REPUBLIC OF CROATIA

MINISTRY OF SCIENCE, EDUCATION AND SPORTS

IBRD LOAN NO 8258-HR

Second Science and Technology Project

ANNEX 3 TO THE PROJECT OPERATIONAL MANUAL

ENVIRONMENTAL MANAGEMENT FRAMEWORK

Zagreb, April 2016

Contents

ENVIRONMENTAL REVIEW PROCEDURES

Background

This section of the project Operation Manual presents the Environmental Management Framework that serves as a tool to screen the sub projects financed and based on the screening guides on the environmental due diligence procedures.

All sub-loans/grants to be provided under the STPII and project preparation should be subjected by Project Beneficiaries to an environmental review process incorporating the procedures described in this section. The Project Beneficiaries – HAMAG-BICRO, CSF(UKF) and MSES, should use these procedures in reviewing and appraising sub-borrowers/sub-projects, and to inform Sub-Borrowers of environmental requirements for 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.

Two types of sub-loans/projects will be considered under the project: (a) technical assistance – preparation of documentation for financing, and (b) sub project investment.

The procedures essentially consist of Environmental Screening, Environmental Assessment, and Environmental Mitigation where necessary. The Environmental Screening will be carried out by the respective Project Beneficiary (PB) at an early stage in their sub-loan review procedures to determine the appropriate environmental risk category for the sub-borrowers/sub-projects, and may require the contracting of external expertise. Following screening, an Environmental Assessment (EA) in line with the environmental classification of the sub-borrower/sub-project will be recommended. The sub-borrowers will be responsible for carrying out any environmental assessment and for confirming that the proposed sub-projects comply with national environmental guidelines, and for obtaining the necessary clearance from the appropriate licensing authorities. Once the analysis is performed and recommendations incorporated into the sub-project, the respective Project Beneficiary will appraise the proposed sub-loan package which would include, where appropriate, an environmental management plan. The implementation of the environmental management plan will be monitored by the PB. The overall review process will be monitored by the Project Implementation Unit (PIU). The environmental screening process and responsibilities of key parties are described in detail below.

The project and the components

Project description

While continuing the dual approach of the STP, combining technical assistance to the public sector and financing of risk-sharing programs supporting R&D in SMEs (sub-financing), STP II will use these instruments with a focus on preparing Croatia for efficient absorption of EU funds for R&D by: (A) capacitating the public sector to absorb structural funds, including the preparation of a pipeline of structural funds project applications ; and (B) maintaining and increasing the pool of SMEs that could apply to the upcoming EU funded risk-sharing programs. The funds targeted will be available under three key facilities: (i) European Regional Development Fund (ERDF); (ii) European Social Fund (ESF); and (iii) EU's HORIZON 2020 – the Framework Program for Research and Innovation.

Key Components

Component A: **Technical Assistance** (EUR 6.0 million)

Croatia's institutional framework for R&D and innovation is still to be made fully consistent with EU requirements for use of upcoming structural funds and a number of preparatory improvements will be necessary to fully prepare the country to absorb available resources. The first component of the proposed STP II therefore

aims to build capacity in the public sector to ensure absorption of structural funds, including preparation of a pipeline of project applications by the public sector.

A.1. Improving management of national resources of research, development and innovation (2.0 M EUR). This activity will:

i. assist the Government in the formation of a national Science and Technology Strategy in Croatia that sets the framework for R&D and innovation policies, in conformity with the Europe 2020 Strategy, in order to enable the efficient absorption of EU structural funds and avoid delays in project submission and approval;

ii. support the preparation of a Research Infrastructure Roadmap, deepening the overall Science and Technology Strategy in the area of research infrastructure and making it coherent with the European Research Infrastructure Roadmap;

iii. provide technical support for capacity building in selected institutions in order to strengthen the governance of the country's National Innovation System;

iv. support the strategic planning, financial management, and preparation of performance-based contracts between MSES and Public Research Institutes, in line with the objectives of the draft Science Law;

v. enhance governmental and institutional support to increase the absorption capacity for EU's– the Framework Program for Research and Innovation[1] HORIZON 2020, particularly by nurturing young researchers and integration to the international scientific community;

vi. support the development of a proper institutional framework for UKF programs, taking into account UKF's other similar existing programs and institutions (strengthening UKF-type programs will be essential to the increase competitiveness and performance in FP7); and adjusting the UKF grant schemes to be nominated for financing from the ESF; as well as

vii. assist in building capacity of MSES and HAMAG-BICRO to adjust its operational procedures and programs to structural funds (ERDF).

viii. finance related costs of operating the PIU, including staff, financial management, audits, equipment, training and technical assistance

A.2. Preparation of R&D infrastructure projects for EU structural funds (4.0 M EUR). Consistent with the envisaged Science and Technology Strategy and the Research Infrastructure Roadmap, this component will finance training for preparation, along with the full preparation of selected projects, including feasibility studies, cost-benefit analysis and technical documentation. Infrastructure projects will be selected in close consultation with MSES.

Component B: <u>Sub-financing</u> (EUR 14.0 million)

This component will maintain and increase the pool of SMEs that could apply to the upcoming EU funded risk-sharing programs, ensuring the existence of a sound pipeline of private projects. In addition, it will continue to support connections with the Diaspora and target research activities among young scientists that are contributing to expand Croatia's participation in the EU FP7 and follow up programs. The specific activities under this component are listed below.

B.1. Maintain and expand the pool of SMEs eligible for EU funded risk-sharing programs *(10.0 M EUR).*

<u>HAMAG-BICRO</u> would continue having the role of upgrading the innovation and technological capabilities of SMEs by providing financial support for technology-based companies, R&D centers and incubators and fostering links between the R&D community and industry. Financial support is provided through a mix of financial instruments, including matching grants, loans and equity investments. In

[1]New name for the EU funding program for research and innovation to follow after the completion of the FP7.

addition, the Ministry of Science, Education and Sports (MSES) delegated implementation of the European-wide EUREKA program to HAMAG-BICRO – a Europe-wide program dedicated to supporting research-performing SMEs in international collaboration. STP II would support the development of three of HAMAG-BICRO's programs: Component I, II I III of the Innovation Process Support Framework. Some funds will be reserved for a running pilot of programs under the structural fund guidelines.

- The objective of the Component II (former Program RAZUM) is to support the development of knowledge-based SMEs through conditional loans covering up to 70 percent of new product development costs. STP II contribution would focus on ensuring a sustainable increase in the number of knowledge-based technology-driven SMEs, by financing additional 10-15 companies (out of estimated 80-100 applications), while further developing procedures and visibility.

- Component III (former Program IRCRO) has the main objective to support industrial companies to substantially increase their R&D activities and create demand for services from scientific research institutions. At the same time, maximum usage of infrastructure in scientific research centers is stimulated, supporting collaboration with SMEs. Funding is provided to SMEs on the basis of 50:50 matching grants. As part of STP II, the program would finance roughly an additional 15 projects (out of estimated 100-120 applications).

