MEDIUM-SIZED PROJECT PROPOSAL
REQUEST FOR GEF FUNDING

AGENCY'S PROJECT ID:
GEF SEC PROJECT ID: 3023
COUNTRY: Slovak Republic
PROJECT TITLE: Support the Implementation of the National Biosafety Framework of Slovakia
GEF AGENCY: UNEP
OTHER EXECUTING AGENCY(IES):
DURATION: 48 MONTHS
GEF FOCAL AREA: BD
GEF OPERATIONAL PROGRAM: EA
GEF STRATEGIC PRIORITY: BD3
ESTIMATED STARTING DATE: January 2006
IMPLEMENTING AGENCY FEE:

FINANCING PLAN (US$)	
GEF PROJECT/COMPONENT	
Project	466.000
PDF A*	
Sub-Total GEF	
CO-FINANCING**	
GEF Agency	
Government	139.000
Bilateral	
NGOs	
Others	
Sub-Total Co-financing:	
Total Project Financing:	605.000
FINANCING FOR ASSOCIATED ACTIVITY IF ANY: EU-ESF	**10.000**

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

CONTRIBUTION TO KEY INDICATORS OF THE BUSINESS PLAN: The project belongs to the Biodiversity Focal Area and within the four strategic priorities of this focal area it is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety

RECORD OF ENDORSEMENT ON BEHALF OF THE GOVERNMENT:

Date*: 3 November 2005*

Katarina Novakova
GEF Focal Point
General Project Manager
Ministry of Environment SR

Letter of endorsement (Attached)

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.

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

Laszlo Miklos
Minister of Environment
Ministry of Environment of SR
Nám. L. Stura 1
812 35 Bratislava
Slovak Republic
Tel: +421 2 5956 2140

Date: December 1, 2005

LIST OF ACRONYMS

BCH	Biosafety Clearing House
BSS	Biosafety Strategy
BO	Biosafety Officer
CA	Competent Authority
CB	Control Body
CBD	Convention on Biological Diversity
CCTIA	Central Control and Testing Institute of Agriculture
CP	Cartagena Protocol
EC	European Commission
ENGL	European Network of LMO Laboratories
EP	European Parliament
EU	European Union
FNS	Faculty of Natural Sciences
GEF	Global Environment Facility
GMO(s)	Genetically Modified Organism(s)
LMO(s)	Living (Genetically) Modified Organism(s)
GT	Gene Technology
IMB SAS	Institute of Molecular Biology, Slovak Academy of Sciences
MoA SR	Ministry of Agriculture of the Slovak Republic
MoE SR	Ministry of Environment of the Slovak Republic
MoEc	Ministry of Economy of the Slovak Republic
MoH	Ministry of Health of the Slovak Republic
NBBP	National Biosafety and Biotechnology Policy
NCBS	National Coordination centre for Biological Safety
NEA	National Executing Agency
NBF	National Biosafety Framework
NCC	National Coordinating Committee
NDS	National Development Strategy
NGO(s)	Non-governmental Organisation(s)
NPC	National Project Coordinator
PHA	Public Health Authority
RA	Risk Assessment
SEI	Slovak Environmental Inspection
SHMI	Slovak Hydro-Meteorological Institute
SVFA	State Veterinary and Food Agency
UNEP	United Nations Environmental Programme

A. PROJECT SUMMARY

The Slovak environmental policy is based on the precautionary principle and reflects the need to protect the environment and improve human health as well as to promote a sustainable economic growth. However, as Slovakia has a fast growing economy based mostly on Industrial and Technology development, there are worries that this growth may happen at the expense of the environment. In this context, the elaboration of a specific National Biosafety and Biotechnology Policy, together with Biosafety embedded into the National Development Strategy, will guarantee that the conservation of the environment be put as priority within the country development process

The Slovak Republic has ratified the CBD in 1994 and the CP in November 2003. However, the national biosafety legislation has been in force even earlier: the Act on Genetic Technologies and Genetically Modified Organisms (Act No. 151/2002 Coll.), as well as the Decree to implement it (Decree No. 252/2002 Coll.) came into force in April and June of 2002 respectively. In the same year, the National Biodiversity Strategy and Action Plan, adopted in August 1998 was updated (more detailed description provided under section *B2: Country Driveness*)

The background and context of the project is described in Annex 1.

The UNEP/GEF NBF Development Project has helped Slovak Republic to complete the design of its National Biosafety Framework, which now contains a better-structured legislative framework for LMOs. Based on this, in January 2005, Act No. 77/2005 Coll. amended the Act on Genetic Technologies and Genetically Modified Organisms and consequently the Slovak Biosafety Committee, Slovak Expert Group and Advisory Board were set up at MoE SR (details see in Annex 2).

This project would help Slovakia to improve and strengthen the above-mentioned institutional and technical structures and infrastructures in order to meet its obligations as Party to the CP and make its NBF fully operational. For these purposes Slovakia needs:

- To initiate the discussion on national policy for biotechnology and biosafety, so as to draft a truly country-driven National Development Strategy encompassing an updated action plan on Biological safety
- To revise the current legislation and update this by decrees, orders and other secondary legal acts, non binding manuals etc
- To strengthen the appropriate institutional structures of NBF e.g. for risk assessment and decision making by putting them under the umbrella of the National Coordination centre for Biological Safety (NCBS), which is also responsible for other administrative and educational tasks
- To reinforce the existing infrastructure for monitoring of LMOs and the use of gene technology (GT)
- To strengthen communication and information exchange relating to biosafety, nationally and internationally through the NCBS and the BCH
- To strengthen public involvement, education and participation in decision-making on LMOs

Brief description of current status and institutional arrangements:

- MoE SR (Department of Biological Safety of the Ministry) is the competent body for CP and for relevant EU directives.
- MoA SR is the national competent body for food and feed in respect of communication with EC and is also responsible for the seed and plant variation legislation and organic farming co-existence (more on legislation and competencies in Annex 2).

As mentioned above, the competencies and responsibilities in Slovakia are divided between several institutions and competent bodies at present. Therefore this project, which aims to establish network between them through the coordination of the NCBS will not only harmonise their activities but will also forge a strong coordination mechanism. An effective coordination and collaboration mechanism is not included in the present National Biosafety and Biotechnology Policy. This has caused a main bottleneck in the country at present.

The **Overall Goal** of the project is that by 2010 the Slovak Republic has a workable and transparent national biosafety framework, in line with its national development priorities and international obligations

Specific Objectives:

A. To integrate Biosafety into the National Biosafety and Biotechnology Policy (NBBP) and National Development Strategy (NDS).

B. To review and update regulatory regime in line with CP and its national needs and priorities.

C. To make the administrative and control system fully operational under the guidance of the National Coordination centre for Biological Safety (NCBS) and to strengthen the system for handling requests, risk assessment, decision-making and other administrative and educational tasks.

D. To assist Slovakia to consolidate a functional system for "follow-up", namely monitoring of environmental effects and enforcement.

E. To assist Slovakia to enhance a functional system for public awareness, education, participation and fully available access to information on Biosafety.

Project Outcomes

A. Biosafety is integrated in the national development plans and policies.
   - Slovakia has a National Biotechnology and Biosafety Policy.
   - Biosafety is integrated into National Development Strategy for Slovakia.
   - Governmental officers understand Biosafety policy issues better.

B. Slovakia has a revised and fully functional biosafety regulatory regime in place and in line with CP and is equipped with tools for capacity building
   - Amended GMO law, new decrees and secondary acts, for example on organic farming, and guidelines for interpreting and implementing of GMO act published.

C. Slovakia has a fully operational national administrative system coordinated by the National Coordination centre for Biosafety (NCBS).
   - NCBS is in place to facilitate and organize all biosafety matters in Slovakia.
   - Increased national competence on risk assessment is available.
     - Consultations and trainings held for different stakeholder groups
     - Guidelines for handling request and manuals for RA published.

D. Slovakia has an effective national system for monitoring and enforcement.
   - National Reference laboratory equipped and internationally accredited
   - trained staff for GMO detection and surveillance

- Methodologies and procedures for monitoring and enforcement activities are in place
- Increased national competence of inspection, monitoring and enforcement

E. Public education and participation in decision-making on LMOs are addressed as a part of national implementation plan.
   - Public involvement is promoted and information is easily accessible.
     - drafted and adopted action plan for involving public in the decision-making process, and public education and awareness
     - information about biosafety made available through different channels such as publications and workshop, mass media and national website.

More details in attached Log Frame Matrix (Annex 3)

Estimated budget in US$:

GEF: Project Cost:	**466,000** US $
Co-financing: (Slovak government):	**139,000** US $
In cash:	
In kind	139.000 US $
Total:	**605,000 US $**
Associate financing, if any:	**10,000 US $ (EU ESF)***

***Comenius University in Bratislava is awarded a grant by the EU to build a Natural Sciences Education centre. This grant includes a subproject, which focuses on GMO and Biosafety Education (Subproject Nr.5).**

Information on Project proposer:

Ministry of Environment, Department of Biological Safety, contact person Mr. Igor Ferencik, ferencik.igor@enviro.gov.sk, phone: 04212 5956 2185 FAX: 04212 5956

Ministry of Environment of the Slovak Republic is the governmental body, which has an umbrella function in biosafety fields in Slovakia. The Biosafety department of MoE SR is the competent authority for approving GMOs under contained use, deliberate releases to the environment and placing on the market of GM products and transboundary movements of GMOs, under the Act No. 151/2002 Coll. as amended. According to the same Act, the Biosafety department is also the contact point for the Cartagena Protocol (the Director of Biosafety department is nominated to be National Focal Point for Cartagena Protocol, BCH and contact person for Emergency Measures).

B - COUNTRY OWNERSHIP

B1. Country eligibility

Slovak Republic ratified the Convention on Biological Diversity in August 1994 and the Cartagena Protocol in November 2003. Slovakia finalized draft NBF in October 2004.

B2. Country Driveness

State Project linkage to national priorities, action plans and programmes:

The National Biodiversity Strategy and Action Plan for Slovakia were adopted by the government on August 4, 1998. This NBSAP was updated under number 1209/2002 on November 11, 2002. The document is available at http://www.biodiv.org/doc/world/sk/sk-nbsap-01-p3-en.pdf

According to NBSAP, biosafety belongs to goal nr 12, which is to increase safety in biotechnologies and to promote access to biotechnologies and /or benefits resulting from them. The following strategic directions were given in this document:

- Initiate the elaboration of national biotechnology transfer programmes including transfer of technologies into developing countries,
- Develop appropriate administrative rules to promote access to the results of biotechnologies,
- Introduce basic standards for testing, importing, exporting and commercial use of LMOs,
- Designate authorities for biosafety control including establishment of an early warning system,
- Elaborate detailed procedures and measures for risk assessment concerning the release of GMOs.

Biosafety is also part of the country's Programme on Development for Progressive Technologies for Efficient Economy (Ministry of Economy SR) and its strategies, namely:

- Strategy for Industrial Development
- Strategy in Industrial Policy
- Consumer Policy Strategy
- State Science and Technology Policy

C – PROGRAM AND POLICY CONFORMITY

C1. PROGRAMME DESIGNATION AND CONFORMITY

The project belongs to the Biodiversity Focal Area and is relevant to:

(3) Capacity Building for the Implementation of the Cartagena Protocol on Biosafety, i.e. "Developing systemic and institutional capacity building for biosafety: Provision of support to countries for the development and implementation of National Biosafety Frameworks including the Biosafety Clearing House and enabling activities including the development and training in risk assessment and management of modified living organisms with the participation of relevant government sectors such as agriculture, fisheries, forestry, industry, environment, education, manufacturing, trade and health as well as community and private sector stakeholders."

It is therefore most relevant to the implementation of GEF Operational Programs 1-4 and 13.

C2. PROJECT DESIGN

(Details shown in LogFrame attached as Annex 3)

C2.A BACKGROUND AND CONTEXT

Slovakia participated in the UNEP/GEF Global Project on "Development of National Biosafety frameworks" from 2 December 2002 to 1 June 2004. In order to design its **National Biosafety Framework**, Slovakia carried out the following activities:

1. The Act on the use of GT and GMO which came in force in 2002 was amended in 2005.
2. Competent authority MoE SR has established a Slovak Biosafety Committee and developed a system to handle notifications or contained use applications of LMO with the help of the Commission for Biosafety (Ministers advisory board)
3. Slovak Environmental Inspection has adopted the biosafety legislation and it became the main competent authority regarding the control on biosafety .
4. State Veterinary and Food Agency and the Central Control and Testing Institute of Agriculture became responsible for food, feed and seeds control in Slovakia. A central reference laboratory at the IMB SAS was built. This laboratory, which is dedicated to method development, began to focus on the detection of unique LMOs. This laboratory needs to be refurnished in order to be accredited.
5. The National legislation supports public information and public participation in decision-making processes. In general, the Act 211/2000 Coll gives procedure and scope of the right of the public to free access to information.
6. Several workshops and seminars for general public, consumer association, primary and secondary school teachers, environmental inspectors, researchers, toxicologist and scientists were organized.
7. Several publications have been prepared.
8. Public perception survey has been conducted.

A summary of the background and context to the project is attached as Annex 1. A copy of the draft National Biosafety Framework resulting from the development project is found in Annex 2.

C2.B Current situation in Slovakia with respect to the NBF

Biosafety policy

Slovak Republic has adopted a system of legislations for the protection of biological diversity and safe use of biotechnology and LMOs in environment and agriculture. Its environmental policy reflects the need for protection of human health and conservation of Slovak environment and is based on the precautionary principle, the principle of sustainable development, together with endeavours to enhance environmental education and public participation. The legislative system has implemented some international legislative documents (e.g. Cartagena protocol and European Union directives). This demonstrates that Slovakia accepts international biosafety rules. However, despite all these commitments, Slovakia still lacks a critical comprehensive policy, which integrates biological safety into the National Biosafety and Biotechnology Policy and/or National Development Strategy.

Regulatory regime for biosafety

Basic Act on the use of Genetic Technologies and GMOs (Act No. 151/2002 Coll.) amended by the Act No. 77/2005 Coll. and the Decree to the Act (Decree No. 399/2005 Coll.) came into force in 2002, amending versions in 2005. These two legislative documents serve as an umbrella for using other specific acts, e.g. Act No. 152/1995 on food, Act No. 291/1996 on seeds, act on feed, act on human health etc and relative regulations.

The relevant legislation covering the wide range of application of GMO is as follows:
Food legislation

Act No 23/2003 Coll. that amends Act 159/1995 Coll. on food. Giving the option to use GMOs in food; require approval of Ministry of Health SR.

Under current amendment the Genetically Modified Foods can be put on the Slovak market under the condition approved by European Commission.

Food Codex, decree 1865/2001-100, §142a on obligatory labelling foods containing GMO.
Responsible institution - Ministry of Health SR, Ministry of Agriculture SR.

Seed and plant variation legislation

Act No 470/2002 Coll. that amends Act no. 291/1996 Coll. on varieties and seeds.
Responsible institution - Ministry of Agriculture SR.

Act No 184/93 Coll. on feedstuffs (with three ordinances from January 2002; on ingredients used; on technical equipment and special nutritional value indicators; on use of additives).
Responsible institution - Ministry of Agriculture SR.

