MSP PROJECT BRIEF

PROJECT IDENTIFIERS	
1. PROJECT NAME: Support to the National Biosafety Framework	**2. GEF IMPLEMENTING AGENCY:** UNEP
3. COUNTRY/IES IN WHICH THE PROJECT IS BEING IMPLEMENTED: Cuba	**4. COUNTRY ELIGIBILITY:** Cuba ratified the Convention on Biological Diversity on March 8, 1994 and signed the Cartagena Protocol on May 24, 2000. Cuba is in the process of ratifying the Protocol.
5. GEF FOCAL AREA: Biodiversity/biosafety	**6. OPERATIONAL PROGRAMME:** The project cross-outs the Biodiversity Operational Programmes 1,2,3,4 and follows the Initial Strategy for the Entry into Force of the Cartagena Protocol adopted by the GEF Council in November 2000.

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

1. In Cuba, the creation of the **Biological Front** as an integrating element for the activities carried out in biotechnology helped structure specific programs. These programs are associated with the development of applications and work methodologies in genetic engineering, with the development of programs for the biological struggle against plagues and diseases, and those programs related to increasing agricultural outputs and culture resistance to plagues and diseases.
2. The Ministry of Science, Technology, and Environment was created in Cuba under Decree-Law 147/94 on Reorganisation of the Central Administration Bodies of the State. This Ministry is in charge of, among other functions, providing a response to the environment-related problems. As part of its structure, the National Centre of Biological Diversity was conceived.
3. The National Centre of Biodiversity has performed biological diversity studies of the country, and executes the national strategy about this topic that includes biosafety aspects. This Centre, also, instruments the mechanism of information exchange, which will be part of the National Centre for Biological Safety once the necessary means and equipment are available.
4. In 1993, the Cuban government decided to focus its interests on the organisation of the activities associated with biosafety within the country. This fact proves its political willingness to provide this activity with the scope and legal status it certainly requires, despite the blockade and the lack of material and financial resources. The Cuban government, by Law 81 on the Environment, appointed the Ministry of Science, Technology and Environment to hold responsibility for outlining, executing and controlling the policy of the State and the Government in the matter of biological safety.
5. The Ministry of Science, Technology, and Environment as per Resolution 67/96 created the National Centre for Biological Safety in order to organise, conduct, perform, supervise, and control the National System of Biological Safety. It also organises, conducts and controls the measures aiming at complying with the obligations assumed by the country as State Party in international instruments on biosafety or related to it.
6. The National Centre for Biological Safety acts as the Regulatory Body in the matter of biological safety. From a strategic point of view, to organise the activity, it has structured the

National System for Biological Safety, and identified a legislative pyramid. In addition, this centre carries out supervisions and executes a national program for professional training and upgrading.

7. Cuba is, therefore, developing and consolidating its National Biosafety system by implementing Decree-Law 190/99 on biosafety and drafting complementary regulations in order to guarantee the fulfilment and management of safety in biotechnology as per the Cartagena Protocol. This Decree-Law aim at protecting human health, improving the environment and reducing to the minimum the negative effects on the preservation and sustainable use of biological diversity.
8. Cuba during 1998 and part of 1999 satisfactorily executed the Pilot Project on Biosafety that helped the country in carrying out the following activities:

- To perform national training and workshops.
- To print and divulge the Decree-Law and other resolutions.
- To print and distribute the book entitled "Temas de Seguridad Biológica" ("Issues on Biological Safety")
- To develop the collaboration with Bolivia concerning training and risk assessment.
- To set up, as part of the national plan, a training program formed by post-grade, advance, and basic courses, as well as mastery on biosafety.
- To perform a national inventory about biotechnologies.
- To create and start a National System of Biological Safety.
- To have the specialists from the Centre involved in training activities such as international courses and events on biosafety.

In the final report on the results of the Pilot Project and its evaluation by the UNEP the subsequent follow-up actions are identified, among others:

- To complete the implementation, development and strengthening of the National System of Biological Safety.
- To fulfil the performance of workshops, seminars, and specialists meetings about different biosafety topics, as well as continuing executing the national training program, and developing didactic materials.
- To finish writing up the regulatory documents to adequately implement the Decree-Law and the Cartagena Protocol.
- To set up and develop a National System for Information Exchange.

Both documents acknowledge the need for an extra financial support to carry out the identified activities.

9. The UNEP/GEF Pilot Project "Development of the National Biosafety Framework" went through some important stages and provided the foundation of the National Biosafety Framework allowing the inception of the mentioned activity. To date, given the particular economic conditions of the country, a further financial support is needed to integrate the resources already made available by the country and, therefore, proceed with the biosafety framework implementation.
10. Cuba ratified the Convention on Biological Diversity on March 8, 1994 and signed the Cartagena Protocol on May 24, 2000. Cuba is in the process of ratifying the Protocol
11. Cuba, a developing country, is still facing a special period caused by the economic blockade imposed by the Unites States for more than forty years. In addition, the recent laws approved against the country as well as some meteorological hardships like draught and others have stiffened the economic situation.

    Notwithstanding, the Cuban government, since 1992, has been giving safety in Biotechnology the place it deserves covering the expenses derived from the activity. Such financial support is not enough to meet the needs for the implementation of the Cartagena

Protocol. Today, a National System and a regulatory framework on Biosafety are already set up based on the Decree-Law 190/99 on Biological Safety (both in progresses). Their advance is subject to the existing financial capacities.

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

Endorsed: **20/8/01**

GEF Focal Point: Jorge Luis Fernández Chamero. Director. International Co-operation Division. Ministry of Science, Technology and Environment (CITMA). Capitolio Nacional, Prado y San José, La Habana 10200. Cuba. Tel: 537 670606. FAX: 537 338054

Project Objectives and Activities

Project rationale and objectives:	*Indicators*
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 Cuba.	
Specific objectives are set as follows:	
(A) To support the implementation of Decree Law N.190/99 on Biological Safety by drafting and enacting additional relevant regulations and therefore 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, and meet the obligations foreseen under the Cartagena Protocol	• The legal instruments to implement the NBF and the Cartagena Protocol on Safety in Biotechnology are in force. A national system able to meet the requirements of the Convention on Biological Diversity and the Cartagena Protocol about safety in Biotechnology organised and strengthened.
(B) Improve the ability to 1) assess, manage and monitor the risks associated to LMOs handling, transport, use, transfer and release and 2) produce and validate the related data	• Developed methodologies to provide guidance for assessing and managing LMOs related risk
C) Strengthen national capacities by carrying out training activities and providing facilities for capacity building purposes	• National capacities strengthened in terms of training and equipment
D) Strengthen the information system by setting up a database to be linked to the Biosafety Clearing House	• Improvement of Technological Capacity for information exchange and development of a national network to be linked to the BCH.
E) Strengthen capacity building for public awareness on biosafety related issues	• Strengthened capacity for enhancing awareness between public and policy-makers to guarantee the safe and rational use of modern technology, and demonstrate on scientific basis the results of risk management and monitoring.

