MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEF SEC PROJECT ID: 2837
COUNTRY: Estonia
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of Estonia
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES):
DURATION: 48 months
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: SP3
ESTIMATED STARTING DATE: September 2005
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	
PDF A*	
Sub-Total GEF	
CO-FINANCING**	
GEF Agency	669 000
Government	80 000
Bilateral	
NGOs	
Tallinn Technical University	204 000
Sub-Total Co-financing:	284 000
Total Project Financing:	953 000
FINANCING FOR ASSOCIATED ACTIVITY IF ANY: Ministry of Agriculture, European Commission **700 000 USD**	

* Indicate approval date of PDFA
** Details provided in the Financing Section

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to SP3: Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

GEF OFP
Mr Allan Gromov, Deputy Secretary General, Ministry of Environment

Date:23 May 2005
See letter of endorsement at Annex AA.

This proposal has been prepared in accordance with GEF policies and procedures and meets the standards of the GEF Project Review Criteria for a Medium-sized Project.

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LIST OF ACRONYMS

ACGM	Advisory Committee for Genetic Modification
AF	Action Field
BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CITET	The International Centre for Environmental Technologies at Estonia
COP	Conference of the Parties
CPB	Cartagena Protocol on Biosafety
GEF	Global Environment Facility
GMMs	Genetically Modified Micro-organisms
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol
IPPC	International Plant Protection Convention
LMO	Living Modified Organism
MOA	Ministry of Agriculture
MOE	Ministry of Environment
MOP	Meeting of the Parties to the Protocol
MOSA	Ministry of Social Affairs
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategy and Action Plan
NCA	National Competent Authority
NCC	National Coordinating Committee
NEA	National Executing Agency
NPC	National Project Coordinator
RA/RM	Risk Assessment/Risk Management
TTU	Tallinn Technical University
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

A. PROJECT SUMMARY

Estonia regained independence on 20 August 1991. Estonia has inherited numerous environmental problems from the Soviet era. The disintegration of the former Soviet Union brought about several neglected areas, including the policy and practice of environmental legislation, review and regulation of environmental standards. The development of new Estonian environmental legislation that started already in the early days of regained independence, has despite of the brief time period, attained successful approaches in various areas of nature conservation and environmental protection, including legislative regulation of the risks of biological pollutants. The overall aim of the Estonian legal acts on biotechnology is the safe use of the technology, taking into account human health and environmental safety as well as ethical considerations. Although Estonia has more or less succeeded in implementing the EU regulations concerning the release of genetically modified organisms (LMOs) and the country is ready to deal with biosafety issues in theory, however, our relevant authorities/officials lack the practical experience and means to do so. There is very little information about the use of LMOs in industry and agriculture, or about the enterprises which use them. In addition, there is at present little public understanding of the transboundary movement of GM-associated products.

There is a possibility that new crop varieties that are/will be obtained with the help of biotechnology might come into trials in Estonia in the near future. Estonia joined EU in May 2004, thus Estonia's market is open to all LMOs that are approved in EU. Before 2004 there were officially no goods containing LMOs or other modern biotechnology-derivatives marketed in Estonia (excluding GM pharmaceuticals for humans). However, initial tests performed at the National Institute of Chemical Physics and Biophysics show that at least some of the products on sale in Estonia contain genetically modified organisms (GMOs) or their products. To date, the lack of appropriate laboratory equipment, prevents the quantitative analysis of GMOs in Estonia. Estonia is the only country in the EU which does not have equipment for quantitative analysis of DNA. Therefore, there is an urgent need for the implementation of a strict control over the above-mentioned issues. The building-up of such control mechanisms has already started with the help of the NBF Development Project support by GEF/UNEP, but still needs additional financial resources.

Estonia signed the Cartagena Protocol on Biosafety (CPB) in September 2000, and ratified it on March 24, 2004. Estonia participated in the Development of NBF Project during 2001 – 2003 and established initial draft framework. Estonia has adopted the Act of Deliberate Release of GMOs into the Environment in May 2004 (the draft was worked out during UNEP-GEF development project), which is aimed at regulating the issues arising from or related to LMOs. The Act is harmonized with the Cartagena Protocol. However, several secondary legal acts need to be drafted, including amendments (updating) of the GMO Act and secondary legislation: regulation on processing applications coming from other EU member states, on establishment and maintaining of GMO register, on obligations of importers and on state monitoring and surveillance.) Many other legal acts, including an act regulating GMOs in contained use, use of GM test animals, use of GM seeds and plant propagation material, and GM fertilizers, have been worked out and are in force.

The main purpose of this project would be to help Estonia to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol and have a National Biosafety Framework fully operational by:

- completing drafting the legislation (Amendments of GMO Act) and secondary legislative acts under the responsibility of Ministry of Environment (MOE)

(secondary legislation: regulation on processing applications coming from other EU member states, on establishment and maintaining of GMO register, on obligations of importers and on state monitoring and surveillance) and non-binding guidelines and manuals to meet the obligations under CPB (risk assessment and management, monitoring). Adopt and implement these legislative acts and non-binding guidelines;

- the strengthening of appropriate institutional structures for risk assessment and decision making;
- inclusion of GMO policy into agricultural policy, especially in the light of coexistence; environmental policy and biotechnology policy;
- Train relevant people to handle requests (under advisory bodies and technical personnel in labs) and make decisions (under competent authorities), including scientific, technical and legal training;
- Enhance monitoring and surveillance system;
- Strengthen existing infrastructures (laboratory in TTU) and equip it appropriately so as to ensure good quality of GMO detection and suveillance; and
- Enhance public awareness (in all levels, starting with wider public and ending with governmental higher officials) and promote information exchange.

National institutional arrangements

The nominated focal point for the Cartagena Protocol is the Ministry of Environment. Administrative systems for biosafety are in place on paper, although not all are functional yet.
Responsibilities in regard of different types of LMOs and different activities are divided between three ministries:

- MoE - LMOs in environment and market,
- MoA – GM food and feed, GM test animals other than GMMs,
- MoSA – GMMs in contained use.

Since 1999, the Advisory Committee for Genetic Modification at the Ministry of the Environment as an advisory body for the government in giving licenses for handling LMO matters.
A Novel Food Committee has been set up at the Ministry of Agriculture that acts as an advisory body for the government. However, in order to efficiently control the issuing of licenses, Estonia needs effective control mechanisms to perform the risk assessment and monitoring of the LMOs and LMO products. The implementation of these control mechanisms is proposed by the current project.

Inspections and monitoring for environmental effects is mainly the responsibility of Environmental Inspectorate and also the Food and Veterinary Board, but the system needs strengthening and improved cooperation with different institutions (including Customs, etc.).

A public participation process for biosafety is also in place. Estonia has ratified the Aarhus Convention and included this into their legislation, so everybody has right for an access to environmental information and to participate in decision making process, includingg for the safe use of biotechnology.

Project **Overall Goal**

By 2009, Estonia has a workable and transparent national biosafety framework, in line with its national development priorities (environmental, agriculture and biotechnology strategies) and

international obligations

Project Specific Objectives

A. to assist Estonia to integrate biosafety into a national strategy on environment, agriculture (especially in the light of co-existence of LMOs and organic farming) and biotechnology,

B. to assist Estonia to finalize, adopt and implement a fully functional and responsive regulatory regime in line with CPB, national needs and other international obligations.

C. to assist Estonia to improve the system for handling requests, including risk assessment, decision-making and administrative processing;

D. to assist Estonia to improve the system for "follow-up", especially monitoring of environmental effects and enforcement and make the system functional,

E. to assist Estonia to improve system for public awareness, participation, education and access to information.

Project Outcomes

A. Biosafety is integrated into the national environmental, biotechnology and agriculture strategy in Estonia and has public and political support.

- biosafety policy is part of agricultural policy, in line with coexistence guidelines and in agreement with MoE and MoA, other relevant ministries; and part of environmental strategy and biotechnology policy:

B. Estonia has a fully functional and responsive regulatory regime in line with CP and national needs and other international obligations

- GMO Act amended, amendments adopted and in force;
- Secondary regulations on processing applications coming from other EU member states, on establishment and maintaining of GMO register, on obligations of importers and on state monitoring and surveillance drafted and adopted;
- Officials from different institutions (customs, different ministries) better educated on legal issues as well as NGOs, exporters-importers and companies,
- Guidelines for legal issues worked out and published.

C. Estonia has a functional national system for handling requests and decision-making, including performing risk assessment and management related to LMOs and administrative processing

a) Guidelines for handling applications of LMOs (including RA/RM) are published
b) Different trainings for handling requests carried out.
c) GMO register created and operational

D. Estonia has functional national systems for monitoring of environmental effects and enforcement

a) Laboratory equipped for monitoring and surveillance,
b) Personnel trained (different practical trainings and lecture courses carried out), training guidelines etc in place.
c) Inspection for compliance of regulatory regime carried out (for labelling, conditions of contained use, importing conditions etc).

E. Estonia has a functional national system for public awareness, participation, education, and access to information

a) Awareness raised on the level of general society, schools, universities and officials through info-days, lecture courses, TV broadcasts, newsletters etc
b) Public opinion poll carried out.

For Indicators: see attached log frame at Annex B.

Estimated budget (in US$)

GEF: Project Cost: 669 000 US $

Co-financing: (Estonian government and TTU 284 000 US $

In cash: 0 US $
In kind 284 000 US $

(TTU 204 000 USD, MoE 80 000 USD)

Total: 953 000 US $

Associate financing: "Development of GMO chain management for co-existence of genetically modified, conventional and organic crops", 610 500 EUR (ca 700 000 USD), under MoA, European Commission

Information on Project Proponent:

The Project "Capacity building for the Implementation of the National Biosafety Framework of Estonia" will be executed by the Tallinn Technical University (TTU), under the supervision of the MoE. The TTU will constitute a project coordinating committee from major stakeholders, based on the members of NCC from the UNEP-GEF NBF Development Project**.** The MoE will ensure the financing in kind and in cash of part of this project as well as the necessary logistics all through its fulfilment.

The TTU will have a special Memorandum of Understanding with official CA for Biosafety – Ministry of the Environment, to ensure proper functioning of project and to guarantee assistance from other ministries. TTU has been the only laboratory in Estonia conducting GMO tests for governmental bodies (qualitative analysis so far only). TTU has well equipped facilities and well trained personnel. The contact person of the project is the Chairperson of advisory body for GMOs and a member of the Committee for Novel Food and was also member of NCC during the previous NBF Development Project.

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B - COUNTRY OWNERSHIP

B1. Country eligibility

Estonia ratified the Convention on Biological Diversity on July 27, 1994 and signed the Cartagena Protocol on Biosafety on September 06, 2000. The Cartagena Protocol on Biosafety was ratified on March 24, 2004.

B2. Country Driveness

Project linkage to national priorities, action plans and programmes:
Estonia ratified CBD in 1994. The National Biodiversity Strategy and Action Plan (NBSAP) was completed in 1999. As biosafety was not a priority issue in Estonia at the times, this issue was dealt with briefly under the paragraph of the genetic resources and biotechnology. The term biosafety itself is not used in the document and no actions except working out relevant legislation was foreseen.

However, shortly after completion of NBSAP, biotechnology has become one of the main priorities for Estonian Government. With its Human Genome Project, Estonia is one of the leading countries in the overall world, according to the amount of money spent per capita for biotechnology in the country. However, the topic of biosafety is generally still clearly underfinanced.

There is no special national policy for biosafety in Estonia. As part of EU, the general policy is similar to this of EU. Estonia is currently harmonising its legislation with EU directives and regulations regarding biosafety as well as the CPB. While working out legislation for biosafety, it slowly becomes a natural part of agricultural policy and food and feed safety regulations. Ministry of Agriculture is currently working out policy for coexistence of GM crops and conventional, especially organic crops. Ministry of Environment is working with environmental strategy and policy for biotechnology is being worked out by Ministry of Economy and Ministry of Finance.
Although a general legal framework is in place, it needs some amendments and some secondary legal acts need to be drafted (see previous chapters).
Estonia is lacking a cross-sectoral biosafety strategy and action plan to be integrated into other national strategies and action plans.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the GEF Biodiversity Focal Area and relates to Operational Programmes OP 1-4, and 13. Within the four strategic priorities of this focal area, it is most relevant to biodiversity focal areas Strategic Priority SP3: Capacity Building for the Implementation of the Cartagena Protocol on Biosafety.
i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living

organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private sector stakeholders."

C2. PROJECT DESIGN

Details shown in logframe, attached as Annex B.

C2.A BACKGROUND AND CONTEXT

In 1997, responding to the third Conference of the Parties to the Convention which called for GEF to provide the necessary financial resources to developing countries for **Capacity Building In Biosafety**, the GEF Council approved a US$ 2.7 million Pilot Biosafety Enabling Activity Project.

The Pilot Project involved 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia and Malawi) and consisted of the following two components:

A *National Level Component* aimed at assisting the eighteen countries to prepare National Biosafety Frameworks (US$ 1.9 million), and

A *Global Level Component* aimed at facilitating the exchange of experience at regional level through the organisation of regional workshops (2 workshops in each of four regions) which involved a very large number of countries (US$ 0.8 million).

The Cartagena Protocol on Biosafety was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity in Montreal, Canada, on 29 January 2000. It was opened for signature in Nairobi, on 24 May 2000 and as of 1 November 2004, 110 countries have already ratified or acceded to the Protocol. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements of LMOs".

In November 2000 the GEF Council approved the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety" (GEF/C.16/4). The main objectives of the strategy are to a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and sub-regional level, and c) promote collaboration with other organizations to assist capacity-building for the Protocol.

In December 2001, the GEF Council approved 12 demonstration projects to support countries in the implementation of their national biosafety frameworks. Two projects (Malaysia and Mexico) are implemented by UNDP, eight projects are being implemented by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and World Bank is implementing two projects (India and Colombia).

Parties at the seventh Conference of the Parties to the Convention, serving as the first Meeting of the Parties to the Cartagena Protocol (COP7/MOP1), which was held in Kuala Lumpur, (Malaysia) in February 2004 focused on setting up an operational framework for the effective implementation of the Protocol. They approved Decision VII/20 on Further Guidance to the

financial mechanism. The decision invites the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.

The COP/MOP decision specifically calls upon the GEF to "provide additional support for the development and/or strengthening of existing national and regional centres for training; regulatory institutions; risk assessment and risk management; infrastructure for LMO detection, testing, identification and long-term monitoring; legal advice; decision-making; handling of socio-economic considerations; awareness-raising and technology transfer for biosafety." This project fulfils these criteria.

