

STANDART SUMMARY PROJECT FICHE

1. Basic Information

1.1	CRIS Number	BG2004/016-711.07.01
1.2	Title	Transposition and implementation of the environmental acquis at national level
1.3	Sector	Environment
1.4	Location	Bulgaria
1.5	Duration	18 months

2. Objective

2.1 Overall Objectives

The overall objective of this project is improvement of the institutional and administrative framework necessary to implement and enforce the Bulgarian legislation in order to fully comply with the laws, rules and procedures adopted by the EU.

2.2 Project Purpose

The purpose of this project is to improve the institutional and administrative framework necessary to implement and enforce the legislation in the field of fuel quality and marketing requirements (FQMR), supervision and control over transboundary movement of waste and genetically modified organisms.

The sub-purposes aim to assist the Bulgarian authorities in:

- Transposition of the new EU FQC directives and survey of the possibilities for implementation of the new EU fuel quality control (FQC) directives and parallel study of the quality control and marketing requirements for each fuel type;
- Assist Bulgaria with the development of institutional capacities for the implementation of EU requirements in the genetically modified organisms sector and to ensure adequate level of GMO management;
- Preparation of the experts responsible for supervision and control of transboundary movement of wastes for implementation of the *acquis communautaire* within this scope, through assessment of the existing legislative solutions, organizational systems and comparison of the services' experiences in this area with those of the EU Member States.

2.3 Accession Partnership and NPAA Priority

The Accession Partnership 2003 identifies the following priorities for environment:

- Continue transposition of the acquis, including secondary legislation, with particular on environmental impact assessment, access to information, waste management, industrial pollution and risk management, nature protection, chemicals and genetically modified organisms, and

nuclear safety and radiation protection. Ensure consultation with all relevant stakeholders (other ministries, economic operators, NGOs);

- Continue implementation of the acquis with particular emphasis on access to information, air quality, waste management, water quality, nature protection, industrial pollution and risk management as well as nuclear safety and radiation protection;
- Ensure and reinforce the administrative structures necessary for the full implementation, monitoring and enforcement of the acquis, in particular through further strengthening of the Regional Environmental Inspectorates (REIs), municipalities and other public bodies at the local level, with an emphasis on water quality, industrial pollution and risk management, as well as waste management. Reinforce staffing of the Ministry and other public bodies. Ensure adequate training and staff development plans;
- Continue implementation of the European Environmental legislation especially the FQC legislation, including the common format for the submission of annual report on national fuel quality data and the use of renewable energy resources (biofuels and others).

This project is in accordance with the National programme for adoption and implementation of the European Environmental legislation (NPAA) concerning the Ambient Air Quality (AAQ) legislation and its short-term and middle-term priorities, namely the full implementation of the European legislation in the field of FQC.

The project is in accordance with the country's negotiation position for accession to the EU on Chapter "Environment" (CONF-BG-4/03), including with the Programme for implementation of Directive 99/32/EC, and in particular with the commitments to implement and enforce the:

- limit value of 10mg/kg sulphur content in motor fuels (since 01.01.2009) and make gradually available such low-sulphur fuels according to Directive 2003/17/EC;
- limit values according to COM (2002) 595 final for 1,5% sulphur content in marine fuels, and 0,2(0,1)% sulphur content in fuels used within the area of the harbours.

2.4 Contribution to the National Development Plan

Not applicable.

2.5 Cross Border Impact

Not applicable.

3. Description

3.1 Background and Justification

The project addresses a number of challenges and problems related to the implementation of specific EU environmental requirements. Assistance is needed for administrative strengthening of public administration at national level, for practical application of the environmental acquis in the field of fuel quality and marketing requirements, supervision and control over transboundary movement of waste and genetically modified organisms.

Fuel Quality

Directives 98/70/EC and 99/32/EC are fully transposed in the national legislation through a special amendment of the Clean Air Act /CAA/ (in 2001) and the recently developed Regulation on FQC adopted by a Cabinet Ordinance No156 from 15.07.2003. The time schedule for implementing the relevant fuel quality requirements is in line with the negotiation position of Bulgaria for accession to the EU (CONF-BG-4/03) and the developed Programme for implementation of Directive 99/32/EC (CONF-BG-4/03, Annex 4).

According to the CAA and the new Regulation on FQC:

- The national competent authority for approximation of the EU FQC directives is MOEW. It has the responsibility for the overall organization, coordination and control of the relevant activities, including for preparation of reports to EC on the status of implementation;
- The competent authority for implementation and enforcement of the FQMS is the SAMTS. To this end a General Directorate (GD) on FQC was established by the 2001 CAA amendment.

The establishment of a National FQMS in regard to Directive 98/70/EC and 99/32/EC, is based on the demands on the Commission Decision 2002/159/EC concerning the common format for the submission of summaries of national fuel quality data. At present GD FQC has a staff of 30 experts, which is not enough to establish effective liquid fuel quality control in the whole country. In regard to this in the National Administrative Capacity Building Plan it is assumed in 2004 the recruitment of 28 new experts, including the regional structures. The supply of the required equipment for effective control, including education of the experts, will be completed in 2005, according to approved PHARE Project 2003 of GD FQC and pointed at 3.5.1 – Linked Activities.

With regard to COM/2002/595 final, special attention is to be given to the introduction for first time of special requirements covering all types of marine fuels (in comparison to 99/32/EC), which are to be enforced through checks within and outside the harbor areas. These requirements are totally new for the Bulgarian administrations. To this reason, they will lead the involvement of the Harbor Administrations in the FQM system (since SAMTS does not have the relevant competencies and experience).

The established requirements of Directive 2003/30/EC there are again totally new for the national administration, but the appointment of a national competent authority is still to be done. In addition, at present in the country there are some small producers of biofuels, trying to put them on the market and some attempts for import of such fuels. Therefore Bulgaria lacks experience with regard to promotion of the large scale industrial production and use of such fuels. The last is expected to impose significant difficulties before the implementation of the main 2003/30/EC requirement for gradual increase of the use of biofuels for transport as part of the overall consumption of motor fuels in the country (respectively, up to 2% by 31.12.2005 and 5,75% by 31.12.2010г.). In this regard, the numerous approaches in the member states and the lack of experience in the country require the execution of a specific preliminary survey, which will recommend the most appropriate national approach to implement the Directive. The survey will include relevant cost assessments, as well as proposals for sources of funding.

Genetically modified organisms

GMOs have to be considered in four sectors of activities: contained use of GMOs, 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 three issues are regulated in European Union by two directives: Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms as amended with Council Directive 98/81/EC of 26 October 1998 and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, repealing 90/220/EEC.

The transboundary movement is addressed by the Cartagena Protocol on Biosafety, ratified by Bulgaria on the 25 of May 2000.

The issues related to GMOs are still not fully addressed by Bulgarian Law. In 1996 the government undertook a first step toward the establishing of legislation on GMOs by introducing a Regulation for Safe Use of Genetically Modified Higher Plants.

With the ratification of Cartagena protocol and within the framework of the negotiations with the European Union, Bulgaria is obliged to establish proper regulatory and institutional structures in the area of GMOs.

The National Strategy on Environment and the Action Plan set as priority the formulation of Law on GMOs . As a result in 2003 a draft Law on GMOs was drawn-up, which was adopted on the first reading by the National Assembly and it is expected to be adopted in May 2004.

The draft Law will fully transpose the requirements of Directive 98/81/EC on the contained use of genetically modified microorganisms and Directive 2001/18/EC on the deliberate release into the Environment of genetically modified organisms (GMO) and repealing Directive 90/220/EEC as well will creates a legal basis for the implementation of Cartagena protocol.

The draft Law envisages the introduction of a permit regime for the contained use of GMO, release of GMO into the environment and the placing on the market of GMO as or in products, with the exception of GM foods, foods stuffs, human medicines and veterinary-medical products which contain or are made of GMO or combination of GMO, the import and the export and the control over activities with GMO.

According the draft Law on GMO, the Minister of Environment and Water is the competent authority for the issuance, change or withdrawal of the permits for the contained use of GMO and the registration of the premises for the contained use. The Minister of Agriculture and Forestry is the competent authority for issuance, change or withdrawal of the permit for placing of GMO on the market as or in products. For the purpose of supporting the both Ministers activities creation of a consultative body is envisaged – a Committee on the GMO, consisting of experts of the interested state institutions and scientific organizations. The Committee will consist of 15 scientists and 7 governmental officials and will gives scientific opinions on the proposed contained use, deliberate

release and placing on the market of GMOs as well as of the drafting of legislative acts in the field of biotechnology. In view of the full implementation of the requirements of the European legislation and guaranteeing the strict control of the activities with GMO it is envisaged that the control is done by the Ministry of Environment and Water, Ministry of Agriculture and Forestry, Ministry of Economy and Ministry of the Labour and Social Policy in the framework of their competencies.

Issues concerning the GMOs are quite new in the national regulations; therefore they need further work which can be supported by experts from more experienced EU member states. The ministries lack experience and resources to undertake these activities. It is expected that this project will provide a number of institutional strengthening experts to develop the required system and expertise in the above mentioned area.

Transfrontier Shipment of Waste

In connection with the accession process, Bulgaria is engaged in the modification and transformation of its legal and institutional system within the environment sector, so as to meet the requirements of the EU environmental policy. In 1997 the Bulgarian Parliament approved the Reduction of the Harmful Impact of Waste upon the Environment Act, which creates the legal basis for further transposition, and implementation of EU environmental legislation in the waste management sector. Following the legal requirements, a wide range of secondary legislation was approved in the period 1998 – 2001 (see Annex 4 for reference). The full transposition of present EC waste management legislation is to be achieved in the end of 2004.

The present waste management practices in Bulgaria are not up to the European standards. One of the main reasons for this is the insufficient institutional and administrative capacity and the lack of coordination between institutions.

In the EU, the rules of transboundary movement of wastes are specified in the Council Regulation (EEC) No. 259/93 on supervision and control of shipment of waste within, into and out of the European Community. This Regulation currently is in an advanced stage of amendment and it is planned new simplified notification procedures and new waste lists to be introduced.

According to the current national legislation (the *Waste Management Act* and the *Regulation on the cases when a permit for import, export and transit of waste is required and on the conditions and the procedure for its issuance*), import, export and transit of wastes to the country requires a permit by the Ministry of Environment and Water. The permit may be issued after the notifier has met the conditions specified in the Act and in the Regulation. The Waste Management Act requires that new Regulation should be adopted till the 30th of September 2004.

For the introduction of the Council Regulation (EEC) No. 259/93 on supervision and control of shipment of waste within, into and out of the European Community into Bulgarian legislation the following main changes should be brought in: elaboration of list containing wastes that in the conditions of landfill are explosive, corrosive, oxidising, highly flammable or flammable and therefore subject to import ban in regard to the engagements undertaken by the country during the negotiations with EU; the introduction of the obligation to obtain a permit by the Ministry of Environment and Water for export of green listed wastes to specific (non-OECD) countries;

introduction of procedure for supervision of the ban on the import of green listed waste destined for disposal. After the adoption of the new EU Regulation on transfrontier shipments of waste the existing Bulgarian legislation should also be amended.

