E4779

ENVIRONMENTAL MANAGEMENT FRAMEWORK

CROATIA: VENTURE CAPITAL PROJECT

Zagreb, February 2015

ABBREVIATIONS AND ACRONYMS

Bank, IBRD	International Bank for Reconstruction and Development
HAMAG-BICRO	Croatian Agency for SMEs, Innovations and Investments
EU	European Union
PIU	Project Implementation Unit
SB	Sub-borrower
PB	Project Beneficiary
EA	Environmental Assessment
EIA	Environmental Impact Assessment
EMF	Environmental Management Framework
EMP	Environmental Management Plan
FMC	Fund Management Company
MSDS	Material Safety Data Sheet
MEC	Ministry of Entrepreneurship and Crafts
MENP	Ministry of Environmental and Nature Protection
RoC	Republic of Croatia
VCF	Venture Capital Fund

Contents

1 INTRODUCTION

This section of the Project Operation Manual presents the Environmental Management Framework for the Venture Capital (VC) Project that serves as a tool to screen the sub-projects financed based on the screening guides on the environmental due diligence procedures.

All investments and sub-loans to be provided under the VC project should be subjected by Project Beneficiaries (PB) to an environmental review process incorporating the procedures described in this section. The PBs under the VC project are: a) HAMAG-BICRO and b) fund management company (FMC). PBs should use these procedures in reviewing and appraising sub-projects, and to inform sub-Borrowers of environmental requirements for investment/sub-loan appraisal, so that sub-projects can be implemented in an environmentally sound manner. These procedures and requirements incorporate the Republic of Croatia's regulatory requirements for environmental legislation and the World Bank's safeguard policies. As FMC will not be established by the project appraisal, the PIU will make sure that implementation of EMF becomes a standard FMC operation.

This section starts by describing the VC project, its objectives and main components. It then looks at the World Bank Safeguards policies and the relevant national policies. With these limitations in mind, non-eligible economic activities are defined. The section then describes the environmental review process in details. It distinguishes three main steps: Environmental Screening, Environmental Assessment, and Environmental Mitigation where necessary. Necessary forms and check lists are incorporated as annexes.

Once the environmental review process is performed and recommendations incorporated into the sub-project, the respective PB will appraise the proposed investment/sub-loan package which would include, where appropriate, an environmental management plan.

2 PROJECT DESCRIPTION

The Venture Capital Project consists of three components.

Component 1. Pilot Venture Capital Fund (€15.5 million)

The Pilot VC Fund will be structured as an open ended fund in Croatia and under the supervision of HANFA. It must be set-up in accordance with the Alternative Investment Funds Act. It will be a 10-year euro-denominated fund, with an option for a two year extension. The Fund will consist of both public and private financing, in a ratio consistent with EU state aid regulation. It will be established with the purpose of providing financing, in the form of equity or quasi equity instruments, to innovative SMEs with the locus of activity in Croatia. The Fund will be managed by a private fund manager selected through an international tender process. The legal framework for establishing a venture capital fund in Croatia conforms to the EU AIFM standards and is considered to be sound. The Fund Manager must have an EU AIFM passport, meaning that it is either registered in Croatia or licensed by HANFA or that it is registered in another Member State and licensed by the relevant Regulatory Authority. To ensure the commercial viability of the fund, and its uptake by private investors, the Government of Croatia will provide financial contribution towards the Fund's structure (up to €3.5 million of the loan will be used to cover management fees – in effect, lowering the cost to private investors from management fees -- to ensure the viability of the fund structure)[1].

Component 2. Seed Co-investment Fund (€2.5 million)

This component will provide €2.5 million towards establishing a Seed Co-Investment Fund ("Co-Investment Fund"). The Co-Investment Fund will be an open-ended fund with initial capital of €2.5million that will financed by proceeds of the World Bank loan. It will be administered by the implementing agency of the whole Project, HAMAG-BICRO. The objective of this component is to strengthen the early stage investing industry in Croatia by providing smaller amounts of risk capital financing alongside investors in the market such as angel investors and incubators. It is envisaged that the fund will provide smaller amounts of financing than will be made available by the Pilot VC Fund. The Co-Investment Fund is expected to provide a range from €30k- €200k (ticket size; €300k maximum per beneficiary) of flexible debt financing to young knowledge intensive SMEs with the locus of activity in Croatia. Specifically, the Seed Co-Investment Fund will provide financing through loans that will be subordinated to other debt holders, and will not require collateral. The loan will be paid out of income from the investment over the 15 year life of the loan. The terms of the loan are envisaged to be that the initial income generated from the investment will be paid to the co-investor(s) and HAMAG-BICRO on a pro rata basis. Once the return on the investment has exceeded a hurdle rate (6 percent) the subsequent income will be distributed asymmetrically to the benefit of the co-investor(s). After the hurdle rate has been achieved HAMAG-BICRO would receive around 10 percent of any additional income from the investment.

[1] This means the net amount available for investment under the VC Fund is €12 million.

Component 3. Technical Assistance (€1.5 million)

This component of the program would be established to assist in the creation and operation of the program. This component will have five sub-components.

a) Sub Component 3.1: The Global Advisory Network (€400 k). The objective of this sub-component is to establish a network of experts who will provide advice and guidance for the implementation of both funds designed under this Project (Pilot VC Fund and Co-Investment Fund).

b) Sub Component 3.2: Capacity Building and Networking (€400 k). The objective of this sub-component are twofold. First, to develop human capabilities of the main actors involved in the infant early stage financing industry in Croatia; such as HAMAG-BICRO staff, investors and entrepreneurs. Second, to strengthen social capital and networks – both local and global among incubators, accelerators, business angel networks, matchmaking services, entrepreneurs and larger investors.

c) Sub Component 3.3: Monitoring & Evaluation (€100 k). The aim of this subcomponent is to ensure accountability in the use of government's money, and provide guidance on how the program can be improved

d) Sub Component 3.4: Project Management (€600 k). This subcomponent will finance necessary activities for establishment of the PIU, project management and implementation, and carrying out outreach activities.

Eligible applicants are SMEs engaged in innovative activities with the aim at creating new (or upgrading existing) products (good or services), processes, marketing methods, and/or business models.

3 WORLD BANK SAFEGUARD POLICIES RELEVANT FOR THE PROJECT

The World Bank's environmental and social safeguard policies present a cornerstone of its support to sustainable poverty reduction. The objective of these policies is to prevent and mitigate undue harm to people and their environment in a development process. These policies provide guidelines for the Bank and borrowers' staff in the identification, preparation, and implementation of programs and projects.

During the assessment of the VC project two World Bank safeguards policies were triggered.

OP/BP 4.01 Environmental Assessment is triggered. An overall EMF is envisaged, following World Bank policies on consultation and disclosure, and prepared in advance of project appraisal. EMF will be a part of the project operation manual. Category A projects will not be supported. Environmental assessments (EAs) / Environmental Management Plans

(EMPs) would be prepared for the sub-projects to be financed that would be classed as category B.

OP/ BP 4.12 Involuntary Resettlement. The project would not trigger OP 4.12. Therefore, no potential beneficiaries can participate in the project if they would need land acquisition for the activities to be supported under this project. Re-habilitation and reconstruction (which could involve demolition of no longer suitable structure and construction of a new one) of existing buildings within the same footprint would be permissible. If reconstruction would exceed footprint of existing structure in any way, the PBs must ascertain that any additional land used is unencumbered (i.e. no squatters or encroachers or not requiring the eviction of anyone resident in such property) and provide proof in form of pictures and ownership title. The PBs should verify for each sub project the unencumbered status of the property prior to approving any sub-project which could raise such issues.

OP 17.50 Disclosure Policy is triggered with reference to the EMF and EAs/EMPs for the sub-projects to be financed.

4 CROATIAN NATIONAL POLICIES

Croatian environmental policy has been strongly shaped by adoption of the sustainable development framework and EU accession. The Strategy for Sustainable Development of the Republic of Croatia (OG 30/09) proposes development concept fully compliant with the European Union Community Strategic Guidelines on Cohesion, which promotes synergies between the economic, social and environmental dimensions.

Croatia employs mix of policy instruments to implement country's environmental policy. Legal instruments such as Environmental Impact Assessment (EIA) and strategic environmental assessment assure application of preventive actions and sustainable development concept in operational terms.

EIA is an assessment of the acceptability of the intended intervention (project) for the environment. It determines any direct or indirect impact of the project on environmental components (soil, water, sea, air, etc.) and on natural and cultural heritage as well as the mitigation measures necessary to minimize the impacts of the intervention to the least possible extent and achieve the best possible preservation of environmental quality. The assessment process is carried out at early stage of the project planning, before issuing the location permit or other approval for intervention for which the issuing of a location permit is not required.

As a member country of the European Union, Croatia has harmonized its environmental legislation with the EU environmental *aquis*. The Environmental Protection Act (OG 80/13) and the Regulation on the EIA (OG 61/14) prescribe the EIA process implementation. By entering in the force of these legislation, Croatia ensured compliance with the relevant EU

directives: Council Directive 85/337 / EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, amended by Council Directive 97/11/EC of 3 March 1997, and Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003.

The EIA is mandatory for project categories listed in Annex I of the Regulation on the EIA. The list of interventions included in Annex II, as an integral part of the Regulation, sets out projects for which the screening on the need for EIA is required under the authority of the Ministry of Environmental and Nature Protection (MENP). The list of interventions included in Annex III sets out procedures for which the screening is needed under the authority of competent administrative body in the county or in the City of Zagreb.

Adopted legislation is also based on provisions of the Convention on Environmental Impact Assessment in a Transboundary Context, which Republic of Croatia ratified (OG International Treaties 6/96).

5 ACTIVITIES GENERALLY INELIGIBLE FOR IBRD FINANCING

1. Trade in wildlife and wildlife products prohibited under the CITES convention,
2. Release of genetically altered organisms into the natural environment,
3. Manufacturing, distribution and sale of banned pesticides and herbicides,
4. Drift seine netting in the marine environment,
5. Manufacturing, handling and disposal of radioactive products,
6. Hazardous waste storage, treatment and disposal,
7. Manufacturing of equipment and appliances containing CFCs, halons and other substances regulated under the Montreal Protocol,
8. Manufacturing of electrical equipment containing polychlorinate biphenyls (PCBs) in excess of 0,005 % by weight,
9. Manufacturing of asbestos containing products,
10. Nuclear reactors and parts thereof,
11. Tobacco, unmanufactured or manufactured,
12. Tobacco processing machinery, and
13. Manufacturing of firearms.

