site	Works contractor	Works contractor

	all potentially impact on existing utilities, community safety and day-to-day operation of existing/adjacent hospitals.	public, including warning signs to alert the public to potential safety hazards, barriers to prevent public access to construction sites, and a watch person, where necessary.			
Road safety (through movement of vehicle and equipment for construction)	Increased motorized vehicle movement including heavy goods vehicles to and from the site during construction may increase road safety risks for residents and passers-by.	- Ensure that drivers of all vehicles strictly follow road rules and maintain good road safety standards - Properly supervise deliveries of construction materials to the site by heavy good vehicles using banksmen/traffic marshals	Pasteur site and Indotaisei site	Works contractor	Works contractor
Human health and environmental pollution – Site Hand Over	Hazardous waste materials, unprotected latrines and organic waste remaining after construction will pose a risk to human health and safety.	- Remove all unused or discarded construction materials from the site before hand-over - Landscape surroundings to reinstate original site conditions - Remove all temporary dwellings, cook houses, and latrines upon completion of the construction; clean the site.	Pasteur site and Indotaisei site	Works contractor	Works contractor
Construction completion	Facility does not conform to approved plans and specifications; Improper site clean-up and restoration	- Secure a Fire Safety Inspection Certificate from the city/municipal Fire Marshal - Secure an occupancy permit from the local government - Contractor will submit a completion report together with as-built drawings to Bio Farma during turn-over - Ensure proper restoration of disturbed areas and clean-up of site	Pasteur site and Indotaisei site	Works contractor	Works contractor
Operation Phase					
Vaccine production	Vaccine production lines do not conform to cGMP requirements of BPOM and WHO	- Prior to operation, secure validation and qualification of facilities, utilities, equipment and production process for new production lines before commercial production - Secure NRA approval of vaccine prior to circulation in the market. - During operation, Bio Farma to conduct internal audits and BPOM and WHO to conduct external audits of production facilities.	Pasteur site and Indotaisei site	Bio Farma, BPOM, WHO	Bio Farma

EHS performance during facility operation	Bio Farma to maintain EHS system and diligently implement internal EHS procedures	- Maintain and renew accreditations for ISO 9001:2015 (on quality management and quality assurance), ISO 14001:2015 (on environmental management system), OHSAS 18001:2007 (on occupational health and safety), ISO/IEC 17025:2016 (on requirements for the competence of testing and calibration laboratories). - Bio Farma Safety and Environment Unit to supervise, monitor and report on the implementation of Bio Farma's EHS management system in accordance with BF Director Regulation Number PER-00013-DIR-III-2020 on Occupational Safety and Health, and BF procedure 236K-SIS-EK on Evaluation of Compliance with Environmental & K3 Laws and Regulations. - Occupational Health and Safety Guidance Committee Team (P2K3) to conduct regular internal safety audits of facilities and production lines in accordance with BF procedure 236K-SIS-EK on Evaluation of Compliance with Environmental & EHS Laws and Regulations and BF procedure 236K-SP-01 on Safety Patrol - Maintain and update as needed a work hazards, impacts and safety analysis in accordance with BF procedure 236K-SIS-IAP on Identification of Hazards & Impacts or Risks and BF procedure 236K-SIS-JSA on Work Safety Analysis. - Maintain emergency preparedness and response mechanism in accordance with BF procedure 236K-KTD-01 on Emergency Preparedness and Response.	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Air emission from production process	The production process may generate VOCs, acid gases and particulates	- Provide exhaust ventilation hoods - venting of emissions from sterilization chambers into control devices such as	Pasteur site and Indotaisei site	Bio Farma	Bio Farma