Currently the notification procedures are in line with the requirements of the Basel convention but do not follow strictly the procedures of the Regulation (EEC) No. 259/93. A draft regulation by the Council of Ministers is in a process of elaboration and it is expected to be adopted in the first half of 2004.

The responsible authorities for control of transfrontier shipments of waste in Bulgaria - Customs Authorities and Regional Inspectorates of Environment and Water - face difficulties in implementing the legislative requirements in the area of due to lack of the necessary institutional and administrative capacity and coordination. There is a need for training of Customs officers for recognizing illegal shipments and other waste trafficking violations. Till the date of entry into force of Waste Management Act (30th September 2003) the inspectors from RIEWs were not involved in the process of waste imports and there is necessity for training for distinguishing hazardous materials and hazardous wastes, defining and identifying hazardous waste, knowing transfrontier shipments of waste notification system and other issues. Waste Management Act requires that RIEWs should support Customs officers in taking of decisions for stopping of waste cargos but currently there are no procedures and practices established for exchanging of information between these two institutions and carrying out of spot inspections.

In accordance with the official data from 1999 when permit regime for import of all types of waste was in force significant waste quantity was imported in the country - 675 000 tones from Green and Amber lists.

In the course of the negotiations on Chapter 22 in order to facilitate a gradual implementation of Directive 1999/31/EC on the landfill of waste, specific transitional measures for the implementation of Regulation EEC/259/93 have been granted as follows:

- until 31 December 2009 shipments of wastes for recovery of certain Amber List wastes 7 shall be notified to competent authorities by using the consignment note as prescribed in Article 3 of Regulation (EEC) 259/93 and allowing the application of Article 4 by the Bulgarian competent authorities.
- until 31 December 2009, shipments of very hazardous wastes, i.e. Red List wastes and waste not listed under Annexes II, III and IV of Regulation (EEC) 259/93 (so-called "unlisted" waste) should also be controlled according to the procedures applying to shipments for disposal in order to safeguard the gradual implementation of Directive 1999/31/EC. Until that date, shipments of these wastes must be notified to competent authorities by using the consignment note as prescribed in Article 3 of Regulation (EEC) 259/93 and allowing the application of Article 4 by the Bulgarian competent authorities.

In order to give solutions to most of the above-mentioned outstanding issues, the following 3 sub-projects have been identified:

- **Sub-project 1 - *Implementation of EU fuel quality control and marketing requirements;***
- **Sub-project 2 - *Implementation of Directive 90/219/EEC as amended by Directive 98/81/EC on the contained use of genetically modified microorganisms and Directive 2001/18/EC on the***

deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC;

- **Sub-project 3 - *Strengthening of administrative capacity of the Ministry of Environment and Water, Regional Inspectorates of Environment and Water and the Customs Agency for implementation and enforcement of the requirements of Regulation (EEC) 259/93 on the supervision and control of shipment of waste within, into and out of the European Community.***

3.2 Sectoral rationale

Not applicable.

3.3 Results

3.3.1. Sub-project 1:

- Regulation amending the present Regulation on FQC (to the CAA) transposing directives 2003/17/EC and COM(2002)595 final drafted;
- Competent authorities of MoEW, GD FQC and EAMA responsible for implementation and enforcement of above directives trained;
- National Programme for production and use of biofuels ensuring the timely and effective implementation of Directive 2003/30/EC drafted;
- Systems for monitoring/collecting/sampling under the Fuel Quality Directives established.

3.3.2. Sub-project 2:

- Administrative structures capable to manage and enforce requirements as outlined in 90/219/EEC as amended by 98/81/EC and 2001/18/EC Directives (Committee on GMOs, and administrative unit within the Ministry of Environment and Water and Ministry of Agriculture and Forestry as well as supervisory authorities) ;
- Assessment of existing laboratories and preparation for their accreditation in order to conduct risk assessment and monitoring of GMO that are released or introduced to the market
- A notification system by those proposing the registration of containment facilities and permission for contained use, addressed to the competent authorities.
- Up-dated electronic information system and public registers in an electronic format to record licensed premises, consents granted for GMO containment, release and placing in the market, conditions of containment, risk assessment and monitoring results and other pertinent information outlined in the EC Directives.
- Inform the public on the legislation and the implementation of the regulations included in the two EC Directives.

3.3.3. Sub-project 3:

- Establishment of an effective border and in-country control system based on close co-operation between the Regional Inspectorates of Environment and Water, as the unit responsible for

control on the compliance with the environmental legislation , the Customs Agency and other institutions such as Police if necessary.

- Implementation of the notification procedures according to the requirements of Regulation (EEC) No 259/93 (the Ministry of Environment and Water is the responsible authority).
- Developed guideline/manual for beneficiaries, describing wastes from the European green, amber and red lists of wastes, including explanation of their quick identification methods.
- Publication and distribution of a guideline/manual describing wastes from the European green, amber and red lists of wastes and their quick identification methods.
- Approximately 150 people from the Ministry of Environment and Water, Regional Inspectorates of Environment and Water, Customs Agency and Border authorities to be trained.

3.4 Activities

3.4.1. Sub-project 1:

1. Transposition of the new EU FQC Directives (Directive 2003/17/EC amending Directive 98/70/EC relating to the quality of petrol and diesel fuels; COM (2002) 595 final amending Directive 99/32/EC relating to a reduction in the sulphur content of certain liquid fuels):
 - Gathering of the necessary information about the above-mentioned European legislation, including MSs national programmes and plans for implementation of the requirements of the FQC Directives.
 - Examination of the information collected and analysis of the approaches to its implementation.
 - Gathering of the necessary information and analyzing of the current situation of the local refinery industry, including the commitments under Directive 99/32/EC Implementation programme.
 - Examination of the information received from the refinery, coordination between the competent authorities and a site visit at the refinery, including member- state experts.
 - Examination of the possibilities of production/import of “free of sulphur” motor fuels and marine fuels with low sulphur content, including their storage and distribution.
 - Elaboration of a draft ordinance amending the Ordinance for the requirements to the quality of liquid fuels, terms, procedure and methods of control.
 - Training of the authorized inspectors from EAMA for ship fuels sample taking in and out of harbors area.
 - Issuance of EAMA instruction for carrying out joint inspections by GD FQC and EAMA for ship fuels control.
 - Study visits to MSs regarding practical acquaintance with the MSs experience on implementation of the FQC legislation.
 - Studying the latest amendments to EN and ISO standards and the possibilities for their implementation as Bulgarian State Standards.
2. Development of a National Programme for production and use of biofuels according to the requirements of Directive 2003/30/EC on the promotion of the use of biofuels or other renewable fuels for transport

- Gathering of the necessary information about the above-mentioned European legislation, including MSs national programmes and plans for implementation of the requirements of the Biofuels Directive.
- Overview and analysis of the existing legal arrangements for production of rape oil and biodiesel.
- Defining the potential for the production of rape oil and biodiesel in Bulgaria and analysis and defining of different possibilities for producing rape oil and biodiesel in Bulgaria
- Defining the locations for cultivation of rape seed and building the installations for production of biodiesel.
- Analyzing the possibilities for involving investments in the process of production of rape oil and biodiesel.
- Study visits to MSs regarding practical acquaintance with the MSs experience on implementation of the biofuels legislation.
- Studying the different MSs approaches in supplying the rape seed for the production of biodiesel and in the process of production.
- Studying of the European, international and MSs national standards for use of biodiesel in transport and for biodiesel analyzing.
- Studying the methods of storage of biodiesel, the possibilities for adapting the motor vehicles in Bulgaria to this fuel and using biodiesel in transport.
- Elaboration of a draft of a National Programme for production and use of biodiesel in transport and an Action Plan to it.

3.4.2. Sub-project 2:

- Training of the members of the newly established Committee to evaluate submitted notifications according to the requirements of the two Directives (accuracy, correctness of risk assessment and efficiency of risk management plan, proposed containment and waste management measures etc)
- Training of state officials (12 persons) within the MOEW and MAF to provide administrative support to the Commission (initial evaluation of notifications for accuracy and completeness, interactions with the applicants for clarifications on the notifications documentation recording of pertinent information and updating of the electronic information system, etc)
- Training of supervisory authorities dealing with GMO (approx. 60 persons; inspectors of containment conditions and safety measures in the contained premises, inspectors of field tests and monitoring plans as well as inspectors of compliance with the labelling and traceability requirements etc),
- Assessment of the infrastructure of research institutions and other bodies dealing with GMO in order to establish reference (accredited) laboratories.
- Preparation of tender documents for supply of laboratory equipment needed to support the infrastructure of existing research facilities so as to meet accreditation requirements.
- Establishment of notification forms to be utilized by applicants for registration of containment facilities and contained use activities.
- Establishment within the electronic information system developed under UNEP-GEF (see below -linked activities) of public registers for all granted consents, new and renewed GMO releases,

and pertinent information associated with these, according to the format defined in the EC Directives.

- Further development, so as to include all specifications of risk assessment, monitoring, labelling and traceability, described in detail in the EC Directives, and regular updating of the electronic information system and the special GMO-web site, established under UNEP-GEF project.
- General education of the public through media, lectures, printed materials on biological safety and the regulations imposed by the EC Directives aimed to continue and expand the public awareness activities, undertaken under the UNEP-GEF project, as well as to enable the participation of the public in the decision-making process on GMO-related issues.

3.4.3. Sub-project 3:

- Assessment of existing legislative, technical and institutional conditions and elaboration of proposals for amendment of the existing legislation, installation of equipment, strengthening the administrative capacity, improvement of coordination between institutions and involvement of new institutions if necessary.
- Joint training inspections by the services of the Regional Inspectorates of Environment and Water and Customs Agency.
- Developing and publishing of guidelines/manual for beneficiaries, describing wastes from the European green, amber and red lists of wastes, together with their quick identification methods, and of guidelines regarding practical application of notification procedures.
- Training for the Inspection personnel (the Regional Inspectorates of Environment and Water and Customs Agency) regarding developed guideline describing wastes from the European green, amber and red lists of wastes, including explanation of their quick identification methods. And carrying out of seminars introducing developed guideline regarding practical application of notification procedure.
- Preparation of TOR for purchasing and installation of proposed equipment.

3.5 Linked activities

3.5.1. Sub-project 1:

The sub-project is a continuation of a Phare 2003 Twinning Project executed by SAMTS – Strengthening of the administrative and measurement capacity for enforcement of legislation on liquid fuels and measuring medical devices. The project aims are as follows:

- Staff training on specific technical and operational issues related to implementation of the liquid fuels quality monitoring system (FQMS);
- Consulting engineering on customising applications and assistance to staff in putting into operation of a computerised management system for liquid fuels quality control and related activities;
- Staff training on use of the IT-system;
- Organisation and participation in international proficiency testing.
- Procurement of equipment for testing of liquid fuels and of IT-system hardware and software and their putting into operation. Procurement of fuel flow rate equipment, traceable to internationally recognised measurement standards.