Further endorsement of the above is reflected in the decision on *Agenda Item 9, at* the Joint Summary of the Chairs of the GEF Council, held from 19-21 May 2004, which states "*The Council welcomes the guidance of the Conference of the Parties to the CBD inviting the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries*

Estonia is a Party to the Cartagena Protocol on Biosafety, which entered into force on September 11, 2003, on the 90th day after the date of deposit of the fiftieth instrument of ratification or accession.

Estonia participated in the Global Project on "Development of National Biosafety frameworks". In order to design its **National Biosafety Framework**, Estonia:

- Completed inventories of current use of modern biotechnology in Estonia as defined in the Cartagena Protocol; existing legislation or legal instruments related to biotechnology / biosafety, etc.; active or planned National Projects for capacity building related to the safe use of biotechnology.
- Completed roster of relevant experts within the country, identifying their experience and expertise so that adequate coverage in all areas of expertise is obtained and potential gaps can be identified. Roster is available also through BCH.
- Organized many training workshops, including workshop on GMOs and new requirements resulting from implementation of the CPB in Estonia; workshop on "Identification and analyses of options to implement relevant provisions of the CPB and to review the findings of the surveys, identification of gaps, needs and priorities"; training on GM food safety; workshop on national biosafety framework; public awareness workshop on the national biosafety framework with the participation of NGOs, consumer organizations, the scientific community and the private sector incl farmers, the food and feed industry; seminar on Biological Safety and DNA-laboratory work targeted to college teachers of chemistry and biology;
- Many brochures were published (20 questions about GMOs, CPB, GMOs and agriculture, GM food).
- GMO Act was amended and amendments were adopted by Parliament.
- Act on ratification of CPB prepared and sent to the Parliament.

NBF was drafted. A copy of the draft National Biosafety Framework which was accomplished under the above project, is attached at Annex A.

C2.B Current situation (in the country with respect to the NBF)

The current situation of biotechnology resources in Estonia

In Estonia, fundamental biotechnological research has been carried out over more than 30 years. Genetic technology research in Estonia is primarily carried out in Tallinn and Tartu. In Tartu, this is done at the Institute of Molecular and Cell Biology (IMCB) of Tartu University. The main avenues of research at IMCB are concerned with human hereditary diseases and molecular diagnostics of human pathogenic bacteria and viruses. On the other hand, a technology that has already been used for about ten years in Põlva for the biological removal of phenolic compounds from the wastewater of a timber glue lamination plant was first devised at IMCB. The uses of plant and animal genetic technology are being developed at the Estonian Agricultural University. Genetic technology has been studied in Tallinn for 15 years at the National Institute of Chemical and Biological Physics and Tallinn Technical University (TTU). From the beginning of 2005 a new building of natural sciences at TTU formed the basis of the modern molecular biology and gene technology research.

GMOs are used in Estonia primarily for fundamental research work. The three most important establishments where such research is conducted are the Estonian Biocentre and the Institute of Molecular and Cell Biology in Tartu, and TTU, Tallinn. Work on the applied aspects is carried out at Tartu University in the Genetic Technology Department of the Technology Center and in the Genetic Technology Group of the Environmental Technology Department, and at Tallinn Technical University in the Department of Gene Technology.

Biotechnology as an industrial sector is in its early phase of development in Estonia. Although, the first biotech companies in Estonia were started even before regaining independence in 1991. The management of these companies had a background of the Estonian Biocentre (EB) or National Institute of Chemical and Physical Biology. Their activities included making protein preparations from blood sera and bacterial cultures. Introduction of the hybridoma technology in early eighties gave rise to production of numerous panels of monoclonal antibodies against different plant viruses, including potato viruses widespread in Estonia. The political turmoil and the following recession hit hard on Estonia's life sciences. Today, a few years later, fostered by the country's successful reforms and change in orientation, biological research is thriving again. There is awareness of and interest in the development of biotechnology in Estonia on a governmental level. Genetic and environmental technology have been recognized as priorities for Estonian scientific research.

Biotechnology sector in Estonia is full of suitably qualified personnel. The publicity surrounding biotechnology has had a chain-reaction effect within the country, spurring an explosion of interest in the field among students. Last year, Tartu University and TTU experienced a sharp rise in the number of students enrolled in genetics courses. This sparking interest of youngsters can be visioned as a future reservoir of researchers in the life sciences

There is a sufficiently good overview of the use of GMOs in academic institutions; only information about smaller research laboratories is missing. There is, however, a shortage of information about the use and planned use of GMOs in private enterprise and agriculture.

Biosafety policy

There is no special national policy in biosafety in Estonia. As Estonia joined EU in May 2004, the general policy is similar to this of EU. Estonia is currently harmonising its legislation with EU directives and regulations regarding biosafety as well as Cartagena Protocol.

Estonia is lacking of cross-sectoral biosafety strategy and action plan to be integrated into national strategies and action plans. This includes also involving actions planned by MoA: national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic

farming. The current environmental strategy is in force until 2010 where biotechnology and LMOs have mentioned briefly. Mainly in concern with the emphasis on precautionary principle and in concern with the need to preserve national breeds and species; also the food has been mentioned. The next period planned for the strategy is until 2030. Strong and straightforward biosafety policies and goals are needed and will be integrated into the strategy until year 2030.

Regulatory regime for biosafety

In 1999, the Estonian Act on Deliberate Release into the Environment of Genetically Modified Organisms came into force. This Act was replaced by a new version in the beginning of 2004. It is important to mention here that although there was no legal framework for the production and marketing of GMOs in Estonia until the adoption of the GMO Act (1999), the Seed and Vegetative Propagation Material Act (RT I 1998,52,771) required the labelling of the retail packaging of certified genetically modified seed and vegetative propagation and cultivation material with the letters "GMO". The purpose of the 1999 Act is to protect human health and the environment from the consequences of the release into the environment of GMOs, to ensure the safe use of genetic modification techniques and the development of such techniques in an ethically acceptable manner. In Estonia, the task of monitoring the introduction of GMOs into the environment has been assigned to the Environmental Inspection Division and is regulated by the Environmental Control Act (RT I 1997,86,1460). Contained use of GMOs is the responsibility of the Ministry of Social Affairs.

An Advisory Committee for Genetic Modification (ACGM) has been set up by Cabinet of Ministers (a new one 17.06.2005 OJ RTL, 30.06.2004, 87, 1383) to advise MoE on issuance of licenses for the deliberate release of GMOs into the environment and the marketing of such entities. There are 17 persons appointed by various ministries (MoE, MoA, MoSA) and institutions (universities, consumer protection board, academy of sciences, 4 members from NGOs etc) in the Committee at present.

Applications should be sent to the Ministry of Environment, which will do the initial check for completeness. ACGM has to give a written reply to comments made by public within two weeks. The committee will send a recommendation (in the form of a draft decision) to the Minister within 90 days starting from the submission date. The Minister then has 14 days to decide and give a permit or refuse.

Concerning GM animals for contained use, the legislation is in place under the Ministry of Agriculture (Animal Protection Act) since 2003. Advisory Committee for Genetic Modification at the Ministry of the Environment has been granted a task to evaluate the risk analysis GM animals and, on the basis of the analysis results, the advisory body can advise MoA about the issuance of a permit for the experiment the application has made for.

ACGM is also involved in assessing the environmental aspects under the Novel Food regulations (if the LMO will be used in the environment in the process). The use of GMOs in food is regulated by the Food Act (RT I 2004, 34, 236) in force since 1 May 2004). Paragraph 13 discusses "novel foodstuffs" which include foodstuffs "...which have not been used extensively as food before and which contain or consist of genetically modified organisms, or which are produced by GMOs but do not contain them...". The law requires that novel foodstuffs be investigated and evaluated in regard to the respective standards and that a license for their processing be obtained from the Veterinary and Food Inspection.

The MoA is responsible for the implementation of European Union's "Regulation 1829/2003/EC on genetically modified food and feed" and "Regulation 1830/2003/EC concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms". The Novel Food Committee has been established by law to advise the MoA during the novel food permit notification process and for the risk assessment. Competent Authority

for the regulation is Veterinary and Food Board of MoA (assessing EU applications for food with Novel Food Committe). The feed side is covered by Plant Production Inspectorate of MoA.

Regulation No. 176 of 30 May 2000 of the Government of the Republic "Special requirements for the labeling of food produced of genetically modified soybean or genetically modified maize and for presentation of information in any other manner" (RT I 2000, 43, 275); entered into force 09.06.2000.

Advisory Committee for Genetic Modification advises also Ministry of Social Affairs in regard of contained use of GMM-s (see below) and Ministry of Agriculture in regard of GM animal tests. On December 10, 2001, the Act on the contained use of genetically modified micro-organisms (GMMs) came into force (Official Journal RT I 2001, 97, 60). The objective of the act is to regulate safe use of GMMs in contained use in order to protect human health and the environment. The Act also aims to implement Directive 90/219/EEC, as amended by Directive 98/187/EEC. The Act requires permits for the contained use of GMMs. Detailed requirements for applications are given in the Regulation No 10 of 8 January, 2002. A list of data to be included in a risk assessment and procedure for making risk assessment is given in the Regulation No 8 of 8 January, 2002. The Ministry primary responsible for the implementation is the Ministry of Social Affairs.

System for handling request for permits

The responsibility for regulating of use of GMOs is divided between three ministries in Estonia:

1. *Ministry of the Environment* is responsible for issuance of permits for deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;

2. *Ministry of Agriculture* is responsible for issuance of permits for handling and marketing of novel food (including genetically modified food), permits of use of seeds and plant propagation material, fertilizers, feed and permits for conducting of tests with animals;

3. Ministry of Social Affairs is responsible for issuance of permits for contained use of genetically modified micro-organisms (GMMs).

As a requirement of CPB, Estonia has nominated the Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs as Competent Authorities, according to the abovementioned division of tasks (see http://bch.biodiv.org/Pilot/SearchResults.aspx?SearchID=77629&Page=1&DocumentType=2).

As Estonia is a small country, it was not considered to be necessary to create separate advisory bodies in every mentioned ministry. There are two advisory committees in Estonia responsible for making risk assessment for GMOs and products containing of GMOs or consisting of GMOs:

- *Advisory Committee for Genetic Modification,*
- *Novel Food Committee (*in addition to GM-food also conducts risk assessment for products that are obtained from GMOs, but not containing GMOs).

Systems for monitoring of environmental effects and enforcement

Similarly to the system of handling requests, also the monitoring and enforcement are divided between three ministries in Estonia:

- *Ministry of the Environment*:
    - *The Environmental Inspectorate* is responsible for surveillance of deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;
- *Ministry of Agriculture:*
    - *The Veterinary and Food Board and Health Protection Inspectorate* are responsible for surveillance of novel foods (including genetically modified food),
    - *The Plant Production Inspectorate under Ministry of Agriculture* is responsible for surveillance of use of seeds and plant propagation material and feed,
    - *The Veterinary and Food Board, Environmental Inspectorate and Policy Board* are responsible for surveillance of conducting tests with animals;
- *Ministry of Social Affairs:*
    - *The Labour Inspectorate under* is responsible for surveillance of contained use of genetically modified micro-organisms (GMMs).
    - *The Consumer Protection Board* is responsible for checking the proper labelling of the products at retail level.

There is no functional environmental surveillance and monitoring system in place yet.

The Veterinary and Food Board in cooperation with the Ministry of Agriculture has introduced programs for monitoring of presence of genetically modified soya and maize in food. Monitoring of GM soya and GM maize was first carried out during May-November 2001. The monitoring focused on the products that potentially could contain GM soya or maize. The aim of the monitoring program was to get an overview of what kinds of and how many food products which are produced from genetically modified soya or maize are on the Estonian market. Sixty-one samples containing soya ingredient and 81 samples containing maize ingredient were taken from state border and wholesalers. The variety of foodstuffs from which the samples were taken was quite wide. For example, samples were taken from soy flour, maize starch, soy sauces, cornflakes, meat products, biscuits etc. The samples were analysed in the National Institute of Chemical Physics and Biophysics using a Polymerase Chain Reaction (PCR) method. A commercial kit was used allowing the detection of Maximizer Bt 176, Bt 11, Liberty Link and Yield Gard corn and Roundup Ready soybean. Forty-nine samples out of 142 did not give a result. No samples containing GM maize were detected. However, 8 samples containing soybean ingredient were found to be genetically modified.

Public Information and Participation

In Estonia every citizen has access to information regarding GMOs and the right to participate in the decision making process. The main legal act is **Act on Release into the Environment of Genetically Modified Organisms** (RT I 2004, 30, 209). This act contains provisions on active and passive information to the public and public participation in decision making.
Upon receipt of an application, the Ministry of the Environment will send a copy to the Advisory Committee for Genetic Modification (ACGM). The advisory body is established by the Act and comprises of 17 members appointed by various ministries and institutions, with a request for advice. MoE makes the application available to public for comments (30-60 days) announcing it on Official Announcements web site http://www.ametlikudteadaanded.ee/. In the need public hearings will be convened. Advisory Committee will answer the questions in 2 weeks upon receiving. Final decisions are taken by the Ministry of the Environment. These are also made public.

Additionally, there is also a general Act on access to information – the Public Information Act which entered into force in January 2001. The purpose of this Act is to ensure that the public and every individual has access to information intended for public use, based on the principles of a democratic and

social rule of law and an open society, and to create possibilities for the public to monitor the performance of public duties.

According to the Act on Contained Use of GMMs it is not obligatory to publish information about GMMs in contained use, but competent authority (Ministry of Social Affairs) could do it accordingly to Public Information Act.

Data on GMOs both in the environment, on the market and in contained use (name of GMO, site of use, purpose of use etc, except confidential information) will be available in the public GMO register. Due to reconstruction of this database it is currently not available electronically.

Estonia has also ratified the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) on 2 August 2001.

C2.C PROJECT Rationale

Estonia ratified the CPB on 24 March 2004 and as a Party is now obliged to meet the requirements of the CPB.

Due to the possible risk arising from the use of GMOs and GMO-containing products to the environment, human and animal health, a number of legal regulations have been developed and introduced for handling of LMOs and LMO-containing products in EU and worldwide. The main purpose of this project would be to help Estonia to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the Protocol and have a National Biosafety Framework fully operational.

Administrative system is in place in paper, although it is not quite functional yet. Since 1999 the Advisory Committee for Genetic Modification has served Estonia at the Ministry of the Environment as an advisory body for the government in giving licenses for handling LMO matters. A Novel Food Committee has been set up at the Ministry of Agriculture that acts as an advisory body for the government. However, in order to efficiently control the issuing of licenses, Estonia needs effective control mechanisms to perform the risk assessment and monitoring of the LMOs and LMO products. The implementation of the control mechanisms is proposed by the current project.