System for handling request for permits

The competent authority for handling matters related to Gene technology (GT) and GMOs is the Ministry of the Environment SR (MoE SR). Manipulation of GMOs in contained conditions and their use, such as their introduction into the environment, require under the Slovak legal system, approval by the competent authority. The competent authority, which is the MoE SR, after receiving request from applicant, will publish it and then submit it for assessment to the Commission for Biosafety, an advisory body of MoE SR. The commission was established by the Minister of MoE SR as an advisory body consisting of twelve members (Details are in Annex 2). The members are:
- representatives from involved ministries: agriculture, health, education and defence,
- scientists, working in institutes of Slovak Academy of Sciences and in universities,
- representatives of public: consumer and environmental NGOs.

In order to strengthen the commission, there is a board of 15 experts comprising scientists from different areas *viz.* environment, human and veterinary medicine, food and feed production, plant and animal breeding and microorganisms. These board members serve in their capacity as experts for the Commission, at meetings related to their expertise.

Forms for applications are prescribed by the implementing Decree (available also on the website: www.enviro.gov.sk).

All cases of handling GMOs, either their contained use or releases to the environment, are submitted to the approval process. It means that every legal entity or person intending to exploit GMOs, has to receive approval in advance. The user of genetic techniques and GMOs is defined as the legal entity or person using GMOs, and not the consumer, who is the end user. The procedural framework for contained use of GMOs is different from that of introduction into the environment.

Contained Use

The operator of a facility has an obligation to be registered with MoE SR. The facility may be entered into the facility register only if complying with construction and technical equipment requirements and requirements concerning its location, internal operational arrangements, 17

laboratory procedures and system of work in contained rooms, the handling of waste and waste water treatment.
There are currently 17 registered GMOs users for contained use with more than 200 labs in the Slovak Republic. These users are mainly institutions of the Slovak Academy of Sciences and the Universities. Three of these registered users are private companies.

Deliberate Release
Deliberate release is any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms or their placing on the market, for which no containment measures have been used to limit their contact with population and environment with the aim to provide high level of safety.

Introduction or release into environment includes every use of genetically modified organisms such as seeding, planting, farming and release into the wild.

Placing on the market is defined as every accessing of the products to third persons on the market with the exception of accessing of the genetically modified organisms including culture collections for contained use or release into the environment.

No field trials are carried out in Slovakia to date.

Systems for monitoring of environmental effects and enforcement

Descriptions of system for monitoring
The national system for monitoring safe use of GMO depends upon the provisions of Act No. 151/2002 Coll. (in force since April 1st, 2002), on Use of Genetic technologies and Genetically Modified Organisms, relevant secondary legislation to this act and, of course on the relevant EU directives. The competencies for monitoring for compliance with legislative requirements are devoted to the Slovak Environmental Inspection (SEI), an inspection body of the Ministry of Environment. SEI is competent for control of using of GMOs in contained use and field trials. It is responsible for inspection of the labelling of those special products on the market, which are not included under the competency of other authorities.
Other authorities responsible for monitoring are Ministry of the Environment, Ministry of Agriculture and Ministry of Health. Besides SEI, the specialized control bodies of these ministries are:
- The State Veterinary and Food Agency – competent for control of food and veterinary products
- The Central Control and Testing Institute of Agriculture – competent for control of feed and seed products
- The Public Health Authority – competent for control food in public catering enterprises.

Slovak Environmental Inspection, biosafety department (SEI)
SEI is the main competent authority for supervision and control of GMOs, as designated by the Act No. 151/2002 Coll. The general Act on State Control No. 10/1996 Coll. is applied by the SEI as well. The Slovak Environmental Inspectorate is an authority providing state supervision and imposition of fines on matters concerning environment protection.

The Biosafety department for supervision of the use of gene technologies and GMOs was established in 2003. The main task of SEI is to control the implementation of the Act in the

process of utilisation of GMOs in contained use. At the same time SEI controls the conditions for laboratory use, and affirmed by MoE SR in the approval process.

The State Veterinary and Food Agency (SVFA)
SVFA executes control of food products on the market, particularly food safety aspects and also the correctness of labelling. The competency of SVFA is given by Act No. 159/1995 Coll. as amended by No. 23/2003 Coll. on Food and Decree No.1865/2001-100 of Food Codex.

The Central Control and Testing Institute of Agriculture (CCTIA)
CCTIA, one of the oldest control bodies in Slovak Republic, was established in 1951 on the basis of Kings Hungarian Seeds Control Institute (founded in 1884).
Acts (later amended) that give the scope of the activity of CCTIA (www.uksup.sk) are namely Act. No. 184/93 Coll. (for feeds), Act. No. 291/1996 Coll (for Varieties and seeds), Act. No. 136/2000 Coll (for fertilizers**)** and Act. No. 291/1996 Coll (for state phytosanitary service).

CCTIA is responsible for control in the above-mentioned areas. In addition, it is responsible for GMO monitoring in seed and feed materials. For this purpose CCTIA created its own laboratory, which is in the process of being accredited by the national authority – Slovak National Accreditation Service. Their task is to monitor for the presence of GM components mostly in animal feed, as GM seeds are not used in Slovakia. The CCTIA is also responsible for the registration and control of organic farmers, in line with Act No. 224/1998 Coll. on Organic Farming.

The Public Health Authority (PHA)
The responsibility of PHA is given by the Act on Food No. 159/1995 Coll. as amended by No. 23/2003 Coll. Novel Foods including GM foods have to be approved by PHA before they are put in the market. PHA assess the safety of novel foods for human consumption and performs the monitoring of the presence of food products that may contain traces of genetically modified organisms in the market and exchanges this information with the Ministry of the Environment. The institute is independent of other monitoring and control bodies.

Laboratories for detection and assessment of GMOs
SEI and PHA do not perform laboratory examinations and tests for GMOs. For control purposes they utilize the installation of the others inspection agencies.

SVFA possess two labs, one of which is based in Dolny Kubin. This lab is accredited for detection of quality and quantity of GM Food.

CCTIA has a well-equipped laboratory in Bratislava. This laboratory is in the final phase of the accreditation process for the detection GMOs in plants and feed materials.

The Institute of Molecular Biology, Slovak Academy of Sciences (IMB SAS Laboratory) is being created especially for method development with special focus on the detection of unique GMOs produced for research purposes. The institute will also serve as the reference laboratory, when it is accredited.

Public Information and participation

National legislation supports public information and public participation in decision-making processes. Act 211/2000 Coll gives general conditions, procedures and scope of the right of public to free access to information.

As regards particularly to GMOs, the **Act on use of genetic technologies and genetically modified organisms 151/2002 Coll.** has implemented the obligation of the MoE SR to inform public. The Act contains a provision, which is transposed from the EU legislation (Directives 90/219/EHS, 98/81/ES, 2001/18/ES) and the crucial ideas of the Cartagena Protocol and the Aarhus Convention.

The Department of biological safety of the MoE SR as the national competent authority for handling requests for GMO endorsement has the obligation of providing general information and information on request. There are several other paragraphs dealing with the obligation to provide information in the case of transboundary movement of GMOs, accidents and measures for their removal etc. One of them is the requirement to label genetically modified products on the market. Summaries are published on the MoE SR website, together with a link the SNIF website.

Biosafety Clearing House

The National database and central portal were created at the MoE official website, http://www.enviro.gov.sk. It contains the basic information on Slovak legislative acts, competent authorities and decision made to date. It collects data and enables exchange of information, publication of reports, etc. In the meantime the basic information is on the same web site, without interoperability with the central portal. The web contains:

- Slovak and English text of the Act 151/2000 Coll. on use of genetic technologies and genetically modified organisms, and Decree 252/2002 Coll. to the Act 151/2002
- Registers of GMOs, according to their use: placing on the market, introduction into the environment, contained use
- Register of GMOs users
- Expert reports of the Slovak Biosafety Commission
- Information on applications received and permits issued
- News - links to the websites, and where possible, to allow public to send in comments

Workshops and courses

During the life span of the UNEP/GEF Developing Project there were several workshops and seminars for general public, consumer association, primary and secondary school teachers, environmental inspectors, researchers, toxicologist and scientists. Slovak Republic invited lecturers from Czech Republic for Slovak Inspectors training. The reason was that Slovak Inspectorate was just established and our Czech partners are experienced in the field. Members of the National Coordinating Committee participated in Regional and Sub Regional Meetings on the topic.

Publications

The paper form of publications plays an important role in dissemination of information, as internet access is still limited by age of users, language and social factors. As the information accessible to general public comes from “tabloid” newspapers and several “green” organizations it is still necessary to provide stakeholders with scientifically based facts. Several such publications have been prepared in the framework of UNEP/GEF Project.

C2.C Project Rationale

Slovakia has established the basic framework for biological safety according to Cartagena Protocol, however it needs to be completed and improved according to the current situation.

The act on GMOs needs amendments to meet current EU legislation on LMOs and labelling requirement as well as to comply with future internationally-agreed procedures under the Cartegena Protocol on liability and redress etc.

The CA (MoE SR) lacks a central co-ordination body like a National Coordination Centre to provide full scientific reference, advisory, training and education services to the Ministry. A reference laboratory is almost equipped, but it has not been accredited yet and is not in use at present. Since presently, there are several divided competencies and control bodies, these need closer coordination and harmonisation in their responsibilities to LMO. Slovakia does not have a unified Biosafety and Biotechnology State policy, even though certain principles are present in many strategies and policy documents. Therefore we need to elaborate a National Biosafety and Biotechnology Policy and also establish a National Coordination centre for Biological Safety for coordinating all activities connected to biosafety in Slovakia as well as to ensure integration of biosafety into national policies.

The bottleneck of Slovak Biosafety system is training of laboratory staff and equipment for LMO detection, rules on the co-existence of traditional, organic and GM varieties farming. These should be prepared by MoA SR in 2006. More discussions of experts involved in risk assessment and management as well as the users trainings are necessary. Workshops, trainings, seminars or courses will improve also the control and monitoring processes.

The access of public to more clear information and environmental education are the aims of Slovak government. However there are still ways to improve so that more consistent information can be disseminated, by building upon the National Biosafety Clearing House etc. Further development of public awareness and participation in biosafety appears to be crucial for public understanding and possibly acceptance of biotechnological products including LMOs. The improvement of primary and secondary education in biosciences of the young generation together with education of stakeholders should increase acceptance of modern biotechnology, which is inseparable part of development of the society based on knowledge in the future.
On the other hand, sustainable development and nature conservation must remain within the priorities of the country. For this purpose we plan to initiate discussion on the National Development Strategy with the aim of including Biosafety within this Strategy.

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

a. Implementation of Protocol
Lack of funding could slow down the process, which was started successfully by the Developmental Project, but would not stop it. However, it would be difficult to monitor the transboundary movement of LMO without GEF support while the infrastructure is in development stage. Lack of funding will endanger the control over LMO in Slovakia.

b. Economic situation
Slovak Republic bases its future development on knowledge. Biotechnology is one of the crucial priorities of this process but the Biosafety Framework needs to be fully

accepted by the public. Therefore, the future will depend very much on the trust that environmental safety will be realised through effective implementation of the CP as well as the level of awareness and education in Biosafety of the public and state officers. Without an effective and robust NBF, Slovakia's trade in LMOs can be adversely affected.

c. Environmental and Development Viewpoint

Slovakia as a Party to the Protocol, cooperates in the field of biosafety with other European countries by the creation of structures for monitoring of LMO impact on the environment. Slovak priorities on economic development have to go hand in hand with biosafety, based on the precautionary principle adopted also by EC and EP in European legislation. Without GEF support Slovakia will be not be able to completely fulfil all its obligations to guarantee biodiversity and nature conservation.

EXPECTED PROJECT OUTPUTS BY COMPONENT

Table 1: Expected project outputs by components

Component A	**NATIONAL BIOSAFETY POLICY** Biosafety is integrated into the national development plans and policies of Slovakia by 2010
Outputs	*Analysis of how best to integrate biosafety into a new biosafety and biotechnology state policy and how the national development strategy is carried out; Two governmental meetings for parliamentarians and main stakeholders will be held on the National Biosafety and Biotechnology Policy and the National Development Strategy for up to 50 people in 2006 and 2008; National Biosafety and Biotechnology Policy elaborated, agreed and published; section on biosafety of the National Development Strategy is drafted and agreed; four annual NBC meetings organised*
Component B	**REGULATORY REGIME** Slovak regulatory regime is in line with CP and consistent with Slovakia's international agreements *viz.* SPS, IPPC, WTO; EU legislation and its national needs by 2010
Outputs	*Analysis of the biosafety regulatory regime carried out; amendments to the GMOs Act and decrees carried out, secondary legislation identified; GMOs Act and decrees amended by 2010; guidelines for governmental officers on the Biosafety Act and policy developed and published by 2009.*
Component C	**ADMINISTRATIVE SYSTEM for REQUEST HANDLING, RISK ASSESSMENT etc.** Slovakia has a functional national system for handling requests, including risk assessment and management, administrative processing and decision-making and by 2010
Outputs	*Existing bodies and infrastructures are re-organised into a National Coordination Centre for Biological Safety; two consultations for CA on handling request are carried; manuals for requests are reviewed and published; guidelines on risk assessment and risk management are updated; three one-day workshops on different aspects of risk assessment are organized*
Component D	**MONITORING and FOLLOW-UP SYSTEM** Slovakia has an effective national system for "follow-up" activities namely monitoring and enforcement by 2010
Outputs	*Equipment for the National Reference Laboratory (NRL) equipped and accredited in 2006; national guidelines for LMO monitoring are prepared and published; methodology for monitoring of environmental effects are revised and related*

	guidelines prepared and published; yearly plan of inspections are elaborated and executed yearly; final report on yearly follow-up activities and compliance with CP obligations.
Component E	**PUBLIC AWARENESS, EDUCATION and INFORMATION** Slovakia has a functional national system for public awareness, participation, education with free access to information by 2010
Outputs	*An action plan for public information and participation in decision-making is developed and adopted; two national workshops for the public, consumers and NGOs , and including teachers are held on LMOs and biosafety in 2006 and 2009; Outreach materials are published; radio and TV broadcasts on biosafety matters are organised; the national GMO web page is updated and improved.*

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES

Planned activities to achieve outcomes

Component A: BIOSAFETY POLICY

1. Analysis of how best to integrate biosafety into a new biosafety and biotechnology state policy and the national development strategy

2. Two national meetings with main stakeholders to discuss and agree on the National Biosafety and Biotechnology Policy and the section of the National Development Strategy (NDS) relating to Biotechnology and Biosafety (One day each for up to 50 participants in 1st and 3rd year of project (Total: 8.000 USD; GEF: 6000 USD, GOV: 2.000 USD)

3. Elaboration of the National Biosafety and Biotechnology Policy in 2nd and 3rd year and its agreement and publication in 4th year

4. Draft of the section of the National Development Strategy relating to Biotechnology and Biosafety completed in year 2008
   (Total: 14.000 USD; GEF: 9.000 USD, GOV: 5.000 USD)

5. Four NBC meetings to support and coordinate project activities (years 1,2,3,4)
   (Total: 4.000 USD; GEF: 2.000 USD, GOV: 2.000 USD)

Total costs (TOT: 26.000 USD; GEF: 17.000 USD; Government 9.000 USD)

Component B: REGULATORY REGIME

1. Revision of current regulatory regime in 2006

2. Drafting and adoption of amended Biosafety Act
   (Total 10.000 USD; GEF: 8.000 USD, GOV: 2.000 USD)

3. Drafting of the secondary legal acts on:
   - Organic farming protection
   - Decree relating to the import, conditions and procedures with LMOs

- Order relating the information required in the notifications of deliberate release and marketing of LMOs, including products made of LMOs

- Order setting out the evaluation principles of LMOs risks for biological diversity, environment and public health with clear responsibility of NCBS in this matter

(Total 8.000 USD; GEF: 6000 USD, GOV: 2.000 USD)

4. Guidelines on the interpretation and implementation of GMO Act for government officers
(Total: 6.000 USD; GEF: 3000 USD, GOV: 3.000 USD)

Total costs (TOT: 24.000 USD; GEF: 17.000 USD; Government 7.000 USD)

Component C: ADMINISTRATIVE SYSTEM of REQUEST HANDLING, RA etc.