	from mixing, formulation, fermentation and filling processes.		catalytic converters or carbon adsorption - installation of dedicated filtration system - installation of high efficiency particulate air (HEPA) filters in the heating, ventilating and air conditioning (HVAC) systems to control particulate matter emissions internally and externally to prevent air cross-contamination from different processes and to ease air stream treatment - use of closed-loop liquid and gas collection equipment for cleaning of reactors and other equipment,			
Air emissions from incinerator	Hazardous waste incinerator does not comply with relevant emission standard	-	Operate, maintain and monitor performance of waste incinerator in strict conformity with BF procedure 236K-INCI-M1 Incinerator Operation and Maintenance. - Monitor hazardous waste incinerators in accordance with BF procedure 236K-INCI-M1 Incinerator Operation and Maintenance; ensure compliance with stack emission standard as defined in MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Medical Service Facilities.	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Air emission from boiler and generator	Air emission from fuel combustion may generate CO2, CO, NOx, SOx and particulate matter.	-	conduct regular maintenance on the equipment - monitor stack emissions and submit report to DLH	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Generation of ash from incinerator	Fly ash and bottom ash from operation of incinerator may contaminate land and groundwater	-	Collect fly ash and bottom ash in separate container at the B3 waste storage area - Dispose ash through MOEF-licensed 3rd party hazardous waste transporter and treater	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Production wastewater from	Production wastewater contains pollutants such	-	Operate, maintain and monitor performance of wastewater treatment	Pasteur site and Indotaisei site	Bio Farma	Bio Farma

washing of equipment and media solutions, condensed steam from sterilization, and facility washing	BOD, COD, TSS, ammonia, toxicity, biodegradability and pH which could cause pollution of receiving surface water; Microorganisms may be present in the wastewater which can cause health and safety risks to the community.	facilities in strict conformity with BF procedure 236K-LIMB-01 on Operation of Wastewater Treatment Systems and BF procedure 214K-PLD-01 on Domestic Wastewater Treatment. - Provide disinfection/heat treatment as pre-treatment of production wastewater before it is channelled into the wastewater treatment plant. - reuse the treated effluent as boiler feed water to reduce water consumption as well as reduce pollution load into the receiving water body.			
Hazardous waste	Hazardous solid waste such as packaging waste, used air filter media, rejects and expired products, laboratory wastes, and sludge from the wastewater treatment plant will be generated and may cause contamination of land, surface and ground water and cause health and safety risks to the community.	- Manage hazardous waste in strict compliance with MOEF Regulation No. 12/2020 on Hazardous Waste Storage; MOEF Regulation 101/2014 Regarding the Management of Toxic and Hazardous Substances; MOEF Decree No. 56/2015 on Procedures and Technical Requirement of Hazardous Waste Management from Medical Service Facilities, and BF procedure 236K-LIMB-B3, Handling and Storage of Hazardous Waste. - Monitor hazardous waste storage facilities in accordance with BF procedure 236K-LIMB-B3, Handling and Storage of Hazardous Waste.	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Solid waste (non-hazardous)	Non-hazardous solid waste such as food wastes, paper, cartons, plastics, containers and other similar garbage may result to unsanitary condition at the site.	- Manage non-hazardous waste in strict compliance with BF procedure 214K-PS-01, Handling of Non-B3 Waste	Pasteur site and Indotaisei site	Bio Farma	Bio Farma
Occupational health and safety risks	Workers may be exposed to hazards and biosafety risks from handling and accidental releases of substances.	- Implement biosafety procedures and hazardous material management plan. - assess hazards in the workplace and institute process safety measures	Pasteur site and Indotaisei site	Bio Farma	Bio Farma

		- Provide autoclaves to decontaminate material from virus culture facilities and for aseptic filling rooms. - Conduct training of workers including contractors on health and safety - Implement an incident investigation procedure in accordance with 236K-SIS-IAP and 236K-SIS-JSA.			

B. Institutional Arrangements and Responsibilities

263. **Executing and Implementing Agency.** Bio Farma will serve as the executing agency for the proposed project. To ensure smooth implementation, Bio Farma will appoint the Operations Directorate[102] as the project management unit (PMU) which will be responsible for overall project management, including project supervision, monitoring, accounting, and consolidated reporting, and the project management division[103] as the project implementing unit (PIU) which will be responsible for the implementation of all project components. Both PMU and PIU will be staffed with sufficient personnel to support different aspects of the project, including social and environmental safeguards, gender, procurement, financial management and technical issues. Bio Farma's Safety and Environment Unit will support the PMU and PIU in supervising compliance with the EMP during project implementation. The PMU and PIU will be responsible for environmental safeguards, including:

- ensuring meaningful public consultation and ensuring that information disclosure requirements are met;
- securing necessary permits, licenses and approvals prior to facility construction and vaccine production and distribution;
- supervision of, monitoring of, and reporting on the implementation of environmental management plan;
- developing corrective action plans, as needed, and ensuring that corrective actions are undertaken; and
- establishment and operation of grievance redress mechanism (GRM);

264. The extent of **monitoring activities by the PMU and PIU** will be commensurate with the project activities' risks and impacts. Project activities will be checked through monthly site visits by the PMU/PIU, or more frequently in case there are problems with EMP implementation. The PMU/PIU is required to ensure the implementation of safeguard measures and relevant safeguard plans, as provided in the legal agreement, and to submit periodic monitoring reports on their implementation performance. The PMU/PIU will:

- monitor the progress of implementation of EMP and verify the compliance with environmental measures and standards and progress toward intended outcomes;
- document monitoring results through preparation of semiannual monitoring reports, and identify necessary corrective and preventive actions in the periodic monitoring reports;
- follow up on these actions to ensure progress toward the desired outcomes;
- submit semi-annual monitoring reports on safeguard measures as required by local environmental protection agency (DHL) and ADB.

265. **Consultant support (consultants).** Bio Farma will recruit a project management and supervision consultant (PMSC) that will support the PMU/PIU in implementing the EMP, ensure financial management, and oversee construction supervision. The PMSC will, on behalf of Bio Farma and the PMU/PIU: (i) prepare the required environmental documents (DELH, UKL/UPL, RKL/RPL) and coordinate with the local environment authorities (DLH, see below) in securing approval of project activities; (ii) undertake day-to-day implementation supervision activities; and

[102] Directorate/department responsible to manage and oversee the whole activities in Bio Farma.
[103] The division is under the coordination of the Operations Directorate.

(iii) prepare semi-annual environmental safeguards monitoring reports for all project activities. The consultants' role will also include training of Bio Farma on implementation, monitoring and reporting of the EMP, and briefing contractors on EMP requirements and ensuring compliance with EHS requirements as defined in the IFC EHS Guidelines. The TOR of the PMSC are described in detail in the project administration manual (PAM), which is disclosed on the project website at www.adb.org.

266. **The provincial environmental protection agency (DLH)** is the relevant authority to ensure that all project activities comply with the national legal and regulatory framework for environmental safeguards. The DLH has the responsibility for screening and categorizing project activities in accordance with Indonesia's Law No. 32/2009 on Environmental Protection and Management and Minister of Environment and Forestry (MOEF) Regulation P.38/2019 on Types of Activities requiring Environmental Impact Assessment, the approval of UKL/UPL or RKL/RPL including issuance of environmental permits, and the supervision of compliance with approved plans and issued permits during project activity implementation.

267. **Badan Pengawas Obat & Makanan** (BPOM, the National Agency of Drug and Food Control of Indonesia), through the BPOM Technical Implementation Unit, will conduct the evaluation of the new production facilities to determine the general conditions of the goods and their surroundings and evaluate the manufacturing process as part of product registration before any drug is circulated in the market. BPOM will oversee product registration and issue distribution licenses for new vaccines. BPOM will implement laboratory examinations, certification of products, production and distribution facilities.

268. The **Asian Development Bank** (ADB) is responsible to ensure that the RECOVER project and all its activities comply with ADB's Safeguard Policy Statement. ADB will monitor and supervise overall RECOVER project implementation and oversee compliance with all SPS requirements. Specifically, ADB will:

- conduct site visits for project activities with unanticipated adverse environmental or social impacts;
- conduct supervision missions with detailed review by ADB's safeguard specialists/officers or consultants;
- review the semiannual monitoring reports submitted by Bio Farma to ensure that adverse impacts and risks are mitigated as planned and that necessary corrective actions have been identified are being implemented and being monitored;
- work with Bio Farma to rectify to the extent possible any failures to comply with their safeguard commitments, as covenanted in the legal agreements, and exercise remedies to reestablish compliance as appropriate; and
- prepare a project completion report that assess whether the objective and desired outcomes of the IEE/EMP have been achieved and all project activities supported under the project comply with ADB's SPS.