Inspections and monitoring for environmental effects is mainly the responsibility of Environmental Inspectorate and also Food and Veterinary Board and Plant Production Inspectorate but the system needs much strengthening and cooperation with different institutions (incl customs etc). The lack of the relevant laboratory equipment does not permit the quantitative analysis of GMOs so far in Estonia. Estonia is the only country in EU who does not have equipment for quantitative analysis of DNA. Therefore, strengthening existing infrastructures (laboratory in TTU) and equipping it appropriately so as to ensure good quality of GMO detection and surveillance is of utmost importance for Estonia.

There is also a possibility that new crop varieties that are/will be obtained with the help of biotechnology might come into trials in Estonia. Therefore, there is an urgent need for the implementation of a strict control over the above-mentioned issues. The up-building of such control mechanisms has already started with the help of the NBF Development Project support by GEF/UNEP, but still needs additional financial resources.

Although Estonia has more or less succeeded in implementing the EU directive and regulation concerning the release of genetically modified organisms and the country is ready to deal with biosafety issues in theory, however, relevant authorities/officials lack the practical experience and means to do so. There is a need to train relevant people to handle requests (under advisory bodies and technical personnel in labs) and make decisions (under competent authorities), including scientific, technical and legal training.

In this respect, the Project would addresses most of the capacity building needs of Estonia. These needs range from building legal, scientific and administrative expertise to strengthening laboratory for risk assessment, evaluation and inspection purposes. Without this project Estonia could remain for long time on the level it is now – theoretically everything seems to be in place, on paper it looks good, but there are serious problems in practical implementing even the minimum obligations of CPB.

In the absence of GEF contribution, the baseline scenario is as follows:

a. Implementation of Protocol

Lack of funding will prolong and postpone the implementation of the Biosafety regulations in Estonia that will endanger the control over GMO/LMOs in Estonia.

Lack of appropriate surveillance system makes Estonia dependent on other countries and will be more expensive in longer term, if Estonia should continue to order tests and expertise from other countries. According to preliminary calculations it is almost 1/3 or in some cases even 1/2 cheaper to make GMO tests in Estonia than to order them from abroad (transportation costs, service fees, etc).

b. Economic situation

Biosafety could remain a priority for Estonia on paper only, not being practically included into other sectorial policies and consequently not being implemented or taken into account at all.
Currently a union of NGOs has raised the issue of declaring Estonia as GMO free zone. For finding a compromise solution it would need active discussions and agreement on governmental level. At the moment the government has not allocated money for that. Awareness of politicians about biosafety issues is very low and they are very easily manipulated by interest groups, and it could lead to wrong political decisions for Estonia in regard of GMO policy that would affect economy and especially agriculture and farmers.

c. Environmental and Development Viewpoint

Even though Estonia is not centre of diversity or centre of origin of any crops, uncontrolled use of GMOs could still affect its nature and biodiversity. Many wild plants *(Cruciferaceae*) are able to cross pollinate with rape seed. As rape seed pollen could "travel" long distances, even kilometres, then it would need good investigation and precaution and special measures for growing and using these GM plants in Estonia. Other GMOs could have rather indirect effects to non-target insects and soil micro-fauna, but these effects need some more investigation.

As Russia has not yet ratified CPB, but they are growing GMOs (no official data available, though) then it might cause problems to Estonia due to differences in regulatory system, over-border cross-pollination, problems with transit of GMOs through and to Estonia (unintentional transboundary movements) might occur. Therefore effective border control and monitoring systems should be put in place.

EXPECTED PROJECT OUTCOMES, WITH UNDERLYING ASSUMPTIONS AND CONTEXT

Outcome A	Biosafety is integrated into the national environmental, biotechnology and agriculture strategy in Estonia and has public and political support by 2009
Outputs	- Info day (lecture course) carried out for members of government (MoE, MoA and others) and parliament (Commission of Environment), 1 day, 40 participants, 1st and 3rd year - policy paper drafted, strategy and action plan for biosafety composed and integrated into Environmental Strategy 1st – 2nd year, adopted 3rd – 4th year. - biosafety policy harmonized within strategy of agriculture, 1st and 3rd year, meeting carried out for 20 persons from MOA and MOE. - biosafety policy harmonized within biotechnology policy, 1st and 3rd year, meetings carried out for 25 persons from MOE, MOA and M of Finance and M of Economy
Outcome B	Estonia has a fully functional and responsive regulatory regime in line with CP and national needs and other international obligations by 2009
Outputs	- Composed drafting group of 3-4 lawyers, their meetings and consultation with stakeholders carried out. As a result, GMO Act amended, amendments prepared for ministerial approval, then for governmental approval and then. adopted. Same for secondary regulations on processing applications coming from other EU member states, on establishment and maintaining of GMO register, on obligations of importers and on state monitoring and surveillance. - 60 persons from customs personnel, importers and exporters and other company representatives trained legal aspects of transboundary movements of LMOs and related products, two one-day lecture courses carried out (1st and 4th year), - - Guidelines for legal issues worked out and published. - 15-20 lawyers from MoE, MoA and interested NGOs trained on legal aspects of LMOs and its connection to other international legal acts (WTO, IPPC), 5 days training, 2nd year.
Outcome C	Estonia has a functional national system for handling request and decision-making including performing risk assessment and management related to LMOs and administrative processing by 2008
Outputs	Guidelines for handling applications of LMOs (including RA/RM) published 1st – 2nd year. Different trainings for handling requests carried out. 20-30 persons from Ministry of Social Affairs and private companies and members of ACGM trained on the safety aspects of handling of GMO-s in containment; 20 members of the Institute of Gene Technology, members of ACGM trained on the evaluation and risk assessment of the LMO field tests and other procedures important in setting up a field test; - GMO register created and operational.
Outcome D	Estonia has a functional national system for monitoring of environmental effects and enforcement by 2009
Outputs	- TTU laboratory equipped for GMO detection, - Inspection for compliance of regulatory regime carried out (for labelling, conditions of contained use, importing conditions etc). - Staff of the food and veterinary inspection trained on the monitoring and inspection issues, 1st and 4th year, 50 persons from customs trained on regulations of the transboundary movement of LMOs according to the CPB as well as the use of the Biosafety Clearing House, 1st and 4th year; 15-20 persons from animal nutrition and food monitoring authorities trained on taking samples and on practical monitoring, 3th

	year; 25 TTU workers and ACGM members trained on the methodology, handling PCR machine, interpretation of the results etc, 1st and 2nd year. - Set of guidelines for customs control purposes, including a mechanism for efficient control of transboundary movements of LMOs, published and disseminated. - 1-2 experts from TTU participate in ENGL yearly meetings in order to gain information about GMO tests and to be trained in GMO testing.
Outcome E	Estonia has a functional national system for public awareness, education, participation, access to information
Outputs	- Popular informative material distributed on the risks and benefits of the use of LMOs; newsletter distributed, twice a year; informative materials for secondary schools distributed and used in conjunction with biology lessons about the Cartagena Protocol and the development of LMOs and related products; an educational TV broadcast carried out on the Cartagena Protocol, the use of LMOs and the risks of the use of LMOs, 2nd and 4th year; course of biosafety for Universities worked out and used in TTU (working out 1st and 2nd year, used 3th and 4th year). One day info day carried out for consumers and NGOs about possible risks and benefits of LMOs, 60-70 participants, 2nd and 4th year; 2nd and 4th year organized public info days about the project and its outcomes, one day, 50-60 participants; one-day informative training carried out for the representatives of NGO-s and general public on the biosafety decision-making issues. Public opinion poll carried out 2nd or 3rd year.

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

Details shown in logframe, attached as annex B.

Planned activities to achieve outcomes

1. **Activities for Biosafety Policy: Total costs (TOT:16 000 USD; GEF 10 000 USD: Government 8000 USD)**

1.1 Organization of an one-day info day (lecture course) for members of government (MoE, MoA and others) and parliament (Commission of Environment), for informing all stakeholders about project and its expected outcomes., and discuss the best options for achieving them. Total costs (TOT: 2000 USD; GEF 1000 USD: Government 1000 USD)

1.2.Drafting a policy paper, strategy and action plan for biosafety, integrate it into Environmental Strategy 1st – 2nd year, adoption 3rd – 4th year. Total costs (TOT: 8000 USD; GEF 6000 USD, Government 2000 USD)

1.3 In order to ensure that strategy of coexistence of GMOs and conventional crops, being worked out under MoA, is in line with requirements of CP and biosafety policy, there will be organized 2 meetings for 20 persons from MOA and MOE for analysing and integrating the biosafety issues within strategy of agriculture. Total costs (TOT: 4000 USD; GEF 2000 USD: Government 2000 USD).

1.4 For the same reason similar meetings will be organized for harmonizing biosafety policy within biotechnology policy, meetings for 25 persons from MOE, MOA and M of Finance and Economy. Total costs (TOT:2000 USD; GEF: 1000 USD Government 1000 USD).

2. Activities for Regulatory regime Total costs (TOT: 39 500 USD; GEF 28 000 USD: Government 11 500 USD)

2.1. Even though regulatory regime for biosafety is in general in place, it still needs some adjustments. Therefore it is planned to draft, discuss and adopt of amendments for GMO act and secondary legal acts on:

a) regulation on processing applications coming from other EU member states,
b) regulation on establishment and maintaining of GMO register,
c) regulation on obligations of importers
d) regulation on state monitoring and surveillance.

This work will include composing drafting group of 3-4 lawyers, their work, meetings, consultation with stakeholders, preparation for ministerial approval, and then for governmental approval). Total costs (TOT:18 000 USD; GEF 10 000 USD: Government 8000 USD)

2.2 Organize two one-day lecture courses for customs personnel, importers and exporters and other company representatives about the legal aspects of transboundary movements of LMOs and related products (60 participants) Total costs (TOT: 6000 USD; GEF 5000 USD: Government 1000 USD)

2.3 Publishing of guidelines for a) Governmental organizations on LMOs legislation; b)Importers and exporters about the transboundary movements and legal aspects of LMOs. Total costs(TOT: 9000 USD; GEF 7000 USD: Government 2000 USD)

2.4 Organize legal training for lawyers from MoE, MoA and interested NGOs on legal aspects of LMOs and its connection to other international legal acts (WTO, IPPC), 15-20 participants, 5 days, 2006. Total

costs (TOT 6500 USD; GEF 6000 USD: Government 500 USD)

3. Activities for Handling requests for permits Total costs (TOT:38 000 USD; GEF 33 000 USD: Government 5000 USD)

3.1. Publish technical guidelines for handling of requests (incl RA/RM guidelines), separately for GMMs and GM higher plants. Total costs (TOT 10 000 USD; GEF 8000 USD, Government 2000 USD)

3.2. Organize a three-day hands-on advanced training course for the Ministry of Social Affairs and private companies and members of ACGM on the safety aspects of handling of GMO-s in containment and in environment, 20-30 participants. Total costs (TOT 8000 USD; GEF 7000 USD, Government 1000 USD)

3.3. Organize a seven-day practical advanced course on the evaluation and risk assessment of the LMO field tests and other procedures important in setting up a field test for the members of TTU, members of ACGM (20 participants). Total costs (TOT: 9000 USD; GEF 8000 USD: Government 1000 USD)

3.4. Create and operationalize GMO register for data input from different ministries (MoA, MOE, MOSA), and authorized members from ACGM. Total costs (TOT: 11 000 USD; GEF 10 000 USD: Government 1000 USD)

4. Activities for System for follow-up (Monitoring of environmental effects, inspections and enforcement) Total costs (TOT: 434 500 USD; GEF 253 000 USD: Government 181 500 USD)

4.1. There is no accredited laboratory in Estonia for making quantitative GMO tests, therefore a reference laboratory of TTU will be equipped for detection and inspections on LMOs and related products. List of equipment – see Annex G. Total costs (TOT 352 000 USD; GEF 200 000 USD: Government 152 000 USD)

4.2. Organize two days lecture course for the staff of the food and veterinary inspection on the monitoring and inspection issues. Total costs (TOT 4000 USD; GEF 3000 USD: Government 1000 USD)

4.3. Carry out ispection for compliance of regulatory regime (for labelling, conditions of contained use, importing conditions etc). Total costs (TOT 24 000 USD; GEF 20 000 USD: Government 4000 USD)

4.4. The experts of the reference laboratory attended ENGL yearly meetings. Total costs (TOT: 8000 USD; GEF 0 USD: Government 8000 USD)

4.5. Purchase literature and relevant journals concerning LMO analyses for TTU and experts from ACGM. Total costs (TOT: 9 000 USD; GEF 3000 USD: Government 6000 USD)

4.6. Organize two-day lecture course for the Customs personnel, including relevant persons from each customs station in Estonia on regulations of the transboundary movement of LMOs according to the Cartagena Protocol as well as the use of the Biosafety Clearing House Mechanism (50 participants).. Total costs (TOT 5000 USD; GEF 4000 USD: Government 1000 USD)

4.7. Publish and disseminate set of guidelines for customs control purposes, including a mechanism for efficient control of transboundary movements of LMOs, Total costs (TOT: 4000 USD; GEF 4000 USD: Government 0 USD)

4.8. Organize practical training on taking samples and on practical monitoring for all animal nutrition and food monitoring authorities, 15-20 participants, 5 days. Total costs (TOT 6000 USD; GEF 5000 USD: Government 1000 USD)

4.9. Organize technical training for TTU workers and for ACGM members regarding the methodology, handling PCR machine, interpretation of the results etc, 25 participants. Total costs (TOT: 14 000 USD; GEF 10 000 USD: Government 4000 USD)

4.10. Organize a workshop for consumer protection, veterinary and food board inspection officers, environmental inspectorate and plant production inspectorate on biosafety and genetic modification to equip them with inspection of GM activities, (20-30 participants). Total costs (TOT: 4500 USD, GEF 4000 USD: Government 500 USD)

5. Activities for Public information, participation, awareness Total costs (TOT: 70 000 USD; GEF 56 000 USD: Government 14 000 USD)

5.1. Publish and disseminate popular informative material on the risks and benefits of the use of LMOs. Total costs (TOT: 6000 USD; GEF 5000 USD: Government 1000 USD)

5.2. Publish and disseminate newsletter, twice a year, in collaboration with journal Estonian Nature (or Greengate). Total costs (TOT: 6000 USD; GEF 4000 USD: Government 2000 USD)

5.3. Work out and distribute informative materials for secondary schools and used in conjunction with biology lessons about the Cartagena Protocol and the development of LMOs and related products Total costs (TOT: 5 000 USD; GEF 5 000 USD: Government 0 USD)

5.4. Carry out an educational TV broadcast on the Cartagena Protocol, the use of LMOs and the risks of the use of LMOs. Total costs (TOT: 12 000 USD; GEF 10 000 USD: Government 2000 USD)

5.5. Organize one day info day for consumers and NGOs about possible risks and benefits of LMOs, 60-70 participants. Total costs (TOT: 5000 USD; GEF 4000 USD: Government 1000 USD)

5.6. Organize public opinion poll. Total costs (TOT: 4500 USD; GEF 4000 USD: Government 500 USD)

5.7. Organize public info days about the project and its outcomes, one day, 50-60 participants. Total costs (TOT: 3000 USD; GEF 2000 USD: Government 1000 USD)

5.8. Organize one-day informative training for the representatives of NGO-s and general public on the biosafety decision-making issues. Total costs (TOT:2500 USD; GEF 2000 USD: Government 500 USD)

5.9. Work out and use curricula for course of biosafety for Universities, used at least in TTU (working out 1st and 2nd year, used 3rd and 4th year). Total costs (TOT:10 000 USD; GEF 4000 USD: Government 6000 USD)

6. Project coordination, including institutional set-up, staffing, audit etc. Total costs (TOT: 285 000 USD; GEF 225 000 USD: Government 60 000 USD)

7. Other project support, including UNEP management, Total 86 000 USD, GEF 80 000 USD, government 6000 USD

For Indicators for the above activities, see the attached log frame, Annex B.