1. Re-organisation the different units of the biosafety administrative system for efficient handling of applications, to be under one body, National Coordination Centre for Biosafety (under the Ministry of Environment, which is the designated Competent Authority)
(Total: 10.000 USD; GEF: 5.000 USD, GOV: 5.000 USD)

2. Organise two consultations for CA (decision makers) on handling request in 1st and 3rd year of project, for up to 30 people per consultation.
(Total: 14.000 USD; GEF: 12.000 USD, GOV: 2.000 USD)

3. Review and publication of the manual for handling request
(Total: 3000 USD; GEF: 2000 USD, GOV: 1000 USD)

4 Update the guidelines on risk assessment and management in 2nd Year (Total: 3.000 USD; GEF: 2.000 USD, GOV: 1.000 USD)

5. Three 'hands-on' workshops on risk assessment for Biosafety Officers (One each for RA of GMMs in contained use, on releases of GM higher plants, and on release of GMMs and GM animals, including GM fish, into the environment. (1-day workshop, each for up to 50 people)
(Total: 17.000 USD; GEF: 14,000 USD, GOV: 3.000 USD)

Total costs (TOT: 47.000 USD; GEF: 35.000 USD; GOV: 12.000)

Component D: MONITORING and FOLLOW-UP SYSTEM

1. Purchase of the equipment for the National Reference Laboratory. Provisional list of equipment needed is described in Annex 4.
(Total: 130,000 USD; GEF: 130,000 USD, GOV: 0)

2. Accreditation of reference laboratory
(Total: 2,000 USD; GEF: 0, GOV: 2000 USD)

3. Revision of methodology for LMO monitoring, publication of guidelines for monitoring of LMO (Total: 8,000 USD; GEF: 6,000 USD, GOV: 2,000 USD)

4. Preparation and publication of the manual on new methods of LMO detection, identification, etc. (Total: 4,000 USD; GEF: 2,000 USD, GOV: 2,000 USD)

5. Organization of trainings for control bodies – namely the Slovak Environment Inspection body (SEI) and staff from control laboratories- on new methods of LMO on sampling, detection, identification and interpretation of results obtained, with up to 20 participants (Total: 16,000 USD; GEF: 14,000 USD, GOV: 2000 USD)

6. Elaboration and execution of a yearly "Plan of inspections" in year 1,2,3 and publish a final report on follow-up activities in year 4
(Total: 30,000 USD; GEF: 24,000 USD, GOV: 6,000 USD)

Total costs (TOT: 190,000 USD; GEF: 176,000 USD; GOV: 14,000)

Component E: PUBLIC AWARENESS, EDUCATION and INFORMATION

1. Development and adoption of an action plan for involving public into decision-making process and public education and awareness, 1-2 year
(Total: 8,000 USD; GEF: 6,000 USD, GOV: 2,000 USD)

2. Organization of two informational workshops for wider public, including teachers, consumers and NGOs in year 1 and year 4 for up to 100 people.
(Total: 10,000 USD; GEF: 8,000 USD, GOV: 2,000 USD)

3. Publication of outreach materials: popular publication on GMO and Biosafety published by NCBS (yr.2)
(Total: 6,000 USD; GEF: 5,000 USD, GOV: 1,000 USD)

4. Organization of TV and radio broadcasts on Biosafety matters in connection with developed Biosafety policy and or Strategy (yr1 and 4.)
(Total: 6,000 USD; GEF: 4,000 USD, GOV: 2000 USD)

5. Updating the national GMO web page
(Total: 4,000 USD, GEF: 2,000 USD, GOV: 2,000 USD)

Total costs (TOT: 34.000 USD; GEF: 25.000 USD; GOV: 9.000)

Project management, including institutional set-up, staffing etc.

Project coordination			**GEF**	**GOV**	**Total**
F1	NPC (part time)		24.000	48.000	72.000
F2	Assistant 1 (full time)		36.000		36.000
F3	Assistant 2 (part time)		16.000	16.000	32.000
F3	Accountant/WEB		20.000	20.000	40.000
F5	Audit		8000		8.000
F5	Equipment & Premises		4.000	2.000	6.000
F7	Travels		16.000		16.000
F9	Reports edition		2.000	2.000	4.000

F10	Technical support service		70.000		70.000
Total Project Coordination			**196.000**	**88.000**	**284000**

Total costs (TOT: 284.000 USD; GEF: 196.000 USD; Government 88.000)

Indicators for the activities see in the attached Log Frame analysis (Annex 3).

C.3 Sustainability

Institutional sustainability

Under this project, the National Coordination Centre for Biological Safety will be coordinating the existing numerous biosafety bodies and infrastructures, which are currently scattered among several national institutions, after these bodies are re-organised. Once such a coordination centre is established and its competences anchored in the Slovakian legislation (one of the main objectives of this MSP), the sustainability of the NBF will be guaranteed at institutional and operational levels.

The NCC, which was successfully established during the NBF Development project, is expected to continue to work for the Implementation project. Since most NCC members are from institutions, which will come under the coordination of the National Coordination Centre for Biological Safety, these NCC members, after completion on the Implementation project, will return to their respective institutions and be part the National Coordination Centre for Biological Safety. This, together with the National Biosafety Commission (as an Advisory board), and the National Reference Laboratory will also ensure sustainability.

Operational sustainability

The Implementation project is closely linked to the biosafety activities currently running (and planned) in Slovakia. Some of them have already started, as, for example the revision of the regulatory regime and the preparation of the law on "co-existence". This project will provide operational support to the National Coordination Centre for Biological Safety, which is to be part of the Ministry of Environment, namely the National Competent Authority. The Centre will promote operational sustainability by ensuring that adequate capacity is built through training workshops (including curricula development) on biosafety in order to limit the loss of knowledge due to movement of people and the development of tools (as manuals, guidelines etc). In fact, this project has been designed to focus on capacity building for all those involved in the biosafety-related activities, i.e. decision-makers, inspectors and scientists.

Financial and political sustainability

Political sustainability is directly linked to the political awareness and involvement of several Ministries of Slovak government in the project. The project plans to further educate decision-makers and government officers on the biosafety issues and involve them in the elaboration of the National Biosafety and Biotechnology Policy and National Development Strategy. Once these policy and strategy are adopted and the GMO Act is amended, the budget necessary for biosafety will be fully incorporated into the state budget. At the moment, biosafety is run under the Biodiversity Conservation Fund of the Ministry of Environment. 30 million SKK of this fund are made available for biosafety yearly. As per the GMO Act amended in 2005, Slovakia has also adopted a fee-based system for handling of requests. This allocation and the income generated from fees, will be used to sustain the NCBS and cover part of the costs of operation.

The upcoming elections (2006) will not change these positive developments. However, as the elections may slow down the process, the GEF support is considered crucial at this specific phase of implementation of the NBF.

Environmental sustainability
The involvement of an interdisciplinary commission for biosafety as established by law guarantees ownership as well as that the best available knowledge and experience is made available and contributes to decision-making in environmental issues. In addition, the revision and updating of the current methodologies and guidelines for monitoring of environmental effects and inspections will help to minimise negative impacts on the environment and support its conservation.

C.4 Replicability

The lessons learned and best practices from other previous projects run in the region will be used as opportune to implement national policies and processes related to Biological Safety and bring applications of modern biotechnology into life in Slovakia, without serious concerns for the possible negative effect on its population and/or environment.

The National Centre for Biological Safety will disseminate lessons learned and best practices from this project to other countries within the region and to other regions. So far, the Comenius University in Bratislava was contacted by the Ministry of Environment of Laos to help and educate their Biosafety Officers. Additionally collaboration was established with Bosnia/Herzegovina to help them in the development of their regulatory regime. .

To promote dissemination of the project results and exchange experiences, the National Project Coordinator of the Slovakian Project plans to participate in the annual meetings of national project coordinators of the UNEP-GEF NBF Implementation Projects.

C. 5 Stakeholder involvement

The main stakeholders are listed in Table 2 (below). These include all relevant Ministries and other governmental agencies and control bodies that expressed their needs for this project. Then there are members of academic and scientific institutions that together with some civil society representatives participated actively in this project elaboration, incorporating their specific issues into the project design.

Information will be disseminated in several adequate ways, based on the target group of each activity. All activities of the project should appear on the Internet, some will achieve national publicity from relevant media, some will be organised more at an institutional level.

Table 2: Major Stakeholders and their Participation

STAKEHOLDERS	Type of involvement
Parliamentarians, decision-makers	Drafting of policy and strategy papers, ensuring state financing for biosafety activities
Ministry of Environment SR – CA for contained use and field trials Ministry of Agriculture SR – CA for food, feed, seeds and plant cultivation and control Ministry of Health - CA for human health safety Ministry of Economy – responsible for	All ministries will be involved in revision of current legislation/ amendments to legislation. They will participate in the elaboration of the National Biosafety and Biotechnology Policy as well as on that part of the National Development Strategy that relates to biosafety/biotechncology.

Biotechnology/Biosafety development strategy	
Other Government Agencies State/specialized control bodies are: SHMI SEI SVFA CCTIA PHA NRL	All are responsible for including LMO issues in their statutory activity plans. NRL is responsible for - harmonization of methods of LMO detection NEA is responsible for NCBS creation - responsible for monitoring and follow-up - food and veterinary products - seeds and co-existence with organic farmers - human health and novel food - methodology on LMO detection
Scientific community (all relevant universities and academic institutions), namely: Institute of Molecular Biology Slovak Academy of Sciences Faculty of Natural Sciences Comenius University in Bratislava	Equipment and accreditation of National Reference Laboratory as well as setting up of the National Centre for Biological Safety Preparation of instruction, guidelines and other materials for workshops, trainings and other educational activities, collaborating with NCBS
Civil society: Consumer's association of SR, Society for sustainable life, Friends of the Earth and other main environmental NGOs Modern biotechnologies and society	Participation in the decision making process Representation of public in workshops and discussions on national biosafety policy Representative body for biotechnology support (NGO – also helpful in the project elaboration)
Private sector: Biotika a.s. Slovenská Ľupča Representatives of other industrial and/or agricultural associations (feed and seed importers, feed processors, farmer unions and other companies dealing with GMOs	Representative of the only biotechnology enterprise in Slovakia. Involved in the elaboration of the state Biosafety and Biotechnology Policy; Benefit from the information produced within the project. Contribute to make the biosafety framework operational. Invited to participate to the national meetings and for active collaboration.

C6. MONITORING AND EVALUATION PLAN

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

Project execution performance, delivered outputs (Table 1) and project impact (Table 6 in Annex 5) will be measured according to the indicators developed in the project log frame (Annex 3), and using this specific Monitoring and Evaluation Plan (Annex 5). The general and specific objectives of the project, and the list of its planned outcomes, provide the basis for this monitoring and evaluation plan. The project 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 5.

D. FINANCING

D1. Incremental cost

The following table provides a summary of baseline and incremental costs by output/component as well as information on GEF financing and national co-funding. A detailed incremental cost analysis, and global and domestic benefits and related schematic representation are presented in Annex 6 together with an incremental cost matrix. The total baseline expenditure amounts to US $ 2.198.000, with main components relating to NCBS. The increment has been estimated at US $ 605.000. The national contribution in kind amounts to US $ 139.000. The remaining total cost of US $ 466.000 is requested from GEF. These figures were derived from key indicators and baselines as enclosed in Annex 7.

Table 3. Summary incremental cost analysis in US $

Activity	Baseline (US $)	Alternative (US $)	Increment (US $)	Cost to GEF (Global Benefit)	Co-financing (in kind/in cash contributions)
Biosafety Policy	200.000	226.000	26.000	17 000	9000
National Biosafety legislation	678.000	702.000	24 000	17.000	7.000
Handling of requests	480.000	527.000	47.000	35.000	12.000
Monitoring of environmental effects and inspections	400.000	590.000	190.000	176.000	14.000
Public awareness and participation	229.000	263.000	34.000	25.000	9.000
Project coordination and management	211.000	495.000	284.000	196.000	88.000
TOTAL	2.198.000	2.803.000	605.000	466.000	139.000

D2. BUDGET and PROJECT IMPLEMENTATION PLAN

The detailed budget of the project is shown in Annex 8. A summary of the budget by components with co-financing details and staff costs are shown in Tables 4 and 5 respectively (below).

Table 4: Project Budget by Components.

	Component	GEF (US $)	Government (US $)	Total (UD $)
1	Biosafety and development strategy	17.000	9.000	26.000
2	Regulatory regime	17.000	7.000	24.000
3	Handling applications	35.000	12.000	47.000
4	Monitoring and Inspection	176.000	14.000	190.000
5	Public participation and information	25.000	9.000	34.000
6	Project coordination	196.000	88.000	284.000
	TOTAL	**466.000**	**139.000**	**605.000**

Table 5: Staff costs – not directly linked to a specific activity (US $)

Personnel	GEF	National Co-financing	TOTAL
National coordinator of the project	24.000	48.000	72.000
One project assistant (full time) AP1	36.000	0	36.000
One project assistant (part time) AP2	16.000	16.000	32.000
Financial Officer /WEB administrator	20.000	20.000	40.000
Travel for NPC, Staff and NCC members	16.000	0	16.000
TOTAL	**112.000**	**84.000**	**196.000**

Equipment and operating costs:

Office equipment and operating costs of 6000USD cover the purchase of computers, software upgrades, maintenance etc. as well as office utilities, stationary and communication costs. This amount is shared between GEF and Slovakia that contributes 33%.

D3 PROJECT IMPLEMENTATION PLAN

The project will be carried out for four years. The implementation plan is provided in Annex 9.

E - INSTITUTIONAL COORDINATION AND SUPPORT

E1 CORE COMMITMENTS AND LINKAGES

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

This portfolio has already produced relevant results, generated lessons learned and best practices being used /which can be used in other countries of the world. In this respect, the project will benefit from UNEP's experience and expertise to develop a fully operational NBF in Slovak

Republic, where best practices and lessons learned will add to those being acquired through the eight demonstration projects currently running under UNEP.

LINKAGE TO PHARE TWINNING PROJECT

The Phare –Twinning Project ended in September 2005. The project has covered the following activities:

- Setting up and purchase of basic equipment for the reference laboratory
- Setting up the Slovak Inspection Office on Biosafety
- Initial training of inspectors.

The GEF project complements the above mentioned activities and addresses some specific needs, which could not be covered under the Phare-Twinning initiative. These are namely:

- Purchase of a few key instruments for the reference laboratory to equip it adequately for accreditation (Annex 4)
- Training of the reference laboratory staff
- Specialized training of inspectors, biosafety officers and decision-makers
- Identification of specialized methods of LMO detection crucial for monitoring of environmental effects and enforcement
- Public information and participation, which is still very much needed in the country.

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

E2.a National Co-ordinating Committee

The National Co-ordinating Committee (NCC) will be established by the National Executing Agency (NEA), namely the Ministry of Environment of SR, 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 10.

E2.b National Project Co-ordinator

The National Project Coordinator will be appointed by the National Executing Agency, namely the Ministry of Environment of SR, 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 10.

