MSP PROJECT BRIEF

PROJECT IDENTIFIERS	
1. PROJECT NAME: Support for the implementation of the National Biosafety Framework for Bulgaria	**2. GEF IMPLEMENTING AGENCY:** UNEP
3. COUNTRY IN WHICH THE PROJECT IS BEING IMPLEMENTED: Bulgaria	**4. COUNTRY ELIGIBILITY:** Bulgaria has ratified both the Convention on Biological Diversity on April 17,1996 and the Cartagena Protocol on May 25, 2000
5. GEF FOCAL AREA: Biodiversity/Biosafety	**6. OPERATIONAL PROGRAMME:** The project cross-cuts the Biodiversity Operational Programmes 1,2,3,4, and follows the Initial Strategy for the Entry into Force of the Cartagena Protocol on Biosafety adopted by the GEF Council in November 2000.

7. PROJECT LINKAGE TO NATIONAL PRIORITIES, ACTION PLANS AND PROGRAMMES:

- Bulgaria ratified the Cartagena Protocol on Biosafety on the 25th of May 2000 and is preparing for its entering into force. This project, "Implementation of the National Biosafety Framework (NBF)", aims to support Bulgaria in meeting the obligations foreseen under the Protocol by providing the needed capacity building.
- The project is consistent with the priorities on *genetic preservation and biosafety* set up in the National Biodiversity Action Plan Preservation for Bulgaria, finalized in 1999. Among those priorities, which resulted from a close collaboration between NGOs and scientists to address public concerns, 1) the preparation of a *Living Modified Organisms Act (LMO Act)*, 2) the development of a genetic preservation system, and 3) the creation of a gene bank, are identified.
- Bulgaria has already started to promote biosafety and genetic preservation efforts. However, the country's economical situation did not allow for the full implementation of these objectives. Only the *Regulation for Biosafety of GM Higher Plants* has been adopted by the Ministry of Agriculture (1996).
- A special Taskforce was set up in 2000 to finalise the draft of the *Living Modified Organisms Act*, taking into account the Action Plan and the National Biosafety Framework. However, the taskforce did not manage to complete its task because of lack of time and insufficient human and financial resources.
- Biosafety is an important topic in the negotiations for joining EU. Bulgaria, as associate member of EU, must synchronize its legislation with the corresponding EU directives. One of the Bulgarian priorities is the formulation of a national biosafety regulatory system and the setting up of its operational mechanism in accordance with the requirements of the EU (Directives 90/219 as amended and 2001/18) and of the Protocol.
- The project complements the European Union *Centre of Excellence* programme on biodiversity, biotechnology and biosafety, which takes fully into account the expectations of Article 22 of the Protocol. This programme aims at supporting development of scientific and technological potential. Study visits, exchange of expertise, know-how and experimental material will assist and improve:
  - Participation in the European Union Framework Programme 5 (www.cordis.lu/eu) and other highly competitive international programs that fund research and cooperation be-

tween partner organisations;

- Participation in international cooperation and networks and the preparation of joint international projects in relation to biosafety and biotechnology;
- Twinning and networking with leading European centres, including Centres of Excellence.
- Further development of the research institute, ABI, as a centre for high-output plant science and biotechnology research.

8. GEF NATIONAL OPERATIONAL FOCAL POINT AND DATE OF COUNTRY ENDORSEMENT:
Submitted: Acknowledged: Endorsed:

Christo Bojinov,
Director, National Nature Protection Service
Ministry of the Environment and Water Resources
67 William Gladstone Street
1000 Sofia, Bulgaria
TEL: (359-2) 87 53 18
FAX : (359-2) 986 48 48
Christo Bojinov@moew.govern.bg

Project Objectives and Activities

9. **Project rationale and objectives**:	**Indicators:**
Goal: To support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries	• Legislative, economic, and social policies and programs for Biosafety in place
Objective: Implementation of the National Biosafety Framework in Bulgaria.	• Reliable systems and procedures for risk assessment and management of LMO
Specific objectives are set as follows:	
(A) To set up a regulatory and administrative basis to enable an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs), resulting from modern biotechnology, in Bulgaria. The transboundary movements and meeting the obligations foreseen under the Cartagena Protocol are from especial importance.	• Active participation in activities aimed at implementing the Cartagena Protocol • Legislation, regulations, and/or guidelines will be in place to allow for the assessment and management of risk associated with the 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, including where appropriate contained use, deliberate, accidental or incidental release into the environment, import or export of living modified organisms.
(B) Publish technical guidelines for risk assessment and monitoring in order to ensure the safe use of modern biotechnology taking into account national, sub-regional and regional needs and decisions. Pilot data collection from mini-field trials and various biochemistry and molecular approaches for the purpose of risk evaluation.	
(C) Strengthen capacity building on • risk assessment and risk management as identified in Articles 15 and 16 and Annexes I-III of the Pro-	

tocol, • testing and monitoring in order to manage risk and assure the safe use of living modified organisms • Legal issues that relate to the implementation of the Protocol to ensure the safe use, import and export of living modified organisms, • Identify and control the transboundary movement of LMOs (that might have an adverse effect on the conservation and sustainability of biodiversity) between Bulgaria and other countries. (D) Set up a Biosafety Database System to be connected to the Biosafety Clearing House Mechanism (E) Enhance public awareness and promote dissemination among the relevant stakeholders in accordance with Article 23 of the Protocol Promote	• Laboratories equipped for risk assessment and for testing LMO products as defined in the Protocol. • Information dissemination system in place, allowing for consultation and response by the authorities as required under Article 23 of the Protocol and relevant European Union Directives.
10. **Project outcomes**: (A.1) "Living Modified Organisms Act of Bulgaria" finalized and submitted to Parliament; (A.2) Regulations needed for the implementation of the Law, drafted. (A.3) National procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force (A.4) Ecological, economic, and sociological surveys undertaken to guide the implementation of the National Biosafety Framework and an integrated ecosystem management planning/ implementation carried out. (A.5) Assessment of national biotechnological capacity at public and private level carried out to identify the needs for ensuring the safe use, import and export of living modified organisms as required in the Protocol. (A.6.1) Two days workshop for 50 representatives of governmental bodies and organizations, and NGOs, on: "Biosafety issues and the regulations for the implementation of the LMO Law organised. (A.6.2) Four days conference for 80 experts in legislation and politics including those expected to have to implement the law and guidelines: "National biosafety legislation and the Biosafety Protocol" organised.	**Indicators:** • LMOs Act finalised and submitted for Parliamentary approval and enactment; • Regulations for implementing the Law drafted and published; • Full compliance of Bulgarian legislation with the Cartagena Protocol and the Biosafety and biodiversity regulations of EU • Surveys result published on Web page. Main outcomes outlined in special survey report published by the NEA • Assessment results reported in the first project progress report to UNEP and the GEF • Technical guidelines for performing risk assessment and management adopted and enforced • Fully equipped laboratories certified and caring on risk assessment tasks • Working database used for risk

(B.1) Technical guidelines for performing risk assessment and management in force. (B.2) Certified laboratory and research groups performing assessment and monitoring the deliberate release and commercial use of LMOs strenghtened. (B.3) Data from mini field trials, and various biochemistry and molecular experiments as well as biodiversity data including those on taxonomy and existing genetic diversity collected to allow for risk assessment and management (C.1) Five training courses for twelve trainers held on: • risk assessment and risk management, • testing and monitoring, • Legal issues particularly in relation to use, import and export, • Administrative Procedures, and • Controls over the transboundary movement of LMO. (C.2) Two training workshops carried out as follows: • "Transboundary movement of Living Modified Organisms and the Cartagena Protocol on Biosafety", Relative start month: month 3, timetable – two days; Supposed number of participants – 100 • "Safety of biotechnology trials and applications", Relative start month: month 6, timetable – tree days; Supposed number of participants – 100: representatives of government, media,, NGOs and science community and involving interested members of the public. (D.1) National Biosafety Database System set up and linked to the Biosafety Clearing House Mechanism (D.2) National web site in place and operational (D.3) One workshop for 100 government officials, journalists, scientists and NGO representatives on "Information exchange and biosafety" organised. (E) Raising public awareness through newsletter, videos, brochure, website and ensuring that the public are consulted their views are heeded. Best practices and lessons learnt disseminated.	assessment and management • Minutes and proceedings of the courses printed and disseminated among the participants and interested parties • Minutes and proceedings of the workshops printed and disseminated among the participants and interested parties • Integration of the Biosafety Database with the Biosafety Clearing House, ensuring that the local databases are compatible with the requirements of the Clearing House Mechanisms. • Registered domain name and designed web page registered at the main search engines in Internet • Minutes and proceeding of the workshops printed and disseminated among the participants and interested parties • One video film produced, regular newsletter is printed and delivered monthly, web page is updated regularly
11. Planned activities to achieve outcomes (including	**Indicators:**

cost in US$ or local currency of each activity):	
(a.1) Setting up a trans-institutional task force for finalising the *"Bulgarian Living Modified Organisms Act*" to meet the requirements of the Cartagena Protocol, and submit it to Parliament for approval.	• Act finalised and submitted for Parliament approval;
(a.2) Draft the following regulations for the implementation of the Act: • Regulations produced by the Council of Ministers for issuing licenses and permits. • Regulations produced by the Council of Ministers on Contained Use and disposal of LMOs and containment of waste • Regulation produced by the Council of Ministers for releasing genetically modified organisms into the environment. • Regulation produced by the Council of Ministers on requirements needed for involving living modified organisms[1]. • Regulation produced by the Council of Ministers on risk assessment.	• Regulations for implementing the Law drafted;
(a.3) Drafting, finalisation and implementation of national procedures to enable active participation to and functioning of the Clearing-House Mechanism as required by the Protocol and the LMO Act.	
(a.4) Ecological, economic, and sociological survey among the general public to provide information, including indigenous knowledge, to guide NBF implementation. (a.5) Assessment of national technological capacity at public and private level, its effect on implementation of national biosafety frameworks, and means to improve it.	• Minimum of 150 people surveyed (don't know how only 150 people could produce a balanced report – needs careful selection to ensure that results are 'real') • Results of the survey processed and publicly available on Internet or printed.
(a.6) Two days workshop for 50 representatives of governmental bodies and organizations, and NGOs, on: "Biosafety issues and the regulations for the implementation of the LMO Law". The workshop will focus on biosafety issues of regulating and controlling the contained use and the deliberate release of LMOs. (Accommodations – 4 nights x 2 int. participants x $100, 3 nights x 48 nat. participants x $70)	• Assessment report and related recommendations available for the purpose of the project itself • Proceedings of the workshop available within two weeks • Assessment of the main differences between current regional regulations; recommenda-