10. **Project outcomes**: (A.1) Rules that are part of Decree-Law 190/99 on Biological Safety finalised and submitted for approval as follows: 1) Rule of Licenses of Biological Safety, 2) Rule of Biological Safety for facilities handling biological agents at small and large scale that may affect animals, man and plants 3) Rule for the State Environmental Inspection of Biological Safety. (A.2). Standardisation Committee for biosafety established and technical rules defined. (A.3). A National Biosafety Strategy worked out, and to be implemented. (a.4) Following workshops organised: • 2 national workshop on the implementation of legal documents, technical rules and methodologies; • 3 local workshops for defining, analysing and approving the national Biosafety Strategy; • 1 National workshop for adopting the National Strategy of Biological safety. (A.5) Two annual meetings of specialists held in order to assess the organisation and management of biosafety issues at provincial level and define the way forward (three days, 45 participants) (B.1) Finalised methodology for: Risk assessment/management. Monitoring of GMOs released into the environment started. (B.2) Defined procedure for LMOs data collection and validation (C.1) Strengthened National Biosafety Centre with the needed equipment for capacity building purposes (C.2) 4 training courses for decision-makers, government officials, technicians and custom officials run on: • risk assessment and risk management, • testing and monitoring, • Legal issues particularly in relation to use, import and export, • Administrative Procedures, and • Controls over the transboundary movement of LMO.	• *Indicators:* ➢ Draft Regulations available Approval of "Technical rules related to standards Formal Adoption of the National Biosafety Strategy Publication of the methodology on "Risk Assessment and Risk Management of LMOs in Cuba" and "Monitoring of GMOs released into the environment" National Biosafety Centre with the needed equipped for capacity building purposes

(C.3) 2 Workshops organised as follows: ➢ "Biosafety issues and the regulations for the implementation of Decree Law 190/99" ➢ "Risk assessment, risk management, transboundary movements of Living Modified Organisms and the Cartagena Protocol on Biosafety"	
(d.1.1) Developed National Database System for Information Exchange based on facilities, micro-organisms, negative impacts, transgenic organisms, environmental releases, experts and others with related network linked to the BCH. (d.1.2) National Portal of Biosafety in operation. (d.1.3) Two workshops organised on the use, handling of database and system evaluation;	Survey of the main information users
(e.1) National Program of public education on biosafety related issues developed and operational. (e.2.1) Teaching materials prepared and published (e.3) Biosafety Information and related Technical Literature collected for public awareness purposes. (e.4) Project Newsletter Published (e.5) Best practices and lessons learnt disseminated	National Program of Public Education approved and in operation
11. **11. Planned activities to achieve**	**Indicators:**
(a.1) Finalisation of the Rules that are part of Decree-Law 190/99 on Biological Safety and submit them for approval. They are: • Rule of Licenses of Biological Safety • Rule of Biological Safety for facilities handling biological agents at small and large scale that may affect animals, man and plants. • Rule for the State Environmental Inspection of Biological Safety. (a.2) Establish a Standardisation Committee for biosafety standards. Identification and working out technical rules on Biosafety. (a.3) Working out and development of the National Strategy of Biosafety (a.4) Organisation of the following workshops: • 2 national workshops on the implementation of legal documents, technical rules and methodologies (5 days, 100 participants); • 3 local workshops for defining, analysing	3 Rules for the implementation of the Decree-Law 190/99 submitted for approval Finalised Technical rules for standards

and approving the national Biosafety Strategy (3 days, 30 participants) • 1 National workshop for adopting the National Strategy of Biological safety (3 days, 100 participants) (A.5) Held two annual meetings of specialists in order to assess the organisation and management of biosafety issues at provincial level (three days, 45 participants) **(TOT: 195,264USD ;GEF: 94,320USD)**	Finalised National Strategy of Biosafety 4 workshops held and related findings/recommendations available Minimum of 35 specialists attending the meetings
(b.1) Develop a methodology for: • risk assessment, management and • monitoring of GMOs released into the environment (b.2) Develop procedure for LMOs data collection and validation in the country and in co-operation with other countries in the region **(TOT: 62,880;GEF: 67,296)**	Finalised methodology for risk assessment, management and monitoring of GMOs available Finalised procedure for LMOs data collection and validation
(C.1) National Biosafety Centre strengthened with the needed equipment for capacity building purposes **(TOT: 256,382USD;GEF: 228,100)** (C.2) Run 4 training courses for decision-makers (1 day, 60-100 participants), government officials, technicians and custom officials (8 days, 30-40 participants, 60 hours) as follows: • risk assessment and risk management, • testing and monitoring, • Legal issues, particularly in relation to use, import and export, • Administrative Procedures, and • Controls over the transboundary movement of LMO. (C.3) Organise 2 training workshops on (3-5 days, 100 participants) : ➢ "Biosafety issues and the regulations for the implementation of Decree Law 190/99" ➢ "Risk assessment, risk management, transboundary movements of Living Modified Organisms and the Cartagena Protocol on Biosafety" **(TOT: 138,000;92,000)**	Equipment needed for capacity building purposes purchased Quality survey on the training courses run Minimum of 80% of estimated participants attending
(d.1.1) Develop a National Database System for Information Exchange based on facilities, micro-organisms, negative impacts, transgenic organisms, environmental releases, experts etc, and related network to be linked to the BCH.	➢ National Database System and related network in operation

(d.1.2) Open the National Biosafety Website, to be linked to the BCH. (d.1.3) Organise two workshops on the use, handling of database and system evaluation (5 days,45 participants; **(TOT: 131,420;GEF:96,200)**	➢ Website active ➢ Minimum of 35 participants/workshop attending
(e.1) Develop a National Program of public education on biosafety related issues. (e.2.1) Develop and publish teaching materials (e.3) Collect Biosafety Information and related Technical Literature for public awareness purposes. (e.4) Publish project newsletter (e.5) Dissemination of best practices and lessons learnt **(TOT: 79,400;GEF:73,000)**	➢ National Program of public education finalised ➢ Teaching materials available

12. **Estimated budget (in US$ or local currency):**

GEF: Project Cost:	**646,500 USD**
Co-financing: Cubans government:	**284,142 USD**
Total:	**930,642 USD**

13. **Information on project proposer**:

National Executing Agency (NEA) Centro Nacional de Seguridad Biológica
Ministerio de Ciencia, Tecnología y Medio Ambiente.