6 ENVIRONMENTAL SCREENING CATEGORIES

Depending on the type, location, sensitivity, and scale of the sub-project and the nature and magnitude of its potential environmental impacts, the proposed sub-project should be classified into one of four categories.

The following examples of sub-borrowers/sub-projects and their suggested categorization are indicative only. Each project's categorization will need to be reviewed and confirmed separately, in order to be able to assess their appropriateness concerning the types of sub-projects which are actually submitted to the PBs. As it would be impossible for this list to be exhaustive, sub-projects which cannot be identified as belonging to one of the categories below should be brought to the attention of the PIU to transmit it to the World Bank environmental specialist for further guidance.

6.1 CATEGORY A

ACTIVITIES WHICH WILL NOT BE FINANCED THROUGH THE EQUITY INVESTMENT /SUB-LENDING SCHEME

A proposed sub-project is classified in this category, if it is likely to have highly significant, diverse, and/or long-term adverse impacts on human health and natural environment, the magnitude of which is difficult to determine at the sub-project identification stage. These impacts may also affect an area broader than the sub-project sites. Measures for mitigating such environmental risks may be complex and costly.

These projects coincide with Annex 1 of the national Regulation on EIA (OG 61/14). In addition, projects that would be characterized by environmental sensitivity of the planned location and surroundings and nature and magnitude of impacts which might be of high magnitude shall be excluded.

As agreed during the project preparation and appraisal, category A sub-projects would not be supported by VC project.

6.2 CATEGORY B

A proposed sub-project is classified as Category B if its potential adverse environmental impacts on human populations or environment are less adverse than those of Category A sub-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 sub-projects. Although knowledge-intensive activities are in the Project's focus other type of investments might be proposed and will therefore be screened on case by case basis taking into account that the scope of EA for a Category B sub-project may vary from sub-project to sub-project. The EA, in case of category B project, examines the sub-project's potential negative and positive environmental impacts and recommends any measures needed to prevent, minimize, mitigate, or compensate for adverse impacts and improve environmental performance.

6.2.1 CATEGORY B+

ACTIVITIES WHICH MAY BE FINANCED THROUGH THE EQUITY INVESTMENT /SUB-LENDING SCHEME, SUBJECT TO POSITIVE EIA CONCLUSION BY THE MINISTRY OF ENVIRONMENTAL AND NATURE PROTECTION OR INCLUDE PROJECTS WITH SHORT TERM ENVIRONMENTAL IMPACTS (EIA REPORT AND/OR EMPS REQUIRED)

These would include sub-projects which may have significant, negative and/or short-term environmental impacts, the magnitude of which are difficult to determine at the sub-project identification stage. A full EIA (if recommended by the MENP, or included in the annex 2 or 3 of the National Regulation on EIA) (see annex C), otherwise EMP (see annex D) would be prepared by the investee/sub-borrower. The costs of the mitigation measures would be included in the EIA / EMP and incorporated in the tendering documentation if applicable. If PBs determines that it is not easy to classify the project, it will advise PIU and the World Bank. The environmental due diligence documents would as well describe and assess testing phase of the product if applicable.

6.2.2 CATEGORY B-

ACTIVITIES WHICH MAY BE FINANCED THROUGH THE EQUITY INVESTMENT /SUB-LENDING SCHEME (EA REPORT AND EMPS REQUIRED)

This category includes sub-projects which may have intermediate levels of regular and accidental emissions and typical simple construction related impacts. They might include:

a) all construction of buildings or any infrastructure not included in Annex 2 or 3 of the national EIA regulation for which full EMPs would be prepared;

b) all physical investments (rehabilitation, refurbishing, etc.) on existing buildings for which EMP checklist would be applicable;

c) all sub-projects involving assembling for which Material Environmental Management Plan (MEMP) would be prepared. This MEMP includes identification of materials and processes used (mechanical, chemical, etc.), and good laboratory and engineering practices. The checklist should be accompanied with Material safety data sheets (MSDS) for all dangerous chemicals used. The environmental due diligence documents would as well describe and assess testing phase if applicable;

d) all sub-projects involving use of cancerogenic, mutagenic and teratogenic substances, also use of testing animals that might be used for life science, medical or pharmaceutical research for example, will have explained in detail the handling practices together with supplying and disposal techniques. In addition, all licenses for handing these materials and accreditation of the laboratories should be submitted with the MEMP checklist. Same practice would be followed when testing is done on laboratory animals.

6.3 CATEGORY C

ACTIVITIES WHICH MAY BE FINANCED THROUGH THE EQUITY INVESTMENT /SUB-LENDING SCHEME

These would include sub-projects whose environmental impacts are expected to be negligible, for which no EA would be required. Example of these is IT software development and other non physical intellectual work.

7 ENVIRONMENTAL SCREENING PROCEDURES

Environmental Screening is the first step in the environmental due diligence process of reviewing the sub-borrower application. Its purpose is to determine the environmental risk associated with the proposed sub-borrower/sub-project, reject applications which are unacceptable due to the nature of the proposed activities, classify acceptable applications by environmental categories and identify the type of environmental due diligence document that will be required. Environmental Screening is based on Environmental Screening Form (Annex A).

In the VC project, there will be two types of applications:

a) Applications for equity investment by the VCF (see component 1); and

b) Applications for sub projects directly financed by the HAMAG-BICRO (see component 2)

a) Applications for equity investment by the VCF

The sub-borrower will provide sufficient information for VCF to determine the environmental category of proposed sub-project by filling out Environmental Screening Form (Annex A). Results of the Environmental Screening shall be reflected in the Environmental Category Form (Annex B), completed by VCF, and submitted to the PIU and sub-borrower.

The screening report should describe relevant aspects to be addressed in the course of assessment, especially when dealing with animal testing and use of cancerogenic and mutagenic substances. VCF and/or PIU will request additional information if needed by using form provided in Annex B. The WB environmental specialist would closely work with the FMC in determining appropriate environmental category and provide suggestions / advice accordingly.

These applications may include requirement to consult the Ministry of Environment and Nature Protection whether the EIA would be required for planned project. If so, the EIA will be prepared with the rest of the technical documentation (design, permits, bidding documents, etc.) for financing.

b) Applications for sub projects directly financed by the HAMAG-BICRO

Results of the Environmental Screening shall be reflected in the Environmental Category Form (Annex B), completed by HAMAG-BICRO and submitted to PIU and the sub-borrower. Through the Environmental Screening Form (Annex A), the sub-borrower will provide sufficient information for HAMAG-BICRO to determine the environmental category of proposed sub project. Application form described in Annex A will be a part of a sub-loan application package.

The screening report should describe relevant aspects to be addressed in the course of assessment, especially when dealing with animal testing and use of cancerogenic and mutagenic substances. In form provided in Annex B, HAMAG-BICRO and/or PIU will request additional information if needed.

8 ENVIRONMENTAL ASSESSMENT – ENVIRONMENTAL DUE DILIGENCE DOCUMENTS

An Environmental Assessment (EA) is a process conducted by the sub-borrower to identify, predict, evaluate, and mitigate the environmental impacts and risks which may arise from the proposed sub-project. The EA's purpose is to recognize environmental impacts/consequences early in the sub-project preparation process, so that they can be incorporated into the sub-project design. The scope of EA will depend on the environmental category attached to each sub-project, though the purpose of any type of assessment is to identify ways of improving sub-projects environmentally by minimizing, mitigating or compensating for adverse impacts. An EMP alone will serve as environmental assessment report or should be made an integral part of an environmental assessment report, which lists environmental risks related to the specific types of sub-project activities and prescribes mitigation measures. An EA would also describe the steps that were taken for public consultation.

8.1 TYPE OF DOCUMENTS PER SUB-PROJECT ENVIRONMENTAL CATEGORY

For Category B +

Three types of documents might be required:

a) A full EIA would be required for Category B+ if the proposed project is listed in Annex 2 or 3 of the National EIA regulation (OG 61/14) and positive opinion given by the MENP. The EIA will be prepared according to national regulation and will undergo national approval procedure. In addition to EIA the sub-borrower will prepare EMP to comply with World Bank safeguards procedures. This implies two public disclosures requesting comments (first on the scope EIA and second on the final draft) followed by public consultation of both EIA and EMP.

For category B – one type of environmental due diligence is expected

a) Material Environmental Management Plan (MEMP) (Annex F). This checklist includes identification of materials and processes used (mechanical, chemical, etc.), and good laboratory and engineering practices. The checklist should be accompanied with MSDS for all dangerous chemicals used. The environmental due diligence documents would as well describe and assess testing phase if applicable.

b) EMP will be prepared for category B - subprojects which include construction of new buildings and infrastructure that is not covered in annex 2 or 3 of the National EIA

regulation (OG 61/14). EMP will undergo one public disclosure and consultation. Content of the EMP is defined in Annex D.

c) EMP checklist will be prepared for rehabilitation of buildings not included in the annex 2 or 3 of the National EIA regulation (OG 61/14). The document will be publically disclosed requesting written comments. Sample of the EMP checklist for rehabilitation is presented in annex E

d) Description of handling practices, supplying, and disposal techniques together with MEMP should be prepared for activities using cancerogenic, mutagenic and teratogenic substances. In addition, all licenses for handing these materials and accreditation of the laboratories should be submitted with the MEMP or any other environmental due diligence document required.

8.2 HANDLING SUB-PROJECTS THAT DEAL WITH BIOLOGICAL HAZARDS AND THOSE WITH ETHICAL ISSUES

Supporting projects in life and biotechnologies might involve scientific, medical or pharmacological research that will deal with biological hazards as well animal testing.