[1] Annex 1(i) of the Protocol: Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

(a.7) Four days conference for 80 experts concerning legislation and policies: "National biosafety legislation and the Biosafety Protocol". The conference will deal with aspects of practical implementation of the Biosafety Protocol provisions in the National Biosafety Regulatory System. Social and economic aspects, environmental and health issues of LMO utilisation and the impact of the Cartagena Protocol will be discussed. (Accommodations – 5 nights x 30 int. participants x $100) **(TOTAL 158 504 USD; GEF: 113 745 USD)**	tions • Written Principles for harmonised data collection and validation defined and approved by the Ministry of Agriculture, Ministry of Environment and Ministry of Health
(b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act (b.2) Strengthening of certified laboratories at ABI and appointment of expert research groups by the Biosafety state Committee, in order to perform the assessment and monitoring on the release LMOs according to the LMO Act. (b.3) Pilot collection of data from mini-field trials and biochemistry and molecular approaches for the purpose of risk assessment. (b.4) Prepare or identify pre-existing botanical information files for the purpose of risk assessment and management of LMOs that might pose risks to the conservation of biodiversity. **(TOTAL: 78 000 USD; GEF: 66 000 USD)**	• Technical guidelines for performing risk assessment and management adopted and enforced • Laboratories at ABI strengthened to perform risk assessment and monitor the deliberate release and commercial use of LMOs, according to the LMO Act. • Pilot data form mini field trials collected and proceeded • Proceedings of the workshop available after two weeks from the conclusion
(c.1) Five training sessions for 12 trainers – officials of the Ministry of Agriculture and Forestry, the Ministry of Environment and Waters, the Ministry of Education and Science, the Ministry of Finance, the Ministry of Justice and the Interior Ministry, selected on the basis of their background and work appointments trained on: • LMOs risk assessment and risk management, • LMOs testing and monitoring, • Legal issues, • Administrative Procedures and • The control over the transboundary movement of LMO. (c.2) Training workshop: "Transboundary movement of LMO and the Cartagena Protocol on Biosafety", Relative start month: month 3, timetable – two days; Sup-	• Minutes and proceeding of the workshops printed and disseminated among the participants and interested parties

posed number of participants – 100 participants. The workshop will focus on risk assessment and risk management, the legal ways to preserve the native species and the role of the national gene bank. Pilot data gathering and the botanical files will be discussed. (Accommodations for 4 nights x 6 int. participants x $100) (c.3) Training workshop: "Biosafety of biotechnology research, trials and applications", Relative start month: month 6, timetable – four days; Supposed number of participants – 21 representatives of government, media, NGOs and science community. Safety requirements and procedures for LMOs contained use, deliberate release and commercial use will be discussed. (Accommodations for 3 nights x 2 int. participants x $100) **(TOTAL: 63 640 USD; GEF: 54 960 USD)**	
(d.1.1) Setting up a national information database of registers, dossiers, trial data, deliberate release, commercial use, import and export, and any other information required under the Cartagena Protocol on Biosafety with an adequate mechanism for information sharing/networking and security management. The database will include regional biosafety information. (d.1.2) Development of a national website, linked to the information database as per point d.1.1, by the Biosafety Committee in order to: 1. Provide project related information; 2. Provide public information and provide for public involvement in accordance with Article 23 of the Protocol; in particular to ensure that the public are able to access the database and Clearing House. 3. Provide a linkage to the Biosafety work programmes of other countries in order to spread experience and best practices; and 4. Provide links to other relevant biosafety web pages Different types of access to the web site will be set up for government organizations, NGOs, journalists and the main stakeholders and the general public so as to ensure maximum use of the information in the database and website and protect any commercial information as identified in the European Directives and in the Protocol (Article 21). (d.1.3) Organise a workshop for 100 government officials,	• National information database on-line and contains relevant data. • Domain registered and Web page posted on-line. • Minutes and proceeding of the workshops printed and disseminated among the participants and interested parties

journalists, scientists, NGO representatives and members of the public on "Information exchange and biosafety". The workshop will investigate the relationship between Information exchange and perception of the biotechnology and its products as safe or hazardous. (Accommodations for 3 nights x 26 int. participants x $100) **(TOTAL: 112,486 USD; GEF: 81,545 USD)**	
(e.1) Develop and disseminate outreach materials training materials, technical manuals including publications, one video movie, brochures, etc. for public awareness raising purposes; (e.2) Prepare and disseminate a newsletter on a quarterly basis; (e.3) Disseminate best practice and lessons learnt; **(TOTAL: 91,629 USD; GEF: 91,629 USD)**	• One video movie and other relevant information materials produced and disseminated to assist the public to use the Database and Clearing House for information in accordance with Article 23 (3) of the Protocol.

12. **Estimated budget (in US$ or local currency):** (the budget should include an estimate of the GEF financed portion of project execution costs, the portion expected to be financed form other sources and the total)

GEF: USD 407,879
Co-financing: USD 96 ,380
Total: USD 504,259

13. **Information on project proposer**:
ABI-AgroBioInstitute, 2232 Kostinbrod, Bulgaria, is the Centre of Excellence in biodiversity in Bulgaria and the region. It is the successor of Institute of Genetic Engineering - Kostinbrod, and, by acquisition, of the Institute of Flowers and the Potato Institute.
ABI is the Sub-regional centre for Biosafety on the Balkans and is actively involved in the development of national regulation on LMO. Prof. Atanas Atanassov is executive secretary of the Council for Biosafety of Genetically Modified Higher Plants.
Contact person: Prof. Atanas Atanassov, Director of AgroBioInstitute
2232 Kostinbrod, Bulgaria

14. **Information on proposed executing agency (if different from above):** NA

15. **Date of initial submission of project concept**:

16. **Project Identification number**:

17. **Implementing Agency contact person:**
Ahmed Djoghlaf, Executive Co-ordinator, UNEP/GEF Coordination Office

18. **Project linkage to Implementing Agency program**(s):
As the financial mechanism of the Convention on Biological Diversity, the GEF is also called upon to serve as the financial mechanism of the Cartagena Protocol on Biosafety.

GEF Council during its meeting in May 9-11, 2000, "welcomed the adoption of the Cartagena Protocol on Biosafety, including Article 28 of the Protocol which provides that "the financial mechanism established in Article 21 of the Convention shall, through the

institutional structure entrusted with its operation, be the financial mechanism for this Protocol". The Council requested the Secretariat, in consultation with the Implementing Agencies and the Secretariat of the Convention on Biological Diversity, to inform the Council at its next meeting of its initial strategy for assisting countries to prepare for the entry into force of the Protocol. The Council also requests UNDP and the GEF Secretariat to take into account the provisions of the Cartagena Protocol in the on-going work of the Capacity Development Initiative".

A Ministerial Round Table on "Capacity-building in Developing Countries to Facilitate the Implementation of the Protocol" was held in Nairobi on 23 May 2000 during the Fifth Conference of the Parties to the CBD. The Ministerial Round Table acknowledged the need for capacity-building at the national level, in order to allow "the safe use of modern biotechnology, in particular the safe transfer of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity between countries which may have very different climatic, social and economic conditions". Paragraph 9 of the Statement of the Ministerial Round Table emphasizes "the importance of the financial mechanism and financial resources in the partnership that the Protocol represents and welcomes the commitment of **GEF to support a second phase of the UNEP/GEF Pilot Biosafety Enabling Activity project**". The need for capacity-building was also emphasized at the GEF workshop on the UNEP/GEF Pilot Biosafety Enabling Activity held on 24th May 2000 in the margins of CBD COP5 with the participation of more than 150 delegates.

The decisions adopted by the Fifth Conference of the Parties to the Convention on "Further guidance to the financial mechanism" (Decision V/13) as well as on the Biosafety Protocol (Decision V/1) welcomed "the decision taken by the Council of the Global Environment Facility at its fifteenth meeting with regard to supporting activities which will assist countries to prepare for the entry into force of the Protocol".

The GEF Initial Biosafety Strategy as well the UNEP/GEF biosafety projects, including the results of the pilot project, which included Bulgaria, were presented and discussed during the plenary meeting of Working Group II of the First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpelier on 11-15 December 2000. The UNEP/GEF projects were further discussed during a side event held on 13th December at the margins of the meeting. The Montpellier Declaration reiterated that capacity-building for many Parties, especially developing countries, in particular the least developed and small island developing States among them, is the foremost priority for the moment, acknowledged that action to address these needs must be demand driven, identified the framework of these needs and highlighted various means to meet these needs, including the UNEP/GEF biosafety initiative." The meeting urged UNEP "to expedite the implementation of the project entitled Development of National Biosafety Frameworks in a flexible manner, having regard to the comments made by the Intergovernmental Committee for the Cartagena Protocol on Biosafety at its first meeting, and to support the implementation of national biosafety frameworks."

Project rationale and objectives

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.

2. The Pilot Project involved 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia, Malawi) and consisted of the following two components:
   - A *National Level Component* aiming at assisting the eighteen countries to prepare National Biosafety Frameworks (US$ 1.9 million), and
   - A *Global Level Component* aiming at facilitating the exchange of experience at regional levels through the convening of 2 workshops in each of four regions and involving a very large number of countries (US$ 0.8 million).

3. In order to design a National Biosafety Framework, each country that participated in the National Level Component was required to:

   - Assess the existing national capacity and roles in environmental release of LMOs and their products;
   - Develop methods, techniques, standards, guidelines, and indicators for assessing and monitoring the risks. Develop control and regulatory measures for those risks likely caused by the transportation, release, commercialisation and application of LMOs;
   - Facilitate the national capacity building for biosafety management and formulate a package of plan needs;
   - Promote the establishment of the institutional arrangements and operational mechanisms for biosafety management;
   - Develop human resources for biosafety management through formulating and implementing a series of training plans to upgrade the expertise in this field;
   - Undertake publicity activities at the national and local levels to increase the awareness and the understanding of the public and major decision makers of the potential benefits and risks of biotechnology application;
   - Enhance international cooperation and communication on scientific research, legislation, information exchange and personnel training in the field of biosafety.

