### 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, February 2015

### Contents

ENVIRONME	ENTAL REVIEW PROCEDURES	3
1 Backgr	round	3
2. The proje	ect and the components	3
Project de	escription	3
Key Com	ponents	3

#### **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 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 Beneficiariy 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;
- 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<sup>1</sup> 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: Sub-financing (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

<sup>&</sup>lt;sup>1</sup>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 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 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 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 precommercialization proof of concept activities. As part of STP II, the Proof of Concept program will further develop its procedures and visibility, while financing additional 70-80 projects (out of estimated 200 applications).

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

The <u>Unity through Knowledge Fund within Croatian Science Foundation</u> / <u>(CSF/UKF)</u> 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.

<u>Technology Transfer Offices</u> (TTOs) in Croatia are not expected to be sustainable in the near future. The Government of Croatia is currently running the Science Innovation Investment Fund (SIIF), an IPA project mainly dedicated to technology transfer and commercialization capacities of Higher Education Institutions and Public Research Institutes. The B2 component of STP II aims to complement IPA projects and would design a TTO development strategy and capacities of TTOs for the period 2014-2020 that could serve as a guide in preparing projects for structural funds.

#### IV.2 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.3 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 traceing 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 sub-borrower would include Material Environmental Management Plan Checklist (Annex E). 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 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.4 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 E). 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 150/2005,49/2011) 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 28/2010) see Annex G

**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) see Annex H

#### IV.5 Environmental Review Process (Role of PBs, PIUs and WB)

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

<u>STEP 1</u>: 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.

<u>STEP 2</u>: 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).

<u>STEP 3</u>: 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 +.

<u>STEP 4</u>: 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.

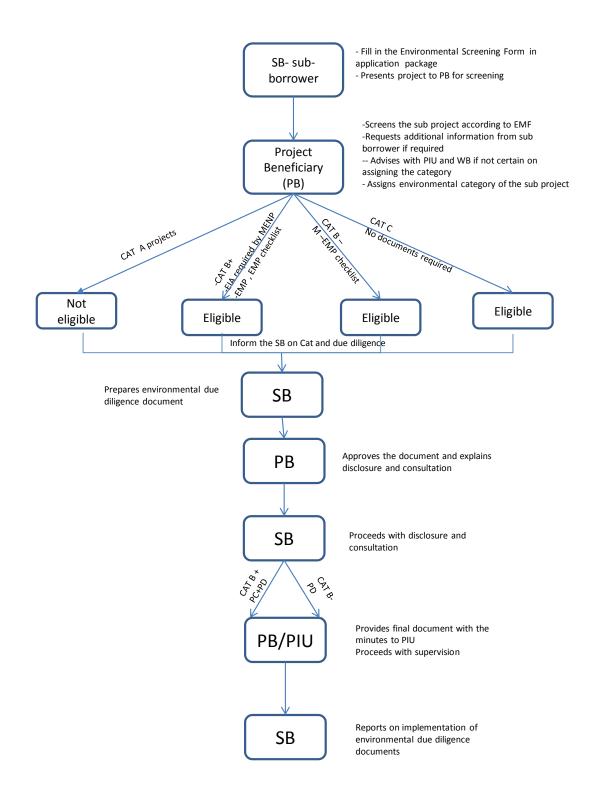
<u>STEP 5</u>: The sub-borrower incorporates the recommendations provided in the analysis into the sub-project design and implementation plan, including associated estimated costs.

<u>STEP 6</u>: 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.