- Assessment and preparation of recommendations for improvement of the administrative and technical capacity for the implementation of New Approach Directive on Measuring Instruments - Flow rate measuring instruments. Training of staff.
- Elaboration of strategy for development of metrological activities regarding measuring instruments used in health care after the implementation of New Approach Medical Devices Directive

The project outcomes are:

- Staff capable to autonomously implement the national liquid fuels quality monitoring system (FQMS);
- An IT-system for management of data and activities related to liquid fuels quality control established and customised for the respective application;
- Staff trained to be able to effectively use that IT-system.
- Equipment for testing liquid fuels quality supplied and operational
- IT-system hardware and software supplied and operational
- Analysis with recommendations for improvement of the administrative and technical capacity for the implementation of New Approach Directive on Measuring Instruments - Flow rate measuring instruments.
- Staff trained on implementation of draft New Approach Directive on Measuring Instruments - Flow rate measuring instruments - and respective WELMEC documents to be able to carry out the respective measurements;
- Fuel flow rate equipment, traceable to internationally recognised measurement standards, supplied and operational

3.5.2. Sub-project 2:

In September 2002 a project called “Support for the Implementation of the National Biosafety Framework for Bulgaria” has started. It is financed by the UNEP-GEF and will end in September 2005. The national executing agency for the project is the AgroBio Institute, Sofia, Bulgaria. The project aims therefore at supporting Bulgaria in meeting the obligations foreseen under the Cartagena Protocol on Biosafety (ratified on the 25 of May 2000). In particular, the **specific objectives of the project** are set as follows:

- (1) 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 of especial importance.
- (2) 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.
- (3) Strengthen capacity on
 - risk assessment and risk management as identified in Articles 15 and 16 and Annexes I-III of the Protocol,

- 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.

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

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

For additional information – see ANNEX 6

The objectives of the GEF project do not overlap with the scope of the project fiche proposed herein. In order to facilitate the review process some of the differences of the two proposals are outlined below:

- 1) The GEF project targets the implementation of the Cartagena protocol which focuses on the safe transfer and handling of GMOs during transboundary movements. The regulatory area covered by the two EC Directives is broader, including containment as well as release and marketing of GMOs.
- 2) Along the same lines, the EC Directives impose specific regulations with regards to risk assessment and management, labeling and traceability which are not included in the Cartagena protocol.
- 3) The training process proposed herein is focused and targets the specific administrative and scientific bodies that will perform the various aspects of the EC Directives' implementation, including the evaluation of notifications for GMO registration, contained use, release and marketing, as well as inspections for compliance with the regulations. Such process is not supported by the GEF project.
- 4) The assessment of the infrastructure of existing laboratories (other than the ABI), the identification of their deficiencies and preparation of tender documents for the acquisition of needed equipment, are not included in the GEF protocol.
- 5) The preparation of notification forms for the registration of premises and contained use of GMOs is also not covered by the GEF proposal.
- 6) Establishment of a National Biosafety Database System linked to the Biosafety Clearing House Mechanism is supported by GEF. With the proposed study, we target the further development of this system so as to include registers in the format defined by the EC Directives.
- 7) Increase in public awareness in GMO-related issues is addressed in the GEF proposal. However, as proposed, continuation and expansion of this process to achieve the constant education of the public on any new developments in this area, is considered of paramount importance, due to the rapid evolution of Biotechnology and the controversial opinions associated with this.

3.6 Lessons learned

Not applicable.

4. Institutional Framework

Sub-project 1:

The beneficiary institutions are:

- The Ministry of Environment and Water
- The State Agency for Metrology and Technical Surveillance
- The Executive Agency Maritime Administration to the Ministry of Transportation and Communications
- The Executive Agency for Energy Efficiency

MOEW is the national competent authority (through Air Protection Directorate) for the harmonization of the European Directives for FQC in the National legislation; takes the responsibility for the organization, coordination and control over the activities concerning its implementation; summarizes data from the information systems of other institutions (NSI, SAMTS, EEA), and also prepares reports for the EC for the way of implementation of the Directives.

SAMTS through the newly created GD FQC is the national competent authority on the basis of CAA for the implementation and enforcement of the requirements of the Directives, including the issuance of penalty decrees; monitoring and control over the liquid fuels; assessment of the liquid fuels compliance of the liquid fuels with the quality requirements; undertakes measures to limit or forbid the placing on the market, distribution, use or drawing out the liquid fuels of the market.

Ministry of Transport and Communications through Executive Agency “Maritime Administration” (EAMA) is the national competent authority for the navigation safety and protecting the marine environment from pollution caused by shipping. The EAMA through its laboratory is engaged with the control of the quality of the marine fuels (sulfur content) and emissions from ships (NO_x, Sox, VOC and ozone – depleting substances).

EAEE is the national competent authority for implementing the energy efficiency policy and the use of renewable energy resources, in particular the production and use of biodiesel.

Sub-project 2:

The Ministry of the Environment and Waters (MoEW) and the Ministry of Agriculture and Forestry (MAF) are responsible for the enforcement of the legislation.

The administrative units within MoEW and MAF as well as scientific body – Commission on GMOs will be established after the adoption of the Law on GMO. These structures will be in charge with the co-ordination, the leading and monitoring of the implementation process on GMO legislation and will be the beneficiaries of the project.

Sub-project 3:

The Ministry of Environment and Water, through the Waste Management Directorate, is the responsible authority for the permitting of the transfrontier shipments of waste. The Waste

Management Directorate is divided into two departments, i.e. Municipal and Construction Waste Management Department and Industrial and Hazardous Waste Management Department.

The Regional Inspectorates of Environment and Water, are responsible for the control of the activities' compliance with the provisions of the permit and current legislation.

The Customs Agency, is the national responsible authority for customs control.

5. Detailed Budget

Year 1/Phase 1	Phare Support					
	Investment Support	Institution Building	Total Phare (=I+IB)	National Co-financing*	IFI*	TOTAL
Sub-project 1						
<i>Contract 1</i> Twinning		700,000	700,000			700,000
Sub-project 2						
<i>Contract 1</i> Twinning		700,000	700,000			700,000
Sub-project 3						
<i>Contract 1</i> Twinning		700,000	700,000			700,000
Total		2,100,000	2,100,000	0		2,100,000

(*) The national co-financing up to 10% of the Twinning project will be covered from the national budget through the National Fund Directorate at the Ministry of Finance. The national co-financing will be covered from the national budget, through the National Fund Directorate at the Ministry of Finance.

6. Implementation Arrangements

6.1 Implementing Agency

The project is proposed for twinning.

The CFCU – Ministry of Finance of Bulgaria is the Implementing Agency for this project. The financial management of the twinning arrangements will be the responsibility of CFCU.

Mr Tencho Popov
Secretary General – PAO
Ministry of Finance
102, Rakovski Str. 1000 Sofia, Bulgaria
Tel. + 359 2 9859 2772; Fax + 359 2 9859 2773

The Beneficiaries of the project will be the Ministry of Environment and Water, Ministry of Agriculture and Forests, the Customs Agency, the State Agency for Metrology and Technical Surveillance, the Executive Agency Maritime Administration to the Ministry of Transportation and Communications and the Executive Agency for Energy Efficiency.

6.2 Twinning

The responsible person for twinning arrangement at the MOEW is:

Ms Slavitzza Dobрева
Head of European Integration Department
Ministry of Environment and Water.
67, William Gladstone Str. 1000 Sofia, Bulgaria
Tel. + 359 2 940 62 58; Fax + 359 2 988 53 16

In her tasks, she will be assisted for the specific project tasks by:

Sub-project 1:

MOEW

Mr Angel Kostov
Head of Ambient Air Quality Department
MoEW, 22, Maria Luisa Str. 1000 Sofia, Bulgaria
Tel. + 359 2 940 65 40; Fax + 359 2 980 39 26

Mr George Mihajlov
Chief Expert of Ambient Air Quality Department
MoEW, 22, Maria Luisa Str. 1000 Sofia, Bulgaria
Tel. + 359 2 940 65 35; Fax + 359 2 980 39 26

SAMTS

Ms Maia Topalova
Head Director of Quality Fuels Inspection Directorate
21, 6-th september Str., 1000 Sofia
Tel. +359 2 975 38 12, Fax +359 2 76 24 90

EAAE

Ms Ekaterina Slavova
Chief Expert of Programmes, projects and international cooperation Department
37, Ekzarh Jossif Str., 1000 Sofia
Tel. +359 2 915 40 40, Fax +359 2 981 58 02

EAMA

Mr Liubomir Stoianov
Chief inspector of Control and preservation of sea area Sector
to Varna Sea administration Directorate
9, Diakon Ignatii Str., 1000 Sofia
Tel. +359 52 633 553

Sub-project 2:

Ms Iskra Valtcheva
Integration Policy Directorate

Ministry of Agriculture and Forestry
55, blvd. Hristo Botev
1440 Sofia, Bulgaria
tel.: + 359 2 985 11 334/fax: + 359 2 981 23 18
i.valtcheva@mzgar.government.bg

Sub-project 3:

Mr. Mikhail Asenov
Chief Expert
Industrial and Hazardous Wastes Management
Ministry of Environment and Water
22, Maria Luiza blvd. 1202 Sofia, Bulgaria
Tel.: + 359 2 940 6639 Fax: + 359 2 980 96 41

Ms. Lubomila Popova
Senior Expert
European Integration Department
Ministry of Environment and Water
67, William Gladstone St. 1000 Sofia, Bulgaria
Tel.: + 359 2 940 63 95 Fax: + 359 2 988 53 16

For **Sub-project 1** the twinning partner shall make available to the project long and short-term senior experts, working continuously on site for the following periods:

<i>Category</i>		<i>Position</i>	<i>No. of Experts</i>	<i>Duration of assignment (Man-month)</i>
Pre Accession Advisor	Long term experts		1	18
	Short term experts		4	10

The twinning partner is expected to propose **long term expert** and **short term experts** for the above-mentioned positions who will have in general the following qualification requirements:

- Minimum 5 years of working experience in a relevant administrative structure of a Member State (preferably in the Ministry of Environment).
- Knowledge of EU acquis as well as practical experience in policy implementation and project management.
- Broad knowledge of the specific directives and proven technical background.
- Computer literacy.
- Ability to lead a process, communicate clearly and regularly and train staff.

For **Sub-project 2** the twinning partner will support national authorities in the preparation of the training curricula, educational materials, conducting training, building information and control system, identification of investment needs and for quality driven effective implementation of the project.

The twinning partner shall make available to the project long and short-term senior experts, working continuously on site for the following periods:

<i>Category</i>	<i>Position</i>	<i>No. of Experts</i>	<i>Duration of assignment (Man-month)</i>
Pre Accession Advisor	Long term experts	1	18
Senior experts	Short term experts	8	8

The twinning partner is expected to provide a team of experts having accrued years of experience in a relevant central administrative structure of a Member-State as outlined below, good familiarity with EU Environmental Acquis, in the field of genetically modified organisms, as well as very good practical experience in the implementation and management of the specific regulations.

- **Long terms expert:** the Pre Accession Advisor is expected to perform:
 - assessment of the existing system in GMO management in Bulgaria
 - advisory assistance for supervising the GMO-related activities,
 - support in preparation of the tasks for the Short Term Experts,

The PAA should have very good knowledge of the current GMO-related European legislations and must have been trained for and acquired at least 10 years of experience on the implementation of legislation in the field of genetically modified organisms. Some experience in the establishment of national biosafety framework and GMO management would be useful.