8.2.1 BIOLOGICAL AGENTS

Biological agents represent potential for illness or injury due to single acute exposure or chronic repetitive exposure. Biological hazards must be prevented most effectively by implementing the following measures:

- If the nature of the activity permits, use of any harmful biological agents should be avoided and replaced with an agent that, under normal conditions of use, is not dangerous or less dangerous to workers. If use of harmful agents cannot be avoided, precautions should be taken to keep the risk of exposure as low as possible and maintained below internationally established and recognized exposure limits.
- Work processes, engineering, and administrative controls should be designed, maintained, and operated to avoid or minimize release of biological agents into the working environment. The number of employees exposed or likely to become exposed should be kept at a minimum.
- The employer should review and assess known and suspected presence of biological agents at the place of work and implement appropriate safety measures, monitoring, training, and training verification programs.
- Measures to eliminate and control hazards from known and suspected biological agents at the place of work should be designed, implemented and maintained in close co-operation with the local health authorities and according to recognized international standards.

The employer should at all times encourage and enforce the highest level of hygiene and personal protection. Work involving agents should be restricted only to those persons who have received specific verifiable training in working with and controlling such materials.

As Croatian legislation is in line with the EU legislation, laboratories applying for sub-project support should submit in addition to relevant due diligence document the following:

- Type and quantity of biological agent use
- License for the use of the same
- Describe practices of handling such materials, especially disposal practices
- Describe storing and handling practices
- **All other defined by the Law on Chemicals (Official Gazette 18/13) – *see Annex G***

8.2.2 THE ETHICAL ISSUES

The ethical issues faced by pharmaceutical or biotechnology enterprises are potentially complex and depend significantly on business activity. These issues may include the animal testing.

Recommended bioethics management approaches include:

- Well established ethics mechanisms including management commitment; access and use of external expertise (e.g. consultants and advisory boards); internal training and accountability mechanisms; communications programs to engage with suppliers and external stakeholders; and evaluation and reporting mechanisms;
- Adherence to internationally accepted ethical principles applicable to genetic research, clinical trials involving human participants, and any other activities with critical bioethical issues;
- The use of animals for experimental and scientific purposes should be conducted according to industry good and Croatian Law on Animal Protection (articles attached) practice which includes reduction of the numbers of animals used in each study to the absolute minimum necessary to obtain valid results and refinement of the use of research animals to use less painful or the least invasive procedures whenever possible.

As Croatian legislation is in line with the EU legislation, laboratories applying for sub project support should submit in addition to relevant due diligence document the following:

- Species and number of animal used
- License for the use of the same
- Describe practices of handling animals, especially disposal practices
- Describe procurement of the animals
- Describe storing and handling practices

- **All other defined by the Animal Protection Act (Official Gazette 135/06, 37/13, 125/13) – *see Annex I***

9 ENVIRONMENTAL REVIEW PROCESS (ROLE OF PBS, PIU AND WB)

9.1 STEPS OF THE PROCESS

All sub-borrowers/sub-projects will follow the environmental review process presented schematically below.

STEP 1: The sub-borrower prepares an initial sub-project application, filling, among the others the Environmental Screening Form presented in Annex A. Following informal discussion with the PB, in which the PB alerts the sub-borrower of its environmental assessment requirements, the PB assists the sub-borrower in finalizing the Environmental Screening Form if needed. At this time, it is the responsibility of the sub-borrower to initiate discussions with the MENP in order to fulfill any local and national environmental review requirements (such as investment incentive certificate and/or other official approval/permits). It will be the responsibility of the sub-borrower to obtain the appropriate permits and licenses as required by national law in order to facilitate the clearance process with the MENP. These requirements are considered separate, but parallel, to those presented here and complying with those is the responsibility of the sub-borrower.

STEP 2: The PB screens the sub-project and informs the sub-borrower of the environmental category (Annex B) and provides information for follow-up requirements for equity investment / sub-loan processing.

STEP 3: The sub-borrower, or its consultants, submits the environmental due diligence document (if applicable). If required, the sub-borrower will obtain a positive EIA report, given by the MENP, in conformity with applicable Environmental Regulations for the activities under Category B +.

STEP 4: The PB reviews the environmental due diligence document that has been submitted and reports its findings to the sub-borrower. The PB provides its clearance once the analysis is satisfactory. In case where cancerogenic, teratogenic or mutagenic substances will be used, as well as animal testing conducted, the PB will advise PIU and WB on quality of the environmental due diligence document.

STEP 5: The sub-borrower incorporates the recommendations provided in the analysis into the sub-project design and implementation plan, including associated estimated costs.

STEP 6: The PB finalizes the equity investment/sub-loan application package, including the relevant environmental documentation.

STEP 7: The PB monitors the implementation of the EIA mitigation plan (if necessary) and informs the PIU.

9.2 PUBLIC CONSULTATIONS AND DISCLOSURE

EMF was disclosed on HAMAG-BICRO website both in English and Croatian on _____, 2015 and hardcopy was available at HAMAG-BICRO reception in Planinska 1, Zagreb.

The draft document, along with individual invitations was sent out to the key stakeholders in the project. The Public Consultations meeting was held at the premises of the _____, on March ____ and additional period for commenting was enabled. All written comments and questions raised in the public consultation were addressed, than summarized and are attached to EMF as annex. Only then EMF can be considered as final version.

The minutes of public consultation in annex G reflect the process and the outcome of public consultation and disclosure of EMF.

Each EIA/ EMP / EMP checklist prepared for individual sub projects will have to be publicly disclosed before a sub-project is approved by HAMAG-BICRO. Comments will be requested on the documents disclosed. The in-country disclosure within Croatia will be done through the internet site of HAMAG-BICRO and local newspaper advertisements might be used as a mean for calling the public to comment on the same documents. For category B+ in addition to public disclosure and call for comments, a public consultation in form of meeting will be done.

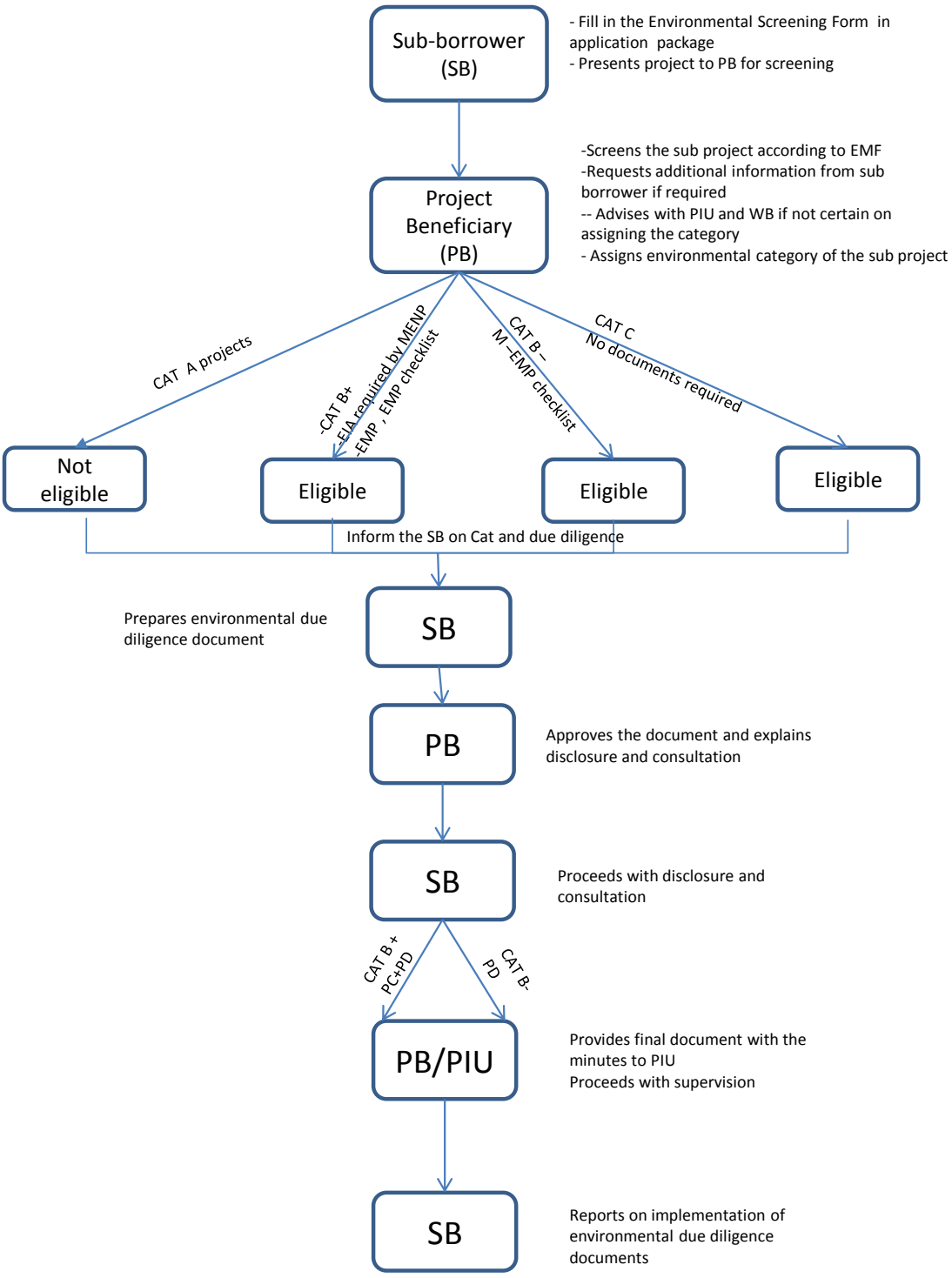
9.3 PRIOR AND POST-REVIEW – WB/PIU

Environmental evaluations and review procedures will be subject to ad-hoc review by the PIU and WB supervision missions. WB will perform:

a) prior review and clearance of all sub-projects falling in category B+ requiring full EIA and EMP,
b) prior review of first five (5) category B- sub-projects under each PB,
c) prior review all projects involving use of testing animals, cancerogenic, teratogenic or mutagenic substances;
d) post review for all other projects.