### **Responsibilities of Key Participants**

Participant	Activity	Supporting Documentation
Sub-beneficiary	<ul> <li>Submission of sub-project concept to PB</li> <li>Arrangement and financing of environmental due diligence documents</li> <li>Obtain required permits/licenses</li> <li>Implementing and financing of environmental due diligence</li> </ul>	<ul> <li>Copies of permits, licenses</li> <li>Clearance statement</li> <li>Periodic reports and sub-project completion report</li> </ul>
Participating Financial Institutions – Project Beneficiary (PBs)	<ul> <li>Finalize the environmental screening form, assign the environmental category</li> <li>Review of sub-loan application package for required environmental documentation and licences/permits from the State authorities</li> <li>Maintain complete files of environmental documentation for review by the PIU and WB</li> <li>Monitoring compliance with mitigation plans (if necessary)</li> </ul>	<ul> <li>Include environmental information with sub-loan application</li> <li>Include environmental monitoring / supervising information in regular portfolio reporting to PIU</li> <li>Include environmental documentation in normal PB records</li> <li>Periodic monitoring / supervising reports (if necessary)</li> </ul>
PIU	<ul> <li>Distribution of Operational manual to PBs</li> <li>Assist to the PBs about environmental requirements</li> <li>Verification that PBs have followed EIA procedures</li> </ul>	• Include environmental category and EIA status in normal periodic reporting activities
WB	<ul> <li>Organize training for PB and PIU staff regarding environmental review procedures</li> <li>Carry out prior and post reviews</li> <li>Identification of problems/ issues and proposal of solutions</li> </ul>	<ul> <li>Provide assistance</li> <li>Document status of project implementation in Implementation Status and Results reports and the mission Aide-Memoires</li> </ul>

### Annex A: Environmental Screening Form

PART 1: APPLICATI	ON (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	<b>G</b> (filled by applicants, checked by <b>P</b>	<b>B</b> )					
Screening category	Annex 1 Yes				No		
according to national	Annex 2 Yes				No		
Regulation on EIA	Annex 3 Yes				No		
	No annex Yes			1	No		
If no annex:	Does it include construction	or					
	rehabilitation of buildings	or	Yes			No	
	infrastructure?						
	Does it include assembling?		Yes			No	
	Does this sub project include softwa	are					
	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	Yes			No	
	mutagenic substances?						
	• If so what substances and for	r					
	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: SCREE	NING RESULTS (	filled by PB)			
Screening		inica sy i b)			
category					
according to the	Α	<b>B</b> +	B -	С	
project					
framework					
EXPLANATION					
<b>DUE DILIGENCH</b>	C				
Category A					
	Will not be financ	ed by the project			
Category B +	1				
	a)EIA if project included in annex 2 or 3 of the Regulation on EIA b)EMP or EMP checklist				
Category B -					
	Material EMP tog	gether with the nece	essary licenses and	MSDSs	
Category C					
	No due diligence				
Additional explanation required					

# 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*.<sup>3</sup> 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup> 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 Ph	nase			
Activity	Expected Environmental Impact	Proposed Measure for Mitigation	Responsibility for Implementing Mitigation Measure	Period of Implementing Mitigation Measure
1.				
2.				

Operation Phase	2		
1.			
2.			

#### **Monitoring Plan**

Construction Pha	ase			
What	Where	How	When	By Whom
parameter is to be monitored?	is the parameter to be monitored?	-		is the parameter to be monitored– (responsibility)?
1.				
2.				
Operation Phase				
1.				
2.				

#### CHECKLIST ENVIRONMENTAL MANAGEMENT PLAN (EMP)

for the small reconstructions and rehabilittaions

#### **Potential Environmental Impacts**

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

#### CHECKLIST EMP

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

The checklist has one introduction section and three main parts:

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

#### **Application of the EMP-Checklist**

The design process for the envisaged civil works in the Education Excellence and Equity Project will be conducted in three phases:

 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: INSTITUTIO	)NAL & ADMINISTI	RATIVE						
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	Í	π		• • •	_			
Screening category	Annex 1	Yes 🗆		No				
according to national Regulation on EIA	Annex 2	Yes 🗆		No				
Regulation on LIA	Annex 3	Yes 🗆		No				
	No annex	Yes 🛛	I	No				
If no annex:	Does it include	construction or	• 7	_		<b>N</b> 7	_	
	rehabilitation of	buildings or	Yes			No		
	infrastructure?	· •	<b>T</b> 7			<b>N</b> T	_	
	Does it include assembl		Yes			No		
	Does this sub project development or similar		Var	-		Na	-	
	Does the project include		Yes			No		
	material?	e use of fauloactive	Yes			No		
		for what purposes?	105			110		
		÷÷.						
	What quantitie							
	• What accredita for use of such	tion laboratory has						
		include use of						
	cancerogenic, theratoge		Yes	п		No	п	
	substances?	enie of mutagenie	105			140		
	If so what subs	stances and for						
	what purposes	?						
	What quantitie							
		ation laboratory has						
	for use of such							
	Does the project pr animals?	redicts testing on	Yes			No		
		topage and fair						
	If so what subs what purposes							

