MSP PROJECT BRIEF

Project Identifiers

1. **Project name:**	2. **GEF Implementing Agency**:
Support to the Implementation of the National Biosafety Framework	UNEP
3. **Country/ies in which the project is being implemented**: Poland	4. **Country eligibility**: Poland ratified the Convention on Biological Diversity on 16 January, 1996 and signed the Cartagena Protocol on biosafety on 24 May, 2000
5. **GEF Focal Area**: Biodiversity	6. **Operational Programme**: The project relates to biosafety issues and cross cuts the Biodiversity Operational Programmes 1,2,3,4, and follows the Initial Strategy adopted by the GEF Council in November 2000.

7. **Project linkage to national priorities, action plans and programmes**:

- Products of modern biotechnology will be soon on the market in Poland and new crop varieties obtained with biotechnological methods are already being tested in strictly controlled field trials. It means that the experimental deliberate release of LMOs plant is taking place. Both these factors make the implementation of the National Biosafety Framework (NBF) an urgent need. The task of the National Biosafety Framework is to provide biological security with respect to release and use of genetically modified organisms.
- The development and implementation of a National Biosafety Framework is consistent with the Polish Biodiversity Conservation Strategy, which sets it up as high priority.
- Due to the risk arising from the use of products obtained from genetically modified organisms in human and animal feed, and in the light of possible negative ecological effects and moral reservations related to releasing such organisms to the environment, there is a need for legal regulations to be developed and introduced for handling LMOs and their products. International commitments undertaken by Poland set the need for laws concerning living modified organisms to be in compliance with international standards set by:
  - The Convention on Biological Diversity
  - The Cartagena Protocol
  - The EU Directives: Council Directive 90/220/EEC of 23rd April 1990 on deliberate release into the environment of genetically modified organisms (*Official Journal No L117/15*) as amended by Directive 2001/18/EC of 12 March 2001 (*Official Journal L106/1*),
  - Council Directive 90/219/EEC of 23rd April 1990 on the closed use of genetically modified organisms (Official Journal No L 117/15) as amended by Directive 98/81/EC (Official Journal L 330/13).
- The National Biosafety Framework (NBF) for Poland was prepared thanks to the support given by UNEP and GEF in the form of Pilot Biosafety Enabling Activity project (GF 1200-98-84) NBF for Poland was prepared. For the implementation of the National Biosafety Framework a substantial effort in capacity building is needed and this project outline is prepared in order to obtain UNEP/GEF support. Such support would be crucial for successful implementation of the NBF in Poland and will enable the ratification and fulfilment of Poland's obligations under the Cartagena Biosafety Protocol.
  An "*Act on Genetically Modified Organisms*" aiming at regulating problems arising with respect to LMOs has signed, published in the Polish Official Journal on 25
  july 2001 No. 76. 811 and entered into force on the 26 october 2001. This has been formulated as the priority 22.7 "Establishment of monitoring system of utilisation of LMOs" within the framework of harmonisation of Polish legislation with European Union regulations.

8. **GEF national operational focal point and date of country endorsement:**
   Submitted: **Acknowledged**: **Endorsed**:

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Project Objectives and Activities

9. **Project rationale and objectives**: **Goal: To support the implementation of the objective of the Cartagena Protocol on Biosafety in the signatory countries** **Objective:** Implementation of the National Biosafety Framework in Poland. **Specific objectives** are set as follows:	**Indicators:**
A) Strengthen the national infrastructure needed for risk assessment and monitoring of Living Modified Organisms (LMOs)	➢ Enforcement of new biosafety legislation
B) Strengthen, and where needed build, capacity on biosafety issues, especially in the areas of: • Risk assessment and risk management taking into account Articles 15 and 16 and Annexes I-III of the Cartagena Protocol • Testing and monitoring • Legal issues • Administrative arrangements.	➢ Functioning of a system of control and monitoring of contained use and deliberate release to the environment and transboundary movement of Living modified organisms ➢ Development of an information system on biosafety related issues as required in the Cartagena Protocol
C) Strengthen information sharing by developing integrated databases to be linked to the Biosafety Clearing House (BCH).	➢ Increase capacity of governmental administration and society on GMO
D) Enhance national capacity for public awareness on biosafety related issues	
10. **Project outcomes**:	**Indicators:**
A.1) 2 reference laboratories equipped to carry out analysis on LMOs and related products as follows: • LMOs involved in transboundary movement; • Living modified plants released to the environment, • LMOs used in containment, • for food products or where appropriate, products thereof (Article 20(3c), Annex I(i) and Annex III(5) of the Cartagena Protocol)	➢ 2 reference laboratories active to carry out LMOs analysis. ➢ Minimum of 10 participants/training
(B.1) 7 Training carried out to train trainers (12 participants/courses) on: • risk assessment and risk management according to Articles 15 and 16 of the	

Protocol • testing and monitoring • Legal issues • Administrative arrangements in biosafety. (B.2) A final national workshop with 70 participants including NGOs and media and international experts organized on the various aspects of the implementation of the Act "On Genetically Modified Organisms" in relation to the requirements of the Cartagena Protocol. It will focus on transboundary movements issues, risk assessment, management and monitoring of LMOs as well as socio-economic considerations arising from the impact of LMOs. (C.1) Set up a Biosafety Database System (to be connected to the Biosafety Clearing House Mechanism); (C.2) Website in operation (D.1) Published and disseminated : • guidelines to be used by different users and managers. The guidelines will cover LMO related aspects, for example, customs controls, monitoring and control, variety registration, risk assessment, central administration, reference laboratories, notifiers. (D.2) Developed strategies for public awareness (TV and radio programme, newsletter, etc). (D.3) Two opinion polls on biosafety related issues carried out at the beginning and at the end of the project (D.4) Best practices and lessons learnt disseminated	➢ Workshop organized, proceedings available ➢ Database in operation and connected to the BCH ➢ Website active and connected to the database and the BCH ➢ Technical Guidelines published and disseminated among the main stakeholders ➢ Report on the quality of the survey, results available
11. Planned activities to achieve outcomes (including cost in US$ or local)	**Indicators**:
(a.1) Equip 2 reference laboratories to carry out inspections on LMOs and related products • In relation to the transboundary movement of GMOs; • For LMOs released to the environment, • For LMOs used in containment, • For food products **(TOTAL: 1,369,000 USD;GEF:244,000 USD)**	➢ Laboratory equipment purchased
(b.1) Organise the following 7 training workshops for twelve trainers as follows: (training is not really a noun in English) • Two days workshop for decision-makers on biosafety decision-making issues; • Four days workshop for senior officials from the Ministry of Agriculture, Ministry of	1.

