MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID: ……
GEF SEC PROJECT ID: 2838
COUNTRY: Lithuania
PROJECT TITLE: Support for the Implementation of the National Biosafety Framework for Lithuania
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY (IES):
GMO DIVISION, MINISTRY OF ENVIRONMENT, LITHUANIA
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*	N/A
Sub-Total GEF	
CO-FINANCING**	
GEF Agency	687,400
Government	404,000
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	404,000
Total Project Financing:	1,091,400
FINANCING FOR ASSOCIATED ACTIVITY IF ANY:	

* 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 as an Enabling Activity and addresses Strategic Priority 3: Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

Mr G. Gaigalas
GEF Operational Focal Point,
Ministry of Environment
A. Jaksto st. 4/9, LT-01105, Vilnius
Lithuania
Phone: (+370 5) 2663 539
Fax: (+370 5) 2663 668
E-mail: g.gaigalas@am.lt

Date: 26.05.2005
(see letter of endorsement at Annex A)

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.

IA Contact Person

Ahmed Djoghlaf,
Assistant Executive Director
Director, Division of GEF Coordination
United Nations Environment Programme
P.O. Box 30552, Nairobi 00100
Tel: 254 20 624166
Fax: 254 20 624041/42
E-mail: ahmed.djoghlaf@unep.org
Date: (Month, Day, Year)

Project Contact Person:

Dr. Danius Lygis
Head of GMO Division, MoE
Tel.: (+370 5) 2663 562
Fax: (+370 5) 2663 668
E-mail: d.lygis@am.lt

LIST OF ACRONYMS

BCH	Biosafety Clearing House
nBCH	national Biosafety Clearing House (national database)
CBD	Convention on Biological Diversity
CNDD	National Commission for Sustainable Development
CPB	Cartagena Protocol on Biosafety
GEF	Global Environment Facility
GMMO	Genetically Modified Micro Organism
GMO/LMO	Genetically Modified Organism/Living Modified Organism[1]
GMP	Genetically Modified Product
MoA	Ministry of Agriculture
MoE	Ministry of Environment, Lithuania
MoH	Ministry of Health, Lithuania
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
NVL	National Veterinary Laboratory under the State Food and Veterinary Service
MSP	Medium Size Project
R&D	Research and Development programs
SFVS	State Food and Veterinary Service
SPPS	State Plants Protection Service under the Ministry of Agriculture
SSGS	State Seeds and Grain Service under the Ministry of Agriculture
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme

[1] Other terms often used in the NBFs often include: „genetically modified organisms "(**GMOs**), „transgenic organisms", „recombinant DNA organisms", to denote organisms that have been derived using techniques of modern biotechnology. In this document the common term **"genetically modified organisms" (GMOs)** is used.

A. PROJECT SUMMARY

An outline of country efforts undertaken for implementation the concept of sustainable development, NBSAP, Convention of Biological Diversity (CBD), CPB to the CBD

1. Lithuania has developed the National Strategy for Sustainable Development proving a national concept of sustainable development as a reasonable compromise between the environmental (healthy environment), economic (efficient economy) and social objectives of the developing society. It is based on guidelines for the long-term development of the country (until the year 2020) and on the main principles of sustainable development formulated in the 1992 Rio de Janeiro United Nations Conference on Environment and Development. This Strategy takes into account interests and peculiarities of Lithuania as a country with the economy in transition. Taking into account that crosscutting issues are considered among the major constraints for sustainable development, relevant efforts should be made to link closely the objectives and tasks of different sectors involved. For example, it is foreseen that expansion of the amount of rapeseed and crops cultivated for energy purposes (bio-diesel and bio-ethanol) would cover 15% of transport fuel needs. In that case, the environmental sector has to regulate the deliberate release into environment and placing to the market of (possibly GM) crops and grains.
2. The National Strategy for Sustainable Development has been initiated and prepared by the Ministry of Environment in close collaboration with UNDP country-office. The Strategy was approved by the Resolution No. 1160 on September 11, 2003 by the Government of the Republic of Lithuania, and authorized the Ministry of Environment (MoE) to co-ordinate the implementation of the National Strategy of Sustainable Development. The implementation measures for mid-term biodiversity sector objectives include, *inter alia*: revision of below mentioned National Biodiversity Strategy and Action Plan (NBSAP); preparation of a national study on biological diversity and implementation of biodiversity research programs; integration of biodiversity (including genetic diversity) monitoring, legitimating case-specific monitoring and general surveillance methods. Therefore, there is a clear need to integrate the relevant Biosafety issues into the nationally agreed long-term strategic governmental documents.
3. Being a Party to the Convention on Biological Diversity since February 1, 1996, Lithuania has addressed the issues of genetic diversity conservation needs in the compiled NBSAP, adopted by the Ministry of the Environmental Protection and Ministry of Agriculture on 1 January, 1998. Thus, the MSP project proposal is consistent with the national priorities documented in the NBSAP, resulted from the close collaboration between scientific community and NGOs: 1) preparation of a *Genetically Modified Organisms Act (GMO Act)*, 2) development of a national genetic preservation system, and 3) creation of the national gene bank. There are acknowledged biodiversity conservation priorities, preserving ecosystems and habitats, *inter alia*, enabling access and transfer of modern technologies, thus protecting environment, agriculture and human health from the possible adverse effects there from. Lithuania has already started to promote biological safety efforts since late 2000. Thus, the *Law on Genetically Modified Organisms (GMO Act)* and some relevant implementing regulations (secondary legislation) have been adopted since that time, for which subsequent revisions need to be elaborated in order to comply with varied international requirements and national obligations, for example, the frame *GMO Act* envisaged the general state management, control and inspection provisions, however the clear identification and separation of responsibilities and functions between the NCA and other authorized state institutions (responsible for monitoring, control and inspection) should be elaborated, documented and implemented.
4. The National Biosafety Framework (NBF) was drafted and the CPB was ratified in Lithuania employing the UNEP-GEF support provided in the form of a Global Biosafety Enabling Activity project. The UNEP-GEF Sub-Project on the "Development of the National Biosafety Framework for Lithuania" (GFL/2716-02-4546, commenced in November, 2002 and completed in August, 2004) aimed in assisting Lithuania to mobilize the required efforts for the preparation of the draft NBF, which main elements were identified as follows:
   - Formation of national Biosafety policy;
   - Development of national regulatory regime;
   - Set up of national administrative system to handle notifications, requests for authorization;
   - Preparation of the national environmental monitoring and enforcement mechanisms;
   - Development of public education, participation and information exchange mechanisms.

   Thus, the completed UNEP-GEF project on the Development of the National Biosafety Framework (NBF) for Lithuania (GFL/2716-02-4546) enabled to identify and draft the main constituent parts of NBF in the Party of

the Cartagena Protocol. A copy of the summary draft National Biosafety Framework for Lithuania is attached in Annex B to this MSP proposal.

5. Lithuania ratified the Cartagena Protocol on Biosafety (CPB) on the 18th of September 2003, which became legally binding national law since March 2004. Therefore, the MSP proposal "Support for the Implementation of the National Biosafety Framework of Lithuania" aims to promote and expedite the initial measures undertaken by national authorities in meeting the obligations foreseen under the Protocol by providing the needed capacity building activities. It aims to support the NCA in order to meet the Party's obligations foreseen under the CPB by providing the needed capacity building for the main identified NBF elements: Biosafety policy, regulatory regime, administrative system, monitoring & enforcement, public participation. The proposed MSP, when implemented, shall contribute to the enforcement of the NBF, i.e. strengthening the existing institutional capacities required and human resources needed to have fully operational and enforced ("up and running") National Biosafety Framework in Lithuania.
6. In this respect, the MSP proposal supports key aspects of the draft NBF enabling Lithuania to strengthen the existing institutional and technical structures and infrastructures needed to meet the obligations of the CPB and have a National Biosafety Framework fully operational by 2009. The Medium Size Project will contribute to:
   - The development and implementation of consolidated national Biosafety policy through integration of Biosafety and biotechnology sector into the long-term strategic documents on sustainable development, thus securing continuous broader political and public support for consistent implementation of Biosafety policy in Lithuania;
   - The implementation of fully operational and responsive national legislative framework in line with the CPB and other international obligations on the safe use of biotechnology through decrees, orders, operational regulations, technical guidelines and internal manuals;
   - The strengthening of constituted institutional administrative structures to handle notifications and requests for risk assessment and informed decision-making;
   - The education and training of decision-makers, scientists, administrative and technical personnel of NCA and responsible institutions concerned on administrative, regulatory and technical matters for implementation and enforcement of NBF;
   - The reinforcement and, where needed, building capacities of existing infrastructures (national GMO laboratory, inspectorate, etc.) needed to strengthen monitoring, control and inspection, thus enabling to identify and eliminate, where possible, risk factors which could make considerable harm to environment, agriculture and human health;
   - The strengthening of communication and information exchange mechanisms for handling, storage and exchanging of Biosafety related information, both at national level (the interoperable expanded national Biosafety database, nBCH) and international level (integration of the nBCH into the Biosafety Clearing House (BCH));
   - The elaboration and strengthening of effective and operational national mechanisms for public awareness, education, access to information and participation in decision making on Biosafety related issues.
7. Summarizing, the MSP is consistent with the national priorities to promote safe use and handling of GMOs and GMPs on different Biosafety applications in Lithuania. This project will help to support and reinforce, where needed, the existing institutional and technical infrastructures required in order to meet the obligations of the CPB and have a National Biosafety Framework (NBF) fully operational in Lithuania.
8. The state management of activities involving the use of GMOs and GMPs is regulated by the national Law on Genetically modified organisms (*GMO Law*) and carried out by the appointed NCA – Ministry of Environment. The NCA has established a consultative committee – GMOs Steering (Regulatory Management) Committee (established by the Order of MoE No. 602 on December, 2001). It is a political advisory body for the development and enforcement of national regulatory regime with respect to Biosafety issues and giving advice in handling the requests for the contained use, deliberate release into environment and placing on the market of GMOs and GMPs in Lithuania. The GMOs Steering Committee consists of main national Stakeholders (Ministries of Environment, Health, Agriculture, State Food and Veterinary Service), representatives from interested NGOs, the private sector, consumer associations, etc.

Development Objective of the medium-sized project (MSP) is that by 2009 Lithuania has a workable and transparent National Biosafety Framework (NBF) in line with its national development priorities and international obligations in order to comply with the requirements of CPB through the indicated national capacity building needs.

Project specific Objectives:

A. To assist Lithuania to integrate and incorporate Biosafety policy into the nationally agreed long-term strategic governmental program on sustainable development and elaborated national Biosafety strategy documents.

B. To assist Lithuania to amend and consolidate fully operational, workable and responsive regulatory regime in line with the CPB, EU law and other relevant international obligations.

C. To assist Lithuania to consolidate a functional and efficient national system to handle notifications or requests for authorization, perform risk assessment and administrative tasks of informed decision-making.

D. To assist Lithuania to establish and consolidate a functional national system for monitoring of environmental effects and enforcement (control and inspection).

E. To assist Lithuania in elaboration of the relevant operational systems for public awareness and education, access to information and participation in the decision-making processes.

Project specific Outcomes:

A. Biosafety is integrated into the nationally agreed long-term strategic Governmental Program on Sustainable Development and other elaborated national Biosafety strategic documents in Lithuania

A. 1. Biosafety issues integrated and incorporated in:
- National Strategy on Biosafety/ modern biotechnology development elaborated & approved;
- National Program and Action Plan for safe use on various applications of modern biotechnology elaborated and approved

A.2. Strengthened public and political support for consistent implementation of Biosafety policy in Lithuania

B: Lithuania has a fully operational and responsive regulatory regime in line with CP and existing national laws needs and other international obligations

B. 1. National regulatory regime amended, approved and in place, depending on the agreed Biosafety policy, provisions of CPB including CoP-MoP Decisions, EU law & other international obligations. In particular the:
- Framework GMO Law amended, adopted and in place;
- Secondary legislation on Biosafety (implementing regulations, orders, decrees, and guidelines) drafted, concerted, adopted and in place.

B.2. National competence on regulatory issues is increased and equipped with tools for related additional capacity building activities in Lithuania:
- Building national and regional networks for exchange of regulatory experiences;
- National workshops and thematic trainings on legal issues organized.

C. Lithuania has an efficient national system for handling requests, which includes administrative processing, risk assessment and management, and decision-making,

C.1. A fully operational national administrative system to handle notifications or requests for authorization, including established operational emergency response procedures, in place.

C.2. A fully operational national administrative and methodological risk assessment (RA) and management systems finalized and in place.

C.3. A fully operational national decision-making system finalized and in place.

C.4. Increased in-house competence on handling of requests available and equipped with tools for related additional capacity building activities in Lithuania.

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

D.1. Elaborated national institutional setting for monitoring of environmental effects in place.

D.2. Improved and strengthened national enforcement (control and inspection) mechanisms.

D.3. Increased in-house competence on monitoring, control and inspections are available and equipped with tools for related additional capacity building activities in Lithuania.

E. Lithuania has an efficient functional national system for promoting public awareness, participation, education, and access to information

E.1. National public awareness and education mechanisms, strengthening public access to Biosafety / modern biotechnology information, elaborated and operational in place.

E.2. National system for public participation in the decision-making process strengthened and enforced in Lithuania.

E.3. Increased in-house competence on public awareness, information and participation in decision-making process is available and equipped with relevant tools in Lithuania.

Estimated budget (in US$):

GEF: Project Cost: 687,400 US $

Co-financing: Lithuanian government contribution

In kind: 404,000 US $

Total: budget in US $: 1,091,400 US $

Information on Project Proposer:

GMO Division: National Executive Agency (NEA)
Ministry of Environment (MoE) is National Competent Authority (NCA) for Biosafety in Lithuania, official focal point for BCD and CP.

Contact person:

Dr. D.Lygis, Head of GMO Division, NEA A. Jaksto str.4/9 – 411,LT-01105, Vilnius, Lithuania

Tel.: (+370 5) 2663 562

Fax: (+370 5) 2663 668

E-mail-1: d.lygis@am.lt, E-mail-2: gmo@gamta.lt

B - COUNTRY OWNERSHIP

B1. Country eligibility

Lithuania ratified the Convention on Biological Diversity on 1 February 1996 and the Cartagena Protocol to the CBD on 18 September 2003.

B2. Country Driveness

Project linkage to national priorities, action plans and programs :

- The Project is fully consistent with the country's priorities as documented in the National Biodiversity Strategy and Action Plan (NBSAP), namely: preparation and revision, upon necessity, of a frame *Law on Genetically Modified Organisms (GMO Law)*. For that purpose, the *GMO Law* was adopted on 2001, for which subsequent revisions need to be elaborated in order to comply with changed and varied international requirements and subsequent national obligations. Thus, the framework *GMO Law* envisaged the general state management, control and inspection provisions. The identification and clear separation of responsibilities and functions between the NCA and its subordinated organizations (national agencies, responsible for control, monitoring and enforcement) need to be undertaken. The main national administrative authorities have been nominated by the framework *GMO Law*, however there is an obvious need to identify and establish subordinated agency, responsible for monitoring and enforcement (control and inspection) in Lithuania.
- There is no particular unified national policy document for Biosafety on application and usage of modern biotechnologies, consolidating different sectors (environmental protection, agriculture, health protection, science and education) adopted in Lithuanian yet. However, there are different related policies outlined in

the strategic governmental programs and long-term plans adopted, addressing different Biosafety aspects: National Environmental Action Plan (NEAP), National Food and Nutrition Strategy and Action Plan (2003-2010), National program for Agricultural development, National Biodiversity Strategy and Action Plan (NBSAP), Lithuanian Strategy for High-Tech Science and Modern Technology. The national science and technology policy promotes R&D, including safe use and applications of biotechnology in Lithuania. Thus, the national priority identifies the national strategy documents, which need to be formulated, drafted and approved: National Strategy on Biosafety Development, National Program and Action Plan for safe use on various applications of modern biotechnology in Lithuania.

- As identified, Research and Development (R&D), scientific applications of biotechnology are among the main priorities in Lithuania. They include, *inter alia*, promotion of genomic and modern life sciences lying down new possibilities to promote economic development in developing society. The MSP proposal will, therefore, complement the currently on-going European Union *Centre of Excellence* Program on biodiversity, biotechnology and Biosafety, which is related to the Article 22 of the CPB. This program aims at supporting development of scientific and technological potential. Trainings, workshops, study visits, exchange of expertise of "know-how" will promote and encourage participation in international cooperation and networks and facilitate the preparation of joint international projects related to Biosafety and biotechnology; twinning /networking with leading European centers, including Centers of Excellence. Several national scientific research institutes specializing in the biotech research works (Institutes of Biotechnology, Biochemistry) were acknowledged for the achievements by the EC Centre of Excellences.
- Biosafety is a complex cross-sectional topic in the European Union policy. As Lithuania joined the European Union (EU) in May 2004, thus the general policy for the safe usage and handling system of GMOs are similar to that of EU policy on Biosafety. Currently, there are among national priorities to adopt the functional and responsive national Biosafety regulatory regime with appropriate set-up of the operational administrative system, which would enable to develop the effective national decision-making and follow-up mechanisms for monitoring and enforcement of the draft NBF in Lithuania.
- The National Biosafety Framework (NBF) was drafted during the UNEP-GEF Sub-Project on the "Development of the National Biosafety Framework for Lithuania", which has been completed in 2004. The support received during the finalized UNEP-GEF project has been considered by the National Competent Authority (MoE) and other national stakeholders concerned as a very helpful and efficient tool, which had enabled to commence national activities towards better understanding of current situation, formulating future capacity building needs and elaborating the current MSP project proposal in order to complete institutional gaps in regulatory, administrative, decision-making, monitoring and enforcement, public awareness and participation mechanisms. Summarizing the current NBF situation, it is a need of another substantial effort for national capacity building to continue the implementation and enforcement of the NBF in Lithuania.
- The implementation of the drafted and consolidated NBF will ensure the risks likely to be caused by the modern biotechnology and its products are minimized and the biodiversity, human health and environment are protected in the maximum ways possible. At the same time, it should ensure the promotion of research, development and commercialization of the modern biotechnology, thus regulating the trans-boundary movement of GMOs through formulation of relevant policies, regulations, and technical guidelines (national laws, governmental orders, secondary legislation, etc.), establishing fully functional and responsive national regulatory regime, consolidated administrative institutions and effective supervisory mechanisms for control and enforcement. The implementation of the above-mentioned challenging tasks requires meeting national capacity building needs, which include development of human resources and strengthening of competent institutions.
- The proposed MSP will contribute to the implementation of the drafted NBF, strengthening the existing institutional capacities and human resources in order to have fully operational the enforced NBF in Lithuania.

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAM DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area as an Enabling Activity and addresses Strategic Priority 3: Capacity Building for the Implementation of the Cartagena Protocol on Biosafety and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e.

"Developing systematic and institutional capacity building for Biosafety: Provision of support to countries for the development of 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, trade and health as well as community and private sector stakeholders".

The project will assist Lithuania, as Party to the Cartagena Protocol on Biosafety, to meet the undertaken obligations by building and strengthening the institutional capacities needed to have an operational National Biosafety Framework in place.

The project falls within the activities contained in the Initial Strategy for entry into force of the Cartagena Protocol on Biosafety, adopted by the GEF Council in November 2000. This project will support coordination and collaboration activities among the countries concerned so as to promote exchange of information and sharing of experience, best practices and lessons learnt through "global tools", currently under development. Those tools, which tackle the items listed in this pillar of the GEF emerging priorities, will be used for the implementation of the proposed project as well as for other countries, which are going to be involved in the implementation of their respective National Biosafety Frameworks (NBFs) in the coming future.

C2. PROJECT DESIGN

The MSP proposal was developed employing a logical framework analysis methodology; details of the logframe are presented in Annex C to this document.

C2.A BACKGROUND AND CONTEXT

BACKGROUND AND CONTEXT

1. 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 organization of regional workshops (2 workshops in each of four regions) which involved a very large number of countries (US$ 0.8 million).

2. 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".

3. 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.

4. 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).

5. Lithuania 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.

6. 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.

7. 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." The project fulfils these criteria.

8. 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.*

Lithuania participated in the UNEP-GEF Global Project on "Development of National Biosafety frameworks". In order to design its **National Biosafety Framework**, Lithuania carried out the following activities and produced the following main outputs:

- Assessed the national capacity building needs and priorities for safe use and handling of GMOs and their products in order to draft the National Biosafety Framework (NBF);
- Survey of existing uses and the arrangements for safe use of modern biotechnology as defined in the CPB;
- Review and assessment of existing legislation and other legal instruments related to implementation of the CPB that my impact on the use of modern biotechnology;
- Survey on existing available mechanisms for harmonization of risk assessment and management posed to the environment, agriculture and human health by GMOs and GMPs;
- Set up of pilot National Biosafety Database, development of information flow system, completing it with the data gathered during the national surveys, identifying how information should be stored and managed for input into Biosafety Clearing House Mechanism (CHM);
- Identified how information should be stored and managed for input in the nBCH mechanism and for promoting public participation in accordance with the requirements of the CPB;
- Issued the relevant material on public awareness and access to national biosafety information (educational book on GMOs, brochure for National Biosafety Framework, leaflets, etc.);
- Organized national training workshops (on risk assessment posed to the environment, agriculture and human health by GMOs and GMPs and the information required for the appropriate measures to manage risk) and public awareness and participation seminars.

A copy of the summary National Biosafety Framework for Lithuania, which was accomplished as a result of the above-mentioned project, is attached in Annex B.

C2.B CURRENT SITUATION IN LITHUANIA WITH RESPECT TO THE NBF

National Biosafety/ biotechnology industry and research

Research and development (R&D), scientific applications of modern biotechnology are among the main national priorities in Lithuania. Contemporary sector of modern biotechnologies has been included for long-term programming in EU (5th and 6th Framework programs and LIFE program), as well as into the Lithuanian science and research development programs. The long term, 5 years national program "Molecular Basis of Biotech: Gene Structure, Function and Regulation" was approved and funded as five-year state program in Lithuania. The national priority for promotion of modern life sciences was endorsed by the Regulation of the Government of Lithuania "Regarding the approval of underlying directions for the scientific research and experimental development in Lithuania" (July 2002). The state Order of the Government of Lithuania "Concerning the establishment and implementation of high-tech programs in Lithuania" (December 2003) and subsequent Regulation of the Minister of Science and Education "Concerning the establishment of order to finance the priority scientific research and experimental development projects" (March 2004) have greatly promoted the research and development sector, setting up the background rules for competition among scientific and experimental research projects and programs. Modern life sciences (including biotechnology) are considered as the second step forward, after the Information Technology (IT), which lies down brand new possibilities to promote economic development of the modern society. Therefore, it is likely to have good starting position for the future development of biotechnology sector in Lithuania. During the last decade national industrial biotech companies have developed patenting, marketing and advertising systems in Lithuania. Moreover, several scientific research institutes have gained international acknowledgement for their biotech research works. The EU International Centres of Excellence was awarded to the Cathedral of Biochemistry and Biophysics of the Vilnius University, Natural Science Faculty, Laser Research Centre and National Institute of Biotechnology. There are line national scientific research institutes, which are working with scientific applications of GMMOs in laboratories (contained use of GMOs), namely: Institute of Biotechnology (since 1975), Institute of Biochemistry, Institute of Botany (dealing with investigations of micro-organisms, enzymes, eukaryotic modified cells), Institute of Agriculture, Institute of Forestry, State Plant research Centre, Institute of Veterinary, Vilnius University Faculty of Medicine and Faculty of Natural Sciences.

The main activities of the Institute of Biotechnology comprise development of classical fermentation and purification technologies to produce enzymes for scientific research, clinical analysis, industries and agriculture. The most successive investigations have been made in the particular field of restriction endonucleases. There are more than 200 such enzymes collected in the Biotech institute now. Many new enzymes have been discovered and commercialized (thus, since 1985 the enzymes have been started to be sold worldwide). When new possibilities turned up to carry on commercial activities, several joint-stock companies (JSC) were established: "Fermentas", "Sicor Biotech" (joint private companies of Biotechna and Biofa), Biocentras. The national Institute of Biotechnology has been supported on the basis of contracts and grants from the afore-mentioned local biotech companies, thus proving successful co-operation of science and industry in the field of modern biotechnologies in Lithuania. There have been 4 permits issued by the Ministry of Environment for contained use of GMMOs in the Republic of Lithuania until 1 May 2005, namely for the applied laboratory work with 1 risk class of GMMOs in: JSC "Fermentas", JSC "Sicor Biotech", Institute of Biotechnology and Institute of Horticulture.

The separate state laboratory of Genetically Modified Organisms, established and equipped during the recent several years (2003-2004), carries on analyses and GMOs detection tests at the State Food and Veterinary Service (SFVS). The accredited national veterinary laboratory (NVL) is the designated state laboratory to carry out the required detection of GM organisms and GM products throughout their life-cycle and different application (contained use, deliberate release into environment, placing on the market). The National Veterinary Laboratory (NVL) under the SFVS has started to implement monitoring program for the state control of labelled and unlabeled food products for the content of GMOs since the middle of 2004. The NVL needs to be reinforced in terms of human capacities and validation of methods used for detection of GMOs.

Biosafety policy

During the last fourteen years Lithuania has been developing through the transitional transformation phase from a central to a market oriented economy. The executive administrations had to reorganize their structures routinely. These processes triggered new relationships and collaboration between the state organizations and scientific community, when prominent scientists have been increasingly involved in the decision-making processes concerning the formation of the official policy based on scientific principles and approaches.

According to the globally unified principles of sustainable development (environmental protection, economic development and social integrity), called Agenda 21, it was agreed to coordinate harmonization of those pillars on international, regional and national (local) levels. Lithuania, as a country with economy in transition, has developed a National Strategy to implement those principles of sustainable development encompassing different strategies and plans (i.e. on economic and rural development, environmental protection & biodiversity conservation, public health protection, education and science, R&D, etc.). Although there is no particular single national Biosafety policy elaborated up to date in Lithuania yet, there are number of different associated sectors' strategies, outlined in the approved governmental programs and long-term plans, among others: National Program for Environmental Protection, NBSAP, National Food Strategy, and National Strategy for High-Tech Sciences and Modern Technologies, etc. The latter strategy promotes the research and development programs, including safe use and application of modern biotechnology methods. At this transitional stage of Biosafety development, the different national inter-related national plans and programs should be comprehensively reviewed in order to elaborate prioritized country-driven outcomes: National Biosafety Strategy, and national Program and Action Plan for safe use on various applications of modern biotechnology, thus enabling its implementation.

Regulatory regime for Biosafety

The state management of activities involving the use of GMOs and GMPs is regulated by the national Law on Genetically Modified Organisms (*GMO Law*) and carried out by the appointed NCA – Ministry of Environment. The NCA has established a consultative committee – GMOs Steering (Regulatory Management) Committee (established by the Order of MoE No. 602 on December, 2001). It is a political advisory body for the development and enforcement of national regulatory regime with respect to Biosafety issues and giving advice in handling the requests for the contained use, deliberate release into environment and placing on the market of GMOs and GMPs in Lithuania. The GMOs Steering Committee consists of main national Stakeholders (Ministries of Environment, Health, Agriculture, State Food and Veterinary Service), representatives from interested NGOs, the private sector, consumer associations, etc.

As Lithuania became the Member State of EU since May 2004, all national legal acts, which regulate different kinds of GMOs usage, have been prepared taking into account the requirements of relevant EU directives, regulations, decisions and recommendations, thus in principle corresponding to the requirements of EU *acquis*. Further to that, the national Biosafety-related pieces of legislation have been drafted considering with the main requirements posed by the CPB and other international obligations.

The Parliament and Government of the Republic of Lithuania is responsible for the formation of national Biosafety policy for the safe use and handling of GMOs and GMPs. The national government began to prepare the rules and administrative acts to regulate some aspects of the biotechnology R&D and the related Biosafety applications a few years ago. Thus, there have been only a few governmental laws drafted and complemented regulations adopted directly on Biosafety related issues until recently (during 2002-2004). Some of them are indirectly related to Biosafety, regulating products and applications of food, veterinary and agricultural industries.