	<ul> <li>What animals?</li> <li>What accreditation laboratory has for testing?</li> </ul>
	Does the project include Activities Yes D No D Generally Ineligible for IBRD financing?
Signature Confirming truthfulness of the provided in the table	

Will the site	Activity	Status	Additional references
activity	A. Building rehabilitation	[] Yes [] No	See Section <b>B</b> below
include/involve	B. New construction	[ ] Yes [] No	See Section <b>B</b> below
any of the	C. Individual wastewater treatment system	[] Yes [] No	See Section C below
following:	D. Historic building(s) and districts	[] Yes [] No [] Possible	See Section <b>D</b> below
	E. Acquisition of $land^2$	[ ] Yes [] No	See Section E below
	F. Hazardous or toxic materials <sup>3</sup>	[ ] 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 <b>H</b> below
	I. Traffic and Pedestrian Safety	[] Yes [] No	See Section I below

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
A. General	Notification and Worker	(a) The local construction and environment inspectorates and communities have been notified
Conditions	Safety	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>B.</b> General	Air Quality	(a) During interior demolition use debris-chutes above the first floor
Rehabilitation		(b) Keep demolition debris in controlled area and spray with water mist to reduce debris dust
and /or		(c) Suppress dust during pneumatic drilling/wall destruction by ongoing water spraying and/or

<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> Toxic / hazardous material includes and is not limited to asbestos, toxic paints, removal of lead paint, etc.

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST
Construction Activities	Noise	<ul> <li>installing dust screen enclosures at site</li> <li>(d) Keep surrounding environment (side walks, roads) free of debris to minimize dust</li> <li>(e) There will be no open burning of construction / waste material at the site</li> <li>(f) There will be no excessive idling of construction vehicles at sites</li> <li>(a) Construction noise will be limited to restricted times agreed to in the permit</li> <li>(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</li> </ul>
	Water Quality Waste management	<ul> <li>(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.</li> <li>(a) Waste collection and disposal pathways and sites will be identified for all major waste types</li> </ul>
		<ul> <li>expected from demolition and construction activities.</li> <li>(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.</li> <li>(c) Construction waste will be collected and disposed properly by licensed collectors</li> <li>(d) The records of waste disposal will be maintained as proof for proper management as designed.</li> <li>(e) Whenever feasible the contractor will reuse and recycle appropriate and viable materials (except asbestos)</li> </ul>
C. Individual wastewater treatment system	Water Quality	<ul> <li>(a) The approach to handling sanitary wastes and wastewater from building sites (installation or reconstruction) must be approved by the local authorities</li> <li>(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</li> <li>(c) Monitoring of new wastewater systems (before/after) will be carried out</li> </ul>
<b>D</b> . Historic building(s)	Cultural Heritage	<ul> <li>(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</li> <li>(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</li> </ul>