269. **Works contractor(s).** To address potential impacts and risks to environment, health and safety of workers and communities, the works contractor must:

- appoint a qualified environment, health, and safety specialist to supervise construction works in compliance with the IEE and the Indonesia regulatory and policy framework for environment, health and safety;

- execute works and all associated operations on the work sites or off-site in conformity with statutory and regulatory environmental requirements of the Government of Indonesia and the ADB SPS 2009;
- take all measures and precautions to avoid any nuisance or disturbance arising from the execution of construction works and their related activities. This will, wherever possible, be achieved by suppression of the nuisance (or unwanted effects to the physical environment and people) at source rather than abatement of the nuisance once generated;
- compensate for any damage, loss, spoilage, or disturbance of the properties and health of affected people during execution of the construction works as specified in the bidding documents;
- keep the construction site clear of stagnant water, food residuals, or any other waste or material that can attract pests and disease-carrying vectors like mosquitoes and rodents;
- recruit local skilled and unskilled labor to increase the direct benefits in the subproject area(s) and to minimize potential environmental issues related to construction camps, disease transmission and socio-cultural disputes;
- ensure that the International Labor Organization (ILO) Core Labor Standards and the applicable laws and regulations of Indonesia are applied to the contractor's workers (including workers employed by sub-contractors), including laws related to their employment, health, safety, and welfare during the construction of the isolation facilities. More specifically, each contractor shall: (a) comply with the Borrower's applicable labor law and regulations and incorporate applicable workplace occupational safety norms; (b) do not use child labor; (c) do not discriminate workers in respect of employment and occupation; (d) do not use forced labor; and (e) allow freedom of association and effectively recognize the right to collective bargaining;
- establish a simple system to receive, register, and address community concerns and complaints. Contact number of the contactor including name, position and telephone number will be shared with local authorities and Bio Farma; and
- demonstrate how the impacts associated with the construction works are complied with. For that purpose, conduct weekly monitoring of compliance with EHS requirements, and include section in the monthly report to the Bio Farma.

C. Monitoring and Reporting

270. **Supervision, monitoring.** The PMU/PIU (with the support of the PMSC) is responsible for supervision and monitoring of the contractors' implementation of the EMP. To ensure that potential environmental problems are detected and addressed promptly and appropriately, supervision and monitoring will take place during implementation. The PIU and consultants will conduct periodic (at least monthly for all construction sites) supervision and environmental compliance monitoring of project activity activities.

271. Bio Farma shall notify in writing to the relevant DLH and ADB any breaches of its obligations or other performance failures or violations of the environmental permit and the EMP as soon as reasonably possible and in any event, in respect of any breach which would have a serious impact or where the urgent attention of the DLH and ADB is or may be required, within not later than twenty-four (24) hours, and in all other cases within 7 days of Bio Farma or the PMU/PIU becoming aware of such incident.

272. **Table 17** presents the environmental monitoring plan of the project.

273. **Reporting.** The works contractor will be required to prepare and submit monthly reports and submit these to the PMU/PIU. Such reports will also include reporting on the contractor's environment management and supervision activities, in accordance with the monitoring plan in **Table 17**. Bio Farma's PMU/PIU (with support of the consultants) will prepare semi-annual environmental monitoring reports that covers all project activities classifying as category B, and submit these to ADB. The first report will be submitted the first January or July after start of construction. Reporting shall continue until a project completion report (PCR) is issued. The semi-annual environmental monitoring reports shall include:

- documentation of compliance with all conditions;
- progress made to date on implementation of the EMP against the submitted implementation schedule;
- difficulties encountered in implementing the EMP and recommendations for remedying those difficulties and steps proposed to prevent or avoid similar future difficulties;
- number and type of non-compliance with the EMP and proposed remedial measures and timelines for completion of remediation;
- accidents or incidents relating to the occupational and community health and safety, and the environment;
- number and type of grievances/complaints received, and status of their resolution; and
- monitoring data of environmental parameters and conditions as committed in the EMP or otherwise required.