Considerable experience in project management, as well as leadership and good communication and training skills are also required. Furthermore, international practice and fluency in English, as well as ability to design training programmes, as proven by his involvement in respective activities, are also required.

Short term experts: knowledge of current EC-legislation on GMO, and 5 years professional experience on at least one of the following issues associated with the use and release of genetically modified organisms :

risk assessment and risk management, GMO waste treatment, inspections of GMO- containing facilities to ensure that appropriate containment measures, good laboratory practice and personnel training are observed, accreditation of laboratories, monitoring of GMO release, dissemination of information to the public so as to increase public awareness on GMO, establishment of electronic database systems for GMO pertinent information.

For **Sub-project 3** the twinning partner shall make available to the project long and short-term senior experts, working continuously on site for the following periods:

<i>Category</i>	<i>Position</i>	<i>No. of Experts</i>	<i>Duration of assignment (Man-month)</i>
Pre Accession Advisor	Long term experts	1	15
Senior experts	Short term experts	8	8

The twinning partner is expected to provide a team of experts having accrued at least 5 years of experience in a relevant central administrative structure of a Member-State, good familiarity with EU Environmental Acquis, in the field of transfrontier shipment of waste, as well as practical experience in the implementation and management of the specific regulations.

Long-term expert: educational background: higher technical education, professional experience: five-years experience, knowledge of the waste management issues and control system of transboundary shipment of waste in EU as well as practical use of notification procedures.

Short-term experts: educational background: higher chemical education, professional experience: five-years experience, knowledge of the waste management issues and various methods of chemical analysis useful for identification and classification of substances.

6.3 Non-standard aspects

PRAG will be followed.

6.4 Contracts

Three contracts will be implemented under twinning covenants for 2,310,000 Euro.

7. Implementation Schedule

Sub-project 1	
7.1. Start of tendering	October 2004
7.2. Start of project activity	February 2005
7.3. Completion	July 2006
Sub-project 2	
7.1. Start of tendering	October 2004
7.2. Start of project activity	February 2005
7.3. Completion	July 2006
Sub-project 3	
7.1. Start of tendering	October 2004
7.2. Start of project activity	April 2005
7.3. Completion	July 2006

The whole project duration is 18 calendar months.

8. Equal Opportunity

The twinning partner in formulation of his proposal shall ensure equal rights and opportunities to men and women.

9. Environment

Not applicable.

10. Rates of return

Not applicable.

11. Investment criteria

Not applicable.

12. Conditionality and sequencing

- Establishment of a working group with representatives of MoEW, SAMTS, EAEE and EAMA responsible for the transposition and steps for future implementation of the newly adopted FQC legislation.
- Adoption of the draft Law on GMO by National Assembly.
- Establishment of the Commission on GMO and of new units responsible for GMO in MoEW and MAF.
- Adoption of the draft Regulation on transfrontier shipment of waste by the Council of Ministers.

ANNEXES TO PROJECT FICHE

- 1. Logical framework matrix**
- 2. Detailed implementation chart**
- 3. Cumulative contracting and disbursement schedule**
- 4. List of relevant laws and regulations**
- 5. List of national strategic plans**
- 6. UNEP/GEF Project “Support for the Implementation of the National Biosafety Framework for Bulgaria”**

ANNEX 1

Phare log frame

LOGFRAME PLANNING MATRIX FOR Project Transposition and implementation of the environmental acquis at national level	Programme name and number	
	Contracting period (year 1) expires End 2006	Disbursement period (Year 1) expires end 2007
	Total budget year 1 : EURO 2,310,000	Phare budget year 1: EURO 2,100,000

Overall objective	Objectively verifiable indicators	Sources of Verification	
Improvement of the institutional and administrative framework necessary to implement and enforce the Bulgarian legislation in order to fully comply with the laws, rules and procedures adopted by the EU.	<ul style="list-style-type: none"> • Adoption of CM Decree amending the ordinance on the requirements to liquid fuels, terms and method of control. • Legislation on GMO –implemented in accordance with the EU requirements • Administrative structures, dealing with GMO issues – trained; • Introduction of institutional and procedural changes in line with requirements of EU Regulation on waste shipment 	<ul style="list-style-type: none"> - MEW - EC Delegation to Bulgaria - Technical reports of the working partners 	
Project purpose	Objectively verifiable indicators	Sources of Verification	Assumptions
<ul style="list-style-type: none"> • Transposition of the new EU FQC directives and survey of the possibilities for implementation of the new EU fuel quality control (FQC) directives and parallel study of the quality control and marketing requirements for each fuel type; • Assist Bulgaria with the development of institutional capacities for the implementation of EU requirements in the genetically modified organisms sector and to ensure adequate level of GMO management; 	<ul style="list-style-type: none"> • The frame of reference, the criteria and the measures have been coordinated. • Institutional set-up established in 2004; • Legislation on GMO –implemented in accordance with the EU requirements; • Staff of the competent authorities, dealing with GMO issues trained • Efficient information flow to the general public (Internet, web-site, publications, databases), 	<ul style="list-style-type: none"> • Ministry of Environment and Water • EU Delegation in Bulgaria • Progress reports 	<ul style="list-style-type: none"> • The capability of the responsible institutions to fully implement the recommendations of the project. • Regional and local institutions interested and effectively involved in the project activities. • Financing available. • National and regional

<ul style="list-style-type: none"> Preparation of the experts responsible for supervision and control of transboundary movement of wastes for implementation of the <i>acquis communautaire</i> within this scope, through assessment of the existing legislative solutions, organizational systems and comparison of the services' experiences in this area with those of the EU Member States 	<ul style="list-style-type: none"> Functioning system of accredited laboratories, trained staff of the laboratories; Functioning system of utilizing GMO established Certificates of training. Publication of a manual (handbook) on the classification of waste. Number of manuals/guidelines delivered to border points, custom offices and to the Regional Inspectorates of Environment and Water (600 copies). 		<p>instruments co-ordinated.</p> <ul style="list-style-type: none"> Realization of contracts on time.
Results	Objectively verifiable indicators	Sources of Verification	Assumptions
<ul style="list-style-type: none"> Regulation amending the present Regulation on FQC (to the CAA) transposing directives 2003/17/EC and COM(2002)595 final drafted; Competent authorities of MoEW, GD FQC and EAMA responsible for implementation and enforcement of above directives trained; National Programme for production and use of biofuels ensuring the timely and effective implementation of Directive 2003/30/EC drafted; Systems for monitoring/collecting/sampling under the Fuel Quality Directives established 	<ul style="list-style-type: none"> National legislation and implementing programme transposing the relevant EU acquis adopted Systems for monitoring /collecting/sampling functioning 	<ul style="list-style-type: none"> MEW Regular reporting on the project development 	<p>Participation by the refinery's representatives in the elaboration of the assignment. Exchange of information between the competent authorities. State officials from the "Air Quality Protection" Directorate within MEW will take part in the project</p>
<ul style="list-style-type: none"> Administrative structures capable to manage and enforce requirements as outlined in 90/219/EEC as amended by 98/81/EC and 2001/18/EC Directives (Committee on GMOs, and administrative unit within the Ministry of Environment and Water and Ministry of Agriculture and Forestry as well as supervisory authorities) ; Assessment of existing laboratories and preparation for their accreditation in order to conduct risk assessment and monitoring of GMO that are released or introduced to the 	<ul style="list-style-type: none"> Units on GMOs in MoEW and MAF established in 2004; Staff of the competent authorities (up to 30 experts) dealing with GMO trained; Electronic information system installed and used; System of accredited laboratories created; Staff of the laboratories (at least 2 laboratories) trained; General public acquainted with the 	Ministry of Environment and Water	<ul style="list-style-type: none"> The Ministry of Environment and Water and Ministry of Agriculture and Forestry staff is co-operating on the implementation of the project Sources of financing available – adequate provision from the state budget, adequate

<p>market</p> <ul style="list-style-type: none"> • A notification system by those proposing the registration of containment facilities and permission for contained use, addressed to the competent authorities. • Up-dated electronic information system and public registers in an electronic format to record licensed premises, consents granted for GMO containment, release and placing in the market, conditions of containment, risk assessment and monitoring results and other pertinent information outlined in the EC Directives. • Inform the public on the legislation and the implementation of the regulations included in the two EC Directives. 	<p>newly adopted requirements;</p> <ul style="list-style-type: none"> • System of utilizing GMO created and functioning 		<p>management and available human resources, support from other relevant institutions.</p>
<ul style="list-style-type: none"> • Establishment of an effective border and in-country control system based on close co-operation between the Regional Inspectorates of Environment and Water, as the unit responsible for control on the compliance with the environmental legislation, the Customs Agency and other institutions such as Police if necessary. • Implementation of the notification procedures according to the requirements of Regulation (EEC) No 259/93 (the Ministry of Environment and Water is the responsible authority). • Developed guideline/manual for beneficiaries, describing wastes from the European green, amber and red lists of wastes, including explanation of their quick identification methods. • Publication and distribution of a guideline/manual describing wastes from the European green, amber and red lists of wastes and their quick identification methods. • Approximately 150 people from the Ministry of Environment and Water, Regional Inspectorates of Environment and Water, Customs Agency and Border authorities to be trained. 	<p>Trained staff - 150 officials and specialists Published manual Methodology guidelines concerning the Waste Shipment Regulation requirements Technical reports and studies Number of joint training inspections by the experts of the Regional Inspectorates of Environment and Water and Customs Agency.</p>	<p>Ministry of Environment and Water Customs Agency</p>	<p>Quality of TA services provided stimulates expected results. Trainees able to utilize their knowledge gained from training and TA in practical actions. Sources of financing available.</p>

Activities	Means		Assumptions
<p>Transposition of the new EU FQC Directives:</p> <ul style="list-style-type: none"> • Gathering of the necessary information about the above-mentioned European legislation, including MSs national programmes and plans for implementation of the requirements of the FQC Directives. • Examination of the information collected and analysis of the approaches to its implementation. • Gathering of the necessary information and analyzing of the current situation of the local refinery industry, including the commitments under Directive 99/32/EC Implementation programme. • Examination of the information received from the refinery, coordination between the competent authorities and a site visit at the refinery, including member- state experts. • Examination of the possibilities of production/import of “free of sulphur” motor fuels and marine fuels with low sulphur content, including their storage and distribution. • Elaboration of a draft ordinance amending the Ordinance for the requirements to the quality of liquid fuels, terms, procedure and methods of control. • Training of the authorized inspectors from EAMA for ship fuels sample taking in and out of harbors area. • Issuance of EAMA instruction for carrying out joint inspections by GD FQC and EAMA for ship fuels control. • Study visits to MSs regarding practical acquaintance with the M experience on implementation of the FQC legislation. • Studying the latest amendments to EN and ISO standards and the possibilities for their implementation as Bulgarian State Standards. <p>Development of a National Programme for production and use of biofuels according to the requirements of Directive 2003/30/EC</p> <ul style="list-style-type: none"> • Gathering of the necessary information about the above-mentioned European legislation, including MSs national programmes and plans for implementation of the requirements of the Biofuels Directive. 	<ul style="list-style-type: none"> - The processing and the analysis of the information necessary for the elaboration of the draft ordinance has been completed. - The draft ordinance is fully in compliance with the EC requirements. - The frame of reference, the criteria and the measures have been coordinated. 	<p>Regular reporting by the PAA on the progress achieved.</p> <p>GD FQC, BSI, TC 67, EAMA, NSI, ME, MOEW</p> <p>Technical reports of the working partner.</p>	<p>Time allocation and implementation.</p> <p>Coordination between the competent authorities and the refinery.</p> <p>Coordination between the responsible authorities to fully implement the recommendations of the project.</p>