ACTIVITY	PARAMETER	MITIGATION MEASURES CHECKLIST		
		activities delayed or modified to account for such finds.		
<b>E</b> . Acquisition of land	Land Acquisition Plan/Framework	<ul> <li>(a) If expropriation of land was not expected and is required, or if loss of access to income of legal or illegal users of land was not expected but may occur, that the bank task Team Leader is consulted.</li> <li>(b) The approved Land Acquisition Plan/Framework (if required by the project) will be implemented</li> </ul>		
F. Toxic Materials	Asbestos management	<ul> <li>(a) If asbestos is located on the project site, mark clearly as hazardous material</li> <li>(b) When possible the asbestos will be appropriately contained and sealed to minimize exposure</li> <li>(c) The asbestos prior to removal (if removal is necessary) will be treated with a wetting agent to minimize asbestos dust</li> <li>(d) Asbestos will be handled and disposed by skilled &amp; experienced professionals</li> <li>(e) If asbestos material is be stored temporarily, the wastes should be securely enclosed inside closed containments and marked appropriately</li> <li>(f) The removed asbestos will not be reused</li> </ul>		
	Toxic / hazardous waste management	<ul> <li>(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</li> <li>(b) The containers of hazardous substances should be placed in an leak-proof container to prevent spillage and leaching</li> <li>(c) The wastes are transported by specially licensed carriers and disposed in a licensed facility.</li> <li>(d) Paints with toxic ingredients or solvents or lead-based paints will not be used</li> </ul>		
G. Affects forests and/or protected areas	Protection	<ul> <li>(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.</li> <li>(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</li> <li>(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</li> <li>(d) There will be no unlicensed borrow pits, quarries or waste dumps in adjacent areas, especially not in protected areas.</li> </ul>		
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	waste management	and/or rehabilitated health care facilities include sufficient infrastructure for medical waste
(not applicable)		handling and disposal; this includes and not limited to:
		<ul> <li>Special facilities for segregated healthcare waste (including soiled instruments</li> </ul>
		"sharps", and human tissue or fluids) from other waste disposal; and
		<ul> <li>Appropriate storage facilities for medical waste are in place; and</li> </ul>
		<ul> <li>If the activity includes facility-based treatment, appropriate disposal options are in</li> </ul>
		place and operational

	What	Where	How	When	Why	Cost	Who
Phase	(Will the parameter be monitored?)	(Is the parameter to be monitored?)	(Is the parameter to be monitored?)	(Define the frequency / or continuity?)	(Is the parameter being monitored?)	(if not included in project budget)	(Is responsible for monitoring?)
activity prepara tion							
During activity implementation							
Duri <b>impl</b> e							
activity supervisi on							

#### Annex E: 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? <sup>4</sup>	

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

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.

<sup>&</sup>lt;sup>4</sup> All permits should be attached to the final document

List of materials / chemicals that are going to be used	If possible assign CAS <sup>5</sup> number to material / chemicals <sup>6</sup>	According to the Law on chemicals is this material hazardous	Please assign category according to the Law on chemicals, Article 2 (Annex F)
		Y/N	

<sup>&</sup>lt;sup>5</sup> Chemical Abstracts Service Number <sup>6</sup> MSDS sheets should be attached to the final document

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

Assembling and Testing Phase					
What parameter is to be monitored?	Where <i>is the parameter to be</i> <i>monitored?</i>	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 F: Excerpts on Law on Chemicals (Official Gazette 150/2005, 49/2011):

#### Article 2

9. Dangerous chemicals are classified as the following chemicals:

a) explosive chemicals are solid, liquid substances in the form of paste or jelly, which can be exothermic reactive, even in the absence of oxygen from the air; very quickly create and emit gases under certain conditions, detonate, quickly ignite or due to warming and high pressure explode

b) oxidizing chemicals are substances and preparations which react when in contact with other substances (especially flammable)

c) (very easy) flammable chemicals are those liquid substances and preparations having an extremely low flash point and low boiling point, and gaseous substances and preparations which are flammable in contact with air at normal temperature and pressure,

d) easily flammable chemicals are:

- Substances and preparations flammable in contact with air, at normal temperature and pressure without bringing in an outside power

- Solid substances and preparations which are easy to ignite in brief contact with flame source, and then continue to burn when the flame source is removed,