Health, Ministry of Environment on biosafety administrative procedures (as required by the GMO Act) • Four days workshop for potential applicant companies on biosafety administrative procedures and risk assessment. • Five days workshop for food and veterinary inspection officers on risk assessment, management and monitoring • Two days workshop for custom officials introducing general information on laws, regulations, practice of domestic and foreign biosafety management, introducing the procedures for the application and approval of LMOs. • Five days workshop for technicians from the reference laboratory on methods of GMO detection, legal status of GMO in Poland and other countries, methods of monitoring and risk assessment. • Three days workshop for local governments and non-governmental organisations on the objectives of existing and prepared law, responsibilities and rights coming from the national law and international agreements. (b.2) Organisation of a final national workshop with 70 participants including NGOs, media as well as international experts, in order to report on the implementation of National Biosafety Framework **(TOTAL: 556,500USD;GEF:96,000 USD)**	• Proceedings from the workshop. • List of participants.
(c.1) Setting up a database to be linked to the BCH and containing all the information required by the Cartagena Protocol (Article 20 and Articles 6, 10, 11, 12, 13, 14, 17, 19, 23, 24 and 25) as follows: • applications for permits, • laboratory and field trails, • permits for the release of GMO to environment/market, • product containing GMO, • transboundary movement of LMO (import and export), • GMO risk assessment, monitoring and control. (c.2) Open a project website **(TOTAL:482,750USD;GEF:50,000 USD)**	• Real time interaction between the Biosafety Database System and the Biosafety Clearing House Mechanism • Number of hits on the web
(d.1) Preparation, publication, dissemination of set of guidelines to be used by different users and managers. The guidelines will cover LMO related aspects, for example, customs controls, monitoring and control, variety registration, risk assessment, central administration, reference	Finalization of the different sets of technical guidelines by user .

laboratories, notifiers. (d.2) Develop strategies for public awareness (TV and radio programme, newsletter, etc). (d.3) 2 Public opinion polls among a representative sample of the population about the National Biosafety Framework, to be held at the beginning and at the end of the project (d.4) Dissemination of best practices and lessons learnt **(TOTAL: 175,200 USD;GEF:70,000 USD)**	

12. Estimated budget (in US$)

GEF:	460, 000USD
Associated financing (EU, PHARE programme) :	2,068, 450USD
In-kind contribution:	88,100
Total:	2,616, 550USD

13. Information on project proposer:

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15. **Date of initial submission of project concept**: 1 September 1999

16. Project Identification number:
Not yet assigned

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

18. **Project linkage to Implementing Agency program**(s):

As the financial mechanism of the Convention on Biological Diversity, the GEF is also called upon to serve as the financial mechanism of the Cartagena Protocol on Biosafety.

GEF Council during its meeting in May 9-11, 2000, "welcomed the adoption of the Cartagena Protocol on Biosafety, including Article 28 of the Protocol which provides that "the financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol". The Council requested the Secretariat, in consultation with the Implementing Agencies and the Secretariat of the Convention on Biological Diversity, to inform the Council at its next meeting of its initial strategy for assisting countries to prepare for the entry into force of the Protocol. The Council also requests UNDP and the GEF Secretariat to take into account the provisions of the Cartagena Protocol in the on-going work of the Capacity Development Initiative".

A Ministerial Round Table on “Capacity-building in Developing Countries to Facilitate the Implementation of the Protocol” was held in Nairobi on 23 May 2000 during the Fifth Conference of the Parties to the CBD. The Ministerial Round Table acknowledged the need for capacity-building at the national level, in order to allow “the safe use of modern biotechnology, in particular the safe transfer of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity between countries which may have very different climatic, social and

economic conditions". Paragraph 9 of the Statement of the Ministerial Round Table emphasizes "the importance of the financial mechanism and financial resources in the partnership that the Protocol represents and welcome the commitment of **GEF to support a second phase of the UNEP/GEF Pilot Biosafety Enabling Activity project**". The need for capacity-building was also emphasized at the GEF workshop on the UNEP/GEF Pilot Biosafety Enabling Activity held on 24th May 2000 in the margins of CBD COP5 with the participation of more than 150 delegates.

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

The GEF Initial Biosafety Strategy as well the UNEP/GEF biosafety projects, including the results of the pilot project, which included Poland, were presented and discussed during the plenary meeting of Working Group II of the First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety, held in Montpelier on 11-15 December 2000. The UNEP/GEF projects were further discussed during a side event held on 13th December at the margins of the meeting. The Montpellier Declaration reiterated that capacity-building for many Parties, especially developing countries, in particular the least developed and small island developing States among them, is the foremost priority for the moment, acknowledged that action to address these needs must be demand driven, identified the framework of these needs and highlighted various means to meet these needs, including the UNEP/GEF biosafety initiative." The meeting urged UNEP "to expedite the implementation of the project entitled Development of National Biosafety Frameworks in a flexible manner, having regard to the comments made by the Intergovernmental Committee for the Cartagena Protocol 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, covering 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda, Zambia, Malawi), consisted of the following two components:

- a *National Level Component* aiming at assisting eighteen eligible 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 (US$ 0.8 million).