The review of evaluations will ensure that: the work was of satisfactory quality, community participation took place when appropriate, the appropriate recommendations were made, all documentation was properly filed and recorded, and that the conditions of approval by the MENP were met. During the VC project preparation and implementation, PIU together with WB representatives will supervise the overall screening process and implementation of environmental recommendations for selected sub-borrowers/sub-projects. PIU's and WB supervision team will also review, ad-hoc, environmental documentation. Therefore, all this documentation should be kept on file with the PBs and forwarded to the PIU as needed. The prior site visits will be done by IBRD and HAMAG-BICRO for all the sub-projects for which categorization / screening process is not easily determined.

The diagram of the steps to follow is presented in the next pages as well as responsibilities of different parties.


Sub-borrower (SB)
- Fill in the Environmental Screening Form in application package
- Presents project to PB for screening
Project Beneficiary (PB)
-Screens the sub project according to EMF
-Requests additional information from sub borrower if required
-- Advises with PIU and WB if not certain on assigning the category
- Assigns environmental category of the sub project
CAT A projects
-CAT B+ -EIA required by MENP -EMP , EMP checklist
CAT B – M -EMP checklist
CAT C No documents required
Not eligible
Eligible
Eligible
Eligible
Inform the SB on Cat and due diligence
Prepares environmental due diligence document
SB
PB
Approves the document and explains disclosure and consultation
SB
Proceeds with disclosure and consultation
CAT B + PC+PD
CAT B- PD
PB/PIU
Provides final document with the minutes to PIU
Proceeds with supervision
SB
Reports on implementation of environmental due diligence documents

9.4 REPORTING

HAMAG-BICRO (or PBs or PIU) will inform the World Bank on the environmental due diligence applied through the general reporting on the project progress. The World Bank will track environmental performance of the HAMAG-BICRO and VCF by regular review of their reports as well as by supervision of the overall screening process and implementation of environmental recommendations for the selected sub-projects, including random visits to the sub-project sites. Such practice of supervision is aimed at ensuring that: the work was of satisfactory quality, community participation took place when appropriate, the appropriate recommendations were made, all documentation was properly filed and recorded, and that the conditions of approval by the authorized bodies were met. Therefore, PBs shall properly keep all sub-project documentation on file and make it available for the World Bank as needed.

9.5 RESPONSIBILITIES OF KEY PARTICIPANTS

The role of sub-beneficiary, Project beneficiaries, PIU and the WB is described in the table below.

Participant	Activity	Supporting Documentation
Sub-beneficiary	• Submission of sub-project concept to PB • Arrangement and financing of environmental due diligence documents • Obtain required permits/licenses • Implementing and financing of environmental due diligence	• Copies of permits, licenses • Clearance statement • Periodic reports and sub-project completion report
Project Beneficiary (PBs)	• Finalize the environmental screening form, assign the environmental category • Review of sub-loan application package for required environmental documentation and licenses/permits from the State authorities • Maintain complete files of environmental documentation for review by the PIU and WB • Monitoring compliance with mitigation plans (if necessary)	• Include environmental information with sub-loan application • Include environmental monitoring / supervising information in regular portfolio reporting to PIU • Include environmental documentation in normal PB records • Periodic monitoring / supervising reports (if necessary)

PIU	• Distribution of Operational manual to PBs • Assist to the PBs about environmental requirements • Verification that PBs have followed EIA procedures	• Include environmental category and EIA status in normal periodic reporting activities
WB	• Organize training for PB and PIU staff regarding environmental review procedures • Carry out prior and post reviews • Identification of problems/ issues and proposal of solutions	• Provide assistance • Document status of project implementation in Implementation Status and Results reports and the mission Aide-Memoires

10 ANNEXES

10.1 ANNEX A: ENVIRONMENTAL SCREENING FORM

PART 1: APPLICATION (filled by applicants)			
Name of applicant/ sub-beneficiary			
PROJECT TITLE			
Scope of project and activity – project description			
Institution supporting/supervising the project			
What are the potential environmental impacts of the project?			
TESTING			
Will the project finance testing phase?			
Please describe testing phase			
Please specify outdoor or indoor?			
PERMITS			
What permits are required for project preparation and / or testing?			
PART 2: SCREENING (filled by applicants, checked by PB)			
Screening category according to national Regulation on EIA	**Annex 1**	**Yes** ☐	**No** ☐
	Annex 2	**Yes** ☐	**No** ☐
	Annex 3	**Yes** ☐	**No** ☐
	No annex	**Yes** ☐	**No** ☐
If no annex:	Does it include construction or rehabilitation of buildings or	**Yes** ☐	**No** ☐

	infrastructure?	
	Does it include assembling?	**Yes** ☐ **No** ☐
	Does the project include software development or similar IT work?	**Yes** ☐ **No** ☐
	Does the project include use of cancerogenic, theratogenic or mutagenic substances?	**Yes** ☐ **No** ☐
	▪ If so what substances and for what purposes?	
	▪ What quantities?	
	▪ What accreditation laboratory has for use of such materials?	
	Does the project predict testing on animals?	**Yes** ☐ **No** ☐
	▪ If so what substances and for what purposes?	
	▪ What animals?	
	▪ What accreditation laboratory has for testing?	
	Does the project include Activities Generally Ineligible for IBRD financing?	**Yes** ☐ **No** ☐
Signature Confirming truthfulness of the provided in the table		

10.2 ANNEX B: ENVIRONMENTAL CATEGORY FORM

PART 1: SCREENING RESULTS (filled by PB)				
Screening category according to the project framework	A	B +	B -	C
EXPLANATION				
DUE DILIGENCE				
Category A				
	Will not be financed by the project			
Category B +				
	EIA if project included in annex 2 or 3 of the Regulation on EIA			
Category B -				
	Material EMP together with the necessary licenses and MSDSs EMP or EMP checklist			
Category C				
	No due diligence			
Additional explanation required				

10.3 ANNEX C: MINIMUM REQUIREMENT FOR PROJECTS THAT WOULD REQUIRE FULL EIA ACCORDING TO DECISION OF MINISTRY OF ENVIRONMENT AND NATURE PROTECTION

The EA report should include the following items (not necessarily in the order shown):

(a) *Executive summary*. Concisely discusses significant findings and recommended actions.

(b) *Policy, legal, and administrative framework*. Discusses the policy, legal, and administrative framework within which the EA is carried out. Explains the environmental requirements of any co-financiers. Identifies relevant international environmental agreements to which the country is a party.

(c) *Project description*. Concisely describes the proposed project and its geographic, ecological, social, and temporal context, including any offsite investments that may be required (e.g., dedicated pipelines, access roads, power plants, water supply, housing, and raw material and product storage facilities). Indicates the need for any resettlement plan or indigenous peoples development plan. Normally includes a map showing the project site and the project's area of influence.

(d) *Baseline data*. Assesses the dimensions of the study area and describes relevant physical, biological, and socioeconomic conditions, including any changes anticipated before the project commences. Also takes into account current and proposed development activities within the project area but not directly connected to the project. Data should be relevant to decisions about project location, design, operation, or mitigatory measures. The section indicates the accuracy, reliability, and sources of the data.

(e) *Environmental impacts*. Predicts and assesses the project's likely positive and negative impacts, in quantitative terms to the extent possible. Identifies mitigation measures and any residual negative impacts that cannot be mitigated. Explores opportunities for environmental enhancement. Identifies and estimates the extent and quality of available data, key data gaps, and uncertainties associated with predictions, and specifies topics that do not require further attention.

(f) *Analysis of alternatives*.[3] Systematically compares feasible alternatives to the proposed project site, technology, design, and operation--including the "without project" situation--in terms of their potential environmental impacts; the feasibility of mitigating these impacts; their capital and recurrent costs; their suitability under local conditions; and their institutional, training, and monitoring requirements. For each of the alternatives, quantifies the environmental impacts to the extent possible, and attaches economic values where feasible. States the basis for selecting the particular project design proposed and justifies recommended emission levels and approaches to pollution prevention and abatement.

(g) *Environmental management plan (EMP)*. Covers mitigation measures, monitoring, and institutional strengthening;

(h) *Appendixes*

(i) List of EA report preparers--individuals and organizations.

(ii) References--written materials both published and unpublished, used in study preparation.

(iii) Record of interagency and consultation meetings, including consultations for obtaining the informed views of the affected people and local nongovernmental organizations (NGOs). The record specifies any means other than consultations (e.g., surveys) that were used to obtain the views of affected groups and local NGOs.

(iv) Tables presenting the relevant data referred to or summarized in the main text.

(v) List of associated reports (e.g., resettlement plan or indigenous peoples development plan).

10.4 ANNEX D: TEMPLATE FOR ENVIRONMENTAL MANAGEMENT PLAN

A project's environmental management plan (EMP) consists of the set of mitigation, monitoring, and institutional measures to be taken during implementation and operation to eliminate adverse environmental and social impacts, offset them, or reduce them to acceptable levels. The plan also includes the actions needed to implement these measures[2]. Management plans are essential elements of EA reports for Category A projects; for many Category B projects, the EA may result in a management plan only. To prepare a management plan, the sub-borrower and its EA design team (a) identify the set of responses to potentially adverse impacts; (b) determine requirements for ensuring that those responses are made effectively and in a timely manner; and (c) describe the means for meeting those requirements[3]. More specifically, the EMP includes the following components.

Mitigation

The EMP identifies feasible and cost-effective measures that may reduce potentially significant adverse environmental impacts to acceptable levels. The plan includes compensatory measures if mitigation measures are not feasible, cost-effective, or sufficient. Specifically, the EMP

(a) identifies and summarizes all anticipated significant adverse environmental impacts (including those involving indigenous people or involuntary resettlement);

(b) describes with technical details each mitigation measure, including the type of impact to which it relates and the conditions under which it is required (e.g., continuously or in the event of contingencies), together with designs, equipment descriptions, and operating procedures, as appropriate;

(c) estimates any potential environmental impacts of these measures; and

(d) provides linkage with any other mitigation plans (e.g., for involuntary resettlement, indigenous peoples, or cultural property) required for the project.