- Liquid substances and preparations having a very low flame point,

- Substances and preparations which in contact with water or steam discharge dangerous quantities of flammable gases,

e) flammable chemicals are substances and preparations which have a low flash point,

f) very toxic chemicals are substances and preparations which, if swallowed or by skin contact and inhalation of very small amounts can cause death or very serious acute or chronic damage to health,

g) toxic chemicals are substances and preparations which if swallowed or by skin contact and inhalation of small quantities can cause death or very serious acute or chronic damage to health,

h) harmful chemicals are harmful substances and preparations which if swallowed or by skin contact and inhalation may cause death or very serious acute or chronic damage to health,

i) corrosive chemicals are substances and preparations which, if in contact with healthy skin, may cause damage to all layers of tissue,

j) irritant chemicals are substances and preparations which if in short, long or repeated contact with skin or mucous membranes may cause infection,

k) chemicals that cause sensitization are substances and preparations which, if inhaled or after passing through the skin may cause a hypersensitive reaction,

l) carcinogenic chemicals are substances and preparations which, after inhalation, ingestion, or passing through the skin may cause cancer or increase the frequency of its occurrence,

m) mutagenic substances and preparations are substances that after inhalation, ingestion, or passing through the skin may cause heritable genetic damage or significantly increase their occurrence,

n) teratogenic chemicas are substances and preparations which, after inhalation, ingestion or passage through the skin may cause or increase the likelihood of nonhereditary adverse effects on offspring and / or disrupt the male or female reproductive functions or after ingestion, inhalation, or passing through the skin (contact with skin) may affect fertility,

o) hazardous to environment are substances and preparations which, because of its caracteristics, quantities, and the introduction into the environment can be harmful to the health of people, wildlife, and biological and landscape diversity.

Article 41

A legal person that uses hazardous chemicals for scientific purposes or in analytical laboratories must meet the requirements in terms of special protection measures to work with hazardous chemicals in accordance with the regulations on occupational safety.

#### Annex G: Excerpts from Law on radiological and nuclear safety (Official Gazette 28/2010)

2. Measures of protection against ionizing radiation

Professional competence

Article 29

(1) Exposed workers must have appropriate education, and 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.

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

Requirements for premises and equipment

Article 33

(1) Property, plant and equipment where the sources of ionizing radiation or practices involving ionizing radiation, 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, with the consent of the Minister of Health.

Identification and implementation of measures to protect exposed workers and control jobs

#### Article 34

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

- Exposed workers healt check,
- Measuring personal doses of exposed workers,
- Education on the implementation of measures for protection against ionizing radiation for exposed workers,
- 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 .

#### Annex H: Excerpts from Animal Protection Act (Official Gazette 135/2006)

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.

Treatment of animals that suffer from incurable pain

Article 10

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

#### **II. SPECIAL PROVISIONS**

1. Protection of animals during transport

Article 11

(1) The transport of animals may be carried out by transporters who are authorised by the competent authority and those who have obtained permission from the competent authority to carry out this activity.

(2) The competent authority shall keep a register of transporters of animals.

(3) By way of derogation from the provisions of paragraphs 1 and 2 of this Article, of Article 12, paragraph 2, item 5, and Articles 13 and 14 of this Act, farmers may transport domestic animals using agricultural vehicles or other means of transport belonging to them in the following cases:

- seasonal transhumance of animals to other climatic areas and

- transport of their own animals for a distance of up to 50 km from their holding.

(4) The provisions of Article 12, paragraph 2 to Article 15 of this Act shall not apply to the transport of animals which does not take place in connection with an economic activity, to the transport of companion animals in one's own means of transport, and to the transport of animals for the purposes of obtaining veterinary care.

(5) The provisions of paragraphs 1 and 2 of this Article, of Article 12, paragraph 2, item 5, and Articles 13 and 14 of this Act, shall not apply to persons transporting animals up to a maximum distance of 65 km counted from the place of departure to the place of destination.

Requirements for the transport of animals

Article 12

(1) It is prohibited to transport animals in a way that causes them pain, suffering, injury or death.