According to the provisions of the framework ***Law on GMOs***, which legally came into force in December, 2002; the following responsible governmental institutions were identified and authorized to execute the state management and supervision of Biosafety sector in Lithuania: Ministry of Environment (NCA), Ministry of Agriculture, Ministry of Health Care, State Food and Veterinary Service, GMO Steering (Regulatory management) Committee. The framework ***Law on GMOs*** applies to deliberate release into environment, placing on the market and contained use of GMOs in Lithuania. The established **GMOs Steering (Regulatory management) Committee** is an advisory body for the development and further implementation of the national Biosafety regulatory regime. The main task of inter-institutional Regulatory Committee is to advise the NCA and other interested state organizations, responsible for implementation and enforcement of national legal acts, EU law, international binding agreements (i.e. CPB), to initiate country discussions on strategic Biosafety programs/projects in order to secure safe handling and usage of GMOs in Lithuania. The GMOs Steering Committee has been an instrument to govern and co-ordinate the development and further implementation of the NBF in Lithuania. Thus, in response to changing needs, it was decided to amend the framework Law on GMOs making necessary adjustments (e.g. on information expertise, GMOs monitoring, co-existence, etc.) and supplemented additions concerning provisions for the implementation of the national legal act.

There are number of secondary legislation (i.e. ministerial orders, technical regulations, guidelines) concerning notification, permitting procedures on decision-making for contained use, deliberate release into environment, marketing, transboundary movement (import/export) of GMOs/GMPs drafted in Lithuania. The NCA and other interested institutions are of opinion to amend and consolidate a workable regulatory regime in response to changing needs. Summary of the national laws, decrees and regulations is presented in Annex D.

Despite a fact that most of the national regulations were drafted quite recently, some of them need to be reviewed taking into account specific requirements of CPB and other international obligations (rules of the WTO, Codex Alimentarius, and IPPC, etc.) Thus, a frame Law on GMOs (2001) pending for the comprehensive review and adjustments shall be supplemented with new provisions of specialized terminology on issues of Liability and Redress; principles of the Co-existence; Monitoring (case-specific and general surveillance) and Enforcement mechanisms. Although Lithuania has an operational Code on Administrative Right's Violation, the appropriate domestic measures to prevent and penalize illegal transboundary movements of GMOs needs to be incorporated therein, and Civil Codex (developed specifically oriented methodology). Several national orders, decrees and regulations of the secondary legislation in Biosafety sector need to be reviewed (Regulation of Risk Assessment of GMOs; Order for preparation of general surveillance and monitoring plan of GMOs after placing on the market (post-commercial monitoring, etc.) introducing amendments therein. Some of new legal acts, such as Regulation on Co-existence with conventional agricultural plants, Regulation on prohibition the deliberate release of GMOs in the Protected Areas in Lithuania should be drafted, concerted and approved.

Thus, the national Biosafety legislative framework is considered as a quite new evolving mechanism, responsive to the needs of existing national particularities and international obligations.

Summing up the above-given explanations, it is evident that development and enactment (realization in practice) of a national regulatory regime has been partially completed and is still on-going process. The national legislative framework should be reviewed and amended in order to ensure Lithuania has fully operational and responsive regulatory regime in place.

System for handling request for permits

According the approved framework Law on GMOs, different national authorities have certain responsibilities regulating the usage of GMOs in Lithuania. The framework ***Law on GMOs*** determines the background competences and general division of responsibilities among the main National Competent Authority – Ministry of Environment and other interested responsible state institutions: Ministry of Health Care (MoH), Ministry of Agriculture (MoA), State Food and Veterinary Service (SFVS).

The Ministry of Environment is the national competent authority (NCA) authorized to execute the following administrative functions (according to the article 4 of Law on GMOs):

1) lay down the procedure for submission of notifications about GMOs and GMPs;
2) Together with the Ministry of Health and the Ministry of Agriculture, the State Food and Veterinary Service establishes the procedure for assessing the risks presented to the environment, human and animal health by GMOs and GMPs, and the information required for risk assessment;
3) Receive, handle and assess notifications and requests for authorization from natural and legal persons;
4) Give authorization for activities involving the use of GMOs and GMPs, revoke and cancel the authorization according to the procedure laid down by this Ministry;
5) In the manner prescribed by the Government announce to the public and the institutions authorized by the State, which are responsible for market surveillance and state safety examination, about the giving, suspension and revocation of authorization and about the cases of accidents, publishing a notice to the effect in the Official Gazette "VZ" (supplement of national OJ "Information announcements");
6) Establish obligatory labeling requirements for GMOs and GMPs, except food products, consisting of or composed from GMOs;
7) Together with the Ministry of Health, the State Food and Veterinary Service establish criteria for the classification of genetically modified organisms;
8) Set up and manage the database of GMOs and GMPs.

Ministry of Environment receives notifications and requests according to the EU directive 2001/18/EC on GMOs deliberate release into the environment and in line with the provisions of Ministerial Order on ***"Detailed procedures for the deliberate release into environment and placing on the market of GMOs and/or GMPs in Lithuania"*** (further - Order) in force since May 1 2004 concerning:

- Deliberate release of GMOs (as or in products) into the environment (for the purpose of research);
- Placing to the market of GMOs or GMPs, except human medicines, pharmaceuticals for use in human and veterinary medicine and novel food (including GM food) for use in human products, containing GMOs or consisting of them or their combinations.

According to the current national procedures, a notifier (natural or legal person) is obliged to receive a permit or written consent to execute the following activities:

- For deliberate release into environment of GMOs for any other purposes than placing on the market, - according to the Annex 8 of Order No. D1-225 (document issued – Permit for the deliberate release into environment of GMO);
- For placing on the market of GMOs as or in products, - according to the Annex 9 of Order No. D1-225 (document issued – Consent for placing on the market of GMO).

An applicant is obliged to submit an application to the Ministry of Environment along with theses documents:

1. Request for authorization for deliberate release into environment of GMOs/GMPs or placing them on the market;
2. Notification with filled-in information about GMOs or GMPs;
3. Monitoring plan;
4. Evaluation of risk assessment to the environment, human health and agriculture;
5. Conditions for product placing on the market;
6. Description of labelling;
7. Suggestions for packaging and storage, expiry dates for product.

No requests for authorization, thus no permits for deliberate release into environment have been issued in Lithuania yet. No consents for placing on the market GMOs or GMPs have been granted in Lithuania either.

According to the provisions of the framework ***Law on GMOs***, the Ministry of Environment (MoE) has been authorized to receive notifications and issue permits for the contained use of GMMOs in Lithuania, according to:

- ✓ EU directive 98/81/EC „On Contained use of GMMOs"; and
- ✓ ***Order on Regulation on Contained Use of GMOs,*** adopted by the Minister of the Environment on 29/04/2004 No. D1-233 **"Concerning the amendments made in the *Order on Regulation on Contained Use of GMOs*** (Official gazette 2004, No. 78 -2765).

Brief summary of permitting system for contained use of GMMOs in Lithuania:

- According to the national regulation a notifier (legal or natural person, having intention to use GMMOs in contained premises in Lithuania) is obliged to submit dully filled-in special form "Application for contained use of GMMOs in Lithuania" to the MoE, informing the intention for which classes of risk (containment 1, 2, 3, 4 levels) the GMMO(s) shall be assigned;
- Ministry of Environment, having scrutinized and analyzed recommendations received from national GMO Experts and GMO Management Committees, responsible national institutions, takes the final decision within the period of 45 days (for class 1-2 contained use) and during 90 days (for 3-4 class) for issuing/or not issuing permit for the contained use of GMMOs;
- Ministry of Environment issues special permit for contained use of GMMOs, completing the special format of „One-time Permit" formulary (annex to the Order of MoE);
- The public should be informed about the decisions taken in accordance with the requirements set out in the national legislation.

There have been 4 permits issued by the Ministry of Environment for contained use of GMMOs in the Republic of Lithuania until 1 May, 2005.

The administrative system to handle notifications for issuing permits in Lithuania is presented in diagram No 1.

Systems for monitoring of environmental effects and enforcement

The development of national mechanisms for monitoring (general surveillance) of environmental effects is based on the provisions of the *Order on Regulation for Preparation of General Surveillance and Monitoring Plan of GMOs and/or GMPs after placing on the market (post-commercial monitoring)* and EU directive 2001/18/EC, with obligations to the notifier to prepare and implement monitoring plan, according which estimation of possibility to identify and examine any direct or indirect, acute or delayed, unexpected influence to the human health and environment of GMO(s) or containing them, after the placement on the market is being made. According to the provisions of the above-indicated Order, a notifier shall develop the post-market monitoring plan taking into account the experiences and data from monitoring of experimental releases of the GMO(s). It shall be included in the notification along with proposed duration of the monitoring plan, which is evaluated by the National Competent Authority (NCA). The notifier shall ensure that post-market monitoring and subsequent reporting are carried out according to the conditions and methodology specified in the consent granted.
Any natural or legal person is responsible for the preparation of case-specific monitoring plan and development of general surveillance strategy, which has to be implemented at the cost of GMO(s) and/or GMP(s) user.

Monitoring Plan of GMOs and/or GMPs after their placing on the market (post-commercial monitoring) is defined as an integral part of the compiled notification. Any legal or natural person (subject), having intention to start using GMO(s) or GMP(s) in Lithuania has to prepare and submit a notification according to the requirements set by the MoE. There are 3 parts, which constitute the Monitoring Plan to be prepared and submitted by the notifier: 1) General strategy; 2) Program; 3) Data analysis, reporting, subsequent repeated examination.

For the implementation of the general monitoring strategy, a notifier has to prepare monitoring program, with the certain obligatory information, indicating: foreseen executives of the monitoring program; frequency of monitoring, number and time for inspections; formats for data registration and aggregation, methods for data gathering, analysis, possibilities for statistical; identified parameters according approved research methods; approved GMO detection methods; monitoring of methods for GMO negative influences; methods for public information of monitoring results; risk management plans in case of accidental releases.

GMO(s) and GMP(s) user is responsible for the gathering of monitoring data, analysis and their quality assurance. Legal and natural persons, responsible for implementation of monitoring, are responsible for provision of data and subsequent reporting to the Ministry of Environment in accordance with the concrete requirements stated in the issued Permit. Reports on monitoring programs and data obtained should be communicated to the CA of other MS and to the EC through the GMO Information System (database), administered by the Ministry of Environment.

The current above-described interim measures concerning the preparation of general surveillance and monitoring plans of GMOs are considered as only initial measures. The primary needs comprise the identification; assessment and proposal for appropriate national institutional set up, dividing the roles and responsibilities among the national institutions concerned.

According the interim provisions of the current framework ***Law on GMOs,*** the certain responsibilities and functions for enforcement and state safety control of GMOs and GMPs in the Republic of Lithuania as follows:

1. The Ministry of Environment or its subordinated institutions (for example, State Environmental Protection Inspectorate or prospective new GMO Service under the Ministry of Environment), shall be responsible for safety control of the deliberate release into the environment of GMOs, inspecting whether the foreseen monitoring plan or special conditions of permitting are being kept.
2. The State Food and Veterinary Service, the Ministry of Agriculture or their authorized institutions, which shall be responsible to issue the relevant Orders on regulations and shall carry out, according to their competences, safety control of placing on the market of genetically modified organisms and genetically modified products and market surveillance, namely:

   2.1. SFVS shall be responsible for preparation of Orders on regulation for control of GM food products in customs, GM animals, products of animal origin, veterinary preparations, industrial feedstuffs, containing GMOs;

   2.2. SPPS shall be responsible for border control and market surveillance of GM plants, vegetative products and reproductive material;

   2.3. SSGS under the MoA shall be responsible for control of GM plants' reproductive material, GM seeds within the home market;

   2.4. State Animals' Breeding Service under the MoA shall be responsible for control of GM stock animals within the home market;

   2.5. GMO Laboratory under the National Veterinary laboratory (NVL) shall be responsible for laboratory analyses and control of GM food products, GM animals, GMMOs, veterinary preparations, industrial marketable feedstuffs, which could contain or being made of GMOs, GM plants, vegetative products, and GM plants' reproductive material.
3. The Ministry of Environment or its authorized institution (for example, the State Environmental Protection Inspectorate), according to the competencies, which shall carry out safety control of the contained use of genetically modified organisms, inspecting whether the actual GMMO conforms to the risk class indicated, or whether the regulations for waste disposal are being kept;
4. The Ministry of Health or its authorized institutions, which shall carry out safety control of medicines for human use, which contain or are derived from genetically modified organisms;

The State Food and Veterinary Service, which shall be responsible for safety control of veterinary products and preparations, feedstuffs, which contain or are derived from GMOs. The State Food and Veterinary Service (SFVS) (or its authorized subordinated institution) is currently responsible for the monitoring of state control in the Republic of Lithuania.

The National veterinary Laboratory (NVL) under the SFVS has been started to implement monitoring program for the state control of labelled and unlabeled food products for the content of GMOs since the middle of 2004. The GMO laboratory has recently acquired the high-tech of real time Polymerase Chain Reaction (PCR) to employ for

quantitative method detection of GMO content in food and feed products. Meanwhile, gel electrophoresis, DNR reactions' and some other methods are used in laboratory practices. According to information provided from the GMO Laboratory, several consignments of soya, maize and oil seed rape have been analyzed for the content of GMOs presence. Most of the results were negative, except of one very recent shipment from Belarus of 23 tones soya intended to be used as feed for animals. 9 soya samples (from total 40 taken) contained GM soya more than 29 %. Shipment was withdrawn from the market and the legal penalties are foreseen according to the provisions of the national Administrative Violence Codex for illegal transboundary movement (however no decisions on particular liability have been taken yet).

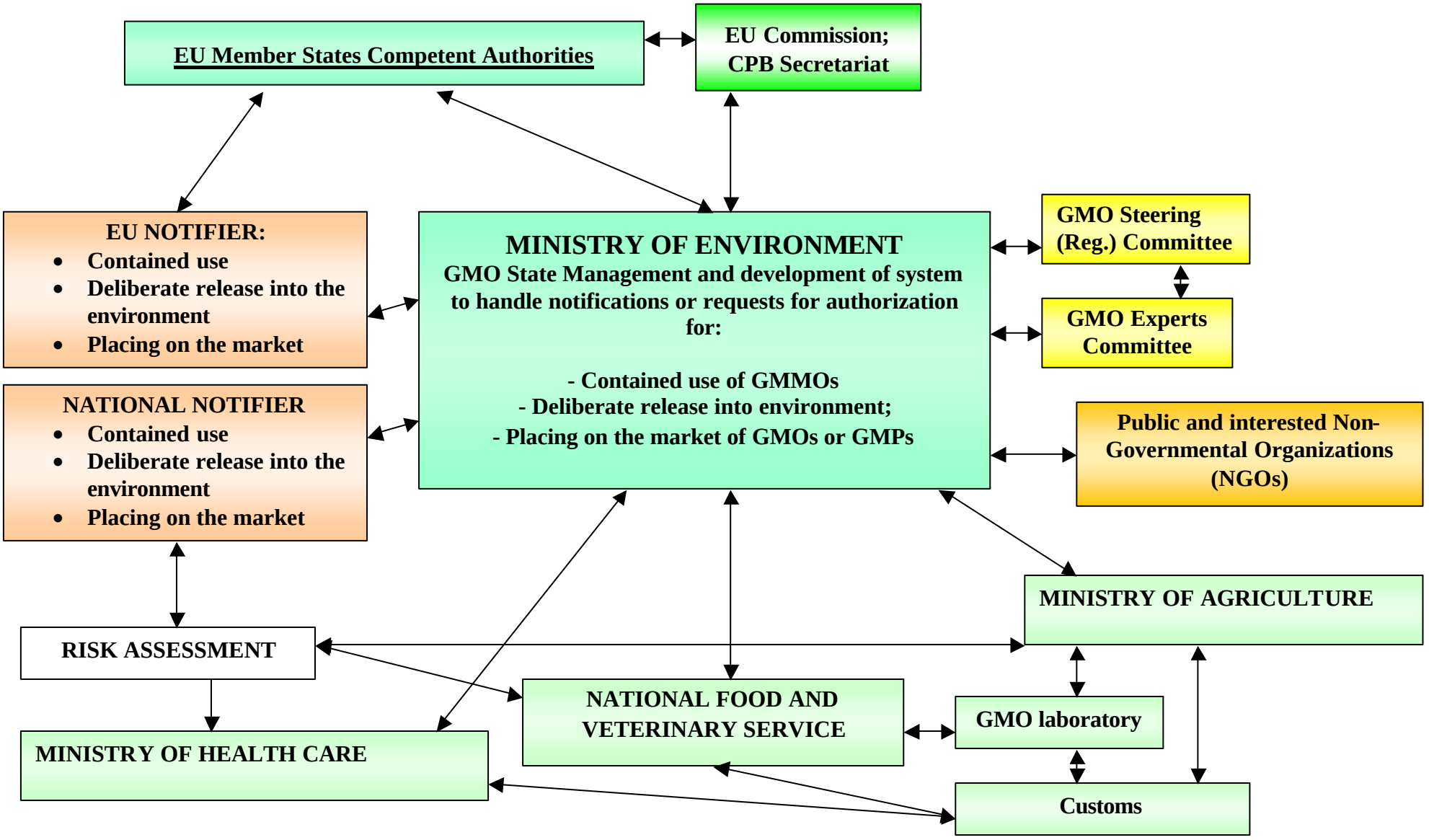

Diagram No 1. National administrative system to handle notifications or requests for issuing permits in Lithuania

Public Information and participation

The requirements to provide information to the public is based on the Governmental Order of 22 October 1999 (No. 1175) *"Concerning the delivery of environmental information to the public in Lithuania"*, where the basic principles of compulsory scheme ensuring adequate response to supply information is stated. It has been recently and amended trying to regulate the information delivery dates and means of response to an applicant/petitioner. However, there are certain deficiencies in the frame national legal act, because of its nature: the environmental information could be delivered upon request mainly.

Another national act, *"The Order on Regulation on Public Information and Participation in Issuing authorizations for Use of GMOs"*, adopted by the Minister of Environment on 11/06/2003, although corresponds to the formal International (Aarhus Convention, Cartagena Protocol on Biosafety) and EU requirements, but also implies passive (thus, inefficient) methods. Consequently, it does not guarantee real participation in the decision-making process, involving most of the interested stakeholders concerned. Level of general awareness and knowledge on GMOs/ Biosafety/modern Biotechnology issues among the general national public is really quite low, thus having no particular opinion on the subject.

In order to ensure Lithuania has set up an operational national system, promoting public awareness, education, access to information in decision making, certain activities should be implemented, employing different modern techniques available. Reliable and objective information should be presented timely, consulting the targeted groups of stakeholders for the Biosafety issues concerned. According to the paragraph 2 of Art 23, CPB, "the parties shall, (…) consult the public in the decision making process regarding GMOs and shall make the results of such decisions available to the public (…)". The proposed national sociological surveys and consultations with public shall serve precisely as a basis to verify the level of public awareness on GMOs issues. To that end, factual information on the level of awareness of different targeted stakeholders' groups concerning Biosafety awareness issues needs to be revealed and explicated. The separated opinions form the single groups of national public shall be distinguished making national public surveys, during the meetings of stakeholders concerned. Timely presented reliable objective information and consulting the local population prevents possible mismanagement and protests in future. Public opinion could be voiced (for the formation of the Biosafety policy), using articles in local and national press, through radio and TV, and other mass media means.

According to the provisions of Aarhus Convention, which need to be taken fully into account by Lithuania, Party of the latter international instrument, the recommendations to inform interested stakeholders at the possible earliest discussion phase shall be observed, when state authorities could assist in organizing such public hearings. Further, there should be necessary to recall the public opinion during the decision-making process. The more effective implementation of the latter opinion should be envisaged in the national program of public education. To that end it could be recommended to develop curricula programs on biotechnology/ Biosafety in higher educational institutions (in relation to the conservation and sustainable use of biodiversity, taking into account possible risks to human health). The NEA, currently responsible for the implementation of public information and participation component has planned to elaborate and execute national public awareness and education strategy and action plan for participation in decision-making processes on Biosafety issues; organize training courses for the main stakeholders (including trainers for media, etc.), broad participation seminars on national Biosafety issues. Appropriate mechanisms for promoting and facilitating public awareness, education and participation, i.e. informing and involving the general public (and its target/interested groups) in the implementation of the NBF has to be further detailed in the above-indicated National Public Awareness and Education Strategy and Action Plan. The following means and measures in order to promote and encourage public education, information and participation have been suggested by the NCA:

- Identification of target (interested) groups (state institutions and organizations); scientists and scientific organizations (universities, research institutes); public scientific organizations (genetics society, others); local communities; non-governmental organizations (environmental, women, consumer, others); farmers (propagating intensive farming or ecological agriculture) and organizations represented by them; industrial sector (food industry, producers of biotechnology products, seeds importers and others); others;

- Sociological surveys, public opinion polls: analysis of the sociological data of the surveys – the very important basic reference point for further strategic work plan on public consultations and participation;
- Discussions, seminars, important for the formation of public opinion;
- Development and Implementation of national Biosafety policy in Lithuania (during the meetings of interested stakeholders and further formation of national Biosafety policy);
- Internet sites, publications, mass media.

C2.C PROJECT Rationale

The development of the National Biosafety Framework (NBF) for Lithuania was carried out employing the support provided by UNEP-GEF in the form of Global Biodiversity Enabling Activities during 2002-2004. The National Competent Authority (MoE) and other national stakeholders evaluated the support received and considered the previous capacity-building initiative as a very helpful and efficient initiative to prepare for the implementation of the CPB. Based on the outcomes of the afore-mentioned UNEP-GEF development project, the future immediate capacity building needs and priorities in order to complete institutional gaps in regulatory, administrative, decision-making, monitoring and enforcement mechanisms, were formulated and the current MSP proposal for GEF funding has been prepared.

Lithuania ratified the CPB, thus made commitment to undertake both national and international measures to implement its requirements in full. This project aims therefore at supporting Lithuania to meet the obligations foreseen under the CPB, in harmony with EU law and other international treaties. In particular, with requirements coming from Articles 1 and 2 of the CPB, Lithuania needs to enforce the draft NBF developed, and consolidate the appropriate regulatory regime to assess any possible impact on the environment and human health ensuring their adequate protection in the field of safe transfer, handling and use of GMOs, by the appropriate human and infrastructural capacities. Relevant secondary legislation (regulations, orders, etc.), based on the CPB and EU law, will assure proper implementation of the revised national *GMO Law*.

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

A. Implementation of Protocol

As there are no unified national Biosafety policy strategic documents elaborated yet in Lithuania, thus it is an obvious need to review and amend incorporating Biosafety issues into the national development plans and programs. For that purpose, the appropriate institutional setting should be established and enforced. The similar situation with the national Regulatory regime, which could not be enforced because of the undetermined responsibilities within existing administrative framework and/or lack of institutional support from implementing subordinated agencies. Another set of constraints are related to lack of required national human resources, inappropriate budgetary allocations for the planned activities.

B. Economic and Environmental situation

The national Strategy on Sustainable Development takes into account the crosscutting issues of current economic situation. The Biosafety sector might play important role in future sustainable development of the country, thus possible polarized debates pertaining to trade of GMOs and Biosafety are planned to be explored during the certain MSP activities (workshops and national consultations to discuss how to integrate the relevant socio-economic issues into the informed decision-making). It is predicted that expansion of the amount of rapeseed and crops cultivated for energy purposes could cover around 15% of transport fuel needs. The MSP will definitely contribute to the preparation of the revised afore-mentioned national Strategy on Sustainable Development, incorporating Biosafety and trade issues therein.

Expected project outputs by component

Component A	Biosafety issues integrated and incorporated into the nationally agreed strategic governmental program on sustainable development in Lithuania by 2009
Outputs	National Biosafety Development Strategy elaborated and approved; National Program and Action Plan for safe use on various applications of modern biotechnology elaborated and approved by the national executing authority; 2 workshops plus 1 national Conference on the "Consensus building and conflict resolution on national Biosafety policy issues" organized and carried out.
Component B	Lithuania has a fully functional and responsive regulatory regime in line with the national needs, provisions of CPB and other international obligations by 2008
Outputs	National framework and secondary legislation drafted and submitted for concerted approval: Framework GMO Law reviewed, amended, approved and in force; Secondary legislation (implementing orders, decrees, regulations, guidelines) drafted and approved; Two consultative workshops on possible options/implications of amending the existing regulatory regime for implementation of CPB organized and carried out; Procedural manuals (training guides for national trainers) on regulatory issues produced and disseminated; National specialized training workshop and national Conference on "Implementation of the reviewed Biosafety regulatory framework on national level carried out.
Component C	Lithuania has an operational national system for handling requests and informed decision making as well as performing risk assessment and management by 2008
Outputs	Agreed set of "Procedures manual", operational guidelines for handling requests, transport, packing and identification of GMOs drafted; National procedures and rules for handling of confidential information drafted and national emergency response procedures established; National Biosafety database (nBCH) containing all relevant information required under the CPB, improved and updated; compliance with BCH obligations reached Administrative regulations, specifying the main principles for setting up the national Public Register (for tracking dossiers received, linking it with aggregated nBCH); National institution (GMO Risk Assessment Coordination Centre) appointed and authorized with adopted operational internal administrative rules; Three training workshops on handling requests for authorization for the basic requirements of RA and management (methods, equipment, costs, etc.) carried out; 35 persons trained Two on-job trainings on simulations (case studies) to test the functionality of "follow-up" systems organized and carried out 15 persons trained
Component D	Lithuania has a functional national system for "follow-up" activities, namely monitoring of environmental effects and enforcement by 2009
Outputs	Internal procedures dividing roles and responsibilities among the national institutions responsible for monitoring of environmental effects written and approved; Two rounds of national consultations with key principle stakeholders to discuss issues of accountability and division of responsibilities organized and carried out; Methodological guidelines and rules (administrative procedures) for monitoring of GMOs environmental effects and enforcement (control and inspections) measures, required for handling, transport, use, transit and release of GMOs, prepared; A set of training guides for trainers on monitoring of environmental effects and on

	the enforcement measures (control and inspections) drafted, approved and published One national workshop on the "Control of GMOs transboundary movements" to discuss relevant methods for control of the GMO transboundary movements and the detection of the GMOs organized, 40 participants; Two intense training courses for technical personnel on GMOs detection/testing and monitoring activities carried out, 20 persons trained; Technicians trained and enabled to carry out laboratory inspection activities; 15 persons trained.
Component E	Lithuania has a functional national system for public awareness, education, participation and access to information by 2009
Outputs	National Biosafety Public Awareness and Education Strategy and Action Plan for public involvement and participation in decision-making processes drafted for adoption; Two national surveys and public opinion poles to verify the level of general public awareness on national Biosafety policy organized and carried out; Educational materials on national Biosafety/Biotechnology issues developed and disseminated; National entity (Public Authority/state institution) to organize public awareness and education campaigns nominated and appointed; Relevant tools (training guides) for public information and participation incorporating lessons learnt from other MSPs pilot projects drafted; Two training courses on the topic of "Public information and participation in Biosafety for national trainers organized and carried out, 25 persons trained; Two national public awareness seminars on relationship between information exchange and perception of the modern Biotechnology and its applications ("Safe or hazardous") organized and carried out, 60 participants; Outreach public awareness materials for different targeted stakeholders disseminated during the organized debates and meetings.

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

A. Biosafety Policy (TOT: 41,400 USD; GEF: 29,400 USD; Government Co-financing: 12,000 USD)

In order to integrate Biosafety into the national agenda on sustainable development, the NEA sets up the interdepartmental working group (Task Force) with mandate to coordinate the process on Biosafety intersectional integration, elaborating nationally agreed political strategy documents. The Terms of References for individual experts and consultants to collect prepare and disseminate the global and regional experiences on best practices of national policies and strategies on Biosafety are prepared. On the basis of results obtained (reviews and assessments), the NEA prepares the administrative assignments to elaborate the required national Biosafety strategy documents, incorporating Biosafety issues therein. These are discussed during the advance consultations with national stakeholders concerned. The NEA will organize several workshops on elaborated national Biosafety policy on consensus building and conflict resolution on national Biosafety policy issues. Summarizing, the national policy on Biosafety issues will be addressed in national development plans and programs, and adjusted according to changing needs.