Monitoring

Environmental monitoring during project implementation provides information about key environmental aspects of the project, particularly the environmental impacts of the project and the effectiveness of mitigation measures. Such information enables the borrower and the Bank to evaluate the success of mitigation as part of project supervision, and allows corrective action to be taken when needed. Therefore, the EMP identifies monitoring objectives and specifies

[2] The management plan is sometimes known as an "action plan." The EMP may be presented as two or three separate plans covering mitigation, monitoring, and institutional aspects, depending on borrowing country requirements.

[3] For projects involving rehabilitation, upgrading, expansion, or privatization of existing facilities, remediation of existing environmental problems may be more important than mitigation and monitoring of expected impacts. For such projects, the management plan focuses on cost-effective measures to remediate and manage these problems.

the type of monitoring, with linkages to the impacts assessed in the EA report and the mitigation measures described in the EMP. Specifically, the monitoring section of the EMP provides(a) a specific description, and technical details, of monitoring measures, including the parameters to be measured, methods to be used, sampling locations, frequency of measurements, detection limits (where appropriate), and definition of thresholds that will signal the need for corrective actions; and (b) monitoring and reporting procedures to (i) ensure early detection of conditions that necessitate particular mitigation measures, and (ii) furnish information on the progress and results of mitigation.

Capacity Development and Training

To support timely and effective implementation of environmental project components and mitigation measures, the EMP draws on the EA's assessment of the existence, role, and capability of environmental units on site or at the agency and ministry level[4]. If necessary, the EMP recommends the establishment or expansion of such units, and the training of staff, to allow implementation of EA recommendations. Specifically, the EMP provides a specific description of institutional arrangements--who is responsible for carrying out the mitigatory and monitoring measures (e.g., for operation, supervision, enforcement, monitoring of implementation, remedial action, financing, reporting, and staff training). To strengthen environmental management capability in the agencies responsible for implementation, most EMPs cover one or more of the following additional topics: (a) technical assistance programs, (b) procurement of equipment and supplies, and (c) organizational changes.

Implementation Schedule and Cost Estimates

5. For all three aspects (mitigation, monitoring, and capacity development), the EMP provides (a) an implementation schedule for measures that must be carried out as part of the project, showing phasing and coordination with overall project implementation plans; and (b) the capital and recurrent cost estimates and sources of funds for implementing the EMP. These figures are also integrated into the total project cost tables.

Integration of EMP with Project

6. The borrower's decision to proceed with a project, and the Bank's decision to support it, are predicated in part on the expectation that the EMP will be executed effectively. Consequently, the Bank expects the plan to be specific in its description of the individual mitigation and monitoring measures and its assignment of institutional responsibilities, and it must be integrated into the project's overall planning, design, budget, and implementation. Such

[4] For projects having significant environmental implications, it is particularly important that there be in the implementing ministry or agency an in-house environmental unit with adequate budget and professional staffing strong in expertise relevant to the project (for projects involving dams and reservoirs, see BP 4.01, Annex B).

integration is achieved by establishing the EMP within the project so that the plan will receive funding and supervision along with the other components.

The EMP will contain following chapters:

1. GENERAL PROJECT AND SITE INFORMATION

1.1. DESCRIPTION OF THE PROJECT

Project title

Project location

Project purpose

Scope of project and activity

1.2. LEGISLATION and ADMINISTRATION

National legislation

1.3. STATUS OF PROJECT DESIGN DOCUMENTATION AND PERMITS

Ownership of the land or the object

Type of document or permit

2. DESCRIPTION OF THE ENVIRONMENT (BASELINE CONDITIONS)

General description of project site environment

Physical environment

Socio-cultural environment

3. DETERMINATION OF THE POTENTIAL IMPACTS

4. MITIGATION AND MONITORING PLAN

Mitigation Plan

Construction Phase				
Activity	Expected Environmental Impact	Proposed Measure for Mitigation	Responsibility for Implementing Mitigation Measure	Period of Implementing Mitigation Measure
1.				
2.				
…				
Operation Phase				
1.				
2.				

…				

Monitoring Plan

Construction Phase				
What *parameter is to be monitored?*	**Where** *is the parameter to be monitored?*	**How** *is the parameter to be monitored (what should be measured and how)?*	**When** *is the parameter to be monitored (timing and frequency)?*	**By Whom** *is the parameter to be monitored– (responsibility)?*
1.				
2.				
…				
Operation Phase				
1.				
2.				
…				

10.5 ANNEX E: ENVIRONMENTAL MANAGEMENT PLAN (EMP) CHECKLIST

for the small reconstructions and rehabilitations

Potential Environmental Impacts

The environmental impacts of the sub project are expected to be of manageable, temporary and of local impact as they are related to the general construction activities on already known and previously used locations. These impacts most commonly include: a) Dust and noise due to excavation, demolition and construction; b) Management of demolition construction wastes and accidental spillage of machine oil, lubricants, etc., c) Encroachment to a private property; d) damage to historical or cultural property or unknown archaeological sites; e) Traffic disturbance; (f) surface or ground water and g) soil pollution or erosion.

CHECKLIST EMP

Checklist EMP is applied for minor rehabilitation or small-scale building construction. It provides "pragmatic good practice" and it is designed to be user friendly and compatible with WB safeguard requirements. The checklist-type format attempts to cover typical mitigation approaches to common civil works contracts with localized impacts.

The checklist has one introduction section and three main parts:

- Introduction or foreword part in which the project is introduced, environmental category defined, and checklist EMP concept explained.
- **Part 1** constitutes a descriptive part ("*site passport*") that describes the project specifics in terms of physical location, the institutional and legislative aspects, the project description, inclusive of the need for a capacity building program and description of the public consultation process.
- **Part 2** includes the environmental and social screening in a simple Yes/No format followed by mitigation measures for any given activity.
- **Part 3** is a monitoring plan for activities during project construction and implementation. It retains the same format required for standard World Bank EMPs. It is the intention of this checklist that Part 2 and Part 3 be included as bidding documents for contractors.

Application of the EMP Checklist

The design process for the envisaged civil works in the VC Project will be conducted in three phases:

1) *General identification and scoping phase*, in which the objects for rehabilitation, extension and/or construction are selected and an approximate program for the potential work typologies elaborated. At this stage, Part 1, 2 and 3 of the Checklist EMP

are filled. Part 2 of the Checklist EMP can be used to select typical activities from a "menu" and relate them to the typical environmental issues and mitigation measures.

2) *Detailed design and tendering phase*, including specifications and bills of quantities for individual objects. Checklist EMP is revised according to the detailed design at this stage. As such, the Checklist is presented to the public, prior to the tendering procedure. This phase also includes the tender and award of the works contracts. The whole filled in tabular EMP (Part 1, 2 and 3) should be additionally attached as integral part to the works contract as well as supervision contract, analogous to all technical and commercial terms, has to be signed by the contract parties.

3) *During the works implementation phase* environmental compliance is checked on the respective site by the site certified inspector(s) / supervisor(s), which include the site supervisory engineer or supervisor of the project. The mitigation measures in Part 2 and monitoring plan in Part 3 are the basis to verify the Contractor's or project investor compliance with the required environmental provisions.

Monitoring and Reporting

For the monitoring of the safeguards due diligence, the site supervisor works with **Part 3** of the EMP Checklist, *i.e.* with the monitoring plan. Part 3 is developed for a specific site and in necessary detail, defining clear mitigation measures and monitoring which can be included in the works contracts, which reflect the status of environmental practice on the construction site and which can be observed/measured/ quantified/verified by the inspector during the construction works.

Such mitigation measures include the use of Personal Protective Equipment (PPE) by workers on the site, dust generation and prevention, amount of water used and discharged by site, presence of proper sanitary facilities for workers, waste collection of separate types (mineral waste, wood, metals, plastic, hazardous waste, e.g. asbestos, paint residues, spent engine oil), waste quantities, proper organization of disposal pathways and facilities, or reuse and recycling wherever possible.

Reporting on implementation of practices should be described in the regular report toward PIU.

PART 1: INSTITUTIONAL & ADMINISTRATIVE			
Name of applicant/ sub- beneficiary			
PROJECT TITLE			
Scope of project and activity – project description			
Institution supporting/ supervising the project			
What are the potential environmental impacts of the project?			
TESTING			
Will the project finance testing phase?			
Please describe testing phase			
Please specify outdoor or indoor?			
PERMITS			
What permits are required for project preparation and / or testing?			
PART 2: SCREENING (filled by applicants, checked by PA)			
Screening category according to national Regulation on EIA	**Annex 1**	**Yes** ☐	**No** ☐
	Annex 2	**Yes** ☐	**No** ☐
	Annex 3	**Yes** ☐	**No** ☐
	No annex	**Yes** ☐	**No** ☐
If no annex:	Does it include construction or rehabilitation of buildings or		

	infrastructure?	**Yes** ☐ **No** ☐
	Does it include assembling?	**Yes** ☐ **No** ☐
	Does the project include software development or similar IT work?	**Yes** ☐ **No** ☐
	Does the project include use of cancerogenic, theratogenic or mutagenic substances?	**Yes** ☐ **No** ☐
	▪ If so what substances and for what purposes?	
	▪ What quantities?	
	▪ What accreditation laboratory has for use of such materials?	
	Does the project predicts testing on animals?	**Yes** ☐ **No** ☐
	▪ If so what substances and for what purposes?	
	▪ What animals?	
	▪ What accreditation laboratory has for testing?	
	Does the project include Activities Generally Ineligible for IBRD financing?	**Yes** ☐ **No** ☐
Signature Confirming truthfulness of the provided in the table		

PART 2: ENVIRONMENTAL /SOCIAL SCREENING			
Will the site activity include/involve any of the following:	**Activity**	**Status**	**Additional references**
	A. Building rehabilitation	[ ] Yes [] No	See Section **B** below
	B. New construction	[ ] Yes [ ] No	See Section **B** below
	C. Individual wastewater treatment system	[ ] Yes [ ] No	See Section **C** below
	D. Historic building(s) and districts	[ ] Yes [ ] No [ ] Possible	See Section **D** below
	E. Acquisition of land[5]	[ ] Yes [] No	See Section **E** below
	F. Hazardous or toxic materials[6]	[ ] Yes [ ] No	See Section **F** below
	G. Impacts on forests and/or protected areas	[ ] Yes [ ] No	See Section **G** below
	H. Handling / management of medical waste	[ ] Yes [ ] No	See Section **H** below
	I. Traffic and Pedestrian Safety	[ ] Yes [ ] No	See Section **I** below

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
A. General Conditions	Notification and Worker Safety	(a) The local construction and environment inspectorates and communities have been notified of upcoming activities (b) The public has been notified of the works through appropriate notification in the media and/or at publicly accessible sites (including the site of the works)

[5] Land acquisitions includes displacement of people, change of livelihood encroachment on private property this is to land that is purchased/transferred and affects people who are living and/or squatters and/or operate a business (kiosks) on land that is being acquired.