C.3 Sustainability

This project is a logical and necessary continuation of biosafety capacity building activities carried out to date, including those completed during the Development Project.

Institutional sustainability

Under the existing legislation, responsibilities for implementing CPB is divided and in place, only the division of responsibilities and tasks in relation of surveillance and monitoring has not been finalized.

Advisory bodies for government are established and financed under governmental funds. Institutional system is in place and functioning, apart from laboratory able to detect GMOs (quantitative analysis).

TTU will sign a special MoU with MoE for ensuring that TTU will provide services for certain price and that they get governmental funds for GMO surveillance. All equipment will remain the property of TTU, but government will have priority access to equipment and services.

The NCC established during the NBF Development Project will continue working also for Implementation Phase and it serves as general coordinating body for biosafety issues in Estonia, involving members from advisory bodies, ministries and other stakeholders.

Operational sustainability

Many training activities will be carried out during the project. In order to avoid loss of knowledge and ensure sustainability, many persons from different institutions will be trained and training manuals will be produced.

Financial and political sustainability:

Financial sustainability is directly linked to the political awareness and involvement of high-level politicians into the project. It is planned to educate politicians as to understand the biosafety issues. It is also planned to draft biosafety policy and integrate it into already existing or not yet existing policies (coexistence under MoA). Once a topic is listed in policy papers, it will get some funds from governmental sources for implementation.
State budget is composed on yearly basis and it is based on existing and adopted strategies or action plans. Currently, the state budget for GMO issues is less than 10 000 USD per year (running costs, as there is no biosafety strategy in place year), and it is clearly not sufficient for implementing CPB. In order to increase the budget, Ministry has to make proposal one year in advance, explaining also the necessity for these activities. During the project Estonia could step by step increase the state budget so as to be appropriate for implementing CBP (not only MoE, but also other ministries). After the lab of TTU has been equipped and accredited, government could foresee funds for surveillance and monitoring activities. It is foreseen that after the project end Estonia should be able to sustain the system without foreign funds, based on state budget allocations.

Environmental sustainability

The project aims to harmonize biosafety policy with agricultural policy, hence ensuring safe coexistence of GMOs and conventional crops.

Key project risks and how they will be addressed (so mitigation measures), including specific provisions for capacity, policy, incentives, and institutional arrangements see project log frame, Annex B.

C. 4 Replicability

Estonia was the very first country starting their NBF development project. Unfortunately, Estonia has not, to date, been very eager to share their experience with other countries and it is planned to improve this situation through information dissemination, passively through internet and published materials, and actively, through information days, seminars and lecture courses. (see log frame, especially part 5).

This project will directly influence national policies and processes by harmonizing institutional and legal framework of biosafety. Estonian environment and people will benefit from fully operational and effective system that can be set as a good example for the neighbouring and other countries.

Estonia will share their experience in yearly meetings of NPCs, and from other side, gain experience from other countries. The outcomes of the project will be made available through website of the project so other countries may benefit from the results. National BCH node will be created under BCH project, this project would help to collect and input data into nBCH. Website and BCH are not the same things, nBCH will be interoperable with BCH central portal in CBD Secretariat while website provides wider information like training possibilities, articles, project outcomes etc.

C. 5 Stakeholder involvement

Stakeholder identification

The main stakeholders of the project are:

- ✓ National authorities: Ministries of Environment, Agriculture, Social Affairs, Finance, others, politicians;
- ✓ Scientists, especially members of advisory body to the government;
- ✓ NGOs association, Consumers Board, research laboratory under TTU, the representatives of private companies and industry associations; (eg oil refinerys, feed and seed importers, feed processors, farmer unions, companies dealing with GMM's);
- ✓ General public.

Stakeholders have been involved in the project planning process from the very beginning. Working out of the project action plan started already during the development phase, in 2003. Then draft initial workplan was worked out and later, in 2004-2005, elaborated and completed. Final log frame was sent for comments out to different ministries and NGOs association and the project proposal was drafted, based on their comments.

Identification of national and local stakeholder was carried out during the development phase via a thorough process of consultation and dialogue. The main parties concerned by the project are listed in the sections below.

NEA and reference laboratory was chosen in 2004 among possible laboratories in Estonia. Decision was made in agreement with Minister of Agriculture and signed by Minister of Environment. For the selection different laboratories were compared for their facilities, quality of services, available equipment, number and qualification of staff, possible unit price for GMO tests and other criteria.

During development phase Estonia had a very well working and effective NCC. New NCC for Implementation Phase will try to involve as many members from these persons as possible to ensure institutional memory. During development phase, 2001-2003, there was no NGOs association composed yet, so NGOs were represented by REC (Regional Environmental Centre) Estonia. During the Implementation phase NGOs will have a bigger role than before.

The strategy for information dissemination is described in log frame Section 5 – info days, seminars, trainings, newsletter, etc. Consultations will be carried out through regular NCC meetings (there will be represented all main stakeholders). Respective representatives of stakeholders should ensure that they have performed discussions beforehand inside their institution or interest group.

Table 1: Major Stakeholders and their Participation

In the project the following stakeholders will be involved:

STAKEHOLDERS	Type of involvement
Parliamentarians, decision-makers	Participating in drafting policy papers, ensuring state financing for biosafety activities
Ministries: Ministry of Environment, Ministry of Agriculture, Ministry of Social Affairs, Ministry of Finance	Preparing and implementing legislation, policies and action plans.
Scientific community (including academic institutions): Tallinn Technical University, Advisory Committee for Genetic Modification (advisory body, consisting mainly of scientists, to government)	TTU is NEA, hence responsible for overall execution of the project, organization of workshops, trainings, etc. TTU laboratory responsible for surveillance activities. Scientists assist with the formulation of the implementing regulations, manuals and training guidelines
Veterinary and Food Board Plant Production inspectorate Environmental Inspectorate Customs	Taking part and helping in the project in seminars and worksops in concern with food, feed, seed etc issues.
Consumers associations Estonian Consumer Protection Board	Taking part and helping in the project in seminars and public information dissemination.

(*Names of associations and specific role*)	
NGOs: Estonian Association of Environmental NGOs	Being member of the NCC, assist in the formulation of the legislation, public participation, information development and dissemination
Private sector	The representatives of private companies and industry associations (e.g. oil refineries, feed and seed importers, feed processors, farmer unions, companies dealing with GMM's) will benefit from information gaining and from operating biosafety framework.

C6. MONITORING AND EVALUATION PLAN

The monitoring of the progress of project activities will be undertaken in accordance with UNEP's internal guidelines for project monitoring and evaluation. In this respect, self-evaluation will be ongoing throughout the project and GEF/UNEP's requirements of quarterly and half-yearly reports on substantive and financial matters will be provided. This process will include a mid-term assessment (desk review) and end-of-project assessment undertaken by external review teams arranged by UNEP. Deliverables will be identified on a timetable agreed between UNEP and each participating country, and country-specific final reports will be prepared at the end of the activities foreseen by this project.

Project execution performance, delivered outputs (Annex E, C.6 a) and project impact (Annex E, C6.b) will be measured according to the indicators developed in the project log frame (Annex B), and using this specific Monitoring and Evaluation Plan. The general and specific objectives of the project, and the list of its planned outcomes, provide the basis for this monitoring and evaluation plan. The project co-ordinator, with the assistance of the NCC, will be in charge of the monitoring and evaluation component of the project and will take action whenever needed so as to guarantee that the M&E activities of the project and related indicators adequately reflect the needs of the project.

The Monitoring and Evaluation Plan is detailed in Annex E. The M&E Plan should cover the general and specific objectives of the project, its planned outcomes and outputs, and should look at:

i. The **efficiency** (in terms of time, resource inputs and costs) with which project activities were carried out;
ii. The **effectiveness** (quality, quantity and timeliness) with which project outputs were achieved;
iii. The **impacts** of project outcomes.

Details of indicators are shown in log frame, attached as annex B.

The monitoring and Evaluation Plan includes Table 2 Indicators and Means of Verification, Table 3 reporting and monitoring responsibilities, Table 4 information on reporting requirements.

D FINANCING

D1. Incremental cost assessment

Estonia's data for the baseline – recent expenses and current commitments of the government on the five NBF components.

The following table provides a summary of baseline and incremental costs by output/component as well as information on GEF financing and national co-funding. A detailed incremental cost analysis, and global and domestic benefits and related schematic representation are presented in Annex F together with an incremental cost matrix. The total baseline expenditure amounts to US $ 200 000, which main components relate to activities under Ministry of Environment and Ministry of Agriculture, based on their activities during years 2003-2005. The increment has been estimated at US 953 000 $. The national contribution in kind amounts to US $ 284 000, there is no in cash national contribution. The remaining total cost of US $ 669 000 is requested from GEF.

Table 5. Summary incremental cost analysis

Activity	Baseline	Alternative	Increment	Cost to GEF (Global Benefit)	Co-financing (in kind contributions)
Biosafety strategy	10 000	26 000	16 000	10 000	6000
National biosafety legislation	30 000	69 500	39 500	28 000	11 500
Handling of requests	90 000	128 000	38 000	33 000	5000
Monitoring of environmental effects and inspections	40 000	474 500	434 500	253 000	181 500
Public awareness and participation	30 000	84 000	54 000	40 000	14 000
Project coordination and management	-	285 000	285 000	225 000	60 000
Other project support	-	80 000	80 000	80 000	6000
TOTAL	200000	1 147 000	953 000	669 000	284 000

D2. BUDGET and PROJECT IMPLEMENTATION PLAN

The detailed budget of the project is shown in Annex C and summarised below in Table 6. A summary of the budget by components with co-financing details and the staff costs are shown in Tables 7 and 8

respectively (below). A sum for technical support has been included under "other project support". This sum will be allocated after project approval.

Table 6: Project Budget by Components.

	Component	GEF (US $)	Government (US $)	Total (UD $)
1	Biosafety strategy	10 000	6000	16 000
2	Regulatory regime	28 000	11 500	39 500
3	Handling applications	33 000	5000	38 000
4	Monitoring and Inspection	253 000	181 500	434 500
5	Public participation and information	40 000	14 000	54 000
6	Project coordination	225 000	60 000	285 000
7	Other project support	80 000	6000	86 000
	TOTAL	669 000	284 000	**953 000**

CO-FINANCING SOURCES				
Name of Co-financier (source)	Classification	Type	Amount (US$)	Status*
Ministry of Environment	Official CP CA	Committed in-kind co-financing	80 000	Confirmed (see endorsement letter)
Tallinn Technical University	NEA	Committed in-kind co-financing	204 000	Confirmed (see confirmation letter)
Sub-Total Co-financing			284 000	

Table 7: Staff costs – not directly linked to a specific activity

Personnel	GEF	National Co-financing	TOTAL
National coordinator of the project	48 000	0	48 000
One project assistant (full time)	96 000	0	96 000
Financial Officer	40 000	0	40 000
National Coordination Committee Meetings, travel for NPC, Staff and NCC members	24 000	43 000	67 000
TOTAL	208 000	43 000	251 000

Equipment and operating costs

Office equipment and operating costs (US $ 30 000) cover the purchase of computers, software upgrades, maintenance etc. as well as office utilities, stationery and communication costs. This amount is shared between GEF and the country: GEF covers ca 40% and Government ca 60% (GEF 11 000 USD, Government 19 000 USD)

D3 PROJECT IMPLEMENTATION PLAN

The implementation plan will be associated to the budget provided in Annex C. The project will be carried out over four years as follows:

PROJECT ACTIVITIES	6	12	18	24	30	36	42	48
1 Biosafety strategy								
1.1 Info day (lecture course) for members of government (MoE, MoA and others) and parliament (Commission of Environment), 1 day, 40 participants, 2005, 2007	X				X			
1.2. Drafting a policy paper, strategy and action plan for biosafety, integrate it into Environmental Strategy 2005-2006		X	X	X				
1.3. Analyse and integrate the biosafety issues within strategy of agriculture (new strategy on co-existence, being worked out by MoA with the help of EC), meeting for 20 persons from MOA and MOE.		X				X		
1.4. Analyse and integrate biosafety issues within biotechnology policy, 2 meetings for 25 persons from MOE, MOA and M of Finance		X				X		
2 Regulatory regime								
2.1. Drafting, discussion and adoption of amendments for GMO act and secondary legal acts (list in the end of the document) (Composing drafting group of 3-4 lawyers, their work, meetings, consultation with stakeholders, preparation for ministerial approval, and then for governmental approval)	X	X	X	X	X	X	X	X
2.2. Two one-day lecture courses for customs personnel, importers and exporters and other company representatives about the legal aspects of transboundary movements of LMOs and related products (60 participants)		X					X	
2.3 Publishing of guidelines for a) Governmental organizations on LMOs legislation; and b) Importers and exporters about the transboundary movements and legal aspects of LMOs			X	X				
2.4. Legal training for lawyers from MoE, MoA and interested NGOs on legal aspects of LMOs and its connection to other international legal acts (WTO, IPPC), 15-20 participants, 5 days			X	X				
3 Handling requests for permits								
3.1 Publish technical guidelines for handling of requests (incl RA/RM guidelines), separately for GMMs and GM higher plants. 2005-2006		X	X	X				
3.2. A three-day hands-on advanced training course for the Ministry of Social Affairs and private companies and members of ACGM on the safety aspects of handling of GMO-s in containment, 20-30 participants			X	X				
3.3. A seven-day practical advanced course on the evaluation and risk assessment of the LMO field tests and other procedures important in setting up a field test for the members of the Institute of Gene Technology, members of ACGM (20 participants)					X	X		
3.4 Operationalize GMO regier	X	X						
4 System for follow-up (Monitoring of environmental effects and enforcement)								