Planned activities to achieve outcomes

A.1 Setting up the trans-institutional working group [Task Force, TF] with mandate to co-ordinate the process on Biosafety intersectional integration, elaborating nationally agreed political strategy documents (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

A.2 Collection, preparation and dissemination of the global and regional experiences on best practices available for different applicable models of regional policies & strategies on Biosafety (Surveys: reviews and assessments) (TOT: 9,700 USD; GEF: 7,200 USD, Co-financing: 2,500 USD)

A.3 Organization of two rounds (for one day each) national consultations with government agencies (MoE, MoH, MoA, SFVS) and the main stakeholders deliberate and identify the key elements of the national Biosafety Strategy (2 d/30 participants) (TOT: 1,800 USD; GEF: 1,300; Co-financing: 500 USD)

A.4 Elaboration of the required national Biosafety strategy documents, i.e. National Strategy on Biosafety Development issues; National Program and Action Plan for safe use on various applications of modern biotechnology in Lithuania [2 workgroups of national experts (3 in each)] (TOT: 17,200 USD; GEF: 13,200 USD; Co-financing: 4,000 USD)

A.5 Organization of 2 national workshops (2 days each) on implementation of elaborated national Biosafety policy "Consensus building and conflict resolution on national Biosafety policy issues" (2x2 days/60 participants) (TOT: 10,700 USD; GEF: 7,700 USD; Co-financing: 3,000 USD)

B. Regulatory regime (TOT: 111,500 USD; GEF: 62,000 USD; Government Co-financing: 49,500 USD)

In order to coordinate the process of review and adjustments for Biosafety regulatory regime in response to changing needs, the NCA sets up the interdepartmental working group (Task Force) composed of representatives from different governmental agencies. The Terms of References for individual experts and consultants to make legal reviews for final adoption of the Frame and Secondary legislation will be prepared and required resources will be contracted. The NEA will organize the start-up consultative workshops on modalities and implications of amending the existing national regulatory regime. The NEA will organize several planned training workshops and national Conference on "Implementation of the reviewed Biosafety regulatory regime on national level". Summarizing, the national Biosafety regulatory regime (depending on the agreed Biosafety policy) will be reviewed, amended, approved and in place by the end of the MSP in Lithuania.

Planned activities to achieve outcomes

B.1. Setting up the inter-institutional Task Force (TF) composed of representatives from different governmental authorities to coordinate the process of review and adjustments for Biosafety regulatory regime in response to changing needs. (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

B.2 Review and final adoption of the national Biosafety regulatory regime, including: *Framework GMO Law* related to the contained use, deliberate release, placing on the market, importation and transit/transboundary movements of GMOs; (TOT: 43,300 USD; GEF: 14,400 USD, Government Co-financing: 28,900 USD)

B.3 Review and final adoption of the *National Biosafety secondary legislation* (Orders, decrees, regulations), as following: (TOT: 30,740 USD; GEF: 20,500 USD; Co-financing: 10 240 USD):

- Regulations setting out the conditions for granting authorizations for the contained use, deliberate release and placing on the market of GMOs;
- Regulations for import conditions and procedures for GMOs;
- Regulations for the information required in the notifications of deliberate release and placing on the market of GMOs;
- Regulations and/or procedures for risk assessment and management;
- Regulations and/or procedures for decision making;
- Regulations for labeling, packaging, stocking and handling of GMOs

B.4 Identification, development and adoption of internal explanatory manuals on the national Biosafety legislation (TOT: 8,300 USD; GEF: 6,300 USD; Co-financing: 2,000 USD)

B.5. Ssetting up nationally agreed mechanism for a responsive and flexible revision of the national Biosafety legislation, when needed (TOT: 1,960 USD; Government Co-financing: 1,960 USD)

B.6 Preparation of the required training manuals for trainers on Biosafety regulatory regime (TOT: 6,400 USD; GEF: 4,800 USD; Government Co-financing: 1,600 USD)

B.7 Organization of two rounds (for 2 days each) start-up consultative workshops on: possible options and implications of amending the existing regulatory regime; legal gap analysis for implementation of CPB (4 days/60 participants) (TOT: 6,800 USD; GEF: 5,600 USD; Co-financing: 1,200 USD)

B.8 Organization of a national specialized training for environmental lawyers (4 days/ 20 participants) (TOT: 8,600 USD; GEF: 7,600 USD; Co-financing: 1,000 USD)

B.9 Organization of a national conference on topic "Implementation of the reviewed Biosafety regulatory framework at national level" (1 days/40 participants) (TOT: 3,400 USD; GEF: 2,800 USD; Co-financing: 600 USD)

C. Handling requests for authorization (including administrative processing for risk assessment and informed decision-making) (TOT: 126,700 USD; GEF: 82,200 USD; Government Co-financing: 44,500 USD)

In order to consolidate a functional and efficient national administrative system to handle notifications and requests for authorization, perform risk assessment and proceed with the informed decision-making, the NEA sets up administrative procedures for state authorities and other responsible subordinated organizations (procedural manuals, guidelines), including the emergency response procedures in place. The NEA sets an assignment to revise and amend currently valid and usable three interim statutory forms. The composed internal ad-hoc working group is responsible for setting up the national Public Register in order to track dossiers received, linking it and making interoperable with the updated nBCH. The NEA plans to appoint and authorize the Risk Assessment Coordinating Centre, responsible for the methodological aspects of RA and RM guidelines and procedures. Further to that, the technical manuals for training purpose will be prepared and several workshops and on-job trainings organized.

Planned activities to achieve outcomes

C.1. Identification of the national institutional set up, i.e. authorities and their subordinated organizations responsible for application and enforcement of the developed regulatory regime (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

C. 1A Setting up and making operational the national emergency response procedures in place (TOT: 6,800 USD; GEF: 5,000 USD; Co-financing: 1,800 USD)

C. 1B Preparation of the operational national "Procedures manual" for internal use by the personnel in the Biosafety office of NCAs on handling requests for permits in the following cases:
- Accidental release and emergency response,
- Illegal movement, transit;
- Contained use,
- Deliberate release into environment,
- Placing on the market,
- AIA and FFP, handling, transport, packaging and identification of GMOs, including handling of confidential information,) (TOT: 7,200 USD; GEF: 5,700 USD; Co-financing: 1,500 USD)

C. 1C Revision and amendment of current interim statutory application forms for administrative regulators for handling notifications/ requests for authorizations on (TOT: 6,900 USD; GEF: 5,300 USD; Co-financing: 1,600 USD):
- Permission for contained use;
- Deliberate release into environment;
- Import of GMOs/GMPs and placing on the market

C.2. Setting up the national Public Register for tracking dossiers received, designing a separate official NCA's website, by linking it and making interoperable with the aggregated and up-dated nBCH (specifying the principles for identification, collection, input and update of the Biosafety information sharing, management of confidential information) (TOT: 18,700 USD; GEF: 14,400 USD; Co-financing: 4,300 USD)

C.3 Setting up, maintain and update an inventory of technical assistance required for emergency response, ensuring continued replacement and/or procurement of any additional equipment needed (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

C.4 Review and update national system for data collection, validation and inputting into the nBCH (TOT: 10,100 USD; GEF: 7,800 USD; Co-financing: 2,300 USD)

C.5 Designing and setting up a separate aggregated website of the NCA Biosafety Office, linking it to the official websites of NCAs', thus ensuring provision of available information to the national stakeholders (TOT: 16,700 USD; GEF: 9,000 USD; Co-financing: 7,700 USD)

C.6 Definition of criteria for identification, appointment and revision of RA experts and development of the internal administrative rules for the designated authorized entity, i.e. GMO Scientific Coordination Centre (TOT: 5,900 USD; Government Co-financing: 5,900 USD)

C.7 Definition, approval and publishing of methodological national guidelines on risk assessment (RA) and management procedures for handling, transport, usage and release of GMOs (TOT: 9,700 USD; GEF: 7,500 USD; Co-financing: 2,200 USD)

C.8 Revision of the administrative roles and responsibilities of the NCAs' personnel, setting up the rules and procedures for decision-making bodies, identifying relevant socio-economic issues of specific national interest to be taken into consideration during decision-making process (TOT: 4,000 USD; Government Co-financing: 4,000 USD)

C.9 Organization of 2 consultations with relevant stakeholders to discuss how to approach and integrate socio-economic issues into informed decision-making. Participation of the principle national key stakeholders concerned: decision-makers from central (NCA, NCC) local (municipalities); NGOs, scientists, public groups, etc. Estimated 1x2 times/30 participants (TOT: 6,900 USD; GEF: 5,600 USD; Co-financing: 1,300 USD)

C.10 Preparation of technical guides/manuals on handling requests for permits, including administrative processing of risk assessment and informed decision-making, for training purposes (TOT: 8,900 USD; GEF: 6,900 USD; Co-financing: 2,000 USD)

C.11 Organization of 3 national training workshops (in total for 2 days each) for senior administrative officers from different state institutions, National GMO Management Committee, Members of NEAs involved in handling of notifications and requests, according to Articles 15-16, of the CPB (administrative and methodological aspects of RA and risk management (methods, equipment, etc.); (3 x 2 days/15 participants from key stakeholders (NCAs) (TOT: 10,100 USD; GEF: 7,800 USD; Co-financing: 2,300 USD)

C.12 Organization of two on-job trainings (2 sessions) with case studies (simulations) to test that the administrative and "follow-up" systems are designed, set-up in place and functioning;
Estimated: (2 x 2 days/ 10-15 participants) (TOT: 12,800 USD; GEF: 7,200 USD; Co-financing: 5,600 USD)

In fact, the chosen approach of interactive participatory methods (C. 11 and C. 12 activities) is based on the national need to test the national administrative and decision-making procedures in place (i.e. based on national circumstances). This is because no permits for deliberate release into environment and placing on the market in the territory of Lithuania have been issued in Lithuania until 1May, 2005 yet.

D. Follow-up mechanisms (Monitoring of environmental effects and enforcement: control and monitoring) (TOT: 46,100 USD; GEF: 34,400 USD; Government Co-financing: 11,700 USD)

In order to establish the functional follow-up national mechanisms for monitoring of environmental effects and enforcement (control and inspection), the NEA initially envisages to organize national consultations for separation of responsibilities between different state agencies and institutions to be eventually responsible for monitoring of environmental effects (including preparation of the operational guidelines and administrative procedures required for handling, usage, transfer and release of GMOs). The NEA will prepare the set of necessary training guides for trainers on the relevant enforcement measures (control and inspection) and will organize a national workshop on the control of GMOs transboundary movements, several specialized training workshops for environmental inspectors and custom officers and several intense training courses for technical personnel on GMOs detection/testing and monitoring activities.

Planned activities to achieve outcomes

D.1 Clarification and separation of roles and responsibilities for national institutions (i.e. GMO Unit of the MoE, future GMO State Service under the MoE, role of Environmental Protection Agency under the Ministry of Environment, others) to be responsible for monitoring of environmental effects (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

D.2 Preparation of the operational methodological guidelines and rules (i.e. administrative procedures) for monitoring of GMOs environmental effects and enforcement (control and inspections) measures required for handling, transport, usage, transfer and release of GMOs (TOT: 10,100 USD; GEF: 7,800 USD; Co-financing: 2,300 USD)

D.3 Preparation of technical methodological materials, i.e. training guides for trainers on proposed national monitoring system and enforcement measures for handling, transport, usage, transfer and release of GMOs (TOT: 8,700 USD; GEF: 6,700 USD; Co-financing: 2,000 USD)

D.4 Organization of national workshop on the "Control of GMOs transboundary movements" (for 2 days), inviting specialists from the national governmental administrations in charge of implementation enforcement mechanisms (control and inspection): to discuss relevant methods for control of the transboundary movements of goods and the detection of GMO (methods, equipment, documentation requirements for GMO shipments) (2 days/ 15 participants) (TOT: 4,700 USD; GEF: 3,800 USD; Co-financing: 900 USD)

D.5 Organization of 2 specialized training workshops (total for 3 days each) providing instructions and professional training for environmental inspectors and custom officers on inspection of field releases of GMOs; GM products placed on the market; (2x3 days/ 15 participants) (TOT: 9,400 USD; GEF: 7,400 USD; Co-financing: 2,000 USD)

D.6 Organization of 2 intense specialized training courses (4 days each) for technical personnel on GMOs detection/ testing and monitoring activities (2x4 days/ 15 participants) (TOT: 11,200 USD; GEF: 8,700 USD; Co-financing: 2,500 USD)

E. Public information, participation and awareness raising (TOT: 116,300 USD; GEF: 87,400 USD; Government Co-financing: 28,900 USD)

The NEA will incorporate public awareness, access to information & participation issues into the national Strategy on Sustainable Development, national Program and Action Plan for safe use and various applications of modern biotechnology. For that purpose, the separate national Biosafety Public Awareness and Education Strategy and Action Plan for participation in decision-making processes on Biosafety issues will be elaborated during the project lifetime. The initial (mobilization) and terminal public opinion polls on the level of public awareness about national Biosafety policy will be organized by the NEA, which results will be summarized identifying the major information gaps and needs to be covered. The NEA will identify and designate the authorized national institution responsible for managing public awareness activities, establishing regular mechanisms for networking with media on Biosafety related issues. The afore-mentioned national institution in cooperation with NEA plan to organize 2 training courses for local trainers (prior, preparing training guides incorporating lessons learnt from other MSPs) and broad participation public awareness seminars on perceptions of the biotechnology's applications by different national stakeholders concerned.

Planned activities to achieve outcomes

E.1 Elaboration of national public awareness and education strategy and action plan for participation in decision-making processes on Biosafety issues (TOT: 12,600 USD; GEF: 9,600 USD; Co-financing: 3,000 USD)

E.2 Develop curricula programs on Biosafety/ Biotechnology in higher educational institutions in relation to the conservation and sustainable use of biodiversity, taking also into account risks to human health (TOT: 3,900 USD; Government Co-financing: 3,900 USD)

E.3 Organization of 2 national surveys and public opinion poles on the level of awareness on the national Biosafety public relations policy and related issues (TOT: 14,700 USD; GEF: 11,200 USD; Co-financing: 3,500 USD)

E.4 Identification of national entity (designated and authorized national institution, agency) responsible for managing public awareness, access to and dissemination of thematic information, and education campaigns related to Biosafety/ modern Biotechnology issues (TOT: 2,000 USD; Government Co-financing: 2,000 USD)

E.5 Definition and specification of entry points for public participation in decision-making process on GMOs in relevant regulations and administrative procedures (TOT: 6,300 USD; GEF: 4,800 USD; Co-financing: 1,500 USD)

E.6 Establish regular mechanisms for networking with media on Biosafety related issues (TOT: 4,000 USD; Government Co-financing: 4,000 USD)

E.7 Prepare technical training guides for public information and participation incorporating lessons learnt from other pilot MSPs (TOT: 12,600 USD; GEF: 9,600 USD; Co-financing: 3,000 USD)

E.8 Organization of 2 training courses on the topic of "Public information and participation in Biosafety" for national trainers" (local officers from the public service/agency), inviting international experts to teach short-term courses and give public presentations on public education and information; duration 2 times/2 days each training, tentative number of participants: 20 (TOT: 8,700 USD; GEF: 6,700 USD; Co-financing: 2,000 USD)

E.9 Organization broad participation national public awareness seminars (2 events/ for a day each); estimated number of participants 40-60) for different public stakeholders, including governmental officials, media, journalists, scientists, NGOs representatives of the general public (TOT: 18,000 USD; GEF: 12,000 USD; Co-financing: 6,000 USD)

E.10 (A, B, C) Preparation and dissemination of the outreach public awareness materials for different targeted stakeholders during the organized public debates and meetings (TOT: 16,300 USD; GEF: 6,700 USD)

Lithuania is quite different form other CEE countries concerning public perception of mass media: about 80% of citizens trust mass media even more comparing to the official Church or President (politics). So, employing relevant techniques of mass media is the most important for the creation of actual public awareness mechanisms in Lithuania. The identified afore-mentioned public awareness techniques shall include, among others, mass media reports (e.g. in case the cloning of sheep Dolly, future possibilities for human cloning); Telecast programs (e.g. weekly broadcast entitled "It can't be" in collaboration with Lithuanian Academy of Sciences); environmental actions by NGOs (e.g. in previous case of the Baltic Bee Tour called "Baltic States free of GMOs"), etc. The environmental companies (NGOs) and scientific organizations shall be more involved in raising public awareness. This would prevent from prevailing attitude that scientists are not engaged in raising public awareness, when TV and other mass media tends to formulate only negative public attitude in society. The special attention shall be paid to the education and training of prospective representatives of food industry: national producers and retailers, consumers' organizations, foreign trade associations and Agricultural organizations.

Project Coordination and Management, including institutional set-up, Office equipment and Premises operating costs

The Genetically Modified Organisms (GMOs) Division of the Nature Protection Department, Ministry of Environment, acting as the National Executing Agency (NEA), shall be the legal entity responsible for executing the National Project in Lithuania. The National Coordinating Committee (NCC) will be established by the National Executing Agency (NEA) to advise and guide the implementation of the draft National Biosafety Framework. The National Project Coordinator (NPC) will be appointed by the National Executing Agency (NEA), on a full time basis for the duration of the National Project and contracted by the UNDP country office in Lithuania.
The Terms of References (TORs) for the MSP Management structures namely, NEA, NCC and NPC are provided in Annex J.
The MSP coordination costs are shared between the UNEP-GEF (for the MSP Project Personnel) and the National Government (for institutional set-up of the project office, its operating and running costs, sub-contract to Governmental Agencies, IT communications, relevant premises, etc.) as following:

Project coordination and management, including Office equipment and Premises operating costs amount of 577,400 USD is shared between: GEF: 322,000 USD and national Government contribution: 255,400 USD (Table 6).

Summary table of planned practical workshops and training activities

Subject	Duration	Number of participants	Type of participants	Total cost
National consultations to deliberate, discuss and agree on key elements of the National Biosafety Strategy documents	2 days	30 participants	NEA, other interested governmental agencies	1.800
2 workshops on Implementation of elaborated national Biosafety Strategy documents and policy : "Consensus building and possible conflict resolution on the national Biosafety policy"	2x2 days	60 participants	Participation of all interested national key stakeholders: decision-makers NCC, NEA, MPs, local governments, NGOs, scientific community	9.000
2 rounds of start–up workshops on consultations for: 1) possible options on and implications of amending existing regulatory regime; 2) legal gap analysis for implementation of CPB, EU law, etc. international requirements	2x2 days	30 participants	Officials and experts (legal and administrative staff) from NCA and other responsible governmental institutions, that will be involved in implementation of the national regulatory regime	6.800
National specialized training workshop for environmental lawyers: the in-depth scrutinizing regulatory provisions, as required by the amended GMO law and secondary legislation, applying the reviewed regulatory regime	3 days	20 participants	Senior officers/regulators and environmental lawyers from key institutions, responsible for implementation of the regulatory regime in compliance with CPB, EU law, other international obligations	7.600
National conference on Implementation of the reviewed Biosafety regulatory framework on national level"	1 day	40 participants	High-level politicians (MPs), decision-makers from governmental institutions, holding responsibilities for implementation of Frame law drafted regulations and secondary legislation	3.400
National consultations to discuss how to approach the and integrate socio-economic issues into informed decision-making	2 days	30 participants	Decision-makers from central (NCA, NCC) local (municipalities), NGOs; scientific community	6.900
National training workshops & a seminar on administrative and methodological parts of risk assessment (RA) and handling requests for authorization (basics of RA and management requirements: methods, equipment, costing, etc.)	4 days	35 participants	Experts from the NCA, members of the GMO Regulatory management Committee; NEAs involved in handling of notifications and requests according to Art. 15-16 of CPB; facilitators: foreign expert(s)	10.100
Several (2-3 sessions) on-job trainings with case-studies (simulations) to test the functionality of administrative, methodological RA, and further developed "follow-up" framework	6 days	40 participants	Responsible administrative officers of middle-to-senior levels; during the interim project phase; facilitators: foreign expert(s)	12.800
National workshop on the Control of GMO transboundary	2 days	40 participants	Specialists from the NCAs in charge of implementation &	4.700

movements			enforcement mechanisms,	
Specialized professional training workshops on inspection procedures on: contained use; field releases of GMOs; GM products placed on the market	6 days	20 participants	Environmental inspectors, custom officers and professionals from NCA; possible facilitators: foreign expert(s)	9.400
Intensive training courses on GMOs detection, testing and monitoring activities	8 days	10-15 participants	Technical personnel form the Central GMO laboratory; specialists form SFVS, other interested subordinated organizations; possible facilitators: foreign expert(s)	11.200
Training Courses (2x2) on "Public information and participation in Biosafety " for national trainers	4 days	10-15 participants	Local officers from the NEAs; inviting international experts to teach and provide presentations on public education/information	8.700
National public awareness seminars on relationship among information exchange and perception of the applications of modern biotechnology ("Safe or hazardous"?)	2 days	40-60 participants	Broad participation from different national stakeholders, incl. governmental officials, media, journalists, scientists, NGOs, representatives of the local community concerned.	12.000

C.3 Sustainability and Risk Assessment

The following main assumptions should be taken into account concerning the sustainability analysis during the implementation of the UNEP-GEF Project in Lithuania:

(a) Institutional sustainability

Implementation of this Medium-Size Project will strengthen the continuity of interdepartmental coordination mechanism between different national institutions involved in the management of financial and technical assistance received from the UNEP-GEF (follow-up of the previous NBF Development phase). To that end, the national receiving environment will make the necessary preparatory work in terms of organizing and institutionalizing the NCC, efficient steering the financial (both, UNEP-GEF and national co-financing) and technical measures undertaken by the MSP Biosafety management team.

(b) Operational sustainability

National Executing Agency (NEA) is of opinion that the implementation of this MSP is closely related with the planned and on-going national capacity-building organizational arrangements. Thus, for example, political and process of amending the main *Law on GMOs*, which needs to be revised, encompasses the challenges ahead for different Governmental Institutions involved in the organizational arrangements and securing adequate finances for the implementation of the regulatory framework in Lithuania. The MSP will provide operational support for the establishment of a national Biosafety Regulatory Service, which is planned to be a subordinated organization to the National Competent Authority (CA), based on the National Biosafety Framework and drafted regulations.

(c) Financial and political sustainability

The afore-mentioned national Biosafety Regulatory Service should be able to accumulate the needed funding for its activities by itself. The operational and running costs should be included in the revised Law on GMOs. Thus, its is presumed that in the future the funds collected from application fees, could cover part of costs involved for the administration, functioning of GMO laboratory, and costs of risk assessment.

The National Competent Authority (NCA), Ministry of Environment, is responsible to comply with the requirements of International Conventions, *inter alia*, Convention of Biological Diversity (CBD). To that end, the relevant proposal to draft amendments for the NBSAP has been included in this MSP, which will ensure the most recent Biosafety considerations incorporation into the national environmental agenda (ex. case-specific monitoring, general surveillance methods, risk assessment and management, national mechanisms for control and inspection, etc.). The national decision-making bodies are responsible for securing political sustainability during the implementation of National Biosafety Framework in Lithuania.

(d) Implementation of the MSP will contribute to national social and economical development and will promote environmental sustainability having positive impact on the biodiversity conservation in Lithuania. Generally sustainability refers to specific factors that ensure the continuation of project benefits (see next chapter C.4 Replicability) after the MSP completion. Thus, the financial sustainability shall be achieved through the application of a fee-based approach, among others:

- Creating demand for risk assessment services and offering them;
- Drafting application formats for GMO releases for private and public sector applicants;
- Translating application formats for GMO releases for private and public sector applicants

Despite the above-listed assumptions for positive implications on sustainability, the implementation of the MSP could face with possible risks, as following:

- Lack of requisite consensus on Biosafety issues among national stakeholders (insufficient public awareness and institutional support for NBF making fully operational);
- Lack of required competent expertise to carry out the assignments, polarization of the debates disabling co-ordination mechanisms for Biosafety intersectional integration;
- Delays in administrative set up due to political or bureaucratic constraints (ex. postponed revision of the frame national regulatory regime on Biosafety issues, etc.);

The overall summary of risks and constraints could be briefed as: “change of environmental, political, economical and social priorities regarding integration of biological safety into the national governmental policy”. The above-mentioned risks will be addressed by “promotion of broader political and institutional collaboration, supporting national stakeholders and promoting awareness on responsibilities taken to implement objectives of CPB and other international obligations” (Log Frame Matrix, Annex C).

C. 4: Replicability

During the MSP project preparation phase, the national stakeholders involved have consulted and gained experiences from several other CEE countries, namely Poland and Bulgaria, in order to absorb the best lessons learnt and practices from their experiences during the implementation of pilot projects in sub-region. There have been established permanent correspondence via e-mail with key personnel of the above-mentioned pilot MSP, as well as the hands-on experience was gained during the regional workshop for CEE countries preparation for Implementation Phase (Riga, 25-26 November, 2004) and the 2nd annual NPC meeting (Geneva, 19-24 March, 2005). It has been considered as a very efficient approach, which triggered the preparatory activities on the national level. Therefore, it is likely that the best practices and lessons learnt after the implementation of the current MSP could be disseminated in other countries of the region also. The implementation of this MSP will have the following elements of replicability:

a) Scaling upwards to bring relevance of the global Biosafety issues to the national policy level;

b) Scaling outwards to other neighbouring countries of sub-region.

There are several targeted activities, promoting exchange of information, listed in the MSP work plan, which results obtained could be used for replication and disseminated in some other similar situations in other countries, namely:

- Collection, preparation and dissemination of the global and regional experiences on the "best practices" from different applicable models of national policies and strategies on Biosafety issues, identifying relations between Biosafety and other sectors' policies;
- Setting up the nationally agreed mechanism for a responsive and flexible revision of the national Biosafety regulatory regime (upon the country needs);
- Identification of relevant socio-economic issues of specific national interest to be taken into consideration during decision-making processes.

There are several outputs and tools envisaged for related capacity building activities, which could be modified and adapted accordingly to be used for other purposes, namely:

- Training guides and manuals for trainers on the NBF regulatory regime;
- Methodological guidelines and rules for risk assessment and management procedures, for monitoring of GMOs environmental effects and enforcement (control and inspection);
- Technical guides/manuals on handling requests for authorization, including administrative processing of RA and informed decision-making;
- Training guides for public information and participation, incorporating lessons learnt form other pilot MSPs;
- Outreach public awareness materials for different targeted stakeholders.

In addition to that, access to information will be ensured through different mass-media providing to the public information on Biosafety issues that are not confidential. Data compiled in the nBCH and interlinked with international databases will be accessible (e.g. via Internet) and other relevant data sources will be interlinked with the national database (nBCH).

Finally, the public opinion polls on the level of awareness of awareness on Biosafety-related issues are planned to be conducted at the beginning and at the end of the MSP. The results are expected to have substantial influence on national policies and will show a political "acceptance" level in Lithuania in the long-run.

Dissemination of the results obtained will take place during the scheduled meetings of relevant stakeholders (ex. interdepartmental NCC), during the routine meetings of the MSP Biosafety management team, via publications and via the chosen relevant means of national mass-media and international occasions (ex. annual sub-regional meetings).

The Monitoring and Evaluation Plan (see Chapter C.6, Annex E,) includes methods to collect information on replication activities as a result of the project.

C. 5: Stakeholder involvement

The current MSP proposal has been drafted by the NCA (GMO Division, MoE responsible for the Implementation of the MSP). The NCA has promoted several rounds of consultations with relevant national stakeholders concerned (state institutions, scientific community, national consumer rights protection board, NGO Environmental information centre, etc.), thus ensuring broad participation during the preparatory phase and proving firm country ownership.

The main groups of national stakeholders consulted during the MSP preparatory phase:

- National Competent Authorities (NCAs), i.e. responsible national Ministries and their subordinated organizations;
- Representatives of Scientific institutions (Universities, Research Institutions);
- Civil society: National Consumers' association, Professional Societies;
- National Agricultural Organizations;
- NGOs and community-based organizations;
- National sector of modern biotech industry

The representatives of the afore-mentioned stakeholders were consulted during the last several GMO Steering (Regulatory Management) Committee meetings, and were asked to comment draft log frame (brainstorming on development and specific objectives level), formulation of the main preferable outcomes for each of the basic MSP component. The representatives of scientific institutions (Vytautas Magnus University) have reviewed and commented the MSP initial draft.

The following indicated groups of stakeholders shall be consulted and invited to take part during the implementation of the MSP in Lithuania (workshops and seminars/ public information and participation campaigning), namely:

- Association of Lithuanian Chambers of Commerce (Lithuanian Agricultural Palace), *inter alia*:
  - Chamber of Agriculture of the Republic of Lithuania (responsible for promotion of foreign trade & international co-operation, promotion of small & medium-sized businesses, agricultural production);
  - Lithuanian Association of Agro-chemistry enterprises (professional society);
  - Lithuanian Association of Rural Communities and Association of Small Businessmen (professional society);

- Association of Lithuanian Agricultural Producers, *inter alia*:
  - Lithuanian Association of Seed producers (Arvi, Alfa Agro, Agra corporation);
  - Lithuanian Association of flax and rape growers' and processors;
  - Lithuanian Association of Grain growers and grain processors;
  - Lithuanian Association of Organic Agriculture and Farming (community-based organizations "Gaja", "Tatula", "EkoAgros", etc.);
  - Lithuanian Agricultural Consulting Service & Regional Farmers' Association etc.