[6] Toxic / hazardous material includes and is not limited to asbestos, toxic paints, removal of lead paint, etc.

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		(c) All legally required permits have been acquired for construction and/or rehabilitation (d) All work will be carried out in a safe and disciplined manner designed to minimize impacts on neighboring residents and environment. (e) Workers' PPE will comply with international good practice (always hardhats, as needed masks and safety glasses, harnesses and safety boots) (f) Appropriate signposting of the sites will inform workers of key rules and regulations to follow.
B. General Rehabilitation and /or Construction Activities	Air Quality	(a) During interior demolition use debris-chutes above the first floor (b) Keep demolition debris in controlled area and spray with water mist to reduce debris dust (c) Suppress dust during pneumatic drilling/wall destruction by ongoing water spraying and/or installing dust screen enclosures at site (d) Keep surrounding environment (side walks, roads) free of debris to minimize dust (e) There will be no open burning of construction / waste material at the site (f) There will be no excessive idling of construction vehicles at sites
	Noise	(a) Construction noise will be limited to restricted times agreed to in the permit (b) During operations the engine covers of generators, air compressors and other powered mechanical equipment should be closed, and equipment placed as far away from residential areas as possible
	Water Quality	(a) The site will establish appropriate erosion and sediment control measures such as e.g. hay bales and / or silt fences to prevent sediment from moving off site and

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		causing excessive turbidity in nearby streams and rivers.
	Waste management	(a) Waste collection and disposal pathways and sites will be identified for all major waste types expected from demolition and construction activities. (b) Mineral construction and demolition wastes will be separated from general refuse, organic, liquid and chemical wastes by on-site sorting and stored in appropriate containers. (c) Construction waste will be collected and disposed properly by licensed collectors (d) The records of waste disposal will be maintained as proof for proper management as designed. (e) Whenever feasible the contractor will reuse and recycle appropriate and viable materials (except asbestos)
C. Individual wastewater treatment system	Water Quality	(a) The approach to handling sanitary wastes and wastewater from building sites (installation or reconstruction) must be approved by the local authorities (b) Before being discharged into receiving waters, effluents from individual wastewater systems must be treated in order to meet the minimal quality criteria set out by national guidelines on effluent quality and wastewater treatment (c) Monitoring of new wastewater systems (before/after) will be carried out
D. Historic building(s)	Cultural Heritage	(a) If the building is a designated historic structure, very close to such a structure, or located in a designated historic district, notify and obtain approval/permits from local authorities and address all construction activities in line with local and national legislation (b) Ensure that provisions are put in place so that artifacts or other possible “chance

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		finds" encountered in excavation or construction are noted, officials contacted, and works activities delayed or modified to account for such finds.
E. Acquisition of land	Land Acquisition Plan/Framework	(a) If expropriation of land was not expected and is required, or if loss of access to income of legal or illegal users of land was not expected but may occur, that the bank task Team Leader is consulted. (b) The approved Land Acquisition Plan/Framework (if required by the project) will be implemented
F. Toxic Materials	Asbestos management	(a) If asbestos is located on the project site, mark clearly as hazardous material (b) When possible the asbestos will be appropriately contained and sealed to minimize exposure (c) The asbestos prior to removal (if removal is necessary) will be treated with a wetting agent to minimize asbestos dust (d) Asbestos will be handled and disposed by skilled & experienced professionals (e) If asbestos material is be stored temporarily, the wastes should be securely enclosed inside closed containments and marked appropriately (f) The removed asbestos will not be reused
	Toxic / hazardous waste management	(a) Temporarily storage on site of all hazardous or toxic substances will be in safe containers labeled with details of composition, properties and handling information (b) The containers of hazardous substances should be placed in an leak-proof container to prevent spillage and leaching (c) The wastes are transported by specially licensed carriers and disposed in a licensed

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		facility. (d) Paints with toxic ingredients or solvents or lead-based paints will not be used
G. Affects forests and/or protected areas	Protection	(a) All recognized natural habitats and protected areas in the immediate vicinity of the activity will not be damaged or exploited, all staff will be strictly prohibited from hunting, foraging, logging or other damaging activities. (b) For large trees in the vicinity of the activity, mark and cordon off with a fence large tress and protect root system and avoid any damage to the trees (c) Adjacent wetlands and streams will be protected, from construction site run-off, with appropriate erosion and sediment control feature to include by not limited to hay bales, silt fences (d) There will be no unlicensed borrow pits, quarries or waste dumps in adjacent areas, especially not in protected areas.
H. Disposal of medical waste (not applicable)	Infrastructure for medical waste management	(a) In compliance with national regulations the contractor will insure that newly constructed and/or rehabilitated health care facilities include sufficient infrastructure for medical waste handling and disposal; this includes and not limited to: ▪ Special facilities for segregated healthcare waste (including soiled instruments "sharps", and human tissue or fluids) from other waste disposal; and ▪ Appropriate storage facilities for medical waste are in place; and ▪ If the activity includes facility-based treatment, appropriate disposal options are in place and operational
I. Traffic and	Direct or indirect hazards to public traffic and	(a) Traffic and Pedestrian Safety Direct or indirect hazards to public traffic and pedestrians by construction activities In compliance with national regulations the

PART 3 : MONITORING PLAN

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
Pedestrian Safety	pedestrians by construction activities	contractor will insure that the construction site is properly secured and construction related traffic regulated. This includes but is not limited to: . (b) Signposting, warning signs, barriers and traffic diversions: site will be clearly visible and the public warned of all potential hazards. (c) Traffic management system and staff training, especially for site access and near-site heavy traffic. Provision of safe passages and crossings for pedestrians where construction traffic interferes. Provision of safe passages and crossings for pedestrians where construction traffic interferes. (d) Adjustment of working hours to local traffic patterns, e.g. avoiding major transport activities during rush hours or times of livestock movement. (e) Active traffic management by trained and visible staff at the site, if required for safe and convenient passage for the public. (f) Ensuring safe and continuous access to office facilities, shops and residences during renovation activities, if the buildings stay open for the public.

Phase	What (Will the parameter be monitored?)	Where (Is the parameter to be monitored?)	How (Is the parameter to be monitored?)	When (Define the frequency / or continuity?)	Why (Is the parameter being monitored?)	Cost (if not included in project budget)	Who (Is responsible for monitoring?)
During activity preparation							
During activity **implementation**							
During activity supervision							

10.6 ANNEX F: MATERIAL EMP

MATERIAL EMP	
Name of applicant /sub-beneficiary	
PROJECT TITLE	
Scope of project and activity – project description	
Institution supporting/ supervising the project	
What are the potential environmental impacts of the project?	
TESTING	
Please describe testing phase	
PERMITS	
What permits are required for project preparation and / or testing?[7]	

List all materials that will be used in the process, hazardous material should be identified according to legislation on chemicals (Annex F). The MSDS sheets and all the permits should be attached to the final document.

[7] All permits should be attached to the final document

The overall objective of hazardous materials management is to avoid or, when avoidance is not feasible, minimize uncontrolled releases of hazardous materials or accidents (including explosion and fire) during their production, handling, storage and use. This objective can be achieved by:

- Where practicable, avoiding or minimizing the use of hazardous materials.
- Preventing uncontrolled releases of hazardous materials to the environment or uncontrolled reactions that might result in fire or explosion;
- Using engineering controls commensurate with the nature of hazard;
- Implementing management controls (procedures, inspections, communications, training, and drills) to address residual risks that have not been prevented or controlled through engineering measures.

List of materials / chemicals that are going to be used	If possible assign CAS[8] number to material / chemicals[9]	According to the Law on chemicals is this material hazardous	Please assign category according to the Law on chemicals, Article 2 (Annex F)
		Y/N	

[8] Chemical Abstracts Service Number
[9] MSDS sheets should be attached to the final document

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
	Waste management	(f) Waste collection and disposal pathways and sites will be identified for all major waste types expected from demolition and construction activities. (g) Assembling waste will be collected and disposed properly by licensed collectors (h) The records of waste disposal will be maintained as proof for proper management as designed. (i) Whenever feasible the contractor will reuse and recycle appropriate and viable materials (except asbestos)
	Toxic / hazardous waste / materials management	(e) Temporarily storage on site of all hazardous or toxic substances will be in safe containers labeled with details of composition, properties and handling information according to MSDS sheets (f) The containers of hazardous substances should be placed in an leak-proof container to prevent spillage and leaching (g) The wastes are transported by specially licensed carriers and disposed in a licensed facility. (h) Paints with toxic ingredients or solvents or lead-based paints will not be used

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		(i) All materials used should be identified and MSDS sheets printed out

Assembling and Testing Phase				
What *parameter is to be monitored?*	Where *is the parameter to be monitored?*	How *is the parameter to be monitored (what should be measured and how)?*	When *is the parameter to be monitored (timing and frequency)?*	By Whom *is the parameter to be monitored– (responsibility)?*
1.				
2.				
…				

10.7 ANNEX G: EXCERPTS ON LAW ON CHEMICALS (OG 18/13)

Dangerous chemicals are defined according to the Article 3.

Article 3.

For the purpose of this Act, the following definitions apply:

1. Chemicals are substances or mixtures.
2. Dangerous chemicals in terms of this Act are:
   a) substances and preparations which meet the criteria for physical hazards, health hazards or environmental laid down in Directive 67/548 / EEC and Directive 1999/45 / EC,
   b) substances and mixtures meeting the criteria for physical hazards, health hazards or environmental established in the second to fifth part of Annex I to Regulation (EC) No. 1272/2008.