The National Centre of Biological Safety is in charge of the co-ordination and fulfilment of the project through the establishment of a working group identified as NEA which will be responsible for planning and carrying out the above activities. This working group will carry out quarter meetings to check the results and the progress of the project taking proper measures for each case.
Contact Person:
Director: José Rodríguez Dueñas. Calle 28 No. 502 e/ 5ta and 7ma Ave, Playa, Havana City, Cuba. Tel: 537 223281/238040. E-mail: cnsb@unepnet.inf.cu

14. **Information on proposed executing agency (if different from above):**
(Information on the entity that will actually execute the project should be written here)

15. Date of initial submission of project concept:

16. Project Identification number

17. Implementing Agency contact person:
Ahmed Djouglaf GEF/PNUMA Nairobi.

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 involved Cuba, 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 Description

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 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, 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 understanding the public and major decision makers of the potential benefits and risks of biotechnology application;
- Enhance international co-operation 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 Cuba 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. In Cuba *Decree N.190 on Biological Safety* was approved in 1999. Cuba is therefore developing and consolidating its National Biosafety System by implementing the Decree and drafting regulations in order to guarantee the fulfilment and management of safety in biotechnology as required in order to fully implement the Cartagena Protocol. It aims at protecting human health, improving the environment and reducing to the minimum the negative effects in the preservation and sustainable use of biological diversity.
   The first stage, the Pilot Project on Biosafety, allowed the inception of this activity, which now requires a further financial support for its completion, integrating in this way the resources already made available by the country. In particular, there is a need:

- To organise and strengthen the national structure in order to be able to meet the requirements of the Cartagena Protocol and the Convention on Biological Diversity.
- To develop national capacities, both in human resources and institutions, to fulfil the activities related to Biosafety at national, regional and international level. This need is the main element that requires urgent attention. Its fulfilment will help in implementing the Cartagena Protocol on Safety of Biotechnology.
- To increase the capacity to evaluate risks 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, and specifically focusing on transboundary movements. as well as produce and validate the related data.
- Enhance awareness at the level of the public and policy-makers on risks and benefits coming from LMOs so as to guarantee the safe and rational use of modern technology where appropriate and in accordance with Article 23 of the Protocol

In particular, there is a need for help in applying the principles coming of the Convention on Biological Diversity and the Biosafety Protocol to be used as proper guidelines for the

governments, the institutions and the other stakeholders in their efforts to develop and apply methodologies for biological risk assessment and management procedures at national, regional and international levels.

Current situation

The Ministry of Sciences, Technology, and Environment (CITMA) was designated (per Law 81 about Environment (15) issued by the Cuban Government), to be the State Agency of the Central Administration of the State responsible for outlining, performing, and controlling the policy of the State in the matter of biosafety, as well as organizing, conducting, and controlling the compliance of the agreements contracted by the country

The National Centre of Biological Safety was created by Resolution 67/96 (16) issued by the Ministry of Sciences, Technology, and Environment. This centre is in charge of organizing, conducting, performing, supervising, and controlling the National System of Biological Safety (See Scheme 1), as well as organizing, conducting and controlling the measures directed to meet the obligations assumed by the country that form part of international legal instruments on biosafety or related to it. (See Annex)

The National Centre of Biological Safety, functions as the Regulatory Body. Biological safety is defined in Decree-Law 190/99 (17). The four main work directions identified for the development of its functions are:

Biological Safety in facilities where biological risks are handled.

Biological Safety due to the releases into the environment of all organisms that might pose a risk to the conservation and sustainable use of biological diversity, taking also into account risks to human health (whether ordinary, exotics, or genetically modified)

Safeguard and Safety in International Agreements.

Technical and Professional Training and Upgrading in order to assure biological safety when handling, using, importing or exporting living modified organisms.

This Centre has prepared and submitted for approval a group of regulatory documents that have entered into force. These documents are the Decree-Law 190/99 on Biological Safety, Resolution 42/99 on the Official List of the Biological Agents and their classification in Risk Groups, Resolution 8/00 on the General Rule of Biological Safety for facilities where biological agents and products thereof, organisms and parts of them with genetic information are handled, and the Resolution 76/00 on the Rule relating to Authorisations.

Resulting from the regulatory activity, 139 files have been evaluated, and 108 authorisations have been issued. All the areas where transgenic organisms have been released into the environment have been fully inspected (100%). Approximately, 600 inspections are carried out yearly in those facilities with biological risk, and in the areas where organisms are released into the environment, as part of the system developed by the Ministry of Science, Technology, and Environment. The book entitled "Temas de Seguridad Biológica" (Issues on Biological Safety) has been published.

Several courses on this topic have been organised, including the annual post-graduate course (60 hours) at the Faculty of Biology of the university of Havana, Advanced Courses (50 hours) run

yearly, Basic Courses run in the facilities, and two of them in each territory annually, and short-term courses for members of the board (one per territory annually). A Masters Course on Biosafety is also run (1200 hours). National workshops, seminars, and discussions on Biosafety have been performed. The Biosafety scope has been included in scientific events and two meetings involving the participation of territorial specialists that deal with the activity are held annually.

Despite all the achievements financial stringency is hampering the strengthening and developing of Biosafety in order to fully implement the Cartagena Protocol. Despite all the achievements obtained, financial needs come up to go on strengthening and developing Biosafety within the country in the light of reaching a safe use of the results in biotechnologies, and adequately implementing the Cartagena Protocol.

Þ **Institutional strengthening of the National System of Biological Safety**

- The administrative and operational facilities of the regulatory body need to be extended, strengthened and updated.
- The territories need to be provided with means of transportation to perform the inspections in the facilities and areas where releases into the environment are carried out.
- The legislation completing the regulatory pyramid needs to be finalised and divulged.
- Human resources need to be trained in ensuring biosafety

Þ **Strengthening the Information System.**

This includes:

- The development and maintenance of a National System of Information Exchange (database and related network).
- The setting-up of a technological support and its Intranet connection.
- An Internet connection to allow interaction with the Biosafety Clearing House
- The identification, elaboration, harmonisation, and completion of databases along with the access to international databases.
- The provision of computing devices to allow full and transparent systems for biosafety to be implemented.
- The creation, completion and updating of the National Portal of Biosafety.
- Training of human resources.

⇒ **Strengthening the National Biosafety Centre for capacity building purposes.**

Aiming at:

- Consolidating the performance and development of courses, and national workshops.
- Continuing holding national meetings with the participation of specialists in Biosafety.
- Including biosafety topics in the missing pre-grade courses.
- Developing didactic materials.
- Develop specific information material on biosafety.
- Training human resources.

⇒ **Creation of the National Centre for Validation and Monitoring.**

Including:

- Design, construction, and setting-up of specialised laboratories.
- Development of techniques and procedures for sample taking.
- Availability of equipment, materials, and other necessary means.
- Training of human resources.

Cuba is going through a very difficult economic situation derived from the blockade, from adverse weather conditions, and from having to import staple products at very high prices. The aforementioned hinders the possibility of having the necessary financial resources that all the activities require. However, all efforts are being made to maintain the biosafety levels reached heretofore, even though additional financial resources are needed for its development and for the implementation of the Cartagena Protocol.

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

The serious engagement and effort done by the Cuban Government in giving the required importance and priority to biosafety is remarkable. However, the country own resources are not sufficient for addressing and implementing the requirements of the Cartagena Protocol and establishing active co-operation with other countries in the region.

This project will help therefore in strengthening the National System of Biological Safety (in line with the Convention on Biological Diversity, the Cartagena Protocol, the International Technical Guidelines and other international legal and technical documents and national needs) and developing human and institutional resources through national training, development of resources, legal support to the regulatory body, coordination with other agencies and institutions such as the Ministry of Agriculture, Ministry of Fishery, Ministry of the Sugar Industry, Ministry of Public Health, Ministry of High Education) that are part of the biosafety system and rule specific branches of Biotechnology.