- Key objectives of the Component I (former Program PoC) are to provide innovative companies and researchers an opportunity to verify and validate commercial viability of research results and establish an appropriate strategy for continued commercialization. The program is administered by Recognized centers with which HAMAG-BICRO signed an Agreement on Rights and Obligations to Program Implementation. HAMAG-BICRO in cooperation with Recognized centers provides grants on a competitive basis: for the entrepreneurs up to 70 percent and for the scientists and researchers up to 90 percent of total project costs, supporting external expenditures on pre-commercialization proof of concept activities. As part of STP II, the Proof of Concept program will further develop its procedures and visibility, while financing additional 100-110 projects (out of estimated 500 applications).

- The objective of the Program to Support Technology Transfer Offices (TTO program) is to strengthen the role of technology transfer offices (TTO) in universities and public research institutes in Croatia as focal points for the promotion and implementation of the technology transfer activities. The specific objective of the program is to encourage the commercialization of existing stocks of the projects of listed TTO's. The program provides for the award of grants - amounting to between 10 000 and 75 000 EUR - for the implementation of projects of technology transfer. The program is funded 100% of the eligible project costs and duration of the projects is limited to 18 months

B.2. Strengthening human resources, research excellence and commercialization (4.0 M EUR).

The Unity through Knowledge Fund within Croatian Science Foundation / (CSF/UKF) has as objectives to strengthen research collaboration between Croatian scientists in the country and the international community, in particular Diaspora, through provision of grants for joint scientific projects, as well as through targeting research activities among young scientists. The impact of the program on research excellence may be inferred from a rate of approval of CSF/UKF supported programs in EU FP7 (Seventh Framework Program) twice as large as those Croatian projects not supported by the program.

IV.1 Safeguard Policies That Might Apply

Environmental Category B, with B and C subprojects would be applied.

OP/BP 4.01, (Environmental Assessment) is triggered. An overall EMF will be prepared, following World Bank policies on consultation and disclosure, in advance of appraisal. EAs/EMPs would be prepared for the sub-projects to be financed that would be classed as category B.

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

IV.2 Environmental Screening Categories

Environmental Screening is the first step in the environmental due diligence process of reviewing the sub-loan application.

In the STP two distinctive types of applications will be provided:

a) Applications for technical assistance, i.e. preparation of documents for future financing by EU funds (see component A); and

b) Applications for sub projects directly financed by the project (see component B)

The purpose of environmental screening is to determine the environment 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.

a) Applications for technical assistance

These applications will 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 EU financing.

b) Applications for sub projects directly financed by the project

Results of the Environmental Screening shall be reflected in the Environmental Category Form (Annex B), completed by PBs and submitted to PIU and the sub-borrower. Through the Environmental Screening Form (Annex A), the sub-borrower will provide sufficient information for PB 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 radioactive tracing materials, animal testing and use of cancerogenic and mutagenic substances. In form provided in annex B, PB and PIU will request additional information if needed.

The following examples of sub-borrowers/sub-projects and their suggested categorization are indicative only and will need to be reviewed throughout STP II implementation 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-borrowers/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 to the IBRD environmental specialist for further guidance.

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.

For the purpose of the project in licensed research laboratories, the use small amount of radioactive trace materials will be allowed for use following the due diligence described.

Category A activities which will not be financed through the 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.

Category B+ activities which may be financed through the sub-lending scheme, subject to positive EIA conclusion by the Ministry of Enivironmental 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 sub-borrower. The costs of the mitigation measures would be included in the EIA / EMP and incorporated in the tendering documentation if applicable. The EMP checklist (see annex E) would be prepared for all physical investments (rehanilitation, refurbishing, etc) on existing buildings and full EMPs for all construction of buildings or any infrastructure not included in Annex 2 or 3 of the national EIA regulation. If PB determines that it is not easy to classify the project, it will advise PIU and the Bank. The environmental due diligence documents would as well describe and assess testing phase of the product if applicable.

Category B- activities which may be financed through the sub-lending scheme (EA report and EMPs required)

This category includes sub-projects which may have intermediate levels of regular and accidental emissions and will generally be applicable for all projects including assembling.

The examples are:

a) All construction of facilities or infrastructure, which are not included in Annex 2 or 3 of national legislation concerning the assessment of the environmental impact for which it is necessary to prepare an Environmental Management Plan (EMP)
b) All physical investments (upgrading and rehabilitation) on the existing facilities for which EMP checklist
c) All projects involving assembling for which EMP for materials will be prepared. This plan includes identification of materials and processes used (mechanical, chemical, etc), and good laboratory and engineering practices. The checklist should be accompanied with MSDS (Material safety data sheets) for all identified materials used. The environmental due diligence documents would as well describe and assess testing phase if applicable.

If the radioactive trace material will be used for medical or pharmaceutical research for example, or cancerogenic, mutagenic and teratogenic, the handling practices will be in detail explained 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.

Category C activities which may be financed through the 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.

IV.3 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 purpose of the EA 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 Environmental Assessment will depend on the environmental category attached to each sub-project, though the purpose of any type of assessment is to identify ways of environmental improving the proposed activities by minimizing, mitigating, or compensating for their adverse impacts. An Environmental Management Plan 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. EAs identify ways of improving sub-projects environmentally by minimizing, mitigating or compensating for adverse impacts. An EA would also describe the steps that were taken for public consultation.

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 and positive opinion given by the MENP. The EIA will be prepared according to national regulation and will undergo national approval system. In addition to EIA the sub-borrower will prepare EMP. 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.

b) EMP will be prepared for category B + subprojects for all new buildings and infrastructure that is not covered in annex 2 or 3 of the National EIA regulation. 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. The document will be publically disclosed requesting written comments. Sample of the EMP checklist for rehabilitation is presented in annex E.

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

a) Material Environmental Management Plan Checklist (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 (Material safety data sheets) for all identified materials used. The environmental due diligence documents would as well describe and assess testing phase if applicable.

If the radioactive trace material will be used, or cancerogenic, mutagenic and teratogenic, the handling practices will be in detail explained 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 or any other environmental due diligence document required.

Handling sub projects that deal with biological and radiological hazards and those with ethical issues

Supporting projects in research might involve scientific, medical or pharmacological research that will deal with biological and radiological hazards (radiation trace materials) as well animal testing.