4. The project "Implementation of the National Biosafety Framework" for Bulgaria is consistent with the "*Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"*(GEF/C.16/4) adopted by GEF Council in November 2000. Such strategy foresees that:

"In countries that …. have participated in the pilot project, it is proposed that the GEF undertake country-based demonstration projects to assist in the implementation of a country's national biosafety framework.

This type of assistance might best be provided to countries that have already ratified the Protocol, in much the same way that assistance through the financial mechanism of the Convention on Biological Diversity is to be provided to Parties to the Convention. However, in the interest of gaining experience and developing good practices that may promptly and effectively be provided to assist Parties once the Protocol enters into force, it is proposed that the GEF finance a limited number of country-based demonstration projects (maximum of eight countries - two per region for Africa, Asia,

Eastern Europe, and Latin America and the Caribbean).”

The strategy was further supported in the Final Decisions of 21st Governing Council of UNEP. The GC21 has:

- *Congratulated the 18 countries that participated in the United Nations Environment Programme/Global Environment Facility Pilot Enabling Activity Project for their exemplary execution of the national component of the pilot project, and*

- *Invited the Global Environment Facility to provide further financial support to these and other countries for the implementation of national biosafety frameworks (or similar policy administrative, legislative biosafety frameworks) they have developed in preparation for the entry into force of the Cartagena Protocol on Biosafety and for the first phase of the Biosafety Clearing House.*

5. Bulgaria ratified the Biosafety Protocol on the 25th of May 2000 and is preparing for its implementation. This project aims therefore at supporting Bulgaria in meeting the obligations foreseen under the Cartagena Protocol on Biosafety. In particular, with respect to the requirements coming from Articles 1 and 2 of the Cartagena Protocol, Bulgaria needs to set up a comprehensive framework for biosafety as developed during the pilot phase, and put in place appropriate legal and regulatory systems to assess any possible impact on the environment and human health and ensure their adequate protection in the field of safe transfer, handling, and use of LMO, by the means of proper infrastructure and human potential. Relevant regulations, based on the Cartagena Protocol on Biosafety and the EU Directives, will assure proper implementation of the LMOs Act.

The main objectives of the project are:

(A) To set up a regulatory and administrative basis to enable an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology in Bulgaria, with a specific focus on transboundary movements, and meet the obligations foreseen under the Cartagena Protocol on Biosafety.

(B) Publish technical guidelines for risk assessment and monitoring in order to ensure the safe use of modern biotechnology products. Pilot data collection from mini field experiments and various biochemistry and molecular approaches for the purpose of risk assessment evaluation. Prepare botanical files for the purpose of risk assessment and management.

(C) Strengthen capacity building on
- LMOs risk assessment and risk management,
- LMOs testing and monitoring,
- Legal issues,
- Administrative Procedures and
- The control of the transboundary movement of LMO.

(D) Set up a Biosafety Database System to be connected to the Biosafety Clearing House Mechanism

(E) Enhance public awareness and promote dissemination among the relevant stakeholders in accordance with Article 23 of the Protocol Promote.

Current situation

1. For the last ten years Bulgaria has been going through its transformation from a central to a market oriented economy. The government had to re-organise its structures and organizations. This implied new kind of relationships between the government and scientists, who have been increasingly involved in the decision-making process on science policy. NGO representatives have been involved in the decision making process at the level of the Ministry of Environment.

   The Bulgarian government began to study and prepare rules and administrative acts to regulate some aspects of the biotechnology R&D and applications, but until 1996, there were few governmental and institutional decisions on biosafety related issues. Some of them are only indirectly related to biosafety, but in general they regulate products and applications of food, veterinary and agricultural industries.

2. In 1996, because of the local development of biotechnology and the beginning of commercialisation of LMOs in the USA and EU, the government undertook a first step towards the establishing of legislation on LMO by introducing a *Regulation for Safe Use of Genetically Modified Higher Plants.* The main features of the Regulation are:

   - The release into the environment of genetically modified plants is controlled by the Ministries of Agriculture and the Environment.
   - A Council for Biosafety of Genetically Modified Higher Plants (CBGMHP, here below called the Council) under the Ministry of Agriculture, Forestry and Agricultural Reform was set up. The Minister of Agriculture chairs the Council. The Scientific Secretary, an eminent scientist with international academic rank in the field of genetic engineering, co-ordinates the activity of the Council. The members include representatives of the Ministry of Environment and the Ministry of Health. Experts in the respective fields. If needed, foreign experts may be drawn in the activity of the Council as consultants. The Council has full authority to permit or reject the release of GM Plants in Bulgaria. It also controls the allowed releases and keeps the records.
   - The notification procedure is similar to that adopted in Directive 90/220 of the EU. A notification, containing the information required by Directive 90/220, must be submitted to the Council, which must respond within sixty days. Labelling of the goods containing GM Plant material that are placed on the market is required.
   - Consent for a release does not exempt the notifier from other relevant liabilities in case of damage resulting from the release of transgenic plants.

3. The Council has developed the following principles for regulation of GM Plants in Bulgaria:

   - The regulatory processes should be open, transparent, clear, nationally uniform, consistently applied, and enforceable;
   - Risks assessment should be objective, science-based, and independent with respect to environmental and human safety, and should be conducted prior to release, use, and marketing of GM Plants in Bulgaria;
   - Decision making should be the result of professional, science-based risk assessments, and take into account the wide range of benefits and costs involved;
   - The regulatory processes should be sufficiently flexible to adjust the degree of regulation according to the inherent risks of individual GM Plants or products as experience and knowledge are gained;
   - The regulatory processes should be designed to minimize the costs of administration to government and of compliance by individuals, businesses and organizations;

- Bulgaria's regulatory system should be harmonized with those of our major trading partners;
- Bulgaria's international competitiveness should be enhanced; and
- Consistency with Bulgaria's international rights and obligations should be ensured.

To date, around 10 transgenic hybrids are awaiting permits for commercial distribution. The Council is currently performing a broad range of field trials as a part of the review process of the application system.

4. Biosafety is very important for the future of Bulgaria in respect of the rapid development of biotechnology around the world and regulation is a consistent and important condition for the technology's development. Recognizing this importance, UNEP supported Bulgaria, among 18 countries, for the formulation of a National Biosafety Framework (See Annex 1, The National Biosafety Framework in Bulgaria). Bulgaria is now facing the problem of its implementation. The Action Plan and the National Biosafety Framework of 1999 set as a priority the formulation of a LMO Act. In accordance with these documents, a Task Force for developing such law was appointed in 2000. However, the Taskforce did not manage to conform to all views and opinions about the structure of the implementation body, and the competence of the ministries on biosafety related issues. The underdevelopment of the national legislative system promotes public concerns about the safety of the biotechnology applications in the everyday life. The main ministries involved in the biosafety process are:

   - **Under the Ministry of Agriculture and Forestry functions:**
     - Council for Biosafety of Genetically Modified Higher Plants
     - National Service for Plant Protection, Quarantine and Agrochemistry – pests and plant diseases
     - Executive Agency for Approbation and Seed Control - approves new plant varieties
     - Central Veterinary Service - animal quarantine

   - **Under the Ministry of Health Care function**:
     - Central Institute for Drugs - approves new drugs and medicines, as well as imports
     - Central Hygiene Epidemiological Inspection - controlling the safe production and distribution of foods
   - The Ministry of Environment, in charge of the environmental impact assessment, is also the Focal point for the CBD.

5. Although on its way to improve its economic performance, and considered one of the leading countries in biosafety in the Balkans, Bulgaria still does not have the required capacity to meet its obligation on Cartagena Protocol on Biosafety. With the ratification of Cartagena Protocol and the beginning of the negotiations with the European Union, Bulgaria is obliged to establish proper regulatory and organisation structures for Biosafety.

6. In 1999, the top national research institute on biotechnology - AgroBioInstitue was appointed as a Sub-regional Biosafety Centre. ABI is the successor of the Institute of Genetic Engineering - Kostinbrod, and, by acquisition, of the Institute of Flowers and the Potato Institute. The coordination of the efforts for establishing Biosafety regulations in the countries at the region is one of its main duties. Along with the Center of Excellence program, the project will contribute to the expansion of the work of ABI for it will allow more intensive collaboration and development of training system with the neighbour countries.

7. The draft High Technology Act, currently under approval, introduces the development of high-tech parks in the biotechnology area. Those parks are required to operate within certain biosafety measures, and the use of LMO products must be risk-free for the environment and human health.

The GEF Alternative: expected project outcomes, with underlying assumptions and context

The GEF intervention is crucial for the implementation of the National Biosafety Framework (NBF) in Bulgaria. The pilot project carried out in 1999 for developing a NBF enabled Bulgaria to improve the understanding among politicians and the public about Biosafety and biodiversity issues.

Today, Bulgaria has poor capacity for establishing a proper national legislation and the related management system on Biosafety as shown by the delay in working out the LMOs Law. This project will help the Task Force to boost its work, calling also for foreign experts on biosafety legislation. The project will also involve more local specialists in the development of appropriate policies.

The expected outcomes of this project proposal can be detailed as follows:
(A.1) "LMOs Act of Bulgaria" finalised and submitted to Parliament;

(A.2) Regulations needed for the implementation of the Law, drafted.

(A.3) National procedures for Biosafety Clearing-House Mechanism in force

(A.4) Ecological, economic, and sociological surveys among the general public to guide the NBF implementation and the integrated ecosystem management planning/implementation carried out.

(A.5) Assessment of national technological capacity at public and private level carried out.
(A.6.1) Two days workshop for 50 representatives of governmental bodies and organizations, and NGOs, on: "Biosafety issues and the regulations for the implementation of the LMO Law", carried out.
(A.6.2) Four days conference for 80 experts in legislation and politics: "National biosafety legislation and the Biosafety Protocol" carried out.

(B.1) Technical guidelines for performing risk assessment and management in force.
(B.2) Certified laboratory at ABI strengthened and research groups appointed in order to perform assessment and monitoring the deliberate release and commercial use of LMOs
(B.3) Data from mini field trials, and various biochemistry and molecular experiments as well as biodiversity data including those on taxonomy and existing genetic diversity proceeded for risk assessment and management purposes.