<ul style="list-style-type: none"> • Overview and analysis of the existing legal arrangements for production of rape oil and biodiesel. • Defining the potential for the production of rape oil and biodiesel in Bulgaria and analysis and defining of different possibilities for producing rape oil and biodiesel in Bulgaria • Defining the locations for cultivation of rape seed and building the installations for production of biodiesel. • Analyzing the possibilities for involving investments in the process of production of rape oil and biodiesel. • Study visits to MSs regarding practical acquaintance with the MSs experience on implementation of the biofuels legislation. • Studying the different MSs approaches in supplying the rape seed for the production of biodiesel and in the process of production. • Studying of the European, international and MSs national standards for use of biodiesel in transport and for biodiesel analyzing. • Studying the methods of storage of biodiesel, the possibilities for adapting the motor vehicles in Bulgaria to this fuel and using biodiesel in transport. • Elaboration of a draft of a National Programme for production and use of biodiesel in transport and an Action Plan to it. 	<p>- Elaboration of a National Programme for production and use of biodiesel and an Action Plan to the Programme.</p>	<p>Ministry of Environment and Water EAAE, MEW, MEER, ME, Ministry of Transport, Ministry of Agriculture and Forestry, NGOs Regular reporting on the project development. Regular reporting on the progress achieved by the PAA.</p>	<p>Active participation and exchange of information between the competent authorities. The experts from the “Clean Air Protection” Directorate should participate actively in the project. Coordination between the competent authorities.</p>
<ul style="list-style-type: none"> • Training of the members of the newly established Committee to evaluate submitted notifications according to the requirements of the two Directives (accuracy, correctness of risk assessment and efficiency of risk management plan, proposed containment and waste management measures etc) • Training of state officials (12 persons) within the MOEW and MAF to provide administrative support to the Commission (initial evaluation of notifications for accuracy and completeness, interactions with the applicants for clarifications on the notifications documentation recording of pertinent information and updating of the electronic information system, etc) • Training of supervisory authorities dealing with GMO (approx. 60 persons; inspectors of containment conditions and safety measures in the contained premises, inspectors of field tests and monitoring plans as well as inspectors of compliance with the labelling and traceability requirements etc), 	<ul style="list-style-type: none"> • One PAA with STEs under Twinning arrangements • Office space and equipment for the project implementation teams 	<ul style="list-style-type: none"> • Project implementation team • The Ministry of Environment and Water • EU Delegation 	<ul style="list-style-type: none"> • The Ministry is providing necessary support, including office space • Effective co-operation with other institutions, adequate provision from state budget, adequate human resources available.

<ul style="list-style-type: none"> • Assessment of the infrastructure of research institutions and other bodies dealing with GMO in order to establish reference (accredited) laboratories. • Preparation of tender documents for supply of laboratory equipment needed to support the infrastructure of existing research facilities so as to meet accreditation requirements. • Establishment of notification forms to be utilized by applicants for registration of containment facilities and contained use activities. • Establishment within the electronic information system developed under UNEP-GEF (see below -linked activities) of public registers for all granted consents, new and renewed GMO releases, and pertinent information associated with these, according to the format defined in the EC Directives. • Further development, so as to include all specifications of risk assessment, monitoring, labelling and traceability, described in detail in the EC Directives, and regular updating of the electronic information system and the special GMO-web site, established under UNEP-GEF project. • General education of the public through media, lectures, printed materials on biological safety and the regulations imposed by the EC Directives aimed to continue and expand the public awareness activities, undertaken under the UNEP-GEF project, as well as to enable the participation of the public in the decision-making process on GMO-related issues. 			
<ul style="list-style-type: none"> • Assessment of existing legislative, technical and institutional conditions and elaboration of proposals for amendment of the existing legislation, installation of equipment, strengthening the administrative capacity, improvement of coordination between institutions and involvement of new institutions if necessary. • Joint training inspections by the services of the Regional Inspectorates of Environment and Water and Customs Agency. • Developing and publishing of guidelines/manual for beneficiaries, describing wastes from the European green, amber and red lists of wastes, together with their quick identification methods, and of guidelines regarding practical application of notification procedures. • Training for the Inspection personnel (the Regional 	<p>One twinning covenant: PAA Short Term Experts</p>	<ul style="list-style-type: none"> • Project implementation team • The Ministry of Environment and Water • EU Delegation 	<p>Effective preparation of training schemes. Bulgarian and Member necessary staff available. Effective co-operation with other institution involved in proposed project Sources of financing available</p>

<p>Inspectorates of Environment and Water and Customs Agency) regarding developed guideline describing wastes from the European green, amber and red lists of wastes, including explanation of their quick identification methods. And carrying out of seminars introducing developed guideline regarding practical application of notification procedure.</p> <ul style="list-style-type: none"> • Preparation of TOR for purchasing and installation of proposed equipment. 			
			<p>Preconditions</p> <ul style="list-style-type: none"> • EAMA responsible for the transposition and steps for future implementation of the newly adopted FQC legislation. • Adoption of the draft Law on GMO by National Assembly. • Establishment of the Commission on GMO and of new units responsible for GMO in MoEW and MAF. • Adoption of the draft Regulation on transfrontier shipment of waste by the Council of Ministers.

ANNEX 2

DETAILED IMPLEMENTATION CHART

Activities	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Sub-project 1																		
Gathering and examination of the new EC fuel quality control (FQC) directives (Directive 2003/17/EC amending Directive 98/70/EC relating to the quality of petrol and diesel fuel and COM(2002)595 final amending Directive 99/32/EC relating to a reduction of sulphur content in certain liquid fuels); parallel study of the quality control and marketing requirements for each fuel type, including marine fuels																		
Transposition of the new EC FQC directives – development of a draft Regulation amending the present Regulation on FQC adopted by a Cabinet Ordinance No:156 from 15.07.2003 and transposing directives 2003/17/EC and COM(2002)595 final																		
Establishment of competent authorities and improvement of the administrative capacity of GD FQC and EAMA for implementation and enforcement of above directives Identification of training needs at regional and central level; Development of a Draft National Training and Educational Program with regard to the needs identified under above item;																		
Discussion and co-ordination of the draft and adoption of the Final Program; Initial steps for the Program's implementation – organization of a Seminar for its presentation and training of the relevant officials.																		
Development of a National Program for production and use of biofuels according to the requirements of Directive 2003/30/EC on the promotion of the use of biofuels or other renewable fuels for transport																		
Reports				R1				R2				R3						FR
Sub-project 2																		
Training of the members of the newly established Committee to evaluate submitted notifications according to the requirements of the two Directives (accuracy, correctness of risk assessment and efficiency of risk management plan, proposed containment and waste management measures etc).																		
Training of state officials (12 persons) within the MOEW and MAF to provide administrative support to the Commission (initial evaluation of notifications for accuracy and completeness, interactions with the applicants for clarifications on the notifications documentation recording of pertinent information and updating of the electronic information system, etc).																		
Training of supervisory authorities dealing with GMO (approx. 60 persons; inspectors of containment conditions and safety measures in the contained premises, inspectors of field tests and monitoring plans as well as inspectors of compliance with the labelling and traceability requirements etc).																		
Assessment of the infrastructure of research institutions and other bodies dealing with GMO in order to establish reference (accredited) laboratories.																		

Preparation of tender documents for supply of laboratory equipment needed to support the infrastructure of existing research facilities so as to meet accreditation requirements.																			
Establishment of notification forms to be utilized by applicants for registration of containment facilities and contained use activities.																			
Establishment within the electronic information system developed under UNEP-GEF (see below -linked activities) of public registers for all granted consents, new and renewed GMO releases, and pertinent information associated with these, according to the format defined in the EC Directives.																			
Further development, so as to include all specifications of risk assessment, monitoring, labelling and traceability, described in detail in the EC Directives, and regular updating of the electronic information system and the special GMO-web site, established under UNEP-GEF project.																			
General education of the public through media, lectures, printed materials on biological safety and the regulations imposed by the EC Directives aimed to continue and expand the public awareness activities, undertaken under the UNEP-GEF project, as well as to enable the participation of the public in the decision-making process on GMO-related issues.																			
Reports				R1				R2				R3							FR
Sub-project 3																			
Assessment of existing technical and institutional conditions.																			
In-country thematic training on practical implementation of the Council Regulation No. 259/93.																			
Joint training inspections by the services of the Regional Inspectorates of Environment and Water and Customs Agency.																			
Developing and publishing of a guideline/manual for beneficiaries, describing wastes from the European green, amber and red lists of wastes, together with their quick identification methods.																			
Training for the Inspection personnel (the Regional Inspectorates of Environment and Water and Customs Agency) regarding developed guideline describing wastes from the European green, amber and red lists of wastes, including explanation of their quick identification methods.																			
Developing of guideline regarding practical application of notification procedures.																			
Carrying out of seminars introducing developed guideline regarding practical application of notification procedure																			

ANNEX 3

CUMULATIVE CONTRACTING and DISBURSEMENT SCHEDULE (Million euro)									
Date	30/10/04	31/12/04	31/03/05	30/06/05	30/09/05	31/12/05	31/07/06	30/09/06	31/12/06
Sub-project 1									
Contracted	0,7								
Disbursed		0,1	0,1	0,1	0,1	0,2	0,1		
Sub-project 2									
Contracted	0,7								
Disbursed		0,1	0,1	0,1	0,1	0,2	0,1		
Sub-project 3									
Contracted	0,7								
Disbursed		0,1	0,1	0,1	0,1	0,1	0,1	0,1	
<i>NB: 1. All contracting should normally be completed within 6-12 months and must be completed within 24 months of signature of FM</i>									
<i>2. All disbursements must be completed within 36 months of signature of the FM</i>									

(*) The national co-financing for the Twinning project should be up to 10 % from the State budget through the national fund.

ANNEX 4

List of relevant laws and regulations

- Clean Air Act (SG, 45/1996; as amended SG, 27/2000; as amended SG, 102/2001)
- “MARPOL” Convention 73/78” (not yet published)
- Commercial Navigation Code (SG, 113/2002)
- Ordinance on the requirements to liquid fuels, terms and method of control (SG, 66/2003)
- Draft Law on Energy Efficiency
- Law of Waste Management (State Gazette 86/2003);
- Regulation for the cases when a permit is required for the import, export and transportation of waste and the conditions and order of the issuing the permit (State Gazette No 6/2000). The regulation defines also the cases when a bank guarantee or insurance is required;
- Law on Ratification of the Basel Convention on the Control of Transboundary Movements of Hazardous Waste and their Disposal;
- Regulation on the requirements for treatment and transportation of industrial and hazardous waste (adopted with Decree of the Council of Ministers No 53/1999; State Gazette No 29 /1999).