The expected outcomes consist therefore in:

(A.1) Rules that are part of Decree-Law 190/99 on Biological Safety finalised and submitted for approval as follows:
1) Rule of Licenses of Biological Safety,
2) Rule of Biological Safety for facilities handling biological agents at small and large scale that may affect animals, man and plants
3) Rule for the State Environmental Inspection of Biological Safety.
(A.2). Standardisation Committee for biosafety established and technical rules defined.
(A.3). A National Biosafety Strategy worked out, and to be implemented.
(a.4) Following workshops organised:

- 2 national workshop on the implementation of legal documents, technical rules and methodologies;
- 3 local workshops for defining, analysing and approving the national Biosafety Strategy;
- 1 National workshop for adopting the National Strategy of Biological safety.

(A.5) Two annual meetings of specialists held in order to assess the organisation and management of biosafety issues at provincial level and define the way forward (three days, 45 participants)

(B.1) Finalised methodology for:

Risk assessment/management.

Monitoring of GMOs released into the environment started.
(B.2) Defined procedure for LMOs data collection and validation

(C.1) Strengthened National Biosafety Centre with the needed equipment for capacity building purposes
(C.2) 4 training courses organised for deicison-makers, government officials, technicians and custom officers on:

- risk assessment and risk management,
- testing and monitoring,
- Legal issues particularly in relation to use, import and export,
- Administrative Procedures, and
- Controls over the transboundary movement of LMO.

(C.3) 2 Workshops organised as follows (3-5 days, 100 participants):

- "Biosafety issues and the regulations for the implementation of Decree Law 190/99"
- ""Risk assessment, risk management, transboundary movement of Living Modified Organisms and the Cartagena Protocol on Biosafety"

(d.1.1) Developed National Database System for Information Exchange based on facilities, micro-organisms, negative impacts, transgenic organisms, environmental releases, experts and others with related network linked to the BCH.
(d.1.2) National Portal of Biosafety in operation.
(d.1.3) Two workshops organised on the use, handling of database and system evaluation;

(e.1) National Program of public education on biosafety related issues developed and operational.
(e.2) Worked out and published teaching materials
(e.3) Collected Biosafety Information and related Technical Literature for public awareness purposes.
(e.4) Published project newsletter
(e.5) Best practices and lessons learnt disseminated

ACTIVITIES AND FINANCIAL INPUTS NEEDED TO ENABLE CHANGES.

1. The establishment of the legal and administrative mechanism for biosafety management in Cuba

At the national level, this activity is in correspondence with Article 2, item 1) of the Cartagena Protocol in which it is set forth that "Each Party shall adopt the legislative, administrative and other kind of measures that would be necessary and convenient to comply with the obligations derived from the present Protocol". In this respect, the Decree-Law 190/99 on Biological Safety

was approved. This Decree-Law requires other provisions to be correctly implemented. Some of the provisions have already entered into force. However, to complete the legislative pyramid the following rules need to be finalised, approved, implemented, printed, and disseminated:

- *Rule of Licenses of Biological Safety*
  This Rule establishes the procedures and terms for risk assessment as per article 15 of the Protocol, and the contents of the technical files. It disposes that as a result of the performance of risk assessment a biological safety authorisation shall be granted or declined showing the conditions for authorisation or reasons for refusing authorisation.

- *Rule of Biological Safety for facilities handling biological agents at small and large scale that may affect animals, man and plants*
  This rule shall establish the constructive characteristics for each biosafety level, the equipment and the laboratory good practices, or the production characteristics that must be fulfilled in the facilities.

- *Rule for the State Environmental Inspection of Biological Safety*
  This rule establishes the procedures to be taken into consideration for the performance of the inspections as part of the risk assessment and authorisation processes. Simultaneously, it disposes the performance of inspections as part of the monitoring process and other inspections to check how the established biosafety measures are achieved in practice.

The law, passed before the Cartagena Protocol was agreed, will be implemented so as to fully ensure that living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements are handled in a safe manner. The rules will be drafted to comply with Articles 15 and 16 and Annexes I to III of the Protocol.

A Technical Committee on Food obtained from biotechnological means has been formed, and another committee with responsibility for technical standards of biosafety will be created. The first consists of experts from several ministries such as the Ministries of Public Health, Science, Technology and Environment, Higher Education, Food Industry, Agriculture, Sugar Industry and Fisheries. This Committee is in charge of assessing risks in food obtained from biotechnological means, developing LMOs' traceability, surveillance and establishing the necessary technical standards to this purpose.

The Ministries of Science, Technology, and Environment, Public Health, Agriculture and others will form the Committee on Technical Standards of Biosafety. It will hold responsibility for elaborating the technical standards that suit the Decree-Law and the remaining rules.

The National Strategy for Biological Safety represents an important document to be elaborated. It will constitute the program that allows us lead our work in the next years. It will include the policy that covers the structure to be assumed by biosafety at national, territorial, and institutional levels, as well as the legislative documentation that shall govern in the country to organise biosafety and to comply with the Cartagena Protocol on Safety in Biotechnology. It will also include biological safety supervision, technical documentation, training and professional upgrading.

As part of the development and implementation of the documents, six national workshops are expected to be performed that will last from three (3) to five (5) days, and at which the number of participants will range from thirty (30) to one hundred (100):

- 2 national workshops on the implementation of legal documents, technical rules and methodologies;
- 3 local workshops for defining, analysing and approving the national Biosafety Strategy
- 1 National workshop for adopting the National Strategy of Biological safety.

3. Development of methodologies for Risk Assessment and Risk Management and related data production

To comply with Article 15 (Risk Assessment), and Article 16 (Risk Management) of the Cartagena Protocol it is necessary to develop methodologies for a scientific risk assessment establishing the necessary or essential requirements and procedures for decision-making, and for performing risk management measures. The monitoring of the GMOs released into the environment constitutes an important aspect. A procedure that allows the development of the necessary infrastructure to validate and determine the changes or any adverse effects, as well as techniques established for sample taking, transportation and analysis in the laboratory.

4. Capacity building and public awareness activities

Capacity building constitutes the cardinal issue to implement the Protocol, and towards that direction programs of studies have been approved, and workshops, seminars, and meetings of specialists are being developed. Article 22 of the Cartagena Protocol refers to this aspect, and disposes that the parties shall co-operate for the development and/or strengthening of human resources and institutional capacities. The following activities are therefore expected to be developed:

Strengthen the National Biosafety Centre for capacity building activities: This Centre is formed by professors coming from institutions like the Faculty of Biology, the Institute of Tropical Medicine, the Veterinarian Institute, Finlay Institute and the National Centre for Plant and Animal Health. Already, many training courses are run allowing us train several hundreds of specialists. Among these are post-graduate, advanced, and basic courses along with a master's course on Biosafety. All of this requires the availability of a facility having the necessary audio-visual systems. There is a need to develop the necessary human resources able to train others, but money is needed for this purpose. A (national) distance course will be prepared to train all people concerned within the country via electronic means. The centre will allow the development of collaboration with other countries of the region. More than fifteen (15) specialists have been trained. At the same time, basic courses have been organised being taught by professors from our national centre.
For public information purposes, national and international technical documentation from various sources on biosafety will be collected and made available at the training centre.