(C.1) Five training courses for twelve trainers held on:
- LMOs risk assessment and risk management,
- LMOs testing and monitoring,
- Legal issues,
- Administrative Procedures and
- The control over the transboundary movement of LMO.

(C.2) Two training workshops carried out as follows:
- "Transboundary movement of LMO and the Cartagena Protocol on Biosafety", Relative start month: month 3, timetable – two days; Supposed number of participants – 100
- "Biosafety of biotechnology research, trials and applications", Relative start month: month 6, timetable – tree days; Supposed number of participants - 100 representatives of government, media, NGOs and science community.

(D.1) National Biosafety Database System linked to the Biosafety Clearing House Mechanism set up

(D.2) National web site in place and operational
(D.3) One workshop for 100 government officials, journalists, scientists and NGO representatives on "Information exchange and biosafety" organised.
(E.1) Raised public awareness through newsletter, videos, brochure, website

Activities and financial inputs needed to enable changes

1) Setting up the legislative framework and operational mechanisms for biosafety management in Bulgaria

In 2000, referring to the Action Plan and to the National Biosafety Framework, a special Task Force representing different institutions was set up to finalize the *Living Modified Organisms Act.* The Ministry of Agriculture submitted this Draft of GMO Law as per his capacity as General Coordinator of GMO matters in the country, for approval to Parliament. This Law was ready by the end of 2000, but it was rejected by Group 22 - responsible for preparation of Bulgarian position on environmental issues in the negotiations with the EU- settled within the Ministry of Environment.

Special trans-institutional Taskforce, composed of the representatives of Ministry of Agriculture and Forestry, Ministry of Environment and Waters, Ministry of Health and Council of Ministries, will use expertise and advice from Bulgarian and foreigner experts, specialized in environmental, science and technology legislation, to finalize the draft LMO Act. Main features of the mentioned Act were conceived during the UNEP/GEF pilot project. However, the Cartagena Protocol on Biosafety was agreed only after the conclusion of the pilot project and a revision of the draft regulatory framework is needed in order to meet the Protocol requirements. For example, part sixth of the draft Act on commercial use of LMOs, required a further improvement in order to explicitly include the transboundary movement.

As part of the project, the following regulations complementing the biosafety Act will be drafted:

- Regulations produced by the Council of Ministers for issuing licenses and permits.
- Regulations produced by the Council of Ministers on Contained Use and disposal of LMOs, and containment of waste
- Regulation produced by the Council of Ministers for releasing genetically modified organisms into the environment.
- Regulation produced by the Council of Ministers on requirements needed for products involving living modified organisms[2].
- Regulations produced by the Council of Ministers on risk assessment.

The regulations are a very important base for the implementation of the Act and the Cartagena Protocol on Biosafety requirements and provisions. The regulations for contained use, the release into the environment, the commercial use, and the risk assessment have scientific content. Thus ABI and some institutes in the system of Bulgarian Academy of Science have to be involved in their formulation.

Bulgaria will establish institutional mechanisms intended to provide the Biosafety Clearing-House with the required information under Article 6:1, Article 10:3, Article 11:1,5,6, Article 12:1, Article 13:1, Article 14:2,4, Article 17:1,2, and Article 19:2 in due time. Means and procedures for automatic

[2] Annex 1(i) of the Protocol: Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.

data collection will be set up. The responsibilities of every organization and every specialist regarding the exchange of information with the Biosafety Clearing-House will be stated. Trainers will undergo the relevant course (see p.3). The Biosafety Clearing-House mechanism will be discussed on the "National biosafety legislation and the Biosafety Protocol" workshop.

The proper setting of the legislation and regulatory system depends on the right assessment of the public opinion on ecological, economical and sociological questions concerning the LMO use. Therefore, sample of 1000 people form all parts of the country will be questioned. The sample will be distributed based on the 2001 census results of regional population distribution. Professional agency will be haired to perform the poll.

Due to rapid changes in the organizational structure of the research and development areas, an assessment of the current technological capacity at public and private level will be undertaken. It will be based on the survey done under the pilot project and it will aim at using all the acquired resources for improving biosafety management. The assessment will be organized, carried out and evaluated by the executing agency. During the development of the project, three ecological, economic, and sociological surveys among the general public to provide information including indigenous knowledge, it will help in guiding the implementation of the NBF as well as the integrated management planning.

A workshop "Biosafety issues and the regulations for the implementation of the LMO Law" and a conference "National biosafety legislation and the Biosafety Protocol" will be organized. The workshop will focus on biosafety issues of contained use and deliberate release of LMOs as well as how the law regulates them. The conference will deal with various aspects of practical implementation of the Biosafety Protocol provisions in the National Biosafety Regulatory System. Social and economical aspects, environmental and health issues of LMO utilisation and the impact of the Cartagena Protocol on Biosafety will be discussed.

2) Establish an operational system for risk assessment and monitoring

This project will take into account risk assessment and risk management procedures as identified in Articles 15 and 16 of the Protocol, including any scientific skills that might be required. This will allow Bulgaria to:

- Regulate, manage and control risks and adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, including risks to human health;
- Ensure adequate protection of the environment;
- Minimize the risks posed to their ability to trade with other countries; and
- Provide mechanisms for technology transfer and benefit sharing.

The lack of procedures for risk assessment and risk management was an important issue during the UNEP/GEF Pilot Biosafety Project. In this respect, technical guidelines will be developed and the related data gathered under this project. In particular, a pilot data collection from field trials and molecular /biochemistry experiments will be undertaken.

Botanical files will be also compiled in order to collect the relevant data concerning host plants that might be applied in genetic modification experiments. The botanical files will help in creating a common base of information for all the involved stakeholders for the following reasons:

- All data will pass a scientific check;
- Both, old and recent floristic data, will be included thus creating a starting point for monitoring activities;
- Original references to the data will be included so that the track history of the information can be

traced.

The collected data will support competent decision-making and advisory bodies in deciding concrete cases of notifications or ongoing monitoring of approved LMOs.

Finally, the laboratories at ABI will be strengthened with the needed equipment and research groups will be appointed by the State Biosafety Committee in order to perform risk assessments and monitoring in particular for compliance with the requirements on transboundary movements and labelling as per LMOs Act. At present, the laboratories at ABI are carrying out evaluation of germplasm and GMO detection (for export and import), but they still lack equipment needed for inspection purposes in the context of the risk assessment and management procedure as requested under the Protocol. In the future, it is expected that these activities, in particular those related to the transboundary movement of LMOs products and risk assessment, will become the main ones.
The set of equipment requested under this project is presented in Annex 3.

3) Training

Training is crucial part of the project. Along with the development of the regulation system, experts will be trained to enforce the law requirements and the Cartagena Protocol on Biosafety provisions. In particular, the first set of training will be devoted to train trainers for capacity building purposes of the Ministries here below because of their competencies as follows:

- The Ministry of Environment: in charge of the environmental impact assessment, is also the Focal point for the CBD and of the Biosafety Protocol activities.
- The Ministry of Agriculture: in charge of the field trials and laboratory risk assessments, it will co-ordinate the risk management of agricultural LMO and their products.
- The Ministry of Finance: the custom authorities are under its jurisdiction, it is the major organisation for enforcement of the transboundary movement control.
- The Ministry of Health: responsible for the food safety, hence for the safety of LMO products used in food processing and production.
- The Ministry of Education and Science: it will be in charge of providing advice and monitor the contained use of LMOs and any scientific work in this area.
- The Ministry of Justice and the Ministry of Interior: are the only institutions with the power to implement the penalties related to private property and personal liberty.

According to the above, the following training activities are planned:

a. Five training courses for 12 trainers from the Ministry of Agriculture and Forestry, the Ministry of Environment and Waters, the Ministry of Education and Science, the Ministry of Finance, the Ministry of Justice and the Interior Ministry, selected based on their background and work appointments. The training courses will separately cover the following subjects:

- risk assessment and risk management. The responsible persons for the performing the risk assessment and risk management tasks will be introduced to the respective provisions of the Cartagena Protocol on Biosafety. The practice in the EU, USA and Canada will be examined and means for their implementation in the conditions in Bulgaria will be looked at. The companies' procedures for risk assessment and risk management will be examined and compared to the regulations requirements. At the end of the course the participants have to be able to perform risk assessment procedures and to evaluate the assessments provided by the companies.

- testing and monitoring. The participants will be trained to use various tests for LMO con-

tamination, like PCR, ELISA and several on-spot tests.

- Legal issues The ways to enforce the Law and the penalties will be the topic of this course. The participants will learn how to ensure that the Law's provisions and the State Committee decisions are executed and followed. The procedures for penalties and enforcement will be practised.

- Administrative Procedures: The structure of the controlling structure within the respective Ministries will be discussed. The participants will learn how to interact with the representatives of other organisations involved with control tasks under the Law. The control procedures will be practised. The coordination with the State Committee will be trained.

- The control of the transboundary movement. The Cartagena Protocol on Biosafety provisions and the ways of interaction with the Biosafety Clearing-House and with the corresponding countries and organisations will be discussed. The methods for control of the transboundary movement of goods and the detection of LMOs will be trained.

b. In the second quarter of the project duration a two days workshop for around 100 participants will be held on "Transboundary movement of LMO and the Cartagena Protocol on Biosafety". The workshop will focus on risk assessment and risk management. The biodiversity preservation in the face of the application of genetic engineering achievements will be focused on two aspects – preventing harmful effects and the possible promoting of the biodiversity. The lecturers will emphasise on the legal ways to preserve the native species and the role of the national gene bank. Pilot data gathering and the botanical files will be discussed. Government officials, scientists, NGOs representatives will participate in the workshop.

c. Four days workshop for 21 representatives of government, media, NGOs and science community on: "Biosafety of biotechnology development, trials and applications" will be held in the third quarter. This workshop will specifically focus on safety requirements and procedures for LMOs contained use, deliberate release and commercial use. The potential risks and risk assessment methods will be discussed. International experts will share their experience with the control of the release of LMO and LMO products.

The training events will include lectures by foreign experts, case studies and experience sharing between the participants.