More specifically, the Directive 1999/45/EC defines substances and preparations as dangerous if they are: explosive, oxidising, extremely or highly flammable, very toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction or dangerous for the environment. A preparation should be considered dangerous if the dangerous component reaches a certain percentage. The classification of dangerous preparations according to the degree and specific nature of the hazards involved shall be based on the definitions of categories of danger laid down in the directive. Evaluation of the hazards shall be carried out in accordance with the methods stated in the Annexes.

The following are 'dangerous' within the meaning of this Directive:

(a) explosive substances and preparations: solid, liquid, pasty or gelatinous substances and preparations which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which, under defined test conditions, detonate, quickly deflagrate or upon heating explode when partially confined;

(b) oxidising substances and preparations: substances and preparations which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances;

(c) extremely flammable substances and preparations: liquid substances and preparations having an extremely low flash-point and a low boiling-point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure;

(d) highly flammable substances and preparations:

— substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, or

— solid substances and preparations which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, or

— liquid substances and preparations having a very low flash-point, or

— substances and preparations which, in contact with water or damp air, evolve extremely flammable gases in dangerous quantities;

(e) flammable substances and preparations: liquid substances and preparations having a low flash-point;

(f) very toxic substances and preparations: substances and preparations which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(g) toxic substances and preparations: substances and preparations which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(h) harmful substances and preparations: substances and preparations which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin;

(i) corrosive substances and preparations: substances and preparations which may, on contact with living tissues, destroy them;

(j) irritant substances and preparations: non-corrosive substances and preparations which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation;

(k) sensitising substances and preparations: substances and preparations which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitisation such that on further exposure to the substance of preparation, characteristic adverse effects are produced;

(l) carcinogenic substances and preparations: substances or preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence;

(m) mutagenic substances and preparations: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence;

(n) substances and preparations which are toxic for reproduction: substances and preparations which, if they are inhaled or ingested or if they penetrate the skin, may produce, or increase the incidence of, non-heritable adverse effects in the progeny and/or an impairment of male or female reproductive functions or capacity;

(o) substances and preparations which are dangerous for the environment: substances and preparations which, were they to enter the environment, would or could present an immediate or delayed danger for one or more components of the environment.

10.8 ANNEX H: REGULATION ON EIA (OG 61/14)

ANNEX 2

LIST OF PROJECTS FOR EVALUATION OF THE NEED FOR ASSESSMENT OF ENVIRONMENTAL IMPACT, UNDER THE AUTHORITY OF THE MINISTRY [2]

INTERVENTION

1. Agriculture, forestry and aquaculture

1.1 Water management projects for agriculture, including irrigation and drainage where the surface of 2000 ha of irrigation and more, and in the catchment area of 300 ha and more

1.2 Installations for the intensive rearing of pigs with more than:

- 1 000 places for production pigs (over 30 kg)
- 500 places for sows

1.3 Marine farms:

- Fish farms in the protected coastal area (PCA) annual production of less than 100 t

1.4 Freshwater ponds:

- For salmonids annual production 10 t or more
- For cyprinids pond area of 100 ha and more

2. Energy (unless included in Annex I)

2.1. Installations for the production of electricity, steam and hot water capacity greater than 10 MW el using:

- solid and fossil fuels
- Renewable energy sources (excluding water and wind)

2.2. Hydroelectric powerplants

2.3. Wind powerplants

2.4. Solar powerplants as detached instalations

2.5. Pipelines for the transport of oil, gas (high lines), steam and hot water 10 km or more

2.6. Power transmission overhead lines of 110 kV and above that are part of the transmission network

2.7. Surface storage of natural gas and other fossil fuel capacity of 5,000 m^3 and more

2.8. Underground storage of combustible gases with a capacity of 5,000 m^3 and more

2.9. Industrial briquetting of coal and lignite

2.10. Biofuel production capacity of 20,000 t / yr or more

3. Production and processing of metals (unless included in Annex I)

3.1. Plants for metal processing capacity of 500 kg / h of raw materials:

- Hot rolling mill (rolling mills)

- Smithies with one or more hammers

- Installations for application of protective fused metal coatings

3.2. Metal foundry

3.3. Installations for the melting of nonferrous metals and alloys excluding precious metals

3.4. Installations for surface treatment of metals and plastic materials using an electrolytic or chemical process

3.5. Installations for the production of motor vehicles (manufacture, assembly, production engine)

3.6. Shipyards

3.7. Installations for the construction and repair of aircraft

3.8. Installations for the production of railway equipment

3.9. Installations for metal using explosives

3.10. Plants for preparation, enrichment, roasting and sintering of metallic ores

4. Industrial processing of mineral raw materials (unless included in Annex I)

4.1. Plants for dry distillation of coal

4.2. Installations for the production of cement clinker cement and lime

4.3. Installations for the manufacture of glass and glass fiber, including production of glass processing scrap glass

4.4. Installations for melting mineral substances including the production of mineral fibers

4.5. Production of ceramic and clay products

5. Chemical industry (unless included in Annex I)

5.1. Processing (processing) of intermediate products and production of chemicals capacity of 10,000 t / yr or more

5.2. Production:

- Pesticides

- Pharmaceutical Products
- Paint and varnish
- Peroxide

5.3. Storage facilities for petroleum, petrochemical and chemical products with a capacity of 10,000 t or more

6. Food industry (unless included in Annex I)

6.1. Installations for the production and processing of oils and fats of vegetable or animal origin
6.2. Installations for the production, processing (canning) and packing of vegetable or animal origin capacity of 1 t / day or more
6.3. Treatment and milk processing capacity of 1 t / day or more
6.4. Installations for the production of malt and yeast
6.5. Installations for the production of candy and syrup capacity of 5 tons / yr or more
6.6. Installations for the production of industrial starch
6.7. Installations for the production of fishmeal and fish oil
6.8. Plant for the production or refining of sugar
6.9. Installations for the production of alcoholic and non-alcoholic beverages capacity of 2,000,000 liters / year and more
6.10. Installations for the production of tobacco products

7. Textile, leather, wood and paper industry (unless included in Annex I)

7.1. Installations for the production of paper and cardboard
7.2. Plants for the treatment of textile fibers
7.3. Installations for the production and processing of cellulose
7.4. Treatment and processing of hides and skins

8. Rubber industry (unless included in Annex I)

8.1. Installations for the production and processing of rubber and rubber

9. Infrastructure projects (unless included in Annex I)

9.1. Urban development projects, including
- Shopping malls and gross building area of 50,000 m2 and more
- Sports and leisure centers of 10 hectares or more
9.2. Industrial zones with area of 5 ha and more
9.3. Railway lines (except for urban and suburban) longer than 10 km and railway terminals for intermodal loading and unloading of cargo
9.4. Airfields
9.5. Dams and other installations designed to hold water or store it with a new or additional amount of water retained or accumulated more than 1,000,000 m3
9.6. Intercity and international aqueducts
9.7. Groundwater abstraction or artificial groundwater recharge
9.8. Works for the transfer of water between the basin (river basins)
9.9. Sea ports with more than 100 berths
9.10. All projects including silting of sea coast, deepening and draining the seabed and sea constructions length of 50 m and more

10. Other projects (unless included in Annex I)

10.1. Exploitation of sand and construction sand from renewable sources
10.2. Exploitation of mineral and thermal waters used for medicinal, balneological and recreational purposes
10.3. Exploitation of mineral and geothermal waters from which accumulated heat can be utilized for energy purposes
10.4. Plants for waste water treatment with associated drainage system

10.5. Plant and equipment for testing engines, turbines and reactors
10.6. Installations for the destruction of explosive substances
10.7. Installations for the production of mineral fibers
10.8. All planned projects in the area of waste management for which is necessary to obtain an environmental permit under a special regulation
10.9. Rehabilitation and reconstruction of landfills
10.10. Facilities for the storage of scrap iron, not included in point 10.8.
11.11. Facilities for storage of scrap cars, not included in point 10.8.

11. Tourism and leisure (unless included in Annex I)

11.1. Tourist zone of 15 ha or more outside the construction zone

12. Urban development projects and other projects for which the developer requests the need assessment for EIA due to international financing.

13. Changes to the projects listed in Annex I and II that could have a significant negative impact on the environment, with a significant negative impact on the environment at the developer's request to the Ministry, and in the assessment of the need for EIA.

14. Reconstruction of the existing plant and equipment for which they are establishing integrated environmental protection requirements that could have a significant negative impact on the environment, with a significant negative impact on the environment at the request of the developer, by the Ministry and in the assessment of the need for EIA.

ANNEX III

LIST OF PROJECTS TO EVALUATION OF THE NEED FOR IMPACT ASSESSMENT ON ENVIRONMENT AND FOR WHICH IS COMPETENT ADMINISTRATIVE AUTHORITY IN THE COUNTY OR CITY OF ZAGREB

INTERVENTION

1. Agriculture, forestry and aquaculture (unless included in Annex I and II.)

1.1. Restoring rural area of 10 ha and more
1.2. The use of uncultivated land or semi-natural areas for intensive agricultural area of 10 ha and more
1.3. Initial forestation for purposes of conversion of land area of 50 ha and more
1.4. Clearing of forests for conversion of the land area of 10 ha and more
1.5. Installations for the intensive rearing of poultry capacity of 30 000 units or more per production cycle
1.6. Installations for the intensive rearing of cattle and other animals of more than 500 heads (which does not include facilities for pigs and poultry)
1.7. Freshwater ponds:
- For salmonids annual production exceeding 5 t
- For cyprinids surface area exceeding 50 ha

2. Infrastructure projects (unless included in Annex I and II.)

2.1. The parking areas as independent projects 2 acres and larger
2.2. Canals, dykes and other structures for protection from flooding and coastal erosion
2.3. Tramways, elevated and underground railways, suspended lines, used for the transport of passengers:
- Urban - 10 km and more
- Suburban - length of 15 km and more

3. Other projects (unless included in Annex I and II.)

3.1. Asphalt nominal capacity of 100 tons / hour or more, except for temporary installations
3.2. Batching plants nominal capacity of 30 m^3 / hour or more, except for temporary installations
3.3. Racetrack for motor vehicles and test tracks for motorized vehicles surface of 1 ha or more
3.4. Slaughter houses for animals daily capacity of 50 unit and more

4. Tourism and leisure (unless included in Annex I and II.)

4.1. Ski runs, lifts and elevators and similar structures with accompanying buildings area of 1 ha or more
4.2. Amusement Parks area of 5 ha and more

5. Changes to the projects listed in this Annex, which could have a significant negative impact on the environment, with a significant negative impact on the environment by request of the developer, by the competent administrative body in the county or in the City of Zagreb, and in the assessment of the need for environmental impact assessment.