3. Each country in the pilot project went through some important stages needed to provide the foundation for the implementation of the National Biosafety Frameworks (and its modification to take account of the terms of the Cartagena Protocol), and included requirements to:

- Assess the existing national capacity and roles in environmental release of LMOs and their products;
- Develop the methods, techniques, standards, guidelines, indicators for assessing and monitoring the risks, and control and regulatory measures for those risks likely caused by the transportation, release, commercialization 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 understanding and concern 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.

5. The project "Implementation of the National Biosafety Framework" for Poland 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*.

6. Thanks to the support given by UNEP and GEF in the form of Pilot Biosafety Enabling Activity project (GF 1200-98-84), the National Biosafety Framework (NBF) for Poland was prepared. The NBF aims at providing the indispensable level of biological security with respect LMOs release and use, given both the risks associated with their use in food and feed nd the possible negative ecological implications of the release of such organisms into the environment. The implementation of the Framework requires a substantial effort in capacity building. GEF support is therefore considered crucial in facing the following needs:

- The development of implementation mechanisms of NBF by strengthening the institutions serving as centres of excellence, expertise and reference laboratories for monitoring.
- Training of the trainers, particularly in the areas of:
  - risk assessment and risk management;
  - testing and monitoring;
  - legal issues;
  - Administrative arrangements
- Increase in public awareness on issues relating to the use of living modified organisms, including providing information and answers for the media and NGOs;
- Development of information resources in the form of various databases (on experts, biosafety programs, research activities etc.).

Current situation

1. In June 1996, following the initiative of the Polish Ministry of Agriculture and Food Industry, an Interdisciplinary Consultative Group on genetically modified organisms (GMOs) was established with the following responsibilities:

- examining legal regulations,
- Assessing applications for the release of GMOs to the environment in Poland (certified field trials).

This interdisciplinary Group assembles the representatives of science and government. The Ministry of Agriculture and Food Industry also appointed a Commission for Registration of Biological and Chemical Plant Protective Agents and Transgenic Plants. An Interdisciplinary Consulting Group elaborated standard application forms for the admission of transgenic plants to field experiments. These formats were prepared according to recommendations of the EU Council Directive 90/220

2. In 1997 the Interdisciplinary Consulting Group received four applications for permission to conduct field experiments. At the same time the Parliament of the Polish Republic addressed a need for establishing the principles for conducting experiments with GMOs and assessing the risks. In July 1997 an Environmental Protection Act was amended. Article 37A of this Act entitles the Minister of Environmental Protection, Natural Resources and Forestry in consultation with the Minister of Health and Social Welfare, Minister of Agriculture and Food Industry and with the Chairman of the Committee for Scientific Research to regulate by decrees the following issues:
   - requirements for applications for permissions to release GMOs to the environment and their marketing,
   - requirements for assessment of environmental and health hazards. The range of studies and analyses which are necessary to prepare an expertise are to be established.
   - requirements for labelling and packaging of GMO s and products thereof.

   Article 37A (see Annex 1) has been in force since 1.01.1999. The decree, containing executive regulations has been signed by the Minister of Environment of 8 Oct. 1999. Application forms were prepared according to the European Union directives.

3. A new act "On Genetically Modified Organisms" was signed, published in Polish Official Journal on 25 July 2001 No. 76. 811 and entered into force on 26 October 2001[1]. The law is consistent with Cartagena Protocol signed by Poland in 2000 and with the standards set by the following International commitments undertaken by the country:
   - Convention on Biodiversity
   - Cartagena Protocol
   - EU Directives: Council Directive No 90/220/EEC of 23rd April 1990 on deliberate release into the environment of genetically modified organisms (Official Journal No L 117/15),
   - Council Directive No 90/219/EEC of 23rd April 1990 on the closed use of genetically modified organisms (Official Journal No L 117/15), as amended by 98/81 and by 2001/18

   This obligation has been formulated as the priority 22.7 “Establishment of monitoring system of utilisation of LMOs” in the framework of harmonisation of Polish legislation with European Union regulations.

[1] The Law is not available in English, it's currently under translation.

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

The GEF Alternative supports specific aspects of the biosafety implementation in Poland and complements other activities currently carried out in the field in view of the country's accession to EU. In particular, this intervention makes sure that the biosafety framework developed during the Pilot Project phase becomes operational through the implementation of the Act on GMOs, and, more in detail, by supporting the achievement of the following outcomes:

A.1) 2 reference laboratories equipped to carry out analysis on LMOs and related products as follows:
- LMOs involved in transboundary movement;
- Living modified plants released to the environment,
- LMOs used in containment,
- for food products or where appropriate, products thereof (Article 20(3c), Annex I(i) and Annex III(5) of the Cartagena Protocol)

(B.1) 7 Training carried out to train trainers (12 participants/courses) on:
- risk assessment and risk management according to Articles 15 and 16 of the Protocol
- testing and monitoring
- Legal issues
- Administrative arrangements in biosafety.

(B.2) A final national workshop with 70 participants including NGOs and media and international experts organized on the implementation of the Act "On Genetically Modified Organisms" in relation to the requirements of the Cartagena Protocol. It will focus on transboundary movements issues, risk assessment, management and monitoring of LMOs as well as socio-economic considerations arising from the impact of LMOs.

(C.1) Set up a Biosafety Database System (to be connected to the Biosafety Clearing House Mechanism);
(C.2) Website in operation

(D.1) Published
- technical guidelines for different groups of users and managers on 1) administrative legislative arrangements for biosafety management, 2) risk assessments, management and monitoring 3) biosafety management practice in neighbouring countries;
- best practices.