274. **Appendix 1** provides an annotated outline for monitoring reports. The environmental safeguard monitoring reports will be disclosed on ADB's website.

Table 17: Environmental Monitoring Plan

Impacts and Issues	Monitoring Activities & Parameters	Means of Monitoring	Location	Responsibility for Implementation & Source of Fund	Responsibility for Supervision
Design and pre-construction phase					
Compliance of facility design with BPOM and WHO requirements	• Design conforms to Guidelines on GMP of BPOM, PIC/S and WHO • Import Certificate (SKI) secured for imported vaccines by bulk • CPOB Certificate (GMP) secured	• Import Certificate (SKI) • CPOB Certificate (GMP)	Pasteur site and Indotaisei site	PIU	PMU
Environmental compliance	• Presentation of proposed modifications at Building 43 to DLH and environmental permit approved by DLH	• Environmental permit	Pasteur site	PIU, PMSC	PMU
	• UKL/UPL and environmental permit approved by DLH	• UKL/UPL • Environmental permit	Indotaisei site	PIU, PMSC	PMU
Construction Phase					
EHS capacity of contractor	• Training on EHS of contractors	• EHS training conducted	Pasteur site and Indotaisei site	PMSC	PIU/PMU
Monitoring and reporting	• Submission of monthly progress reports	• Monthly contractors monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Water pollution, soil runoff, domestic wastewater	• Implementation of water pollution control measures	• Through observation; include status in monthly monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Air emission and dust	• Implementation of dust control, emission reduction measures	• Through observation; include status in monthly monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
	• Quarterly ambient air quality sampling (total particulate matter) at two stations at the site	• Testing thru 3rd party laboratory using high volume sampler; compare with standards (Government Regulation 41/199, Max TPM 230 ug/m^3)	Indotaisei site	PMSC	PIU/PMU

Noise	• Semi-annual noise monitoring at 4 stations (Pasteur site) and 2 stations (Indotaisei site)	• Sound level measurement; compare results with Noise quality standard (MenLH 48/11/1996- max 70dBA for commercial and industrial areas)	Pasteur site and Indotaisei site	PMSC	PIU/PMU
Construction waste and spoils; biodegradable wastes	• Volume and type of construction waste and spoils generated • Disposal method	• Through estimate & observation; include status in monthly monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Hazardous waste	• Quantity of hazardous waste (oils, solvents, empty paint/chemical containers) generated • Disposal method	• Through estimate & observation; include status in monthly monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Occupational health and safety; core labor standards	• Accidents and incidents (workers) • COVID-19 cases • Number of workers hired and ages • Workers grievances (if any) and actions undertaken to resolve complaint	• Incident/ Accident report; include in monthly monitoring report	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Community health and safety	• GRM disclosure • Community complaints (if any) and actions undertaken to resolve complaint	• Documentation of GRM disclosure activities and complaints received (if any)	Pasteur site and Indotaisei site	PIU, PMSC	PMU
Site handover and construction completion	• Satisfactory clearing and rehabilitation of disturbed areas • Safety Inspection	• Through observation • Fire Safety Inspection Certificate • Occupancy Permit	Pasteur site and Indotaisei site	Works contractor	PIU/PMU with support from PMSC
Operation Phase					
Compliance to CGMP requirements of BPOM and WHO	• Internal audit • BPOM and WHO audit/inspection	• Validation and qualification of facilities, utilities, equipment and process • NRA approval	Pasteur site and Indotaisei site	Internal audit by Bio Farma External audit by BPOM and WHO	Risk Management and Compliance Division
EHS performance	• Implementation of EHS management system (PER-00013-DIR-III-2020) and BF procedure 236K-SIS-EK • Identification of hazards or risks register (BF procedure 236K-	• Internal audit reports • External audit reports • Hazards and risks register	Pasteur site and Indotaisei site	All Departments	Environment and Social Management Division