PROJECT ACTIVITIES	6	12	18	24	30	36	42	48
4.1 Equipping of reference laboratory of TTU for detection and inspections on LMOs and related products	X	X	X					
4.2 Two day lecture course for the staff of the food and veterinary inspection on the monitoring and inspection issues carried out.		X				X		
4.3 Inspection for compliance of regulatory regime (for labelling, conditions of contained use, importing conditions etc).			X	X	X	X		
4.4 Participation of 1-2 experts of the reference laboratory in ENGL annual meetings.		X		X		X		X
4.5 Literature and relevant journals concerning LMO analyses purchased	X		X		X		X	
4.6 Two-day lecture course for the Customs personnel, including relevant persons from each customs station in Estonia carried out on regulations of the transboundary movement of LMOs according to the Cartagena Protocol as well as the use of the Biosafety Clearing House Mechanism (50 participants)	X	X					X	X
4.7 Set of guidelines for customs control purposes, including a mechanism for efficient control of transboundary movements of LMOs, published and disseminated		X					X	
4.8 Practical training on taking samples and on practical monitoring for all animal nutrition and food monitoring authorities, 15-20 participants, 5 days					X	X		
4.9 Technical training for TTU workers and for ACGM members regarding the methodology, handling PCR machine, interpretation of the results etc, 25 participants	X	X	X	X				
4.10 Organize a workshop for consumer protection, veterinary and food board inspection officers, environmental inspectorate and plant production inspectorate on biosafety and genetic modification to equip them with inspection of GM activities, (20-30 participants)	X	X					X	X
5 Public participation, awareness and education								
5.1 Popular informative material distributed on the risks and benefits of the use of LMOs			X	X			X	X
5.2 Newsletter distributed, twice a year, in collaboration with journal Estonian Nature (or Greengate)	X	X	X	X	X	X	X	X
5.3 Informative materials for secondary schools distributed and used in conjunction with biology lessons about the Cartagena Protocol and the development of LMOs and related products	X	X	X	X				
5.4 An educational TV broadcast carried out on the Cartagena Protocol, the use of LMOs and the risks of the use of LMOs.			X	X			X	X
5.5 One day info day for consumers and NGOs about possible risks and benefits of LMOs, 60-70 participants	X		X		X		X	
5.6 Public opinion poll				X	X			
5.7 public info days about the project and its outcomes, one day, 50-60 participants			X	X			X	
5.8 One- day informative training for the representatives of NGO-s and general public on the biosafety decision-making issues.		X						X
5.9 Course of biosafety for Universities worked out and used at least in TTU (working out 2005-2006, used 2007-2008)		X	X	X	X	X	X	
6 Cross-cutting Activities								

PROJECT ACTIVITIES	**6**	**12**	**18**	**24**	**30**	**36**	**42**	**48**
6.1 Monitoring activities	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
6.2 NCC meetings	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
6.3 Project Co-ordination and management	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

This project builds on an UNEP's portfolio of enabling activities in over 123 countries and 8 demonstration projects out of 12, on capacity building for the implementation of the CP-carried out through the development and implementation of National Biosafety Frameworks respectively. This reflects UNEP's considerable experience and expertise in the area and therefore its comparative advantage in the field.

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in Estonia, where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

E2. CONSULTATION, COORDINATION AND COLLABORATION BETWEEN IMPLEMENTING AGENCIES, EXECUTING AGENCIES, AND THE GEF SECRETARIAT (WHERE APPROPRIATE)

E2.a National Coordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the National Biosafety Framework. This committee will include representations of all government agencies with mandates relevant to the Cartagena Protocol on Biosafety and will include representations from the private and public sectors. This Committee will be multi-disciplinary and multi-sectoral in fields relevant to the Cartagena Protocol on Biosafety. The NEA may also establish sub-working groups as necessary with clear Terms of Reference as appropriate. The Terms of Reference (TOR) for the NCC are in Annex D.

E2.b National Project Coordinator

The National Project Coordinator will be appointed by the National Executing Agency, after consultation with UNEP, for the duration of the National Project. The National Project coordinator shall be responsible for the overall co-ordination, management and supervision of all aspects of the National Project. He/she will report to the National Co-ordinating Committee and UNEP, and liaise closely with the chair and members of the National Coordinating Committee and National Executing Agency in order to coordinate the work plan for the National Project. He/she shall be responsible for all substantive, managerial and financial reports from the National Project. He/she will provide overall supervision for any staff in the NBF Team as well

as guiding and supervising all other staff appointed for the execution of the various National Project components. The Terms of Reference (TOR) for the NPC are in Annex D.

E2.c UNEP Steering Committee

The Steering Committee provides guidance and direction to the implementation of the project. It is chaired by UNEP, and comprises representatives of the National Executing Agency, two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, whenever technical and scientific issues related to the implementation of the MSP are to be addressed, the representative of STAP as well as experts selected in their personal capacity will be invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

ANNEXES (in separate files)

ANNEX AA	Endorsement letter
ANNEX A	Biosafety Framework for Estonia
ANNEX B	Project Log frame
ANNEX C	Project budget
ANNEX D	Draft Terms of References for the National Executing Agency, National Project Committee, National Project Coordinator
ANNEX E	Monitoring and Evaluation Plan
ANNEX F	Incremental cost assessment
ANNEX G	List of equipment

TABLES

Annex AA
Endorsement letter

LIETUVOS RESPUBLIKOS APLINKOS MINISTERIJA
THE MINISTRY OF ENVIRONMENT OF THE REPUBLIC OF LITHUANIA
A. Jakšto str. 4/9, LT-01105 Vilnius Phone (+370 5) 266 35 62, 266 35 39 Fax (+370 5) 266 36 68, 266 36 66

26 -05-2005 No. (11-3)-28-4141

Mr. Ahmed Djoghlaf,
Director,
UNEP-Division for the GEF Coordination (DGEF),
Nairobi, Kenya
Fax: + 245 20 62 3557

LETTER OF ENDORSEMENT OF THE UNEP-GEF MSP PROPOSAL "SUPPORT FOR THE IMPLEMENTATION OF THE NATIONAL BIOSAFETY FRAMEWORK FOR LITHUANIA"

Dear Mr. A. Djoghlaf,

Herewith the Ministry of Environment would like to express the official support and endorsement of the Medium-Size Project (MSP) proposal **"Support for the Implementation of the National Biosafety Framework for Lithuania"** and would appreciate if the UNEP took all the necessary steps forward to submit the Project Brief to the GEF Secretariat.

The Ministry of Environment as the National Competent Authority (NCA) for Biosafety sector in the Republic of Lithuania confirms the support for securing the proportionally balanced funds (in-kind co-financing), thus contributing to the implementation of the aforementioned MSP as it was formally specified in the letter of 7 October 2004. As an indication of our support for the MSP, we pledge the in-kind co-financing of the project in the total amount of US$ 404,000.

We are looking forward to further co-operating during the actual implementation of the UNEP-GEF Medium-Size Project "Support for the Implementation of the National Biosafety Framework for Lithuania".

Sincerely,

Artūras Kundrotas
Minister

cc: Dr. Christopher Briggs
Global Project Manager
UNEP-GEF Biosafety Unit
Regional Office for Europe, Geneva, Switzerland
Tel.: + 41 22 917 8411/8210
Fax: + 41 22 917 8070

Endorsed by:
GEF Operational Focal Point
G. Gaigalas, (+370 5) 2 663 539,
E-mail: g.gaigalas@am.lt

Annex A
Biosafety Framework for Estonia

ESTONIA

FINAL DRAFT NATIONAL BIOSAFETY FRAMEWORK AS AT COMPLETION OF PROJECT

GENERAL INTRODUCTION

The UNEP-GEF project on the Development of the National Biosafety Framework of Estonia started in November 2001 and ended in June 2003.

The National Project Document was signed by *Mr Sulev Vare, Secretary General*.

The national executing agency for the UNEP-GEF project was the *Ministry of the Environment*, Toompuiestee 24, 15172 Tallinn, Estonia.

Contact person for NEA is Dr *Liina Eek-Piirsoo* (Tel.+ 372 6262 877, Fax:+ 372 6262 901, email leek@ekm.envir.ee).

The project coordinator was *Ms Epp Väli.*

The institutions and people represented in the *National Coordination Committee* are listed in annex 1.

DESCRIPTION OF THE NATIONAL BIOSAFETY FRAMEWORK

Biosafety policy

Estonia is Party to Convention on Biological Diversity since 1994. Estonia signed Cartagena Protocol on 6 September 2000 and it will be ratified by the end of November 2003.

There is no special national policy in biosafety in Estonia. As Estonia will join EU in 2004, the general policy is similar to this of EU. Estonia is currently harmonising its legislation so that EU directives and regulations regarding biosafety as well as Cartagena Protocol will come into force either in the end of 2003 or some secondary legislation also in 2004.

As there is no special policy in biosafety then we cannot also talk about any particular connections to other policies. However, biotechnology is one of the main priorities for Estonian Government. With its Human Genome Project, Estonia is one of the leading countries in the overall world, according to the amount of money spent per capita for biotechnology in the country.

While working out legislation for biosafety, it slowly becomes a natural part of agricultural policy and food and feed safety regulations. As the issue is quite new and there is no general agreement also inside of EU then there are currently several negotiations going on about organic farming and

GM farming, seed production, etc. The overall framework with all its details is not yet worked out, although the general frames and laws are in place.

The target to reach is pretty ambitious – to work out a system that is suitable to everybody – ie a system that allows people to use specific GMOs if they wish to, and at the same time to allow people to refuse specific GMOs if they so decide. Also, the problem with organic farming and GM farming still has to be solved. As we have seen in case of Austria then Estonia as an accession country to EU cannot take measures that are much more restrictive then these set by EU legislation (Austria wanted to restrict cultivating of GMOs in certain regions, but it was rejected by European Commission).

As Estonian Government has taken political decision to join EU and it was approved by referendum in September 2003, then we have to follow the policy of EU.

Regulatory regime

There are several acts dealing with GMOs and biosafety, directly or indirectly. Here are listed only main acts. The complete list of legal acts is attached as an **annex 2.**

Release into the environment and placing on the market of GMOs

1. The Estonian Act on Release into the Environment of Genetically Modified Organisms came into force on January 13, 1999 (Official Journal RT, I ,1999, 10, 151).

The objective of the Act is to protect human health and the environment from the consequences of the release into the environment of GMOs, to ensure the safe use of genetic modification techniques and the development of such techniques in an ethically acceptable manner. The Act also aims to implement EC Directive 2001/18/EC.

The Act covers the release of GMOs into the environment and placing on the marketing of GMOs.

The Act does not apply to: carriage of genetically modified organisms by rail, road, waterway, sea or air; modification of human genes by means of genetic modification techniques; and production of organisms through mutagenesis or cell fusion of plant cells where the resulting organisms can also be produced by traditional breeding methods.

The Act requires permits for the release into the environment and authorisation for the placing on the market of GMOs, and lays down general requirements for applications. Detailed requirements are given in Regulation No 32 of June 5, 2000. The competent authority is the Minister for the Environment.

Applications for permits must be submitted to: the Ministry of the Environment, attn of: Mrs. Liina Eek, Ministry of the Environment, Toompuiestee 24, Tallinn 15172, Estonia, Phone + 372 6262 877,Fax + 372 6262 901, e-mail: leek@ekm.envir.ee.

Formats for applications are available (see **annex 3**).

Upon receipt of an application, the Ministry of the Environment will send a copy to the Advisory Committee for Genetic Modification. The Committee is established by the Act and comprises of 9 members appointed by various ministries and institutions, with a request for advice. The advisory body is also involved in assessing the environmental aspects under the Novel Food regulations. The

advisory body advises also Ministry of Social Affairs in regard of contained use of genetically modified micro-organisms (GMMs) and Ministry of Agriculture in regard of GM animal tests.

Applications for releases and placing on the market of GMOs are published in a electronic newspaper as all the other public announcements. In addition, the Advisory Committee for Genetic Modification can publish any aspect it deems necessary. The Act contains provisions for the handling of confidential information.

Final decisions on requests for permits or authorisations are made by the Ministry of the Environment.

This act will be amended acoording to new obligations under Cartagena Protocol (see **annex 4** for draft amended act).

2. Seed and Plant Propagation Material Act; entered into force 01.07.1998

Regulates the use of plant varieties, the production and packaging of the seed and propagating material of species of agricultural and horticultural plants and the cultivating material of forestry plants for marketing purposes; the marketing, import and export thereof; and state supervision and liability for violation of this Act or legislation established on the basis thereof.

According to this act all the GMOs have to be labelled as required under Act on Release into the Environment of Genetically Modified Organisms.

Responsible institution: Ministry of Agriculture, Estonian Control Centre of Plant Production, Teaduse 6, 75501, Saku , Harjumaa, e-mail info@tmkk.ee, fax +372 6729 149.

3. Feedstuffs Act; entered into force 01.07.2002

Sets the requirements for feedstuffs and for the manufacture and intermediation of feedstuffs, with the aim of ensuring their safety for human and animal health and for the environment and their favourable effect on animals and livestock products (hereinafter livestock products).

Responsible institution: Ministry of Agriculture.

4. *Food Act*; entered into force 01.01.2000

Regulates handling of food and raw material for food for marketing purposes and establishes self-checking by food business operators and state supervision to ensure food safety and the conformity of food to other requirements.

Secondary legislation:

1. Regulation No. 176 of 30 May 2000 of the Government of the Republic "*Special requirements for the labelling of food produced of genetically modified soybean or genetically modified maize and for presentation of information in any other manner*" (RT I 2000, 43, 275); entered into force 09.06.2000;
2. Regulation No. 446 of 30 December 1999 of the Government of the Republic "*Methods for assessment of the conformity of novel food to the requirements and the procedure for*

application for and issue of permits for the handling of novel food" (RT I 2000, 3, 18); entered into force 20.01.2000.