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, namely the Ministry of Environment, and two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. However, whenever technical and scientific issues related to the implementation of the MSP are to be addressed, the representative of STAP as well as experts selected in their personal capacity will be invited to participate. The Steering Committee will meet once a year and communicate mainly by e-mail and phone.

ANNEXES (in separate files)

ANNEX [1]	Background and Context
ANNEX [2]	NBF
ANNEX [3]	Project Log Frame
ANNEX [4]	Provisional list of equipment for laboratory
ANNEX [5]	Monitoring and Evaluation Plan
ANNEX [6]	Incremental cost assessment
ANNEX [7]	Key indicators, Baselines and Data collection
ANNEX [8]	Detailed Project Budget
ANNEX [9]	Implementation Plan – Timetable of planned activities
ANNEX [10]	Draft TOR for the National Executing Agency, National Project Committee, National Project Coordinator

TABLES

ANNEX 1 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 organisation 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. Slovak Republic 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.

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

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

Annex 2:

NATIONAL BIOSAFETY FRAMEWORK

FOR THE SLOVAK REPUBLIC

Peter Siekel and Igor Ferenčík

(Editors)

DRAFT

Institute of Molecular Biology of the Slovak Academy of Sciences

Ministry of the Environment SR

Bratislava

November 2004

Foreword

The active protection of the environment has become a part of economic process, political and social life. There are regularly organized international sessions of local, regional and global importance. The goals of these sessions are to exchange information relevant to the state of components of ecosystems, to gain the experience with conservation of biological species and abiotic elements of the environment, prepare proposals of regional and global legislation, and the experience with using these legislation.

The conservation of the biological diversity remains significant element of the environmental protection. Several important decisions, which encourage the Parties to improve the conservation of biological diversity, were adopted at the COP 7 (COP = Conference of the Parties) in Kuala Lumpur. Another important meeting was the First meeting of the Parties of the Cartagena Protocol to the Convention on Biological Diversity - COP/MOP1. Even though it was the first meeting of the Parties, it contributed to strengthening position of Protocol in international context.

As the President of the COP4, which took place in Bratislava, Slovakia, I have good memories of the period between the years 1998 – 2000. The most intensive discussion about the text of the Protocol was held in different parts of the world within agenda of COP4. The final text of the Protocol was adopted at the Secretariat of the Protocol in Montreal in January 2000.

I gladly recall all discussions about the final version of the text of the Protocol until it was negotiated and acceptable for all negotiating groups very well. It was inspiring despite the fact that debate lasted until late nights or many times until early mornings.

After adopting the Protocol we started with preparation of the national legislation in Slovakia. We exploited the experience of colleagues from different European countries, but the “real impulse” for intensive international cooperation was the Project UNEP/GEF. It allowed not only

concluding the legislative framework for GMOs use and at the same time to join international cooperation in the field of biotechnology. In 2002 Slovakia organized a workshop, where the Secretariat CBD launched the important part of Cartagena Protocol- Biosafety Clearing House. National Council of the Slovak Republic adopted our first Act on GMOs at the same year.

In the scope of implementation of the Project "Developing of National Biosafety Dept. Biosafety MoESR Framework", we prepared the amendment of our Act, that include the provisions of Cartagena Protocol, we improved administrative and information structures and we arranged a lot of seminars and workshops for different target groups.

We took advantage of the experience from the Project for successful ratification of Cartagena Protocol. Slovakia ratified the Cartagena protocol in November 2003, so we had already become the Party to the Protocol at COP/MOP1.

The cooperation in the field of Biosafety as the member of the bureau of Convention and Cartagena Protocol is ongoing.

Our next steps will point toward improvements of the regional cooperation with European countries and at creation of structures for monitoring of GMOs in the environment.

Henceforth we will keep all friendly and collegiate relations that we gained during the cooperation in the field of biotechnologies up to now.

László Miklós

Minister of Environment

Of the Slovak Republic

Information on the Project

UNEP-GEF– GEF Project Number GF/2716-02-4573 (PMS:GF/6010-01-3A) Project

„Development of the National Biosafety Framework for the Slovak Republic“ started in January 2002 and was prolonged till October 2004.

National Executing Agency for the project was:
Institute of Molecular Biology of the Slovak Academy of Sciences
Contact person: Associated Professor Jozef Timko, DrSc.
Address: Dúbravská cesta 21, 845 51 Bratislava 45
Phone: +421 2 54773702
Fax: +421 2 5930 7416
E-mail: umbitimk@savba.sk
Website: http://imb.savba.sk/

National Project Coordinator was:
Institute of Molecular Biology of the Slovak Academy of Sciences
Department of Genetically Modified Organisms
Contact person: Mr. Peter Siekel
Address: Dúbravská cesta 21, 845 51 Bratislava 45
Phone: +421 2 55566114
Fax: +421 2 5930 7416
E-mail: peter.siekel@vup.sk

National Coordination Committee consisted of 9 members, representing:
Ministry of the Environment, Ministry of Agriculture, Ministry of Health, Comenius University, Slovak Academy of Sciences, Scientific Press VEDA, private sector, nongovernmental organizations and civil societies (Annex 1).

Report "National Biosafety Framework for the Slovak Republic" was prepared within the Project UNEP/GEF and edited by Igor Ferenčík, Peter Siekel, Jozef Timko.
Contributors were:
Ms. Lenka Myjavská, Mr. Milan Peško,

Consultations:
UNEP/GEF Biosafety Unit, Geneva (Christopher Briggs, Andrea Gondová / Liina Eek)
UNEP/GEF Biosafety Unit – Division of GEF Coordination, Nairobi (Lydia Eibl-Kamolleh)

Disclaimer

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Abreviations

BCH Biosafety Clearing House

CCTIA Central Control and Testing Institute of Agriculture

EU European Union

GEF Global Environment Facility

GMO Genetically Modified Organism

GMOs Genetically Modified Organisms

LMO Living Modified Organism

MoE SR Ministry of Environment Slovak Republic

MoA SR Ministry of Agriculture Slovak Republic

NBF National Biosafety Framework

NCC National Coordinating Committee

NGO Non-governmental Organisation

PHA Public Health Authority

SEI Slovak Environmental Inspection

SVFA State Veterinary and Food Agency

UNEP United Nations Environmental Programme

1. Biosafety Policy

Slovak Republic has adopted system of legislative norms for protection of biological diversity, safe use of biotechnology and GMOs with their application in the environment and agriculture. The legislative norms adopted allow exploitation of genetically modified organisms under strictly defined conditions. These include releases to the environment, contained use and marketing of GMOs including genetically modified foods and feeds. Slovak Republic ratified the Convention on Biodiversity and Cartagena protocol on Biosafety in November 2003. To strengthen the system on biosafety Slovak Republic joined several international projects. The UNEP/GEF project is aimed on the development of the mechanisms for Biosafety Clearing House and implementation of the Cartagena protocol. The PHARE projects are oriented to the adoption EU environmental legislation and to cover gaps in Biosafety system in governmental control and inspection. Slovak scientific priorities have been stated in 2000 where bioscience plays prominent role. Priorities are consonant to EU priorities with biosafety, food safety, biotechnology and informatics on the first place.

The Environmental Policy reflects the needs of protection and conservation of Slovak environment, improvement of the health of people, economical growth including agriculture, industry and transportation. It is based on the prevention principle, principle of sustainable development, with endeavour to enhance environmental education and public participation.

The prominent role of Cartagena Protocol in shaping legal framework for biosafety was recognized and implemented to Slovak legal system (Notification of ministry of Foreign Affairs 82/2004 Coll.) in February 2004. Important tool for implementation of national biosafety policy is Act on GMOs and Decree to the Act. Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms (Act on GMOs) is in force as of April 1st 2002 and implementing regulation Decree No. 252/2002 Coll. of the Act on GMOs as of June 1st 2002. The law is first instance legislation for GMOs. It regulate releases, marketing, contained use of genetically modified micro-organisms, higher plants, and animals. Approval for any use of GMO must be granted under this Act. Based on this approval the specific uses further require approvals granted by different central institutions.

Other laws that are listed later in the text cover safety aspects for the human health, food and feed safety and agricultural applications. The responsibility for human health is at Ministry of Health, which also share the responsibility for food with Ministry of Agriculture, which has responsibility for regulation of seeds, feed and other agricultural application of GMOs.

2. Regulatory regime

In the last decade the environmental legislation in Slovak Republic was developed with the vision of membership to EU. The harmonization processes of Slovak legislation to EU legislation lead to high complementarities of both systems. During that time Slovak Republic became the party to international conventions with adopting legal system accordingly.

Regulatory regime for biosafety consists of binding international treaties and EU and national legislation.

The provisions of international treaties, EU directives and other EU legislative acts that are not directly applicable are implemented into the national legislation. As EU regulations are directly valid in member countries national legislation does not cover some aspects of GMOs and biosafety issues.

International treaties

Convention on Biological Diversity was ratified November 2003 and entered into force in February 2004.

The following EU directives establish a regulatory framework concerning GMOs and biosafety in the 0EU. The requirements of these directives have been implemented in the national legislation.

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment when:

- Carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community,
- Placing on the market genetically modified organisms as or in products within the Community.

Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified

micro-organisms; Council Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms.

The Directive lays down common measures for the contained use of genetically modified microorganisms with a view to protect human health and the environment. In accordance with the Directive, Member States have to ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment that might arise from the contained use of GMMs.

The directly applicable EU legislative acts concerning GMOs and biosafety.

Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms

Regulation:

- Establishes a common system of notification and information for transboundary movements of genetically modified organisms (GMOs);
- Ensures a coherent implementation of the provisions of the Cartagena Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of the GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account also risks to human health.

The Regulation establishes the procedures that are in compliance with Cartagena Protocol in respect to exports of GMOs to third countries (which are not member states of the EU).

There are different procedures for:

- GMOs intended for deliberate release into the environment and
- GMOs intended for direct use as food and feed, or for processing.

In SR the competent body for CPB and for relevant EU directives is Department of Biological safety of MoE SR. Ministry of Agriculture is national competent body for food and feed in respect of communication with European Commission.

Regulation (EC) 1829/2003 of the European Parliament and Council of 22 September 2003 on genetically modified food and feed

In accordance with the general principles laid down in Regulation (EC) No 178/2002 this Regulation:

- Provides the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring effective functioning of the internal market;
- Lays down Community procedures for the authorization and supervision of genetically modified food and feed;
- Lays down detailed provisions for the labelling of genetically modified food and feed.

The Regulation establishes detailed procedures for the authorization and supervision of genetically modified food and feed.

The Regulation requires labelling of the food and feed, which are to be delivered as such to the final consumer or mass caterers in the Community and which:

(a) Contain or consist of GMOs; or

(b) Are produced from or contain ingredients produced from GMOs.

The Regulation states also that labelling of foods containing a material which contains, consists of or is produced from GMOs is not required in the case when GMOs proportion is not higher than 0.9% of the food ingredients considered individually or for food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. 0.9% limit is for GMOs that are approved for marketing, and 0.5% for GMOs having positive opinion of scientific assessment of EFSA and approved by EFSA and 0% non-approved GMOs.

The institutions responsible for the implementation of this Regulation are basically the EU authorities – the Commission, Food Safety Authority and the Council, making decisions on the use of genetically modified food and feed in the territory of the EU.

Ministry of Agriculture SR is national competent body for food and feed in respect of approval of GM food and for communication with European Commission.

According to the last amendment to the Food law (Act No. **546/2004 Coll). The** responsibility is for:

- Acknowledging of receipts of applications;
- Informing and making the applications, and for any supplementary information supplied by the applicants available to the European Food Safety Authority.

Commission Regulation 641/2004 of 6 April 2004 establishes detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

The Regulation

• Lays down the general principles governing food and feed in general, and food and feed safety, in particular, at the Community and the national level;

• Establishes the European Food Safety Authority;

• Lays down procedures for matters with a direct or indirect impact on food and feed safety in order to provide the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account, in particular, the diversity in the supply of food, including traditional products;

• Establish common principles and responsibilities, the means to provide a strong scientific base, efficient organizational arrangements, and procedures to underpin decision-making in matters of food and feed safety.

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

The Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products from circulation.

This Regulation applies, at all stages of placing the product on the market, to:

• Products consisting of, or containing GMOs placed on the market in accordance with Community legislation;
• Food and feed produced from GMOs placed on the market in accordance with Community legislation.

Regulation establishes detailed requirements for:
• Traceability and labelling of products consisting of or containing GMOs,
• Traceability of products intended only for direct use as food, feed or for processing (requirements for labelling of these products are established by Regulation (EC) 1829/2003).

Compliance with these requirements has to be ensured by the operators.

Traceability and labelling requirements for products consisting of or containing GMOs

At all stages of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators have to ensure that the following information is transmitted in writing to the operator receiving the product:
(a) That it contains or consists of GMOs;
(b) The unique identifier(s) assigned to those GMOs in accordance with Article 8 of the Regulation.

For products consisting of or containing GMOs, operators have to ensure that:
(a) For pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)] appear on a label;
(b) For non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified [name of organism(s)]' must appear on, or in connection with, the display of the product.

Traceability requirements for products for food and feed produced from GMOs

In the event of placing on the market of products for food and feed produced from GMOs, the Regulation states that operators have to ensure that the following information is transmitted in writing to the operator receiving the product:
(a) An indication of each of the food ingredients produced from GMOs;
(b) An indication of each of the feed materials or additives produced from GMOs;

(c) In the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.
The institution responsible for the implementation of this Regulation is Ministry of Agriculture of SR together with national control institutions – the State Veterinary and Food Administration, the Central Control and Testing Agricultural Institute.

Biosafety related legislation Slovak Republic

The relevant legislation covering wide range of application of GMO is as follows:
Food legislation

Act No 23/2003 Coll. that amends Act 159/1995 Coll. on food. Giving the option to use GMOs in food; require approval of Ministry of Health SR.

Under current amendment (as from 1st of January 2005), the Genetically Modified Foods can be put on the market under the condition approved by European Commission.

Food Codex, decree 1865/2001-100, §142a on obligatory labelling foods containing GMO is in line with EU legislation. Responsible institution is Ministry of Health SR, Ministry of Agriculture SR.

Seed and plant variation legislation

Act No 470/2002 Coll. that amends Act no. 291/1996 Coll. on varieties and seeds. Responsible institution - Ministry of Agriculture SR. The amended Act regulates the rights and obligations of natural and legal persons in the registration and testing of plant varieties and in the production, recognition and placing on the market of planting stock and plant varieties. It harmonises the registration and testing of plant varieties and the production, recognition and placing on the market of planting stock and plant varieties. It is necessary to obtain permit for deliberate release issued by MoE for field trials and for testing of GM varieties according to this act. Then the procedure of adopting of new variety is administrated in the European Committee. The last step of adoption is registration to the Common European register of approved varieties.

Feedstuffs legislation

Act No 184/93 Coll. on feedstuffs (with three ordinances from January 2002; on ingredients used; on technical equipment and special nutritional value indicators; on use of additives). Responsible institution is Ministry of Agriculture SR.With effect from 1 March 2002; the Act amends three Ordinances of the Ministry of Agriculture.

1. Ordinance of 31 January 2002 No. 39/1/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/1/1997-100 on the ingredients used in the production of compound feeds and farm feedingstuffs;

2. Ordinance of 31 January 2002 No. 39/2/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/2/1997-100 that lays down the requirements for technological equipment and technological processes employed in the production of compound feeds and specifies the indicators of nutritional value and the use of compound feeds;

3. Ordinance of 31 January 2002 No. 39/3/2002-100, which amends MoA Ordinance of 7 October 1997 No. 1497/3/1997-100 that lays down conditions for use of additives and their putting into circulation.