	SIS-JSA) on work safety analysis • Implementation of emergency prepared and response mechanism (BF procedure 236K-KTF-01) • Accreditation for ISO 9001:2015, ISO 14001:2015, and ISO/IEC 17025:2016				
	• Constitution of the Occupational Health and Safety Guidance Committee Team (P2K3)	• P2K3 committee organized	Indotaisei site	Different department representatives	Environment and Social Management Division
Air emissions	• Quarterly stack emission from incinerator (CO, total particulate matter, SOx, NOx) • Semi-annual stack emission from boiler and generator sets (CO, total particulate matter, SOx, NOx) • Semi-annual ambient air quality (TPM) at 2 stations with site for the following parameters: o TSP – 24 hours o CO – 1 hour o NO_2 – 1 hour o SO_2 – 1 hour	• Testing through 3rd party laboratory; compare with standards (Government Regulation41/1999) • Reports submitted to MOEF and DLH	Pasteur site and Indotaisei site	Environment and Social Management Division	Human Capital and Compliance SEVP
Noise	• Semi-annual noise monitoring at 2 stations within each project site	• Sound level measurement; compare results with Noise quality standard (MenLH 48/11/1996- max 70dBA for commercial and industrial areas)	Pasteur site and Indotaisei site	Environment and Social Management Division	Human Capital and Compliance SEVP
Ash generation	• Volume of ash generated and transferred to B3 area • TCLP test, LC50, LD50 test	• Measurement • Laboratory analysis	Pasteur site and Indotaisei site	Environment and Social Management Division	Human Capital and Compliance SEVP
Wastewater	• Monthly WWTP effluent monitoring (COD, BOD, TSS) • Securing of wastewater discharge permit in accordance with Permen LH No. 1/2010	• Observation of WWTP performance • Sampling/laboratory analysis and reports submitted to MOEF and DLH	WWTP at Pasteur site and Indotaisei site	Environment and Social Management Division	Human Capital and Compliance SEVP

		• Wastewater discharge permit			
Hazardous waste	• Amount of B3 waste generated • Amount of B3 waste treated onsite • Amount of B3 waste hauled and treated by 3rd party licensed transporter and treater • B3 waste management license	• B3 waste manifests/records • Reports submitted to MOEF and DLH • B3 waste management license	Pasteur site and Indotaisei site	Environment and Social Management Division	Human Capital and Compliance SEVP
Solid waste (non-hazardous)	• Quantity of solid waste (non-hazardous)	• Measurement and observation of compliance with BF 214K-PS-01	Pasteur site and Indotaisei site	General Affairs Unit	Environment and Social Management Division
Occupational health and safety	• Implementation of biosafety procedures, material handling and spill prevention measures for biological waste	• Observation and reporting	Pasteur site and Indotaisei site	Bio Safety Officers and Biosafety Committee	Risk Management and Compliance Division

IX. CONCLUSION AND RECOMMENDATION

275. The project will have positive social benefits because of improvements to public health from increased availability of vaccines and the chance for populations to be immunized. The project will help the country to meet MOH's vaccination implementation strategy targets. Vulnerable groups such as health care workers and elderly will be prioritized for vaccination.

276. Any adverse environmental impacts from construction and/or refurbishment of the facilities for outputs 2a and 2b are confined within the premises of Bio Farma. No major works will be required at the Pasteur site and activities will be primarily limited to modifications on the use of the building floor, installation of equipment, and additional manpower. Impacts are anticipated to be localized, short-term and reversible.

277. At the new site in Indotaisei industrial park, construction works for the buildings and utilities of the new plant are similarly localized and confined within the property. Any construction-related impacts can be mitigated through implementation of mitigation measures to control air pollution and dust emissions, water pollution from soil runoff, wastewater from domestic sewage and accidental spills, proper management of wastes, and adherence to ILO core labor standards to ensure health and safety of workers.

278. During operation of vaccine production and packaging lines, Bio Farma will ensure compliance with the GMP guidelines of WHO, PIC/S and BPOM. Bio Farma has a comprehensive pharmaceutical quality control and quality assurance system that will be adopted for the new production lines and facilities.