Four training courses for decision-makers (1 day, 60-100 participants), government officials, technicians and custom officials (8 days, 30-40 participants, 60 hours) will be run on the following 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.

Two national workshops on "Biosafety issues and the regulations for the implementation of Decree Law 190/99" and "Risk assessment, risk management, transboundary movement of Living Modified Organisms and the Cartagena Protocol on Biosafety". At the workshops, the institutions will be able to present their activities, accomplishments and results. Each workshop will last five (5) days with the participation of one hundred (100) specialists.

As part of the training centre, a section for technical documentation with a specialised library on biosafety and related topics will be set up.

A program, which is already defined, will be developed to develop teaching material being the basis for teaching activities, and allowing training of the groups concerned. A specialised project newsletter is expected to be edited quarterly. This newsletter will be fully broadcasted within the country and abroad. The Publishing House has already been identified, and the Technical Committee on Editing is being created.

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

5. Information system

Information sharing is an activity of priority for the Cartagena Protocol. Its Article 20 mentions "the creation of a Centre for Information Sharing", and that "each Party shall provide this centre with a numerous group of information, and that shall receive assistance from it when applying the Protocol, aiming at facilitating information sharing, scientific, technical, environmental, and legal experience in relation with the GMOs.

It is necessary for the National Centre for Biological Safety, appointed as the Regulatory Body and National Focal Point, to be provided with the required technological infrastructure already determined with Internet access. This will allow receive and transmit the necessary information at national and international levels. Today, such infrastructure does not exist hindering our participation in this exchange process. The design and completion of databases about facilities, adverse effects, transgenic organisms, experts, and others that facilitate decision making are also required. Once these databases are defined and worked out, two national workshops will be developed about the use and handling of the same to evaluate its effectiveness. These workshops will last three (3) days involving forty-five (45) participants.

Sustainability analysis and risk assessment

The Cuban Government decided to organise biosafety within the country. The activity is sustained by the legal documents that are already approved and in force, such as Law 81 on the Environment. This Law makes the Ministry of Science, Technology, and Environment the Responsible Body of the Central Administration of the State that outlines, performs, and controls the State and Government policy in the matter of biosafety. It also organises, conducts and controls the commitments assumed by the country in this activity. This Ministry as per Resolution

67/96 created he National Centre for Biological Safety. The groups of professionals that work for the centre are fully devoted to organising the activity by formulating the strategic objectives. They render accounts of the activity quarterly and annually. The Decree-Law 190/99 on Biological Safety appoints CITMA (Ministry of Science, Technology, and Environment) as the Body of the Central Administration of the State that is in charge of the activity, and establishes the responsibilities that the rest of the ministries must fulfil.

There is a National System of Biological Safety in the country that has promulgated several governing documents, assesses risks, issues authorisations, perform inspections for granting authorisations, checks compliance of conditions, and verifies that the biosafety measures set forth in the legal instruments have been accomplished. It has also helped develop a training program all over the country with the inclusion of a task force for assessing and managing risks. This task force is formed by regular, assistant and associated teachers, and by higher level specialists such as doctors of human and animal medicine, specialists holding university degrees in microbiology and biology, agronomy engineers, chemical engineers, and other specialities. Biosafety has been included as a subject in the syllabus of specialities such as microbiology, biology, biochemistry, and veterinarian medicine.

The activity is sustained by complying with the aspects aforementioned, and by the fact that CITMA, governing body of biosafety, renders accounts about the fulfilment of all its assigned functions including biosafety to the Cuban Parliament systematically.

The lack of financial resources hinders the development of the activity that does not go in correspondence with the existing demands and needs, mainly the ones imposed by the Cartagena Protocol and the national biotechnological development itself. For that reason, the GEF financial support is requested.

The non-disposal of the requested financial resources in due time will risk the project for it will delay the execution of the programmed activities.

Stakeholder involvement and social assessment

In Cuba, the stakeholders are assembled in two large groups:

- Ministries and institutions that develop activities involving biological risks form the first group. Their participation is established in the legal documents in force in the country. They are obliged to fulfil the biosafety measures established. The Ministries that are deeply involved are the Ministry of Public Health, Agriculture, Higher Education, Sugar, Fishery, Basic Industry, and Food Industry. They have gradually developed their internal biosafety infrastructure, and have specialists and departments in charge of co-ordinating the ministerial activities all over the country. The National Centre for Biological Safety along with the CITMA territorial branches counts on Committees of Experts that have a consultative character and that are formed by the above mentioned ministries.

- The second group includes the participation of the mass organisations such as the Committees for the Defence of the Revolution, Federation of Cuban Women, Trade Unions etc, and the NGO's associated with the environment like PRONATURALEZA, and others. These organisations are in charge of broadcasting Biosafety measures and ensuring their compliance in the facilities, community, and in those areas where organisms are released into the

environment. These organisations are deeply involved in the decision-making process and make them known through their channels to the rest of the stakeholders.

Both groups have been involved in the preparation of the project and are involved in its development. An active co-ordinating role in this respect is played by the National Biosafety Centre, which functions as the Regulatory Body in the area of biosafety in the country.

INCREMENTAL COST ASSESSMENT

Cuba has signed the Biosafety Protocol on the May 24, 2000 and is in the process of ratifying it. Cuba is developing and consolidating its National Biosafety system by implementing Decree-Law 190/99 on biosafety and drafting complementary regulations in order to guarantee the fulfilment and management of safety in biotechnology as per the Cartagena Protocol. This Decree-Law aims at protecting human health, improving the environment and reducing to the minimum the negative effects on the preservation and sustainable use of biological diversity.

During 1998 and part of 1999 Cuba satisfactorily executed the Pilot Project on Biosafety. In particular, the UNEP/GEF Pilot Project "Development of the National Biosafety Framework" went through some important stages and provided the foundation of the National Biosafety Framework.
Both documents, the final report on the results of the Pilot Project and its evaluation by UNEP, acknowledge the need for an extra financial support to carry out and fulfil the identified activities and gaps.

In particular, the economic conditions of the country call for a further financial support to integrate the resources already made available by the country and, therefore, proceed with the biosafety framework implementation. Cuba, a developing country, is still facing a special period caused by the economic blockade imposed by the Unites States for more than forty years. In addition, the recent laws approved against the country as well as some meteorological hardships like draught and others have stiffened the economic situation.

Nevertheless, the Cuban government, since 1992, has been giving to Biosafety the place it deserves covering the expenses derived from the development of the related activity. Such financing is not enough to fulfil the requirements for the implementation of the Cartagena Protocol and needs additional support. Today, a National System and a regulatory framework on Biosafety, are already set up based on the Decree-Law 190/99 on Biological Safety (both in progresses). Their progress is subject to the existing financial capacities.