The GMO Steering (Regulatory Management) Committee is a political advisory body for initiation, development and implementation of strategic Biosafety-related national and international projects and programs with respect to Biosafety issues. During several meetings the roles and types of future involvement (consultations, information dissemination) of different stakeholders during the practical MSP implementation were discussed. It has been proposed and eventually decided, that during the initial phase of the MSP, the main stakeholders and their contribution will be identified. The number of representatives should be higher comparing to NBF Development phase, because the clear need to incorporate social-economic participatory issues of GMOs management within different economy sectors stressed.

As the Ministry of Environment (MoE) is authorized national competent authority (NCA) for the state management of the GMOs use, other national authorities (ministries and their subordinated organizations) are authorized to assist, support and participate in the development and Implementation phase of the NBF

in Lithuania. Thus, naturally the main MSP project developer has been the responsible NCA, Ministry of Environment of the Republic of Lithuania.

The key national Biosafety Team, comprised from the main national Competent Authority (GMO Division, MoE) with collaborative assistance received from several key stakeholders of NGOs (Public Agencies "Nature Heritage Fund" and "Environmental Information Center") have formulated and detailed this MSP project brief for UNEP/GEF funding.

Most of the stakeholders groups listed in Table 1 will be represented in the Project National Coordinating Committee (NCC), learning from the best practices of the NBF Development phase.

Table 1: Main Stakeholders and their Participatory Roles

STAKEHOLDERS	Type of involvement
Parliamentarians, Decision-makers	MPs of the Environmental Committee at the Parliament shall be informed appropriately and invited to participate in the main events, example National Conference on determining political instruments into practice "Consensus building and conflict resolution on National Biosafety policy issues". That would enable to inform high politicians and executives at the possible earlier discussion stages.
Ministries: MoE – National Competent Authority; MoA, subordinated implementing agencies: - State Plant Protection Service (SPPS) under the Ministry of Agriculture; - State Seeds and Grain Service (SSGS) under the Ministry of Agriculture MoH, subordinated implementing agencies: - National Nutrition Centre (NNC); - Scientific Novel Food Committee (NFC) Ministry of Economy, Ministry of Education and Science	Are involved by providing the project with political advice, regulatory expertise and organizational tasks: preparing legislation and implementing guidelines. It is expected that responsible governmental agencies will actively participate in the work of Task Force (TF) reviewing and final adoption of the national Biosafety regulatory regime, which includes Frame GMO Law and subsequent pieces of secondary legislation (Decrees, Orders, Regulations, etc.) The substantial input is required in the work of TF for elaboration of national Biosafety strategy documents (National Strategy on Biotechnology/ Biosafety development issues; National Public Awareness and Education Strategy and Action Plan). The state responsible institutions shall play the intermediary role between different groups of public concerned.
Scientific community: Academic & Scientific Research institutions: Vilnius University; Vytautas Magnus University; Institute of Biotechnology; Institute of Biochemistry; Institute of Botany; Institute of Agriculture and Forestry, etc.	An important role for implementation of the NBF by providing scientific expertise during formulation of the required specific pieces of secondary legislation Preparing instructions, technical guides and manuals on handling requests for permits, including administrative processing of Risk Assessment; methodological materials on proposed national general surveillance and case-specific monitoring system, etc. Distinguished scientists and specialists will provide expertise (as lecturers) and experience (as resource persons) during national training courses, workshops and seminars.
<u>Civil society:</u> - National Consumers' association, - Producers' and Consumers' associations: - National Consumer Rights Protection	Their involvement will be very important with respect to those GM products of particular interest for the public, e.g. agricultural crop plants, human food products, animal feed, etc. In order to promote effective participation of the civil

Board; - Professional Societies: Lithuanian Bioethics Committee, national Microbiology Society, national Genetics society; -NGOs & community-based organizations: Environmental Information Centre (EIC) Regional Environmental Centre (REC) Lithuanian Fund for Nature; Nature Heritage Fund (NHF)	society, the representatives of NGO's, producers' and consumers' organizations will be encouraged to take part in the decision-making by reviewing the routine pending proposals put on the agenda of GMOs Regulatory Management Committee. There are considerations to organize public hearings concerning the GMOs issues (further cases on deliberate release into the environment, placing on the market, etc.) Several key experts of NGOs (NHF and EIC) shall be involved in project personnel staff (MSP Financial Officer and NPC's Administrative Assistant), thus providing the Local Management Support Services for the implementation of this Medium-Size Project (MSP). The following recommended basic priority means and measures are proposed in order to promote and encourage national public education, information and participation in decision-making processes: • Sociological surveys (opinion polls) for the identified target (interested) stakeholders; • Discussions, during seminars, forming national position and development of National Biosafety Policy, discussions and adoption at the Cabinet of Ministers with clear prospects for further implementation; • Supplement national pilot GMO database, amending it with more simple information, which is more understandable by general public.
<u>Private sector of biotech industry (R&D sector)</u> Industrial organizations consulted: JSC Fermentas, JSC "Sicor Biotech", "Biotechna"	Several executive representatives from the national biotech industry are members of the GMOs Regulatory Management Committee and GMOs Experts Committee. They are able to express their position concerns and position during the statutory meetings of GMOs Steering Committee. It is envisaged that quite a number of aforementioned national regulatory management Committee members should be represented also at the NCC of the UNEP-GEF NBF Implementation Project, thus ensuring sufficient continuity of national biosafety policy-regulatory issues handled in proper way. Furthermore, the NCA plans to make a call of interest for prominent scientists for their possible input in the National Project Teams, inter-sectorial national coordination groups, etc.

C. 6 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 UNEP-GEF 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 H), 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 national project coordinator, 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 covers the general and specific objectives of the project, its planned outcomes and outputs, and looks 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.

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 from other countries. The task manager will facilitate exchange of experiences between countries and during the annual meetings of NPCs and key MSP Biosafety management Team members.

The monitoring and Evaluation plan includes:
Table 2: Indicators and Means of Verification (Annex E);
Table 3: Reporting and Monitoring Responsibilities (Annex E);
Table 4: Information on Reporting Requirements (Annex E).

The Log Frame is attached in Annex C. The matrix on key indicators, baseline and methods of data collection is presented in Table 5 (see attached Annex G).

Please explain the way UNEP will incorporate the recommendations from the evaluation of the GEF Initial Strategy on Biosafety in to the project (as requested by the Review of GEF SEC).

D FINANCING

FINANCING PLAN

The Financing Plan is expected to include the following:

- Project cost, including:
- Costing by activity and sub-activity (detailed project budget, Annex H)
- Project Implementation Plan (Annex I).

D1. Incremental cost assessment

Lithuania has provided 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 components 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 the included incremental cost matrix. The total baseline expenditure amounts to US $ 315,000, which main components relate to 5 main NBF components. The increment is equal to US $ 1,091,400, with US $ 404,000 of national contribution in kind. The remaining total cost of US $ 687,400 is requested from GEF.

Table 6 Incremental Cost Analysis

Activity	Baseline	Alternative	Increment	Cost to GEF	Co-financing (in kind contributions)
Biosafety strategy	41.500	82.900	41.400	29.400	12.000
National Biosafety regulatory regime	80.000	191.500	111.500	62.000	49.500
Handling of requests	105.300	234.000	128.700	82.200	46.500
Monitoring of environmental effects, inspections	32.000	78.100	46.100	34.400	11.700
Public participation and information	56.200	172.500	116.300	87.400	28.900
Project coordination and management, incl. Office Operating Costs*	---	577.400	544.400	322.000	255.400
Technical support, to be allocated after project approval	---	70.000	70.000	70.000	---
TOTAL	315.000	1.406.400	1.091.400	687.400	404.000

* 33,000 USD for UNDP Financial Administration and Implementation Support Services

D2. BUDGET and PROJECT IMPLEMENTATION PLAN

An implementation plan for the project, based on the log frame and using a 48 month timeframe is inserted as Annex I.

The detailed budget of the project is shown in Annex H. A summary of the budget by components with co-financing details and the staff costs are shown in Tables 7 and 8 respectively (below).

Table 7: Project cost by components (Summary Budget)

	Component	GEF (US $)	Government (US $)	Total (US $)
1	Biosafety strategy	29,400	12,000	41,400
2	Regulatory regime	62,000	49,500	111,500
3	Handling applications	82,200	46,500	128,700
4	Monitoring and Inspection	34,400	11,700	46,100
5	Public participation and information	87,400	28,900	116,300
6	Project coordination & management, incl. Office Operating Costs	322,000	255,400	577,400
7	Technical support	70,000	-	70,000
	TOTAL:	**687,400**	**404,000**	**1,091,400**

CO-FINANCING

The Ministry of Environment (NEA) has committed and confirmed 404,000 USD of the total project budget as in-kind co-financing to contribute to the implementation of the MSP, for: the cross-cutting issues of the main project components (ex. NCC meetings); sub-contract to governmental agencies concerned during the project life (ex. MSP working groups activities); Premises costing for the Project Personnel; Office Operating and Communication costs (including access to Internet, E-mail, telephone connectivity).

CO-FINANCING SOURCE				
Name of Co-financier (source)	Classification	Type	Amount (US$)	Status
Ministry of Environment (Governmental contribution)	National Executing Agency (NEA)	Committed in-kind co-financing	**404,000**	Confirmed
Sub-Total Co-financing:			**404,000**	

Table 8: MSP coordination and management, excluding Office Equipment Operating costs (Staff costs not directly linked to a specific activity)

Personnel	GEF	National Co-financing	TOTAL
National coordinator of the project	108,000	-	108,000
One NPCs' Administrative Assistant (full time)	68,400	-	68,400
Financial Officer	49,000	-	49,000
NCC Meetings and Sub-contracts to different Governmental Agencies		144,000	
Travel for NPC, MSP Staff and NCC members	24,000	-	24,000
TOTAL	249,400	144,000	393,400

Office Equipment and Premises Operating Costs:

Office equipment and premises operating costs (US$ 175,000) cover the purchase of computers, software upgrades, maintenance etc. as well as office premises utilities, stationery and communication costs. This amount is shared between the GEF (US$ 63,600) and the country (in-kind contribution in US$ 111, 400).

Project coordination and management, including Office equipment and Premises operating costs amount of 577,400 USD is shared between: GEF: 322,000 USD and national Government contribution: 255,400 USD (see Table 7).

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out over four years. The implementation plan is provided in Annex I.

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 CPB- 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 Lithuania, 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 J.

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 J.

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

ANNEX A	Endorsement letter
ANNEX B	Summary of the Biosafety Framework
ANNEX C	Project Log Frame Analysis
ANNEX D	National Biosafety legislation in Lithuania
ANNEX E	Monitoring and Evaluation Plan
ANNEX F	Incremental cost assessment
ANNEX G	Key Indicators, Baselines and Data Collection
ANNEX H	Detailed Project Budget
ANNEX I	MSP Implementation Plan
ANNEX J	Draft TOR for the National Executing Agency, National Project Committee, National Project Coordinator

TABLES

Annex A
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 B
Summary of NBF

Annex B:

LITHUANIA: SUMMARY OF THE NATIONAL BIOSAFETY FRAMEWORK (NBF)

Draft National Biosafety Framework in Lithuania

The task of the drafted National Biosafety Framework (NBF) for Lithuania is to provide for an obligatory level of biological security with respect to safe use and release of GMOs in country by:

- assessing possible negative effects during deliberate release into environment;
- establishing appropriate case-specific monitoring and general surveillance systems;
- planning emergency actions to deal effectively with possible accidents;
- establishing systems to provide duly authorized consents on each stage of practical experiments and deliberate release into the environment;
- establishing and enforcing national competent authority with the mandate to provide advice, decisions and control on registration, consents for GMO releases;
- updating and reinforcement of national information system;
- establishing appropriate international co-operation mechanisms;
- Education, tuition and post-graduate training of responsible personnel.

Coordinating bodies: National Competent Authority and subordinated organizations

Genetically modified organisms (GMOs) are considered in three sectors of activities: 1) contained use of GMMOs; 2) GMOs deliberate release into environment, and 3) placing on the market of products containing GMOs or consisting of such organisms or their parts. The latter areas of GMO application (deliberate release into environment and products) are addressed by Lithuanian *Law on GMOs* (No. IX-375, Official Gazette, 2001) and are under the responsibility of 4 governmental agencies, namely: the Ministry of Environment (National Competent Authority, NCA), Ministry of Health (MoH), Ministry of Agriculture (MoA) and the subordinated organization - State Food and Veterinary Service (SFVS). Probably, other governmental authorities, i.e. Ministry of Education, Ministry of Social Security and Labour, should be also involved in the future.

The Ministry of Environment is the National Competent Authority authorized to execute the following administrative functions (according to article 4 of *Law on GMOs*):

1) Establish the relevant procedures for submission of notifications about GMOs and GMPs;

2) Together with the MoH and the MoA, SFVS establishes the procedure for assessing the risks presented to the environment, human and animal health by GMOs and GMPs, and the information required for risk assessment;

3) Receive, handle and assess notifications and requests for authorization;

4) Give authorization for activities involving the use of GMOs and GMPs, revoke and cancel the authorization according to the procedure laid down by this Ministry;

5) In the manner prescribed by the Government, announce to the public and the institutions authorized by the State, which are responsible for market surveillance and state safety examination, about the giving, suspension and revocation of authorization and about the cases of accidents, publishing a notice to the effect in the Official Gazette "VZ";

6) Establish obligatory labeling requirements for GMOs and GMPs, consisting of or composed from GMOs;

7) Together with the MoH, SFVS establish criteria for the classification of GMOs;

8) Set up and manage the national database (nBCH) of GMOs and GMPs.

Each individual application should be reviewed with regard to potential risks arising from deliberate or unintentional release of GMO into the environment. As the Ministry of Environment is the National authorized body for the implementation of the Convention on Biological Diversity (CBD), the Biosafety issues falls within its competence.

National Consultative Committees:

- *GMOs Steering (Regulatory management) Committee and*
- *GMOs Experts Committee*

National Competent Authority (MoE) has decided to constitute and apply several administrative instruments (Consultative institutions), giving advice in handling and scrutinizing of notifications and requests for the contained use of GMMOs, deliberate release into the environment, and placing on the market of GMOs and GMPs in Lithuania.

The ***GMOs Steering (Regulatory management) Committee*** is a political advisory body for the development and enforcement of national regulatory system with respect to Biosafety issues. The Committee consists of members appointed by relevant state authorities (e.g. Ministry of Agriculture, Ministry of Health), the subordinated organizations, national biotech industry (Research & Development), NGOs, universities, scientific institutes. Although the Committee acts as a main advisory body, but also may play significant role in decision-making. The Committee may ask an opinion of panels of outside experts designated by other ministries for advice. The main task of GMOs Steering Committee is to advise national competent authorities, responsible for implementation and enforcement of national regulatory legal acts, EU regulations and directives, International binding Agreements (i.e. Cartagena Protocol on Biosafety to the Convention on Biological Diversity); to initiate development and discussions on strategic biotechnology regulatory programs in environmental protection, health care, agriculture in order to secure safe level for handling and usage of GMOs in Lithuania.

The Ministry of Environment considered establishing another ***GMO Experts Committee***, which was composed by Order No.198 on April 25, 2003. This is a consultative Advisory body with a clear task to act as advisor to the Competent Authorities, i.e. for example, carrying out environmental risk assessment connected with experimental releases of GMOs at national level, thus advising GMOs Steering (Regulatory) Committee in relation to risk assessment and management posed to the environment, agriculture and human health by GMOs and GMPs. Therefore the National GMO Experts Committee is formed taking into account the risk assessment requirements from scientific staff of the following specializations: genetics, ecology, botany, health care, agriculture, veterinary, biochemistry, geochemistry, microbiology and some others. The designated experts expected to carry out assessments of the presented dossiers and deliver subsequent recommendations for subsequent decision-making.

The main tasks of the GMO Experts Committee (EC) Committee, according to the established national Regulation and Terms of Reference for its operations is focused on, but not limited to:

- ✓ Assess whether GMOs and/or GMPs, intended to be placed on the market (imported) comply with established safety requirements for human use and nature protection;
- ✓ Determine and assess whether submitted risk assessment reports and monitoring data fulfill conclusions presented by notifier concerning the risk assessment and management posed to the environment, agriculture and human health by GMOs and GMPs;
- ✓ Submit findings and proposals to the GMOs Steering Committee (regulatory management) deciding upon compliance with the established requirements concerning the particular application(s).

In order to carry out the assignments, members of the national GMO Experts Committee shall:

- ✓ Analyze each possible effect and harmful effects of the GMO and/or GMP intended to be placed on the market or imported into the country;

- ✓ Assess possible results of each potential hazard and harmful effects;
- ✓ Assess probabilities for each potential hazard and harmful effect;
- ✓ Generalize the information and data gathered and assess risk form each potential hazard and harmful effect posed to the environment, agriculture and human health by GMOs and GMPs;
- ✓ Make suggestions to the GMOs Steering Committee (responsible for regulatory management) to improve state management and control of GMOs, diminishing influence of risk factors.

Draft national environmental monitoring and enforcement (control and inspection) system

The system of control of GMO release is expected to be based upon existing national law and responsible institutions concerned. There are several subordinated agencies under the competent ministries with responsibility to undertake control measures in defined area of national activities. Those agencies will be included in the control system for GMOs. Competent Agencies which are to be given responsibility for control of GMO marketing are:

- Plant Protection Inspection,
- Market Inspection
- Custom Service,
- Phytosanitary Service,
- Environmental Protection Inspection,
- Veterinary Inspection
- Sanitary Inspection.

The proposed functions for national institutions responsible for enforcement of GMOs/GMPs usage in Lithuania:

1. The Ministry of Environment or its subordinated institution (for example, State Environmental Protection Inspectorate or prospective new GMO Service under the Ministry of Environment), shall be responsible for safety control of the deliberate release into the environment of genetically modified organisms, inspecting whether the foreseen monitoring plan or special conditions of permitting are being kept.
2. The State Food and Veterinary Service, the Ministry of Agriculture or their authorized institutions, which shall be responsible to issue the relevant Orders on regulations and shall carry out, according to their competences, safety control of placing on the market of genetically modified organisms and genetically modified products and market surveillance, namely:

2.1. SFVS shall be responsible for preparation of Orders on regulation for control of GM food products in customs, GM animals, products of animal origin, veterinary preparates, industrial feedstuffs, containing GMOs;

2.2. SPPS shall be responsible for border control and market surveillance of GM plants, vegetative products and reproductive material;

2.3. SSGS under the MoA shall be responsible for control of GM plants' reproductive material, GM seeds within the home market;

2.4. State Animals' Breeding Service under the MoA shall be responsible for control of GM stock animals within the home market;

2.5. GMO Laboratory under the National Veterinary laboratory (NVL) shall be responsible for laboratory analyses and control of GM food products, GM animals, GMMOs, veterinary preparates, industrial marketable feedstuffs, which could contain or being made of GMOs, GM plants, vegetative products, and GM plants' reproductive material.

3. The Ministry of Environment or its authorized institution (for example, the State Environmental Protection Inspectorate), according to the competencies, which shall carry out safety control of the contained use of genetically modified organisms, inspecting whether the

actual GMMO conforms to the risk class indicated, or whether the regulations for waste disposal are being kept;

4. The Ministry of Health or its authorized institutions, which shall carry out safety control of medicines for human use, which contain or are derived from genetically modified organisms;

The State Food and Veterinary Service, which shall be responsible for safety control of veterinary products and preparations, feedstuffs, which contain or are derived from GMOs.

Applications and Risk assessment

Applications for GMO release and utilization should be directed to the Ministry of Environment.

Each application must contain the assessment of risk to environment and suggested procedures of risk management as specified in respective national regulations. All costs connected with risk assessment are the obligation of the applicant.

Ministry of Environment is responsible to receive notifications and requests according to the EU directive 2001/18/EC on GMOs deliberate release into the environment and the Order of the Minister of Environment on *"Detailed procedures for the deliberate release into environment and placing on the market of GMOs and/or GMPs in Lithuania"* (further - Order) (No. D1-225, 29/04/2004, Official Journal, 2004, No. 71-2487, in force since May 1 2004) concerning:

- ✓ Deliberate release of GMOs (as or in products) into the environment (for the purpose of research);
- ✓ Placing to the market of GMOs or GMPs, except human medicines, pharmaceuticals for use in human and veterinary medicine and novel food (including GM foodstuffs) for use in human products, containing GMOs or consisting of them or their combinations.

The overall objective of detailed procedures for the deliberate release into environment and placing on the market of GMOs and/or GMPs in Lithuania - to determine and set up requirements for deliberate release into environment and placing on the market of GMOs and/or GMPs, requirements for scrutinizing notifications and requests for authorizations; procedures for issuing, suspension, termination and renewing of licenses/permits for certain activities in Lithuania.

According to the newly adopted detailed procedures, a notifier (natural or legal person), having intention to use GMOs or GMPs, is obliged to receive a permit or written consent to execute the following activities:

- ➢ For deliberate release into environment of GMOs for any other purposes than placing on the market, - according to the Annex 8 of Order No. D1-225 (document issued – Permit for deliberate release into environment of GMO);
- ➢ Placing on the market of GMOs as or in products, - according to the Annex 9 of Order No. D1-225 (document issued – Consent for placing on the market of GMO).

Notifier is obliged to submit application to the Ministry of Environment along with the completely filled-in a special form of request, according to the provisions of Annex No. 1 of Order No. D1-225 the following obligatory documents:

1. Request for authorization for deliberate release into environment of GMOs/GMPs or placing them on the market;
2. Notification with filled-in information about GMOs or GMPs;
3. Monitoring plan;
4. Evaluation of risk assessment to the environment, human health and agriculture;
5. Conditions for product placing on the market;
6. Description of labeling;

NCA has full right to ask for the further complement information.

Future goals and needs for the National Biosafety regulatory and decision-making strategies

- To separate concrete division of competencies and responsibilities between responsible state institutions concerning the main questions of GMOs usage in the new wording of the amended frame ***Law on GMOs***;
- To ensure versatile public information and participation during the process of permitting of GMOs and GMPs usage in the new wording of the amended frame ***Law on GMOs*** and secondary legislation;
- To describe the main information gathering and systematizing principles, order and guidelines for GMOs and GMPs topical data management in the new wording of the amended frame ***Law on GMOs*** and secondary legislation;
- To draft and approve national legal acts concerning GMOs and/or GMPs selection of sampling sites and evaluation guidelines, namely: Order for prevention of accidental dangers of incidental GMOs releases into environment; methods for penalties and sanctions for breaking off the requirements and compensation for damage done (append national administrative violations Codex); Order for public register (information management).

For that purpose the main frame **Law on GMOs** needs to be adjusted and supplemented:
- Envisaging and delimitate the levels of competencies and division of responsibilities between responsible state institutions;
- Creating topical information gathering and information exchange GMOs safe handling national system;
- Differentiating between the different uses of GMOs and GMPs: contained use, deliberate release into the environment and placing on the market;
- Discussing an issue of GMOs coexistence (rethinking a question of possible territories free of GMOs); monitoring of GMOs, public register, and utilization of GMOs waste;
- Determining special formats, general purpose, functions of data providers and periodic deadlines for the topical data and information supply to the pilot phase of nBCH;
- Institutionalizing consultative advisory and expert committees (GMO state management committee, Experts committee, Novel food products scientific committee);
- Foreseeing the extension of permits, identifying the maximum period for licenses validity;
- Obliging a notifier, upon receipt of the final decision from the Ministry of Environment, informing public (at Official Journal of EU plus at least via the one of the national daily paper);
- Developing the control mechanism over the notifier's obligation to inform public;
- Foreseeing the financial mechanism for the notifier due to risk assessment procedures documented in the dossier;
- Developing concrete order and guidelines for information gathering and systematization about GMOs and GMPs: to develop standard procedures for reporting, periodic deadlines for the topical data and information supply to the pilot phase of national GMO database, identifying responsible persons within the responsible institutions, their character of work, means and methods for data provision and generalization, frequency, etc.;
- Formulating national monitoring and control (surveillance) plans for GMOs placing on the market or release into environment;
- Determining the order and guidelines for reporting process to the EC and other Member States and validation of simplified procedure for the GMOs release into environment.

To prepare the new wording of the amended frame Law on GMOs developing new secondary legislation concerning the safe use of GMOs/GMPs in Lithuania:
- Guidelines for sampling planning, selection and choosing of analyses methods;
- Rules for prevention of accidental dangers of incidental GMOs releases into environment;
- Methods for penalties and sanctions for breaking off the requirements and compensation for possible damage done.

Annex C
Logframe Analysis

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

Components	Indicators	Means of Verification	Risks and constraints	Risk Management
PROJECT: Support for the Implementation of the National Biosafety Framework for Lithuania				
GOAL (DEVELOPMENT OBJECTIVE) To assist Lithuania to implement fully operational, workable and transparent NBF through strengthening the needed capacities in line with objectives of CPB & other international obligations	Legislative environmental, economic and social policies & programs drafted incorporating them into the national Biosafety strategy documents in line with the objectives of CPB and other international obligations in Lithuania	National Biosafety policy strategic documents elaborated and published in periodic national and, if needed, relevant international reports	Change of environmental, political, economical and social priorities regarding integration of biological safety into the national governmental policy	Promote broader political collaboration, supporting national stakeholders and promoting awareness on responsibilities taken to implement objectives of CPB and other international obligations
COMPONENT: A. NATIONAL BIOSAFETY POLICY				
OBJECTIVE **A.** To assist Lithuania to integrate and incorporate Biosafety policy into the nationally agreed long-term strategic governmental program on sustainable development and elaborated national Biosafety strategy documents	• Legislative, environmental, economic, social issues of Biosafety policy integrated into the national strategic program on sustainable development; and • Required documents on national Biosafety strategy elaborated	• The identified Biosafety strategy documents (i.e. National Strategy on Biotechnology/ Biosafety Development; National Program and Action Plan for safe use on various applications of modern biotechnology) elaborated for adoption; • National Biosafety strategy published in the national official gazette (OJ), nBCH	- Biosafety issues are not included in biotechnology-related intersectional plans; - Insufficient political will to integrate Biosafety issues into the unified strategic program; - Lack of public awareness and institutional support for national Biosafety policy making fully operational	- Support institutional consensus between the stakeholders in order to promote agreed national policy on Biosafety issues; - Set up the internal interdepartmental working group [TF] for the preparation of the required national Biosafety strategy documents within the internally defined time frame (project interim phase, by 2006-2007)
1 OUTCOME:				
A1. Biosafety considered as a sustainable development issue in drafted and nationally agreed long-term strategic documents in Lithuania	• National intersectional plans & programs (annual, short-term, long-term) reviewed and amended in line with the objectives of CPB and other international obligations; • Biosafety issues incorporated into the national development plans and programs	• National Strategy on Biotechnology/ Biosafety Development issues elaborated and approved; • National Program and Action Plan for safe use on various applications of modern biotechnology elaborated for the final approval; • National Strategy for Sustainable Development amended, incorporating Biosafety issues therein	- Lack of requisite consensus on Biosafety issues among national stakeholders; - Biosafety issues are not included in biotechnology-related intersectional national plans and programs	- Promote awareness raising activities and necessary synergies between biotechnology and Biosafety among main stakeholders; - Promote relevant debates, discussions and exchange of information on trade (industrial development), agricultural farming (co-existence), medicine, etc. related issues on Biosafety

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

ACTIVITIES:				
A1. 1 Setting up the trans-institutional working group [Task Force, TF] with mandate to co-ordinate the process on Biosafety intersectional integration, elaborating nationally agreed political strategy documents	• Scheduled meetings of duly authorized operational TF set up by the NEA back to back with A1.3 activities during the NBF implementation process: - Initial (mobilization) phase; - Interim phase • Identified relations between Biosafety and other national policies on environmental, legislative, economic, social aspects of Biosafety policy	• Terms of references (ToR) for the identified TF, outlining the objectives and tasks to be achieved within the agreed timeframe (i.e. by the end of 2007) drafted; • Minutes of the TF periodic meetings (discussion items, decisions taken, monitoring of implementation) reported; • List of institutions, invited and involved to make their contributions towards the collaborative achievement of outcome, composed	- MoE (NCA) has no right authorization to lead the Task Force to co-ordinate the process of Biosafety intersectional integration; - Inappropriate attitude of prominent national experts (scientists, academia) towards the national need to integrate Biosafety into the long-term strategic program on sustainable development; - Lack of required expertise to organize the national WGs on different applications of modern biotechnology	- Ensure open-dialogues and awareness of synergies on Biosafety and biotechnology issues between regulators, producers and academia; - Foresee and identify, in consultation with NEA and NCC, prominent executives from the constituted TF to carry out tasks set in order to co-ordinate the preparation of the required surveys
A1. 2 Collection, preparation and dissemination of the global and regional experiences on "best practices" from different applicable models of national policies & strategies on Biosafety (Surveys: reviews and assessments) to key national stakeholders: decision makers, NCC members, parliamentarians, NGOs, public interest groups, etc.	• Administrative assignments for the surveyors to be carried out on various applications of modern biotechnology prepared by the NEA; • Periodic reports on surveys (reviews and assessments) for co-ordination of Biosafety intersectional integration, identifying relations between biosafety and other sectorial policies delivered to the NEA	• Terms of references (ToR) for the individual consultants, outlining their objectives and tasks to achieve within the agreed time period (by the end of 2006) drafted; • Required surveys (Reviews and Assessments) for different applicable models of Biosafety policies and strategies carried out and presented/ disseminated during the TF periodic meetings	- Lack of required competent human resources and expertise to carry out the assignments (assessments and reviews), delivering surveys on "best practices" for different applicable models of national Biosafety policies & strategies	- Develop relevant training materials for conversion of national Biosafety policy into practice; - Involve wide range of key principle stakeholders for their contribution to the process of information collection, preparation, dissemination on commonalities and differences in approaches