1) Information sharing and dissemination activities

Information sharing and dissemination will rely on a sophisticated data base network and web page, developed according the recommendations of the "Note by the Bureau of the ICCP on technical issues associated with the implementation of the Pilot Phase of the Biosafety Clearing-House" and its Annexes 2 and 3 made by a liaison group meeting of technical experts on the BCH convened at the initiative of the Executive Secretary from 19 to 20 March 2001 to provide advice on technical issues associated with the implementation of the pilot phase of the BCH. At its meeting held on 21 March 2001, the Bureau endorsed these recommendations and requested the Secretariat to convey them (as information note) to all Governments and invite feedback in order to ensure transparency in the development of the pilot phase of the BCH.

Under the project activities a project mailing list server will be developed in order to enhance the rapid exchange of information between participating parties, to provide regular updates on significant developments in biosafety and to facilitate the timely provision of specific information on request. The

data are presented in a user-friendly way to the interested parties.

Information network and special workshops are aimed to improve the public perception and participation in the process of implementing the NBF and the use of LMO. Media and major NGO, working on these issues, will be granted access to the information network. This will assure the delivering of actual and proper information on Biosafety and related legislation issues.

A quarterly newsletter, training materials on specific areas of biosafety (to be used also during the regional and sub-regional workshops, or as stand-alone workshops) including technical manuals and press-releases will be produced and published. Additionally, best practice and lessons learnt will be disseminated for replication in other countries of the region.

4.1 Establishment of the Biosafety Database System and Biosafety Clearing-House Mechanism in Bulgaria

An information database and network will be set up: it will contain registers, dossiers, trial data and other related information required by Cartagena Protocol on Biosafety and EU regulations. The information database will be accessible by all the government organizations. NGOs, other interested parties and the public will have access to the database through the website as follows:

- NGOs, journalists and any interested parties can access the not protected (because of commercial confidentiality) information of the database free-of-charge;
- The general public or any interested party can get general information on biosafety-related activities and issues just by accessing the web site.

The database will have an additional regional component containing relevant information on CEE countries or a direct link to their websites and other information sources.

The web site will be linked to other biosafety information sources and to the botanical files once available. A mailing list will be created and maintained by the NEA. It will provide regular updating on the project activities. A discussion forum will be open for public debates.

A four-day Workshop on "Information exchange and biosafety" will be held to introduce the network as a valuable information source also for public awareness. Hundreds of participants among whom regulators, journalists, scientists, NGO representatives and the general public are expected to attend this event.

Sustainability analysis and risk assessment

The efforts to establish biosafety legislation system are part of the preparation of Bulgaria to comply with CBD and the Cartagena Protocol on Biosafety. However, they can be unpredictably influenced by political changes in the government or by other subjective factors. This project will assure continuation of the Biosafety policy of Bulgarian government after the parliamentary elections in June 2001.

The project will support the establishing of National regulatory body that will operate under regulation, based on the National Biosafety Framework and relevant law. This body can accumulate the needed funding for its activities by itself. For the services it provides, it will collect taxes which will allow it to perform required assessments and analyses.

Lack of support by key governmental institutions because of subjective concerns and lack of NGOs support are among the key project risks. Smooth interactions of the governmental bodies are crucial for

the sustainable development of the legislative system. The institutional partnership will help the regulatory body to perform its duties and to gain public approval and confidence in its work. This partnership can be assured by clear statement of stakeholders' duties and rights in the LMO Act and its regulations. Clear procedures and criteria for risk assessment will improve public opinion and will help NGOs to participate in the decision process.

Governmental organizations will promote public discussions and participation in the reviewing process. At least one public hearing and discussion on the LMO Act provisions will be organized

Stakeholder involvement and social assessment

Responses of various stakeholders on the issues clarified by the development of NBF and the work on the Bill for LMO helped to identify the goals and the activities of the project.

Main stakeholders are the governmental organisations, such as the Ministry of Environment and Waters, the Ministry of Finance and the Ministry of Agriculture and Forestry. Experts from these ministries will provide the project with expertise and organisational infrastructure.

The scientific community will have an important role in the implementation of the National Biosafety Framework by providing scientific expertise for formulation of the implementation regulations of the LMO Act.

Efforts to improve public awareness on the issues of biosafety during the Implementation of the Pilot Enabling Project leaded to more active role of the NGO in the regulation of LMO. Green organizations representatives and politicians are involved in these discussions at the Parliament, and at the Ministry of Environment. The views of this ministry, about the form of the needed regulations of LMO, supported by the NGO representatives, postponed the work on the Bill. The implementation of the NBF will consider NGOs advises and public concerns and will incorporate the results of public discussions and round tables.

INCREMENTAL COST ASSESSMENT

Bulgaria has ratified the Cartagena Protocol on Biosafety on the 25th of May 2000 and is preparing for its entering into force. Bulgaria has paid and is paying special attention to biosafety, a priority in the National Biodiversity Action Plan Preservation and an important issue in the negotiations for joining the EU. Furthermore, the previous GEF-funded enabling activity "Development of a National Biosafety Framework" carried out over the past two years in eighteen pilot countries, including Bulgaria, has also shown that the country has actively contributed to it in terms of efforts, time spent and results achieved to promote biosafety issues management at national level. In particular, funding have been made available for drafting the LMOs legislation, carrying out workshops and training, conduct risk assessment studies and field trials.

The *Regulation for Biosafety of GM Higher Plants* was adopted by the Ministry of Agriculture (1996). In 2000, a special Task Force was set up and started drafting the *Living Modified Organisms Act*. The Taskforce did not complete its work. A first LMO Act was presented to Parliament but then rejected. It is being revised in order to go through Parliament again.

Under the Dutch funded capacity building project "Implementation of national biosafety frameworks in pre-accession countries of Central and Eastern Europe", aiming at assisting in developing workable and transparent biosafety frameworks consistent with international obligations, Bulgaria has benefited of a in-kind workshop on "Handling requests for releases of LMOs into the environment" (for an equivalent estimated amount of 10,000USD). Currently, 3.840EURO have been provided by the EU to starting the project "Improving communication and dissemination of bio-sciences in Europe".

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. These activities consist of the following:

Project component	Baseline	Alternative	Increment
The Establishment of legislation system and operational mechanism for biosafety management in Bulgaria	Bulgaria has ratified the Cartagena protocol. A first LMO Act was presented to Parliament but then rejected. It needs revision before being re-submitted to Parliament. The implementing regulations are in their early stage of development.	The draft LMO Act and the implementing regulations finalized, implementing regulation drafted. Institutional capacity further strengthened through workshops	The correct implementation of the Cartagena Protocol is supported by the consolidation of the National Biosafety Framework and its implementing regulations and by a strengthened institutional capacity
LMOs Risk Assessment and Risk Management: procedures and strengthening of certified laboratories	Mechanisms for risk assessment, risk management, enforcement and information supply are in the very early stages of development. Certified laboratories still lack equipment for inspection purposes in the context of the risk assessment and	Technical guidelines for risk assessment and management in place. Iinformation supply for the purpose of the risk assessment strengthened through a pilot collection of mini-data and botanical files. Certified laboratories at ABI equipped with instruments	Risk assessment management is improved once guidelines as well as needed facilities are in place. Data collected support competent decision-making and advisory bodies in deciding concrete cases of notifications or ongoing monitoring of approved

	assessment and management procedure as requested under the Protocol.	with instruments needed for inspection purposes in the context of the risk assessment and management procedure as requested under the Protocol	LMOs.
Training and workshops	Need for strengthening capacity among those involved in the biosafety management system	Capacity strengthened through specific training for trainers on specific subjects (risk assessment and risk management, testing and monitoring, Legal issues particularly in relation to use, import and export, administrative Procedures, and Controls over the transboundary movement of LMO	Strengthened national capacity to meet the commitments under the Cartagena Protocol
The Establishment of a Biosafety Database system to serve for the purpose of the Biosafety Clearing House Mechanism	An organised database system to serve for the purpose of the Biosafety Clearing House is still missing.	A national information system as required by the Protocol for the purpose of the BCH (database as well as web site) set up. A specific workshop for the use and best management of the created BCH system carried out.	The setting up of the national database, the collection of the related information, the opening of a web site are the basic activities needed to make the Central BCHM as structured in the Protocol operational
Capacity building for public awareness	Lack of adequate capacity for public awareness purposes	Capacity for public awareness purposes strengthened through specific dissemination activities	Public awareness capacity enhanced

An estimate of the baseline activities carried out amounts to USD175,000. As shown in the table below, the cost of the increment is of ***USD504,259*** of which ***USD407,879*** is being requested from the GEF; the remaining ***USD96,380*** is provided as in-kind contribution by Bulgaria.

Table 1 - Incremental Cost Table (US$)

Project component	**Baseline**	**Alternative**	**Increment**	**Cost to GEF (Global Benefit)**	**Co-financing (in-kind contributions)**
The Establishment of legislation system and operational mechanism for biosafety management in Bulgaria	27,000	185,504	158,504	**113,745**	**44,759**
Development of procedures for handling LMOs Risk Assessment and Risk Management of LMOs, data collection from limited field trials	97,000	175,000	78,000	**66,000**	**12,000**
Training and workshops	45,000	108,640	63,640	**54,960**	**8,680**
Information component • *database setting up* • *web site*	6,000	118,486	112,486	**81,545**	**30,941**
Public awareness	-	91,629	91,629	91,629	-
Total	**175,000**	**709,259**	**504,259**	**407,879**	**96,380**

The implementation of a National Biosafety Framework for Bulgaria is of extreme relevance given that to date is one of the two countries that have ratified. In particular, it will be an example for the entire countries region: in fact, the legal framework will provide guidance for the LMOs use and commercialisation and will help Bulgaria in synchronizing its legislation and facilitate its correspondence with EU directives and therefore the accession.