(D.2) Two opinion polls on biosafety related issues carried out at the beginning and at the end of the project

Activities and financial inputs needed to enable changes

a. Strengthen national infrastructure (reference laboratories) as needed for risk assessment and monitoring

The system of control of the use of genetically modified organisms and their products have to be supported by reference laboratories, which provide expertise on genetically modified plants, animals, food and feed. These responsibilities are delegated to the already existing scientific institutions e.g. Institute of Food, Plant Breeding and Acclimatization Institute, Institute of Plant Protection, Institute of Biochemistry and Biophysics, Polish Academy of Science and the Institute of Plant Genetics. Based on the GMOs Law just entered into force, the Ministry of Environment in agreement with the Ministry of Agriculture and Ministry of Health will designate the reference laboratories by choosing between the institutions, which are under their jurisdiction[2]. The laboratories will provide expertise with respect to those products, which are within their competence. The reference laboratories will also provide technical support to the biosafety system and will be involved in the training activities.

Under this project, 2 reference laboratories, involved in research on GMO and equipped with basic instruments for DNA isolation, determination and electrophoresis, will be strengthened with additional equipment needed (Quantitative PCR) to meet the requirements of the Cartagena Protocol to carry out inspections on LMOs and related products as follows:

- LMOs involved in transboundary movement
- Living modified plants released to the environment
- LMOs used in containment,
- food products containing LMOs or where appropriate, products thereof (Article 20(3c), Annex I(i) and Annex III(5) of the Cartagena Protocol)

The list of the equipment requested under this project is presented in Annex 4.

b. Training and workshops

Training

Given that many decision-makers, managers, administrators, customs officials and other parties involved are short of knowledge and experience on biosafety management, training activities for 12 trainers per course are to be organized as follows:

- Two days training workshop for decision-makers on biosafety decision-making issues;
- Four days training workshop for senior officials from the Ministry of Agriculture, Ministry of Health, Ministry of Environment on biosafety administrative procedures (as required by the GMO Act)
- Four days training workshop for potential applicant companies on biosafety administrative procedures and risk assessment.
- Five days training workshop for food and veterinary inspection officers on risk assessment,

[2] The Ministry of Environment has taken no official decision in this respect yet. Tentatively, the laboratories should be: the one at Plant Breeding and Acclimatization Institute in Radzikow (05-870 BLONIE) under the Ministry of Agriculture and Rural Development (for Plants, Plant products, Feed, Environmental impact, transboundary movement of LMOs and its products) and the one at National Institute of Hygiene in Warsaw (ul. Chocimska 24, 00-791 WARSZAWA) under the Ministry of Health (for food, cosmetics, chemical consumer goods (detergents, household chemicals, etc.), transboundary movement of the above LMOs and its products)

management and monitoring

- Two days training workshop for custom officials introducing general information on laws, regulations, practice of domestic and foreign biosafety management, introducing the procedures for the application and approval of LMOs.
- Five days training workshop for technicians from the reference laboratory on methods of GMO detection, legal status of LMOs in Poland and other countries, methods of monitoring and risk assessment.
- Three days training workshop for local governments and non-governmental organisations on objectives of existing and prepared law, responsibilities and rights arising from the national law and international agreements.

Workshop

A national workshop will be organised on the aspects of the practical implementation of the Act "On Genetically Modified Organisms" in relation to the requirements of the Cartagena Protocol. It will focus on transboundary movements issues, risk assessment, management and monitoring of LMOs as well as socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity. Senior and medium ranking officials and decision-makers in biosafety matters and international experts will be invited to attend. The presence of NGOs and the media will be expected.

c.Information component

The establishment and implementation of an efficient and effective information system is a key element in the Convention on Biological Diversity as well as in the Biosafety Protocol. Article 20 of this Protocol refers to the issue of information exchange via the Clearing House Mechanism. The UNEP Technical Guidelines for Safety in Biotechnology recommends establishment of *national biosafety information* exchange system. Poland has to adopt CBD standards and also observe those set up by the European Community in respective directives in order to comply with the negotiation process of Polish membership in the EU.

The database will provide a register of all national activities concerning GMO such as trade, industrial and legislative initiatives and products containing GMO. Thus the information gathered in the database files will relate to:

- Applications,
- Laboratory and field trails,
- Permissions for the release of GMO to environment/market,
- Product containing GMO,
- Transboundary movement of GMO (import and export),
- GMO risk assessment, monitoring and control.

The biosafety database will be part of biodiversity information management system (CHM) and will be integrated with currently developed specific biodiversity applications and GIS allowing consolidation of all data necessary for risk assessment.

Data maintained in the database will be available on request for institutions such as those involved in food and pharmaceutical industry. Some information will be maintained confidential and not be released. Confidentiality clause will however not apply to data related to biosafety and environment protection. International database for the purpose of Secretariat of the CBD, prepared as a subset of national

database, will be available to fit in the Biosafety Clearing House Mechanism system (BCHM).

A biosafety website will be opened. It will contain policies, laws, planning, priority and measures for biosafety management, mechanisms for searching other databases, and links to the main biosafety Web sites in the world and in the country. The biosafety-clearing house will be accessible from the web.

d.Public awareness and public participation in the decision making process

Polish society is aware of and interested in biotechnology development and its implication for human life and environment. Society demands and has every right to be granted access to information and to participate actively in the decision making process with regard to matters concerning GMO. Strategies to address the public will be developed as well as sets of technical guidelines to be used by different users and managers will be developed and published. The guidelines will cover the following subjects:

- *Risk assessment* – Each set of technical guideline will describe the risks to the environment as well as suggested procedures for risk management according to the respective regulations,
- *Administration* – The functions of the Minister's and their responsible officers in the LMOs application and monitoring procedure will be described
- *Reference laboratories*- the detection methods of LMOs and information system of the laboratories with respect to the responsible organs of administration, the system of control of genetically modified organisms and their products used by the laboratory (which provide expertise on genetically modified plants, animals, food and feed) will be described.
- *Application*- the procedure for applications to the decision makers through the Experts Committee for Genetically Modified Organisms, the timing for application review, document circulation etc. will be described.
- *Monitoring*- Monitoring and control through different inspections services like food inspection, sanitary inspection, plant protection inspection, veterinary inspection, custom service etc.
- *Variety registration*: according to the new GMO law, the Centre For Registration of Cultivated Plants (Coboru) is responsible for testing and registration of cultivation in Poland

The guidelines will be available in Polish and in English.