(2) The following conditions must be complied with when transporting animals:

1. steps must be taken in advance to minimise the length of the journey and of any delay, and to meet the animals' needs during the journey,

2. the animals must be fit for the journey,

3. the means of transport must be designed, constructed, maintained and operated so as to avoid injury and suffering and ensure the safety of the animals,

4. the loading and unloading facilities and equipment must be designed, constructed, maintained and operated so as to avoid pain, suffering and injury and ensure the safety of the animals,

5. the personnel handling animals must be trained,

6. the conditions of transport of animals must be regularly checked and maintained,

7. sufficient floor area and height must be provided for the animals, appropriate to their species and age and the length of the journey,

8. water and feed must be offered to the animals at suitable intervals and must be appropriate in quality and quantity to the species, size and age of the animals,

9. during the journey, the animals must be rested at appropriate intervals,

10. in the case of aquatic animals transported in special means of transport or containers, a sufficient quantity of water of appropriate temperature and an adequate oxygen supply must be provided during transport, depending on the needs of the particular animal species,

11. late-pregnant females during a period equal to 10% of the length of gestation before giving birth, and females during one week after giving birth shall not be considered fit for transport, except when emergency veterinary treatment is needed,

12. when the upright position of a container in which animals are transported is not readily visible from outside, the said position must be indicated by a sign. Where it is not apparent from the nature of a container that live animals are carried in it, the container must be clearly marked to indicate that it contains live animals as well as the species of those animals.

Obligations of transporters

Article 13

Before engaging in the activity of transporting animals, a transporter must:

1. obtain an authorisation to carry out the activity of transporting animals, issued by the competent authority,

2. designate a person (hereinafter referred to as "an attendant") who shall be responsible for the safety, feeding, watering and resting of the animals during transport,

3. obtain a certificate of approval of means of transport by road, issued by the competent authority.

Qualifications of transporters and other personnel

Article 14

(1) Natural persons engaged in the transport of animals by road and animal attendants must be trained to perform their tasks in accordance with paragraph 2, item 5 of Article 12, and must meet the requirements of Article 16 of this Act.

(2) Staff handling animals at assembly centres and resting points must be trained to take care of animals.

Article 15

(1) The competent authority shall keep a register of resting points for animals.

(2) The resting points for animals shall be entered in the register referred to in paragraph 1 of this Article on the basis of a decision on compliance with the prescribed requirements, issued by the competent authority.

Article 16

The requirements for the transport of animals that must be met by transporters, the requirements that must be met by resting points for animals and the training requirements for drivers and animal attendants and staff at assembly centres and resting points for animals shall be prescribed by the Minister.

2. Protection at the time of slaughter or humane killing of animals kept for production purposes

Stunnig of animals

Article 17

(1) An animal may only be slaughtered if it is stunned before slaughter, except in the case of poultry and rabbits slaughtered for private domestic consumption.

(2) By way of derogation from paragraph 1 of this Article, an animal may be slaughtered without prior stunning only in the cases of emergency slaughter or slaughter according to religious rite.

(3) The stunning, slaughter or killing of animals for ritual purposes is prohibited.

The handling of animals in slaughterhouses

Article 18

(1) The handling of animals in a slaughterhouse must be in accordance with the following:

1. after arrival, animals intended for slaughter must be unloaded from the means of transport, with the use of suitable equipment, in such a way as to spare the animals any unnecessary pain, suffering and fear;

2. the moving of animals within the precincts of the slaughterhouse to their lairages must be done with care and without causing pain, suffering and fear, with the use of suitable tools;

3. slaughterhouses must be equipped with suitable stalls and pens where animals are to be kept, protected from adverse weather conditions, fed and watered;

4. the animals must be stunned by a prescribed method immediately before slaughter;

5. the stunning process must bring animals into a state of unconsciousness, in which state the animals must be slaughtered.

(2) The slaughter of animals must be carried out in a prescribed manner with the use of suitable equipment.

(3) It is prohibited to use stunning equipment or methods that cause unnecessary pain, suffering or fear.

Slaughtering and humane killing

Article 19

(1) The humane killing of animals must be carried out in such a way as to spare the animals any unnecessary pain, suffering, injury or fear, in accordance with the provisions of this Act.