Related legislation

- Act No 11/1992 Coll. on the environment is the basic law to protect environment.
- Act No 543/2002 Coll. on the nature and country protection.
- Act No 237/2002 Coll. on the trade with wild animals and plants (CITES).
- Act No 215/2001 Coll. on the protection on genetic resources of plants aimed for the nutrition and agriculture.
- Act No 415/2002 Coll., which amends Act No 224/98 Coll. on organic farming. The policy of this Act for organic farming is the same as in EU countries. The Act determines the governmental body responsible for register, inventory, control and overall management of the organic food production. According the § 7 article 4b it is forbidden to use GMOs in bioproducts.
- Act No 415/2002 Coll. 471/2001, which amends Act No 285/95 Coll. on phytosanitary care.
- Act No 23/2003 Coll., which amends Act 159/1995 Coll. on food.

- Food Codex, decree 1865/2001-100, §142a on obligatory labelling foods containing GMO with line with EU legislation.
- Act No 514/ 2002 Coll., which amends Act No 272/1994 Coll. on the protection of human health.
- Act No 367/2001 Coll. on the safety and protection of human health at the workplace.
- Governmental Decree No 47/2002 Coll. on the health protection while working with biological factors.

Future plans and needs

- The Act No. 151/2002 Coll. on the use of genetic technologies and genetically modified organisms as well as the Decree No. 252 of the MoE SR on the same topic is prepared for amendments to meet current EU legislation on GMOs.
- The bottleneck of Slovak Biosafety system is trained laboratory staff and equipment for GMO detection in the environment and food chain. The Phare project on the GMOs detection system in Slovakia "**Biosafety Monitoring System"** for Slovakia will start in autumn 2004 to fulfil the EU standards.
- The rules on the "Co-existence" of traditional, organic and GM varieties farming needs to be prepared by MoA SR in future.

3. System to Handle Notifications or Consent for Use of GMOs.

Principles of GMO Act

Competent authority for handling matters on the Genetic technology and GMOs is Ministry of the Environment SR (MoE SR).

The manipulation with GMOs in contained conditions and use of GMO in the case of its introduction to the environment requires, under Slovak legal system, approval by competent authority. The competent authority, MoE SR, after receiving request from applicant, publish it and then submit it for the assessment to the Commission for Biosafety, an advisory body of MoE SR. The commission was established by the minister of MoE SR as an advisory body consisting of twelve members (Details are in Annex 1). The members are:

- representatives from involved ministries: agriculture, health, education and defence,
- scientists, working in institutes of Slovak Academy of Sciences and in universities,
- representatives of public: consumer and environmental NGOs.

For strengthening of the expert level of committee there is an board of experts having 15 members, scientists from different expert areas: environment, human and veterinary medicine, food and feed production, plant and animal breeding, micro organisms. For the actual cause they are also serving as a member of committee in its meeting.

More details are in Annex2.

Forms for applications are prescribed by the implementing Decree (available also on the website: www.enviro.gov.sk, part GMO).

All cases of handling GMOs, either their contained use or releases to the environment, are submitted to the approval process. It means that every legal entity or a person intending exploit GMOs has to receive approval in advance. User of genetic techniques and GMOs is legal entity or a person using GMOs not the final user of it on the market - consumer.

Procedural framework for use of GMOs is different for contained use and for introduction into the environment.

Contained Use

The operator of a facility has an obligation to be registered with MoE SR. The facility may be entered into the facility register only if complying with construction and technical equipment requirements and requirements concerning its location, internal operational arrangements,

laboratory procedures and system of work in contained rooms and the waste handling and waste water treatment.
The user is obliged to:

- establish a safety committee for contained use at each facility,
- appoint a head of the project for each use of genetic technologies and genetically modified organisms

The head of the project should have to have professional qualification that means university education in relevant field, at least three-year experience in genetic engineering and modern biotechnology and regular participation in professional education.
The member of the safety committee should be person with integrity; university education in relevant field and three year experience in using of genetic technologies and genetically modified organisms.
A user should assure the implementation of following principles as regards the occupational safety and health protection and good microbiological practice in facilities.

Prior to the beginning of any contained use the user have to:
- to execute measures for averting of possible harmful effects to humans and environment, that may be resulting from such use, to assess the risk arising from planned contained use, in particular as regards the possible harmful effects to humans and environment, on the basis of result of the risk assessment to assign the prepared use of genetic technology to a risk class,
- to provide the level of protection corresponding to the risk class and its relevant requirements on contained use and particular protective measures,
- to draw up the emergency response plan and make it available via internet, or in other appropriate manner,
- to provide the substantial information on the content of the emergency response plan to persons likely to be affected in case of accident,
- to submit a notification or submit an application for consent with contained use.

The user has to identify the following possible harmful effects in risk assessment:
- allergenic and toxic effects of genetically modified organisms to humans,
- effects of genetically modified organisms to animal and plant health,

- effects causing resistance to antibiotics used in human and veterinary medicine,
- effects deleterious for providing of effective prophylaxis
- effects due to the natural transfer of inserted genetic material to other organisms.

The user has to assign any planned contained use to one of the following risk class:
- risk class 1 – activities of no or negligible risk, for which level 1 containment is appropriate,
- risk class 2 – activities of low risk, for which level 2 containment is appropriate,
- risk class 3 – activities of moderate risk, for which level 3 containment is appropriate
- risk class 4 – activities of high risk, for which level 4 containment is appropriate.

In case of doubt the higher risk class shall be applied to the proposed use, unless the reason for applying lower risk class is justified.

The notifier has to notify Ministry on:
- The data on the head of the project and on members of the safety committee, as well as the changes in these data,
- The commencement of the activity assigned to risk class 1 in facility, for which first consent for contained use has been issued,
- The commencement of the activity assigned to risk class 2 in facility, for which the consent for contained use in activities assigned to classes 2 to 4 has been already issued and for which all requirements of this consent have been met,
- The finding out of new information concerning the activities that may have significant impact on risk.

Deliberate Release

Deliberate release is any intentional introduction into the environment of a genetically modified organism or a combination of genetically modified organisms or their placing on the market, for which no containment measures have been used to limit their contact with population and environment with the aim to provide high level of safety.

Introduction or release into environment is every use of genetically modified organisms in environment, particularly seeding, planting, farming and release into wild nature.

Placing on the market is every accessing of the products to third persons on the market with the exception of accessing of the genetically modified organisms including culture collections for contained use or release into the environment.

Prior to beginning of every deliberate release the user have to:

- describe up the emergency response plan and make it available via the Internet, or, if appropriate in other manner.
- provide substantial information on the content of emergency response plan to the persons that are likely to be affected in case of an accident,
- to carry out measures for prevention of possible adverse effects on humans and environment, which could be caused by the deliberate release,
- assess the risk arising from planned deliberate release, in particular to identify and evaluate direct and indirect, immediate and delayed effects of genetically modified organisms on humans and environment,
- perform the analysis of cumulative long term effects of genetically modified organisms on humans and environment,
- decide on the need for risk management and on the use of the most suitable genetic method,
- assess every case of possible adverse effects arising from direct or indirect transfer of genes from genetically modified organisms to other organisms,
- to apply for a consent and comply with the requirements laid down in the Act on GMOs.

Consent of the Ministry for introduction into the environment is required for:

- first and every other release of a genetically modified organism or a combination of genetically modified organisms into the environment, which means on the market and/or field releases
- change of the purpose of introduction of a genetically modified organism, several genetically modified organisms and a combination of genetically modified organisms, which could have significant effect on humans or environment or which could give rise to new knowledge of such effects,
- import of genetically modified organisms designed for the introduction into the environment.

One consent for introduction into the environment may be issued for the introduction of the same genetically modified organism or the same combination of genetically modified organisms to the same place or to various places but for the same purpose at the same time.

Withdrawal or alteration of the consent to the use – safeguard clause

The MoE SR, on the basis of new evidence regarding risk involved to the use of GMO, may alter or withdraw the consent for use of it. In the case when the GMO is introduced to the common market of EU and, there is good reason to believe that it represent risk for human health or to the environment, the member state can stop the use of it in its territory.

Future plans and needs

The system for handling notifications and permissions for use of GMOs is well established according to EU standards in Slovakia.

The system of presenting Slovak position in the EU Commission by two different ministries (MoE and MoA SR) needs to be co-ordinated, as they often present not consistent opinions.

4. Monitoring and Enforcement

Descriptions of system for monitoring

The national system for monitoring of safe use of GMO depends upon the provisions of the Act No. 151/2002 Coll. (in force since April 1st, 2002), on Use of Genetic technologies and Genetically Modified Organisms, relevant secondary legislation to this act and, of course on the relevant EU directives. The competencies for monitoring of the compliance with legislative requirements are devoted to the Slovak Environmental Inspection (SEI), an inspection body of the Ministry of Environment. SEI is competent for control of using of GMOs in contained use and field trials. It is responsible for inspection of the labeling of those special products on the market, which are not in competency of other authorities.

Other authorities responsible for monitoring are Ministry of the Environment, Ministry of Agriculture and Ministry of Health. Besides of SEI, the specialized control bodies of these ministries are:

- The State Veterinary and Food Agency – competent for control of food and veterinary products
- The Central Control and Testing Institute of Agriculture – competent for control of feed and seed products
- The Public Health Authority – competent for control food in public catering enterprises.

Slovak Environmental Inspection, biosafety department (SEI)

SEI is the main competent authority regarding supervision and control of GMOs designated by the Act No. 151/2002 Coll. The general Act on State Control No. 10/1996 Coll. is applied by the SEI, too.

The Slovak Environmental Inspectorate is an authority providing state supervision and imposing fines on the matters concerning environment protection. The competences of SEI increased substantially in regards to the transposition of the EU legislation into Slovak legal framework. As a result of it a new Biosafety department for supervision on the use of genetic technologies and genetically modified organisms has been established in 2003.

The main task of SEI is to control the performance of the Act in the process of utilisation of GMOs in contained use. At the same time SEI controls the conditions for the labs use, affirmed by MoESR in approval. There are currently registered 19 GMOs users in contained use with

more than 200 labs in the Slovak Republic currently. These are mainly institutions of the Slovak Academy of Sciences and of the Universities. Three of users are private companies.
No serious faults were observed till now, so there was no need to restrict or cease their activities or inflict a fine in line with the "Gene" Act. While controling GMO releases to the environment, the compliance with the conditions established by MoE SR are being checked up. No GM crops trial has been approved and put into practice in the Slovak Republic so far. The process of the market releases of GM commodities are controled, as well as the adherence of their labeling and conditions of their exploitation, which were set up by MoE SR during approval procedure.
Since 1st May 2004, when the Slovak Republic has become the member state of the European Union, the conditions for approval of GMOs and its placing on the market have been guided by European Commission. SEI controls the conformity with EU legislation.

The State Veterinary and Food Agency (SVFA)
SVFA executs control of food products on the market, particularly food safety aspects and also the correctness of labelling. The competency of SVFA are given by the Act No. 159/1995 Coll. as ammended by No. 23/2003 Coll. on Food and Decree No.1865/2001-100 of Food Codex.
When examining the presence of GM food products on the market SVFA found a few goods, which contents was inferior, some products contained higher amount of GMO than limit established by EU.
Since 1st of May 2004, goods approved by European Commission can be sold in the Slovak Republic, too. These goods must comply with EU conditions (labelling, content of GM component, etc.), which factuality is also controled by SVFA.

The Central Control and Testing Institute of Agriculture (CCTIA)
CCTIA, one of the oldest control bodies in Slovak Republic, established in 1951 on the bases of Kings Hungarian Seeds Control Institute (founded in 1884).
Acts (later amended) gives the scope of the activity of the CCTIA (www.uksup.sk) on the feeds (Act. No. 184/93 Coll.), Varieties and seeds (Act. No. 291/1996 Coll.), fertilizers (Act. No. 136/2000 Coll.), state phytosanitary service (Act. No. 291/1996 Coll.).
It is responsible for expert controlling in the above-mentioned areas. Besides this it is responsible for GMO monitoring in the seed and feed materials. For this purpose CCTIA created its own laboratory, which is in the process of accreditation by national authority – Slovak National

Accreditation Service. Their task is to monitor the presence of GM components mostly in feeds as the GM seeds are not used in Slovakia.
The CCTIA is responsible to register and control the organic farmers, in line with Act No. 224/1998 Coll. on Organic Farming.

The Public Health Authority (PHA)

The responsibility of PHA is given by the Act on Food No. 159/1995 Coll. as amended by No. 23/2003 Coll. The Novel Foods including GM foods have to be approved by PHA before putting them on the market. PHA assess the safety of novel foods for human consuption and performs the monitoring of the presence of food products that may contain traces of genetically modified organisms on the market and exchanges this information with the Ministry of the Environment. The institute is independent from other monitoring and control bodies.

Laboratories for detection and assessment of GMOs

SEI and PHA do not perform laboratory examinations and tests for GMOs. For control purposes they utilize the installation of the others inspections.
SVFA possess two labs, one of them is based in Dolný Kubín. This lab is acredited for detection of quality and quantity of GM Food.
CCTIA has got very good equipped lab in Bratislava, and is in the final phase of acreditation process for detection GMOs in plants and feed materials.
The Institute of Molecular Biology Slovak Academy of Sciences (IMB SAS Laboratory) dedicated to the method development and focused on the detection of unique GMOs produced for research purposes is being created. The institute will also serve as the reference laboratory, once acredited.
All introduced labs are the members of the european DNA labs network ENGL of EU Joint Research Centrum, based in Ispra, Italy and are also cooperating with the others worldwide organisations (e.g. ICGEB).

Adresses of institutions responsible for above described actions

Ministry of the Environment
Biosafety Department
Mr. Igor Ferenčík, Head of the Department

Address: Námestie Ľ. Štúra 1, 812 35 Bratislava
Phone: +421 2 59562185
Fax:
E-mail: ferencik.igor@enviro.gov.sk
Website: www.enviro.gov.sk

Ministry of Agriculture
Food Department
Contact person: Mr. Ladislav Brazdovič
Address: Dobrovičova 12, 812 66 Bratislava
E-mail: ladislav.brazdovic@land.gov.sk
Website: www.mpsr.sk

Ministry of Health
Public Health Authority
Contact person: Ms. Katarína Chudíková
Address: Bratislava
Phone: +421 2 492 84 111
Fax: +421 2 443 72 641
E-mail: chudikova@uvzsr.sk
Website: www.uvzsr.sk

Ministry of Health
Central Control and Testing Institute of Agriculture
Contact person: Mr. Ľubomír Horváth
Address: Matúškova 21, 831 00 Bratislava
Phone:+421 2 64462089
Fax: +421 2 64462089
E-mail: horvath@uksup.sk
Website: www.uksup.sk

Ministry of Agriculture
State Veterinary and Food Agency
State Veterinary and Food Institute
Contact person: MVDr. Mária Kantíková
Address: Jánoškova 1611/58, 026 01 Dolný Kubín
Phone:+421 43 5864869
Fax: +421 43 5868207
E-mail: kantikova@svpudk.sk
Website: www.svps.sk

Ministry of Agriculture
State Veterinary and Food Agency
State Veterinary and Food Institute
Contact person: MVDr. Kamil Boleček

Address: Botanická 15, 842 52 Bratislava
Phone: +421 2 60258112
Fax: +421 2 654 27 461
E-mail: kbolecek@svuba.sk, or svuba@svuba.sk
Website: www.svps.sk

Institute of Molecular Biology
Slovak Academy of Sciences
Department of Genetically Modified Organisms
Contact person: Mr. Peter Siekel
Address: Dúbravská cesta 21, 845 51 Bratislava 45
Phone: +421 2 55566114
Fax: +421 2 5930 7416
E-mail: peter.siekel@vup.sk
Website: http://imb.savba.sk/

Future plans and needs

- To create better links between Slovak accredited laboratories involved in the European Network of the GMO laboratories – ENGL.
- To held regular discussions of the experts involved in risk assessment and risk management.
- To provide support to the GMO control institution via organization of workshops, seminars and courses especially in sampling GMOs in order to improve the controlling and monitoring processes.