ANNEX 5

List of relevant strategic plans

- Implementation Programme for Directive 99/32/EC (CONF-BG-4/03, ANNEX 4)
- National Programme for Adoption of the Acquis (NPAA)
- National Environmental Strategy and Action Plan to it for the period 2000- 2006.
- National Plan for Institutional Strengthening and Capacity-Building for Implementation of the EU environmental acquis, 2003-2006.
- National programme for phasing out the production and usage of leaded petrol as adopted by the Council of Ministers (CM Decision 73/1998)
- Draft National Programme for renewable energy sources
- Draft National Programme on Waste Management 2003 – 2007.

ANNEX 6

UNITED NATIONS ENVIRONMENT PROGRAMME GLOBAL ENVIRONMENT FACILITY PROJECT DOCUMENT SECTION 1 - PROJECT IDENTIFICATION

- 1.1 Sub-Programme Title:** Biodiversity 1-4/biosafety
- 1.2 Project Title:** Support for the Implementation of the National Biosafety Framework for Bulgaria
- 1.3 Project Number:** GF / 2 - 02 - 4
- 1.4 Geographical Scope:** Bulgaria
- 1.5 Implementation:** AgroBio Institute (ABI),
1000 Sofia, Bulgaria
Tel: 359-2-963 5407
Fax: 359-2-963 5408
- 1.6 Duration of the Project:** 36 months
Commencing: September 2002
Completion: September 2005

1.7 Project Summary (one paragraph)

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.

Signatures

For AgroBio Institute

For UNEP

Prof. Atanas Atanasov

Date: _____

E.F. Ortega, Chief,
Budget and Financial Management
Service, UNON.

Date: _____

SECTION 2 - BACKGROUND AND PROJECT CONTRIBUTION TO OVERALL SUB-PROGRAMME IMPLEMENTATION

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.
<p>7. Project linkage to national priorities, action plans and programmes:</p> <ul style="list-style-type: none"> 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 <i>genetic preservation and biosafety</i> 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 <i>Living Modified Organisms Act (LMO Act)</i>, 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 <i>Regulation for Biosafety of GM Higher Plants</i> has been adopted by the Ministry of Agriculture (1996). A special Taskforce was set up in 2000 to finalise the draft of the <i>Living Modified Organisms Act</i>, 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 <i>Centre of Excellence</i> 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: <ul style="list-style-type: none"> Participation in the European Union Framework Programme 5 (www.cordis.lu/eu) and other highly competitive international programs that fund research and cooperation between 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. 	

<p>8. GEF national operational focal point and date of country endorsement:</p> <p>Submitted: Fathme Iliaz 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 Fatme.iliazBojinov@moew.govern.bg</p> <p>Acknowledged:</p> <p>Endorsed:</p> <p>The project was endorsed by the GEF Focal point on the 24th October 2001</p>	
<p>Project Objectives and Activities</p>	
<p>9. Project rationale and objectives:</p> <p>Goal: To support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries</p> <p>Objective: Implementation of the National Biosafety Framework in Bulgaria.</p> <p>Specific objectives are set as follows:</p> <p>(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.</p> <p>(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.</p> <p>(C) Strengthen capacity on</p> <ul style="list-style-type: none"> • risk assessment and risk management as identified in Articles 15 and 16 and Annexes I-III of the Protocol, • 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 	<p>Indicators:</p> <ul style="list-style-type: none"> • Legislative, economic, and social policies and programs for Biosafety in place • Reliable systems and procedures for risk assessment and management of LMO • 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. • 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.

<p>of LMOs (that might have an adverse effect on the conservation and sustainability of biodiversity) between Bulgaria and other countries.</p> <p>(D) Set up a Biosafety Database System to be connected to the Biosafety Clearing House Mechanism</p> <p>(E) Enhance public awareness and promote dissemination among the relevant stakeholders in accordance with Article 23 of the Protocol Promote</p>	
<p>10. Project outcomes:</p> <p>(A.1) “Living Modified Organisms Act of Bulgaria” finalized and submitted to Parliament;</p> <p>(A.2) Regulations needed for the implementation of the Law, drafted.</p> <p>(A.3) National procedures required in order to use the Biosafety Clearing-House Mechanism and provide information to the Biosafety Clearing House in force</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(B.1) Technical guidelines for performing risk assessment and management in force.</p> <p>(B.2) Certified laboratory and research groups performing assessment and monitoring the deliberate release and commercial use of LMOs strengthened.</p> <p>(B.3) Data from mini field trials, and various biochemistry and molecular experiments as well as biodiversity data</p>	<p>Indicators:</p> <ul style="list-style-type: none"> • 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 results 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 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.

<p>including those on taxonomy and existing genetic diversity collected to allow for risk assessment and management</p> <p>(C.1) Five training courses for twelve trainers held on:</p> <ul style="list-style-type: none"> • 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. <p>(C.2) Two training workshops carried out as follows:</p> <ul style="list-style-type: none"> • “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. <p>(D.1) National Biosafety Database System set up and linked to the Biosafety Clearing House Mechanism</p> <p>(D.2) National web site in place and operational</p> <p>(D.3) One workshop for 100 government officials, journalists, scientists and NGO representatives on “Information exchange and biosafety” organised.</p> <p>(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.</p>	<ul style="list-style-type: none"> • 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
<p>11. Planned activities to achieve outcomes (including cost in US\$ or local currency of each activity):</p> <p>(a.1) Setting up a trans-institutional task force for finalising the “<i>Bulgarian Living Modified Organisms Act</i>” to meet the requirements of the Cartagena Protocol, and submit it to Parliament for approval.</p>	<p>Indicators:</p> <ul style="list-style-type: none"> • Act finalised and submitted for Parliament approval;

¹Annex 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.

<p>(b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act</p> <p>(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.</p> <p>(b.3) Pilot collection of data from mini-field trials and biochemistry and molecular approaches for the purpose of risk assessment.</p> <p>(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.</p>	<ul style="list-style-type: none"> • 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
<p>(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:</p> <ul style="list-style-type: none"> • LMOs risk assessment and risk management, • LMOs testing and monitoring, • Legal issues, • Administrative Procedures and • The control over the transboundary movement of LMO. <p>(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. (Accommodations for 4 nights x 6 int. participants x \$100)</p> <p>(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</p>	<ul style="list-style-type: none"> • Minutes and proceeding of the workshops printed and disseminated among the participants and interested parties

discussed. (Accommodations for 3 nights x 2 int. participants x \$100)	
<p>(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.</p> <p>(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:</p> <ol style="list-style-type: none"> 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 <p>Different types of access to the web site will be set 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 web-site and protect any commercial information as identified in the European Directive and in the Protocol (Article 21).</p> <p>(d.1.3) Organise a workshop for 100 government officials, 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)</p>	<ul style="list-style-type: none"> • 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
<p>(e.1) Develop and disseminate outreach materials training materials, technical manuals including publications, one video movie, brochures, etc. for public awareness raising purposes;</p>	<ul style="list-style-type: none"> • 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.

<p>(e.2) Prepare and disseminate a newsletter on a quarterly basis;</p> <p>(e.3) Disseminate best practice and lessons learnt;</p>	
<p>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 from other sources and the total)</p>	
<p>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 Atanasov is executive secretary of the Council for Biosafety of Genetically Modified Higher Plants. Contact person: Prof. Atanas Atanasov, Director of AgroBioInstitute 2232 Kostinbrod, Bulgaria</p>	
<p>14. Information on proposed executing agency (if different from above): NA</p>	
<p>15. Date of initial submission of project concept:</p>	
<p>16. Project Identification number:</p>	
<p>17. Implementing Agency contact person: Ahmed Djoghlaif, Executive Co-ordinator, UNEP/GEF Coordination Office</p>	
<p>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.</p> <p>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”.</p> <p>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.</p> <p>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</p>	

“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 Montpellier 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 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 - AgroBioInstitutue 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 – three 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 organisms².
- 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

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.

14:2,4, Article 17:1,2, and Article 19:2 in due time. Means and procedures for automatic 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 from 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 hired 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 coordinate 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 contamination, 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.

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.

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 led 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
<i>The Establishment of legislation system and operational mechanism for biosafety management Bulgaria</i>	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
<i>LMOs Risk Assessment and Risk Management: procedures and strengthening of certified laboratories</i>	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 management procedure as requested under the Protocol.	Technical guidelines for risk assessment and management in place. Information 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 needed for inspection purposes in the context of the risk assessment and management procedure as requested under the Protocol	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 LMOs.
<i>Training and workshops</i>	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
<i>The Establishment of a Biosafety Database system to serve for the purpose of the Biosafety Clearing House Mechanism</i>	An organised database system to serve for the purpose of the Biosafety Clearing House is still missing.	A national information system required by the Protocol for 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	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
<i>Capacity building for public awareness</i>	Lack of adequate capacity for public awareness purposes	Capacity for public awareness strengthened through specific dissemination activities	Public awareness capacity enhanced

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.

SECTION 3 - PROJECT BUDGET AND FINANCING

3.1 Budget

A detailed budget in UNEP format is presented in Annex 10. This budget is based upon the GEF approved budget provided in GEF format in the GEF Medium sized project brief.

3.2 Cash Advance Requirements

Initial cash advance of US\$?????? will be made upon signature of the project document by both parties and will cover expenditures expected to be incurred by ABI during the first three months of the project implementation. Subsequent advances are to be made biannually, subject to:

- (i) Confirmation by ABI, at least two weeks before the payment is due, that the expected rate of expenditure and actual cash position necessitate the payment, including a reasonable amount to cover "lead time" for the next remittance; and
- (ii) The presentation of
 - a satisfactory financial report showing expenditures incurred for the past quarter, under each project activity.
 - Timely and satisfactory reports on project implementation

Requests for subsequent cash advances should be made using the standard format provided in Annex 6.

SECTION 4 - INSTITUTIONAL FRAMEWORK

4.1 Institutional Framework

ABI will be responsible for the implementation of the project in accordance with the objectives and activities outlined in Section 2 of this document. UNEP as the GEF Implementing Agency will be responsible for overall project supervision to ensure consistency with GEF and UNEP policies and procedures, and will provide guidance on linkages with related UNEP and GEF-funded activities. The UNEP GEF Co-ordination Office will monitor implementation of the activities undertaken during the execution of the project. The UNEP GEF Co-ordination Office will be responsible for clearance and transmission of financial and progress reports to the Global Environment Facility. UNEP retains responsibility for review and approval of the substantive and technical reports produced in accordance with the schedule of work.