(2) Animals may be moved, lairaged and cared for in the slaughterhouse, restrained, stunned, slaughtered or humanely killed only by persons who are qualified to perform these tasks.

(3) The slaughter of animals for private domestic consumption must be carried out in such a way as to spare the animals any unnecessary pain, suffering, injury or fear, in accordance with the provisions of this Act.

(4) Where, in the case of emergency slaughter, stunning is not possible, slaughter shall be carried out in such a way as to spare the animals any unnecessary pain, suffering, injury or fear.

(5) The slaughter of animals according to religious rite shall be carried out in a slaughterhouse specially approved by the competent authority for that purpose.

(6) The Minister shall prescribe the requirements for the protection, at the time of slaughter and humane killing, of animals kept for production purposes as well as requirements for training of staff that take care of animals in slaughterhouses and are involved in the restraint, stunning and slaughter processes.

3. The protection of animals used in experiments and for the production of biological preparations

Article 20

(1) Experiments on animals may only be carried out by legal persons that are registered for carrying out this activity for the following purposes:

1. the research of diseases and somatic disorders or the identification of effects of physiological and pathological conditions in man and animals,

2. the testing and development of drugs and medicinal preparations intended for human and animal health protection,

3. the carrying out of studies for the purposes of the registration of drugs and medicinal preparations as prescribed by separate regulations,

4. the investigation of production and other traits and of the ways to improve them in animals farmed for commercial and other purposes,

5. the investigation of causes and consequences of endangering the environment,

6. the testing of materials and products for their harmlessness to the health of humans or animals,

7. basic and applied scientific research,

8. educational purposes.

(2) The experiments on animals referred to in paragraph 1 of this Article may only be allowed if the purpose of the research cannot be achieved by other scientific methods and if the pain, suffering or injury that might be caused to the animals can be ethically justified in terms of the expected results which are of significance for humans or animals or science.

(3) The Minister shall prescribe specific requirements as to the housing and keeping of experimental animals and their identification, the types of experiments conducted on animals and the manner in which they are to be notified as well as the keeping of records required by Article 30 of this Act.

Marking

Article 21

Animals used for experimental purposes and for the production of biological preparations must be marked.

The breeding of animals for use in experiments and for the production of biological preparations

Article 22

(1) Legal and natural persons breeding animals for use in experiments and for the production of biological preparations may not commence the said activity without having obtained a decision from the competent authority confirming the fulfilment of requirements.

(2) Animals used in experiments and for the production of biological preparations must originate from registered breeding establishments, except in the case of wild animals taken from the wild.

(3) By way of derogation from paragraph 2 of this Article, animals not originating from registered establishments or animals taken from the wild may be used for the production of biological preparations if a decision issued by the competent authority has been obtained.

(4) The competent authority shall keep a register of legal and natural persons referred to in paragraph 1 of this Article.

(5) The Minister shall prescribe the requirements for the breeding of animals referred to in paragraph 1 of this Article.

Prohibition on the use of animals in experiments

Article 23

It is prohibited to use animals in experiments for the following purposes:

1. the testing of weapons, ammunition or associated equipment, war equipment and general effects of radiation,

2. the research or development of tobacco products and chemical products used for the cleaning and disinfection of articles of general use,

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

4. the study of the effects of alcohol and narcotics, except when there is no alternative scientific method that does not entail the use of animals.

Article 24

Experiments on animals may be performed by institutions of higher education and scientific-research institutions as well as by qualified legal persons registered for performing experiments on animals, in accordance with the provisions of Articles 20 to 33 of this Act, under the following conditions:

1. the results of the experiment are not sufficiently known or are not available, or the repeated testing through a double or repeated experiment or through other type of research is necessary when it is not possible to prove the results of the experiment by other scientific methods.

2. they must employ qualified staff as specified by the provisions of Article 32 of this Act,

3. they must have the necessary premises, installations, equipment and other means to carry out experiments on animals,

4. they must have premises for the housing and accommodation of animals during the experiment and must be able to ensure that the animals are kept in the prescribed manner, as well as cared for and attended to and provided with regular veterinary care.