5. Public participation and public information in the decision making process

The right of public to be informed, the freedom of speech, the right to freely spread information and ideas is anchored in the Slovak Constitution and further broaden by Act No. 23/1991 on the List of Basic Human Rights and Freedoms.

Within the environmental context there are following international obligation:

Aarhus convention on the access to information, public participation in decision making and access to justice in environmental matters from June 1998.

Status: Not ratified.

Cartagena Protocol on Biosafety to the Convention of Biological Diversity is another international legally binding instrument which recognizes the importance of public awareness and participation (Article 23). The Parties to the Protocol should provide information to the public by means of the Biosafety Clearing-House.

Status: Ratified November 2003

European legislation

Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC

This Directive is based on the principles anchored in the Aarhus Convention that is transposed to European Community legal system.

The objectives of Directive 2003/4/EC are:

a) to guarantee the right of access to environmental information held by or for public authorities and to set out the basic terms and conditions of, and practical arrangements for, its exercise; and

b) to ensure that environmental information is progressively made available and disseminated to the public in order to achieve the widest possible systematic availability and dissemination of environmental information to the public.

The Directive regulates access to environmental information, access to justice, dissemination of environmental information, the quality of environmental information and the review procedure of the Directive based on the experience gained by the Member States.

National legislation

National legislation supports public information and public participation in decision-making processes. General conditions, procedures and scope of the right of public to free access to information is given by the Act 211/2000 Coll.

As regards particularly GMOs the **Act on use of genetic technologies and genetically modified organisms 151/2002 Coll.** has implemented the obligation of the MoE SR to inform public. The Act contains provision transposed from EU legislation (Directives 90/219/EHS, 98/81/ES, 2001/18/ES) and the crucial ideas of Cartagena Protocol and Aarhus Convention.

Department of biological safety of the MoE SR as national competent authority for handling requests for GMO endorsement has the obligation of providing:

General information via:

- publication on the Internet
- publication in the official journal
- publication in the means of mass communication – news papers, leaflets, brochures,
- TV, radio
- Providing seminars, courses

Information on requests:

- Orally, or on telephone request
- Assist in the sending information by post, electronic post or by fax
- assist in the making a copy of request

MoE SR has the obligation to inform public on:

- beginning of the authorization
- a summary the content of requests
- reports on the results of introduction of GMOs into the environment
- activity reports on the results of the Biosafety Committee
- evaluation report for the EU

There are several other paragraphs dealing with obligation to provide information in the case of trans boundary movement of GMOs, accidents and measures for their removal etc. One of them is the requirement to label genetically modified products on the market.

The Act (Article 27) establishes Commission for Biosafety and its board of experts as an advisory body to the Minister of Environment. The task of the Commission is:

a) to deal with the state of the scientific and technologic development in the field of genetic technologies in particular to gather the results of any contained use and deliberate release obtained from notifier's reports and notifications, to generalize it and compare to scientifically proved facts obtained on the international level,
b) to analyze, review and assess the content of submitted notifications and applications for issue of notifications from the point of view of science and available knowledge on genetic methods, genetic techniques and on risks arising from the use of genetically modified organisms,
c) to work out the recommendations as the professional basis for Ministry issuing the consents (Article 13, 17 and 21),
d) to analyze and assess the content of received comments from public,
e) to work out recommendations needed for determination of technical and organizational requirements on facilities, good laboratory practice, monitoring and evaluation of the use of genetic technologies,
f) to assess the proposals for entering the register of used genetic techniques, genetic methods and used modified genes.

The Commission meets regularly every month and on important issues if necessary.
The board of experts scientifically supports the work of Commission.
The rules for decision making process contain mechanism for public involvement. Besides representation of governmental institutions the participant may be non governmental organisations ans civic associations. The summaries of the notifications are published on the web page of MoE SR (www.enviro.gov.sk). The public can send comments while the decision process is not finished. After the sending the notification to the EC, the information of the notificatiom is summarised and published together with link of the SNIF website on the MoE SR web site.

Biosafety Clearing House

In the CBD Secretariat server the Slovak BCH site was created, which contains the basic information on Slovak legislative acts, competent authorities and decision made to date. The national BCH is placed in the Ministry of the Environment website: http://www.enviro.gov.sk

site. It collects data and enables exchange of information, publication of reports, etc. In the meantime the basic information is on the same web site, without interoperability possibility.

The web contains:

• Slovak and English text of the Act 151/2000 Coll. on use of genetic technologies and genetically modified organisms, and Decree 252/2002 Coll. to the Act 151/2002

• Registers of GMOs, according to their use: placing on the market, introduction into the environment, contained use

• Register of GMOs users

• Expert reports of the Slovak Biosafety Commission

• Information on received applications and issued permits

• The news

Links to the web sites, in which is possible to find present applications send and proceeded in European Committee

- links to the web sites, to where is possible to send comments by public

It is necessary to underline that there is endeavor in EC to establish EU BCH as a contact point to the BCH Secretariat.

Workshops and courses

During the life span of the UNEP/GEF Project there were several workshops and seminars for general public, consumer association, primary and secondary school teachers, environmental inspectors, researchers, toxicologist and scientists. Slovak Republic invited lecturers from Czech Republic for Slovak Inspectors training. The reason was that Slovak Inspectorate was just established and our Czech partners are experienced in the field.

Members of the National Coordinating Committee participated in Regional and Sub Regional Meetings on the topic.

Publications

The paper form of publications play an important role in dissemination of information as the Internet access is still limited as regards of the age, language and social factors. As the information accessible to general public comes from "tabloid" newspapers and several "green" organizations it is still necessary to provide stakeholders with scientifically based facts. Several such publications have been prepared in the framework of UNEP/GEF Project (Annex 7).

Public perception

As a part to the project, the public perception survey has been done in Slovak Republic. It is not surprising that the public perception is similar to other similar reports. More than half of the Slovaks who responded to the survey think biotechnology and genetically modified organisms (GMOs) are "useful" or "rather useful" in agriculture, medicine and ecology. They remain negative about using biotechnology in the food. More than 40% of the respondents still think that there is only limited information available on biotech products. Almost 21% responded that they never heard of GMOs. 35% of the respondents believe they knew the meaning of the term "genetically modified organism", and three quarters 27% of these knew the correct meaning. Less than 25% of the respondents were aware that there are already existing laws and regulations for biotech products in Slovakia. Almost 42% of the respondents were not interested in biotechnology or think "it's not their problem", while 37% of respondents is interested (2.4% actively). So it is not true that majority of consumers are highly involved in the issue. In general, Slovaks trust that scientific institutions, medical associations and non governmental environmental organizations protect their interests and rights. However, consumers are susceptible to the influences of non-governmental environmental organizations that try to scare consumers by providing one-sided or partial information.. Small portion of consumers (10%) search Internet for GMOs, majority "receive" information from newspapers, TV and radio. In general, Slovakia still lacks enough information on biotech products even though the situation improved in the last couple of years.

The results of the survey were published as articles in journals and as reports on meetings and also summarized on the web page of MoE SR and US embassy in Vienna.

Goals and Measures

Further development of public awareness and participation in biosafety appears to be crucial for public understanding and possibly acceptance of biotechnological products including GMOs. The improvement of primary and secondary school education in bio sciences of young generation together with education of stakeholders should increase acceptance of modern biotechnology.

The main measures for the nearest periods can be defined as to:

- Start ratification process of the Aarhus Convention together with its implementation,
- Raise environmental awareness focused to different stakeholders groups
- Deliver information on dangerous substances in the environment in comparison to the GMOs
- Develop bilateral cooperation especially with respect to the EU priorities and at national level take measures reflecting European Commission recommendations in respective field.

Annex 1

SLOVAK BIOSAFETY COMMITTEE

Chairman:
Mr. Igor Ferenčík, Biosafety Department, Ministry of the Environment, Námestie Ľ. Štúra 1, 812 35 Bratislava
e-mail: ferencik.igor@enviro.gov.sk

Secretary:
Ing. Magdaléna Farkašová,
Biosafety Department, Ministry of the Environment, Námestie Ľ. Štúra 1, 812 35 Bratislava
e-mail: farkasova.magdalena@enviro.gov.sk

Members:
Ing. Ľubor Miko, Ministry of Agriculture, Dobrovičova 12, 812 06 Bratislava
e-mail:lmiko@land.gov.sk

Ing. Ladislav Brázdovič, Ministry of Agriculture, Dobrovičova 12, 812 06 Bratislava
e-mail: ladislav.brazdovic@land.gov.sk

MUDr. Katarína Chudíková, Public Health Authority, Trnavská 52, 826 45 Bratislava
e-mail: chudikova@uvzsr.sk

Mgr. Ján Jankela, CSc, Ministry of Education, Stromová 1, 813 30 Bratislava,
e-mail: jankela@education.gov.sk

pplk MUDr. Jozef Adámik, Military Institute of Hygiene and Epidemiology, Cesta mládeže 1, 833 03 Bratislava
e-mail: adamikjozef@pobox.sk

Ing. Jozef Šimúth, DrSc., Institute of Chemistry, Slovak Academy of Sciences, Dúbravská cesta 9, 842 38 Bratislava
e-mail: : chemsim@savba.sk

Doc. Ing. Jozef Timko, DrSc., Institute of Molecular Biology, Slovak Academy of Sciences Dúbravská cesta 21, 845 51 Bratislava
e-mail: umbitimk@savba.sk

Prof. RNDr. Ján Turňa, CSc., Department of Molecular Biology, Faculty of Natural Sciences, Comenius University, Slovak Republic, Mlynská dolina B-2, 842 15 Bratislava
e-mail turna@fns.uniba.sk

RNDr. Peter Siekel, CSc., Food Research Institute, Priemyselná 4, P.O.Box 25,
824 75 Bratislava
e-mail peter.siekel@vup.sk

Mgr. Miloš Lauko, Consumer´s Association of Slovak Republic, Vazovova 7,
811 07 Bratislava
e-mail: milos.lauko@test-magazin.sk

RNDr. Ľubica Lacinová, DrSc., Society for sustainable life. Vlárska 5
833 34 Bratislava
e-mail: lubica.lacinova@savba.sk

Annex 2

SLOVAK EXPERT GROUP

No	Name	Expert field	Organization	Contacts
1	Gabriela Borošová, Ing.		Biotika a.s. Slovenská Ľupča	Tel: 048 – 436 8900 Fax: 048 – 418 70 42 Email: raddir@biotika.sk
2	Jozef Grones Doc. RNDr.,	GM mikroorganisms, food produced from GM raw materials	Comenius University, Faculty of Natural Sciences, Department of Molecular Biology, Mlynská dolina B-2, 842 15 Bratislava, Slovak Republic	Tel. 02 - 602 96 649 02 – 602 96 460 Fax: - Email: grones@fns.uniba.sk
3	Milan Bežo, Prof. RNDr., CSc.,	GM plants, food produced from GM raw materials	Slovak Agricultural University, Department of plant genetics and breeding Trieda A. Hlinku 2 949 761 Nitra	Tel. 037 – 650 82 41, 037 – 650 82 42 Fax. 037 – 741 26 26 Email: bezo @afnet.uniag.sk milan.bezo@uniag.sk
4	Ján Kraic, RNDr., PhD,		Research Institute of Crop Production, Laboratory of cell and molecular biology Bratislavská cesta 122 921 68 Piešťany	Tel. 033 - 772 23 11 033 – 772 23 12 Fax. 033 - 772 36 06 Email: kraic@vurv.sk
5	Anna Preťová, RNDr., CSc.,		Institute of Plant Genetics and Biotechnology, Slovak Academy of Sciences Akademická 2 P.O.Box 39A 950 07 Nitra	Tel. 037 - 733 66 59 Fax.: 037 – 733 66 60 Email: anna.pretova@savba.sk

6	Ing. Jana Libantová, CSc.		Institute of Plant Genetics and Biotechnology, Slovak Academy of Sciences Akademická 2 P.O.Box 39A 950 07 Nitra	tel: 037/7335738, kl. 448 037/7336661 fax: 037/7336660 nrgrliba@savba.sk
7	RNDr. Juraj Faragó, CSc.		Research Institute of Crop ProductionDepartment of applied genetics and breeding Bratislavská cesta 122 921 68 Piešťany	tel: 033/7722311 fax: 033/7726036 e-mail: farago@vurv.sk
8	Prof. Ing. Jozef Bulla, DrSc.,	GM animals, feed and food produced from GM raw materials	Slovak Agricultural University, Faculty of Biotechnology nad Food Sciences, Department of Genetics Trieda A. Hlinku 2 949 76 Nitra	Tel. 037/ 6508 524 Fax: 037/ 6546486 0908 733 599 Email: jozef.bulla@uniag.sk
9	Prof. MVDr. Rudolf Cabadaj, CSc.		University of veterinary medicine Komenského 73 041 81 Košice	Tel. 055 – 633 01 27, kl. 112 Fax: 055 – 633 56 41 Email: rektor@uvm.sk
10	Prof. MVDr., Ivan Mikula, DrSc		University of veterinary medicine Komenského 73 041 81 Košice	Tel. 055 – 633 92 87 Fax: 055 – 633 56 41 Email mikula@uvm.sk
11	Prof. RNDr. Oto Majzlan, CSc.,	GMO and influence on the ecosystems	Comenius University Pedagogical faculty Department of Biology and Patobiology Moskovská 3 810 00 Bratislava	Tel. 0904 111842 Fax: 02 /44254960 Email oto.majzlan@fedu.uniba.sk
12	Ing. Peter Urban		State Nature Protection Banská Bystrica Lazová 10 P.O.Box 5 974 01 Banská Bystrica	tel: +421 (048) /4713622 fax: +421 0903563106 e-mail: urban@sopsr.sk

13	MUDr. Iveta Trusková,		National Institute of Health of the Slovak Republic Trnavská 52 826 45 Bratislava	Tel. 443 72 807, (743, 833) Fax: Email truskova@szusr.sk
14	Mgr Tatiana Kašperová,.	GMO and influence on the human health	National Institute of Health of the Slovak Republic Trnavská 52 826 45 Bratislava	Tel. 02 – 444 55 642 Fax: 02 – 444 55 642 Email kasperova@szusr.sk
15	Doc. MUDr., Peter Pružinec, CSc.,		Faculty Hospital Department of clinical imunology and alergology Americké námestie 3 813 69 Bratislava I	Tel. 02 – 529 66 093 Fax: Email

ANNEX 3: Logical Framework

Project Title: "Support the Implementation of the National Biosafety Framework of Slovakia"