Biological agents represent potential for illness or injury due to single acute exposure or chronic repetitive exposure. Biological hazards can 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 F*

Radiation exposure can lead to potential discomfort, injury or serious illness to workers. Prevention and control strategies include:

- Places of work involving occupational and/or natural exposure to ionizing radiation should be established and operated in accordance with recognized international safety standards and guidelines.
- The acceptable effective dose limits are presented in the etable bellow

Exposure	Workers (min.19 years of age)	Apprentices and students (16-18 years of age)
Five consecutive year average – effective dose	20 mSv/year	
Single year exposure – effective dose	50 mSv/year	6 mSv/year
Equivalent dose to the lens of the eye	150 mSv/year	50 mSv/year
Equivalent dose to the extremities (hands, feet) or the skin	500 mSv/year	150 mSv/year

In the case of both ionizing and non-ionizing radiation, the preferred method for controlling exposure is shielding and limiting the radiation source

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 radiological trace agent use
- License for the use of the same
- Describe practices of handling such materials, especially disposal practices
- Describe procurement of the material
- Describe storing and handling practices
- All other defined by the Law on radiological and nuclear safety (Official Gazette 141/13) –

Any natural or legal person, government body or body of local and regional (regional) governments that in carrying out certain activities intended to use ionizing radiation sources must obtain prior authorization for work with sources of ionizing radiation. The approval for carrying out activities with sources of ionizing radiation gives the Director of the State Office for Radiological and Nuclear Safety. The procedure for obtaining authorization depends on the activity and the source of which is the performance of these activities is used.

The request for authorization for the performance of activities shall be submitted to the State Office for Radiological and Nuclear Safety on the appropriate form and shall be accompanied by all the necessary documents.

For carrying out activities with radioactive substances is not required to obtain prior authorization for work if one of the following conditions:

First total activity or activity concentration of radionuclides involved in the practice does not exceed the value determined by the Ordinance on the conditions and measures for protection against ionizing radiation for carrying out activities with radioactive sources (Official Gazette 141/13)

Second activity or radionuclide activity concentration in a radioactive substance does not exceed the value specified in the Regulations on the conditions and measures for protection against ionizing radiation for carrying out activities with radioactive sources (Official Gazette 141/13).

After the acquisition and application of ionizing radiation managed to plow, and prior to its use, the authorization holder or beneficiary must of the State Office for Radiation Protection to obtain a license for use of the same.

Permission for use, except in the case of open radioactive sources, the State Office for Radiation Protection issues involving ionizing radiation source, which is registered in a central register of sources of ionizing radiation.

The ethical issues faced by the pharmaceutical or biotechnology institutes are potentially complex and depend significantly on the activity of the institution. These issues may include the animal testing;

Recommended bioethics management approaches include:

- Well established ethics mechanisms including management commitment; dedicated internal ethics personnel; 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 Law on Animal Protection (Official Gazette 135/2006, *37/13, 125/13*) –

IV.4 Environmental Review Process (Role of PBs, PIUs and WB)

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 satisfying them 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 info follow-up requirements for sub-loan processing (for example on testing or use of radioactive trace materials).

STEP 3: The sub-borrower, or its consultants, submits the environmental due diligence document (if applicable). 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 judged to be satisfactory. In case where radioactive trace materials will used or cancerogenic, teratogenic or mutagenic substances, as well as animal testing conducted, the PB will advise PIU and WB on quality of the environmental due diligence document.

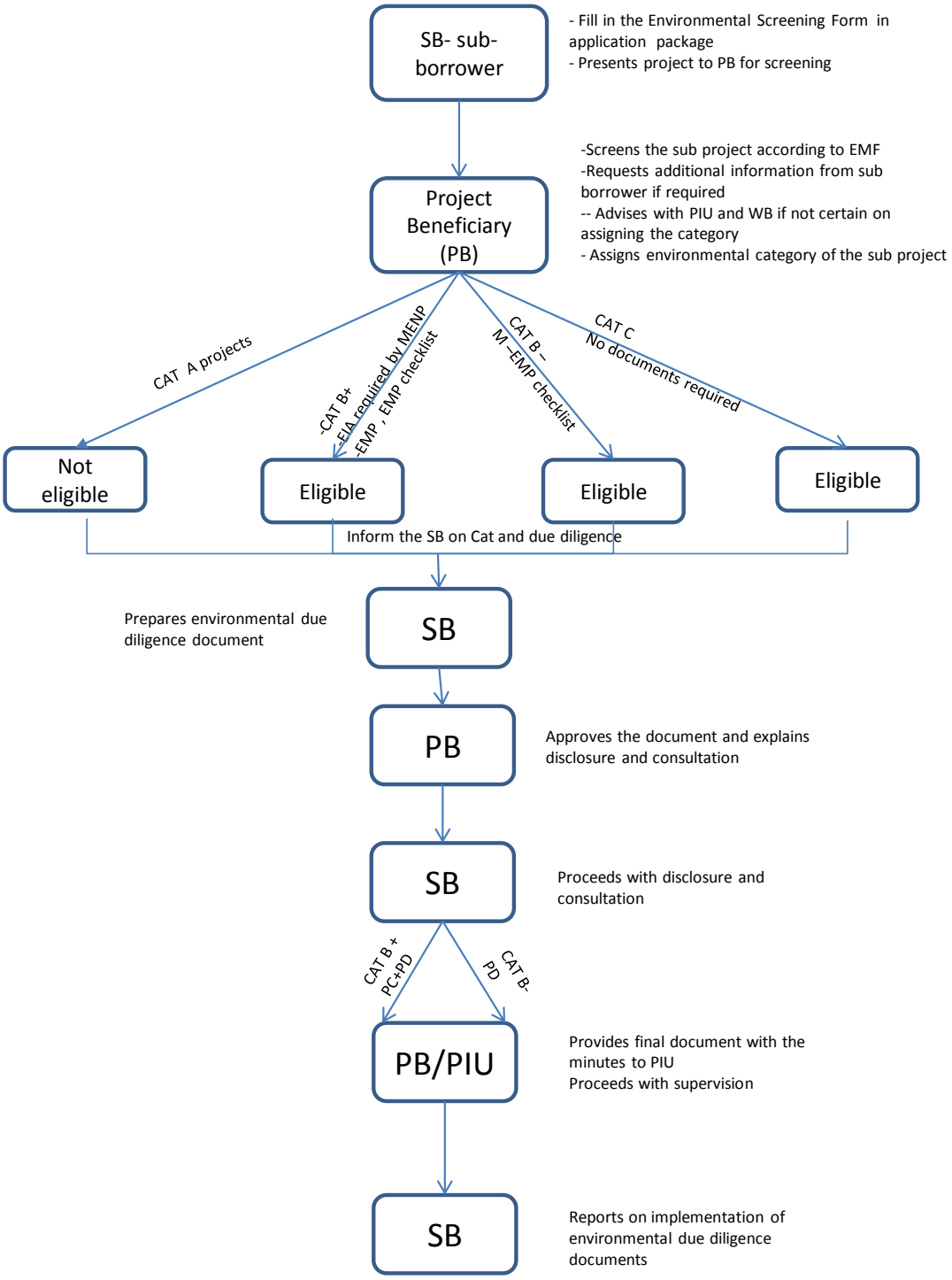
STEP 5: The sub-borrower incorporates the recommendations provided in the analysis into the sub-project design and implementation plan, including associated estimated costs.

STEP 6: The PB finalizes the 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.