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

A1. 3 Organization of 2 rounds national consultations with key principle stakeholders for deliberation of national Biosafety strategy documents: - A separate National Strategy on Biotechnology/ Biosafety Development issues; - National Program and Action Plan for safe use on various applications of modern biotechnology in Lithuania (2 days/30 participants)	• Scheduled meetings (WGs) with relevant national stakeholders, organized by NEA in cooperation with NCC throughout the NBF implementation process: - Initial (mobilization) phase; - Interim phase • Identified relations among biotechnologies/Biosafety and other intersectional policies on environmental, legislative, economic, social aspects of Biosafety policy	• Minutes of periodic WGs meetings (discussion items, decisions taken, monitoring of implementation) reported; • List of institutions, invited and involved to make their contributions towards the collaborative achievement of outcome, composed	- Polarization of the debates disabling co-ordination mechanisms for Biosafety intersectional integration; - Lack of required expertise to organize the national WGs on different applications of modern biotechnology	- Promote cooperation and awareness, exchange of information throughout national stakeholders; - Ensure open-dialogues and awareness of synergies on Biosafety and biotechnology issues between regulators, producers and academia; - Pre-envisage the institutional provisions to set up a Task Force (TF) in order to co-ordinate the WG's activities on Biosafety issues
A1. 4 Elaboration of the required national Biosafety strategy documents in Lithuania, i.e.: - A National Strategy on Biotechnology/ Biosafety Development issues; - National Program and Action Plan for safe use on various applications of modern biotechnology	• National intersectional plans & programs (annual, short-term, long-term), reviewed, amended and published; • Biosafety issues incorporated into national development plans & programs	• National Strategy on Biotechnology/ Biosafety Development issues elaborated for the approval by the national executing authority; • National Program and Action Plan for safe use on various applications of modern biotechnology elaborated for the approval by the national executing authority;	- Lack of political recognition and responsive commitment to harmonize Biosafety with other national policies; - Lack of requisite consensus on Biosafety issues among national stakeholders; - Biosafety not included in biotechnology-related long-term intersectional plans & programs	- Promote awareness on necessary synergies between biotechnology and Biosafety; - Promote relevant debates, discussions and exchange of information on trade (industrial development), agricultural farming (co-existence), medicine, etc. issues related to Biosafety
2 OUTCOME:				
A2. Increased and strengthened public and political support in terms of human resources and institutional capacities for consistent implementation of national Biosafety policy	• Biosafety issues considered as an integral part of the country's strategy for sustainable development (incl. Biotechnology (R&D) sector, Biodiversity conservation, Environmental Protection, etc.); • National policy on Biosafety issues addressed in national development plans & programs, and adjusted according to changing needs	• Drafted amended edition of National study on biological diversity, incl. integration of Biosafety issues on case-specific monitoring, general surveillance methods, etc.; • Procedural guidelines, explaining the policy review systems, drafted and approved; •National public awareness workshops, consensus building seminars, conflict resolution training organized	- Possible resistance from the interest groups/stakeholders (R&D, industry, academia); - Bureaucratic obstacles, resulting in lack of technical capacities to generalize available information; - Inability to sustain political support for continuous implementation of national Biosafety policy	- Promote public awareness on consensus building; conflict resolution training, if necessary; - Thematic data collection (surveys), making analysis of intersectional information; - Capacity building for surveyors, as appropriate; - Draft mechanisms for review/adjustment of Biosafety policy in response to changing needs

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

ACTIVITIES:				
A2. 1 Organization of 2 national 2-days workshops plus 1-day national Conference (total 3 events) [proposed as back to back activities] on implementation of elaborated national Biosafety policy, determining conversion of political instruments into practice on the following subject: "Consensus building and conflict resolution on national Biosafety policy issues". Participation of all interested national key stakeholders concerned: decision-makers from central (NCA, NCC, members of Parliament Committees) local governments (municipalities); NGOs, public interest groups, scientific community, etc. Estimation: 2 days x 2 times / 60 participants	• NEA envisaged to organize several national activities (3, national events, presumably WS, the Conference as back to back with activity under B2.4), i.e. training workshops and national conference on topic of "Consensus building and conflict resolution on national Biosafety policy issues", carried out during the project time-frame by year 2009 during: 1. Interim phase; and 2. Final phase (by the end of project).	• Terms of references for each national WS and Conference, outlining specific objectives and strategy to achieve them drafted; • Periodic reports on the activities' outcomes (timing, experts, facilitation/moderation, lessons learnt, monitoring) delivered; • Lists of beneficiary organizations and delegated participants composed; • Procedural guidelines, explaining the policy review systems, drafted and approved	- Inappropriate budgetary allocations for group Workshops and Training; - Lack of required skilful human resources to organize the practical national Biosafety events	- Verify and prove estimated financial resources required for group WS and Training; - Foresee the sub-regional mechanisms for collaborative activities with other related projects and programs on Implementation of NBFs in the neighbouring countries; - Consider the formation of an ad-hoc body (i.e. internal working group) for drafting amended edition of National study on biological diversity, integrating the actual status of national Biosafety issues therein
A2. 2 Drafting amended editions of: - National Strategy for Sustainable Development, incorporating Biosafety issues therein; - National Biodiversity Strategy and Action Plan, which incorporates the actual status of national Biosafety considerations (i.e. case-specific monitoring, general surveillance methods, risk assessment and management, national mechanisms for control and inspection, etc.)	• Formation of an ad-hoc body (i.e. internal working group) for drafting amended editions of requested national strategy documents; • Scheduled meetings of an ad-hoc body, set up by the NEA, during the implementation project: - Initial (mobilization) phase; - Interim phase	• Administrative assignments (Contracts, ToRs, etc.) for the ad-hoc working group to draft the requested amended editions prepared by NEA; • National Strategy for Sustainable Development amended, incorporating Biosafety issues therein; • Amended edition of the National study on biological diversity, integrating the outstanding issues of modern Biosafety, drafted for adoption	- Lack of requisite competent human resources and/or expertise to carry out the assignments; - Possible resistance from the interest groups/stakeholders (R&D, academia, national enforcing institutions) influencing the violent interpretation of results	- Thematic data collection and thorough analysis of intersectional information; - Foresee and identify, in consultation with NEA and NCC, prominent executives from the constituted internal ad-hoc working group to carry out tasks set in order to co-ordinate the preparation of the required national study

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

COMPONENT: B. NATIONAL REGULATORY REGIME				
OBJECTIVE **B.** To assist Lithuania to revise, amend and consolidate a fully operational, workable and responsive regulatory regime in line with the CPB, EU law & other international obligations	• National regulatory regime (i.e. frame law passed by the relevant governmental authorities) developed and approved, fully encompassing environmental, economic, social aspects of the national Biosafety policy; • Secondary legislation (implementing regulations for all requisite NBF components) defined, drafted and approved in compliance with the CPB and other international obligations	• Biosafety legislation approved and published in the national official gazette (OJ); • Implementing regulations defined, drafted and approved; • Guidelines published and available on the website of national Biosafety database and BCHM; • Internal manuals published and available on the website of national Biosafety database and BCHM	- Lack of public awareness and institutional support for making fully operational of drafted (amended) Biosafety regulatory regime; - Regulatory regime cannot be enforced because due to the absence of implementing regulations, guidelines and internal manuals drafted; - Regulatory regime cannot be enforced because of the undetermined responsibilities within existing national administrative framework or lack of institutional support from implementing agencies; - Regulatory regime is not consistent with the current social interests and economic priorities of modern society	- Develop regulatory regime in accordance with the nationally agreed Biosafety policy; - Support institutional consensus and capacity building to promote consultations with stakeholders during the initial stages of revision and finalization of the regulatory regime; - Provide realistic time frame and relevant mechanisms for periodic reassessments, review and adjustments of legislation approved and enforced; - Develop tools and training for translation of legislation into workable practice; - Separate competencies between political legislative authorities and regulatory enforcement (implementing) agencies
1 OUTCOME:				
B1. National regulatory regime revised, amended, approved and in place, depending on the agreed Biosafety policy, provisions of CPB, EU law & other international obligations by the end of NBF project in Lithuania	• National frame and secondary legislation (frame law, implementing orders, decrees, regulations, guidelines) for the safe use and various applications of modern biotechnology drafted for the final approval by the NCA and other interested organizations; • Former ICCP checklist reviewed by the NCC for the consistency;	• Frame GMO Law revised, adjusted, submitted for the final approval before publishing in the official gazette (OJ); • Secondary Biosafety legislation (implementing orders, decrees, regulations, guidelines) drafted and submitted for approval; • Approved legislative acts published in the national official gazette (OJ);	- Amended pieces of national legislation discussed, but not agreed upon and not approved; - Unworkable regulatory regime as a result of simply copying other regulatory systems and models; - Regulatory regime is not responsive, nor consistent with national Biosafety policy; - National regulatory regime is not consistent with CPB and other international obligations by the end of the project;	- Ensure initial legal analysis and thorough reassessment, reviewing drafted and existing status of national legislation; - Promote cooperation and exchange of information throughout governmental authorities; - Ensure consecutive review precise analysis and continuous monitoring of national legislative acts; - Pre-envisage the institutional provisions to set up the regulative Task Force (TF)

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

ACTIVITIES:				
B1. 1 Setting up the inter-institutional Task Force composed of representatives from different governmental authorities for review and adjustments, when needed, of Biosafety regulatory regime in response to changing needs	• Expert panel to review/revise national regulatory regime composed; • Periodic continuous reports for co-ordination of expert panel (TF) assignments; • Assignments for the TF in order to draft amendments to legal acts outlined	• Terms of references (ToR) for TF operational activities, outlining the objectives and tasks to be achieved under initially agreed timetable; • Number of reviewed and adjusted national legal acts under the agreed timetable	- Lack of required experts/ specialists to organize the efficient functionality of TF; - Diversity and/or polarization of the opinions, disabling to co-ordinate the generation of effective outputs of the TF;	- Ensure open-dialogues and awareness of synergies on biotechnology and Biosafety issues between regulators and academia (experts); - Promote broader public awareness and support for Biosafety and the need for regulatory regime
B1. 2 Revision of the Frame GMO Law to comply with CPB by the Task Force (TF, as composed per activity B1.1) related to: contained use; deliberate release into the environment; placing on the market; importation and transit/ transboundary movements of GMOs	• Scheduled meetings of the composed operational TF; • Independent review by the inter-institutional Task Force; • Drafted revisions and amendments to the Frame GMO Law	• Frame Law on GMO reviewed, adjusted and submitted for the approval by the national Competent Authority (NCA)	- Revised (amended) Frame GMO Law rediscussed during the TF's meetings, but no final agreement reached prior to the official approval submitted by the NCA	- Ensure consistent re-assessment, reviewing revised (amended) Frame GMO Law; - Promote cooperation and exchange of information throughout NCA and other interested organizations
B1. 3 Revision and final adoption by the inter-institutional Task Force (as composed per activity B1.1) of existing, recently drafted and pending for adoption national secondary legislation (Orders, Decrees, Regulations) to comply with CPB	• Work assignments for the experts of TF (as composed per activity B1.1) developed in order to draft adjustments to legal acts, as outlined by NEA; • Periodic management reports for co-ordination of internal TF of local experts; • Number of reviewed pieces of national legislative acts and submitted to the MoE by TF	• Terms of references (ToR) / Contracts prepared for local experts (as composed per activity B1.1) outlining the objectives and tasks to be achieved under initially agreed timetable; • Number of reviewed / revised / adjusted national legal acts under initially agreed timetable;	- Regulatory regime is being developed in isolation; - Biosafety legislation is not harmonized with other sectors' legislation; - Regulatory regime to be reviewed is not available in English, jeopardizing the involvement of inputs from the international expertise	- Promote national consensus on Biosafety; - Promote collection of information on experiences in other countries; - Pre-envisage the legal interpretation of the main national Biosafety legislation in English enabling inputs from relevant international experts
B1. 4 Identification, development and adoption of the internal explanatory manuals on the national legislation for Biosafety (incl. drafted secondary legislation: ministerial orders, decrees, regulations), as requested by the NEA	• Brief summaries of all national legislation, internal explanatory manuals in national language posted on the nBCH; • Enabled access to thematic information by different stakeholders in accordance with national rules on public information dissemination	• Service contracts prepared and implemented for preparation of summaries for the operational internal explanatory manuals under initially agreed timetable; • Summaries of internal explanatory manuals prepared, and available throughout nBCH	- Lack of public interest to access information on the drafted national legislation due to technical and/or bureaucratic reasons; - Inappropriate methods and methodology used for raising awareness and information dissemination throughout different interested stakeholders	- Ensure proper handling of available mechanisms on public information and awareness raising constantly disseminating Biosafety information; - Proper profiling of public for information dissemination to different groups of different interested national and / or international stakeholders;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

B1. 5 Setting up nationally agreed mechanism for a responsive and flexible revision of the national Biosafety legislation, when and if needed	• Relevant mechanisms for monitoring and flexible revision (keeping track) of regulatory compliance in response to changing needs discussed, agreed upon and made operational under agreed timetable	• Appropriate means for internal information exchange (for example, internal newsletter, intranet, front office thematic reports, etc.) established and made operational by the NCA, as requested by the NEA;	- Bureaucratic obstacles, resulting in lack of inter-institutional cooperation to ensure constant and flexible revision, when / if needed; - Inability to sustain political support for continuous implementation of national Biosafety regulatory regime	- Promote permanent consultations with all stakeholders during the initial implementation stages of the worked out regulatory regime
2 OUTCOME:				
B2. Increased in-house competence on regulatory issues is available and equipped with tools for related additional capacity building activities	• Biosafety regulatory regime in place reflecting national policies, plans and programs, defining other relevant NBF components, in compliance with CPB, EU law & other international obligations; • Relevant tools and trainings for translation of legislation into practice developed; • National regulatory regime on Biosafety issues addressed and adjusted permanently, according to changing needs	• Revised frame Law on Biosafety and relevant secondary legislation approved and published in the national official gazette (OJ); • Summaries of outreach materials (guidelines, internal manuals, etc.) produced and available on national Biosafety db and, if agreed upon, - BCHM; • Printed ("hands-on") publications and guidelines in local language available for daily use;	- Regular mechanism cannot be actualised because of inefficiency of existing administrative structures; - Lack of public access to information on the drafted national regulatory regime; - Inappropriate methods for raising awareness on media coverage for information dissemination; - Lack of published updated legal information available due to bureaucratic reasons	- Promote training on CPB, how to meet minimum requirements, international obligations of the country, regulatory instruments related to Biosafety in Lithuania; - Promote national mechanisms for public access to thematic information in country; - Proper profiling of public in order to use appropriate methods for information dissemination to different stakeholders; - Update information on Biosafety regularly (to be provided to nBCH, BCHM, media, different national, international stakeholders)
ACTIVITIES:				
B2. 1 Organization of two rounds (for 2 days each) start-up consultative workshops on: 1) possible options and implications of amending the existing regulatory regime; 2) legal gap analysis for implementation of CPB. Estimated duration: 4 days/30 participants: officials and	• NEA envisaged to organize the first round of the consultative workshops during the project inception phase by the end of 2005-2006 under initially agreed timetable on the following topics: - Transboundary movement of GMOs and regulatory requirements of CPB, other international obligations;	• Minutes and proceedings of the training prepared and disseminated among the participants and other interested stakeholders of the national events; • List of institutions, invited and involved to make their contributions towards the collaborative achievement of outcome, composed;	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as trainers, resource persons) the indicated national Biosafety events; - Lack of cooperation between responsible national agencies concerned;	- Verify and prove estimated financial resources required for group Training and Workshops; - Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Prepare the necessary training manuals for trainers on Biosafety regulatory

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

experts (legal and administrative staff) from NCA and other responsible governmental institutions and organizations, that will be involved in implementation of the national regulatory regime	- National Biosafety regulations required for implementation of the GMO Law	• Lists of beneficiary organizations and delegated participants composed;		issues (addressed in activity B2. 2)
B2. 2 Preparation of the required training manuals for trainers on the national Biosafety regulatory regime	• The required number (3 sets, each set for separate activity) of procedural manuals (guides for national trainers) on Biosafety regulatory issues produced and disseminated; • Enabled access to thematic information by different stakeholders in accordance with national rules on public information dissemination; • Building networking and exchange of experiences throughout the country enabling access to thematic information by different stakeholders in accordance with national rules on public information dissemination	• ToR drafted and contracts implemented for preparation of the required training guides for trainers under the agreed timetable; • Printed ("hands-on") training guides available for daily use by the national stakeholders concerned;	- Absence of explicit assignments (ToR) or contractual commitments to prepare training manuals; - Overlapping institutional responsibilities among national responsible institutions concerned; - Lack of public interest to access the information on the drafted national regulatory regime due to technical and/or bureaucratic reasons; - Inappropriate methods and methodology used for raising awareness and information dissemination throughout different interested stakeholders	- Promote collection of appropriate information on experiences in other countries; - Ensure proper handling of available mechanisms on public awareness raising and information dissemination; - Pre-envisage the translation of national Biosafety legislation into English to enable inputs from international trainers

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

B2. 3 Organization of 3-days national specialized training workshop for the scrutinizing of the in-depth regulatory provisions, as required by the amended GMO Law and revised secondary legislation, applying the national regulatory regime in Lithuania. Total estimation of 20 senior officers/regulators and environmental lawyers from the key governmental institutions, responsible for implementation of the national regulatory regime in compliance with CPB, EU Law and other international obligations (3days/ 20 participants)	• NEA envisaged to organize 3-days specialized national training to be carried out by year 2006 during the Interim phase on the following topic: Biosafety regulations on technology research, trials and applications in compliance with CPB	• Terms of reference for the training workshop, outlining specific objectives and particular strategy to achieve them; • Monitoring report on the management inputs and outcomes (timing, experts, facilitation, lessons learnt); • Lists of beneficiary organizations, participants prepared and delivered;	- Inappropriate budgetary allocations for budget line of group training/workshops; - Lack of required skilful human resources to lead (as lecturers, resource persons) the indicated national Biosafety event; - Reviewed and revised national regulatory regime does not reflect specific issues of public concern	- Verify and prove estimated financial resources required for group WS and Training; - Consider the formation of an ad-hoc interim organizational Committee to coordinate the planning of national activity
B2. 4 Organization of 1-day national Conference on topic "Implementation of the revised Biosafety regulatory framework on national level". Target groups: high-level politicians (parliamentarians), decision-makers from governmental institutions, responsible for implementation of the frame GMO Law, drafted regulations and other secondary legislation. Envisaging total of: 1-day / 40 medium and high-level participants from NCA, the Parliament, Governmental institutions and/or their subordinated organizations	• NEA envisaged to organize one major National Conference during the project interim phase under initially agreed timetable (possibly back to back with the planned conference under activity A2.1); • Thematic focusing on responsibilities and rights coming from the national law and international agreements (particularly, in relation to use, import and export of GMOs/GMPs), documented in the periodic minutes of national Organizing Committee	• Terms of references for national Conference, outlining specific objectives and strategy to achieve them drafted; • Proceedings of the national Conference printed and disseminated materials among the participants and interested parties, i.e. key national stakeholders (parliamentarians, decision makers, NCC members, NGOs, public interest groups, etc.)	- Inappropriate budgetary allocations for group Workshops and Trainings; - Lack of required skilful human resources to lead (as lecturers, resource persons) the indicated national Biosafety event; - Reviewed and revised national regulatory regime does not reflect specific issues of public concern	- Verify and prove estimated financial resources required for group WS and Trainings; - Consider the formation of the Organizing Committee for the national Conference to coordinate its organization

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

COMPONENT: C. ADMNISTRATIVE SYSTEM TO HANDLE NOTIFICATIONS OR REQUESTS FOR AUTHORISATION (INCLUDING ADMINISTRATIVE PROCESSING OF RISK ASSESSMENT AND INFORMED DECISION-MAKING)				
OBJECTIVE C. To assist Lithuania to consolidate a functional and efficient national system to handle notifications or requests for authorisation, perform risk assessment and administrative processing of informed decision-making	- Administrative system, i.e. authorized NCAs and fully operational key interested state institutions are in place; Administrative procedures to handle notifications or requests within the fixed time frame defined and operational; - Advanced use of nBCH and BCHM reached	- Number of informed decisions made as a result of forthcoming requests; - Administrative system to handle notifications for administrative processing set up, including application formats, guidance for applicants, internal manuals for processing, checklists, etc.;	- National institutional system and administrative division of responsibilities are not defined / clarified; - Lack of relevant political experience and appropriate administrative expertise for making administrative system operational, i.e. "up and running"	- Establish interim measures to handle requests for risk assessment and informed decision-making; - Provide technical capacity building support by conducting consultative seminar/trainings, as appropriate, for responsible regulators and technical administrators
1 OUTCOME:				
C1. A fully operational national administrative system in place, i.e. "up and running", including establishment of the operational emergency response procedures and enforcement measures; the usage of the interoperable national Biosafety database (nBCH), as set up under the BCH project	• Administrative procedures for handling requests and scrutinizing risk assessment and notifications prior to informed decision-making clearly separated and personnel trained; • nBCH, containing all relevant information required under CPB, renewed and updated; • National Biosafety information, categorized as non-confidential, made accessible to broad public; • Fully operational BCH NFP; • Administrative procedures to submit ('report') information from nBCH to BCHM defined; • Full compliance with BCH obligations, set up in the CPB (Art. 20, 6; 10; 11; 12; 13; 14; 17; 19; 23; 24 and 25)	- Percentage of requests handled; - Procedures for handling, transport, packaging and identification of GMOs established; - Procedures for handling of confidential information established; - nBCH, containing all relevant information required under the CPB, improved and updated; - Compliance with BCHM obligations reached; - Administrative personnel, capable to follow and practically interpret CPB in place, trained;	- Administrative system is not enforced yet, because the main NBF provisions to be passed as revisions to the main Law on GMOs; - Delay in administrative set up due to political / bureaucratic procedures; - Lack of clarity and transparency in the developed national administrative system; - Lack of technical administrative personnel, having the required combination of inter-disciplinary skills; - Insufficient technical infra-structure developed;	- Establish interim administrative measures until the adoption of the amendments to the revised frame Law on GMOs; - Envisage promotion of on-line (via Internet programs) application in order to reduce administrative burden; - Setting up and updating of nBCH, containing all relevant information required under the CPB; - Envisage further steps for enforcement of national follow-up mechanisms (addressed in C1.1);
ACTIVITIES:				
C1. 1 Identification of the national institutional set up, i.e. authorities and their subordinated organizations	- Administrative mechanisms for enforcement of the national regulatory regime elaborated and in place; - Control and inspections are	- Manuals, operational guidelines produced and available to make operational the drafted national regulatory regime	- Difficulty in setting up institutional arrangements and internal procedures needed to apply and enforce the drafted regulatory regime;	- Promote training on possible options and implications of implementing amended existing regulatory regime;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

responsible for application and enforcement of the developed regulatory regime	carried out according to the developed and agreed administrative procedures;		- Lack of well-trained experienced officials to enforce the regulatory regime; - Lack of collaboration among the national institutions responsible for enforcement	- Elaborate and provide comprehensive manuals and guidelines on the functioning of drafted regulatory system
C. 1 A Setting up and making operational the national emergency response procedures in place	- Rules for emergency response procedures in place; - Authorities, contact persons nominated and made known to public; - Responsible staff trained in dealing with emergency issues; - Guidelines on emergency cases (incl. remediation) for appointed responsible entity / officers prepared;	- Written and approved rules of national emergency response procedures available; - Authorities nominated and approved; - Number of responsible staff, from the appointed authorities, trained to deal with emergencies; - Functional access to nBCH and other Internet resources ensured; - Number of emergency cases solved; - Calculations of financial expenses for possible emergency responses, when applying remediation measures and mitigating accidental releases, available;	- System exists only on paper, is non-functional or with low capacity (functional when dealing with small cases, but helpless with big cases); - Proper notification is not functioning (i.e. somebody who sees an accident cannot access to responsible persons for whatever reasons – bad connection, contact person having holiday, etc.); - Responsible staff does not know what to do (for example, they could be aware how to behave in case of GM plants, but no awareness in different cases of GMMOs); - Emergency cases/events hidden by government or by companies, blocking notification of the accident; - Government is not willing to admit that their country is not able to deal with the issue themselves, thus wish not asking for help from other (sub) regional countries/ international organizations	- Proper education/training for responsible persons, duplication of persons so that there is no one single person responsible for everything (for example, in cases when one contact person is sick, then somebody takes over his task); - Ensure what means for emergency responses are available (cars to access the emergency site, means for eliminating GMOs, etc.); - Develop tools (guidelines) for different emergency cases, possibility to ask for help from other authorities or countries, international organizations; - Ensure that access to emergency lines is free and operational (possible options to have free emergency line, all the calls are taped, etc.); - Raise awareness so that governments/ companies understand that hiding accidents and delays in eliminating GMOs will lead to bigger disaster than immediate action and that hiding accidents (from neighbouring countries also) are legally banned

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

C. 1 B Preparation of the operational "Procedures manual" for internal use by the personnel in the Biosafety office of NCAs in the following cases: - Emergency response, - Accidental release, - Illegal movement, transit; - Contained use, - Deliberate release into environment, - Placing on the market, - AIA and FFP, handling, transport, packaging and identification of GMOs, including handling of confidential information	- Procedural manual with the defined administrative tasks for in-house use by authorized personnel of the NCAs' Biosafety office drafted and approved under initially agreed time -table; - Internal administrative tasks, i.e. written procedures for administrative tasks, risk assessment (while processing of applications and handling of requests and notifications prior to decision-making) drafted, agreed upon and adopted by the ordinance of NCA;	- Required number (sets) of internal manuals for performing administrative tasks of risk assessment and decision-making drafted and published; - Number of simulated (for learning) vs. real administrative cases registered, employing the newly drafted procedural manual in Lithuania	- Delay in administrative set up due to political or bureaucratic procedures; - Lack of technical administrative personnel, having the required combination of inter-disciplinary skills; - Lack of administrative infrastructure needed;	– Setting up and constant updating of nBCH, containing all relevant information required under the CPB and other international obligations; – Envisage setting up the national public register for tracking dossier received;
C. 1 C Revision and amendment of the currently valid statutory (application) forms, making computerized interoperable for handling notifications/ requests for authorisations on: - Permission for contained use; - Deliberate release into environment; - Import of GMOs/GMPs and placing on the market	- Current statutory forms of applications for in-house use by personnel of national Competent Authority (-ies) revised and amended, as appropriate; - New statutory (application) formats drafted and developed for interoperability testing via Internet (on-line operable programs), as requested by the NEA	- Drafted new templates of 3 different statutory (application) forms, for handling applications / requests for authorisations on: - Permission for contained use; - Deliberate release into environment; - Import of GMOs/GMPs and placing on the market; - Review of the statutory forms by selected groups of experts, testing them on Internet operable programs, before these are finalised	- National institutional system and administrative division of responsibilities are not clarified yet; - Lack of technical administrative personnel, having the required combination of inter-disciplinary skills; - Insufficient technical capacities and lack of infra-structure needed for enabling (via Internet) on-line application process;	– Establish and follow up the interim administrative measures until the adoption of the amendments to the revised frame Law on GMOs; – Setting up and constant updating of nBCH, containing all relevant information required under the CPB and other international obligations; – Envisage setting up the national public register for tracking dossier received
C1. 2 Setting up the national Public Register (digital web-based) for tracking dossiers received, by linking it and making interoperable with the aggregated and up-dated nBCH	- Formation of an ad-hoc body (i.e. internal working group) to set up the principles of public register and ToR to develop web-based electronic format of the public register; - Administrative regulations for setting up the national Biosafety register, specifying principles for identification,	- Required administrative regulations, specifying the main public register principles, drafted and published; - Number of simulated (for learning) versus the real administrative cases scrutinized, employing the newly drafted Biosafety	- Delay in administrative set up due to political or bureaucratic procedures; - Lack of technical personnel, having the required combination of inter-disciplinary skills, to carry out administrative tasks; - Lack of technical IT	– Setting up and constant updating of nBCH, containing all relevant information required under the CPB and other international obligations, thus making information accessible to broad public; – Envisage setting up the