Component	Indicators	Means of verification	Risks and constraints	Risk management
GOAL: **To assist Slovakia to implement fully operational workable and transparent NBF through strengthening the needed capacities in line with objectives of CP and other international obligations**	A workable and transparent NBF is in place and in line with its international obligations and national development priorities by 2010	• Report on NBF • Relevant national documents	• Implementation of NBF is carried out in isolation from national context and international obligations • Lack of workable systems for the implementation of the NBF	• Project helps identifying needs • Project helps to set up systems (regulatory, handling request, monitoring, etc) which can fit the national context and international obligations • Promote broader political talks and collaboration, supporting national stakeholders to promote awareness on responsibilities taken to implement the NBF
COMPONENT A. NATIONAL BIOSAFETY POLICY				
Objective 1 **Biosafety is integrated into the National Biosafety and Biotechnology Policy and the National Development Strategy**	By 2010, biosafety is part of the national development objectives	Agreed policies registered on the BCH	• Biosafety is developed in isolation • Ministries act without coordination. • Lack of political commitment. • Polarization of debate on the Biosafety policy	• Adopt the national policy and strategies by promoted cooperation of involved ministries. • Promote greater dialogue between regulators, biotech sector and public.
Outcome A.1 **National Biosafety and Biotechnology Policy is elaborated and agreed, and biosafety is included in the** National Development Strategy **for Slovakia**	• National intersectional plans & programs (annual, short-term, long-term) reviewed and amended in line with the objectives of CPB and other international obligations; • National biosafety and biotechnology policy	• Official government documents • Internal government reports available • Media coverage of biosafety issues • Meeting documents,	• Strategy is developed in isolation • Government does not harmonize biosafety with other policies • Biosafety strategy not translated into practice	• Project identifies relations between biosafety and other policies • Promote mechanism for review, adjustment and application of strategy • Promote debate, discussion

	elaborated, agreed and published • Section of the National development Strategy relating to biosafety is elaborated and agreed	agenda, list of participants, records of decisions, media coverage of the meeting	• Polarised positions cannot be conciliated	and exchange of information among main stakeholders • Promote broader public awareness and information dissemination
Activities relating to A.1 • Analysis of how best to integrate biosafety into a new National Biosafety and Biotechnology Policy and the National Development Strategy • Elaboration of the National biosafety and biotechnology policy in 2nd and 3rd year and submission to the government and parliament in 4th year • Draft the section of the National Development Strategy relating to Biosafety • Organize four (yearly) NBC meetings to support and coordinate project activities (years 1,2,3,4)				
Outcome A.2 **Strengthened understanding of biosafety policy issues**	• Meetings organized as planned by year 2009:	• Documents, material available • Post-meeting evaluation • List of participants	• Quality of the meeting is not satisfactory • Participants are not accurately selected and not enough motivated to participate • Resource persons are not appropriate	• Careful planning of the meeting and related support tools • Careful identification of the target persons • Involvement of the persons and sensitization on their crucial role in the functioning of the NBF
Activities relating to A.2 • Two governmental meetings with main stakeholders to discuss, agree and draft theNational biosafety and biotechnology policy and the National Development Strategy (NDS) (One day each for up to 50 participants in 1st year and 3rd year)				
COMPONENT B. REGULATORY REGIME				
Objective B				
Slovakia has a fully reviewed and updated regulatory regime in line with CP and its national needs and priorities	Regulatory regime in line with CP, EU legislation and other international agreements	• Implementing regulations approved as per Biosafety Law • Technical guidelines available • Operational manuals available	• Regulatory regime cannot be easily finalised because of lack of government support • Regulatory regime cannot be enforced because of lack of implementing regulations, guidelines and manuals • Regulatory regime cannot	• Organize awareness raising initiatives for decision-makers • Develop implementing regulations as per Biosafety Act, • Develop operational manuals for translation of legislation into practice • Promote cooperation and exchange of information throughout the government structure

			be enforced because of inefficiency of existing administrative structures • Regulatory regime cannot be enforced because of lack of capacity of personnel in charge	
Outcome B.1 **Slovakia has a revised and fully functional biosafety regulatory regime in place and in line with CP, and is equipped with tools for capacity building**	• National biosafety law amended and adopted by Parliament by 2010; • National secondary legislation drafted and agreed by 2010;	• Approved laws, decrees and orders published in national gazette • Posting of the summary of the laws, decrees and orders in a UN language on the BCH	• Amended 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 policies; • National regulatory regime is not consistent with CPB and other international obligations	• Ensure thorough legal analysis and thorough assessment of the status of national legislation; • Promote cooperation and exchange of information throughout governmental authorities; • Prepare operational manuals • Clearly defined roles and responsibilities among the responsible staff
Activities relating to B.1 • Analysis of the biosafety regulatory regime, identification of the amendments needed to the biosafety act and discussion with the different stakeholders (year 1) • Drafting and adoption of the amended law and decrees on: - Organic farming protection - Import, conditions and procedures with LMOs - Information required in the notifications of deliberate release and marketing of LMOs, - Products made of LMOs • Elaboration of the guidelines for governmental officers and the public for the interpretation and implementation of the biosafety act (year 2)				
COMPONENT C. SYSTEM OF REQUEST HANDLING, RISK ASSESSMENT etc.				
Objective C				
Slovakia has an operational system for system for handling of requests	• Network of existing institutions represented by National Coordination	• Set of procedures for handling requests available • Decisions are recorded on	• System for handling requests cannot be enforced because of lack of	• Develop tools and training on handling requests, including risk assessment

handling (including systems for risk assessment, decision-making and administrative processing), coordinated by the National Coordination centre for Biosafety;	centre for Biosafety providing the fully functional system for handling requests, risk assessment and other administrative tasks • Set of procedures for handling requests in use by 2010 • Number of decisions made as a result of request within CP timeframe during project life	the BCH	implementing guidelines and manuals • System for handling requests cannot be enforced because of lack of capacity on how to handle the request and how to perform risk assessment • Lack institutional collaboration	• Specify roles and responsibilities so as to minimize inefficiencies
Outcome C.1 **A fully operational national administrative system is in place and coordinated by the "National Coordination Centre for Biosafety"**	• National Coordination Centre for Biosafety is in place; • Clearly defined entity for decision-making with clearly defined roles and responsibilities • Percentage of requests handled • Review of decisions on risk assessment • Manual for handling of requests published	• Decisions are available • Staff nominated and tasks described in their job description • Record of applications received	• Delay in administrative set up due to political/ bureaucratic procedures; • Lack of clarity in the implementation of the national administrative system; • Lack of technical administrative personnel, having the required combination of inter-disciplinary skills; • Insufficient technical infra-structure developed;	• Develop tools and training to build capacity on handling of requests • Define clear roles and responsibilities in the institutional system to minimize inefficiencies • Corrective measures are carried out
Activities relating to C.1 • Re-groupe the different units of the biosafety administrative system under the "National Coordination centre for Biosafety" (NCBS) • Organize two consultations for decision makers (CA) on the procedures for handling requests (with international experts in yr. 1,3, approx 30 participants) • Review and publish the manual for handling of requests (yr.1)				
Outcome C.2 **Increased national competence on risk**	• Methodological procedures for carrying out risk assessment developed	• Procedures for carrying out risk assessment agreed upon;	• Lack of qualified risk assessment experts in place;	• Careful identification and planning of the training tools and activities, including identification of trainers

assessment and management	and operational • National training workshops organized by year 2009:	• Number of personnel educated and trained (final list of participants); • 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	• Lack of consensus in reaching decisions on risk assessment; • 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 national training activities	and feedback mechanism to improve future training • Careful planning of the workshop • Careful identification of the resource persons and participants • Encourage regional cooperation in RA; • Encourage efficient dialogue between proponents (notifiers) and administrators concerning RA applications • Envisage regular training of staff
Activities relating to C.2 • Update the guidelines on risk assessment and management (yr. 2) • Organize three workshops on RA for Biosafety Officers on: - GM microorganisms in contained use - Releases of GM higher plants - Release of GM microorganisms and animals, including GM fish into environment (yr.1,2,3) (each workshop is up to 30 participants)				
COMPONENT D. MONITORING AND FOLLOW-UP SYSTEM				
Objective D				
Slovakia has an effective national system for for monitoring and enforcement	• By 2010, roles and responsibilities for monitoring and enforcement in place • Guidelines for monitoring of environmental effects and inspections are in place by 2010 • Reference laboratories in operation	• Published guidelines and list of persons dispatched to • Manuals published • NRL accredited	• Methods and procedures are not clear and do not cover all the steps • Procedures for enforcement actions are not clear in defining who is who and who does what and do not cover all the steps • System for monitoring and	• Strengthen collaboration and cooperation so as to avoid and/or minimize overlaps and gaps • Experts are consulted for a revision of the technical guidelines • Experts are consulted for a revision of the procedures for enforcement • Funding for key equipment is looked for • Corrective measures as needed

			enforcement does not work efficiently • Laboratories miss key equipment	
Outcomes D.1 **Methodologies and technical means for monitoring and enforcement activities are in place**	• National reference laboratory (NRL) equipped and accredited • National Guidelines for LMO monitoring prepared and published • Division of responsibilities clearly divided among the national institutions authorized for enforcement (control and inspections) • Plan of inspections elaborated and executed yearly	• Certificate of accreditation of the reference laboratory • National Guidelines for LMO monitoring and manual on new methods of LMO detection (control and inspection) broadly disseminated ; • Reports of inspections	• Reference laboratory does not meet standards to be certified • National guidelines and manual for monitoring and enforcement approved and in place, but are not followed either due to political ignorance, low acceptance/ awareness or insufficient institutional capacities among the responsible institutions; • Overlapping (or gapping) institutional responsibilities among national institutions, in charge of enforcement (control and inspections) mechanisms;	• Corrective measures for laboratories as needed; • Raise awareness and train appropriate staff; • Improve the coordination efforts on awareness raising, i.e. how to divide roles, tasks and responsibilities in systematic way among the national institutions in order to avoid either overlapping or gaps;
Activities relating to D.1 • Purchase of the equipment for the National Reference Laboratory (NRL) and complete its accreditation (year1) • Revision of the methodology for monitoring for environmental effects, preparation and publication of the related guidelines; • Elaboration and execution of a yearly "Plan of inspections" in year 1,2,3 and publish a final report on follow-up activities in year 4				
Outcomes D.2 **Increased national competence on monitoring for environmental effects and enforcement**	• National training workshops organized as planned (by year 2009) • Manual on new methods of LMO detection, identification, etc prepared by 2008	• Documents, training material and end- of-training evaluations • Workshop documents and post-training evaluation • List of participants • Manual on new methods of	• Quality of the workshop material is not satisfactory • Participants are not accurately selected and not enough motivated to learn • Resource persons are not appropriate	• Careful planning of the training activities and training tools • Careful identification of the target persons • Involvement of the personnel and sensitizing on their crucial role in the functioning of the NBF

		LMO detection, identification, etc available	• Duration of the workshop is not adequate	
Activities relating to D.2 • Preparation and publication of a manual on new methods of LMO detection, identification, etc. • Organizing trainings for Control Bodies , namely the Slovak environment Inspection (SEI) and control laboratories staff, on new methods of LMO on sampling, detection, identification and interpretation of results obtained – up to 20 participants(year 1 , 3)				
COMPONENT E. PUBLIC AWARENESS, EDUCATION and INFORMATION				
Objective E				
Slovakia has an efficient national system for promoting public awareness, participation, education, and access to information on Biosafety	• Public debate and discussion in media by 2010 • Public service advertising and targeting key audience • Public education and participation plan in use	• Reports, plans • Reports in media	• Lack of political support • Control of media	• Capacity building within government sectors • NCCB involved in strengthening public awareness and in public education
Outcome E.1 **Public education and participation in decision-making on LMOs are addressed as part of national implementation plan**	• Public education and participation plan agreed by 2010 • Media coverage	• Plan available; Internal documents, • Comments received;	• Plan is worked out in isolation, • Plan does not respond to needs	• Plan is circulated to all the involved parties for comments and revision till final agreement • Involvement of main stakeholders to identify and address needs in public awareness, education and participation in decision making;
Activities E • Development and adoption of an action plan on public education and participation in decision-making 1-2 yr				
Outcome E.2 **Public involvement promoted and easy access to information by the public**	• Planned training workshops are carried out by 2010 • Number of different outreach materials distributed to target groups • Number of hits on the website	• Published outreach material • Meeting documents, agenda, list of participants, records of decisions, media coverage of the meeting • Website accessible	• Different categories of audience and related needs are not correctly identified • Quality of the training tools and activities is not satisfactory • Developed tools do not cover adequately the issues • Resource persons are not appropriate	• Identification of the audience and messages before preparation of the outreach material • Careful identification and planning of the training tools and activities, including identification of trainers and feedback mechanism to adapt training

Activities E • Organization of two informational workshops for broad public, including teachers, consumers and NGOs, year 1 and year 4 • Publication of outreach materials: popular publication on GMO and Biosafety published by NCBS, yr.2 • Organize TV and radio broadcasts on Biosafety matters in connection with National Development Strategy (yr. 1 – 4) • Update national GMO web page				
Footnote to this table: MoE – Ministry of Environment; MoA – Ministry of Agriculture MoH – Ministry of Health; MoEc- Ministry of Economy CA – Competent Authority, RA – Risk Assessment BS – Biosafety Strategy; CA – Competent Authority, BO – Biosafety Officer NDS – National Development Strategy, NBSAP – National Biosafety Action Plan NCBS – National Coordination centre for Biological Safety, NRL – National Reference Laboratory SEI – Slovak Environmental Inspection				

Annex 4 Provisional Equipment-for National Reference Lab. (NRL)

DNA Microarray system of GMO detection is currently elaborated and it is possible that in close future it will be adopted for routine screening of LMO and that would be in use for following Slovak environment monitoring done by responsible control bodies with a help of NRL as well. We have two microchip readers at the moment in the country, but no equipment to prepare DNA chips (DNA spotter).

DNA spotter for Glass Slide Microarrayer	95.000 USD	
Electrophoresis equipment with power supplies and pipetes	10.000 USD	
Balances and pH meter	10.000 USD	
Tissue, Plasmid, DNA, PCR and RT PCR kits	**15.000 USD** All together	130.000 USD

Annex 5: Monitoring and Evaluation Plan

C.6 a Execution performance and delivered outputs

Monitoring of the project execution will assess whether the management and supervision of project activities is efficient and seek to improve efficiencies and overall effectiveness of project implementation. It is a continuous process, which will collect information about the execution of the planned activities, allow for improvements in method and performance, and compare accomplished with planned tasks. This activity will be under direct responsibility of the National Coordination Committee (NCC). The UNEP Task manager will, in collaboration with the NCC, track these indicators (Table 6).

Table 6 Indicators and Means of verification

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

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

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

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

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

C6.b Project impact

Evaluation of the project's success in achieving its outcomes will be monitored continuously through the project progress reports, mid-term and final evaluation reports, all of which will use the **log-frame** presented in Annex 3. The full implementation of all components of the NBF (legal system, administrative system, system for monitoring of environmental effects, etc.) will represent the most important tangible output of the project and will be the main focus for assessing the success of the project.
The Project Management team is responsible for monitoring progress as well as ensuring evaluation of impact. These are described in Tables 6 and 7 (below).

Table 7 Responsibilities of the project management entities regarding monitoring and reporting

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

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

identify implementation problems and suggest remedies to annual meeting of the NCC. Engage and prepare terms of reference for independent M&E consultants to conduct the mid-term and final evaluations		

Table 8:_The key content required in the quarterly progress reports and financial reports.