PROJECT BUDGET

Component	GEF	Other sources	Project total
1. PDF	NA	NA	NA
2. Personell	$ 9,000.00	$ 1,000.00	$ 10,000.00
3. SUBCONTRACTS:	**$ 88,000.00**	**$ 24,000.00**	**$ 112,000.00**
3.1 Database network:			
Database project	$ 40,000.00		$ 40,000.00
Web-page	$ 6,000.00		$ 6,000.00
Internet connection		$ 10,000.00	$ 10,000.00
Licenses	$ 5,000.00		$ 5,000.00
Total 3.1	$ 51,000.00	$ 10,000.00	$ 61,000.00
3.2 Act and Regulations drafting:			
Legal consultations with Bulgarian attorneys and legal specialists	$ 10,000.00	$ 2,000.00	$ 12,000.00
Foreigner consultants	$ 6,000.00		$ 6,000.00
Infrastructure (Office space, communication, office equipment, computer network)	$ 15,000.00	$ 10,000.00	$ 25,000.00
Technical guidelines (specialized guidelines for specific purposes of the monitoring and control tasks)	$ 6,000.00	$ 2,000.00	$ 8,000.00
Total 3.2	$ 37,000.00	$ 14,000.00	$ 51,000.00
4. TRAINING:	**$ 54,960.00**	**$ 8,680.00**	**$ 63,640.00**
Accommodations for the Bulgarian participants (12x$80) for 10 days in total	$ 9,600.00		$ 9,600.00
Accommodations for the foreign participants (13x$100) for 12 days in total	$ 10,920.00	$ 4,680.00	$ 15,600.00
Travel	$ 10,000.00	$ 3,000.00	$ 13,000.00
Allowances	$ 10,800.00		$ 10,800.00
Meeting rooms rent	$ 2,040.00		$ 2,040.00
Transfers and internal transport		$ 1,000.00	$ 1,000.00
Lecturers fees	$ 2,600.00		$ 2,600.00
Translation	$ 9,000.00		$ 9,000.00
5. WORKSHOPS:	**$ 94,290.00**	**$ 48,700.00**	**$ 142,990.00**
Accommodations	$ 18,000.00	$ 15,200.00	$ 33,200.00
Travel	$ 35,000.00	$ 26,000.00	$ 61,000.00
Allowances	$ 30,420.00		$ 30,420.00
Meeting rooms rent	$ 1,870.00		$ 1,870.00
Transfers and internal transport		$ 4,000.00	$ 4,000.00
Lecturers fees	$ 3,000.00	$ 1,500.00	$ 4,500.00
Translation	$ 6,000.00	$ 2,000.00	$ 8,000.00
6. Botanical files	$ 20,000.00		$ 20,000.00
7. Equipment for the accredited laboratory at ABI	$ 20,000.00	$ 10,000.00	$ 30,000.00
8. Surveys	$ 20,000.00	$ 4,000.00	$ 24,000.00
9. Information dissemination	$ 50,000.00		$ 50,000.00
10. Risk assessment data collection	$ 20,000.00		$ 20,000.00
11. One 60 min. movie and ten 1 min. thematic video spots	$ 19,420.00		$ 19,420.00

12. CD ROM with information on biosafety issues and promoting the Biosafety Protocol mission	$ 2,750.00		$ 2,750.00
13. Printed materials	$ 6,459.00		$ 6,459.00
14. Miscellaneous	$ 3,000.00		$ 3,000.00
TOTAL	**$ 407,879.00**	**$ 96,380.00**	**$ 504,259.00**

PROJECT IMPLEMENTATION PLAN

Duration of project (in months) 24								
ACTIVITIES	PROJECT-MONTHS							
Completion of project activities	3	6	9	12	15	18	21	24
1. Stakeholder identification	X							
2. Establishing of LMO Act	X	X						
3. Establishing of national regulatory framework			X	X	X			
4. Establishing of network for exchange of information on Biosafety					X	X	X	X
5. Ecological, economic, and sociological surveys	X	X	X	X	X	X	X	X
6. Botanical files	X	X	X	X				
7. 1st training course	X							
8. 2nd training course		X						
9. 3rd training course			X					
10. 4th training course				X				
11. 5th training course					X			
12. Workshop: "Transboundary movement of LMO and the Cartagena Protocol on Biosafety"	X							
13. Workshop: "Biosafety issues and the regulations for the implementation of the LMO Law"		X						
14. Workshop: "Biosafety of biotechnology research, trials and applications"			X					
15. Workshop: "The information exchange and the biosafety"				X				
16. Conference: "National biosafety legislation and the Biosafety Protocol"		X						

PUBLIC INVOLVEMENT PLAN

During the first phase of the project, the main stakeholders in the implementation of NBF will be identified. They have to be more than during the pilot project for it is needed broad social consensus on the role of LMO in our everyday life. The stakeholders will be contacted directly or through governmental organizations as well as NGOs.

The Ministry of Environment and Waters, the Ministry of Agriculture and Forestry, the Ministry of Health and the Ministry of Finance are among the main stakeholder organisations within Government. Other stakeholders are scientists, attorneys and legal advisers, representatives of interested NGOs and the general public.

The Ministry of Environment can give the needed organisation for environment impact assessment. The Ministry of Agriculture will participate in field trials and laboratory risk assessments. It will coordinate the risk management of agricultural LMOs and their products.

The Ministry of Finance has the custom authorities under its jurisdiction and will be a major organisation for enforcement of the trans-boundary movement control.

The Ministry of Health is responsible for the food safety, hence for the safety of LMO products used in food processing and production.

The Ministry of Education and Science will perform advisory and monitoring functions for contained use of LMO and any scientific work in this area.

The Ministry of Justice and the Ministry of Interior are the only institutions with the power to implement the penalties related to private property and personal liberty.

Scientists will form risk assessment and risk management task forces and will have major role in the development of the LMO Acts implementation regulations.

NGOs will be also consulted during the project implementation and requested to provide recommendations.

The work on the implementation of the NBF will be completely transparent. Distinguished scientists and specialists will provide expertise and experience in training courses and workshops. The NAE will organise round tables and discussions on issues of great social interest. The timing of the organising of such round tables and discussions will be chosen taking into account current needs and opportunities.

An information network will be established in the frame of the project. The system will provide the interested parties with needed information and analyses on various issues related to biosafety and LMOs. It will play a proactive role in ensuring that all project national focal points have ready access to appropriate assistance via a range of different mechanisms and media. Training and public awareness materials will be also prepared.

A project website will:

(i) Provide a linkage between the work programmes of individual participating countries in order to spread experience and best practices;
(ii) Establish a resource database representing a distillation of the most important and relevant biosafety information emerging at a global level with links to the Biosafety Clearing House where appropriate; and
(iii) Provide a portal to other relevant internet-based resources;

A project list server will allow rapid exchange of information between participating parties and ensure that essential project information is disseminated quickly and efficiently to all participating countries, to provide regular updates on significant developments in biosafety and to facilitate the timely

provision of specific information, on request, to participating countries.

A project newsletter, to be published on a quarterly basis which will complement the information provided by the list server but which can be used to increase the public awareness of the project;

Biosafety outreach materials including publications, video, brochures, articles in local press, etc. for public awareness raising purposes.

The National Executive Agency will develop and disseminate training materials, including technical manuals and best practice guidelines, on specific areas of biosafety that can be used during the regional and sub-regional workshops, or at stand-alone workshops.

The National Executive Agency will establish a database of regional and national level resources for biosafety public awareness and education, and for monitoring and contributing to press coverage of biosafety issues.

The primary stakeholders in this project are the designated scientific institutions and government departments. All stakeholders that may have a legitimate interest in the use of living modified organisms that may have an adverse effect on the environment or on human health provide mechanisms for consultation and taking the broad range of views into account. The active participation of a broad range of individuals and organisations will be needed to obtain maximum support for the implementation of the Biosafety Framework.

NGO representatives will review the Bill, monitor the capacity building and participate in training workshops. Their expertise in information dissemination and public education will be valuable help.

MONITORING AND EVALUATION PLAN

Monitoring of the progress of all activities will be undertaken by UNEP in accordance with its Monitoring and Evaluation procedures.

The identified indicators in the project will be used for monitoring the development of the project activities.

A mid-term independent evaluation will be undertaken. The evaluation will include an assessment of on-going activities including a diagnosis of possible problems and recommend any corrective measures. A final evaluation of the project will be undertaken in accordance with UNEP.

Dissemination of results will take place via the stakeholders meetings, via periodic meetings between the project management team and the government departments, publications and via the public media.

Recommendations and best practises will be disseminated for replication to other countries in the region.

IMPLEMENTATION ARRANGEMENTS

- A National Coordination Committee is being installed. As appropriate, UNEP, as leading agency, and FAO and UNIDO as collaborating agencies, will provide recommendations and assess the achievements done during the implementation of this project.
- A Steering Co-ordination Committee for the eight projects will be chaired by UNEP and will comprise the representatives of the National Executing Agency, the two other implementing agencies,

the GEF Secretariat as well as FAO and UNIDO. In addition, experts selected on their personal capacity will be part of the Steering Committee as well as the representative of STAP when the Steering Committee will be addressing technical and scientific issues arising from the implementation of the MSPs.

LIST OF ANNEXES

ANNEX 1

Summary of the National Biosafety Framework in Bulgaria

National Biosafety Framework in Bulgaria

The task of the national biosafety framework is to provide for indispensable level of biological security with respect to release and use of living modified organisms by:

- assessing possible negative effects during deliberate release into environment,
- establishing monitoring system,
- planning emergency actions to deal effectively with accidents,
- establishing system to provide consent and certification on each stage of experiments and deliberate release into the environment,
- establishing body with the mandate to make decisions and control on registration, consent for LMO release and codes of practice,
- developing information system,
- establishing international cooperation
- training personnel.

Coordinating body (National Competent Authority)
Living modified organisms have to be considered in four sectors of activities: contained use of LMO, deliberate release into environment, placing on the market and transboundary movement of products containing genetically modified organisms or consisting of such organisms or their parts. The first tree issues are regulated in European Union by two directives: 90/219 (contained use) and 2001/18/EC (deliberate release into environment and products). The transboundary movement is addressed by the Cartagena Protocol on Biosafety. These areas of LMO application (deliberate release into environment and products) are still not fully addressed by Bulgarian law. Bulgaria govemment began to study and prepare rules and administrative acts to regulate some aspects of the biotechnology R&D and applications in the early nineties but until 1995, there were only few governmental and institutional decisions on biosafety related issues. Some of them are only indirectly related to biosafety, but in general they regulate products and applications of food, veterinary and agricultural industries.