Responsible institution: Ministry of Agriculture, Veterinary and Food Board. Contact person: Ms Eveli Kaur, chief officer, Veterinary and Food Board, Väike-Paala 3, 11415, Tallinn, Estonia. Phone Number: +372 605 1718, Fax Number: +372 621 1441, Email address: eveli@vet.agri.ee

Contained use of genetically modified micro-organisms

On December 10, 2001, the *Act on the contained use of genetically modified micro-organisms (GMMs)* came into force (Official Journal RT I 2001, 97, 60).

The objective of the act is to regulate safe use of GMMs in contained use in order to protect human health and the environment. The Act also aims to implement Directive 90/219/EEC, as amended by Directive 98/187/EEC.

The Act requires permits for the contained use of GMMs. Detailed requirements for applications are given in the Regulation No 10 of 8 January, 2002. List of data to be included in a risk assessment and procedure for making risk assessment are given in the Regulation No 8 of 8 january, 2002. The Ministry primary responsible for the implementation is the Ministry of Social Affairs.

Applications for permits for contained use of GMMs must be submitted to: Ms Silja Soon, Labour inspector, Labour Inspection, Teguri 37, 50107, Tartu, Estonia. Phone Number: +372 7366 191, Fax Number: +372 7366 188, Email address: silja.soon@ti.ee. Web site: www.ti.ee

System to handle notifications or requests for authorisations

The responsibility of regulating of use of GMOs is divided between three ministries in Estonia:

1. *Ministry of the Environment* is responsible for issuance of permits for deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;
2. *Ministry of Agriculture* is responsible for issuance of permits for handling and marketing of novel food (including genetically modified food), permits of use of seeds and plant propagation material, fertilizers, feed and permits for conducting of tests with animals;
3. *Ministry of Social Affairs* is responsible for issuance of permits for contained use of genetically modified micro-organisms (GMMs).

As a requirement of Cartagena Protocol, Estonia has nominated Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs as Competent authorities, according to the abovementioned division of tasks (see http://bch.biodiv.org/Pilot/SearchResults.aspx?SearchID=77629&Page=1&DocumentType=2).

As Estonia is a small country, it was not considered to be necessary to create separate advisory bodies in every mentioned ministry. There are two advisory committees in Estonia responsible for making risk assessment for GMOs and products containing of GMOs or consisting of GMOs:

1. *Advisory Committee for Genetic Modification,*
2. *Novel Food Committee (*conducts also risk assessment for products that are obtained from GMOs but not containing GMOs).

Advisory Committee for Genetic Modification is composed as an advisory body at the Ministry of the Environment. Its staff is as follows:

Chair:

Liina Eek-Piirsoo, Ministry of the Environment, Department of Nature Protection

Vice-chair:

Ain Heinaru, Tartu University, Dean of Faculty of Biology and Geography

Members:

Helle Aruniit, Head of Consumers Protection Board
Mati Koppel, Head of Jõgeva Plant Breeding Institute
Jaanus Pikani, Estoniana Genome Foundation, Chairman of the Supervisory Board
Erkki Truve, Professor in gene technology, Director of the Department of Gene Technology, Tallinn Technical University
Mart Ustav, Technology Institute of Tartu University, Director
Toomas Veidebaum, Estonian Institute of Experimental and Clinical Medicine,Director
Richard Villems, Academic of Estonian Academy of Science, Director of Estonian Biocentre

The task of **Advisory Committee for Genetic Modification** is to advise governmental institutions, namely Ministry of the Environment, Ministry of Agriculture and Ministry of Social Affairs, in issues concerning genetic modification:

1. in issues concerning relasing GMOs (including genetically modified novel food, genetically modified seeds, fertilizers and feed) into the environemnt;
2. in issues concerning marketing of products containing of GMOs or consisting of GMOs (including genetically modified novel food, genetically modified seeds, fertilizers and feed);
3. in issues concerning conduction experiments with genetically modified test animals;
4. in issues concerning using of GMMs in contained environment.

Novel Food Committee **is composed as an advisory body at the Veterinary and Food Board of Ministry of Agriculture. Its staff is as follows:**

Chair:

Raimond Strastin, Head of Department of Food Hygiene, Veterinary and Food Board

Members:

Helle Aruniit, Head of Consumers Protection Board
Liina Eek, Ministry of the Environment, Department of Nature Protection, senior officer
Ain Heinaru, Tartu University, Dean of Faculty of Biology and Geography
Jüri Kann, Professor of food chemistry, Tallinn Technical University, Director of Tallinn Technical University Institute of Chemistry
Aadu Kolk, Head of Food Hygiene Laboratory of The Faculty of Veterinary Medicine, Estonian Agricultural University
Heino Lutsoja, Councellor of Health Protection Inspectorate
Marika Mikelsaar, professor of medical microbiology and virology of Tartu University, Head of Institute of Microbiology of Tartu University
Märt Nõges, Adviser of Plant Material Control Centre

Toomas Paalme, Professor of food technology of Tallinn Technical University, senior scientist of National Institute of Chemical Physics and Biophysics
Kairi Ringo, Head of the Bureau of Food Safety of the Department of Veterinary and Food, Ministry of Agriculture
Erkki Truve, Professor of gene technology of Tallinn Technical University, head of Estonian Genome Foundation, senior scientist of National Institute of Chemical Physics and Biophysics
Raivo Vokk, Professor of food science of Tallinn Technical University, Head of Food Institute
Mihkel Zilmer, Professor of medical biochemistry of Tartu University, Head of Institute of Biochemistry

The task of this committee is, according to the documents submitted to the Veterinary and Food Board, decide upon the compliance of the novel food to the established requirements; also decisions will be made on the intended labelling and the issuance or refusal of permit for handling of the novel food.

Risk assessment requirements are regulated by following legal acts:

For GMOs intended for deliberate relase into the environment or marketing:

"The list of data submitted in the application for the permit for release into the environment and the distribution of GMOs and the forms of permits thereof" (RTL 2000, 64, 1010), in force since 19.06.2000

For novel food:

"Assessment methods of the conformity of novel foods to requirements and the procedure of application for and issuing of novel food handling permits" (RT I, 2000, 3, 18) in force since January 1, 2000.

For genetically modified test animals (other than GMMs):

"Requirements for risk assessment for conducting experiments with genetically modified test animals and the list of data to be submitted with the risk assessment" (RTI, 13.12.2002, 101, 595). In force since 10 December 2002.

***For GMMs in the contained use*:**

"Requirements applicable to the risk classes of contained environment" (RTL 2002, 14, 179); in force since 28.01.2002

"List of data to be included in a risk assessment and procedure for making a risk assessment" (RTL 2002, 10, 103); in force since 21.01.2002

"Requirements for work hygiene and work safety for working environment affected by biological risk factors" (RT I, 01.01.2000, 234); in force since 01.06.2002.

The description for applying for permits together with timeframes are attached as annex 5.

Formats for applications are attached as annex 3, 6 and 7 (only for deliberate release of GMOs and contained use of GMMs).

Monitoring and enforcement

Similarly to the system of handling requests, also the monitoring and enforcement are divided between three ministries in Estonia:

1. *Environmental Inspectorate under Ministry of the Environment* is responsible for surveillance of deliberate release and marketing of GMOs or products containing of GMOs or consisting of GMOs;
2. *Veterinary and Food Board under Ministry of Agriculture and Health Protection Inspectorate* is responsible for surveillance of novel food (including genetically modified food),
3. *Plant Production Inspectorate under Ministry of Agriculture* is responsible for surveillance of use of seeds and plant propagation material,
4. *Veterinary and Food Board, Environmental Inspectorate and Policy Board* are responsible for surveillance of conducting tests with animals;
5. *Labour Inspectorate under Ministry of Social Affairs* is responsible for surveillance of contained use of genetically modified micro-organisms (GMMs).
6. *Consumer Protection Board* is responsible for checking the proper labelling of the products at retail level.

There is no functional environmental monitoring system in place yet, as so far, no permits for deliberate release of GMOs and GMO products have been issued by the Ministry of Environment.

There are 2 different laboratories in Estonia that are able to carry out GMO analysis: National Institute of Chemical Physics and Biophysics in Tallinn; Institute of Molecular and Cell Biology, Tartu University. The above-mentioned laboratories use Polymerase Chain Reaction (PCR) method.

None of the laboratories have received accreditation for GM food analyses. The Laboratory of Molecular Genetics of the National Institute of Chemical Physics and Biophysics is currently in the process to receive the accreditation in 2002. Since 2000 the laboratory has participated in proficiency testing of GM maize and GM soya analyses provided by FAPAS (UK). The results have proved good and hence, the results of the analyses are considered to be reliable.

The Veterinary and Food Board in cooperation with the Ministry of Agriculture has introduced programs for monitoring of presence of genetically modified soya and maize in food. First monitoring of GM soya and GM maize was carried out during May-November 2001. The monitoring focused on the products that potentially could contain GM soya or maize. The aim of the monitoring program was to get an overview what kind of and how many food products which are produced from genetically modified soya or maize are on the Estonian market. 61 samples containing soya ingredient and 81 samples containing maize ingredient were taken from state border and wholesalers. The variety of foodstuffs from which the samples were taken was quite wide. For example, samples were taken from soy flour, maize starch, soy sauces, cornflakes, meat products, biscuits etc. The samples were analysed in the National Institute of Chemical Physics and Biophysics using a polymerase chain reaction (PCR) method. A commercial kit was used allowing the detection of Maximizer Bt 176, Bt 11, Liberty Link and Yield Gard corn and Roundup Ready soybean. 49 samples out of 142 did not give a result. No samples containing GM maize were detected. However, 8 samples containing soybean ingredient found to be genetically modified.

Public information and public participation

In Estonia everybody has access to information regarding GMOs and right to participate in decision making process.

Main legal act is **Act on Release into the Environment of Genetically Modified Organisms** (Official Journal RT, I ,1999, 10, 151)

This act contains provisions on active and passive information to the public and public participation in decision making.

Upon receipt of an application, the Ministry of the Environment will send a copy to the Advisory Committee for Genetic Modification (ACGM). The advisory body is established by the Act and comprises of 9 members appointed by various ministries and institutions, with a request for advice.

Final decisions are taken by the Ministry of the Environment.

Applications for releases and placing on the market of GMOs are published in an electronic newspaper, indicating inter alia:

1) the place where it is possible to familiarise oneself with the content of the application (ie the address of Ministry of the Environment);
2) the time period during which it is possible to express opinions about the planned release of GMO into the environment. This time period is not longer than 30 working days.

ACGM have to answer in written form in 14 days to these comments and explain whether these comments have been taken into account in decision making process or not and if no, then why. The questions and answers are not published, but it is considered as public information so that every interested person could request to see them. All the documents except confidential information are available in Ministry of the Environment.

In addition, the Advisory Committee for Genetic Modification can publish any aspect it deems necessary (except confidential information).

ACGM notifies the appropriate local municipality about the location of the site of release into the environment envisaged in the application.

According to this act all the GMO products must be marked and labelled so that every consumer could have relevant information about this product.

Additionally, there is also a general act on access to information - **Public Information Act** (entered into force 01.01.2001). The purpose of this Act is to ensure that the public and every individual has access to information intended for public use, based on the principles of a democratic and social rule of law and an open society, and to create possibilities for the public to monitor the performance of public duties.

According to **Act on contained use of GMM-s** it is not obligatory to publish information about GMM-s in contained use, but competent authority (Ministry of Social Affairs) could do it accordingly to **Public Information Act**.

Data on GMOs both in the environment, on the market and in contained use (name of GMO, site of use, purpose of use etc, except confidential information) will be available in the **public GMO register**. Due to reconstruction of this database it is currently not available electronically.

Estonia has also ratified the UNECE **Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention**) on 2 August 2001.

Information in Estonian about GMOs (legislation, outcome of survey of public opinion in regard of GM agricultural products, contact persons, popular information about novel food and GM agriculture, translated materials about GMOs etc) are available in the website of Ministry of the Environment (http://www.envir.ee/looduskaitse/geneetiliselt.html).

Experience of Estonia

Three permits for scientific purposes have been issued by Labour Inspectorate for contained use of GMMs from 1. and 2. risk classes. No public concern has been shown in regard of them.

So far, only one application has been submitted to Ministry of the Environment for marketing maize MON810. After receiving this application Ministry organised a press conference and the event was widely reflected in mass media (TV, newspapers, radio). Only one journalist came to Ministry to read the application, and no comments were submitted to the Advisory Body. After the Advisory Body expressed their opinion to Minister and advised him to issue the permit, a public letter was sent to Minister by several NGOs and other organisations, asking Minister to refuse to permit GMOs in Estonia. Although the official commenting time was over, Minister still took this letter into account, met with applicant and as a result the application was withdrawn for further discussions and analyses with lawyers.

Annex B
Project LogFrame

Summary	Indicators	Means of verification	Risks and constraints	Risk management
GOAL: assist Estonia in implementing its NBF	Operational NBF implemented by 2008, institutional capacity to implement NBF developed	Reports about implementing of CP to COP/MOP and to EC	Political problems (change of government, no agreement between parties etc)	Educating of all levels of society, incl higher level politicians. Adopt strategies and action plans on the level of Parliament so that it is more difficult to change it due to political changes
Objective 1: to assist Estonia to integrate Biosafety into the national strategy on environment, agriculture (especially in the light of co-existence of LMOs and organic farming) and biotechnology by 2009	Biosafety is part of national strategy of biotechnology, agriculture and environment, by 2008. Strategies agreed and adopted or at least drafted and submitted for adoption	National Strategies published in websites of government (MoE, MoA, others)	Agreements not reached, priorities will be changed on the level of government	Organize regular meetings with different stakeholders, harmonize viewpoints of different ministries so that all policies touching biosafety are in all line and follow general governmental policy. Discuss policy papers publicly and take different opinions into account.
Outcomes 1: Biosafety integrated into a national strategy on environment, agriculture and biotechnology by 2008				
Activities 1:				
1.1. Info day (lecture course) for members of government (MoE, MoA and others) and parliament (Commission of Environment, Commission of Rural Development), 1 day, 40 participants, 1 and 3 year.				