All correspondence regarding substantive and technical matters should be addressed to:

At ABI

Prof. Atanas Atanasov

AgroBio Institute (ABI),

1000 Sofia, Bulgaria

Tel: 359-2-963 5407

Fax: 359-2-963 5408

E-mail: atanas.atanasov@agrobioinstitut.org

At UNEP

Mr. Ahmed Djoghlaif

Executive Coordinator,

UNEP/GEF Coordination Office

P. O. Box 30552

Nairobi, Kenya

Fax: (254) 2-624041

Phone: (254) 2-624166

Email: Ahmed.Djoghlaif@unep.org

All correspondence regarding administrative and financial matters should be addressed to:

At ABI

Mrs. Kristina Georgieva

AgroBio Institute (ABI),

1000 Sofia, Bulgaria

Tel: 359-2-963 5407

Fax: 359-2-963 5408

E-mail: kristina@abi.bg

With a copy to: Prof. Atanas Atanasov

AgroBio Institute (ABI),

1000 Sofia, Bulgaria

Tel: 359-2-963 5407

Fax: 359-2-963 5408

E-mail: atanas.atanasov@agrobioinstitut.org

At UNEP

Mr. E. Ortega
Chief, Budget and Financial Management Service (BFMS)
UNON
P.O. Box 30552
Nairobi, Kenya
Tel: (254) 2 623637
Fax: (254) 2 623755

With a copy to:

Sandeep Bhambra
Fund Management Officer,
UNEP /GEF Co-ordination Office,
P.O.Box 30552
Nairobi, Kenya
Tel: 254-2-623347
Fax: 254-2-623162
Email: Sandeep.Bhambra@unep.org

4.2 Evaluation

Upon completion of the project, UNEP will organize an independent evaluation of the project to measure the degree to which the objectives of the project have been achieved.

4.3 Eligibility

The countries are eligible for GEF funding under the rules and requirements specified in the *Instrument for the Restructured Global Environment Facility*. Given that the project is a pilot one, it will help in gaining experience and developing good practices to be promptly and effectively provided to assist Parties once the Protocol enters into force. Its potential for replication will be ensured from the onset of implementation of the medium sized project by fully involving and collaborating with other key national and regional developing country agencies and governments. In addition, also the development of an information system as well as public awareness activities will support the dissemination of best practices and lessons learnt at regional and global level.

SECTION 5: MONITORING, REPORTING AND EVALUATION

5.1 Management Reports

5.1.1 Progress Reports

Within 30 days of the end of reporting period, ABI will submit to UNEP/GEF Coordination Office, using the format given in Annex 5 , Quarterly Progress Reports as at 31 March, 30 June, 30 September and 31 December.

5.1.2 Terminal Reports

Within 60 days of the completion of the project, ABI will submit to UNEP a Terminal Report detailing the activities taken under the project, lessons learned and any recommendations to improve the efficiency of similar activities in the future, using the format provided in Annex 8.

5.1.3 Financial Reports

(i) Details of expenditures will be reported on an activity by activity basis, in line with project budget codes as set out in the project document, as at 31 March, 30 June, 30 September and 31 December using the format given in Annex 7. All expenditure accounts will be dispatched to UNEP within 30 days of the end of the three-month period to which they refer, certified by a duly authorised official of ABI

(ii) In addition, the total expenditures incurred during the year ending 31 December, certified by a duly authorised official, should be reported in an opinion by a recognised firm of public accountants, and should be dispatched to UNEP within 90 days, i.e 31 March. In particular, the auditors should be asked to report whether, in their opinion:

- ◆ Proper books of account have been maintained;
- ◆ All project expenditures are supported by vouchers and adequate documentation;
- ◆ Expenditures have been incurred in accordance with the objectives outlined in the project document.

(iii) Within 90 days of the completion of the project, ABI will supply UNEP with a final statement of account in the format as for the quarterly expenditure statements duly signed by authorised official of ABI and certified by recognised firm of public accountants.

(iv) Any portion of cash advances remaining unspent or uncommitted by ABI on completion of the project will be reimbursed to UNEP within one month of the presentation of the final statement of accounts. In the event that there is any delay in such disbursement, ABI will be financially responsible for any adverse movement in the exchange rates.

ABI shall retain, for a period of three years, all supporting documents relating to financial transactions under the project. If requested, ABI shall facilitate an audit by the United Nations Board of Auditors and/or the Audit Service of the accounts of the project.

5.2 Substantive Reports

At the appropriate time, ABI will submit to UNEP three copies in draft of any substantive project report(s) and, at the same time, inform UNEP of its plans for publication of that text. Within 30 days of receipt, UNEP will give ABI substantive clearance of the manuscript, indicating any suggestions for change and such wording (recognition, disclaimer, etc.) as it would wish to see figure in the preliminary pages or in the introductory texts. It will equally consider the publishing proposal of ABI and will make comments thereon as advisable. It may request ABI to consider a joint imprint basis. Should ABI be solely responsible for publishing arrangements, UNEP will nevertheless receive 10 free copies of the published work in each of the agreed languages, for its own purposes.

5.3 Terms and Conditions

5.3.1 Non-Expendable Equipment

ABI will maintain records of non-expendable equipment (items costing US\$1500 or more as well as items of attraction such as pocket calculators, cameras, computers, printers, etc.) purchased with UNEP funds (or with Trust Funds or Counter funds administered by UNEP) and will submit, using format in Annex 9, an inventory of such equipment to UNEP, once a year, indicating description, serial no., date of purchase, original cost, present condition, location of each item attached to the progress report submitted on 31 December. Within 60 days of completion of the project, ABI will submit to UNEP a final inventory of all non-expendable equipment purchased under this project indicating description, serial number, original cost, present condition, location and a proposal for the disposal of the said equipment. Non-expendable equipment purchased with funds administered by UNEP remains the property of UNEP until its disposal is authorised by UNEP, in consultation with ABI. ABI shall be responsible for any loss or damage to equipment purchased with UNEP administered funds. The proceeds from the sale of equipment, (duly authorised by UNEP) shall be credited to the accounts of

UNEP, or of the appropriate trust fund or counterpart funds. A duly authorised official of ABI should physically verify the inventory.

5.3.2 Responsibility for Cost Overruns

Any cost overruns (expenditures in excess of the amount in each budget sub-line) shall be met by the organisation responsible for authorising the expenditure, unless written agreement has been received in advance from UNEP. In cases where UNEP has indicated its agreement to a cost overrun in a budget sub-line to another, or to increase the total cost to UNEP, a revision to the project document amending the budget will be issued by UNEP.

5.3.3 Claims by Third Parties against UNEP

ABI shall be responsible for dealing with any claims which may be brought by third parties against UNEP and its staff, and shall hold UNEP and its staff non-liaible in case of any claims or liabilities resulting from operations carried out by ABI or other project partners under this project document, except where it is agreed by ABI and UNEP that such claims or liabilities arise from gross negligence or wilful misconduct of the staff of UNEP.

5.3.4 Amendments

The Parties to this project document shall approve any modification or change to this project document in writing.

LIST OF ANNEXES

- ANNEX 1** Summary of the National Biosafety Framework
- ANNEX 2** Matrix showing the relation between the project activities, the Cartagena Protocol and the National Biosafety Framework
- ANNEX 3** Provisional list of equipment needed to strengthen laboratories and enable them to perform inspections within the risk assessment and management procedure
- ANNEX 4** UNEP Response to the STAP Technical Review
- ANNEX 5** A: Quarterly Progress Report Format for GEF
B: Quarterly Progress Report Format for UNEP
- ANNEX 6** Format for Cash Advance Request
- ANNEX 7** Format for Quarterly Expenditure Statement
- ANNEX 8** Format for Terminal Report
- ANNEX 9** Format for Non-Expendable Equipment Inventory Report
- ANNEX 10** Budget in UNEP Format

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 three 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 government 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 the 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 denies permission for the release of LMHP.

The system of control of LMO release will be built 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
<p>Article 2.</p> <ol style="list-style-type: none"> Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol 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. <p>Article 16.</p> <ol style="list-style-type: none"> 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. 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. Each Party shall take appropriate 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. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any LMO, 	<p>(a.1) Setting up a trans-institutional task force for finalizing the "<i>Bulgarian LMO Act</i>" to meet the requirements of the Cartagena Protocol, and submit it to Parliament for approval.</p> <p>(a.2) Draft the following regulations for the implementation of the LMO Act:</p> <ul style="list-style-type: none"> 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. <p>Regulation of Council of Ministers for risk assessment.</p> <p>(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.</p> <p>(a.4) Ecological, economic, and sociological survey among the general public to provide information, including indigenous knowledge, to guide NBF implementation.</p> <p>(a.5) Assessment of national technological capacity at public and private level, its effect on</p>	<p>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.</p> <p>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.</p> <p>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.</p> <p>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</p>

<p>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.</p> <p>Article 18</p> <p>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.</p> <p>Article 25</p> <p>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.</p>	<p>implementation of national biosafety frameworks, and means to improve it.</p> <p>(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.</p> <p>(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)</p> <p>(b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act</p> <p>(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.</p> <p>(b.3) Pilot collection of data from mini field trials and various biochemistry and molecular approaches for the purpose of risk assessment.</p>	<p>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.</p> <p>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.</p> <p>Establish and implement policies that provide for the safe conduct of recombinant DNA research or release and that ensure compliance with the <i>National Biosafety Framework</i>. As part of its general responsibilities for implementing the <i>National Biosafety Framework</i>, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the <i>National Biosafety Framework</i>. Such procedures may include: (i) statements formulated by the institution for the general implementation of the <i>National Biosafety Framework</i>, and (ii) any additional precautionary steps the institution deems appropriate.</p> <p>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:</p> <ul style="list-style-type: none"> • conducts recombinant DNA research at
---	--	---

		<p>Biosafety Level (BL) 3 or BL4, or</p> <ul style="list-style-type: none"> engages in large scale (for example – greater than 10 liters) research. <p>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.</p> <p>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.</p>
<p>Article 7.</p> <p>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.</p> <p>Article 10.</p> <p>1. Decisions taken by Party of import shall be in accordance with Article 15.</p> <p>Article 11.</p>	<ul style="list-style-type: none"> 	<p>For organisms representing a possible impact or threat due to transboundary movements, the following two points should be followed:</p> <ul style="list-style-type: none"> 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; <p>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</p> <p>Experiments that involve recombinant DNA</p>

<p>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 transboundary 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.</p> <p>Article 33</p> <p>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 Protocol.</p>		<p>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.</p> <p>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 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.</p> <p>The Council for Safety Use of GMO responsibilities include (but are not limited to) the following:</p> <ul style="list-style-type: none"> • 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 notifier; <p>Supervises compliance to regulations governing the permission for release of GMO;</p>
<p>Article 15.</p> <p>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</p>	<p>(b.1) Technical guidelines for performing risk assessment and management for implementing the LMOs Act.</p> <p>(b.2) Two certified laboratories and expert research groups, performing assessment and monitoring on the deliberate release and commercial use of LMOs,</p>	<p>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.</p>

techniques.	<p>according to the LMO Act.</p> <p>(b.4) Prepare botanical files for the purpose of risk assessment and management.</p>	
<p>Article 17.</p> <p>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 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.</p> <p>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.</p> <p>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.</p> <p>Article 20</p> <p>A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention</p> <p>Without prejudice to the protection of confidential</p>	<p>(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 regional biosafety information.</p> <p>(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:</p> <ol style="list-style-type: none"> 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. <p>(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)</p>	<p>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 <i>National Biosafety Framework</i>.</p> <p>For organisms representing a possible impact or threat due to transboundary movements, the following two points should be followed:</p> <ul style="list-style-type: none"> • 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. <p>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.</p>

<p>information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the BCHU.</p>		<p>The Council for Safety Use of GMO responsibilities include (but are not limited to) the following:</p> <ul style="list-style-type: none"> • Serving as the focal point for public access to summary information pertaining 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.
--	--	---

<p>Article 22</p> <p>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.</p> <p style="text-align: center;">Article 23</p> <p>1. The Parties shall:</p> <ul style="list-style-type: none"> ➤ 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. <p>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 such decisions available to the public, while respecting confidential information in accordance with Article 21.</p> <p>3. Each Party shall endeavour to</p>	<p>(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:</p> <ul style="list-style-type: none"> • <i>LMOs risk assessment and risk management,</i> • <i>LMOs testing and monitoring,</i> • <i>Legal issues,</i> • <i>Institutional sets up and</i> <p><i>The control over the transboundary movement of LMO.</i></p> <p>(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.</p> <p>(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.</p> <p>(d.2.1) Prepare and disseminate a newsletter on a quarterly basis</p>	<p>The Council for Safety Use of GMO responsibilities include (but are not limited to) the following:</p> <ul style="list-style-type: none"> • 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.
---	--	---

<p>inform its public about the means of public access to the Biosafety Clearing-House.</p>	<p>(d.2.2) Disseminate outreach materials including publications, video, brochures, articles in local press, etc. for public awareness raising purposes</p> <p>(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)</p>	
---	--	--

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 Secretariat, 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.