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
Development of legislative and technical documents	Cuba needs to finalise regulations to implement Decree-Law 190/99 on biosafety.	Draft Regulations finalized. Institutional capacity further strengthened through specific workshops. National Biosafety Strategy ensuring transparency and clarity in the implementation of the biosafety regulations finalized and formally adopted.	The implementation of the Cartagena Protocol is supported by the consolidation of the the National Biosafety framework and its implementing regulations
Methodologies for 1) development of LMOs risk assessment and management, 2) data production and validation	Mechanisms for risk assessment and management have been developed but need to be further improved through defined methodologies. The production and validation of data is not standardised.	Methodologies for risk assessment and management defined. Procedures for data collection and validation standardised.	Risk assessment management is improved once methodologies are in place. Data collection procedures support competent decision-making and advisory bodies.
Equipment for capacity building purposes	The National Biosafety Centre lacks equipment needed to fulfil its role as training centre on biosafety issues	Equipment purchased for capacity building purposes	National capacity for carrying out training activities is supported and strengthened.
Training and workshops	Need for strengthening capacity among those involved in the biosafety management system in order to adequately implement the Biosafety decree and the Cartagena Protocol.	Capacity strengthened through specific training courses and workshops organised for decision-makers, scientists, technical and other relevant target groups	Strengthened national capacity to meet the requirements of the Cartagena Protocol
The Establishment of a Biosafety Database system to serve for the purpose of the Biosafety Clearing House Mechanism	An organised database system to serve for the purpose of the Biosafety Clearing House is still missing.	A national information system as required by the Protocol for the purpose of the BCH (database as well as web site) set up. Capacity for using and handling the database addressed through two workshops.	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	Need to strengthen current capacity for public awareness purposes	Capacity for public awareness purposes strengthened through the development of a specific National education program on biosafety, published teaching materials, project newsletter, dissemination of best practices and lessons learnt	National public awareness capacity enhanced

As shown in the table below, the cost of the increment is of ***930,642USD***, of which ***646,500USD*** is being requested from the GEF; the remaining ***284,142USD*** is provided as in-kind contribution by Cuba.

*Table 1 - Incremental Cost Table (**in thousand US$**)*

Project component	**Baseline**	**Alternative**	**Increment**	**Cost to GEF (Global Benefit)**	**Co-financing (in-kind contributions)**
Development of legislative and technical documents	384,000	579,264	195,264	94,320	100,944
Methodologies for development of LMOs risk assessment and management methodologies, data production and validation	144,600	274,776	130,176	62,880	67,296
Equipment	15,000	271,382	256,382	228,100	28,282
Training and workshops	230,000	368,000	138,000	92,000	46,000
Information system	22,000	153,420	131,420	96,200	35,220
Public awareness	16,500	95,900	79,400	73,000	6,400
Total	**812,100**	**1,722,742**	**930,642**	**646,500**	**284,142**

PROJECT BUDGET

CONCEPT	I YEAR		II YEAR		III YEAR		TOTAL	
	GEF	IN KIND CONT.	GEF	IN KIND CONT	GEF	IN KIND CONT	GEF	IN KIND CONT
10 Personnel Component								
1100 Personnel								
1101 Project co-ordinator	4800.00	8080.00	4800.00	8080.00	4800.00	8080.00	14400.00	24240.00
1200 Consultants								
1201 National/international consultants	25200.00	33600.00	25200.00	33600.00	25200.00	33600.00	75600.00	100800.00
1202 Other consultants	12400.00	14400.00	12400.00	14400.00	12400.00	14400.00	37200.00	43200.00
1600 Travels on mission								
1601 Official travels	10000.00		10000.00		10000.00		30000.00	-
SUBTOTAL	52400.00	56080.00	52400.00	56080.00	52400.00	56080.00	157200.00	168240.00
30 Training component								
3200 Training in group								
3201 Travel for training	10000.00		10000.00		12000.00		32000.00	-
3300 Events/Meetings								
3301 Workshops (10)	9600.00	6400.00	19200.00	12800.00	19200.00	12800.00	48000.00	32000.00
3302 Meetings with specialists (10)	4000.00	4500.00	4000.00	4500.00	4000.00	5000.00	12000.00	14000.00
SUBTOTAL COMPONENT	23600.00	10900.00	33200.00	17300.00	35200.00	17800.00	92000.00	46000.00
40 Equipment component								
4100 Expendable material								
4101 Office supplies	2700.00	600.00	2700.00	600.00	2700.00	600.00	8100.00	1800.00

4200 Non expendable equipment								
4201 Computers, printers	19000.00	1900.00	14000.00	1400.00	16000.00	1600.00	49000.00	4900.00
4202 Photocopier	5000.00	600.00			5000.00	600.00	10000.00	1200.00
4203 Audiovisual means	12500.00	1500.00					12500.00	1500.00
4204 Transport	63000.00	7560.00	24000.00	2880.00	42000.00	5040.00	129000.00	15480.00
4205 Furniture	5000.00	1101.00	5000.00	1101.00			10000.00	2202.00
4206 Routers, servers, hubs and others	9500.00	1200.00					9500.00	1200.00
SUBTOTAL COMPONENT	116700.00	14461.00	45700.00	5981.00	65700.00	7840.00	228100.00	28282.00
50 Other components								
5100 Operation and maintenance								
5101 Computers, printers	3600.00	3300.00	4000.00	3660.00	4000.00	3660.00	11600.00	10620.00
5102 Other equipment	3000.00	2700.00	3000.00	2700.00	3500.00	3200.00	9500.00	8600.00
5200 Cost of reports								
5201 Translation, printing, etc.	11700.00		11700.00		11700.00		35100.00	
5300 Rest of others								
5301 Communications	12500.00	5000.00	12500.00	5000.00	35000.00	6000.00	60000.00	16000.00
5302 Publication and dissemination	7000.00	700.00	8000.00	700.00	7000.00	1000.00	22000.00	2400.00
5303 Subscriptions and purchase of specialised literature	5000.00	500.00	5000.00	500.00	4000.00	1000.00	14000.00	2000.00
5303 Others	5500.00	500.00	5500.00	500.00	6000.00	1000.00	17000.00	2000.00
SUBTOTAL COMPONENT	48300.00	12700.00	49700.00	13060.00	51200.00	15860.00	149200.00	41620.00
TOTAL GENERAL	241000.00	94141.00	181000.00	92421.00	204500.00	97580.00	**646,500.00**	**284,142.00**

IMPLEMENTATION PLAN (SEE ANNEX1)
Duration of the project: 3 years

PUBLIC INVOLVEMENT PLAN

A primary active role in the project is played by the National Biosafety Centre, that, as already mentioned, functions as the Regulatory Body in the matter of biosafety. The four main work directions identified for the development of its functions are.

- Biological Safety in the facilities where biological risks are handled.
- Biological Safety due to the releases into the environment of organisms (without being genetically modified, exotics, and genetically modified)
- Safeguard and Safety of International Agreements.
- Technical and Professional Training and Upgrading.