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

	collection, input and update of Biosafety information sharing, management of confidential information, drafted and approved	register in Lithuania	infrastructure needed;	separate official website of the National Biosafety;
C1. 3 Setting up, maintain and update an inventory of technical assistance required for emergency response, ensuring continued replacement and/or procurement of any additional equipment needed	- Additional list of equipment for detection and identification of GMOs during the handling, transport, use, transit and release, including post-release monitoring and enforcement, drafted and approved by the NEA; - Guidelines for emergency response cases (i.e. hotline, national contact details) elaborated and operational;	- Written and approved rules set up and available, (for different use of GMOs, incl. contained use, deliberate release into environment, intentional placing on the market, possible remedial cases, etc.); - Responsible entities (i.e. certified national GMO Laboratory) nominated and approved; - Staff of the appointed responsible entity (-ies) trained to deal with emergencies;	- Lack of financial resources, (i.e. remediation equipment for emergency measures could be very expensive), lack of relevant means for eliminating GMOs from the environment; - Difficulty in setting up institutional arrangements and internal procedures needed to apply and enforce the drafted regulatory regime; - Lack of cooperation among the national institutions	– Ensure that people responsible for emergency cases are fully aware of their tasks, probably written contracts in the enterprises should be established; – Envisage preparation of the procedural manual for internal use by the personnel of the civil entities, among others, in the following cases: - Emergency response, - Accidental release, - Illegal movement and transit; - Contained use, - Deliberate release into environment, etc.
C1. 4 Revise and update national system for data collection, validation and inputing into the nBCH	- Country information available and constantly updated on the BCH central portal; - Standards for producing & validating data established; - The updated BCH interoperable by linking it to the BCHM, Secretariat of the European Commission	- Number of hits accessing the revised and updated nBCH; - Number of records on the nBCH; - Developed instructional and user manuals; - Number of people trained to ensure continuity of administrative tasks ahead;	- Different stakeholders are not aware of the nBCH existence; - National BCH is not updated on a regular basis due to dominant turnover of personnel/staff; - Lack of personnel with the right combination of skills; - Lack of technical infra-structure developed in place;	- Raising awareness within government agencies on developed national system for access, handling, storage and sharing of Biosafety information; - Sustained capacity for maintaining and updating the nBCH; - Adequate know-how management tools in place;
C1. 5 Designing and setting up a separate aggregated website of the NCA Biosafety Office, linking it to the official websites of NCAs', thus ensuring provision of available information to the	- Standardized rules and mechanisms for external data input via the developed website (i.e. NGOs, private sector, etc.) developed; - Appropriate methods and mechanisms for inter-institutional cooperation and	- Required number of administrative regulations, specifying the main public register principles, drafted and published; - Continuous functioning the assigned NFP of nBCH, that ensures proper	- Lack of technical personnel, holding the required combination of inter-disciplinary skills, to carry out administrative tasks; - Lack of technical IT infrastructure needed;	- Verify and prove estimated financial resources required for equipment component; - Consider the formation of an ad-hoc interim workgroup to coordinate the planning of national activity

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

national stakeholders	information exchange among national Competent Authorities (CAs) developed;	administration of the developed website of the National Biosafety Office;		
2 OUTCOME:				
C2. A fully operational national administrative and methodological risk assessment (RA) system finalised and in place	- National institution (i.e. Risk Assessment Co-ordinating Centre under the Academy of Sciences) appointed and authorized entity, responsible for methodological aspects of risk assessment (RA); - Defined rules of criteria for identification, appointment and revision (ToRs) of RA experts and entity developed; - National list / roster of RA experts elaborated; - National administrative guidelines - methodological procedures for carrying out risk assessment developed, set in place & operational	- Percentage of assessments completed; - Procedures for carrying out risk assessment agreed upon; - Number of personnel educated and trained;	- Lack of qualified risk assessment experts in place; - Lack of consensus in reaching decisions on risk assessment; - Insufficient scientific data/info provided; - Credibility of data provided for risk assessment;	- Institutional capacity building in risk assessment; - Encourage regional cooperation in RA; - Encourage efficient dialogue between proponents (notifiers) and administrators concerning RA applications
ACTIVITIES:				
C2. 1 Definition of criteria for identification, appointment and revision of RA experts	• Conventional rules of criteria for identification (ToRs), appointment and revision of RA experts elaborated;	- The roster of RA experts elaborated and revised in accordance with the national rules elaborated; - Number of RA experts meetings held	- Lack of national qualified risk assessment experts in place;	- Institutional capacity building in risk assessment; - Encourage regional collaboration in RA;
C2. 2 Development of the internal administrative rules for the designated authorized entity, i.e. GMO Scientific Coordination Centre	• National internal rules (procedures) for carrying out risk assessments agreed and operational; • Roles of trained specialists (trainers) on administrative and methodological parts of RA defined and employed;	- Percentage of risk assessments completed and decisions taken; - ToRs for trainers on administrative and methodological parts of RA drafted; -	- National entity (i.e. Risk Assessment Scientific Co-ordinating Centre under the Academy of Sciences) is not appointed and authorized yet;	- Envisage definition, approval and publishing of methodologies on Risk Assessment and Management procedures; - Encourage regional collaboration in RA;
C2. 3 Definition, approval and publishing of methodological national guidelines on RA	• National guidelines to include, where relevant, assessment and evaluation of socio-economic issues in RA	- Operational manual for internal use by personnel of the national institution (entity), nominated to be	- National entity (i.e. Risk Assessment Scientific Co-ordinating Centre under the Academy of Sciences) is not	- Encourage co-operative dialogue between the proponents (notifiers) and administrators concerning

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

and management procedures	and management in place	responsible for RA, approved and published;	appointed and authorized yet;	RA applications;
3 OUTCOME:				
C3. A fully operational national decision-making system finalized and in place	• National administrative system to handle notifications or requests for authorization institutionalised, tested and making operational with defined responsibilities and internal procedures;	- Number of decisions made; - Number of decisions reviewed on risk assessment; - Number Public consultation in decision held, pursuant to Art.23.2 of the CPB;	- Trade, policy and other issues interrupt smooth decision-making; - Negative national public attitude and/or opinion on Biosafety issues;	- Institute a strong decision-making body which enjoys public confidence and credibility; - Involve the main national stakeholders in informed decision-making; - Envisage to establish an appeal / review mechanism for the decision-making
ACTIVITIES:				
C3. 1 Revision of the administrative roles and responsibilities of the NCAs' personnel, setting up the rules and procedures for decision-making bodies for handling requests for authorization	• Duly authorized national competent authorities, their subordinated organizations, responsible for receiving and handling requests for permits (import, export, domestic use, contained use, AIA, transit, field trials, etc.) in place;	- Operational manual for internal use of NCA(s) drafted; - National guidelines on decision-making process developed;	- National institutional system and administrative division of responsibilities are not clarified ultimately; - Lack of appropriate administrative expertise for making administrative system operational	- Envisage to organise consultative workshops of relevant stakeholders to discuss
C3. 2 Identification of socio-economic issues of specific national interest to be taken into consideration during decision-making process	• Formation of an ad-hoc body (i.e. internal working group) for identifying socio-economic issues of specific interest to the Lithuanian case, delivering their opinion	• Procedural mechanisms to include, where applicable, the social economical considerations in decision-making process elaborated; • Number of meetings and decisions made by the ad-hoc internal working group;	- Lack of appropriate expertise or inability to identify and make broader assessment on national social and economical priorities to be taken into consideration during decision-making process;	- Envisage to organise consultative meetings/ workshops of relevant stakeholders to discuss how to approach and integrate socio-economic issues into informed decision-making
C3. 3 Organization of 2 consultations with relevant stakeholders to discuss how to approach and integrate socio-economic issues into informed decision-making. Participation of the principle national key stakeholders concerned: decision-makers from central (NCA, NCC) local (municipalities); NGOs,	• National consultative meetings organized by the NEA during the project time frame by year 2009: 1. Initial (mobilization) phase; 2. Interim phase; •	• Minutes and proceedings of the consultative meetings prepared and disseminated among the participants of the national events; • List of institutions, invited to make their contributions for the collaborative achievement of outcome, composed; • Lists of beneficiary organizations and delegated participants composed;	- Lack of appropriate expertise or inability to identify and make broader assessment on national social and economical priorities to be taken into consideration during decision-making process; - Lack of required skilful human resources to guide (as resource persons) the indicated national Biosafety	- Promote more efficient collaboration among responsible officials within executing agencies; - Envisage increasing in-house competence on proper handling of requests and equip with relevant capacity building tools (trainings, workshops, etc.)

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

scientists, public groups, etc. Estimation: 1 day x 2 times / 15-30 participants			events;	
4 OUTCOME:				
C4. Increased in-house competence on handling of requests is available and equipped with tools for related additional capacity building activities	• National administrative system to handle notifications or requests for authorization in place; • Relevant tools and trainings for administrative processing of RA and informed decision-making, developed and organized;	• ToR drafted and contracts implemented for the preparation & implementation of additional capacity building activities under the agreed timetable; • Estimated number (5-6) of national training workshops for administrative processing of RA and informed decision-making organized;	- Revised administrative mechanism cannot be implemented because of inefficiency of current administrative structures; - Lack of public access to information on the drafted decisions; - Inappropriate methods for raising awareness throughout the key responsible stakeholders;	- Promote training on methodological aspects of RA and handling requests for authorization, related to Biosafety in Lithuania; - Promote national mechanisms for public access to thematic information in country; - Proper profiling of public in order to use appropriate methods for information dissemination to different stakeholders;
ACTIVITIES:				
C4. 1 Organization of 3 national training workshops/seminars, (in total for 2 days each) inviting experts from the national institution (entity) in charge of administrative methodological aspects of RA and handling requests for authorization on the basic requirements of RA and management (methods, equipment, costs, etc.); Estimated audience: National GMO Management Committee, Members of NEAs involved in handling of notifications and requests, according to Articles 15-16, of the CPB. Estimated number of participants: 15.	• NEA envisaged several (3) training workshops/seminars during the project time frame, possibly back-to-back with the planned workshops under the regulatory issues (B2.1): 1. Initial (mobilization) phase; 2. Interim phase; and 3. Final phase (end of project); • NEA envisaged, in consultation with UNEP-Biosafety, to organize 1 additional training session (for 3 days) on informed decision-making for responsible administrative officers of middle-to-senior level from different state institutions, national experts from different institutions; estimated number of participants: 15-20	• Minutes and proceedings of the training prepared and disseminated among the participants and other interested stakeholders of the national events; • List of institutions, invited and involved to make their contributions towards the collaborative achievement of outcome, composed; • Lists of beneficiary organizations and delegated participants composed; • Proceedings (educational material) of the national trainings printed and disseminated among the participants of the interested parties, i.e. key national stakeholders (decision makers,	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as trainers, resource persons) the indicated national Biosafety events; - Lack of cooperation between responsible officials within the NCAs;	- Verify and prove estimated financial resources required for group Training and Workshops; - Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Prepare the necessary training manuals for trainers on handling requests for authorization (including administrative processing of RA and informed decision-making) (addressed in activity C4.3)

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

Total: 3x2days/20 participants from key stakeholders (NCAs		NCC members, NGOs, public interest groups, etc.);		
C4. 2 Preparation of the technical guides/manuals on handling requests for authorization, including administrative processing of RA and informed decision-making for training purposes	• ToR drafted and contracts implemented preparing the required training guides for trainers under the agreed timetable	• The required number of procedural training manuals (guides for national trainers) on Biosafety administrative issues produced, printed and disseminated ("hands-on" copies for daily use);	- Absence of the explicit assignments (ToR) or contractual commitments to prepare training manuals; - Overlapping institutional responsibilities among the institutions concerned;	- Promote collection of appropriate information on experiences in other countries; - Promote trainings on CPB, national Biosafety administrative system; - Envisage organization of several simulations, as appropriate, for the administrations of NCAs;
C4. 3 Organisation of two on-job trainings (2 sessions) with case studies (simulations) to test that the administrative and further developed "follow-up" systems are functioning in place. Estimated: 2 times / 2 days number of participants: 10-15	• NEA envisaged to organize 2 additional on-job trainings (for 2 days) for responsible administrative officers of middle-to-senior level from different state institutions, estimated number of participants: 15; timing: during the interim project phase; • ToR drafted and contracts prepared for trainers under the agreed timetable;	• 2 on-job training sessions, simulating emergency operations for the principal actors organized and provided • The required number of training materials (case-studies, presentations) on Biosafety administrative and "follow-up" systems (i.e. monitoring and enforcement/ control and inspection) produced, and disseminated (as handouts for daily use)	- Absence of the explicit assignments (ToR) for trainers to deliver on-job trainings; - Lack of required skilful human resources to guide (as trainers, resource persons) the indicated national Biosafety events; - Inappropriate budgetary allocations for group Training and Workshops;	- Prepare the necessary training manuals for trainers on handling requests for authorization (as addressed in activity C4.3) - Promote collection of appropriate information on experiences in other countries;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

COMPONENT: D. **FOLLOW-UP MECHANISMS FOR MONITORING OF ENVIRONMENTAL EFFECTS AND ENFORCEMENT (CONTROL & INSPECTION)**				
OBJECTIVE **D.** To assist Lithuania to establish and consolidate a functional national system for monitoring of environmental effects and enforcement ("follow-up" mechanisms)	• National system for monitoring and enforcement (control and inspection) developed, tested, approved, published and in place	• Follow-up mechanisms for monitoring of environmental effects and enforcement (control and inspections) set up in place for the implementation	- Lack of relevant political experience and appropriate administrative expertise for making follow-up mechanisms operational, i.e. "up and running"	- Identify and develop national institutional setting appropriate for monitoring of environmental effects; - Provide technical capacity building support by conducting consultative seminars/trainings, as appropriate, for responsible regulators and technical administrators
1 OUTCOME:				
D1. Identified and developed national institutional setting for monitoring of potential effects on environment and human health and transboundary movement (registered in BCH) of GMOs	- Roles of accountability and division of responsibilities clearly divided among the national institutions authorized for monitoring of environmental effects; - Written and approved internal procedures dividing roles and responsibilities in place;	- The MoE or its subordinated institution (i.e. Environmental Protection Agency) or State GMO Service under the Ministry of Environment appointed to be responsible for monitoring of GMOs deliberate release into environment & placing on the market; -	- Division of administrative roles and responsibilities either unclear, overlapping or leaving gaps; - Internal procedures dividing administrative roles and responsibilities are not in place and not enforced yet;	- Promote awareness raising among responsible authorities, i.e. how to divide roles, tasks and responsibilities in systematic way in order to avoid either overlapping or gaps;
ACTIVITIES:				
D1. 1 Clarification and separation of roles and responsibilities for national institutions (i.e. GMO Unit of the MoE, future GMO State Service under the MoE, role of Environmental Protection Agency under the Ministry of Environment, others) to be responsible for monitoring of environmental effects	• Scheduled meetings with relevant national stakeholders, organized by NEA in cooperation with NCC throughout the implementation process of NBF during: - Initial (mobilization) phase, - Interim phase; • Organization of 2 rounds national consultations with key principle stakeholders to discus relevant issues accountability and division of responsibilities	- Minutes of periodic meetings (discussion items, decisions taken, monitoring of implementation) reported under the agreed timetable; - List of institutions involved to make their contributions towards the collaborative achievement of outcome, composed; - The MoE or its subordinated institution (i.e. GMO State Service	- Division of administrative roles and responsibilities either unclear, overlapping or leaving gaps; - Polarization of the debates disabling co-ordination for reaching consensus decision;	- Promote awareness raising among responsible authorities, i.e. how to divide roles, tasks and responsibilities in systematic way in order to avoid either overlapping or gaps; - Provide technical capacity building support by conducting consultative seminars/trainings, as appropriate, for responsible regulators and technical administrators;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

	developing efficient national institutional setting for monitoring of environmental effects	under the Ministry of Environment) established and authorized to be responsible for monitoring of environmental effects		
D1. 2 Preparation of the operational methodological guidelines and rules (i.e. administrative procedures) for monitoring of GMOs environmental effects and enforcement (control and inspections) measures required for handling, transport, usage, transfer and release of GMOs	• ToR for preparation of the required operational manual on monitoring of GMOs' environmental effects drafted under the agreed timetable;	- The required sets of operational manual/ guidelines for monitoring of environmental effects drafted under the agreed timetable; - Manual on methodologies for monitoring of environmental effects elaborated for different cases of GMOs usage, including: - Post-release monitoring; - Monitoring for contained use;	- Absence of explicit assignments (ToR) or contractual commitments to prepare training manuals; - Overlapping (or gapping) institutional responsibilities among national institutions, responsible for monitoring;	- Promote collection of appropriate information on experiences in other countries; - Envisage (sub) regional collaboration with other countries developing common guidelines and rules for monitoring of environmental effects (and further effects on human, animal, plant life or health)
D1. 3 Preparation of technical methodological materials, i.e. training guides for trainers on proposed national monitoring system	• ToR for preparation of the national methodological materials on monitoring of environmental effects drafted under the agreed timetable	• A set of training guide for trainers on monitoring of environmental effects drafted, approved and published;	- Absence of explicit assignments (ToR) or contractual commitments to prepare methodological materials; - Overlapping (or gapping) institutional responsibilities among national institutions, responsible for monitoring;	- Improve the knowledge of national experts on monitoring the environmental effects of GMOs' release into the environment; - Envisage (sub) regional collaboration with other countries developing common guidelines and rules for monitoring of environmental effects (and further effects on human, animal, plant life or health)
2 OUTCOME:				
D2. Improved and strengthened national institutional setting and related mechanisms for enforcement (control and inspections)	• National mechanisms for enforcement (control and inspections) the provisions of CPB, EU law and other international obligations drafted under the agreed timetable; • Roles of accountability and	- The MoE or its subordinated institution (i.e. State Environmental Protection Inspectorate), or State GMO Service under the Ministry of Environment established and authorized to be	- National guidelines and rules approved and in place, but are not followed either due to political ignorance, low acceptance/ awareness or insufficient institutional capacities among the responsible	- Train specialists, especially governmental officers in the NCAs, to interpret and to comply with CPB in a proper way; - Improve the coordination efforts on awareness raising, i.e. how to divide

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

	division of responsibilities clearly divided among the national institutions authorized for enforcement (control and inspections);	responsible for safety control and enforcement (control and inspection) of any regulative aspect; - Internal guidelines, rules and regulations on enforcement (control and inspection) of GMOs written and approved; - Regular reporting to the CPB Secretariat about the implementation of CPB;	institutions; - Overlapping (or gapping) institutional responsibilities among national institutions, in charge of enforcement (control and inspections) mechanisms;	roles, tasks and responsibilities in systematic way among the national institutions in order to avoid either overlapping or gaps; - Ensure the regular reporting to the CPB Secretariat about the implementation of CPB, making data available to other interested parties;
ACTIVITIES:				
D2. 1 Development of internal guidelines and rules (administrative procedures) on enforcement activities (control and inspections), required for handling, transport, use, transit and release of GMOs	• Internal guidelines and rules (administrative procedures) on enforcement activities (control and inspections), required for handling, transport, use, transit and release of GMOs drafted under the agreed timetable;	- Internal guidelines and rules (administrative procedures) on enforcement activities (control and inspections), required for handling, transport, use, transit and release of GMOs written and approved;	- National guidelines and rules in place, approved, but are not followed either due to political ignorance, low acceptance/awareness or insufficient institutional capacities within the responsible institutions; - Overlapping (or gapping) institutional responsibilities among national institutions, in charge of enforcement mechanisms (control and inspections);	- Train specialists, especially governmental officers in the NCAs, to interpret and to comply with CPB in proper way; - Ensure the regular reporting to the CPB Secretariat about the implementation of CPB, making data available to other interested parties; - Improve the coordination efforts on awareness raising among the national institutions concerned;
D2. 2 Preparation of necessary methodological materials, i.e. training guides for trainers on the enforcement measures (control and inspections) for handling, transport, use, transit and release of GMOs (is is all one in budget, ie all these 3 activities?	• ToR for preparation of the required national enforcement (control and inspections) methodological materials drafted under the agreed timetable;	• A set of training guide for trainers on enforcement (control and inspections) drafted, approved and published;	- Absence of explicit assignments (ToR) or contractual commitments to prepare methodological materials; - Overlapping (or gapping) institutional responsibilities among national institutions, responsible for monitoring;	- Improve the knowledge of national experts on enforcement measures (control and inspections) for handling, transport, use, transit and release of GMOs - Envisage (sub) regional collaboration with other countries developing common guidelines and rules for enforcement measures (control and inspections) for handling, transport, use, transit and release of GMOs

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

3 OUTCOME:				
D.3 Increased in-house competences on monitoring and inspections are available and equipped with tools for related additional capacity building activities	• National follow-up monitoring and enforcement (control and inspection) mechanisms developed, tested and operational in place; • Additional relevant national activities (workshops, trainings), concerted with NEA, increased in-house competence, thus enabling capacity building;	• ToR drafted and contracts implemented for the preparation & implementation of additional capacity building activities upon the request and under the agreed timetable of NEA; • Estimated number (4-5) of national training workshops for follow-up monitoring and enforcement (control and inspection) mechanisms organized;	- Revised administrative mechanism cannot be implemented because of inefficiency of current administrative structures; - Lack of public access to information on the drafted decisions; - Inappropriate methods for raising awareness throughout the key responsible stakeholders;	- Promote training on methodological aspects of RA and handling requests for authorization, related to Biosafety in Lithuania; - Promote national mechanisms for public access to thematic information in country; - Proper profiling of public in order to use appropriate methods for information dissemination to different stakeholders;
ACTIVITIES:				
D3. 1 Organization of national workshop on the "Control of GMOs transboundary movements" (total for 2 days), inviting specialists from the national governmental administrations in charge of implementation enforcement mechanisms (control and inspection). Purpose: to discuss relevant methods for control of the transboundary movements of goods and the detection of GMO (methods, equipment, costs, etc.) under the CPB and the BCHM provisions; documentation requirements for GMO shipments. Estimated number of delegated participants from key stakeholders (NCAs): 40 (2-days / 40 participants)	• NEA envisaged to organize one (1) national workshop during the second quarter of project duration, possibly back-to-back with the planned specialized trainings under the "follow-up" issues (D 3.2) • Organization of 2 specialized training workshops (total for 3 days each) providing instructions and professional training for environmental inspectors and custom officers on inspection of field releases of GMOs; GM products placed on the market; (2x3 days/ 20 participants)	• Minutes and proceedings of the national workshop printed and disseminated among the participants and other interested parties; • Lists of beneficiary organizations and delegated participants composed;	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as trainers, resource persons) the indicated national Biosafety event; - Lack of cooperation between responsible officials within the NCAs;	- Verify and prove estimated financial resources required for group Training and Workshops; - Consider the formation of a internal workgroup to coordinate the planning of the national workshops; - Prepare the necessary training manuals for trainers on national enforcement (control and inspections) methodological materials (as addressed in activity D2.2)
D3. 2 Organization of 2 specialized training workshops (total for	• NEA envisaged organizing two (2) training workshops during the second and the third	• Material and proceedings of the training workshops (case-studies, simulations, if needed)	- Inappropriate budgetary allocations for group Training and Workshops;	- Verify and prove estimated financial resources required for group Training and

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

3 days each) providing instructions and professional training for environmental inspectors and custom officers on inspection of: - Contained use of GMOs; - Field releases of GMOs; - GM products placed on the market Estimated: 2x3days/20participants	quarters of project duration, one possibly back-to-back with the planned national workshop under the "follow-up" issues (D3.1), focusing on Inspections procedures applied in different cases (contained use; deliberate release; food, feed, processing)	printed and disseminated among the participants and other interested parties; • Lists of beneficiary organizations and delegated participants composed;	- Lack of required skilful human resources to guide (as trainers, resource persons) the indicated national Biosafety trainings; - Lack of cooperation between responsible officials within the NCAs	Workshops; - Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Prepare the necessary training manuals for trainers on national enforcement (control and inspections) methodological materials (as addressed in activity D2.2)
D3. 3 Organization of 2 intense training courses (4 days each) for technical personnel on GMOs detection/ testing and monitoring activities Estimated number of national trainees: 10	• NEA envisaged organizing two (2) training courses during the third and the fourth quarters of project duration, inviting national specialists and experts of GMO detection and quantitative analysis. The participants will be trained to use different tests to detect GMO contamination (ex. PCR, ELISA, on-spots tests); methodologies and procedures for monitoring environmental effects of GMOs	• Material and proceedings of the training workshops (case-studies, simulations, if needed) printed and disseminated among the participants and other interested parties; • Lists of beneficiary organizations and delegated participants composed;	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as trainers, resource persons) the specialized Biosafety training courses; - Lack of cooperation between responsible officials within the NCAs;	- Verify and prove estimated financial resources required for group Training and Workshops; - Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Prepare the necessary methodological materials for trainers on monitoring of environment effects (as addressed in activity D1.3)

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

COMPONENT: E. PUBLIC AWARENESS, PARTICIPATION AND INFORMATION EXCHANGE IN THE DECISION MAKING PROCESS				
OBJECTIVE **E.** To assist Lithuania in elaboration of the relevant operational systems for: Public awareness; Education; Access to information; and Participation in the decision-making process (In accordance with the CPB Articles 20, 22, 23)	- Public awareness, access to information, participation on Biosafety-related issues are integral components of the national strategy on sustainable development; - Biosafety related topics included in the programs of higher education curricula; - National Biosafety Public Awareness and Education Strategy and Action Plan drafted for adoption; - Workshops/trainings on access to and sharing of biosafety information organized; - Educational materials on Biosafety / biotechnology issues developed and distributed among the stakeholders concerned;	- National strategy on sustainable development updated, incorporating public awareness and participation issues therein; - National Strategy on Biotech Development, National Program and Action Plan for safe use on various applications of modern biotechnology involve elaborated chapters on public awareness, education and participation in decision-making; - Public debates and open discussions in media; - National BCH operational and updated on continuous basis; - Reviewed examples on public information and participation compiled;	- Lack of political support; - Biosafety is not considered as a part of the national Strategy on sustainable development; - Lack of capacity (human resources, inappropriate administrative setting, etc.) to organize and address public participation and awareness issues; - Unilateral centralized control and possible dependence on media interests (ex. hypertrophied "front-page" news, etc.); - Mass media is not willing to promote open debates on Biosafety;	- Promote broader political collaboration, supporting national stakeholders and promoting awareness on responsibilities taken to implement objectives of CPB and other international obligations with regard to public awareness, education, participation in the national decision-making process; - Envisage developing strategic unified action plan for public awareness, education, participation in decision making process; - Secure sufficient financial and institutional resources for implementation of the drafted national public awareness action plan;
1 OUTCOME:				
E1. National public awareness and education mechanisms, strengthening public access to Biosafety / Biotechnology information, elaborated and operational	- Strategies for targeted different interested groups of national stakeholders elaborated; - Curricula programs, incorporating Biosafety information, participation themes, developed; - Representatives of local governments, public groups of civil society involved in the work of GMO Steering Committee (as observers)	- Biosafety thematic information incorporated into the training courses of environmental, agricultural, health, customs and other civil refresher courses; - Percentage (%) of students educated and trained on Biosafety curricula topics, supporting development of scientific and technological potential; - Educational materials on Biosafety / biotechnology issues developed;	- Lack of political support, realizing that public awareness and participation on Biosafety issues are not considered as constituent part of national Strategy on sustainable development; - Lack of capacity (human resources, inappropriate administrative setting, etc.) to inform public and create targeted messages to different stakeholders; - Lack of experienced national faculty& academic curricula developers	- Raising awareness of educators/trainers on the need to include Biosafety as part of the biotechnology curriculum for specialists; - Envisage developing strategic unified action plan for public awareness, education, participation in decision making process;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