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 B+ requiring full EIA and EMP, as well as those involving use of radioactive materials, mutagenic, teratogenic or cancerogenic substance and b) 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 STP II 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 diagram of the steps to follow is presented in the next pages as well as responsibilities of different parties.


SB- sub-borrower
- 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

Responsibilities of Key Participants

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
Participating Financial Institutions – Project Beneficiary (PBs)	• Finalize the environmental screening form, assign the environmental category • Review of sub-loan application package for required environmental documentation and licences/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

Annex A: Environmental Screening Form

PART 1: APPLICATION (filled by applicants)			
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 infrastructure?	**Yes** ☐ **No** ☐	
	Does it include assembling?	**Yes** ☐ **No** ☐	
	Does this sub project include software development or similar IT work?	**Yes** ☐ **No** ☐	
	Does the project include use of radioactive material?	**Yes** ☐ **No** ☐	
	• If so what and for what purposes?		
	• What quantities?		
	• What accreditation laboratory has for use of such materials?		
	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		

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 +				
	a)EIA if project included in annex 2 or 3 of the Regulation on EIA **b)EMP or EMP checklist**			
Category B -				
	Material EMP together with the necessary licenses and MSDSs			
Category C				
	No due diligence			
Additional explanation required				

Remark:

For projects there is an obligation of the public consultations, as follows:

For the project category C

- There is no obligation of reporting to the public

For project category B:

- Publication of documents, such as a checklist of materials, the website of final beneficiary or PB

- Printed version available upon request

- Consultation with stakeholders electronically on the basis of published documents, if necessary

For the project categories B +

- The public is involved in the process of assessing the environmental impact through the meeting for public debate, including a public presentation of the project

- The document has already been published on the website MENP / or if not, should publish a document on the website of the end beneficiary or application

- Releases to be available through the website

- Process for stakeholders so that they can submit comments should be established - via the website and through other means

Instructions about the consultation process and its publication will be additionally provided to project managers proposed for funding during the contracting process.

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 cofinanciers. 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 people 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).

Annex D: Template for Environmental Management Plan

1. 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.[1] 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 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.[2] More specifically, the EMP includes the following components.

Mitigation

2. 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

3. 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 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

4. 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.[3] 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 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)
2.1. DESCRIPTION OF THE ENVIRONMENT (BASELINE CONDITIONS)
    General description of project site environment
    Physical environment
    Socio-cultural environment
3. DETERMINATION OF THE POTENTIAL IMPACTS
3.1. POTENTIAL IMPACTS on ENVIRONMENT (related to the preconstruction, construction, operation and maintenance phase of project activities)
3.2. POTENTIAL IMPACTS on SOCIO-CULTURAL ENVIRONMENT (related to the preconstruction, construction, operation and maintenance phase of project activities)
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.				
…				

Annex E: EMP checklist for rehabilitation

CHECKLIST ENVIRONMENTAL MANAGEMENT PLAN (EMP)

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 beneficiary 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 Education Excellence and Equity Project will be conducted in three phases:

1) *General identification and scoping phase*, in which the objects (e.g. schools) 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 site specifically 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			
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 this sub project include software development or similar IT work?	**Yes** ☐	**No** ☐
	Does the project include use of radioactive material?	**Yes** ☐	**No** ☐
	• If so what and for what purposes?		
	• What quantities?		
	• What accreditation laboratory has for use of such materials?		
	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[2]	[ ] Yes [] No	See Section **E** below
	F. Hazardous or toxic materials[3]	[ ] 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) (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	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

[2] 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.

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

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
Construction Activities		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 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 finds" encountered in excavation or construction are noted, officials contacted, and works

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
		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 beneficiaries 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 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	Infrastructure for medical	(a) In compliance with national regulations the contractor will insure that newly constructed

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
PART 3 : MONITORING PLAN		

medical waste (not applicable)	waste management	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

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**							

Annex F: Material EMP checklist

MATERIAL EMP

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?[4]	

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

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

List of materials / chemicals that are going to be used	If possible assign CAS[5] number to material / chemicals[6]	According to the Law on chemicals is this material hazardous	Please assign category according to the Law on chemicals, Article 3 (Annex G)
		Y/N	

[5] Chemical Abstracts Service Number
[6] 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 (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.				
…				

Annex G: Excerpts on Law on Chemicals (Official Gazette 18/13):

Article 3

1. Chemicals are substances and mixtures.

2.. Dangerous chemicals are classified as the following chemicals:

a) substances and preparations which meet the criteria for physical hazards, health hazards or the environment 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 the environment identified in the 2 - 5 of Annex I to Regulation (EC) no. 1272/2008.

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3. EINECS (European Inventory of Existing Commercial Chemical Substances) is a European list of existing commercial materials containing a list of all substances on the market on 18 September 1981, and was released as a European list of existing substances (OJ C 146, 15. 6. 1990 ., p. 4, - 5).

4. CAS (Chemical Abstract Service) number is a characteristic number already discovered substances under international list Chemical Abstract Service.

5. ELINCS (European List of Notified Commercial Substances) is a European registry of new substances.

6. Production is production and processing, design, processing, filling, decanting, mixing chemicals in the intermediate and final products by chemical, physical or biological processes and procedures and the transfer and intermediate storage within the production sites. Production in this respect considers the production of substances and mixtures.

7 The producer is a legal or natural person, which produces chemical in accordance with paragraph 6 of this Article, as well as everyone else who was being worked out, repackage or change her name for further use. By changing the name is not considered translating terminology chemicals into Croatian.

8. The marketing of the import, entry, purchase and sale of chemicals in retail and wholesale, and conduct mediation. Marketing of chemicals is also considered delivering or making available chemicals to a third party for a fee or for free. Import is deemed to be placing on the market. Imports any introduction of chemicals into the customs territory of the European Union. The entry is any entry of chemicals on Croatian territory from other Member States of the European Union.

9. Exports each presenting chemicals outside the customs territory of the European Union.

10. The importer is the natural or legal person who at the time of import of the chemical in the European Union.

11. Exporter is a legal or natural person who at the activities of exported chemicals outside the European Union.

12. Utilization of the processing, formulation, consumption, storage, keeping, treatment, filling into containers, moving from one container to another, mixing, production or any other use. Storage in this respect is keeping chemicals under prescribed conditions.

13. The environment is a natural environment of organisms and their communities, including man, which allows their existence and their further development: air, water, soil, earth's crust, energy and material resources and cultural heritage as part of the environment that is created by man; all in its diversity and overall interaction.

14. Chemicals in common use substances and mixtures of different uses that are placed on the market, and do not know their ultimate purchaser or user, and the possibility of their purchase and use, and are not limited or quantity, or some specific requirements in relation to the end user and buyer.

Liability of legal and natural persons engaged in the production, placing on the market and use of chemicals

Article 5.

(1) (1) Legal and natural persons that produce, use or placing on the market of chemicals must provide instructions for safe handling of chemicals, and is mandatory in accordance with the general regulations on compensation for damages to compensate the damage caused by the production, placing on the market and use of chemicals.