279. Adverse impacts and wastes generated during production will be handled through the implementation of procedures and compliance to standards related to handling and disposal of hazardous and non-hazardous wastes, pollution control, and water and energy conservation measures.

280. The new facilities in Bandung and Indotaisei will apply the existing integrated systems of Bio Farma in order to fulfill the requirements of ISO 9001:2015 on quality management and quality assurance, ISO 14001:2015 on environmental management system, OHSAS 18001:2007 on occupational health and safety, ISO/IEC 17025:2016 on requirements for the competence of testing and calibration laboratories, ISO 26000 guidance for Corporate Social Responsibility (CSR), ISO 31000 Enterprise Risk Management, and International Finance Report Standard (IFRS).

281. Any incremental waste generation at point of vaccine use (used vials and syringes at local health centers and hospitals) will comply with national regulations on segregation of waste at source, provision of medical waste treatment facilities or use of licensed third-party waste management company in accordance with MOH Decree 04/2021 and MOEF Regulation 56/2015. MOH and MOEF are fully committed to addressing regional disparities in immunization waste management capacities.

282. The results of the environmental assessment confirm that the RCC of the project classifies as category C, while the PIC of the project falls under Category B based on ADB SPS (2009). This IEE outlines the environmental management, monitoring and reporting requirements and the

institutional responsibilities for the implementation of mitigation and management measures. The IEE will be uploaded at the ADB website in accordance with the Access to Information Policy (2018) of ADB.

283. Should there be any changes in the project components, scope and location during detailed engineering design, the environmental impacts resulting from the proposed modifications will be assessed to check if these changes will result to environmental impacts that would merit the updating of the IEE and the EMP.

APPENDIX 1: ENVIRONMENTAL MONITORING REPORT OUTLINE

I. Introduction

A. Report Purpose and Rationale

B. Project Objective and Components

II. Project Implementation Progress

Using most recent project progress report, describe status of project implementation, including full list of contracts, status of contract implementation, name of contractors, availability of site-EMPs.

III. Institutional Setup and Responsibilities for EMP Implementation and Supervision

A. Institutional responsibilities for environmental management

Describe institutional arrangements and responsibilities for EMP implementation, monitoring, and reporting, defining roles and capacities of Bio Farma, the PMU/PIU, the Consultant, and Contractors. (Table format appropriate)

B. Incorporation of Environmental Requirements into Project Contractual Arrangements

Define manner by which EMP requirements are incorporated into contractual arrangements, such as with contractors or other parties.
Indicate when CEMPs were submitted by Contractors, and when these were approved by the PMU/PIU/Consultant (Table format appropriate).

IV. Compliance with environment related project covenants

List all environment related loan covenants, and assess project's compliance with the covenants (Table format is appropriate, with concluding statement on compliance or non-compliance, and corrective actions as needed)

V. Environmental Mitigations Measures Implemented in the reporting period

Summarize main mitigation/protection measures implemented in the reporting period (narrative section). Structure in accordance to phases (detailed design, construction preparation, construction, and operation). Include EMP table or updated EMP table if applicable. Assess compliance of environmental management activities with the original or updated EMP.

VI. Environmental Monitoring

A. Monitoring plan and responsibilities

Present the monitoring plan as defined in the EMP or adjusted monitoring plan. Describe monitoring responsibilities.

B. Environmental quality targets, sampling and analytical methods

Describe environmental quality targets for the different sites and environmental media (e.g. effluent quality standards, ambient air, noise, water quality standards etc). Define analytical methods applied for monitoring.

C. Monitoring Results

1. Emission Discharge (Source) Monitoring Results (if relevant)

a. Results

Table format is appropriate. Discharge levels should be compared to the relevant discharge standards and/or performance indicators noted in the EMP. Any non-compliance should be highlighted for attention and follow-up.

b. Assessment

Discharge levels should be compared to baseline conditions (if baseline data is available) and described in qualitative terms. Additional explanatory comments should be provided as necessary. Possible reasons for non-compliance should be identified.