10.9 ANNEX I: EXCPERTS FROM THE ANIMAL PROTECTION ACT (OG 135/06, 37/13, 125/13)

Animal Protection of animals used for scientific research

Article 20

(1) Breeders, suppliers and users must apply for issuing a decision on the approval of breeders, suppliers and users before starting to perform activities of breeding, procurement and use of experimental animals to the competent authority.

(2) The competent authority shall issue a decision on the approval if the breeder, supplier or user meets the statutory requirements for premises, facilities, equipment, devices, competence of staff, provision of animal health care and care of animals, removal of animal by-products not intended for human consumption and if provide expert for the benefit of experimental animals.

(3) Breeders, suppliers and users must provide suitable accommodation and care of experimental animals, proper marking and identification of experimental animals, keeping records and reporting to the competent authority.

(4) Breeders, suppliers and users must establish a committee for the welfare of animals, whose task is to advise staff in relation to animal welfare, the acquisition and use of animals and implementation of the 3Rs principles. Tips, opinions and decisions must be taken in writing and kept for at least three years.

(5) Breeders, suppliers and users have to appoint a veterinarian or the person responsible for animal welfare, and users have to appoint a scientific member into the committee for animal welfare.

(6) For each significant change in the structure or function of the object, which can adversely affect animal welfare, breeder, supplier or user must apply to the Authority for the adoption of the decision approving such a change.

(7) If in the course of inspection and official controls (hereinafter: inspection) determines that the breeder, supplier or user no longer meets the conditions, the veterinary inspector will determine the terms for the removal of irregularities in accordance with Article 64 of this Act. If found irregularities endanger the welfare of animals veterinary inspector will prohibit the operation of breeder, supplier or user until the removal of irregularities.

(8) If a breeder, supplier or user in a specified period do not remove the established irregularities referred to in paragraph 7 of this Article, the competent authority shall revoke the decision referred to in paragraph 2 of this Article.

(9) For the activity's prohibition duration of and after the abolition of the decision referred to in paragraph 8 above, breeder, supplier or user has at his own expense to ensure animal welfare.

(10) The form and content of the application and detailed provisions on the procedure for issuance and cancellation of paragraphs 2 and 6 of this Article, the frequency and scope of inspections and archiving the results of inspections prescribes the Minister by ordinance.

Article 21

(1) The experiment can be carried out only by a user who has been granted in accordance with Article 20 of this Act and whose project was approved by the competent authority.

(2) Prior to conducting the experiment, the user has to submit an application for approval of the project to appropriate authority.

(3) With the application referred to in paragraph 2 of this Article, the user has to submit the Commission's for Animal Welfare opinion under Article 20, paragraph 4 of this Act.

(4) The decision of the project approval is brought by the competent authority on the basis of prior assessment of the project and the Ethics Committee's opinions referred to in Article 34 of this Act.

(5) The competent authority issues the permit for the project within 40 working days of receipt of a complete application. When justified due to the complexity and multi-disciplinary nature of the project, the deadline may be extended for an additional 15 working days, which is the competent authority previously inform the applicant.

(6) The project's approval decision shall determine following information: name and surname or name and address of user, the name and surname of the person responsible for implementing the project and its compliance with the approved project, the name of the Head of the experiment, the location of the project, special conditions under which it was allowed to conduct the experiment and whether it is necessary to conduct a retrospective assessment of the project, and if so, when.

(7) The project approval is issued for a limited period with respect to the purpose of the project, for a maximum of five years.

(8) For multiple generic projects carried out by the same user and that are implemented to meet the requirements of certain specific regulations, production of biological preparations or for diagnostic purposes according to established methods shall be issued for a project approval.

(9) Retroactive project assessment is carried out by the competent authority on the basis of documentation and user reviews of the Ethics Committee.

(10) The form and content of the application referred to in paragraph 2 of this Article, the basic components containing opinion of the committee for the welfare of the animals referred to in paragraph 3 of this Article, the assessment procedure and the retrospective assessment of the project and detailed provisions on the procedure of issuing the decision referred to in paragraph 4 of this Article , the content of the documentation referred to in paragraph 9 of this Article shall be prescribed by the Minister by ordinance.

Article 22

1) The user must:

1. carry out experiments in accordance with the project approving decision,

2. ensure that the test animals after the end of the experiment are treated or humanely killed if it is necessary for the welfare of animals,

3. prevent the death of experimental animals as the final result of the experiment if possible and replace it with a premature killing experimental animals,

4. ensure that the experimental animals that had already been used in one or more trials used in the new experiment only with respect to the prescribed conditions, in particular in relation to the weight of previous experiments and new experiments and state of health of experimental animals,

5. provide the Authority with an annual report on the experiments conducted,

6. keep documentation of experiments at least five years.

(2) The user must submit a request to the competent authority for approval of any changes to the project that may have a negative impact on the welfare of animals on which the competent authority shall issue a decision.

3) The competent authority revokes the project approval decision if the user is implementing a project in contradiction with the approval and thus jeopardizes the welfare of the animals or if he acts contrary to Article 24 of this Act. If found irregularities do not compromise animal welfare, veterinary inspector will determine terms for their removal in accordance with Article 64 of this Act. If the user within a specified period does not remove the irregularities, the competent authority shall repeal his decision approving the project.

(4) The user can re-apply for approval of the project only after the expiry of three months from the enforceability of the project termination decision.

Article 25

(1) A legal or natural person cannot use isolated organs, tissues and dead animals are killed for scientific or educational purposes without competent body approving their work on isolated organs, tissues and carcasses of animals for scientific or educational purposes.

(2) The competent authority shall issue a decision on the approval if the legal or natural person referred to in paragraph 1 of this Article shall meet the prescribed requirements for facilities, equipment and aids, training and competence of staff and removal of animal by-products not intended for human consumption.

(3) The beneficiary referred to in Article 20, paragraph 1 hereof shall be deemed approved and for work on isolated organs, tissues and carcasses of animals for scientific or educational purposes.

(4) A legal or natural person referred to in paragraph 1 of this Article shall ensure that suitable accommodation and care of experimental animals, proper marking and identification of animals used for experimental and keeping proper records.

(5) For the purposes of proceedings under this Article, only laboratory animals may be used. However, the competent authority may at the request of the legal or natural persons

referred to in paragraph 1 of this Article, based on scientific data and opinions of the Ethics Committee referred to in Article 34 of this Act, approve the use of other types of animals.

(6) Without prejudice to the provisions of paragraph 5 of this Article, the use of animals of strictly protected and endangered species taken from nature to work on isolated tissues, organs and carcasses for that purpose killed animals is not allowed.

Article 26

(1) The legal or natural person who grows, acquires or uses animals for the production of biological preparations to appropriately apply the provisions of Articles 20 to 24 of this Act.

(2) Before using animals for the production of biological preparations legal or natural person must apply to the competent authority for issuing a decision on the approval of the use of animals for the production of biological preparations.

(3) The competent authority shall issue a decision on the approval of the use of animals for the production of biological preparations based on prior assessment of the project and the opinions of the Ethics Committee referred to in Article 34 of this Act.

(4) The Authority may revoke the decision referred to in paragraph 3 of this Article under the conditions laid down in Article 22, paragraph 3 of this Act.

Examination required to work with animals used for experimental purposes

Article 32

(1) Experiments on animals and procedures in the production of biological preparations may be carried out by veterinarians, medical doctors, pharmaceutical chemists, medical biochemists, doctors of dental medicine, experts in animal husbandry or biologists, provided they have passed the examination required to work with animals used for experimental purposes.

(2) Surgical operations on animals during an experiment or in the production of biological preparations may be carried out by veterinarians, medical doctors, pharmaceutical chemists, medical biochemists, doctors of dental medicine, experts in animal husbandry or biologists, provided they have passed the examination referred to in paragraph 1 of this Article.

(3) Notwithstanding paragraph 2 of this Article, surgical procedures during the test may be carried out by medical doctors, pharmaceutical chemists, medical biochemists, doctors of dental medicine, experts in animal husbandry or biologists on laboratory animals: mouse, rat, guinea pig, hamster golden, Chinese hamster, Mongolian jumper , frog and zebrafish, if they have passed the examination referred to in paragraph 1 of this Article.

(4) In the case of a surgical procedure referred to in paragraph 3 of this Article not implemented by veterinarian, the person responsible for the protection of animals has to be a veterinarian.

(5) The examination program referred to in paragraph 1 of this Article shall be prescribed by a ministerial regulation.

Article 32 a

Terms for premises, facilities, equipment, devices, competence of staff, ensuring animal health care and animal care, removal of animal by-products not intended for human consumption, the welfare of experimental animals, the method of cultivation, possession, acquisition and use of experimental animals, a list of laboratory animals , way of dealing with animals during anesthesia, commitment and criteria for the classification of experiments with regard to their weight, way of killing animals, the form, content and manner of keeping proper records, content and storage time documentation of experiments, a way of informing the competent authorities, prescribes the Minister by an ordinance.

Article 33

(1) The staff of legal or natural persons referred to in Article 20, paragraph 1, Article 25 paragraph 1 and Article 26 paragraph 1 of this Act shall be trained for conducting experiments on animals, design of experiments and projects, taking care of the animals and killing of animals in accordance with the duties performed.

(2) The training referred to in paragraph 1 of this Article shall be carried out according to the program prescribed by the Minister by ordinance.

10.10 ANNEX J: MINUTES OF PUBLIC CONSULTATION

To be added.