(2) Legal and natural persons that produce, use or marketed chemicals must each user chemicals in the procurement of chemicals warn of its dangerous properties, and at his request he must submit and instructions on proper handling of chemicals and measures for the protection of health and the environment and is mandatory in accordance with the general regulations on compensation for damages to compensate the damage caused by the manufacture, use or marketing of chemicals.

(3) The scope, content and method of notification of chemicals referred to in paragraph 1 of this Article shall prescribe the minister responsible for health (hereinafter: Minister).

Responsibility of the beneficiary

Article 6.

Notwithstanding the provisions of Article 5 of this Act, all users must ensure that the handling of chemicals do not endanger their health and the health of other people and not to cause environmental damage..

Annex H: Excerpts from Law on radiological and nuclear safety (Official Gazette 141/2013 and 39/2015)

6. rofessional competence

Article 47

(1) Workers who handle ionizing radiation must have a special professional training for the handling of sources of ionizing radiation.

(2) Exposed workers and workers who handle ionizing radiation must have special education on the application of measures for protection against ionizing radiation.

(3) Education referred to in paragraph 2 of this Article on the application of radiological safety of exposed workers and workers who handle ionizing radiation is acquired in the course of regular education or additional education.

(4) Exposed workers and workers who handle ionizing radiation must periodically renew their knowledge about the application of measures for protection against ionizing radiation.

(5) Conditions, deadlines and manner of acquiring special professional education referred to in paragraph 1 of this Article, a special education referred to in paragraph 2 of this Article and renewal of knowledge on the application of radiological safety shall be prescribed by an ordinance issued by the director of the Institute

Requirements for premises and equipment

Article 32

(1) Property, plant and equipment where the sources of ionizing radiation or practices involving ionizing radiation, and / or activities referred to in Article 9, paragraph 5 of this Act, ionizing radiation sources, protective equipment and personal protective equipment located, must meet the requirements for ensuring radiation safety and protection of people and the environment from ionizing radiation and contamination from radioactive substances.

(2) The conditions referred to in paragraph 1 this Article shall be determined by ordinance adopted by the director of the National Institute of Radiological and Nuclear Safety,.

(3) The ordinance specifying the requirements for the design, construction, operation and decommissioning of buildings to house the sources of ionizing radiation or where practices involving ionizing radiation and / or activities referred to in Article 9, paragraph 5 of this Act, brings the Director of the Institute, in collaboration with the Minister responsible for construction, and in the part relating to the physical security and the minister responsible for internal affairs

Obligations of the holder

Article 33

The holder of a license for work with ionizing radiation or the holder of the authorization to conduct nuclear activities must ensure:

- Healt check of exposed workers and persons who are trained or educated for work with sources of ionizing radiation,and availability of data exposed workers on the results of monitoring

- Measuring personal doses of exposed workers and availability of data exposed workers on the results of monitoring,

- Education on the implementation of measures for protection against ionizing radiation for exposed workers,

- Education for operating sources of ionizing radiation for workers who handle ionizing radiation sources

- Review of ionizing radiation and working conditions and measurement of required elements,

- Quality assurance program and its implementation,

- Quality control,

- Personal protective equipment and equipment for exposed workers and checking the correctness of these equipment,

- Regular checking and calibration of measuring instruments;

- Checking the radioactive contamination of persons, objects, environment, facilities and air where sources of ionizing radiation are placed

- Adoption, and regular updating of compliance with the act on the establishment and implementation of radiological safety

- Adoption and regular updating of the risk analysis

- Adoption, regular renewal and act in accordance with the written work instructions for the area of exposure

- Informing exposed workers about health risks associated with the area of exposure.

Annex I: Excerpts from Animal Protection Act (Official Gazette 135/06, 37/13, 125/13)

Interventions on animals

Article 8

(1) The partial or total amputation of a sensitive part of the body of an animal shall be prohibited, including:

1. the marking of animals contrary to the provisions of special regulations,

2. ear cropping and tail docking in dogs, declawing of cats, devocalisation and other interventions aimed at changing the phyenotypic appearance of the animal.

(2) By way of derogation from the provision of paragraph 1 of this Article, the partial or total amputation or removal of a sensitive part of the body of an animal shall be permitted if performed with prior anaesthesia and post-operative analgesia and if an intervention:

1. is justified for animal health reasons,

2. is performed for the purpose of conducting experiments on animals,

3. is performed for the purpose of controlling the reproduction of animals.

(3) By way of derogation from the provision of paragraphs 1 and 2 of this Article, the partial or total amputation or removal of sensitive parts of the body of an animal shall be permitted if undertaken for zootechnical purposes including castration, if such intervention prevents pain, suffering and self-injury or injury to other animals, or for safety reasons, and in hunting dogs in compliance with specified kennel standards, with the use of analgesia, in cases to be determined by the Minister.

(4) Interventions likely to cause suffering or severe pain to an animal may only be performed after analgesia or anaesthesia and if post-operative care is provided.

(5) Anaesthesia shall not be used:

1. when the risks posed by anaesthesia would be disproportionate to its benefits,

2. during the marking of animals, unless necessary for the safety of the person carrying out the marking,

3. in certain diagnostic and therapeutic procedures in accordance with the rules of the profession,

4. when the pain caused by anaesthesia is greater than that caused by the intervention itself,

5. when it is incompatible with the results hoped to be achieved by the experiment.

Protection of animals at the time of humane killing

Article 9

(1) It is prohibited to kill animals contrary to the provisions of this Act.

(2) Special-purpose means and prescribed methods shall be used in the humane killing of animals.

(3) An animal may be humanely killed when:

1. medical treatment of the animal is likely to be long lasting and cause suffering, and the outcome of the treatment is uncertain,

2. the animal has reached an advanced age and its vital functions are failing,

3. the animal is suffering from an incurable disease,

4. such procedure is necessary because of the implementation of disease control measures in accordance with the veterinary legislation, in particular for those diseases that can threaten humans or cause great economic damage,

5. the animal constitutes a danger to the community,

6. the time period referred to in Article 57, paragraph 4 has elapsed, and in the case referred to in Article 55, paragraph 5 and Article 65, paragraph 2 of this Act,

7. it is done for the purpose of pest control,

8. the animal kept or bred for production purposes is sick or injured, and slaughter or humane killing under the veterinarian's supervision is not possible,

9. it is necessary for the purpose of performing an experiment on the animal or producing biological preparations or after the completion of the experiment or after using the animal for the production of biological preparations.

(4) In the cases referred to in paragraph 3, items 1 and 2 of this Article, the decision on whether to humanely kill an animal shall be taken by the owner of the animal, based on the opinion of a veterinarian and, in the cases referred to in items 3 to 9 of the same paragraph, by a veterinarian, with the exception of the case referred to in item 8 of the same paragraph in which the decision shall be taken by the owner of the animal.