This Centre has prepared and submitted for approva1 a group of regulatory documents that have entered into force. These documents are the 1) Decree-Law 190/99 on Biological Safety, Resolution 42/99 on the Official List of the Biological Agents and their classification in Risk Groups, 2) Resolution 8/00 on the General Rule of Biological Safety for the facilities where biological agents and its products thereof, organisms and parts of them with genetic information are handled, and 3) the Resolution 76/00 on the Rule of Authorizations. The Centre operates in close collaboration with the other main stakeholders, i.e. - all the Ministries involved in drafting the regulations for implementing Decree Law 190/99, and in particular those Ministries of Public Health, Science Technology and Environment, High Education, Food Industry, Agriculture, Sugar Industry and Fisheries, which members will compose the Committee on technical standards of biosafety, to be created as part of this project.
- are the principal facilities in the country, in particular the Institute of Tropical Medicine, the Veterinarian Institute, Finlay Institute, the National Centre for Plant and Animal Health, The Centre on Genetic Engineering and Biotechnology and from others.

The public, as stakeholder but most of all beneficiary of the project, is addressed through a National Program for public education on biosafety related issues and provided with information materials, informed through a quarterly newsletter and involved by the establishment of a user-friendly web page, which will provide information on the project activities but also invite for comments and feedback.

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 Co-ordination committee is being installed. As appropriate, UNEP, as leading agency, and FAO 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

IMPLEMENTATION PLAN: 3 years

ACTIVITIES	1st year				2nd year				3rd year			
	I	II	III	IV	I	II	III	IV	I	II	III	IV
Establishment of a working group	X											
A. WORKING OUT LEGAL INSTRUMENTS AND TECHNICAL DOCUMENTS ON BIOSAFETY												
Requirements - Rule for licenses - Rule for facilities handling biological agents at small and large scale and that may affect man, animals and plants. - Rule for State Environmental Inspection of Biological Safety	X X X	X X X										
Technical Rules - Establishment of a Standardising Committee on Biological Safety - Identification and drafting of technical rules.	X	X	X	X X	X	X	X	X	X	X	X	X
Working out the National Strategy of Biosafety.	X	X	X	X	X	X	X	X	X	X	X	X
2 National workshop on the implementation of legal documents, technical rules and methodologies.			X					X				
3 Local workshops for working out, analysis and approval of the National Strategy of biosafety. - Eastern Region - Central Region - Western Region							X	X	X			
1 National Workshop for adopting the National Strategy of Biological Safety.												X
Two yearly meetings of specialists in Biosafety		X		X		X		X		X		X
B. DEVELOP METHODOLOGIES												
Methodologies - Methodology for risk assessment - Methodology for monitoring released organisms - Data collection and validation		X	X	X	X X	X	X	X	X	X	X	X

C. STRENGHTENING NATIONAL CAPACITY												
Strengthening the National Centre for Biosafety for capacity Building purposes	X	X	X	X								
Courses in Biosafety			X				X				X	
2 National workshops "Biosafety issues and the regulations for the implementation of Decree Law 190/99" and "Risk assessment, risk management, transboundary movement of Living Modified Organisms and the Cartagena Protocol on Biosafety					X							X
D. STRENGHTEN INFORMATION SHARING AND DISSEMINATION												
Design and completion of databases on facilities, micro-organisms, negative impacts, transgenic organisms, environmental releases, experts and others to be linked to the BCH, open a biosafety portal	X	X	X	X								
Design and installation of a local network on biological safety.		X	X	X	X							
Design and starting of the national network for information exchange on biosafety.		X	X	X	X	X						
2 Workshop on the use, handling of database and system evaluation.		X							X			
Co-ordination, working out and execution of a program for public education.							X	X	X	X	X	X
Development and publishing of teaching materials on biosafety.		X	X	X	X	X	X	X	X	X	X	X
Collect biosafety Information and related technical literature for public awareness purposes			X	X	X	X						
Work out and disseminate a quarterly project newsletter.				X		X		X		X		X
ORGANISATION												
24. Quarter reports	X	X	X	X	X	X	X	X	X	X	X	X
25. Annual reports				X				X				X
26. Disbursement report	X	X	X	X	X	X	X	X	X	X	X	X
27. Final report												X
28. Financial auditing											X	X
29. Identification of follow-up activities											X	X

ANNEX 2

2.1 - DECREE LAW No. 190 OF BIOLOGICAL SAFETY

Fidel Castro Ruz, President of the Council of State of the Republic of Cuba.

LET IT BE KNOWN: that the Council of State has agreed the following:

WHEREAS: Law 81 of the Environment, of July 11, 1997, establishes the principles that rule the environmental policy of the country and the basic standards to regulate the actions of the citizens and the society in general so as to protect the environment and contribute to reach the goals of the sustainable development of the country. According to Article 12, paragraph h) it disposes that the Ministry of Science, Technology and Environment, together with other competent bodies and state agencies, is responsible for implementing the Environmental Policy regarding biological safety and controlling its implementation.

WHEREAS: The Convention on Biological Diversity, to which Cuba is signatory, refers as a duty of contracting parties the establishment and maintenance of the means to regulate and control the risks derived from the use and release of living modified organisms as a result of biotechnology.

WHEREAS: The Convention on the Prohibition of Development, Production and Storage of Bacteriological (Biological) and Toxin Weapons and on their Destruction, to which Cuba is a Party, refers as a duty of the Parties to adopt the necessary measures to assure the fulfilment of the Convention at national level.

WHEREAS: The increasing number of research, production, diagnosis and teaching facilities in our country, and thus the complexity of the research and the diversity of organisms and micro-organisms with potential risk of biological contamination for the environment and particularly for the population, the workers, the plants an the animals demands the existence of a proper legal framework regarding biological safety.

THEREFORE: The Council of State, in exercise of the powers it is conferred by Article 90, paragraph c) of the Constitution of the Republic, adopts the following:

DECREE LAW No. 190
OF BIOLOGICAL SAFETY

CHAPTER I
GENERAL PROVISIONS

Article 1: This Decree Law has the objective of establishing the general principles that regulate, in the national territory:

a) The use, research, test, production, import and export of biological agents and its products thereof, organisms and parts of them with genetic information:
b) The releases into the environment of biological agents, organisms and fragments with genetic information, the actions to guarantee the fulfilment of international agreements assumed by the Cuban State regarding biological safety or related to it, the prevention of accidents that may happen and the adoption of measures to protect the environment and in particular, the population, the workers, animals and plants, from negative effects that may cause the activities related to biological agents, organisms and their fragments with genetic information.

Article 2: This Decree Law shall apply to all natural and legal persons that fulfil, in the national territory, the activities listed in Article 1.

Article 3: The following terms are defined for the best understanding and implementation of this Decree Law:

Biological agents: Viable micro-organisms and their products thereof, prions and other organisms that cause or may cause diseases to man, animals and plants.

Release area: Zone defined in the environment by the Ministry of Science, Technology and Environment, in co-ordination with competent bodies and institutions where the introduction of biological agents, organisms and their fragments with genetic information is produced.

License of Biological Safety: A modality of the Environmental License through which the Ministry of Science, Technology and Environment, after assessing the risks, authorises a natural or legal person to fulfil the activities foreseen and under the conditions and requirements established.