Best practises and lessons learnt will be disseminated for replication in other countries of the region.

In addition, access to information will be ensured through:

- Providing to the public information that are not covered by confidentiality clauses. Data assembled in international database/bases will be accessible (e.g. via internet) as well as information on other sources of relevant data such as databases of international organisations and the CHM will be communicated and made available.
- Important contribution of widely acknowledged periodical on GMO releases, ongoing or completed research, methodology of assessment and management control of GMO hazard.

Finally, public opinion polls on the level of awareness on biosafety related issues will be held at the beginning and at the end of the project. The results will be used for the purpose of the project (development of the technical guidelines) and for identifying the major information needs in the national policy for addressing the public.

Sustainability analysis and risk assessment

The main elements to be considered to analyse the sustainability and the risks associated to this project are the following:

1. Realisation of the project is closely related to implementation of the Act of GMO. The government as initiator of the Act has an obligation to secure adequate finances for its implementation. The implementation costs are estimated in the GMO Act. It is presumed that in the future funds collected, as application fees will cover part of costs involved in administration, functioning of references laboratories and costs of risk assessment.
2. At the present stage of project preparation not all the planned resources are available. PHARE project "Implementation of Biosafety Framework" has not yet started.
3. The limited financing available poses a threat to the implementation of the Cartagena Protocol. In particular the limited financing devoted to the fundamental and applied research related to risk assessment and management.
4. Development of this project will improve the sustainability of social and economic development and will have a positive impact for the environment.

Stakeholder involvement and social assessment

In the project the following stakeholders will be involved as follows:

STAKEHOLDERS	**Type of involvement**
Ministries (Ministry of the Environment, Ministry of Agriculture and Rural Development, Ministry of Economy, Ministry of Health, Committee of Scientific Research)	➢ Preparing legislation and implementing guidelines.
Other Government Agencies	➢ Including GMO issues in their statutory activity plan.
Research Institutions	➢ Preparing instructions for risk assessment
Economic and Consumers Organizations	➢ Implementation of established procedures used for GMO (LMO)
Local Government	➢ Preparing procedures to inform the public
Non Government Organizations	➢ Participation in the decision making process

INCREMENTAL COST ASSESSMENT

Poland has signed the Biosafety Protocol on the 25th of May 2000. The development and implementation of a National Biosafety Framework is consistent with the Polish Biodiversity Conservation Strategy, which sets it up as high priority.

Thanks to the support given by UNEP and GEF in the form of Pilot Biosafety Enabling Activity project (GF 1200-98-84), NBF for Poland was prepared. For the implementation of the above-mentioned NBF a substantial effort in capacity building is needed and this project outline is prepared in order to obtain UNEP/GEF support for this task. Such support would be crucial for successful implementation of NBF in Poland and will enable the ratification and the fulfillment of Poland obligations under the Cartagena Biosafety Protocol. In this respect, the previous GEF-funded enabling activity "Development of a National Biosafety Framework" carried out over the past two years in eighteen pilot countries 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.

A new act "On Genetically Modified Organisms" was signed, published in Polish Official Journal on 25 July 2001 No. 76. 811 and entered into force on 26 October 2001. This obligation has been formulated as the priority 22.7 “Establishment of monitoring system of utilization of GMOs” in the framework of harmonization of polish legislation with the European Union regulations. The Act on GMO contains estimations of minimal costs of implementation of this legislation at administrative level, equal to 182500 USD for the first year and to 472500 USD for the second year.

The project complements activities carried out in the field under the EU programme "PHARE" specifically devoted to CEE countries, as shown in detail in table B of the "Budget". The EU project covers the finalization of the biosafety administrative framework: therefore no additional financing is requested under GEF for this component. Given the above, the baseline is composed of the national financing and the EU financing.

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, Poland has benefited of a in-kind training workshop for an estimated equivalent amount of 10,000USD.

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

Strengthening national facilities	Laboratories in Poland are currently only equipped with basic instruments for DNA isolation, determination and electrophoresis. They need to be strengthened in order to improve its ability to screen LMOs and monitor/ manage the risks associated to their transfer, handling and use	The laboratories at Plant Breeding and Acclimatization Institute in Radzikow (under the Ministry of Agriculture and Rural development) and the National institute of Hygiene in Warsaw (under the Ministry of Health) strengthened with specific laboratory equipment (PCR equipment,…) equipped in order to carry out inspections as required under the risk assessment and management procedure	Risk assessment and management improved through the strengthening of national facility and therefore ability to screen LMOs
Training and workshops	Need for strengthening capacity among those involved in the biosafety management system	Capacity strengthened by training for trainers on specific subjects (risk assessment and risk management according to Articles 15 and 16 of the Protocol, testing and monitoring, legal issues, administrative arrangements in biosafety).	Strengthened national capacity to service commitments under the Cartagena Protocol
The establishment of a Biosafety Database system to serve for the purpose of the Biosafety Clearing House Mechanism	An organized database system to serve for the purpose of the Biosafety Clearing House is still missing.	A national information system as required by the Protocol for the purpose of the BCH (database as well as web site) with all the information required by the Cartagena Protocol (Article 20 and Articles 6, 10, 11, 12, 13, 14, 17, 19, 23, 24 and 25), i.e. applications for permits, laboratory and field trails, permits for the release of GMO to environment/market, product containing GMO, transboundary movement of LMO (import and export), GMO risk assessment, monitoring and control.	The setting up of the national database, the collection of the related information, the opening of a web site are the basic activities needed to make the Central BCHM as structured in the Protocol operational
Capacity building for public awareness	Lack of adequate capacity for public awareness purposes	Capacity for public awareness purposes strengthened through specific activities as dissemination of set of guidelines to be used by different users and managers, strategies for public awareness (TV and radio programme, newsletter, etc), public opinion polls, dissemination of best practices and lessons learnt	Public awareness capacity enhanced