1.2 Drafting a policy paper, strategy and action plan for biosafety, integrate it into Environmental Strategy 1-2 year, adoption 3-4 year (includes public discussions)				
1.3 Analyse and integrate the biosafety issues within strategy of agriculture (new strategy on co-existence, being worked out by MoA with the help of EC), 2 meetings for 20 persons from MOA and MOE, 1 and 3 year.				
1.4. Analyse and integrate biosafety issues within biotechnology policy, 2 meetings for 25 persons from MOE, MOA and M of Finance and M of Economy, 1 and 3 year.				
Objective 2: to assist Estonia to finalize, adopt and implement a fully functional and responsive regulatory regime in line with CP, national needs and other international obligations.	Regulatory regime in line with other international agreements. Legislation adopted and functional.	Legislation published in governmental website. No problems with implementation.	Legislation is not in line with other obligations. Legislation is functional (has gaps) or accepted by public or different stakeholders.	Educate lawyers, discuss with lawyers from outside of Estonia. Follow best practices of other countries, especially in EU. Discuss draft laws, involving different stakeholders according to Arhus Convention and Law on Public Participation.
Outcomes 2: Fully functional biosafety legislative system in place and working by 2009				
Activities 2:				
2.1. Drafting, discussion and adoption of amendments of the existing GMO act and secondary legal acts (list in the end of the document) (Composing drafting group of 3-4 lawyers, their work, meetings, consultation with stakeholders, preparation for ministerial approval, and then for governmental approval)				

2.2. Two one-day lecture courses (1 and 4 year) for importers and exporters and other company representatives and also customs personnel, about the legal aspects of transboundary movements (legal obligations, how to organize import, where to get information and formats, etc) of LMOs and related products (60 participants)				
2.3 Publishing of two separate sets of guidelines for a) Governmental organizations on LMOs legislation (internal manual); b) Importers and exporters about the transboundary movements and legal aspects of LMOs;				
2.4 Organize a legal training for lawyers from MoE, MoA and interested NGOs on legal aspects of LMOs and its connection to other international legal acts (WTO, IPPC), 15-20 participants, 5 days, 2 year.				
Objective 3: to assist Estonia to improve the system for handling requests, including risk assessment, decision-making and administrative processing	Clear rules and division of responsibilities in RA and decision making process. Risk assessors well trained, guidelines available. Number of decisions taken in regard of GMO permits.	Decisions published in website. Guidelines published and available.	Trained personnel leave for another job, leaving no capacity for RA or decision making.	Train more than one person to ensure sustainability. Guidelines available so that it is easier to train new personnel.
Outcomes 3: Fully functional system for handling of requests in place and working				
Activities 3:				
3.1. Publish technical guidelines for handling of requests (incl RA/RM guidelines), separately for GMMs and GM higher plants. 1-2 year				
3.2. Organize a three-day hands-on advanced training course for the Ministry of Social Affairs (as NCA) and private companies and members of ACGM on the safety aspects of handling of GMO-s in containment, 20-30 participants				
3.3. Organize a seven-day practical advanced course on the evaluation and risk assessment (of the LMO field tests and other procedures important in setting up a field test for the members of the TTU, members of ACGM (20 participants)				
3.4 Create and operationalize GMO register				

Objective 4: to assist Estonia to improve the system for "follow-up", especially monitoring of environmental effects and enforcement and make the system functional	Reference lab equipped and able to serve Estonia for GMO detection. Personnel trained for follow up actions. Guidelines available.	Number of GMO tests performed by lab. GMO monitoring reports available in governmental website. Guidelines published and available.	Trained personnel leave for another job, leaving no capacity for RA or decision making. Financial constraints for equipping and sustaining of lab.	Train more than one person to ensure sustainability. Guidelines available so that it is easier to train new personnel. MOU agreed between MoE and TTU.
Outcomes 4: System for follow-up activities in place and working**,** one reference laboratory of TTU equipped to carry out detection and inspections on LMOs and related products.				
Activities 4:				
4.1 Equipping of reference laboratory of TTU for detection of LMOs and related products.				
4.2 Organize two-day lecture course for the staff of the food and veterinary inspection on the monitoring and inspection issues carried out. 1 and 4 year				
4.3 Inspection for compliance of regulatory regime carried out (for labelling, conditions of contained use, importing conditions etc). 2 – 3 year				
4.4. Participation of 1-2 experts of the reference laboratory in ENGL annual meetings				
4.5 Literature and relevant journals concerning LMO analyses purchased				
4.6. Organize two-day lecture course for the Customs personnel, including relevant persons from each customs station in Estonia on regulations of the transboundary movement of LMOs according to the Cartagena Protocol as well as the use of the Biosafety Clearing House Mechanism (50 participants) , 1 and 4 year				
4.7 Prepare, publish and disseminate a set of guidelines for customs control purposes, including a mechanism for efficient control of transboundary movements of LMOs				
4.8 Organize a practical training on LMO samplings and inspection for all animal nutrition and food monitoring authorities, 15-20 participants, 5 days, 3 year				

4.9. Organize technical training for TTU workers and for ACGM members regarding the method and use of the PCR machine, interpretation of the results etc, 25 participants, 1,2 year				
4.10 Organize a workshop for consumer protection, veterinary and food board inspection officers, environmental inspectorate and plant production inspectorate on biosafety and genetic modification to equip them with inspection of GM activities, (20-30 participants), 1 and 4 year				
Objective 5: to assist Estonia to improve system for public awareness, participation, education and access to information.	Available information about GMOs in different formats (electronically, publications, regular trainings. Public acceptance to GMO policy/ issues.	Information available. Public opinion (in newspapers etc).	Public does not accept GMO policy/ issues	Provide information in different ways – infodays, publications, trainings, lecture courses. Involve different stakeholders to GMO activities (for example NGOs for publishing informative material about GMOs).
Outcome 5: Fully functional and widely accepted system for public awareness and participation in place				
Activities 5:				
5. 1 Produce and disseminate popular informative material on the risks and benefits of the use of LMOs				
5.2. Produce and disseminate twice a year, a newsletter in collaboration with journal Estonian Nature (or Greengate)				
5.3. Produce and disseminate informative materials for secondary schools and use it in conjunction with biology lessons about the Cartagena Protocol and the development of LMOs and related products				
5.4. Carry out two educational TV broadcasts on biosafety and the Cartagena Protocol, the use of LMOs and the risks of the use of LMOs, 2 and 4 year				
5.5. Organize a one day info day for consumers and NGOs about possible risks and benefits of LMOs, 60-70 participants, 2 and 4 year				
5.6. Carry out public opinion poll in 2 or 3 year				
5.7 Organize two public info days about the project and its outcomes, one day, 50-60 participants, 2 and 4 year				

5.8. Organize a one- day informative training for the representatives of NGO-s and general public on the biosafety decision-making issues
5.9. Elaborate an University Course on biosafety to be applied at TTU (working out 1-2 year, used 3-4 year)

ACGM Advisory Committee for Genetic Modification, advisory body for government
MoA Ministry of Agriculture
MoE Ministry of Environment
MoSA Ministry of Social Affairs
TTU Tallinn Technical University

List of legislative acts:

1. Amendments of GMO Act,
2. secondary legislation:
    a) regulation on processing applications coming from other EU member states,
    b) regulation on establishment and maintaining of GMO register,
    c) regulation on obligations of importers
    d) regulation on state monitoring and surveillance.

Annex C
Project Budget

ANNEX B: ACTIVITY BASED BUDGET

Activity code	Project activities	1st year GEF	GOV	2nd year GEF	GOV	3rd year GEF	GOV	4th year GEF	GOV	**Total GEF**	**GOV**
1 Biosafety policy											
1.1	Info day for members of government and parliament	500	500			500	500			1000	1000*
1.2	Drafting a policy paper, strategy and action plan for biosafety			3000	1000	3000	1000			6 000	2000*
1.3	Analyse and integrate the biosafety issues within strategy of agriculture (new strategy on co-existence, being worked out by MoA with the help of EC), 2 meetings for 20 persons from MOA and MOE	1000	500		500	1000	500		500	2000	2000*
1.4	Analyse and integrate biosafety issues within biotechnology policy, 2 meetings for 25 persons from MOE, MOA and M of Finance and M of Economy	500	500			500	500			1000	1000*
Total: Biosafety policy:										**10 000**	**6000***
2 Regulatory regime											
2.1	Drafting, discussion and adoption of secondary legal acts	5000	2000		2000		2000	5000	2000	10 000	8000*
2.2	Two one-day lecture courses for the importers and exporters and company representatives about the transboundary movements of LMOs and its legal aspects (60 participants)	2500	500					2500	500	5000	1000*
2.3	3 Publishing of guidelines for a) Governmental organizations on LMOs			3000	1000					3000	1000*

	legislation; b) Importers and exporter about the transboundary movements and legal aspects of LMOs			4000	1000					4000	1000*
2.4	Legal training for lawyers from MoE, MoA and MoSA and interested NGOs on legal aspects of LMOs and its connection to other international legal acts, 15-20 participants, 5 days (incl inviting foreign legal expert, ca 4000 USD)			6000	500					6000	500*
										28 000	**11 500**
Total: Regulatory regime:											
3 Handling requests											
3.1	Publish technical guidelines for handling of requests (incl RA/RM guidelines), separately for GMMs and GM higher plants.	4000	1000	4000	1000					8000	2000*
3.2	Advanced training on handling of GMMs in contained use and release into the environment (3 days, 20-30 participants, mainly members of ACGM)			7000	1000					7000	1000
3.3	7 day practical course on: Evaluation and risk assessment of the possible field tests with LMOs Procedures for setting up a field-test with LMOs. (20 participants)					8000	1000			8000	1000
3.4	Create and operationalize GMO register	10 000	1000							10 000	1000*

										33 000	**5000**
Total: Handling requests											
4 Follow-up, monitoring and surveillance											
4.1	Equipping of reference laboratory of the TTU for detection and inspections on LMOs and related products.	200 000	38000		38000		38000		38000	200 000	152 000
4.2	Two day lecture course for the staff of the food and veterinary inspection on the monitoring and inspection issues carried out. (1st year incl foreign expert)	3000	500					1000	500	3000	1000
4.3	Inspection for compliance of regulatory regime carried out (for labelling, conditions of contained use, importing conditions etc)			10 000	2000	10 000	2000			20 000	4000
4.4	1-2 experts of the reference laboratory attended ENGL yearly meetings		2000		2000		2000		2000		8000
4.5	Literature and relevant journals concerning LMO analyses purchased	1000	1500	1000	1500	500	1500	500	1500	3000	6000
4.6	Two-day lecture course for the Customs personnel, including relevant persons from each customs station in Estonia carried out on regulations of the transboundary movement of LMOs according to the Cartagena Protocol as well as the use of the Biosafety Clearing House Mechanism (50 participants).	2000	500					2000	500	4000	1000*
4.7	Set of guidelines for customs control purposes, including a mechanism for efficient control of transboundary movements of LMOs, published and disseminated			4000						4000	
4.8	Practical training on taking samples and					5000	1000			5000	1000

	on practical monitoring for all animal nutrition and food monitoring authorities, 15-20 participants, 5 days										
4.9	Technical training for TTU workers and for ACGM members regarding the methodology, handling PCR machine, interpretation of the results etc, 25 participants	5000	2000	5000	2000					10000	4000
4.10	Organize a workshop for consumer protection, veterinary and food board inspection officers, environmental inspectorate and plant production inspectorate on biosafety and genetic modification to equip them with inspection of GM activities, (20-30 participants)	2000	250					2000	250	4000	500*
Total: follow-up:											
										53 000+ 200 000	**181500**
5 Public awareness and participation											
5.1	Popular informative material distributed on the risks and benefits of the use of LMOs			3000	500			2000	500	5000	1000*
5.2	Newsletter distributed, twice a year, in collaboration with journal Estonian Nature or Greengate	1000	500	1000	500	1000	500	1000	500	4000	2000
5.3	Informative materials for secondary schools distributed and used in conjunction with biology lessons about the Cartagena Protocol and the development of LMOs and related products	6000		4000						10000	

5.4	An educational TV broadcast carried out on the Cartagena Protocol, the use of LMOs and the risks of the use of LMOs.			10 000	1000			10 000	1000	20000	1000* 1000
5.5	One day info day for consumers and NGOs about possible risks and benefits of LMOs, 60-70 participants			2000	500			2000	500	4000	1000*
5.6	Public opinion poll					4000	500			4000	500*
5.7	2006 and 2008 public info days about the project and its outcomes, one day, 50-60 participants			1000	500			1000	500	2000	1000
5.8	One- day informative training for the representatives of NGO-s and general public on the biosafety decision-making issues	2000	500							2000	500*
5.9	Course of biosafety for Universities worked out and used at least in TTU (working out 1st and 2nd year, used 3rd and 4th year)	2500	2000	2500	2000		1000		1000	5000	6000
	Total:									**56 000**	**14 000**
Total: public awareness and participation											
6 Project coordination											
6.1	National Project Coordinator (part time)	12 000		12 000		12 000		12 000		48 000	
6.2	Project Assistant (full time)	24 000		24 000		24 000		24 000		96 000	
6.3	One staff (half time) in charge of monitoring and evaluation issues and financial reporting	10 000		10 000		10 000		10 000		40 000	
6.4	National Coordination Committee Meetings, NCC travels	6000	10 750	6000	10 750	6000	10 750	6000	10 750	24 000	43 000*
6.5	Equipment and premises component (expendable and non-expendable	5000	3250		3250		3250		3250	5000	2000 11 000*

	equipment)										
6.6	Miscellaneous and others	1000	1000	1000	1000	1000	1000	1000	1000	4000	4000
6.7	audit	2000		2000		2000		2000		8000	
	Total project coordination:									**225 000**	**60 000**
7 Other project support											
7.1	Printing of reports	1000	1000	1000	1000	1000	1000	1000	1000	4000	4000
7.2	Translation	1000		1000		1000		1000		4000	
7.3	Communication costs	500	500	500	500	500	500	500	500	2000	2000
7.4	UNEP management	17 500		17500		17500		17500		70 000	
	Total:									**80 000**	**6000**
	Grand total									**685 000**	**284 000 (80 000 MoE)**

* contribution from MoE

Annex D
Draft Terms of Reference

ANNEX D

DRAFT TERMS OF REFERENCE FOR:

- **National Executing Agency (NEA)**
- **National Coordinating Committee (NCC)**
- **National Project Coordinator (NPC)**
- **National Project Assistant(s)**

a) The **National Executing Agency (NEA),** in addition to other duties given to it by the National Government, will:

- Establish the National Co-ordinating Committee (NCC) as per paragraph b;
- In consultation with UNEP, appoint a full time National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final report within three months from the end of the project.

b) The **National Coordinating Committee (NCC)** will be established by the National Executing Agency (NEA) to advise and guide the implementation of the NBF. This Committee needs to be multi-disciplinary and multi-sectoral, as it will be the key decision-making body. The NCC will work together as a National Project Management team to:

- Develop a common understanding of what is needed to expedite the implementation of the National Biosafety Framework;
- Oversee the execution of the project;
- Approve the detailed work plan and budget produced by the NPC;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project, giving clear directions on what are the next steps and whether remedial actions are needed;
- Ensure that information on the execution of the National Project as well as the National Project outputs is brought to the attention of local and national authorities for follow up;
- Assist in mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;
- Ensure effective communication with the relevant authorities, institutions and government departments
- Ensure that the environmental policy of the Government is fully reflected in the National Project documentation;
- Approve any revision of the work plan and budget produced by the NPC**;**
- Advise Government of the Project's conclusions and make recommendations on the strategy and framework components, content and timing of possible legal instruments as required;

- Seek solutions to operational and political difficulties in reaching the objectives of the implementation of the NBF;
- Act as a discussion forum to air differences and listen to a variety of views and record the process
- Meet on at least once every quarterly

c) The **National Project Coordinator (NPC)** will be appointed by the NEA and will therefore report to the NEA and the NCC. The tasks of the NPC are:

- Act as the secretary of the NCC
- Coordinate, manage and monitor the execution of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Update the detailed work plan and propose adjustments within the agreed budget as needed and under the guidance of the NCC;
- Ensure effective communication with the relevant authorities, institutions and government departments in close collaboration with the National Coordinating Committee;
- Foster, establish and maintain links with other related national and international programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP Biosafety Implementation Project Team;
- Ensure that information is available to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Prepare and submit to UNEP and the NCC, regular progress and financial reports and respond to comment/queries from them.