#### Notification of experiments

Article 25

(1) Before the commencement of an experiment on animals, an application for authorisation to carry out the experiment on animals must be submitted to the competent authority.

(2) The application referred to in paragraph 1 of this Article must be accompanied by an explanation as to ethical and scientific justification to conduct the experiment.

(3) The authorisation to carry out the experiment on animals shall be issued by the competent authority taking into account the opinion of the Ethics Committee referred to in Article 34 of this Act.

(4) The authorisation to carry out the experiment on animals shall specify the period of its validity and shall designate, on the proposal of the applicant, the leader of the experiment and his/her deputy, the person in charge of the animal quarters and his/her deputy as well as the responsible person referred to in Article 32, paragraph 3 of this Act.

#### Article 26

(1) If an experiment on animals is expected to last longer than the period approved, an application for an extension of the approved period shall be submitted to the competent authority seven days before the expiry date of the said period.

(2) If the duration of several experiments of the same type is to be extended, it is sufficient to submit one application for the extension of the duration of all the experiments.

(3) Should the details stated in the authorisation referred to in Article 25, paragraph 3 of this Act change in the course of the experiment, the competent authority must be notified of the changes within three days.

(4) The decision approving the extension of the duration of the experiment referred to in paragraph 1 of this Article and the decision referred to in paragraph 3 of this Article shall be issued by the competent authority.

(5) By way of derogation from paragraph 4 of this Article, a decision approving the use of a greater number of animals, the change of animal species used or the change in the approved experimental procedures shall be issued by the competent authority taking into account the opinion of the Ethics Committee referred to in Article 34 of this Act.

#### Article 27

(1) By way of derogation from the provision of Article 25, paragraph 4, and Article 26 of this Act, the competent authority shall, by a decision authorising the carrying out of experiments for educational purposes, authorise the conduct of experiments for an academic year, and the planned duration of the experiments may not be extended.

(2) By way of derogation from the provision of Article 25, paragraph 4, and Article 26 of this Act, the competent authority shall, by a decision authorising the carrying out of experiments for the purposes of the projects approved by the state administration body responsible for science, authorise the experiments to be conducted during the duration of the project concerned.

#### 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

Experiments conducted on animals and procedures applied in the production of biological preparations as well as the number of animals used must be recorded and records submitted to the competent authority once a year.

#### 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 Article 32, paragraphs 1 to 3 of this Act and by the leader of the experiment or, where relevant, by the person in charge of the production of biological preparations.

(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) When a surgical operation referred to in paragraph 2 of this Article is not carried out by a veterinarian, the person responsible for the protection of animals must be a veterinarian.

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

(5) The exam referred to in paragraph 1 of this Article is also mandatory for:

- staff carrying out procedures on animals for the purpose of producing biological preparations,

- persons in charge of quarters for animals used in experiments and quarters for animals used for the production of biological preparations, as well their deputies,

- staff taking care of animals in establishments for breeding animals for use in experiments and for the production of biological preparations,

- staff taking care of animals being used in experiments and for the production of biological preparations.

Notification of the use of animals for the production of biological preparations

#### Article 33

(1) Before animals are used for the production of biological preparations as provided for in Article 22, paragraphs 2 and 3 of this Act, an application for authorisation to use animals for these purposes must be submitted to the competent authority.

(2) The application referred to in paragraph 1 of this Article must be accompanied by an explanation as to ethical justification to carry out the procedure concerned.

(3) The authorisation to use animals for the production of biological preparations shall be issued by the competent authority taking into account the opinion of the Ethics Committee referred to in Article 34 of this Act, shall be valid for the current year and may not be extended.

(4) The authorisation referred to in paragraph 3 of this Article shall specify the period of its validity and shall designate, on the proposal of the applicant, the leader of the procedure and his/her deputy, the person in charge of the animal quarters and his/her deputy as well as the responsible person referred to in Article 32, paragraph 3 of this Act.

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) The Ethics Committee shall adopt its rules of procedure.