In 1996, the government approved the Regulation for Safe Use of GM Higher Plants. Its main features are:

- The release into the environment of genetically modified plants is controlled by the Ministries of Agriculture and the Environment
- A Council for Biosafety of GM Higher Plants (the Council) under the Ministry of Agriculture, Forestry and Agricultural Reform was set up. The Council is chaired by the Minister of Agriculture. The Scientific Secretary is an eminent scientist with academic ranks in the field of Genetic Engineering who co-ordinates the activity of the Council. The members include representatives of the Ministry of Environment and the Ministry of Health. Experts in the respective fields. If needed, foreign experts may be drawn in the activity of the Council as consultants. The Council has full authority to allow or reject the release of GMP in Bulgaria. It also controls the allowed releases and keeps the records.
- The notification procedure is quite similar to the one adopted in Directive 90/220 of EU. A notification, containing the information required by Directive 90/220 is to be submitted to the Council, which is to respond in one month. Labelling of the goods containing GMP is required.
- Consent for a release does not prevent from other relevant liabilities, occurring in case of damages resulting from the release of transgenic plants.

To date, the main governmental organizations currently involved in the biosafety process:

- Under the Ministry of Agriculture and Forestry functions:
  - Council for Biosafety of Genetically Modified Higher Plants
  - National Service for Plant Protection, Quarantine and Agrochemistry – pests and plant diseases

- Executive Agency for Approbation and Seed Control - approves new plant varieties
- Central Veterinary Service - animal quarantine

➢ Under the Ministry of Health Care function:
- Central Institute for Drugs - approves new drugs and medicines, as well as imports
- Central Hygiene Epidemiological Inspection - controlling the safe production and distribution of foods

Each individual application is reviewed with regard to potential risk arising from deliberate or unintentional release of GMO into environment.

Principles of regulation:
During its activity, the CBGMHP has developed the following principles for regulation of GMP in Bulgaria:

- The regulatory processes should be open, transparent, clear, nationally uniform, consistently applied, and enforceable;
- Risks assessment should be objective, science-based, and independent with respect to environmental and human safety, and should be conducted prior to release, use, and marketing of GMP in Bulgaria;
- Decision making should be the result of professional, science-based risk assessments, and take into account the wide range of benefits and costs involved;
- The regulatory processes should be sufficiently flexible to adjust the degree of regulation according to the inherent risks of individual GMPs or products as experience and knowledge are gained;
- The regulatory processes should be designed to minimize the costs of administration to government and of compliance by individuals, businesses and organisations;
- Bulgaria's regulatory system should be harmonised with those of our major trading partners;
- Bulgaria's international competitiveness should be enhanced; and
- Consistency with Bulgaria's international rights and obligations should be ensured.

Current efforts
In 1998 UNEP supported Bulgaria, among 18 countries in the world, for the formulation of National Biosafety Framework. While the Framework is already established now we are facing the problem for its implementation. The Action Plan and the National Biosafety Framework form 1999, set as a priority the formulation of a LMO Act. In accordance with these documents, a Task Force for developing of such law was appointed in 2000. However, the Taskforce did not manage to conform to all views and opinions about the structure of the implementation body, and the competence of the ministries on biosafety related issues. The underdevelopment of the national legislation system promotes public concerns about the safety of the biotechnology applications in the everyday life.

The forthcoming LMO Act establishes a State Biosafety Committee under the authority of the Council of Ministries. The members of the Committee are representatives of the responsible ministries and group of experts. The Committee acts as he main implementation body of the LMO Act and its regulations. The Committee may ask panels of outside experts, designated by other ministries, for advice.
The State Biosafety Committee will be entrusted with the following responsibilities:

- Preparation of recommendations for risk assessment to human health and environment,
- Licensing the activities related to LMO,
- Evaluation of all applications.

Control of release of LMO
Currently, the control of the release of LMO is under the authority of the Council for Biosafety of Genetically Modified Higher Plants. The Council conducts mini and broad field trials. The goal of these trials is to provide with reliable information for risk assessment and risk management. Four expert groups support the Council and carry on spot monitoring and laboratory analyses related to herbology, entomology and food safety. The analyses are compared with the results provided by the applicants. After 3 to 5 years of trials and assessments the Council approves the application or denials permission for the release of LMHP.

The system of control of LMO release will be build upon existing law and institutions. The State Committee responsibility to undertake control measures in defined area of national activities. Other governmental agencies will be included in the control system for GMO. Competent Agencies which should be granted responsibility for control of GMO marketing are:

- Central Hygiene Epidemiological Inspection
- Custom Service,
- Environmental Protection Inspection,
- Veterinary Inspection
    - Police

Applications

Applications for GMO release and utilisation will be directed to the State Biosafety Committee, as to General Coordinator for GMO matters in the country.

Applications should be send for:

- Approval of GMO use in containment: such applications should contain all necessary data and be prepared according to EU Directive 90/219.
- Approval of GMO deliberate release to environment, such applications should contain all necessary data and be prepared according to EU Directive 2001/18/EC and its annexes.
- Approval for introduction into the market of GMO and its products, according to EU Directive 2001/18/EC and other EU regulations dealing with food and food products, particularly with EU Directive 93/114 and Regulation of European Council and European Parliament NR. 258/97 on novel food.
- Transboundary movement according to Cartagena Protocol rules.

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

Risk assessment

The applicant is responsible for the performance of risk assessment for GMO utilisation he asks in the application. Experts in appropriate scientific disciplines would evaluate the applications. The State Biosafety Committee will prepare and suggest a list of experts for evaluation and review of applications for LMO utilisation. This list should consist of the best experts available in each field of expertise and should also include, if possible, experts with different views on LMO utilisation. In addition, State Biosafety Committee would have the possibility to ask for additional experts (included those from foreign countries), outside this list for evaluation of especially difficult applications.

Decision making strategy

The following steps are proposed for decision making by the State Committee for biosafety on GMO related matters:

1. Application to the LMO General Coordinator should be delivered.
2. Formal screening by the Committee.
3. Formal information to the applicant of receiving of the proposal for evaluation
4. Evaluation of the proposal by State Biosafety Committee and preparation of the decision project.
5. Discussions with NOG and other interested parties in cases from strong public interest are possible.
6. State Biosafety Committee takes the decision and the Council of Ministers publishes it in an official journal.

ANNEX 2

Matrix showing the relation between project activities-Cartagena Protocol-NFB

PROTOCOL ACTIVITIES	PROJECT ACTIVITIES	NATIONAL BIOSAFETY FRAMEWORK
Article 2. 1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol 2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. **Article 16**. 1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of LMOs. 2. Measures based on risk assessment shall be imposed to extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks human health, within the territory of the Party of import. 3. Each Party shall take appropriate	(a.1) Setting up a trans-institutional task force for finalizing the "*Bulgarian LMO Act*" to meet the requirements of the Cartagena Protocol, and submit it to Parliament for approval. (a.2) Draft the following regulations for the implementation of the LMO Act: • Regulation of Council of Ministers for approving of fees gathered for issuance of licenses and permission. • Regulation of Council of Ministers for term and order of contained use and disposal of and containment of waste. • Regulation of Council of Ministers for term and order of the releasing of genetically modified organisms into the environment. • Regulation of Council of Ministers for the requirements to products, containing or consisting of genetically modified organisms. Regulation of Council of Ministers for risk assessment. (a.3) Drafting, finalization and implementation of national procedures to enable active participation to and functioning of the Clearing-House Mechanism as required by the Protocol and the LMO Act.	To implement adequate risk assessment and risk management of the release and use of GMO, Bulgaria needs to establish national institutional mechanisms for oversight and control of the use of GMO. This national institutional mechanism must determine who is responsible for preparing and reviewing risk assessments and proposed risk management. It might consider local review appropriate; it might conduct the review itself; it may establish a multidisciplinary body, consisting of scientific experts; or it may choose to use a combination of particular expertise from inside and outside the country or region. The deliberate release in the environment of recombinant DNA or organisms and products derived from recombinant DNA and their commercialisation cannot be initiated without approval from The Council for Safety Use of GMO. Mechanisms for oversight and/or control must include prior notification to the authority/national institutional mechanism of contained use facilities and certain contained uses and releases of GMO as well as the marketing of products containing or consisting of GMO. The notification and approval of activities under oversight is required

measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism. 4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use. **Article 18** 1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. **Article 25** 1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalising transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.	(a.4) Ecological, economic, and sociological survey among the general public to provide information, including indigenous knowledge, to guide NBF implementation. (a.5) Assessment of national technological capacity at public and private level, its effect on implementation of national biosafety frameworks, and means to improve it. (a.6) Two days workshop for 50 representatives of governmental bodies and organizations, and NGOs, on: "Biosafety issues and the regulations for the implementation of the LMO Law". The workshop will focus on biosafety issues of regulating and controlling the contained use and the deliberate release of LMOs. (a.7) Four days conference for 80 experts in the legislation and politics: "National biosafety legislation and the Biosafety Protocol". The conference will deal with various aspects of practical implementation of the Biosafety Protocol provisions in the National Biosafety Regulatory System. Social and economical aspects, environmental and health issues of LMO utilisation and the impact of the Cartagena Protocol will be discussed. (Accommodations – 5 nights x 30 int. participants x $100) (b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act (b.2) Two certified laboratories and expert research groups, performing assessment and	required. In deciding on the appropriate containment for an experiment, the initial risk assessment should be followed by a thorough consideration of the agent itself and how it is to be manipulated. Factors to be considered in determining the level of containment include agent factors such as: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects such as toxicity, physiological activity, and allergenicity. Risk management is employed during the development and evaluation of an organism in a systematic fashion, for example from the laboratory, through stages of field-testing, to commercialization. The number and forms of these stages are not fixed, but depend on the outcome of risk assessment at the different stages. Progression through the appropriate developmental stages, in order to gain knowledge, generally entails a reduction in control and possibly in monitoring, while often increasing in scale. Establish and implement policies that provide for the safe conduct of recombinant DNA research or release and that ensure compliance with the *National Biosafety Framework*. As part of its general responsibilities for implementing the *National Biosafety Framework*, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the