As shown in the table below, the cost of the increment is of ***USD 548,000*** of which ***USD 460,000*** is being requested from the GEF; the remaining ***88,100USD*** is provided as in-kind contribution by Poland

Table 1 - Incremental Cost Table (US$)

Project	**Baseline**	**Alternative**	**Increment**	**Cost to GEF**	**Co-financing**

component				**(Global Benefit)**	**(in-kind contributions by Poland)**
Project Coordination	-	30,600	-	-	**30,600**
Strengthening national facilities	1,125,000	1,369,000	244,000	244,000	-
Training and workshops	420,500	559,000	138,500	96,000	**42,500**
Information system	422,450	482,750	60,300	50,000	**10,300**
Public awareness	100,500	175,200	74,700	70,000	**4,700**
Total	**2,068,450**	**2,616,550**	**548,100**	**460,000**	**88,100**

BUDGET

Table A here below shows the budget for this project. Being the project carried out in parallel with other undergoing EU initiatives for CEE countries, Table B is showing which and how the activities complement each other.

Table 1a. Proposed budget

Component	**GEF Contribution**	**National co-financing**
1. Equipment component		
3-4 Reference laboratories equipped	244,000	
2. Training and workshop		
➢ 12 persons on decision-makers level x 2 days	4,800	
➢ 12 persons on administrative level x 4 days	9,600	
➢ 12 persons on users level x 4 days	9,600	
➢ 12 persons involved in risk assessment x 5 days	12,000	
➢ 12 persons from custom-house x 2 days	4,800	
➢ 12 persons from reference laboratories x 5 days	12,000	
➢ 12 persons involved in public participation x 3 days	7,200	
Workshop for 70 persons x 5 days	26,000	42,500
International experts	10,000	
Subtotal training component	96,000	
3. Information component		
Computers and software and website	50,000	10,300
Subtotal information component	50,000	
4. Public awareness and dissemination		
Support for publications, dissemination and other media activities	50,000	4,700
Public opinion pool about NBF 2 times at the beginning and at the end of the project	20,000	
Coordination of the project		30600*
Subtotal others	70,000	
Total	**460,000**	**88,100**

******* *salary of the officer working in the project provided by NEA*

Table 1b. Complementary activities carried out under other programmes

Component	**GEF Cost USD**	**Other sources PHARE EU**	**Other sources PHARE National Co-financing**	**Other sources NFOS National co-financing**	**NEA National contribution to GEF**
1. Strengthening of administrative framework					
Development of national legislation				7500	
Establishment of competent administrative framework		395000	25500		
Establishment of system of monitoring for country realises and transboundary movement; reviewing of technical capacities of scientific institutions for reference laboratories service; development of system for waste management		300000	20000		
Subtotal strengthening of administrative framework		***695000***	***45500***	***7500***	
2. Equipment component					
3-4 Reference laboratories equipped	***244000***	***900000***	***225000***		
3. Training and workshop					40,000
12 persons on decision-makers level x 2 days	4800				
12 persons on administrative level x 4 days	9600				
12 persons on users level x 4 days	9600				
12 persons involved in risk assessment x 5 days	12000				
12 persons from custom-house x 2 days	4800				
12 persons from reference laboratories x 5 days	12000				
12 persons involved in public participation x 3 days	7200				
Support for other training		395000	25500		
Workshop for 70 participants x 5 days	36000	4000			2,500
Subtotal training component	***96000***	***395000***	***25500***		***42,500***
4. Information component					
Computers and software	50000	395000	27450		10300
Subtotal information component	***50000***				***10300***
5. Public awareness and dissemination					
Support for publications and other media activities, dissemination	50000	95000	5500		4700
Public opinion pool about NBF 2 times, at the beginning and at the end of the project	20000				
Subtotal public awareness and dissemination	***70,000***				***4,700***
6. Coordination of the project					**30600**
Total	**460000**	2484000	328950	25000	**88,100**

IMPLEMENTATION PLAN
Duration of the project
3 years

	ACTIVITIES					
Completion of project activities	6	12	18	24	30	36
1. Equipment component						
3-4 Reference laboratories equipped	x	x				
2. Training component						
➢ 12 persons on decision-makers level x 2 days	x					
➢ 12 persons on administrative level x 4 days	x					
➢ 12 persons on users level x 4 days			x			
➢ 12 persons involved in risk assessment x 5 days				x		
➢ 12 persons from custom-house x 2 days		x				
➢ 12 persons from reference laboratories x 5 days		x				
➢ 12 persons involved in public participation x 3 days						x
Workshop for 70 persons x 5 days						x
3. Information component						
Computers and software and website	x	x	x	x	x	x
4. Public awareness						
Support for publications and other media activities				x	x	x
Public opinion pool about NBF 2 times at the beginning and at the end of the project	x					x

PUBLIC INVOLVEMENT PLAN

Non Governmental Organizations representing society, producers and consumers organizations will be allowed to actively participate in decision making process regarding all activities with and related to GMO. Their involvement will be extremely importance with respect to those products of particular interest for the public, e.g. agricultural crop plants, human food products, animal feed. In fact, to achieve efficiency and effectiveness of the process, the new regulation ensures that representatives of NGO's, producers' and consumers' organizations will take part to the decision making process by reviewing all the proposals for decision elaborated by the Committee for Genetically Modified Organisms. This procedure will allow the public to voice their opinion, which then would have to be considered and evaluated by the Minister of Environment.