ACTIVITIES:				
E.1. 1 Elaborate national public awareness and education strategy and action plan for participation in decision-making processes on Biosafety issues	- Public awareness, access to information & participation on Biosafety-related issues are integrated into the national Strategy on sustainable development; - National Biosafety Public Awareness and Education Strategy and Action Plan for participation in decision-making processes drafted for adoption	- National Strategy for Sustainable Development amended, incorporating Biosafety issues on public awareness, education, participation in decision making process therein; - National Action Plan for safe use on public awareness, education, participation in decision making process elaborated for final approval by the national competent authority	- Lack of political recognition and responsive commitment to harmonize Biosafety issues with other national sectors (ex. public relations); - Lack of requisite consensus on prioritising Biosafety public awareness and education issues;	- Promote public awareness on necessary synergies between biotechnology and Biosafety; - Promote relevant debates, discussions and exchange of information on best practices for development of curricula program on Biosafety/ Biotechnology in higher educational Institutions
E.1. 2 Develop curricula programs on Biosafety/ Biotechnology in higher educational institutions in relation to the conservation and sustainable use of biodiversity, taking also into account risks to human health	- Strategies for targeting different potential groups of national stakeholders (ex. students, graduates, members of NGOs, civil servants, etc.) elaborated; - Topics related to Biosafety/ Biotechnology included in the higher education curricula studies;	- Percentage (%) of students educated and trained on Biosafety curricula topics, comparing to overall number of graduates; - Educational materials on Biosafety / biotechnology issues developed (ex. printed lectures' abstracts, course's presentations, regular monthly newsletter)	- Lack of academic faculty (lecturers, teachers) to develop thematic curricula; - Lack of capacity (human resources, inappropriate administrative setting, etc.) to inform public and create targeted messages to different stakeholders;	- Promote public debates on the best practices learnt for development curricula on Biosafety/ Biotechnology; - Envisage developing public surveys and opinion polls on the level of general public awareness on Biosafety related issues
E.1. 3 Organization of 2 national surveys and public opinion poles on the level of public awareness of national biosafety policy	- National public opinion poles (2) organized by the NEA, carried out by the contracted independent public relations agency during the project time frame by year 2009: 1. Initial (mobilization) phase; 2. Terminal (final) phase.	- Results of representative public opinion poles on Biosafety related issues documentary summed up; - Summarized surveys, identifying the major information gaps and needs in the national Biosafety public relations policy;	- Insufficient technical and financial capacities (human resources, budget) to contract independent agency in order to carry out representative objective public opinion poles for national surveys	- Verify estimated financial resources required to carry out national public opinion polls; - Employ the best national practices learnt for preparation of the outreach public awareness materials;
2 OUTCOME:				
E.2 National system for public participation in the decision-making process, through enabled access and sharing of Biosafety/ Biotechnology	- Responsible national entity (public agency/state institution) for managing public awareness and education campaigns nominated and appointed;	- Number of hits accessing the revised and updated nBCH; - Number of records on the nBCH; - Regularity of updates to	- Different stakeholders are not aware of the nBCH existence; - National BCH is not updated on a regular basis due to dominant turnover	- Raising awareness within government agencies on developed national system for access, handling, storage and sharing of Biosafety information;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

information, strengthened and enforced	- Records of the access to the national BCH; - Developed instructional user manuals; - Country information available and constantly updated on the BCH central portal	the nBCH requested by the NEA; - Number of people trained to ensure continuity of administrative tasks ahead;	of personnel/staff; - Lack of personnel with the right combination of skills; - Lack of technical infra-structure developed in place;	- Sustained capacity for maintaining and updating the nBCH; - Adequate know-how management tools in place;
ACTIVITIES:				
E.2. 1 Identification of national entity (designated and authorized national institution, agency) responsible for managing public awareness, access to and dissemination of thematic information, and education campaigns related to Biosafety/ Biotechnology issues	- The MoE (or the duly authorized subordinated institution) identified to be responsible for public awareness and public participation campaigning in the decision-making processes related to Biosafety/ Biotechnology issues;	- Roles of competences and responsibilities divided among the national institutions (governmental and public sector) involved in public awareness raising, participation, access to and dissemination of thematic information on Biosafety; - Written and approved internal procedures dividing administrative roles and responsibilities in place	- Internal procedures dividing administrative roles and responsibilities are not in place and not enforced yet; - Lack of capacity (human resources, inappropriate administrative setting, etc.) to inform public and create targeted messages to different stakeholders;	- Promote awareness raising among responsible government and public authorities involved in elaboration of public awareness, education and participation processes;
E2. 2 Definition and specification of "entry points" for public participation in decision-making process on GMOs in relevant regulations and administrative procedures	- Strategic documents (national regulations, guidelines, etc.) for public involvement and participation in decision-making process elaborated;	- Documented minutes of meetings, organized by the NEA; - Public awareness raising materials elaborated by the nominated public service/ agency; - Contact lists of journalists/ media involved in scrutinizing biosafety related issues, compiled;	- Public service/agency does not properly promote messages on Biosafety during campaigning; - Insufficient will from the side of public to participate due to lack of information on biosafety related issues; - Strategies do not target main issues and are biased in favour of one or another influential group of interest	- Promote awareness raising of the need to address clear messages that target the appropriate audience and are directly related to Biosafety/biotechnology issues;
E2. 3 Establish regular mechanisms for networking with media on Biosafety related issues	- Information on different intersectional policies on environmental, legislative, economic, social aspects of current Biosafety policy communicated to relevant stakeholders	- Minutes and the official protocols of the meetings (items discussed, decisions taken, monitoring of implementation) published in the national official gazette, national Biosafety database nBCH ("News	- Polarization of the debates disabling co-ordination mechanisms for Biosafety intersectional integration; - Lack of comprehension from mass media due to complexity of issues	- Promote cooperation and awareness raising, exchange of information throughout national stakeholders; - Ensure open-dialogue for public awareness and support for broader comprehension on Biosafety issues;

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

		section"), by other means (briefings, etc.), as agreed with NEA and NCC		
3 OUTCOME:				
E.3 Increased in-house competence on public awareness, information and participation in decision making process is available and equipped with tools for related additional capacity building activities	- National system of public awareness, information, participation in decision making process in place; - Relevant tools for delivering trainings developed and organized; - Strategies for active public involvement in the work of national state biosafety committee developed and discussed in NEA, NCC; - Strategy for public awareness campaigning developed by the nominated Public service/agency;	- ToR drafted and contracts executed for the preparation, implementation of additional capacity building activities under the agreed timetable; - Estimated number (5) of national training workshops for public awareness, information and participation organized; - Documents (strategies, advertising materials) published, disseminated; - Contact lists of journalists/ media involved in scrutinizing biosafety related issues, compiled;	- Inappropriate methods for raising awareness throughout the key responsible stakeholders; - Lack of public access to information on the NEA initiatives on public awareness and information; - Public service/agency does not correctly promote messages on Biosafety during campaigning;	- Raising awareness of the need to promote messages that target the appropriate audience and are directly related to Biosafety; - Promote national mechanisms for public access to thematic information in country; - Proper profiling of public in order to use appropriate methods for information dissemination to different stakeholders;
ACTIVITIES:				
E.3. 1 Preparation of training guides for public information and participation incorporating lessons learnt from other pilot MSPs	- Relevant tools for delivering trainings developed and organized; -	- ToR drafted and contracts executed for the preparation, implementation of additional capacity building activities under the agreed timetable; -	- Lack of public access to information on the NEA initiatives on public awareness and information; - Public service/agency does not correctly promote messages on Biosafety during campaigning;	- Promote national mechanisms for public access to thematic information in country; - Proper profiling of public in order to use appropriate methods for information dissemination to different stakeholders; -
E.3. 2 Organization 2 training courses on the topic of "Public information and participation in biosafety" for national trainers" (local officers from the public service/agency), inviting international experts to teach short-term courses and give public presentations on public	- NEA envisaged to organize 2 sessions of training courses during the project time frame: 1. Initial (mobilization) phase; 2. Interim phase;	- Terms of references for national trainings, outlining specific objectives and strategy to achieve them drafted; - Monitoring reports on the management inputs and outcomes (timing, experts, facilitation, lessons learnt);	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as facilitators, educators, resource persons) indicated national Biosafety events;	- Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Prepare the necessary training manuals for trainers on public awareness, education and information issues (address in project activity E3.3);

Annex C: Log Frame matrix for the project "Support for the Implementation of the National Biosafety Framework for Lithuania"

education and information; duration 2 times/2 days each training, tentative number of participants: 10-15				
E3. 3 Organization national public awareness seminars (2 events/ for a day each); estimated number of participants 40-60) of broad participation for different public stakeholders, including governmental officials, media, journalists, scientists, NGOs representatives of the general public. The seminars should investigate the relationship between information exchange and perception of the biotechnology and its applications ("Safe or hazardous?")	- NEA envisaged several (2) public awareness seminars/ workshops during the project time frame: 1. Initial (mobilization) phase; 2. Interim phase; - NEA foresees, in consultation with UNEP-GEF, to organize an additional closing public awareness conference (for 2-3 days) during the Final phase (end of project); on the topic of educative informed decision-making for National Biosafety team: responsible administrative officers of different state institutions, NCA, NCC, national experts. Estimated number of participants: 40	- Minutes and Proceedings (printed educative material) of the national public awareness seminars and gala conference printed and disseminated among the participants of the interested parties, i.e. key national stakeholders (decision makers, NCC members, NGOs, public interest groups, etc.);	- Inappropriate budgetary allocations for group Training and Workshops; - Lack of required skilful human resources to guide (as lectors, trainers, educators, resource persons) the indicated national Biosafety events; - Lack of cooperation between responsible officials within the NCAs;	- Consider the formation of a internal workgroup for trainings to coordinate the planning of the activities; - Envisage beforehand preparation of necessary training materials on public awareness, education and information issues (address in project activity E3.3)
E.3. 4 Preparation and disseminatation the outreach public awareness materials for different targeted stakeholders during the organized public debates and meetings	- ToR for the preparation of required outreach public awareness methodological materials (for ex. different educative materials: leaflets, brochures, articles in newsletters, magazines, interviews on TV, radio), including 2 sets of training guides for trainers, drafted under the agreed timetable	- 1-st set of technical Training Guidelines for trainers on public information, education and participation mechanisms drafted, approved and published; - 2-nd set of Training Guide for trainers on access, handling, storage and sharing of Biosafety information, including comprehensive use of the expanded national Biosafety information database (nBCH), drafted;	- Absence of explicit assignments (ToR) or contractual commitments to prepare methodological materials	- Improve the know-how on applicable public awareness & information exchange mechanisms in decision making processes; - Promote (sub) regional collaboration with other countries using the best practices learnt for implementation of their respective public awareness and education mechanisms

Annex D

National Biosafety Legislation in Lithuania

Annex D: National Biosafety legislation in Lithuania

List of adopted valid secondary legislation of Biosafety-related national legal acts:

1. The frame *Law on GMOs* (No.IX-375) was adopted on June 12, 2001 (Official Gazette, 2001, No. 56-1976) legally came into force since 31 of December 2002. New wording of amended paragraphs 2, 4, 8 and Annex of the *Law on GMOs* dated on 20 March, 2003 No. IX-1384, Official Gazette No. 34-1419, Nr. IX-1384.
2. Order of the Minister of Environment (No. D1-225, 29/04/2004) on *"Detailed procedures for the deliberate release into environment and placing on the market of GMOs and/or GMPs in Lithuania"* (Official gazette, 2004, No. 71-2487), since May 2004, amending the previous legal act.
3. *Order on Regulation of GMOs Classification and Labeling* (adopted by the trilateral agreement: Minister of the Environment, Minister of Health and Director of State Food and Veterinary Service, No. 682/688/754, Official Gazette 2003, No. 12-457); has been valid since December31, 2002. Amended on 28 December, 2004 by the Order No. D1-693/V-954/B1-1107 of the afore-mentioned state authorities.
4. *Order on Regulation of Risk Assessment on GMOs* (adopted by the trilateral agreement: Minister of the Environment, Minister of Health, Minister of Agriculture and Director of State Food and Veterinary Service No. 681/689/525/753. Came into force on 31/12/2002; Official Gazette 2003, No. 12-456). Has been valid since December 31, 2002. Amended on 11 October, 2004 by the Order No. D1-530/V-698/3D-557/B1-886 of the afore-mentioned state authorities.
5. *Order on Regulation on Public Information and Participation in Issuing authorizations for Use of GMOs* (adopted by the Minister of Environment on 11/06/2003. No. 299; Official Gazette 2003, No. 62-2832). Valid since January 1, 2004.
6. *Order on Regulation on Contained Use of GMOs* was adopted by the Minister of the Environment on 29/04/2004 No. D1-233 **"**Concerning the amendments made in the *Order on Regulation on Contained Use of GMOs* (Official gazette 2004, No. 78 - 2765). Has been in force since May 12, 2004.
7. *Order on Regulation on Transit and Unintentional Transboundary movement of GMOs and/or GMPs derived there from* (adopted on 01/12/2003, No. 600, Official Gazette 2003, No. 115-5233), *de jure* is not valid since May 1, 2004.
8. *Order on Regulation for Preparation of General Surveillance and Monitoring Plan of GMOs and/or GMPs after placing on the market (post-commercial monitoring)* (adopted on 01/12/2003, No. 601, Official Gazette 2003, No. 115-5234). Has been valid since January 1, 2004.
9. *Order on Regulation on Biosafety information management and set up of a national Biosafety database (Biosafety Clearing House, BCH)* (adopted on 09/12/2003, No. 627, Official Gazette 2003, No. 117-5360). Has been valid since the accession date: May 1, 2004. Amended on 18 October, 2004 by the Order No. D1-542 of the Minister of Environment on *Rules for description of nGMO database handling in Lithuania.*

10. Steering Committee on GMO Management, established by the Order of the Minister of Environment in December 2001, as amended on 20 March, 2003 (No. 127).
11. GMO Experts Committee, composed by the Order of the Minister of Environment in April 2003 (No. 198).
12. Regulation on *"Genetically modified plants and their products, which are not intended to use as food and feed, which are phytosanitary controlled, and genetically modified seed*", adopted by the Order of the Minister of Agriculture in September 2004.
13. Decision on the national reports to the European Commission concerning the implementation of EU Environment sector legislation, and information needed to report to the European Environment Agency, adopted by the Government of Republic of Lithuania in April 2004.
14. Regulation on "Coexistence of Genetically Modified, Traditional and Ecological crops" - planned to be drafted and adopted by the Order of the Minister of Agriculture and/or Minister of Environment by the end of 2005.
15. Administrative Code on Liability and Redress (in the context of the GMOs) was amendment by the national Parliament in February 2004. Amendments pending to be drafted.
16. Authorization of Environmental protection inspections to State Regulatory officials, provided by the Order of the Minister of Environment in August 2004. Amendments pending to be drafted.

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 (see below 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
Supporting organization-UNDP country office-reports and other reviews show sound financial practices.	Financial accountability statements
National Coordinating Committee (NCC) 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 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 C. 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 below in Tables 3 and 4.

Table 3: Reporting and Monitoring Responsibilities

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	Prepare quarterly progress reports (operational and financial) annual summary progress reports for UNEP, and forward quarterly operational	Meet at least on a quarterly basis and receive quarterly progress and financial reports, annual summary progress reports and all substantive

[1] The total expenditures incurred during each year ending 31 December, certified by a duly authorized official, will be provided by the supporting organization, UNDP country office in Lithuania, reports and the financial accountability statements according to general UN regulations

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 identifies implementation problems and suggests 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	and financial reports, with supporting documentation as appropriate, in a timely manner to UNEP. Carry out a program of regular visits to project sites to supervise activities, and pay special attention to those sites with serious implementation problems	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: Information on Reporting Requirements

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	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

half-yearly and annual progress reports Highlights of achievements			
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 program 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 each heading	Yearly, within 45 days of end of the reporting period	NEA

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 audit			
Annual audit	Audit of accounts for project management and expenditures	Annual	Supporting organization-UNDP country office-reports and statements on the financial practices

A summary of the project against key indicators, baseline and method of data collected is presented below in Table 5, Annex [G].

Annex F
Incremental Cost Assessment

ANNEX F: INCREMENTAL COST ANALYSIS

Project Components	Baseline	Alternative	Increment
Biosafety strategy	Biosafety is not a part of the Biodiversity Action Plan, separate governmental programs (on environment, agricultural development, etc.) approved and in place	Biosafety is integrated into the NBSAP, national strategy on Biotechnology development, agreed strategy on sustainable development	The implementation of the Cartagena Protocol is supported by the nationally agreed Biosafety strategy documents
Biosafety regulatory regime	The Biosafety regulatory regime is facing the last stage of preparation for compliance with CPB, EU Law and other international obligations	A regulatory regime reflecting existing policies and defining all the elements of the NBF and related implementing procedures in line with CPB and international obligations are in force.	The implementation of the Cartagena Protocol is supported by a legal regime, which includes 1 Frame GMO Law, three decrees and six orders. Decision-makers and personnel involved in the application of the regulatory regime are trained.
System for handling requests for permits	Lithuania needs to set up 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 and equipment.	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	Lithuania 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. National capacities are strengthened in terms of training, and laboratory equipment needed for LMOs detection and enforcement are provided	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 Articles 20, 22, 23 of the Cartagena Protocol	A plan for public education, awareness, participation and access to information is formulated and implemented. Public debates and discussions in media are carried out; the national Website for Biosafety is operational and updated regularly.	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 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 Lithuania 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 programs 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 amounts to 315,000 USD and is detailed in MSP brief Table 6 "Summary incremental cost analysis". The various components of the NBF are important; but these amounts can support only very minimal activities.

The project builds on experience gained up to date through the pilot demonstration projects.

The commitment of the national Lithuania's Government amounts to US $ 402,000 and is provided in-kind. Details of the MSP proposed budget are enclosed in Annex H.

Finally, though baseline refers only to activities other than the GEF sponsored ones, Lithuania 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 Lithuania to meet the obligations of the Protocol.

GEF alternative

The existing institutional and technical infrastructures need to be reinforced for Lithuania to meet its obligations as Party to the Cartagena Protocol (as of February 2004).

In order to reach this objective, the incremental cost analysis estimated as follows (Table 6):

The total baseline expenditure amounts to US $ 315,000.

The alternative has been estimated at US $ 1,410,000. The incremental cost analysis shows that an amount of US $ 1,095,000 is required to achieve the project's global environmental objectives. The country will cover 37% of the cost of the increment as in-kind contribution (402,000USD). A sum of US $ 693,000, corresponding to the remaining 63 % of the total cost of implementing the project, is required from GEF.

Annex G
Key Indicators

ANNEX G: Key Performance Indicators, Baseline and Methods of Data Collection

Table 5: Key Performance Indicators, Baseline and Method of data collection

Project Intervention Strategy	Key performance indicator	Baseline (if not known, please identify how and when will be established	Method of data collection/data collection strategy (including frequency)
Development Goal: Lithuania has a workable and transparent national Biosafety framework that is in line with its national development priorities, Cartagena Protocol and other international obligations	By 2009, workable and transparent NBF in line with its international obligations and national development priorities	Baseline information is provided by the country and includes the draft laws and secondary legislation. It completes the final report of the GEF enabling activity completed in 1999. Formalized at project start up to constitute a baseline	Information on the status of the NBF and its progression towards fu implementation will be made available through the regular reporting a yearly visit to the country. It will be collected in the final project report
Immediate Objective 1: To integrate and incorporate Biosafety policy into a nationally agreed long-term strategic governmental program on sustainable development and national Biosafety strategy documents	By 2009, Biosafety issues are part of the national development objectives	Biosafety /Biotechnology issues are not included into the national Biodiversity Strategy and Action Plan; separate governmental programs (on environmental, agricultural development,) approved in place	Information on the status of this component of the NBF and its progressi towards full implementation will be made available through the regul reporting and yearly visit to the country. It will be collected in the fir project
Outcome 1.1 Biosafety considered as the sustainable development issue in drafted and nationally agreed long-term strategic documents in Lithuania	Biosafety issues incorporated into the national development plans and programs: National Strategy on Biosafety/ biotechnology related issues approved and in place	Biosafety issues are not included into the national development plans and programs yet	Data will be extracted from the reports of workshops held to develop Biosafety strategy during the first year and internal discussion papers
Outcome 1.2 Increased and strengthened public and political support in terms of human resources and institutional capacities for consistent implementation of NBF in Lithuania	Biosafety issues addressed in national development plans & programs, adjusted according to changing needs; amendments made to the National Strategy on Sustainable Development and NBSAP; National workshops delivered in place	Biosafety issues are not included into the national development plans and programs yet; insufficient institutional capacities and human resources for consistent NBF implementation	Drafted amended editions of National study on biological diversity, in integration of Biosafety issues on case-specific monitoring, gener surveillance methods, etc.; Procedural guidelines on policy review syster drafted and approved; National public awareness workshops, consens building seminars, conflict resolution training organized; Periodic reports on the activities' outcomes (timing, exper facilitation/moderation, lessons learnt, monitoring) delivered;
Immediate Objective 2: To revise, amend and consolidate a fully operational, workable and responsive regulatory regime in line with CPB, EU Law	National regulatory regime (i.e. frame law passed by the governmental authorities) developed and approved, fully encompassing environmental, economic, social aspects of the Biosafety policy; Secondary legislation (implementing regulations for all requisite NBF components) defined, drafted and approved in compliance with the CPB and other international obligations	The national Biosafety regulatory regime is facing the last stage of preparation for compliance with CPB, EU Law and other international obligations	Biosafety legislation approved and published in the national official gaze (OJ); Implementing regulations defined, drafted and approved; Guidelines published and available on the website of national Biosafe database and BCHM; Internal manuals published and available on the webs of national Biosafety database and BCHM

Outcome 2.1 National regulatory regime revised, amended and in place, depending on the agreed Biosafety policy, provisions of CPB, EU Law	Terms of references (ToR) for TF operational activities, outlining the objectives and tasks to be achieved under initially agreed timetable; Number of reviewed and adjusted national legal acts under the agreed timetable	The national Biosafety regulatory regime is facing the last stage of preparation for compliance with CPB, EU Law and other international obligations	Scheduled meetings of the composed operational Taskforce (TF); Independent review by the inter-institutional Task Force; Periodic reports on management of expert panel assignments; Drafted revisions and amendments to the Frame GMO Law
Outcome 2.2 Increased in-house competence on regulatory issues available and equipped with tools for related additional capacity building activities	Biosafety regulatory regime in place reflecting national policies, plans and programs, defining other relevant NBF components, in compliance with CPB, EU law & other international obligations; Relevant tools and trainings for translation of legislation into practice developed; National regulatory regime on Biosafety issues addressed and adjusted permanently, according to changing needs	The national Biosafety regulatory regime is facing the last stage of preparation for compliance with CPB, EU Law and other international obligations	Summaries of outreach materials (guidelines, internal manuals, etc.) produc and available on national Biosafety db and, if agreed upon, BCHM; Periodic reports on the activities' (workshops, seminars) outcomes: timin experts, facilitation/moderation, lessons learnt, monitoring delivered; Minutes and proceedings of the training prepared and disseminated amo the participants and other interested stakeholders of the national events; Decision-makers and personnel involved in the application of regulato regime are trained and provided with training guides and internal explanato manuals of Biosafety legislation
Immediate Objective 3: To consolidate a functional and efficient national system to handle notifications or requests for authorization, perform risk assessment and administrative processing for informed decision-making	Number of informed decisions made as a result of forthcoming requests; Administrative system to handle notifications for administrative processing set up, including application formats, guidance for applicants, internal manuals for processing, checklists, etc.	Lithuania needs to set up appropriate procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively	The implementation of the Cartagena Protocol is supported by an operationa system for handling requests, which includes administrative processing, risk assessment and decision-making
Outcome 3.1 A fully operational national administrative system in place, i.e. "up and running", including establishment of the operational emergency response procedures and enforcement measures	Procedures for handling, transport, packaging and identification of GMOs established; Procedures for handling of confidential information established; nBCH, containing all relevant information required under the CPB, improved and updated; Compliance with BCHM obligations reached; Administrative personnel are capable to follow and practically interpret CPB trained	Lithuania needs to set up appropriate procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively	Percentage of requests handled; Statutory application forms are elaborated; Procedural manuals are develop and include emergency measures; RA and RM methodologies are defined; t public register for tracking dossiers is set up and personnel of NCA trained
Outcome 3.2 A fully operational national administrative and methodological risk assessment (RA) system finalized and in place	National institution (i.e. Risk Assessment Co-ordinating Centre under the Academy of Sciences) appointed and authorized entity, responsible for methodological aspects of risk assessment (RA); Defined rules of criteria for identification, appointment and revision (ToRs) of RA experts and entity developed; A list / roster of RA experts elaborated; National administrative guidelines - methodological procedures for carrying out risk assessment developed, set in place & operational	Lithuania needs to set up appropriate procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively	Percentage of assessments completed during the agreed timeframe; Procedures for carrying out risk assessment agreed upon; Number of personnel educated and trained

Outcome 3.3 A fully operational national decision-making system finalized and in place	Duly authorized national competent authorities, their subordinated organizations, responsible for receiving and handling requests for permits (import, export, domestic use, contained use, AIA, transit, field trials, etc.) in place;	Lithuania needs to set up appropriate procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively	Number of decisions reviewed on risk assessment during the agre timeframe; Number of decisions made during the agreed timeframe; Number Public consultation in decision held, pursuant to Art.23.2 of t CPB
Outcome 3.4 Increased in-house competence on regulatory issues available and equipped with tools for related additional capacity building activities	National administrative system to handle notifications, including administrative processing, risk assessment and decision making set up and in place; Relevant tools and trainings for administrative processing of RA and informed decision-making, developed and organized	Lithuania needs to set up appropriate procedures for handling requests and provide tools and training to staff in charge so as to enable them to carry out their tasks effectively	Summaries of outreach materials (guidelines, internal manuals, etc.) produc and available on national Biosafety db and, if agreed upon, BCHM; Periodic reports on the activities' (workshops, seminars) outcomes: timir experts, facilitation/moderation, lessons learnt, monitoring delivered; Minutes and proceedings of the training prepared and disseminated amo the participants and other interested stakeholders of the national events; Decision-makers and personnel involved in the application of regulato regime are trained and provided with training guides and internal explanato manuals of Biosafety legislation
Immediate Objective 4: To establish and consolidate a functional national system for monitoring of environmental effects and enforcement ("follow-up" mechanisms)	National mechanisms for monitoring of environmental effects and enforcement (control and inspection) developed, tested, approved, published and in place	Lithuania needs to set up appropriate procedures for follow up activities, namely monitoring of environmental effects and enforcement (control and inspection). Technical means and trainings are needed in order to enable inspectors and technicians to carry out their tasks	The implementation of the Cartagena Protocol is supported by an operatior system for monitoring of environmental effects and enforcement draft under the agreed timetable
Outcome 4.1 Identified and developed national institutional setting for monitoring of potential effects on environment and human health and transboundary movement (registered in BCH) of GMOs	The MoE or its subordinated institution (i.e. Environmental Protection Agency) or the State GMO Service under the Ministry of Environment appointed to be responsible for monitoring of GMOs deliberate release into environment & placing on the market; The required sets of operational manual/ guidelines for monitoring of environmental effects drafted under the agreed timetable; Manual on methodologies for monitoring of environmental effects elaborated	Lithuania needs to set up appropriate procedures for follow up activities, namely monitoring of environmental effects and enforcement (control and inspection). Technical means and trainings are needed in order to enable inspectors and technicians to carry out their tasks	Guidelines for monitoring of environmental effects and procedures f enforcement actions are defined (training guides for trainers) and responsit personnel trained
Outcome 4.2 Improved and strengthened national institutional setting and related mechanisms for enforcement (control and inspections)	The MoE or its subordinated institution (State GMO Service under the Ministry of Environment), established and authorized to be responsible for safety control and enforcement (control and inspection); Internal guidelines, rules and regulations on enforcement (control and inspection) of GMOs written under the agreed timetable; Regular reporting to the CPB Secretariat about the implementation of CPB	Lithuania needs to set up appropriate procedures for follow up activities, namely monitoring of environmental effects and enforcement (control and inspection). Technical means and trainings are needed in order to enable inspectors and technicians to carry out their tasks	Systems for monitoring of environmental effects and enforcement of (contr and inspection) set up and in place
Outcome 4.3 Increased in-house competence available and equipped with tools for related additional	ToR drafted and contracts implemented for the preparation & implementation of additional capacity building activities upon	Lithuania needs to set up appropriate procedures for follow up activities, namely monitoring of environmental effects and	Summaries of outreach materials (guidelines, internal manuals, etc.) produc and available on national Biosafety db and, if agreed upon, BCHM; Periodic reports on the activities' (workshops, seminars) outcomes: timir

capacity building activities	the request and under the agreed timetable of NEA; Estimated number of national trainings and workshops for follow-up monitoring and enforcement (control and inspection) mechanisms organized;	enforcement (control and inspection). Technical means and trainings are needed in order to enable inspectors and technicians to carry out their tasks	experts, facilitation/moderation, lessons learnt, monitoring delivered; Decision-makers and personnel involved in the application of regulato regime are trained and provided with training guides and internal explanato manuals of Biosafety legislation
Immediate Objective 5: To elaborate the relevant operational systems for: Public awareness; Education; Access to information; and Participation in decision-making process	Strategies for targeted different interested groups of national stakeholders elaborated; Curricula programs, incorporating Biosafety information, participation themes, developed;	Public awareness and education need to be further strengthened; public involvement need to be a part of the system in order to reflect Articles 20, 22, 23 of the CPB	The implementation of the CPB is supported by a system for publ education, information, awareness raising and participation in decisio making
Outcome 5.1 National public awareness and education mechanisms, strengthening public access to Biosafety information elaborated& operational	National Strategy for Sustainable Development amended, incorporating Biosafety issues on public awareness, education, participation in decision making process therein; National Action Plan for safe use on public awareness, education, participation in decision making process elaborated for final approval by the national competent authority	Public awareness and education need to be further strengthened; public involvement need to be a part of the system in order to reflect Articles 20, 22, 23 of the CPB	The implementation of the CPB is supported by a system for publ education, information, awareness raising and participation in decisio making; Percentage (%) of students educated and trained on Biosafety curricu topics, comparing to overall number of graduates; Data obtained from 2 national surveys and public opinion poles on the lev of public awareness of national Biosafety policy
Outcome 5. 2 National system for public participation in the decision-making process, through enabled access and sharing of Biosafety/ Biotechnology information, strengthened and enforced	The MoE (or the duly authorized subordinated institution) identified to be responsible for public awareness and public participation campaigning in the decision-making processes related to Biosafety/ Biotechnology issues; Representatives of local governments, public groups of civil society involved in the work of GMO Steering Committee (as observers)	Public awareness and education need to be further strengthened; public involvement need to be a part of the system in order to reflect Articles 20, 22, 23 of the CPB	The implementation of the CPB is supported by a system for publ education, information, awareness raising and participation in decisio making; Number of hits accessing the revised and updated nBCH; Number of records on the nBCH; Regularity of updates to the nBCH requested by the NEA; Number of people trained to ensure continuity of administrative tasks ahead
Outcome 5. 3 Increased in-house competence on regulatory issues available and equipped with tools for related additional capacity building activities	ToR drafted and contracts implemented for the preparation & implementation of additional capacity building activities upon the request and under the agreed timetable of NEA; Estimated number of national trainings and workshops for follow-up monitoring and enforcement (control and inspection) mechanisms organized	Public awareness and education need to be further strengthened; public involvement need to be a part of the system in order to reflect Articles 20, 22, 23 of the CPB	Summaries of outreach materials (guidelines, internal manuals, etc.) produc and available on national Biosafety db and, if agreed upon, BCHM; Periodic reports on the activities' (workshops, seminars) outcomes: timir experts, facilitation/moderation, lessons learnt, monitoring delivered; Minutes and proceedings of the training prepared and disseminated amo the participants and other interested stakeholders of the national events; Decision-makers and personnel involved in the application of regulato regime are trained and provided with training guides and internal explanato manuals of Biosafety legislation