Report	Format and Content	Timing	Responsibility
Progress Reports			
Document the completion of planned activities, and describe progress in relation to the annual operating/work plan. Review any implementation problems that impact on performance Summary of problems and proposed action Provide adequate substantive data outcomes for inclusion in consolidated project half-yearly and annual progress reports Highlights of achievements	Reports will use standard UNEP Progress Report format. The project log frame (Annex 3) will be attached to each report and progress reported against outcome and output indicators.	Quarterly, within 30 days of end of each reporting period,	NEA
The Project Implementation Review (PIR) reports	Per GEFSEC format	Yearly (after project has been under implementation for one year)	UNEP Task Manager
Consolidated Annual Summary Progress Reports			
Presents a consolidated summary review of progress in the project as a whole, in each of its activities and in each output Provides summary review and assessment of progress under each activity set out in the annual work plan-,	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	Yearly, within 45 days of end of the reporting period	NEA

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

Annex 6
Incremental cost assessment

Broad development goals

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

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

Baseline

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

The cost of baseline activities at the national level is detailed in Table 3. The project builds on experience gained up to date through the demonstration projects, which can add to the baseline and is complemented by the BCH project – proposals submitted to GEF in 2005.

The commitment of the Slovak Government is demonstrated by the national co-financing to the project, in-kind (US $139000). Details of the budget are enclosed in Annex 8

Finally, although baseline refers not only to activities sponsored by GEF, the Slovak Republic 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 Slovakia to meet the obligations of the Protocol.

GEF alternative

Although Slovak Republic has absorbed the costs of global benefits with respect to biosafety as a priority goal at national level, limited human capacity and financial resources would not allow Slovakia to meet its obligations as Party to the Cartagena Protocol.

In summary, the incremental cost of the project components is estimated as follows:

The total baseline expenditure amounts to US $218000. The alternative has been estimated at

US $283.000 The incremental cost analysis shows that an amount of US $605.000 is required to achieve the project's global environmental objectives. The country will cover nearly 23% of the cost of the alternative as in-kind contribution. A sum of US $466.000, corresponding to the remaining 75% of the total cost of implementing the alternative, is required for GEF support.

ANNEX 7: Key performance Indicators, Baseline and Methods of Data Collection

Project Title: "Support the Implementation of the National Biosafety Framework of Slovakia"

Project Intervention Strategy	Key Performance Indicator	Baseline	Methods and frequency of data collection
Development Goal: Slovakia has a workable and transparent national biosafety framework that is in line with its national development priorities, Cartagena Protocol and other international obligations	By 2010, workable and transparent NBF in line with its international obligations. Biosafety is incorporated into National development strategy And Biotechnology policy.	Baseline information is provided by Final report on NBF Development UNEP/GEF Project that finished in 2004. Some more infrastructures were built during the PhareTwining Programme in 2004-2005.	Information on the status of the NBF and its progression towards full implementation will be made available through the regular reporting and yearly visit to Slovakia. It will be collected in the final report of the project.
COMPONENT A NATIONAL BIOSAFETY POLICY			
Slovakia has integrated Biosafety into national development strategy and biotechnology policy	Elaborated biotechnology policy and Biological Safety imbedded into National Development Strategy.	National Biodiversity Strategy and Action Plan according to CBD adopted in 2004.	Information on the status and progress will be available in the yearly reports, the results will be included in the final report.
COMPONENT B REGULATORY REGIME			
Slovakia has consolidated regulatory regime in line with CP and national needs and priorities	By 2010 is regulatory regime in line with other international agreements and national needs.	GMO Act was adopted in 2002 and amended in 2005. Decrees were issued and legislature process is in continual progress.	Revision and comparation of national legislature will be done in 2006, the result will be in the first year report.
Outcome 1 **Fully functional legislature**	Amended biosafety act and secondary legislature adopted	Lack of so called co-existence law will be solved soon in 2006.	Report on legislature changes will be a part of annual project report.
Outcome 2 **Trained govern. officers**	Guidelines for govern. officers Issued in 2007	After the legislation changes, the guidelines for governmental officers will be published.	A copy of these guidelines will be a part of second year report in 2007.

COMPONENT C SYSTEM OF REQUEST HANDLING, RISK ASSESSMENT etc.			
Slovakia has consolidated system for requests handling, risk assessment and other administrative tasks	System of all administrative tasks consolidated will be on a renewed www.gmo.sk Web site	There are several structured responsible for decision making and lack of institutional collaboration	Information on the status and progress will be available in the first year report;the results of this improvement will be included also in the final report.
Outcome 1 **National Centre for BS**	Network between existing institutions established as a National Centre for Biological Safety approved by Slovak government in 2006.	Decision-making process is workable but rather complicated. The Centre will strengthen its confidence and credibility.	Information on the Centre approval will be available in the first year report;the results of this improvement will be included also in the final report.
Outcome 2 **Functional RA process**	Staff of CA trained, defined criteria and guidelines for RA will be published.	Lack of experts for RA will be solved by trainings of CA officers together with BO	Information on the trainings, manuals for decision making and RA will be reported in annual as well as the final report.
COMPONENT D MONITORING AND FOLLOW-UP SYSTEM			
Slovakia has enforced the monitoring and follow-up system by 2010	Enforced system represented by the National Reference Laboratory and Slovak Environmental Inspection in place.	Two parts of this system were built independent, the low capacity and missing enforcement and awareness will be solved in this project.	Information on the progress will be made available through the regular reporting and yearly visit to Slovakia. It will be collected in the final report of the project.
Outcome 1 **National Reference Lab.**	Fully equipped and accredited in 2006.	It has the basic equipment and is waiting for its accreditation. The lab needs only some special equipment, provided by this project.	Information on purchase of this equipment as well as the NRL accreditation will be given in the first year report and the final report of the project.

Outcome 2 **Monitoring and follow-up systems**	Trained staff of NRI and SEI, Revised methodology, guidelines and manuals published.	Basic methods available, after the advanced equipment in laboratory the revised methodology can take place.	Information on the CB trainings, manuals for monitoring and results of the follow-up will be reported in annual as well as the final report
COMPONENT E PUBLIC AWARENESS, EDUCATION and INFORMATION			
Slovakia has fully functional system for public awareness, education and participation in place by 2010.	Updated web page Action plan on public awareness and education Workshops and other outreach materials for public organized	National BCH not in place. The current web page should be rebuilt into BCH page with curricula and other outreach materials to inform and/or education and awareness.	Information on the progress will be made available through the regular reporting and yearly visit to Slovakia. It will be collected in the final report of the project.

ANNEX 8: Detailed Activity based Budget

Activity Based Budget	GEF year1	GOV Year 1	GEF year2	GOV Year 2	GEF year 3	GOV Year3	GEF Year 4	GOV Year 4	Total GEF	Total GOV contr.	**Total**
Biosafety Strategy											
1.1 Two meetings with main stakeholders	3000	1.000			3000	1000			6.000	2000	8000
1.2 Elaboration of NBBP and a part ofNDS		1.000	4.000	1.000	4.000	2000			8000	4.000	12000
1.3 Adoption of NBBP and agreement on NDS							1000	1000	1000	1000	2000
1.4 NBC meetings to support and coordinate following activities	500	500	500	500	500	500	500	500	2000	2000	4000
Total Biosafety Strategy									**17.000**	**9.000**	**26.000**
Regulatory Regime											
21 Amending GMOact, and its adoption	5.000	1.000	3000	1000					8000	2000	10.000
22 Drafting and adopting secondary legal acts			6000	2000					6000	2000	8000
23 Publishing guidelines for governmental officers for intepreting and implementing of GMOact			2000	2000			1000	1000	3000	3.000	6.000
Total Regulatory Regime									**17.000**	**7.000**	**24.000**
Handling requests (HR)											
3.1 Creation of Coordionat. Centre for Biological Safety	5.000	5.000							5.000	5.000	10.000
3.2 Two consultations for CA (decision makers) on request handling with int. experts	7.000	1.000			5.000	1.000			12000	2000	14.000
3.3 workshops on making	4000	1.000	5.000	1.000	5.000	1.000			14.000	3.000	17.000

	the risk assessment for Biosafety Officers											
3.4	Reviewing and publishing manual for request handling	2.000	1.000							2.000	1.000	3.000
3.5	Updating the guidelines on risk assessment			2.000	1.000					2.000	1.000	3.000
Total Handling Requests		**11.000**	**8.000**	**7.000**	**3.000**	**6.000**	**2.000**			**35.000**	**12.000**	**47.000**
Monitor/inspection												
4.1	Equipping laboratory*	130 000								130 000		130 000
4.2	Laboratory accreditation		2.000								2.000	2.000
4.3	Revision of methodology for GMO monitoring, publishing guidelines for GMO monitoring			3.000	1.000	3.000	1.000			6.000	2.000	8.000
4.4	Publishing manual on new methods of GMO detection, identification, etc			1000	1000	1000	1.000			2.000	2.000	4.000
4.5	Organizing trainings for control bodies (SEI and control laboratories staff) on new methods of GMO on sampling, detection, identification and interpretation of results obtained - up to 20 participants	7.000	1000			7.000	1000			14.000	2.000	16.000
4.6	SEI enforcement control plan	8.000	2.000	8.000	2.000	8.000	2.000			24.000	6.000	30.000
Total Monitor / Inspection										**176.000**	**14.000**	**190.000**
Public awareness												
5.1	Develop and adopt action plan for	3.000	1.000	3000	1000					6.000	2.000	8.000

	involving public into decision making process and publid education and awareness											
5.2	Organize informational workshops for wider public, including teachers, consumers and NGO	4000	1000					4000	1000	8000	2000	10000
5.3	Publish outreach materials: popular publication on GMO and Biosafety published by NCBS			5000	1000					5000	1000	6000
5.4	Organize TV and radio broadcasts on Biosafety matters in connection with National Development Strategy	2000	1000					2000	1000	4000	2000	6000
5.5	Update of national GMO web page	1000	1000			1000	1000			2000	2000	4000
Total Public Awareness										**25.000**	**9.000**	**34000**

Project coordination		**GEF y1**	**GOV y1**	**GEF y2**	**GOV y2**	**GEF y3**	**GOV y3**	**GEF y4**	**GOV y4**	**GEF**	**GOV**	**Total**
F1	NPC (part time)	6.000	12000	6.000	12000	6. 000	12000	6.000	12000	24.000	48000	72000
F2	Assistant 1 (full time)	9000		9000		9000		9000		36.000		36.000
F3	Assistant 2(part time)	4.000	4.000	4.000	4.000	4.000	4.000	4.000	4.000	16.000	16.000	32000
F3	Accountant/WEB	5.000	5.000	5.000	5.000	5.000	5.000	5.000	5.000	20.000	20.000	40.000
F5	Audit	2000		2000		2000		2000		8000		8000
F5	Equipment & Premises	4.000	2000							4.000	2000	6.000
F7	Travels	4.000		4.000		4.000		4.000		16.000		16.000
F9	Rapports edition							2000	2000	2000	2000	4.000
F10	Technical support	17.500		17.500		17.500		17.500		70.000		70.000
Total Project Coordination										**196.000**	**88.000**	**284.000**
Grand Total										**466.000**	**139.000**	**608.000**

ANNEX 9: Implementation Plan - TIMETABLE of the Proposed Activities

Activity	1-6th month	7-12th month	13-18th month	19-24st month	25-30th month	30-36rd month	36-42th month	43-48th month
Biosafety strategy								
1.1. Governmental meetings with main stakeholders	x				x			
1.2Drafting National Development strategy		x	x	x	x	x		
1.3. Submission and adoption of NDS							x	x
1.4 Four NBC meetings to support and coordinate following activities	x		x		x		x	
Regulatory regime								
2.1. Amending GMO act, adoption	x	x	x	x				
2.2Drafting and adopting secondary legal acts			x	x				
2.3. Publishing guidelines for governmental officers for intepreting and implementing of GMO act				x				x
Request Handling								
3.1 Creation of National Centre for Biological Safety	x	x						
3.2Two consultations for CA (decision makers) on request handling with int. experts	x				x			
3.3. workshops on making the risk assessment for Biosafety officers		x		x		x		
3.4. Reviewing and publishing manual for request handling		x						
3.5. Updating the guidelines on risk assessment			x	x				
Monitoring								
4.1 Equipping national reference laboratory	x	x						
4.2National reference lab accreditation	x	x						
4.3 Revision of methodology for MO monitoring, publishing guidelines for MO monitoring			x	x	x	x		
4.4 Publishing manual on new methods of MO detection, identification, etc.				x	x			
4.5 Organizing trainings for control bodies (SEI and control laboratories staff) on new methods of MO on sampling, detection, identification and interpretation of results obtained - up to 20 participants (year 1, 3)		x			x			
4.6 Enforcement of compliance	x	x	x	x	x	x	x	x
Public participation and awareness								
5.1 Develop and adopt action plan for involving public into decision making process and public education and awareness	x	x	x	x				
5.2Organize informational workshops for wider public, including		x						x

teachers, consumers and NGOs year 1 and year 4								
5.3 Publish outreach materials: popular publication on GMO and Biosafety published by NCBS			x	x				
5.4 Organize TV and radio broadcasts on Biosafety matters in connection with National Development Strategy		x			x	X		
5.5. Update national GMO web page	x	x	x	x	x	x	x	x

ANNEX 10: 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 a National Co-ordinating Committee (NCC);
- Appoint a full time National Project Co-ordinator (NPC), taking into account the sustainability of national biosafety activities on completion of the National Project;
- Provide the necessary scientific, technical, financial and administrative support to the work of the NCC, working in close co-operation with relevant government agencies, the scientific community and the public and private sectors;
- Ensure that regular reports, financial accounts, and requests are submitted to UNEP as set out in section 6;
- Review all documentation deriving from the National Project and any other relevant documentation to ensure that these are consonant with National Government;
- Submit the final version of the National Biosafety Framework no later than eighteen months from 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 implementation of the National Biosafety Framework;
- Oversee the implementation of the National Biosafety Framework
- Approve the detailed work plan and budget produced by the NPC;
- Mobilise necessary expertise, as needed for the proper execution of the National Project outputs;
- Provide overall policy advice on the implementation of the National Project;
- Review and advise on the main outputs of the National Project;
- 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 mobilising available data and ensure a constant information flow between all concerned parties;
- Allow for effective communication and decision-making between the National Project Coordinator and other actors;
- Ensure 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 chair 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 programmes and National Projects;
- Prepare and oversee the development of Terms of Reference for National Project components, consultants and experts;
- Organize, contract and manage the consultants and experts, and supervise their performance;
- Coordinate and oversee the preparation of the outputs of the NBF;
- Manage the National Project finance, oversee overall resource allocation and where relevant submit proposals for budget revisions to the NCC and UNEP;
- Manage the overall National Project ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Coordinate the work of all stakeholders under the guidance of the NEA and the NCC and in consultation with the UNEP 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

The **Project Assistant I (PAI)** will carry out the following tasks

- Assist the NPC in the implementation of the National Biosafety Project conducted by the local and international experts, consultants, sub-contractors and co-operating partners;
- Assist with the organisation of National Coordinating Committee meetings;
- Assist with preparation detailed work plan and budget under the guidance of the NCC;
- 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
- Assisting in identifying problems in the implementation of the project and to alert the NPC and NCC

The **Project Assistant II (PAII)** will carry out the following tasks

- Support the NPC in maintaining effective communication with the relevant authorities, institutions and government departments;
- Inform the NPC of other related national and international programmes and National Projects;
- Assist in drafting Terms of Reference for National Project components, consultants and experts;
- Assist with the identification of the consultants and experts, and supervise their performance;
- Assist in overseeing the preparation of the outputs of the NBF;

- Assist the National Project Finance Officer providing information as needed;
- Assist the NPC ensuring that all the activities are carried out on time and within budget to achieve the stated outputs;
- Assist in providing information to the NCC about all Government, private and public sector activities, which impact on any use of modern biotechnology;