Public participation will be ensured also by establishment and implementation of an efficient and effective information system.. Such obligation accrues from the Convention on Biological Diversity and is reinforced by the Biosafety Protocol. The article 20 of this Protocol refers to the issue of information exchange via Clearing House Mechanism. The UNEP Technical Guidelines for Safety in Biotechnology recommends as well the setting up of national biosafety information exchange system.

Finally, as part of the project, public opinion polls are held at the beginning and at the end of the project.

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 indicators identified 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 UNDP as collaborating agency, will provide recommendations and assess the achievements done during the implementation of this project.
- A Steering Co-ordination Committee for the eight projects will be chaired by UNEP and will comprise the representatives of the National Executing Agency, the two other implementing agencies, the GEF Secretariat as well as FAO and UNIDO. In addition, experts selected on their personal capacity will be part of the Steering Committee as well as the representative of STAP when the Steering Committee will be addressing technical and scientific issues arising from the implementation of the MSPs.

LIST OF ANNEXES

ANNEX 1

Act on the Protection and Management of the Environment issued on 31.01.1998 (Official Journal of Law 1994, No 49, item 196 - uniform text, change OJ 1997, No 133, item 885)

Art. 37a.[3]

1. The deliberate release of genetically modified organisms into the environment for experimental purposes or placing of products containing genetically modified organisms or consisting of such organisms or their parts on the market requires permit issued by the Minister of Environmental Protection, Natural Resources and Forestry.

2. Genetically modified organisms mean the organisms with the changed genome structure as a result of removing of one or more genes or change of one or more genes and also by hybrids' breeding with the use of genetic engineering technics.

3. Along with a permit application as stated in paragraph 1, the applicant includes an assessment of threat for environment and human life.

4. The Minister of Environmental Protection, Natural Resources and Forestry should publish a list all publicly available products, as stated in paragraph 1, in form of an executive order.

5. The Minister of Environmental Protection, Natural Resources and Forestry may revoke the issued permit, when there is a threat of an deliberate release of genetically modified organisms to the environment for experimental purposes or when the product placed on the market and containing genetically modified organisms, or being made of such organisms or their parts, may cause a serious threat to the environment and human health than it is presented in the threat assessment as stated in paragraph 3.

6. Organisational unit which was granted the permit referred to in paragraph 1 is obliged to immediately inform the Minister of Environmental Protection, Natural Resources and Forestry on any case of increased threat referred to in paragraph 5.

7. Product referred to in paragraph 1 allowed to be placed on the market should be properly labelled and packed.

8. The Minister of Environmental Protection, Natural Resources and Forestry in agreement with the Minister of Health and Social Welfare, Minister of Agriculture and Food Management and the Chairman of the Scientific Research Committee shall define, in the form of executive order, upon the following:

1) requirements for permit applications referred to in section 1.,

2) requirements for environment and human health threat assessment, referred to in section 3., together with the required range of research and analyses,

[3] Art. 37a entered into force on 01.01.1999

3) requirements for marking and packing, referred to in section 7.

ANNEX 2

Poland: Summary of the National Biosafety Framework

Biosafety Framework in Poland

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

- assessing possible negative effects during deliberate release into environment,
- establishing monitoring system,
- planning emergency actions to deal effectively with accidents,
- establishing systems to provide consent and certification on each stage of experiments and deliberate release into the environment,
- establishing a competent authority with the mandate to provide advice, decisions and control on registration, consent for GMO release and codes of practice,
- developing information system,
- establishing international co-operation
- training personnel.

Coordinating body (National Competent Authority)

Genetically modified organisms have to be considered in three sectors of activities: contained use of GMOs, deliberate release into environment, and placing on the market of products containing genetically modified organisms or consisting of such organisms or their parts. In the European Union GMO issues are regulated by two directives: 90/219 (contained use) as amended by 98/81 in 1998 (which came into force in 2000) and 90/220 (deliberate release into environment and products) as amended by 2001/18 which will come into force in 2002.These two areas of GMO application (deliberate release into environment and products) are addressed by Polish law and are the responsibility of four governmental agencies (in accordance with article 37a of Act on the Protection and Management of the Environment of 31.01.1998 Official Journal of Law 1994, No 49, item 196 – uniform text change OJ 1997, No 133, item 885). These are the Ministry of Environment, Ministry of Health and Social Welfare, Ministry of Agriculture and the Scientific Research Committee.

It is expected that other ministries e.g. industry, education will be also involved in the future.

Each individual application is reviewed with regard to potential risk arising from deliberate or unintentional release of GMO into the environment. As the Minister of Environment is the National Coordinator for the implementation of the Convention on Biological Diversity the biosafety matter falls within its competence.

Committee for Genetically Modified Organisms

The Ministry for Environment will establish the Committee for Genetically Modified Organisms. The members of the Committee are representatives of the responsible ministries and group of experts. The Committee acts as advisory body, but also may play significant role in decision-making. The Committee may ask panels of outside experts designated by other ministries for advice.
The Committee for Genetically Modified Organisms will be entrusted with the following responsibilities:

- preparation of recommendations for risk assessment and management of risks relating to the environment and to human health
- general recommendations for executing agencies,
- evaluation of all applications.

Control of release of GMO

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

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

Applications

Applications for GMO release and utilization will be directed to the Ministry of Environment, as the General Coordinator for GMO matters in the country. The possibility of giving responsibilities to the Ministry of Health and Social Welfare (General Sanitary Inspector) for taking decision in case of food and

drugs derived from GMO is also under consideration.

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 98/81.
- Approval of GMO deliberate release to environment, such applications should contain all necessary data and be prepared according to EU Directive 90/220 and its annexes, soon to be changed in preparation for the coming into force of 2001/18.
- Approval for introduction into the market of GMO and its products, according to EU Directive 90/220 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 performaning the risk assessment. Experts in appropriate scientific disciplines would evaluate the applications. The GMO Commission will prepare and suggest a list of experts for evaluation and review of applications for GMO 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 GMO utilisation. In addition, the GMO Commission may ask for additional experts (including those from outside Poland), for evaluation of especially difficult applications.