(5) The humane killing of an animal may only be carried out by a veterinarian or qualified veterinary technician under the supervision of a veterinarian, except in the following cases:

1. the humane killing of animals bred or kept for production purposes,

2. the humane killing of animals for the purposes of teaching, conducting experiments or producing biological preparations,

3. pest control,

4. when it is necessary to humanely kill an animal without delay because it suffers severe and incurable pain.

5. an animal that suffers from severe and incurable pain must, without delay, have the animal humanely killed.

The protection of animals used in scientific purposes Article 20

(1) Breeders, suppliers and beneficiaries must before the commencement of the activities of breeding, procurement and use of laboratory animals to the competent authority to apply for the issuance of a decision on approval of breeders, suppliers and beneficiaries.

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

(3) The breeders, suppliers and beneficiaries must provide adequate housing and care of laboratory animals, proper marking and identification of experimental animals, keeping records and reporting to the competent authority.

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

(5) The breeders, suppliers and beneficiaries have to the Commission for Animal Welfare to appoint a veterinarian or the person responsible for animal welfare, and beneficiaries have to appoint a scientific article.

(6) For any significant change in the structure or function of the object, which can adversely affect animal welfare, breeder, supplier or beneficiary has to submit an application to the competent authority for issuing a decision approving such a change.

(7) If the course of the inspection and official controls (hereinafter: inspection) determines that the breeder, supplier or beneficiary no longer meets the conditions, the veterinarian will determine the terms for the removal of irregularities in accordance with Article 64 of this Act. If the irregularities threaten animal welfare veterinarian will breeder, supplier or beneficiary to prohibit the operation of removing irregularities.

(8) If the breeder, supplier or beneficiary in a certain period does not remove the 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) During the prohibition of activity and after the abolition of the decision referred to in paragraph 8 above, the breeder, supplier or beneficiary has at their own expense to ensure animal welfare.

(10) The form and content of the application and detailed provisions on the procedure of issuance and cancellation of the decision referred to in paragraphs 2 and 6 of this Article, the frequency and scope of inspections and keeping the results of inspections prescribed by the Minister by ordinance..

Article 21

(1) The experiment may be performed only by a beneficiary who has been granted in accordance with Article 20 of this Act and which the project was approved by the competent authority.

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

(3) The application referred to in paragraph 2 of this Article, the beneficiary must attach the opinion of the committee for the welfare of the animals referred to in Article 20, paragraph 4 hereof.

(4) The decision of the project approval by the competent authority on the basis of previous estimates of the project and the opinions of the Ethics Committee referred to in Article 34 of this Law.

(5) The competent authority issues the permit for the project within 40 working days of receipt of a complete application. When justified by 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 shall inform the applicant previously.

(6) the Decision approving the project shall be determined by the following data: name and surname or name and address, name of the person responsible for implementing the project and its compliance with the approved project, the name of the Head of the experiment, the site of the project, special conditions under which it was allowed to conduct the experiment and that you need to spend a retrospective assessment of the project, and if so, when.

(7) Approval of the design is issued for a limited period with regard to the purpose of the project, for a maximum of five years.

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

(9) the retrospective assessment of the project carried out by the competent authority on the basis of beneficiary documentation and opinion of the Ethics Committee.

(10) The form and content of the application referred to in paragraph 2 of this Article, the basic components of which must include the commission's opinion on the welfare of 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 beneficiary must:

The first experiments carried out in accordance with the decision approving the project,

2. ensure that the experimental animals after the experiment treated or put to death if it is necessary for the welfare of animals,

3rd prevent the death of experimental animals as well as the final result of the experiment if possible and replace it with a premature killing of 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 trials and new experiments and state of health of experimental animals,

5th to the Authority an annual report on the experiments conducted,

6th Keep documentation of experiments at least five years.

(2) The beneficiary must submit a request to the competent authority for approval of any changes to the project that may negatively affect the welfare of the animals on which the competent authority issues a decision.

(3) The competent authority shall revoke the decision the decision approving the project if the beneficiary is implementing the project contrary to the approval and thereby jeopardizes the welfare of the animals or if he acts in contradiction with Article 24 of this Act. If the irregularities do not compromise animal welfare, veterinary inspector will to determine the terms for their removal in accordance with Article 64 of this Act. If a beneficiary at a particular time does not remove the irregularities, the competent authority shall repeal his decision approving the project.

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

Article 23

(1) The experiments can be carried out in order to:

1. basic research,

2. translational or applied research with any of the following purposes:

- Protection, prevention, diagnosis or treatment of disease, poor health or other irregularities, or their effects in humans, animals or plants,

- Assessment, detection, regulation or changes in physiological conditions in humans, animals or plants, or

- Animal welfare and improving production conditions for animals bred and kept for agricultural purposes,

3. any of the purposes referred to in item 2 of this paragraph in the development, manufacturing and testing of the quality, effectiveness and safety of drugs, food products and animal feed and other substances or products,

Fourth of the natural environment to protect the health or well-being of humans or animals,

5. the investigation focused on the protection of species,

6. higher education or training for the acquisition, maintenance or improvement of vocational skills,

7. forensic examinations.

(2) The competent authority shall encourage the development of alternative approaches to ensure data methods that do not involve the use of animals in experiments, or use fewer animals or involving less painful procedures.

(3) The beneficiary must when planning projects take into account the data of the Member States of the European Union gathered in experiments carried out in accordance with EU regulations. However, the competent authority may authorize the duplication of trials only if necessary to protect public health, safety or the environment.

(4) The experiments are not considered: non-experimental agricultural practices, non-experimental clinical veterinary practice, veterinary clinical trials required for the issue of marketing authorizations for veterinary medicinal products on the market, a practice that is carried out for the purposes of recognized animal husbandry and practices carried out primarily for the purpose of animal identification.

Article 24

(1) The experiment must be carried out under the following conditions:

1. Under the approved project,

2, in the premises of the beneficiaries, unless the competent authority exceptionally allowed deviation based on scientific evidence and knowledge,

Third on animals in general or local anesthesia, unless it is unacceptable given the purpose of the experiment and the use of analgesia or another appropriate method that will torment and distress of animals kept to a minimum,

4. At the laboratory animals that have been bred for use in experiments, unless the competent authority exceptionally allowed deviation based on scientific evidence and knowledge,

5 in accordance with the principle of 3R,

6 for the welfare of research animals and the killing of experimental animals at the site of the study must be secured appropriately educated and trained personnel,

7. for the effective and smooth implementation of the experiment must be provided appropriate devices and equipment.

(2) The experiment is not allowed:

1. If you have animals in experiments at long term suffering and distress that can not be facilitated,

2. If you are in the European Union recognizes other experimental methods or strategies for achieving the desired result, which does not involve the use of live animals,

3. For testing of weapons, ammunition or associated equipment, war equipment and general effects of radiation,

4 for the research or development of tobacco products and chemicals for cleaning and disinfection of consumer goods,

5. for the research or development of ingredients, combinations of ingredients and finished cosmetic products,

6 for the study of the effects of alcohol and drugs, except when there are no alternative scientific method that the use of animals,

7. without anesthesia when used means of muscle paralysis.