Desired qualification, skills and experience

- A degree in Science, Law or Management
- At least 5 years post-graduate experience in the field relevant to biotechnology/ biosafety.
- An in-depth knowledge about the Cartagena Protocol
- Ability to command some influence and respect among stakeholders in all biosafety activities at the national level
- Demonstrated successful experience in large-scale project design and implementation.
- Proven experience in project administration and management.
- Well versed in goal-orientated project planning method and participatory methodologies.
- Demonstrated experience working in an international and/or multi-cultural environment.
- Proven ability to work effectively with diverse groups of people including international agencies, governmental officials, NGOs, etc.
- Willingness to travel to partner countries and elsewhere.

- Fluency in written and spoken English.

c) The **Project Assistants (PA)** will carry out the following tasks:

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation of detailed work plan and budget under the guidance of the NCC;
- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outputs of the NBF;
- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;
- Assist the NPC in the preparation and submission to UNEP and the NCC, of regular progress and financial reports
- Assist with the preparation of a project monitoring and evaluation plan
- Assist with identification of appropriate project indicators able to reflect progress of activities as well as impact
- Assist in capturing and incorporating recommendations from NCC meetings into project execution and monitoring and evaluation plan
- Assisting with providing information as needed to carry out any monitoring and evaluation activity as part of the UNEP's internal guidelines

Desired Qualifications

1. Minimum three years experience as Programme or Administrative Assistant.
2. A good knowledge of biotechnology and biosafety issues.
3. Experience in supporting large-scale projects and programmes.
4. Experience working in a multi-cultural environment.
5. Fluent in written and spoken English.

Annex E
Monitoring and Evaluation Plan

Annex E: Monitoring and Evaluation Plan

C.6 a Execution performance and delivered outputs

Monitoring of the project execution will assess whether the management and supervision of project activities is efficient and seek to improve efficiencies and overall effectiveness of project implementation. It is a continuous process, which will collect information about the execution of the planned activities, allow for improvements in method and performance, and compare accomplished with planned tasks. This activity will be under direct responsibility of the National Coordination Committee (NCC). The UNEP Task manager will, in collaboration with the NCC, track these indicators (Table 2).

Table 2 Indicators and Means of verification

Indicator	**Means of Verification**
Half-yearly and annual activity and progress reports are prepared in a timely and satisfactory manner	Arrival of reports to UNEP
Half-yearly disbursement plans and half-year and annual financial reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Yearly GEF Project Implementation Review reports are prepared in a timely and satisfactory manner.	Arrival of reports to UNEP
Performance targets, outputs, and outcomes are achieved as specified in the annual work plans.	Semi annual and Annual progress reports
Deviations from the annual work plans are corrected promptly and appropriately.	Work plans, minutes of SC meetings
Disbursements are made on a timely basis, and procurement is achieved according to the procurement plan.	IMIS system at UNEP and Bank Account statements of executing agency
Audit reports and other reviews show sound financial practices.	Audit statements
National Coordinating Committee is tracking implementation progress and project impact, and providing guidance.	Minutes of NCC meetings
National Coordinating Committee is providing policy guidance, especially on achievement of project impact.	Minutes of NCC meetings

Monitoring and evaluation of project execution will be conducted through constant interaction, namely exchange via email and technical support or supervision missions. Throughout the project, approaches will be integrated with feedbacks, lessons learnt and best practices gained. The task manager will facilitate exchange of experiences between countries in the process of implementing their NBF. A meeting of the NPCs of the ongoing implementation projects is expected to be held annually.

The monitoring plan also covers the risks associated to project management. In this respect, special attention will be devoted to:

Management structure	so as to monitor whether stability and responsibilities are clearly understood
Work Flow	so as to verify if the project is maintaining its planned work load (key role in this case is played by quarterly reports and constant contacts)
Co-financing	so as to ensure that disbursements are carried out in time and with ease
Implementation	To verify if work plan is progressing according to schedule
Budget	So as to ensure that the work plan is progressing according to budget plans

Fund management[1]	So as to ensure that funds are wisely spent and correctly and transparently accounted for
Reporting	So as to monitor that work progress is reported comprehensively and on time. Reports contains critical analysis
Stakeholder involvement	So as to ensure that a multi-stakeholder process is in place and active
Communication	So as to guarantee that communication between management team members is fluid
Leadership	So as to ensure that project has an active and committed management team
Short term/long term balance	So as to guarantee that project meets short term need without compromising on long term outlook
Political influence	So as to verify project is making politically motivated decisions

C6.b Project impact

Evaluation of the project's success in achieving its outcomes will be monitored continuously through the project progress reports, mid-term and final evaluation reports, all of which will use the **log-frame** presented in Annex B.The full implementation of all components of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main focus for assessing the success of the project.

The Project Management team is responsible for monitoring progress as well as ensuring evaluation of impact. These are described in Tables 3 and 4 (below).

Table 3 Responsibilities of the project management entities regarding monitoring and reporting

UNEP Task Manager	National Executing Agency (NEA)	National Coordinating Committee (NCC)
Monitor the agreed M&E plan in accordance with the terms of agreement with GEFSEC Receive quarterly and annual reports (progress and financial), and copies of all substantive reports from (National Executing Agency). Task manager to attend and participate fully in meetings of the NCC Task Manager to conduct supervision missions to selected project sites and identify implementation problems and suggest remedies to annual meeting of the NCC. Engage and prepare terms of reference for independent M&E consultants to conduct the mid-term and final evaluations	Prepare quarterly progress reports (operational and financial) annual summary progress reports for UNEP, and forward quarterly operational and financial reports, with supporting documentation as appropriate, in a timely manner to UNEP. Carry out a programme of regular visits to project sites to supervise activities, and pay special attention to those sites with serious implementation problems	Meet at least on a quarterly basis and receive quarterly progress and financial reports, annual summary progress reports and all substantive reports and outputs and use them to review the progress of work in the project as a whole Advise on implementation problems that emerge, and on desirable modifications to the work-plan Monitor progress of the project, and advise on steps to improve it

Table 4: The key content required in the quarterly progress reports and financial reports.

[1] The total expenditures incurred during each year ending 31 December, certified by a duly authorised official, will be reported in an opinion by a recognised firm of public accountants according to UNEP regulations

Report	Format and Content	Timing	Responsibility
Progress Reports			
Document the completion of planned activities, and describe progress in relation to the annual operating/work plan. Review any implementation problems that impact on performance Summary of problems and proposed action Provide adequate substantive data outcomes for inclusion in consolidated project half-yearly and annual progress reports Highlights of achievements	Reports will use standard UNEP Progress Report format. The project log frame (Annex H) will be attached to each report and progress reported against outcome and output indicators.	Quarterly, within 30 days of end of each reporting period,	NEA
The Project Implementation Review (PIR) reports	Per GEFSEC format	Yearly (after project has been under implementation for one year)	UNEP Task Manager
Consolidated Annual Summary Progress Reports			
Presents a consolidated summary review of progress in the project as a whole, in each of its activities and in each output Provides summary review and assessment of progress under each activity set out in the annual work plan-, highlighting significant results and progress toward achievement of the overall work programme Provides a general source of information, used in all general project reporting	Reports will use a standard format to be developed following the UNEP Progress Report model The project log-frame will be attached to each report and progress reported against outcome and output indicators. A consolidated summary of the half-yearly reports Summary of progress and of all project activities Description of progress under each activity and in each output Review of delays and problems, and of action proposed to address with these Review of plans for the following period, with report on progress under	Yearly, within 45 days of end of the reporting period	NEA

	each heading		
Financial reports			
Report on co-financing that has been provided to project as originally estimated in project proposal approved by GEF	Use Annex as found in project document with supporting documentation of realized co-financing	Six-monthly	NEA
Details project expenses and disbursements	Standardized UNEP format as found in project document Disbursements and expenses in categories and format as set out in standard UNEP format, together with supporting documents as necessary	Quarterly	NEA
Summary financial reports	(Standardized UNEP format as found in project document)		
Consolidates information on project expenses and disbursements	Disbursements and expenses by category. Requirement for coming period: request for cash advance.	Half-yearly, within 30 days of end of period	Project financial officer
Financial audits			
Annual audit	Audit of accounts for project management and expenditures	Annual	Recognised firm of public accountants according to UNEP regulations.

Annex F
Incremental Cost Assessment

ANNEX F: INCREMENTAL COST ANALYSIS

Project Components	Baseline	Alternative	Increment
Biosafety strategy	Biosafety is not part of environmental strategy, agricultural and biotechnology policy	Biosafety is integrated into an agreed environmental strategy and is also included into new agricultural and biotechnology policies	The implementation of the Cartagena Protocol is supported by a national strategic documents
Biosafety regulatory regime	The biosafety regulatory regime is almost in place, but main law needs to be amended and some secondary legal acts need to be drafted	A regulatory regime reflecting existing policies and defining all the elements of the NBF and related implementing procedures in line with CP and international obligations are in force.	The implementation of the Cartagena Protocol is supported by a legal regime Decision-makers and personnel involved in the application of the regulatory regime are trained.
System for handling requests for permits	Estonia needs to strengthen procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively.	A system for handling requests for LMOs, including administrative processing, risk assessment and decision-making is set up. National capacities are strengthened in terms of training to enable them to properly cover their tasks.	The implementation of the Cartagena Protocol is supported by an operational system for handling requests, which includes administrative processing, risk assessment and decision-making
System for follow-up, namely monitoring for environmental effects and enforcement	Country needs to set procedures for follow-up activities, namely monitoring of environmental effects and enforcement. Technical means and training are needed so as to enable inspectors and technicians to carry out their tasks	Systems for monitoring of environmental effects and enforcement are in place. Laboratory of TTU is equipped with upgraded facilities for LMO detection studies National capacities are strengthened in terms of training. Initial compliance study carried out.	The implementation of the Cartagena Protocol is supported by an operational system for monitoring for environmental effects and enforcement
Public information, participation, awareness and education	Awareness and education need to be further strengthened, involvement of the public need to be part of the system so as to reflect Article 23 of the Cartagena Protocol	Public debates and discussions in media are carried out, many awareness raising activities carried out in different levels of society, different publication published. etc.	The implementation of the Cartagena Protocol is supported by a strengthened system for public information, education, awareness and involvement.

Incremental cost assessment

Broad development goals

This project is part of GEF's wider effort in assisting countries to implement a biosafety regulatory regime in accordance with Agenda 21 and the CBD. More specifically, GEF resources will be used to assist Estonia to meet the objective of the Cartagena Protocol (*i.e.* to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements) through the full implementation of its NBF.

The project is consistent with, and based on, stated national priorities, plans and programmes in both the development and conservation sectors, including the National Agenda 21 and the National Strategy of Biological Diversity

Baseline

Within the context of the project, the baseline includes the activities carried out at domestic level with respect to each specific project component; the increment includes the activities proposed under this project proposal for the purpose of meeting the requirements of the Cartagena Protocol, to be financed through GEF contribution and national co-financing.

The cost of baseline activities at the national level is detailed in Table 5, Summary incremental cost analysis. The various components of the NBF are important; but these amounts can support only minimal activities.

The project builds on experience gained up to date through the demonstration projects, which can add to the baseline and is complemented by the BCH project. As Estonia did not ratify CP for 1 COP/MOP, then Estonia is not eligible for BCH project in first round of countries.

The commitment of the Estonian Government is demonstrated by the national co-financing to the project, in-kind (US $ 80 000), and US $ 204 000 from TTU as NEA, also in kind. Details of the budget are enclosed in Annex C.

Finally, though baseline refers only to activities other than the GEF sponsored ones, the Estonia benefited from previous funding through the UNEP/GEF Project to develop a National Biosafety Framework The project is therefore a logical follow-up to the support already provided to Estonia to meet the obligations of the Protocol.

GEF alternative

The existing institutional and technical infrastructures need to be reinforced for Estonia to meet its obligations as Party to the Cartagena Protocol..

In order to reach this objective, the incremental cost analysis estimated as follows (see table 5 in MSP brief):

The total baseline expenditure amounts to US $ 200 000.

The alternative has been estimated at US $ 1 163 000. The incremental cost analysis shows that an amount of US $ 969 000 is required to achieve the project's global environmental objectives. The country will cover nearly 30% of the cost of the increment as in-kind contribution (284 000 USD). A sum of US $ 685 000, corresponding to the remaining 70% of the total cost of implementing the project, is required from GEF.

Annex G
List of equipment

Proposed list of equipment for NBF Implementation Project for Estonia

Real-time PCR system for the quantitative measurement of GMOs	75,000
Gel documentation system	40,000
Centrifuges	21,000
Spectrophotometer for the quantification of nucleic acids	20,000
Balances, pH-meters etc. for the preparation of solutions, buffers etc.	14,000
Electrophoresis equipment with power supplies and pipettes	11,000
Machine for the qualitative PCR	10,000
Refrigerator and freezer	4,000
Consumables (pipettes etc)	5,000
Total:	**200,000 USD**