<u>Issue</u>	<u>Response</u>
Kenya <ul style="list-style-type: none">• <i>Capacity building should also be addressed to inspectors, for example by organising training workshop and developing inspection manuals.</i>	<ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• <i>One important element that is missing, is the development of implementing regulations.</i>• <i>The proposed training activities are very fragmented and it is recommended to merge some of the training activities.</i>	<ol style="list-style-type: none">1) The EU covers the regulatory component and therefore Poland didn't ask for any 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

<ul style="list-style-type: none"> • <i>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.</i> 	<p>current EU ones.</p>
<p>Uganda</p> <ul style="list-style-type: none"> • <i>It is recommended to include training activities on topics such as “other international obligations”.</i> 	<ul style="list-style-type: none"> • Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.

ANNEX 5A: QUARTERLY OPERATIONAL REPORT

(For the period:)

1. IDENTIFIERS

Country

Project Title

Project No.

Focal Area

Implementing Agency

GEF Funding

Co-funding

2. FINANCIAL STATUS

3. IMPLEMENTATION PROGRESS

4. ACHIEVEMENT OF PROJECT OBJECTIVES

5. SPECIFIC ASSESSMENT OF FACTORS RELATING TO THE BIOLOGICAL DIVERSITY FOCAL AREA

ANNEX 5B: FORMAT FOR QUARTERLY PROGRESS REPORT TO UNEP
as at 31 March, 30 June, 30 September and 31 December

Implementing Organization: _____

Project No: _____

Project Title: _____

Reporting Period: _____

1. Project Personnel required (Task Manager/Project Coordinator and Administrative Assistants)

Name / Functional Title	Nationality	Duration of Contract	Fee (in US\$)	Brief Terms of Reference	Object of Expenditure (code per the budget e.g 1101, 1301 etc..)

2. Experts/Consultants required:

Name / Functional Title	Nationality	Duration of Contract	Fee (in US\$)	Brief Terms of Reference	Object of Expenditure (code per the budget e.g 1201, 1202 etc..)

3. Sub-contracts required:

Name and Address of Organisation	Object of Expenditure (code per the budget e.g 2201, 2301 etc..)

4. Major items of equipment ordered: (Value over \$1,500)

Please attach to the 2nd quarter (April - June) and 4th quarter (Oct - Dec) progress reports an **inventory** of all non-expendable equipment, indicating date of purchase, description, serial number, quantity, location, cost and remarks, and for vehicles, give mileage report (see separate inventory list format).

5. Status of the implementation of the activities listed under **WORKPLAN** in the project document, and status of documents, reports, manuals, guidelines, etc.

(a) List actual activities/outputs* **completed/produced** under the following headings where appropriate:

(Please tick appropriate box)

(i) **Meetings** (envisaged under the project)

Intergovernmental (IG) Mtg ☐ Expert Group Mtg ☐ Training/Seminar Workshop ☐ Others ☐

Title _____

Venue and Dates _____

Convened by _____ Organized by _____

Report issued as doc. no. /symbol _____ Languages _____ Dated _____

For Training Seminar/Workshop, please indicate: No. of participants _____ and attach **Annex** giving names and nationalities of participants.
Annex (Participants List, Quarterly Progress Report))

Name	Nationality

(ii) **Printed Materials**

Report to ☒ Mtg ☐ Technical Publication ☐ Technical Report ☐ Others

Title _____

Author(s)/Editor(s) _____

Publisher _____

Symbol (UN/UNEP/ISBN/ISSN) _____

Date of publication _____ (when the above reports have been distributed, attach the distribution list).

(iii) ☐ **Technical Information** ☐ **Public Information**

Description _____

Dates _____

(iv) **Technical Cooperation**

☐ Grants and Fellowships ☐ Advisory Services ☐ Others (describe)

Purpose _____

Place and Duration _____

For Grants/Fellowships, please indicate:

Beneficiaries	Countries/Nationalities	Cost (in US\$)
_____	_____	_____
_____	_____	_____
_____	_____	_____

(b) Status of activities/outputs underway:

- (i) Meetings, seminars, workshops study tours, training courses, fellowships under preparation
- (ii) Status of documents, reports, manuals, guidelines being prepared
- (iii) Status of studies, surveys underway
- (iv) Status of implementation of other activities

6. Summary of the problems encountered in project delivery (if any)
7. Actions taken or required to solve the problems identified in (5) above

ANNEX 6: CASH ADVANCE STATEMENT

Statement of cash advance as at
And cash requirements for the quarter of

Name of cooperating agency/

Supporting organization

Project No.

Project title

I. Cash statement

1. Opening cash balance as at US\$ _____

2. Add: cash advances received:

Date	Amount
.....
.....
.....
.....

3. Total cash advanced to date US\$ _____

4. Less: total cumulative expenditures incurred US\$ (_____)

5. Closing cash balance as at US\$ _____

II. Cash requirements forecast

6. Estimated disbursements for quarter
ending US\$ _____

7. Less: closing cash balance (see item 5, above) US\$ (_____)

8. Total cash requirements for the
quarter US\$ _____

Prepared by _____ Request approved by _____

Duly authorized official of cooperating agency/ supporting organization

ANNEX 7: FORMAT OF QUARTERLY PROJECT EXPENDITURE ACCOUNTS FOR SUPPORTING ORGANIZATIONS

Quarterly project statement of allocation (budget), expenditure and balance (Expressed in US\$) covering the period

..... to

Project No.

Supporting Organization

Project title:

Project commencing:

Project ending:

(date)

(date)

Object of expenditure by UNEP budget code	Project budget		Expenditure incurred				Unspent balance of budget	
	allocation for year.....		for the quarter		Cumulative expenditures this year		allocation for year	
	m/m (1)	Amount (2)	m/m (3)	Amount (4)	m/m (5)	Amount (6)	m/m (7)	Amount (2)-(6)
1100 Project personnel								
1200 Consultants								
1300 Administrative support								
1400 Volunteers								
1600 Travel								
2100 Sub-contracts								
2200 Sub-contracts								
2300 Sub-contracts								
3100 Fellowships								
3200 Group training								
3300 Fellowships								
4100 Expendable equipment								
4200 Non-expendable equipment								
4300 Premises								
5100 Operation								
5200 Reporting costs								
5300 Sundry								
5400 Hospitality								
99 GRAND TOTAL								

Signed: _____

Duly authorized official of supporting organization

NB: The expenditure should be reported in line with the specific object of expenditures as per project budget

ANNEX 8: TERMINAL REPORT (For External Projects Only)

Implementing Organization _____

Project No.: _____

Project Title: _____

1. Project Needs and Results

Re-state the needs and results of the project.

2. Project activities

Describe the activities actually undertaken under the project, giving reasons **why some activities were not undertaken, if any.**

3. Project outputs

Compare the outputs generated with the ones listed in the project document.

List the actual outputs **produced but not included in previous Progress Reports** under the following headings

(Please tick appropriate box)

(a) **MEETINGS** (UNEP-convened meetings only)

Inter-governmental (IG) Mtg. Expert Group Mtg. Training Seminar/Workshop Others

Title: _____

Venue and dates _____

Convened by _____ Organized by _____

Report issued as doc. No/Symbol _____ Languages _____ Dated _____

For Training Seminar/Workshop, please indicate: No. of participants _____ and attach **annex** giving names and nationalities of participants.

(b) **PRINTED MATERIALS**

Report to IG Mtg. Technical Publication Technical Report Others

Title: _____

Author(s)/Editor(s) _____

Publisher _____

Symbol(UN/UNEP/ISBN/ISSN) _____

Date of publication _____

(When technical reports/publications have been distributed, attach **distribution list**)

(c) **TECHNICAL INFORMATION**

PUBLIC INFORMATION

Description _____

Dates _____

(d) **TECHNICAL COOPERATION**

Grants and Fellowships

Advisory Services

Staff Missions

Others (describe)

Purpose _____

Place and duration _____

For Grants/Fellowships, please indicate:

<u>Beneficiaries</u>	<u>Countries/Nationalities</u>	<u>Cost(in US\$)</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(f) **OTHER OUTPUTS/SERVICES**

For example, Networking, Query-response, Participation in meetings etc.

4. **Use of outputs**

State the use made of the outputs.

5. **Degree of achievement of the objectives/results**

On the basis of facts obtained during the follow-up phase, describe how the project document outputs and their use were or were not instrumental in realizing the objectives/results of the project.

6. **Conclusions**

Enumerate the lessons learned during the project execution. Concentrate on the management of the project, indicating the principal factors which determined success or failure in meeting the objectives set down in the project document.

7. **Recommendations**

Make recommendations to:

(a) Improve effect and impact of similar projects in the future;

(b) Indicate what further action might be needed to meet the project objectives/results.

8. **Non-expendable equipment (value over US\$1,500)**

Please attach to the terminal report a **final** inventory of all non-expendable equipment (if any) purchased under this project, indicating the following:

Date of purchase, description, serial number, quantity, cost, location and present condition, together with your **proposal** for the disposal of the said equipment.

**ANNEX 9: INVENTORY OF NON-EXPANDABLE EQUIPMENT PURCHASED AGAINST UNEP PROJECTS
UNIT VALUE US\$1,500 AND ABOVE AND ITEMS OF ATTRACTION**

As at _____

Project No. _____

Project Title _____

Executing Agency: _____

Internal/SO/CA (UNEP use only) _____

FPMO (UNEP) use only _____

Description	Serial No.	Date of Purchase	Original Price (US\$)	Purchased / Imported from (Name of Country)	Present Condition	Location	Remarks/recommendation for disposal

The physical verification of the items was done by:

Name: _____

Signature: _____

Title: _____

Date: _____