(3) It is forbidden to conduct experiments on endangered animal species, the primates that do not involve humans, the animals that were taken from the natural environment and the abandoned animals, unless the competent authority exceptionally allowed conducting experiments based on scientific evidence and knowledge, in line with the conditions prescribed in this Act.

Article 25

(1) A legal or natural person can not be in the scientific and educational purposes using isolated organs, tissues and carcasses of animals that are killed for this purpose 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 premises, 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 considered approved and 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 laboratory animals, proper marking and identification of experimental animals and keeping proper records.

(5) For the purposes of proceedings under this Article may be used only laboratory animals. In exceptional cases, the competent authority may at the request of legal or natural persons referred to in paragraph 1 of this Article, based on scientific data and the opinion of the Ethics Committee referred to in Article 34 of this Act, authorize the use of other types of animals.

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

(7) If the course of the inspection determines that a legal or natural person referred to in paragraph 1 of this Article no longer fulfills the conditions referred to in paragraph 2 of this Article, or if the animal is not killed to their prescribed manner, veterinarian will determine the terms for removal irregularities in accordance with Article 64 of this Act. If the irregularities endangering the welfare of animals, veterinarian the undertaking referred to in paragraph 1 of this Article stop the work on isolated organs, tissues and carcasses of animals to the removal of the established irregularities.

(8) If the legal or natural person referred to in paragraph 1 of this Article by a certain date does not remove the irregularities referred to in paragraph 7 above, or if he acts contrary to the provisions of paragraphs 5 and 6 of this Article, the competent authority shall terminate any approval referred to in paragraph 1 . hereof

.Article 26

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

(2) Prior to the start of the use of 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 the previous assessment of the project and the opinion of the Ethics Committee referred to in Article 34 of this Law.

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

Article 27

(1) The Authority shall keep a register of approved breeders, suppliers and beneficiaries, legal or natural persons authorized to operate on isolated organs, tissues and carcasses for this purpose have been killed and legal or natural persons approved for the use of animals for the production of biological preparations.

(2) A legal or natural person shall be removed from the register referred to in paragraph 1 of this Article, the decision of the competent authority in the following cases:

1. Request for deletion from the register,

The second cancellation of the approval of breeders, suppliers and beneficiaries,

Third cancellation of the authorization to work on isolated organs, tissues and carcasses for this purpose have been killed,

4. The revocation of the existing authorization to use animals for the production of biological preparations.

(3) The content, form and manner of keeping the register referred to in paragraph 1 of this Article shall be prescribed by the Minister by ordinance.

Article 28

It shall be the responsibility of the leader of the experiment to ensure that the experiment on animals is conducted in accordance with the provisions of this Act.

Article 29

(1) Experiments on animals which cause them pain, suffering and injury or death may not be performed for educational purposes.

(2) By way of derogation from the provision of paragraph 1 of this Article, the competent authority may allow such experiments if they are performed in institutions of higher education or scientific-research institutions and when they are necessary for the education of veterinarians, medical doctors, experts in pharmacy and biochemistry, experts in animal husbandry, biologists and doctors of dental medicine and if satisfactory results cannot be obtained by the use of other teaching aids (e.g. computer simulations, films, illustrations, models, preparations etc.), provided that only one animal may be used for each group.

Article 30

(1) The competent authority on the basis of received applications for approval of projects and annual reports for leading statistical records.

(2) The aggregate statistics on the number and species of animals used and the type of trials are public.

(3) The competent authority at the website publishes non-technical summaries of projects implemented taking into account the protection of intellectual property and confidentiality

Article 31

(1) The course of an experiment on animals and the procedures used in the production of biological preparations must be recorded in logbooks.

(2) The logbooks referred to in paragraph 1 of this Article must be signed by the persons referred to in Articles 28 and 32, paragraphs 1 to 4 of this Act.

(3) The logbooks referred to in paragraph 1 of this Article must be retained for three years and must be made available to the competent authority on request.

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)

(4) When a surgical operation referred to in paragraph 3 of this Article is not carried out by a veterinarian, the person responsible for the protection of animals must be a veterinarian.

(5) The programme of the examination referred to in paragraph 1 of this Article shall be prescribed by the Minister.

Article 32a

Requirements for premises, facilities, equipment, devices, competence of staff, ensuring animal health care and animal care, elimination 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, the method of notifying the competent authority shall be prescribed by the Minister by 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 in accordance with the duties performed, trained to conduct animal experiments, design experiments and projects, animal welfare and killing of animals.

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

Ethics Committee

Article 34

(1) The Minister shall establish an Ethics Committee.

(2) The membership of the Ethics Committee shall include experts in the fields of veterinary medicine, human medicine, biology, pharmacy, biochemistry and agronomy, as well as representatives from the state administration body responsible for science and education and representatives from animal protection associations.

(3) The Ethics Committee shall:

– give opinions on ethical and animal protection issues in relation to the use of animals for experimental and educational purposes,

– propose criteria and give opinions to the competent authority during the procedure for granting authorisation to carry out an experiment,

– prepare an annual report on its work and forward to the Minister, by the end of March of the current year, the report for the preceding year.

(4) costs of producing the opinion referred to in paragraph 3, items 1, 2 and 3 of this Article shall be borne by the applicant.

(5) The members of the Ethics Committee are entitled to compensation for work in the commission in the amount specified by the Minister in accordance with the decision of the Croatian Government.

(6) The Ethics Committee shall adopt its rules of procedure.

Aneks X

Enclosure II.

LIST OF PROJECTS SUBJECT TO EVALUATION OF THE NEED FOR IMPACT ASSESSMENT ON ENVIRONMENT, UNDER THE MINISTRY[2]

INTERVENTION	
1.	**Agriculture, forestry and aquaculture (unless included in Annex I)**
1.1.	Water management projects for agriculture, including irrigation and drainage projects whereby the irrigation surface area is 2,000 ha or more, in the Adriatic catchment area 300 ha or more
1.2.	Installations for the intensive rearing of pigs with a capacity of more than: - 1000 places for production pigs (over 30 kg) - 500 places for sows
1.3.	Marine farms: - Fish-farms in protected coastal area (PCA) annual production of less than 100 t
1.4.	Freshwater fish-farms: - For salmonids annual production 10 t more - For cyprinids surface area of 100 ha or 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: - Fossil and solid fuels - Renewable energy sources (other than water, sun and wind)
2.2.	Hydroelectric power plants
2.3.	Wind power plants
2.4.	Solar power as detached objects
2.5.	Pipelines for carrying oil and gas (high-pressure lines), steam and hot water 10 km long and more
2.6.	Transmission of electricity overhead lines of 110 kV and more that are part of the transmission network
2.7.	Surface storage of natural gas and other fossil fuel capacity of 5000 m^3 and more
2.8.	Underground storage of combustible gases with a capacity of 5000 m^3 and more
2.9.	Industrial briquetting of coal and lignite
2.10.	Biofuel production capacity of 20,000 tons / year and more
2.11.	The plant to capture gases for permanent disposal gas in geological structures
3.	**Production and processing of metals (unless included in Annex I)**
3.1.	Plants for processing metal processing capacity of 500 kg / h of crude material: - Hot rolling mills (installations for hot-rolling)