	monitoring on the deliberate release and commercial use of LMOs, according to the LMO Act. (b.3) Pilot collection of data from mini field trials and various biochemistry and molecular approaches for the purpose of risk assessment.	*National Biosafety Framework*. Such procedures may include: (i) statements formulated by the institution for the general implementation of the *National Biosafety Framework*, and (ii) any additional precautionary steps the institution deems appropriate. Establish an Institutional Biosafety Committee that meets the requirements set forth in Section IV 2.1. Appoint a Biological Safety Officer (who is also a member of the Institutional Biosafety Committee) if the institution: • conducts recombinant DNA research at Biosafety Level (BL) 3 or BL4, or • engages in large scale (for example – greater than 10 liters) research. The Council for Safe Use of GMO will realize monitoring on the commercial use of the products from GMO or such, containing GMO even after the approval for deliberate release. Depending on the characteristics of the organism with novel traits and of the intended use, a user intending to transfer such organisms from one country to another must provide relevant information to the user or appropriate focal point(s) in the receiving country. This request for information transfer would still apply even if the organism has been exempted from oversight in the supplying country. Information could, in some cases, be supplied together with the transferred GMO and, in other cases, in advance of the transfer. The provision of information prior to transfer involves a

		mechanism of "advance informed agreement", i.e. the transfer of GMO to another country first requires the agreement of Republic of Bulgaria.
Article 7. 1. Subject to Articles 5 and 6, the advance informed agreement procedure in Article 8 to 10 and 12 shall apply prior the first intentional transboundary movement of living modified organism for intentional introduction into the environment of the Party of import. **Article 10.** 1. Decisions taken by Party of import shall be in accordance with Article 15. Article 11. 1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organisms that may subject to trans-boundary movement for direct use as food or feed , or for processing shall, within fifteen days of making that decision, inform the Parties through the BCH. **Article 33** Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the	•	For organisms representing a possible impact or threat due to transboundary movements, the following two points should be followed: • The potentially affected country should be given notice of the intended use and the opportunity to state whether particular measures will be needed to protect its interests, in particular its biodiversity; The potentially affected country should be informed immediately in the event of an adverse effect of the use of a organism with novel traits which could affect it Experiments that involve recombinant DNA technology cannot be initiated without submission of relevant information on the proposed experiment to the Institutional Biosafety Committee review by GMO Advisory Committee, and specific approval by the Council for Safety use of GMO. Research proposals involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects (human gene transfer) will be considered through a review process involving both Council for Safety use of GMO and GMO Advisory Committee. Investigators shall submit relevant information on the proposed human gene transfer experiments to Council for Safety use of

Protocol.		GMO. With special decision the Council must specify the format of the submissions of gene transfer protocols to the Council for Safety use of GMO. The Council for Safety Use of GMO responsibilities include (but are not limited to) the following: • Issues licenses for release of GMO; • Maintains registers of the research and commercial release of GMO; • Evaluates the quality of the assessments of environmental hazards posed by the release of GMO and the effect of the proposed safety measures on the basis of information submitted by the notifaer; Supervises compliance to regulations governing the permission for release of GMO;
Article 15. 1. Risk assessment undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques.	(b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act. (b.2) Two certified laboratories and expert research groups, performing assessment and monitoring on the deliberate release and commercial use of LMOs, according to the LMO Act. (b.4) Prepare botanical files for the purpose of risk assessment and management.	Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators (Project leaders), and laboratory staff regarding laboratory safety and implementation of the National Biosafety Framework.
Article 17. 1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organisations, when it knows of an occurrence under its jurisdiction resulting in a release that	(d.1.1) Setting up a national information database on registers, dossiers, trial data, deliberate release, commercial use, import and export, and any other information required under the Cartagena Protocol on Biosafety with an adequate mechanism for information sharing/networking and security management. The database will include	Submission to Council for Safety use of GMO shall be for registration purposes and will ensure continued public access to relevant gene transfer information in compliance with the *National Biosafety Framework*. For organisms representing a possible impact

leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation. 2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article. 4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures. **Article 20** A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the BCHU.	regional biosafety information. (d.1.2) Development of a national website, linked to the information database as per point d.1.1, by the Biosafety Committee in order to: 5. Provide project related information; 6. Provide a linkage to the Biosafety work programmes of other countries in order to spread experience and best practices; and 7. Provide links to other relevant biosafety web pages. (d.1.3) Organise a workshop for 100 government officials, journalists, scientists and NGO representatives on “Information exchange and biosafety”. The workshop will inquire the relationship between the Information exchange and the perception of the biotechnology and its products as safe or hazardous. (Accommodations for 3 nights x 26 int. participants x $100)	or threat due to transboundary movements, the following two points should be followed: • The potentially affected country should be given notice of the intended use and the opportunity to state whether particular measures will be needed to protect its interests, in particular its biodiversity; • The potentially affected country should be informed immediately in the event of an adverse effect of the use of a organism with novel traits which could affect it. Depending on the characteristics of the organism with novel traits and of the intended use, a user intending to transfer such organisms from one country to another must provide relevant information to the user or appropriate focal point(s) in the receiving country. This request for information transfer would still apply even if the organism has been exempted from oversight in the supplying country. Information could, in some cases, be supplied together with the transferred GMO and, in other cases, in advance of the transfer. The provision of information prior to transfer involves a mechanism of "advance informed agreement", i.e. the transfer of GMO to another country first requires the agreement of Republic of Bulgaria. The Council for Safety Use of GMO responsibilities include (but are not limited to) the following: • Serving as the focal point for public access to summary information pertain-

		ing to human gene transfer experiments; • Serving as the focal point for data management of human gene transfer experiments; • Transmitting comments/recommendations arising from public GMO Advisory Committee discussion of a novel human gene transfer experiment to the Council for Safety use of GMO. GMO Advisory Committee recommendations shall be forwarded to the Principal Investigator, the sponsoring institution, and other components, as appropriate; • Publishing annual reports and regular opinion on different issues related with biosafety. • Canceling the approval for deliberate release or commercialization of GMO if it is shown that this GMO can harm the environment and/or human health.

Article 22 The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations and, as appropriate, through facilitating private sector involvement. **Article 23** 1. The Parties shall: ➢ Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; ➢ Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported. 2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of	(c.1) Five trainings for 12 trainers – officials of the Ministry of Agriculture and Forestry, the Ministry of Environment and Waters, the Ministry of Education and Science, the Ministry of Finance, the Ministry of Justice and the Interior Ministry, selected on the basis of their background and work appointments trained on: • *LMOs risk assessment and risk management,* • *LMOs testing and monitoring,* • *Legal issues,* • *Institutional sets up and* *The control over the transboundary movement of LMO.* (c.2) Training workshop: "Transboundary movement of LMO and the Cartagena Protocol on Biosafety", Relative start month: month 3, timetable – two days; Supposed number of participants – 100 participants. The workshop will focus on risk assessment and risk management, the legal ways to preserve the native species and the role of the national gene bank. Pilot data gathering and the botanical files will be discussed. (c.3) Training workshop: "Biosafety of biotechnology research, trials and applications", Relative start month: month 6, timetable – four days; Supposed number of participants – 21 representatives of government, media, NGOs and science community. Safety requirements and procedures for LMOs contained use; deliberate release and commercial use will be	The Council for Safety Use of GMO responsibilities include (but are not limited to) the following: • Conducting and supporting training programs in safety for Institutional Biosafety Committee members, Biological Safety Officers and other institutional experts (if applicable), Principal Investigators, and laboratory staff.

such decisions available to the public, while respecting confidential information in accordance with Article 21. 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.	discussed. (d.2.1) Prepare and disseminate a newsletter on a quarterly basis (d.2.2) Disseminate outreach materials including publications, video, brochures, articles in local press, etc. for public awareness raising purposes (d.2.3) Develop and dissemination of training materials, including technical manuals and best practice guidelines, on specific areas of biosafety (to be used also during the regional and sub-regional workshops, or as stand-alone workshops)	

ANNEX 3

Provisional list of equipment needed to strengthen laboratories and enable them to perform inspection within the risk assessment and management procedure

Equipment

- PCR hardware and software Perkin Elmer or Biosystem or Roche Diagnostics
- Server to preserve all the data bases related with the above mentioned activities separated from those of the Institute.

ANNEX 4

UNEP Response to the STAP Technical Review

The STAP Technical Review provided that "the implementation of these 8 projects needs to be co-ordinated and assisted by an experienced facilitator or facilitators… What is needed is an expert - and preferably a group of experts - who have long experience in this highly complex legal and technical field and who have good connections with similar capacity building activities in the regions. The need for assistance is even stronger with these first 8 countries, as these are demonstration projects from which others have to learn". In addition, the STAP Review made a strong case to enhance regional collaboration. To respond to these requirements, and after consultation with the GEF Secreatariat, UNEP will establish a overarching Steering Committee for the implementation of the 8 Medium Size Projects.

The Steering Committee for the eight projects will be chaired by UNEP and will comprise the representatives of the National Executing Agency, the two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. In addition, experts selected on their personal capacity will be part of the Steering Committee as well as the representative of STAP when the Steering Committee will be addressing technical and scientific issues arising from the implementation of the MSPs.

UNEP fully agree on the STAP review on promoting regional collaboration. This request is in line with priorities identified by the National Governments during the development phase of the MSPs, but will require additional financial resources. UNEP will consult with the participating countries, during the implementation phase, on the ways and needs to address this issue.

Country's Specific Issues

The STAP comments relate mainly to the implementation of the projects. They have therefore been noted and will be fully taken into account during the development of the projects.

STAP Reviewer's comments on specific issues have been addressed in the revised version as evidenced in the attached table. They will be further taken into account during the appraisal phase of the MSPs.

Issue	Response
Kenya • *Capacity building should also be addressed to inspectors, for example by organising training workshop and developing inspection manuals.*	• Capacity building for inspectors in training workshop is now explicitly mentioned in the project proposal. It will be further addressed during the implementation of the project
Poland • *One important element that is missing, is the development of implementing regulations*	1) The EU covers the regulatory component and therefore Poland didn't ask for any

development of implementing regulations. • *The proposed training activities are very fragmented and it is recommended to merge some of the training activities.* • *Further clarification is needed as to how the proposed activities will be co-ordinated with the activities under the EU twinning project for which Poland has applied.*	further financing from GEF. 2) In the Polish project proposal there is a table under the paragraph "Budget" showing what is financed by the EU and what should be financed by the GEF. That's why the activities may appear as fragmented, because they complement current EU ones.
Uganda • *It is recommended to include training activities on topics such as "other international obligations".*	• Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.