2. Ambient Monitoring Program

a. Results

Table format is appropriate. Ambient environmental conditions should be compared to the relevant ambient standards and/or performance indicators noted in the EMP. Any non-compliance should be highlighted for attention and follow-up.

b. Assessment

Ambient environmental conditions should be compared to the baseline conditions (if baseline data is available) and described in qualitative terms. Additional explanatory comments should be provided as necessary. Possible reasons for non-compliance should be identified.

VII. Public consultation, grievance redress mechanism

Describe mechanisms established to address and redress public complaints and grievances. Summarize grievances received, if any, and measures implemented to redress them. Describe public consultation activities during the reporting period. Confirm compliance with consultation plan defined in the IEE/EMP, or justify deviation from this plan. Present planned consultation activities in next reporting period.

VIII. Health and Safety

Describe health and safety management arrangements at project and contract level, including safety supervision and reporting procedures, people assigned (table format appropriate), training provided (table format appropriate), full list of fatal and serious occupational accidents including reference to minutes of investigation report meetings (to be attached).

IX. INSTITUTIONAL STRENGTHENING AND TRAINING

Present training activities conducted in the reporting period (Table format appropriate). Compare training activities with approved training plan defined in EMP/PAM, if any. Present planned training and institutional strengthening activities in next reporting period.

X. Key Issues Identified, Actions Taken, Additional Actions Required

Include a concise and clearly articulated table that lists (i) all observed non-compliances with the approved EMP; (ii) corrective actions taken; (iii) implementation responsibility and timeframe.

XI.CONCLUSION

A. Overall Progress of Implementation of Environmental Management Measures
B. Problems Identified and Actions Recommended

XII.APPENDICES

1. Site Inspection / Monitoring Reports
2. Monitoring Results
3. Accidents/Incident investigation meeting minutes
4. Photographs
5. Others

APPENDIX 2: WHO GOOD MANUFACTURING PRACTICE (GMP) AND OTHER GUIDELINES

The following are WHO GMP guidelines relevant to the project:

WHO good manufacturing practices (GMP) for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eighth Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
Short name: WHO TRS No. 986, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/ trs_986/en/

WHO good manufacturing practices (GMP) for biological products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 3
Short name: WHO TRS No. 996, Annex 3
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex03.pdf

WHO good manufacturing practices (GMP) for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
Short name: WHO TRS No. 961, Annex 6
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

WHO Good Manufacturing Practices (GMP): water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-sixth Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
Short name: WHO TRS No. 970, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
Short name: WHO TRS No. 929, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

Supplementary guidelines on good manufacturing practices (GMP): validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
Short name: WHO TRS No. 937, Annex 4
http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1
Short name: WHO TRS No. 961, 957), Annex 1
http://www.who.int/medicines/publications/44threport/en/

WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
Short name: WHO TRS No. 957, Annex 2
http://www.who.int/medicines/publications/44threport/en/

WHO guidelines on transfer of technology in pharmaceutical manufacturing. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
Short name: WHO TRS No. 961, Annex 7
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

WHO model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9
Short name: WHO TRS No. 961, Annex 9
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5
Short name: WHO TRS No. 992, Annex 5
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

WHO general guidelines for the establishment, maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-first Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3
Short name: WHO TRS No. 943, Annex 3
http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2
Short name: WHO TRS No. 961, Annex 2
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2
Short name: WHO TRS No. 981, Annex 2
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

WHO guidelines on variation to a prequalified product. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 3
Short name: WHO TRS No. 981, Annex 3
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

WHO guidelines for drafting a site master file. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 14
Short name: WHO TRS No. 961, Annex 14
http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

WHO General guidance on hold-time studies. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 4
Short name: WHO TRS No. 992, Annex 4

http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

WHO Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fiftieth Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
Short name: WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf

APPENDIX 3: COMPLAINTS ACCEPTANCE FORM

Date :……

Type/category : ……

Recipient's name : ……

Information source : ……

Complainant/reporter name : ……

Address : ……

Phone number : ……

Description of the report/complaint: ……

……

……

……

Bandung, …….

Complainant/reporter, Complaint/report receivers,

_____ _____