	- Smithies with one or more hammers - Installations for application of protective fused metal coats
3.2.	Metal foundry
3.3.	Installations for smelting non-ferrous metals and alloys making except 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 (production, assembly, production of motor)
3.6.	Shipbuilding
3.7.	Installations for the construction and repair of aircraft
3.8.	Installations for the production of railway equipment
3.9.	Installations for metal swaging by explosives
3.10.	Installations for the roasting, enrichment, sintering and molding of metallic ores
4.	**Industrial processing of minerals (unless included in Annex I)**
4.1.	Installations for dry coal distillation
4.2.	Installations for the production of cement clinker, cement and lim
4.3.	Installations for the production of glass and glass fiber, including production of glass generated by processing scrap glass
4.4.	Installations for melting mineral substances, including the production of mineral fibers
4.5.	Production of ceramics and brick products
5.	**Chemical industry (unless included in Annex I)**
5.1.	Treatment (processing) of intermediate products and production of chemicals capacity of 10,000 t / year and more
5.2.	Production: - Pesticides - Pharmaceutical products - Paints and varnishes - 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 (preservation) and packing of vegetable or animal origin with 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 beer and beverage preparation of fermented malt
6.5.	Installations for the production of confectionery products and syrup with a capacity of 5 t / year and more
6.6.	Installations for the production of industrial starch
6.7.	Installations for the production of fishmeal and fish oil
6.8.	Installations for the production or refining of sugar

6.9.	Installations for the production of alcoholic and soft drinks and water bottling capacity of 2,000,000 liters / year and more
6.10.	Installations for the production of tobacco products
7.	**Textile, leather, wood and paper industries (unless included in Annex I)**
7.1.	Installations for the production of paper and cardboard
7.2.	Plants for the pretreatment and dyeing of textile fibers
7.3.	Installations for the production and processing of cellulose
7.4.	Installations for the treatment and processing of leather and fur
8.	**Rubber industry (unless included in Annex I)**
8.1.	Installations for the production and treatment of elastomer
9.	**Infrastructure projects (unless included in Annex I)**
9.1.	Urban development projects, including: - Commercial and sales centers with gross construction area of 50,000 m2 and more - Sports and recreation centers area of 10 ha and more
9.2.	Industrial zones of 5 ha and more
9.3.	Railway lines (except for urban and suburban) and railway terminals for intermodal freight loading and unloading
9.4.	Airfields and airports
9.5.	Dams and other installations designed to hold water or store where a new or additional quantity of held or stored water exceeds 1,000,000 m3
9.6.	Intercity and international aqueducts
9.7.	Groundwater abstraction or artificial groundwater recharge
9.8.	Facilities for the transfer of water between river basins (river basin)
9.9.	Sea ports with more than 100 berths
9.10.	All projects including silting of sea coast, deepening or desiccation of the seabed and sea constructions 50 m in length more
10.	**Other projects (unless included in Annex I)**
10.1.	Operation of gravel and construction sand from renewable sources
10.2.	Exploitation of mineral and thermal waters used for medicinal, biological and recreational purposes
10.3.	Exploitation of mineral and geothermal waters from which it may use the accumulated heat for energy purposes
10.4.	Installations for waste water treatment with associated drainage system
10.5.	Plant and equipment for the testing of engines, turbines and reactors
10.6.	Installations for the destruction of explosive substances
10.7.	Installations for the manufacture of artificial mineral fibers
10.8.	All planned projects in the field of waste management which is necessary to obtain an environmental permit under a special regulation..
10.9.	Rehabilitation and reconstruction of landfills
10.10.	Storage of scrap iron, which are not covered by section 10.8.
10.11.	Storage life vehicles not covered by section 10.8.
11.	**Tourism and leisure (unless included in Annex I)**

11.1.	Tourist zone of 15 ha or more outside the boundaries of the construction zone
12.	**Interventions of urban development and other projects for which the developer works of international financing requests evaluation of the need for environmental impact assessment.**
13.	**Changes to the projects listed in Annex I and II. that could have a significant negative impact on the environment, with a significant environmental impact on request of the developer, by the Ministry, or in the evaluation of the need for environmental impact assessment.**
14.	**Reconstruction of the existing plant and equipment which was obtained the environmental permit, which could have a significant negative impact on the environment, with a significant environmental impact on the request of the developer, by the Ministry, or in the evaluation of the need for environmental impact assessment..**

ZAHVAT	
1.	**Agriculture, forestry and aquaculture (unless included in Annex I and II.)**
1.1.	Restoring rural area of 10 ha or more
1.2.	Use of uncultivated land or semi-natural areas for intensive agricultural area of 10 ha or more
1.3.	Initial afforestation for the purpose of conversion of the land area of 50 ha or more
1.4.	Deforestation for the purpose of conversion of the land area of 10 ha or more
1.5.	Installations for the intensive rearing of poultry with a capacity of 20,000 pcs 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 installations for pig and poultry)
1.7.	Freshwater fish-farms: - For salmonids annual production exceeding 5 t - For cyprinids surface area of 50 ha or more
2.	**Infrastructure projects (unless included in Annex I and II.)**
2.1.	Car parks as independent projects area of 2 ha or more
2.2.	Canals, dykes and other structures for flood and coastal erosion
2.3.	Tramways, elevated and underground railways, suspended railway that used to carry passengers: - Urban - 10 km or more - Suburban - the length of 15 km and more
3.	**Other projects (unless included in Annex I and II.)**
3.1.	Asphalt mixing nominal capacity of 100 t / hour or more, except for temporary installations
3.2.	Concrete plants with 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 area of 1 ha or more
3.4.	**Slaughterhouses daily capacity of 50 livestock units and more**
4.	**Tourism and leisure (unless included in Annex I and II.)**
4.1.	Ski runs, lifts and cable cars and similar constructions with pertaining structures of 1 ha and more

4.2.	Theme Parks area of 5 ha or more
5.	**Changes to the projects of this Annex that might have a significant adverse impact on the environment, with a significant environmental impact on the request of the developer by the competent administrative body in the county or in the City of opinion ie the evaluation of the need for environmental impact assessment..**
6.	**For other interventions of urban development that are not listed in Annex II. and III., which could have a significant negative impact on the environment, with a significant environmental impact on the request of the developer by the competent administrative body in the county or in the City of opinion ie the evaluation of the need for environmental impact assessment..**

[1] The term "plant" in Annexes I, II. and III., include construction works as prescribed by the special law governing construction.

2 Nuclear power plants and other nuclear reactors cease to be such installations after all nuclear fuel and other radioactive contaminated parts of equipment have been permanently removed from the installation.