Annex H
Detailed Project Budget

ANNEX H: 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**	**Total GOV**
A. Biosafety policy											
A1	Setting up an operational Task Force (TF) to co-ordinate the process on Biosafety intersectional integration and elaborate consolidated biosafety strategy documents		750		750		250		250		2.000
A2	Collection, preparation and dissemination of the global and regional experiences on best practices available from different applicable models of regional policies & strategies on Biosafety issues (surveys)	3.600	1.250	3.600	1.250					7.200	2.500
A3	Organization of two rounds (each 1 day) of national consultations with government and main stakeholders to identify and deliberate the key elements of the political national Biosafety strategy documents	750	250	550	250					1.300	500
A 4	Elaboration of the required national Biosafety strategy documents on National Strategy on Biotechnology/ Biosafety Development; National Program and Action Plan for safe use on various applications of modern biotechnology in Lithuania	3.900	1.200	3.900	1.200	3.900	1.200	1.500	400	13.200	4.000
A 5	Organization of 2 national workshops (2 days each) on implementation of elaborated national Biosafety policy "Consensus building and conflict resolution on national Biosafety policy issues" (2x2 days /60 participants)			3.850	1500	3.850	1500			7.700	3000
Total: Biosafety policy:		8250	3450	11900	4950	7750	2950	1500	650	**29.400**	**12.000**

Activity code	Project activities	1st year GEF	GOV	2nd year GEF	GOV	3rd year GEF	GOV	4th year GEF	GOV	**Total GEF**	**Total GOV**
B. 1. Regulatory regime											
B1	Setting up an operational Task Force (TF)		750		750		250		250		2.000

	to coordinate the process of review, adjustments, and final adoption of biosafety regulatory regime in response to changing needs										
B2	Drafting, review and final adoption of the national biosafety regulatory regime, incl.: Frame GMO Law related to the contained use, deliberate release, placing on the market, import and transit (transboundary) of GMOs; and identify of priority actions to implement it	4.800	9.000	4.800	9.000	3.000	7.500	1.800	3.400	14.400	28.900
B3	Drafting, review and final adoption of the national biosafety secondary legal acts, incl. Ministerial orders, decrees, regulations on GMOs, namely for: Reg. setting out the conditions for granting authorizations for the contained use, deliberate release and placing on the market of GMOs; Reg. for GMOs' import conditions and procedures; Reg. for the information required in the notifications of deliberate release and placing on the market of GMOs; Reg. and/or procedures for risk assessment and management; Reg. and/or procedures for informed decision making; Reg. for GMOs' packaging, labeling, storage	6.000	2.800	6.000	2.800	5.800	2.800	2.700	1.840	20.500	10.240
B4	Identification, development and adoption of internal explanatory manuals on the national biosafety legislation, as requested by the NEA	2.300	500	4.000	1.500					6.300	2.000
B5	Setting up nationally agreed mechanism for a responsive and flexible revision of the national Biosafety legislation, when needed		980		980						1.960

Activity code	Project activities	1st year GEF	GOV	2nd year GEF	GOV	3rd year GEF	GOV	4th year GEF	GOV	**Total GEF**	**Total GOV**
B. II Training on Regulatory issues											
B6	Preparation of the required training manuals for trainers on the biosafety regulatory regime	2.400	800	2.400	800					4.800	1.600
B7	Organization of two rounds (for 2 days each) start-up consultative workshops on: possible options and implications of amending the existing regulatory regime; legal gap analysis for implementation of CPB (60 participants)	2.800	600	2.800	600					5.600	1.200
B8	Organization of a national specialized training for environmental lawyers (4 days/ 20 participants)					7.600	1.000			7.600	1.000
B9	Organization of a national conference for the importers and exporters and company representatives about the transboundary movements of GMOs and its legal aspects on topic of: "Implementation of the reviwed Biosafety regulatory framework on nationa+l level" (1day/ 40 participants)							2.800	600	2.800	600
Total Regulatory regime (B.1+B II):		18.300	15.430	20.000	16.430	16.400	11.550	7.300	6.090	**62.000**	**49.500**
C I. Handling requests for authorization (including administrative processing for risk assessment and informed decision-making)											
C 1	Identification of the national institutional set up, i.e. authorities and their subordinated organizations responsible for application and enforcement of developed regulatory regime		1.000		1.000						2.000
C1.a	Setting up & making operational the national emergency response procedures in place			2.500	900	2.500	900			5.000	1.800
C1.b	Preparation of the operational "Procedures manual" for internal use by the personnel in the Biosafety office of NCAs on handling requests for permits in the following cases: Emergency response; Accidental release; Illegal movement, transit; Contained use; Deliberate release			5.700	1.500					5.700	1.500

	into environment; Placing on the market; AIA and FFP, handling, transport, packaging, identification of GMOs (incl. handling of confidential information)										
C1.c	Review and amendment of the current interim statutory application forms for administrative regulators for handling notifications/ requests for authorizations on: Permission for contained use; Deliberate release into environment; Import of GMOs/GMPs and placing on the market	4.000	1.000	1.300	600					5.300	1.600
C 2	Create and make operational (set up) the national Public Register for tracking dossiers received; linking it and making interoperable with the aggregated and up-dated nBCH (specifying the principles for identification, collection, input and update of the Biosafety information sharing and networking, management of confidential information)	4.200	1.000	4.200	1.100	4.200	1.100	1.800	1.100	14.400	4.300
C 3	Setting up, maintain and update an inventory of technical assistance required for emergency response procedures to be operational		1.000		1.000						2.000
C 4	Review and update national system for data collection, validation, inputting into the nBCH			3.900	1.150	3.900	1.150			7.800	2.300
C 5	Designing & setting up a separate aggregated website of the NCA Biosafety Office, linking it to the official websites of NCAs', thus ensuring provision of available information to the national stakeholders	2.800	2.000	2.800	1.900	2.800	1.900	600	1.900	9.000	7.700
C 6	Definition of criteria for identification, appointment and revision of RA experts & development of the internal administrative rules for the designated authorized entity, i.e. GMO Scientific Coordination Centre				2.950		2.950				5.900
C 7	Definition, approval and publishing of methodological technical guidelines for			3.750	1.100	3.750	1.100			7.500	2.200

	handling of requests (including RA & RM procedures) for transport, usage and release of GMMOs, and GM higher plants										
C II. Training on Handling requests for authorization											
C 8	Revision of the administrative roles and responsibilities of the NCAs' personnel, setting up the rules and procedures for decision-making bodies, identifying relevant socio-economic issues of specific national interest to be taken into consideration during decision-making process		1.000		1.000		1.000		1.000		4.000
C 9	Organization of 2 consultations with relevant stakeholders to discuss how to approach and integrate socio-economic issues into informed decision-making. Participation of the principle national key stakeholders concerned: decision-makers from central (NCA, NCC) local (municipalities); NGOs, scientists, public groups, etc. (2 times / 30 participants)	2.800	650			2.800	650			5.600	1.300
C 10	Organization of 3 national training workshops (for 2 days each) for senior administrative officers from different state institutions, National GMO Management Committee, Members of NEAs involved in handling of notifications and requests, according to Articles 15-16, of the CPB (administrative and methodological aspects of RA and risk management (methods, equipment, etc.); (3 x 2 days/20 part.) from key stakeholders			2.600	900	2.600	900	2.600	500	7.800	2.300
C 11	Preparation of technical guides/manuals on handling requests for permits, including administrative processing of risk assessment and decision-making, for training purposes			3.450	1.000	3.450	1.000			6.900	2.000
C 12	Organization of two advanced on-job trainings on handling GMMOs in contained use and deliberate release into					3.600	2.800	3.600	2.800	7200	5600

	environment; incl. case studies (simulations) to test that administrative and further developed "follow-up" systems are functioning in place. Estimated: 2x2 days/15-20 target participants										
Total: Handling requests		13.800	7.650	30.200	16.100	29.600	15.450	8.600	7.300	**82.200**	**46.500**

D. Follow-up mechanisms (monitoring of environmental effects and enforcement: control and inspections)											
D1	Clarification and separation of roles and responsibilities for national institutions (i.e. GMO Unit of the MoE, future GMO State Service under the MoE, role of Environmental Protection Agency under the MoE, etc.)		1.000		1.000						2.000
D 2	Preparation of the operational methodological guidelines and rules (i.e. administrative procedures) for monitoring of GMOs environmental effects and enforcement (control and inspections) measures required for handling, transport, usage, transfer and release of GMOs	2.600	1.100	2.600	600	2.600	600			7.800	2.300
	D II training component on Foolo up (monitoring of environmental effects, control and inspections)										
D3	Preparation of technical methodological materials, i.e. training guides and rules (administrative procedures on enforcement: control and inspections) for trainers on proposed national monitoring system and enforcement measures for handling, transport, use, transit and release of GMOs	3.350	1.000	3.350	1.000					6.700	2.000
D 4	Organization of a national workshop on the "Control of GMOs transboundary movements", for specialists of the national governmental administrations in charge of implementation enforcement mechanisms (control and inspection). To discuss relevant methods for control of the transboundary movements of goods and GMO detection (methods, equipment,					3.800	900			3.800	900

	docs. requirements for GMOs shipments) (2 days /40 participants)										
D 5	Organization of 2 specialized training workshops (total for 3 days each) providing instructions and professional training for environmental inspectors and custom officers on monitoring and inspection of field releases of GMOs; GM products placed on the market (2x3 days/ 20 participants)			3.700	1.000			3.700	1.000	7.400	2.000
D6	Organization of 2 intense training courses (4 days each) for technical personnel, inspectors and officers to improve their capacity/expertise on GMOs detection/ testing and monitoring activities (2x3 days/ 10 participants)			4.350	1.250	4.350	1.250			8.700	2.500
Total: Follow-up:		5.950	3.100	14.000	4.850	10.750	2.750	3.700	1.000	**34.400**	**11.700**
E. Public awareness and participation											
E1	Elaborate national public awareness and education strategy and action plan for participation in decision-making processes on Biosafety issues	3.200	1.000	3.200	1.000	3.200	1.000			9.600	3.000
E 2	Develop curricula programs on Biosafety/ Biotechnology in higher educational institutions in relation to the conservation and sustainable use of biodiversity, taking also into account risks to human health		1.300		1.300		1.300				3.900
E 3	Organization of 2 national surveys and public opinion poles on the level of public awareness of national biosafety policy	5.600	1.750			5.600	1.750			11.200	3.500
E 4	Identification of national entity (designated and authorized national institution, agency) responsible for managing public awareness, access to and dissemination of thematic information, and education campaigns related to Biosafety/ Biotechnology issues		1.000		1.000						2.000
E 5	Definition and specification of "entry points" for public participation in decision-making process on GMOs in relevant regulations and administrative procedures			2.400	750	2.400	750			4.800	1.500

E 6	Establish regular mechanisms for networking with media on Biosafety related issues		1.000		1.000		1.000		1.000		4.000
	E II Training component on public awareness issues										
E 7	Prepare technical training guides for public information and participation incorporating lessons learnt from other pilot MSPs	3.200	1.000	3.200	1.000	3.200	1.000			9.600	3.000
E 8	Organization 2 training courses on the topic of "Public information and participation in biosafety" for national trainers" (local officers from the public service/agency), inviting international experts to teach short-term courses and give public presentations on public education and information; duration 2 times/2 days each training, tentative number of participants: 20			3.350	1.000			3.350	1.000	6.700	2.000
E 9	Organization broad participation national public awareness seminars (2 events/ for a day each); estimated number of participants 40-60) for different public stakeholders, including governmental officials, media, journalists, scientists, NGOs representatives of the general public. Thematic'll investigate the relationship between information exchange and perception of the biotechnology and its applications ("Safe or hazardous?")			6.000	3.000	6.000	3.000			12.000	6.000
E 10	Preparation and dissemination of the outreach popular public awareness informative material for different targeted stakeholders (incl. on the risks and benefits of the use of GMOs). To be distributed during the organized public discussions, debates and meetings			5.900		5.900		4.500		16.300	
E 10a	Preparation and publishing costs for required national biosafety strategy documents (as per activities A.1.4 and A.2.2)					3.250		3.250		6.500	

E 10b	Preparation and publishing costs for internal explanatory manuals for trainers on the national biosafety regulatory regime (as per activities B.1.4 and B.2.2)					2.750		2.750		5.500	
E 10c	Preparation and publishing costs of methodological national guidelines on RA and RM procedures and technical manuals on handling requests for authorization (as per activities C.2.3 and C.4.2)					2.600		2.600		5.200	
Total: public awareness and participation:		12.000	7.050	24.050	10.050	34.900	9.800	16.450	2.000	**87.400**	**28.900**

F. Project coordination											
6.1	National Project Coordinator	27.000		27.000		27.000		27.000		108.000	
6.2	Project Administrative Assistant	17.100		17.100		17.100		17.100		68.400	
6.3	Financial Officer (part time) in charge of monitoring and evaluation issues and financial reporting	12.250		12.250		12.250		12.250		49.000	
6.4	National Coordination Committee (NCC) Meetings, Travels for NPC, staff and NCC members (sub)regional meetings/seminars	6.000	36.000	6.000	36.000	6.000	36.000	6.000	36.000	24.000	144.000
6.5	Office premises costs	-	21.600	-	21.600	-	21.600	-	21.600	-	86.400
	Office Equipment (expendable and non-expendable equipment) and office Operating costs (utilities, stationery, internet connections)	5.125	3.750	5.125	3.750	5.125	3.750	5.125	3.750	20.500	15.000
6.6	UNDP Financial administration support costs (i.e. General Management Services and Implementation Support Services)	8.250		8.250		8.250		8.250		33.000	
F. Total project coordination:		75.725	61.350	75.725	61.350	75.725	61.350	75.725	61.350	**302.900**	**245.400**
7 Other project support											
7.1	Printing of reports (included into 7.2)										
7.2	Translation, interpretations and copying	1.500		3.750		3.750		5.500		14.500	
7.3	Communication costs	1.150	2.500	1.150	2.500	1.150	2.500	1.150	2.500	4.600	10.000
7.4	Technical support	17 500		17500		17500		17500		70 000	
	Total:	20.150	2.500	22.400	2.500	22.400	2.500	22.400	2.500	**89.100**	**10.000**
	Grand total									**687.400**	**404.000**

Annex I

MSP Implementation Plan

ANNEX I: IMPLEMENTATION PLAN

Duration of the project: 4 years

The proposed MSP consists of 5 main components to be carried out over 48 months according to the following schedule:

	SPECIFIC ACTIVITIES according to the proposed MSP Budget																
	Completion of project activities/months	**3**	**6**	**9**	**12**	**15**	**18**	**21**	**24**	**27**	**30**	**33**	**36**	**39**	**42**	**45**	**48**
1.	Establishment of MSP coordinating office and appointment of project personnel: a full-time NPC, Administrative Assistant and Financial Officer	X															
2.	Ensuring institutional Office set up and running throughout the MSP life (48 months)	X	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3.	Establishment of NCC, communicate to UNEP the composition of the NCC; Regular NCC meetings	X		X		X		X		X		X		X		X	x (fin)
4.	Detailed planning and oversight of assignments for 5 MSP components to be carried out by project experts, consultants, sub-contractors and co-operating partners (review each year)	X			X				X				X				
A.	**NATIONAL BIOSAFETY POLICY**																
A.1	Setting up the trans-institutional working group [Task Force, TF] with mandate to co-ordinate the process on Biosafety intersectional integration		X														
A.2	Collection, preparation and dissemination of the global and regional experiences on best practices		X	X	X												

	available from different applicable models of regional policies & strategies on Biosafety (Surveys: reviews and assessments)																
A.3	Organization of two rounds of one day national consultations for government and main stakeholders to deliberate the key elements of the national Biosafety strategy documents (2 days/30 participants)		X		X	(X)											
A.4	Elaboration of the required national Biosafety strategy documents, i.e. National Strategy on Biotechnology/ Biosafety Development issues; National Program and Action Plan for safe use on applications of modern Biotech.			(X)	X	X	X	X	X	X	(X)	(X)	(X)				
A.5	Organization of 2 national workshops (2 days each) on implementation of elaborated national Biosafety policy "Consensus building and conflict resolution on national Biosafety policy issues" (2x2 days /60 participants)			X			X										
A.6	Drafting amended editions of: National Strategy for Sustainable Development, incorporating Biosafety issues therein; National Biodiversity Strategy and Action Plan								X	X							
B.	**REGULATORY REGIME**																
B.1	Setting up the inter-institutional Task Force (TF) composed of representatives from different		X														

	governmental authorities to coordinate the process of review and adjustments for Biosafety regulatory regime in response to changing needs																
B.2	Review and final adoption of the national Biosafety regulatory regime by the TF, incl.the *Frame GMO Law*			X	X	X											
B.3	Review and final adoption of the national Biosafety regulatory regime by the TF, including drafting and/or amending the *secondary legislation*				X	X	X	(x)									
B.4	Identification, development and adoption of internal explanatory manuals on the national Biosafety legislation (incl. drafted secondary legislation: ministerial orders, decrees, regulations), as requested by the NEA							X	X								
B.5	Setting up nationally agreed mechanism for a responsive and flexible revision of the NBF legislation, when/if needed				x	x	x	x	x	x							
B.6	Preparation of the required training manuals for trainers on the national Biosafety regulatory regime		X			X											
B.7	Organization of two rounds (for 2 days each) start-up consultative workshops on: possible options and implications of amending the existing regulatory regime; legal gap analysis for implementation of CPB;		X			X											
B.8	Organization of a national specialized training for environmental lawyers (3				X												

	days/20 participants)																
B.9	Organization of a national conference on topic "Implementation of the revised Biosafety regulatory framework on national level" (1day/ 40 participants)							X									
C.	**HANDLING REQUESTS FOR AUTHORIZATION**																
C.1	Identification of the national institutional set up, i.e. authorities and their subordinated organizations responsible for application and enforcement of the developed NBF	x	x	x	x												
C.1A	Setting up and making operational the national emergency response procedures in place (checking throughout the MSP)					X	X	X	X	(x)	(x)	(x)	(x)				
C.1B	Preparation of operational "Procedures manual" for internal use by the personnel in the Biosafety office of NCAs on handling requests					X	X										
C.1C	Revision and amendment of the current interim statutory application forms for administrative regulators for handling notifications/ requests for authorisations on: - Permission for contained use;- Deliberate release into environment; - Import of GMOs/GMPs, placing on the market				X	X											
C.2	Setting up the national Public Register for tracking dossiers received by linking it and making interoperable with the aggregated and up-dated					X	X	X	X	X	X	X	(x)	(x)	(x)		

	nBCH (specifying the principles for identification, collection, input and update of the Biosafety information sharing and networking, management of confidential information)																
C.3	Setting up, maintain and update an inventory of technical assistance required for emergency response		x	x													
C.4	Revise and update national system for data collection, validation and inputting into the nBCH			x	x	x	x	x	x	(x)_	(x)_	(x)_					
C.5	Designing and setting up a separate aggregated website of the NCA Biosafety Office, linking it to the official NCAs' website, thus ensuring information provision to the NCAs					X	X	X									
C.6	Definition of criteria for identification, appointment and revision of RA experts and development of the internal administrative rules for the designated authorized entity, i.e. GMO Scientific Coordination Centre				X	X	X	(X)	(X)								
C.7	Definition, approval and publishing of methodological national guidelines on risk assessment (RA) and management procedures for handling, transport, usage and release of GMOs					X	X	X									
C.8	Revision of the administrative roles and responsibilities of the NCAs' personnel, setting up the rules and procedures for decision-making bodies, identifying relevant socio-			X	(x)	(x)											

	economic issues of specific national interest to be taken into consideration during decision-making process																
C.9	Organization of 2 consultations with relevant stakeholders to discuss how to approach and integrate socio-economic issues into informed decision-making. The principle national key stakeholders concerned: decision-makers from central (NCA, NCC) local (municipalities); NGOs, scientists, public groups, etc. Estimated: 2 times/30 participants				X			X									
C.10	Preparation of technical guides/manuals on handling requests for permits, including administrative processing of RA and informed decision-making, for training purposes					X	X										
C.11	Organization of 3 national training workshops (in total for 2 days each) for senior administrative officers from different state institutions, National GMO Management Committee, Members of NEAs involved in handling of notifications and requests, according to Articles 15-16, of the CPB (administrative and methodological aspects of RA and risk management (methods, equipment, etc.); Total: [3 x 2 days/20 participants from key stakeholders]				X			X			X						
C.12	Organization of two on-job trainings								X			X					

	(2 sessions) with case studies (simulations) to test that the administrative and further developed "follow-up" systems are functioning in place. Estimated: (2 x 2 days/ 15 participants)																
D.	**FOLLOW –UP MECHANISMS**																
D.1	Clarification and separation of roles and responsibilities for national institutions (i.e. GMO Unit of the MoE, future GMO State Service under the MoE, role of Environmental Protection Agency under the Ministry of Environment, others) to be responsible for monitoring of environmental effects			X	X	X	(X)										
D.2	Preparation of the operational methodological guidelines and rules (i.e. administrative procedures) for monitoring of GMOs environmental effects and enforcement (control and inspections) measures required for handling, transport, usage, transfer and release of GMOs					X	X	X	X	(X)	(X)						
D.3	Preparation of technical methodological materials, i.e. training guides for trainers on proposed national monitoring system and enforcement measures for handling, transport, use, transit and release of GMOs						X	X	X	(X)							
D.4	Organization of a national workshop on the "Control of GMOs								X								

	transboundary movements" (for 2 days), inviting specialists from the national governmental administrations in charge of implementation enforcement mechanisms (control and inspection). Purpose: to discuss relevant methods for control of the transboundary movements of goods and the detection of GMO (methods, equipment, documentation requirements for GMO shipments) (2 days/ 40 participants)																
D.5	Organization of 2 specialized training workshops (total for 3 days each) providing instructions and professional training for environmental inspectors and custom officers on inspection of field releases of GMOs; GM products placed on the market; (2x3 days/ 20 participants)								X	(X)		X	(X)				
D.6	Organization of 2 intense training courses (4 days each) for technical personnel on GMOs detection/ testing and monitoring activities (2x3 days/ 10 participants)									X			X				
E.	**PUBLIC INFORMATION, PART, AWARENESS RAISING**																
E.1	Elaborate national public awareness and education strategy and action plan for participation in decision-making processes on Biosafety issues			(X)	X	X	X	X	X	X	X						
E.2	Develop curricula programs on Biosafety/ Biotechnology in higher				X				X				X				

	educational institutions in relation to the conservation and sustainable use of biodiversity, taking into account risks to human health																
E.3	Organization of 2 national surveys and public opinion poles on the level of public awareness of national Biosafety policy			X	(X)										X	(X)	
E.4	Identification of national entity (designated and authorized national institution, agency) responsible for managing public awareness, access to and dissemination of thematic information, and education campaigns related to Biosafety/ BTissues				X	(X)	(X)	(X)									
E.5	Definition and specification of "entry points" for public participation in decision-making process on GMOs in relevant regulations and administrative procedures					X	X										
E.6	Establish regular mechanisms for networking with mass media on Biosafety related issues					X	(X)	(X)	(X)								
E.7	Prepare technical training guides for public information and participation incorporating lessons learnt from other pilot Medium-Sized Projects						X	X			X	X			X	X	
E.8	Organization 2 training courses on the topic of “Public information and participation in Biosafety” for national trainers” (local officers from the public service/agency), inviting international experts to teach short-							X	(X)				X	(X)			

	term courses and give public presentations on public education and information;																
E.9	Organization broad participation national public awareness seminars (2 events/ for a day each); estimated number of participants 40-60) for different public stakeholders, including governmental officials, media, journalists, scientists, NGOs representatives of the general public. The seminars should investigate the relationship between information exchange and perception of biotech applications ("Safe or hazardous?")										X	(X)				X	(X)
E.10	Preparation and dissemination of the outreach public awareness materials for different targeted stakeholders during the public debates & meetings									X	X			X	X	X	X
E.10a	Preparation and publishing of required national Biosafety strategy documents (as per activities A. 2; A.6)						X	X	(X)								
E.10b	Preparation and publishing costs for internal explanatory manuals for trainers on the national Biosafety regulatory regime (activities B.4, B.6)			X					X								
E.10c	Preparation and publishing costs of methodological national guidelines on RA and management procedures and technical manuals on handling requests for authorization (activities C.7; C.10)							X			X						

Annex J
Terms of Reference

Annex J

Draft Terms of Reference for:

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

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

- Establish the National Co-coordinating Committee (NCC);
- Appoint a full time National Project Co-coordinator (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;
- 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 version of the National Biosafety Framework no later than forty eight months from the signature of this Memorandum of Understanding.

b) The **National Coordinating Committee (NCC)** will work together as a team on management of the National Project and meet at least on a quarterly basis with the following duties:

- Develop a common understanding of what is needed to expedite the preparation of a National Biosafety Framework;
- Oversee the preparation of the National Biosafety Framework;
- Approve the detailed work plan and budget produced by the NPC;
- Mobilize 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;
- Ensure that information on the implementation 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 mobilizing 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 that the environmental policy of the Government is fully reflected in the National Project documentation.

c) The **National Project Coordinator (NPC)** will carry out the following tasks:

- The National Project Coordinator (NPC) will act as the secretary of the NCC;
- Coordinate, manage and monitor the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Organize National Coordinating Committee meetings;
- Prepare detailed work plan and budget 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 programs 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 Global National 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.

d) The **Project Assistants (PA): Financial Officer and Administrative Assistant** 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 organization of National Coordinating Committee meetings;
- Assist with preparation 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 programs 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 with 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.