Decision making strategy

The following steps are proposed for decision making by the Minister of Environment:

1. Application sent to the GMO General Coordinator.
2. Formal screening and review by the Secretariat.
3. Applicant informed of receipt of the proposal for evaluation
4. Evaluation of the proposal by the GMO Commission and preparation of the decision dossier for the Minister
5. Clarification of any issues raised during the review with the applicant.
6. Discussion with the applicant of the proposed decision dossier
7. Discussion with NGOs and other relevant organisations.
8. Final proposal of GMO Commission forwarded to the Minister of Environment.

9. Minister of Environment takes a decision and publishes it in the official journal.

ANNEX 3

Matrix showing the relation between the project activities, the Cartagena Protocol and the National Biosafety Framework

PROJECT ACTIVITIES	*NATIONAL BIOSAFETY FRAMEWORK SET UP FOR THE ENTRY INTO FORCE OF THE CARTAGENA PROTOCOL*	*CARTAGENA PROTOCOL ARTICLES*
• To support the implementation of the regulatory and administrative biosafety system 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, with a specific focus on transboundary movements, in Poland, and meet the obligations foreseen under the Cartagena Protocol • To support the national infrastructure needed for LMOs risk assessment and monitoring	• Enforcement of new legislation • Establishment of system of control and monitoring of contained use and deliberate realize to environment of GMO and transbundary movement • Establishment reference laboratories	**Article 2.** 1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol 2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health. **Article 16**. 1. The Parties shall, taking into account Article 8(g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of LMOs. 2. Measures based on risk assessment shall be imposed to extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biological diversity, taking also into account risks human health, within the territory of the Party of import. 3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment

		to be carried out prior to the first release of a living modified organism. 4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any LMO, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use. **Article 18** 1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. **Article 25** 1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalising transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.
• Equip 2 reference laboratories to carry out analysis on LMOs and related products as follows: – LMOs involved in transboundary movement of; – LMOs plants released to the environment, – LMOs used in containment, – for food products	• Functioning of system of control and monitoring of contained use and deliberate realize to environment of GMO	**Article 7.** 1. Subject to Articles 5 and 6, the advance informed agreement procedure in Article 8 to 10 and 12 shall apply prior the first intentional transboundary movement of living modified organism for intentional introduction into the environment of the Party of import. **Article 10.** 1. Decisions taken by Party of import shall be in accordance with Article 15. Article 11. 1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organisms that may subject to 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. **Article 33**

		Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.
• Set up a Biosafety Database System (to be connected to the Clearing House Mechanism); • Set up a website	• To carry out the verification of the technical systems, equipment used for biological safety and containment barriers. • To implement the procedures for accounting and controlling biological and toxic agents and organisms released into the environment in co-ordination with the corresponding bodies, state agencies, and entities. • To promote and develop information exchange on biosafety • Setting up a database to be linked to the BCH and containing all the information requested by the Cartagena Protocol	**Article 17**. 1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant international organisations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation. 2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article. 4. In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures. **Article 20** A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the BCHU. **Article 23** 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.
		Article 22

• Strengthen, and when needed build, capacity on biosafety issues, especially in the areas of: – Risk assessment and risk management – Testing and monitoring – Legal issues – Institutional set-ups. • Organization of a national workshop with 70 participants including NGOs and media in order to report on implementation of NBF	• Increase of knowledge on biosafety issues of policy makers, governmental administration and society on GMO.	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.
• Preparation and publication of set of guidelines to be used by different users and managers. The guidelines will cover LMOs related aspects, as custom, monitoring and control, variety registration, risk assessment, central administration, reference laboratories, notifiers. • Public opinion polls among a representative sample of the population about the National Biosafety Framework, to be held at the beginning and at the end of the project	➢ Involvement of the public opinion	**Article 23** 1. The Parties shall: ➢ Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; ➢ Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported. 2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21.

ANNEX 4

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

1. At Plant Breeding and Acclimatization Institute in Radzikow, under the Ministry of Agriculture and Rural Development for:
   - Plants
   - Plant products
   - Feed
   - Environmental impact
   - Transboundary movement of LMOs and its products.

Equipment needed to meet the requirements of the Cartagena Protocol
1. PCR (quantitative) - 1
2. Laminar flow cabinet -2
3. Electrophoresis set - 1
4.Spectrophotometer - 1
5. Computer+printer - 1

2. At National Institute of Hygiene in Warsaw (ul. Chocimska 24, 00-791 WARSZAWA) under the Ministry of Health for:

- Food
- Cosmetics
- Chemical consumer goods (detergents, household chemicals, etc.)
- transboundary movement of the above LMOs and its products

Equipment needed to meet the requirements of the Cartagena Protocol
1. PCR (quantitative) - 1
2.Analytical kits

ANNEX 5

UNEP Response to the STAP Technical Review

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

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

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

Country's Specific Issues

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

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

Issue	Response
Kenya • *Capacity building should also be addressed to inspectors, for example by organising training workshop and developing inspection manuals.*	• Capacity building for inspectors in training workshop is now explicitly mentioned in the project proposal. It will be further addressed during the implementation of the project
Poland • *One important element that is missing, is the development of implementing regulations.* • *The proposed training activities are very fragmented and it is recommended to merge*	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

some of the training activities. • *Further clarification is needed as to how the proposed activities will be co-ordinated with the activities under the EU twinning project for which Poland has applied.*	why the activities may appear as fragmented, because they complement current EU ones.
Uganda • *It is recommended to include training activities on topics such as "other international obligations".*	• Training activities are based on country's priorities and are limited to the activities eligible under the Protocol.