Containment barriers: All that opposes the spreading of potentially dangerous materials. They can be primary or secondary. They include, among other elements, the system for waste treatment.

Facilities: Laboratories that carry out biotechnological activities, namely: diagnosis, research, production and teaching. It also includes rooms and areas where biological risk is present.

Organism: All genetically modified biological entity or exotic for the country, able to reproduce itself or transfer genetic material.

Genetically Modified Organisms: Organism which genetic material has been modified by the man in a way different to normal.

Biological Safety: A group of scientific and organisation measures. They include human, technical and engineering measures including physical ones aiming at protecting the workers of the facility, the community and the environment from the risks that pose the work with biological agents or the release of organisms into the environment being them genetically modified or exotic; diminish to the minimum the effects that can present and quickly eliminate their possible consequences in case of contamination, negative effects, releases or loses.

Use: The use, handling, storage, transport and control of biological agents and genetically modified organisms or not.

CHAPTER II
Competence

First Section
ABOUT THE MINISTRY OF SCIENCE, TECHNOLOGY AND ENVIRONMENT

Article 4: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions:

a) Evaluate, guide the risk management and approve field trials or research and releases into the environment of biological agents and their products, organisms and their fragments with genetic information, independently of the risk group to which they may belong;
b) Organise, direct and fulfil inspections to facilities and all national area where biological agents and their products, organisms and their fragments with genetic information are used or released,
c) Grant, suspend and revoke authorisations for carrying out activities related to the use, research, test, production, release, import and export of biological agents and their products, organisms and their fragments with genetic information;
d) Establish classifications regarding:

- The organisms that are released into the environment taking into account their origin and the risk they pose for human health and the environment,
- The biological agents that affect the man, animals and plants and their distribution in risk groups,
- The facilities that use biological agents and their products, organisms and their products with genetic information.

e) Establish mechanisms for the study, assessment and management of the risks of the release into the environment of biological agents and their fragments with genetic information and the procedures to control, mitigate and treat dangerous biological wastes.
f) Establish the National System of Accountancy and Control of biological and toxin agents and organisms that will be released into the environment;
g) Guide and carry out checking to containment barriers existing in the facilities that handle biological agents and organisms;
h) Arrange the total or partial closing of facilities that handle biological agents and organisms if these facilities do not have safety measures and pose risks for human health and the environment;
i) Study, assess, organise, co-ordinate, promote, participate and perform, as the case may be, all activity derived from the responsibilities and functions assigned to Cuba as State Party of International Conventions on the matter or related to it;
j) Appoint reference centres from different bodies and institutions according to their technical and scientific conditions and specify the functions to be developed in co-ordination with them;
k) Adopt necessary measures to prohibit, prevent and control the development, production, storage, acquisition or retention of:

- Biological agents and toxins, be it as it may be their origin or way of production, of types and in quantities not justified for preventive, protection and other peaceful purposes, weapons, equipment or vectors aimed at using those agents or toxins with hostile purposes or in a war;

l) Establish proper procedures in the transfer, handling and use of organisms that may have negative effects for the conservation and sustainable use of biological diversity, particularly agriculture products;
m) Others assigned by the state and the Government.

Section Two
ABOUT OTHER BODIES AND STATE AGENCIES

Article 5: The Bodies and Agencies of the Central Administration of the State and, in particular, those in charge of facilities and release areas, will have the following duties, rights and functions without detriment of the ruling action of the Ministry of Science, Technology and Environment:

a) Establish the necessary conditions with the Ministry of Science, Technology and Environment to carry out any activity related to the use of biological agents and their products, organisms and their fragments with genetic information, as well as to establish the National System of Biological Safety.
b) Add the aspects regarding biological safety in its programs of research and development, inspections, investments and internal regulations, assigning the necessary resources for that, and promoting pure research regarding biological safety;
c) Carry out a proper information of the public before any release into the environment of biological agents and their products, organisms and their fragments with genetic information;
d) Send to the Ministry of Science, Technology and Environment the data that might result from the research of accidents and infections happened in areas of biological risk, plant health, epizootiological and epidemiological emergencies, as well as any other information required on biological safety;
e) Promote the training and re-qualification of the personnel working in the facilities and release areas regarding biological safety;
f) Work out and organise, in co-ordination with the Civil Defence, the emergency plans to be developed in their respective facilities and areas.

CHAPTER III
ABOUT THE FACILITIES

Article 6: The holders of entities in charge of facilities that use biological agents and their products, organisms and their fragments with genetic information, must meet the safety measures and requirements established to the following activities:

a) The levels of biological safety in the facilities according to the risk group to which the organisms being manipulated belong and taking into account the practices, safety equipment and facility design;
b) The handling, transport and sending of samples,
c) The work with laboratory plants and animals,
d) Setting up of structures that support biological safety in the facilities and the determination of its power and functions in agreement with current laws;
e) The qualification, training and information of the personnel;
f) Emergency plans and simulacrum;
g) Treatment and disposal of dangerous biological wastes, and;
h) The establishment of proper procedures to guarantee safeguard and safety.

CHAPTER IV
ABOUT THE RELEASE OF BIOLOGICAL AGENTS AND THEIR PRODUCTS, ORGANISMS AND THEIR FRAGMENTS WITH GENETIC INFORMATION INTO THE ENVIRONMENT

Article 7: The entities in charge of release areas will undergo a process of risk assessment and management that comprises a multiple analysis, on scientific basis, to characterise and identify the nature and the magnitude of hypothetical situations of danger, if they existed, their probability of occurrence and the possible extent of the damages caused by the activities related to the use and release of biological agents and their products, organisms and their fragments with genetic information and the measures aimed at guaranteeing that such a release be carried out in safe conditions.

Article 8: The holders of the entities referred to in the above article, that propose the release of biological agents and their products, organisms and their fragments with genetic information, should present to the Ministry of Science, Technology and Environment for their approval:
a) The technical record for the proposed release;
b) Proper recommendations for the protection of the worker and the environment in general and for setting up any negative effect, no matter the guarantees and authorisations they should give to other Bodies of the Central Administration of the State.

Article 9: The representatives of the Bodies and Agencies from the Central Administration of the State, the entities, and the researchers, in what they are concerned and once the view from the Ministry of Science, Technology and Environment is heard, are in the obligation of developing a proper information and preparation of the public. In one way or another, it will have the direct or indirect relation with the release once it is approved. For that, they should base on the services of the National System of Health, the political and mass organisations and the mass media.

CHAPTER V
ABOUT STATE ENVIRONMENTAL INSPECTION OF BIOLOGICAL SAFETY

Article 10: Objects of state environmental inspection of biological safety are: entities with facilities that handle biological agents and their products, organisms and their fragments with genetic information that may affect the man, animals and plants, and the areas where they are released into the environment.

Article 11: Inspectors from the Ministry of Science, Technology and Environment fulfil the biological safety inspection. In case the participation of inspectors from other Bodies and Agencies of the Central Administration of the State is required, the mentioned Ministry will issue the corresponding request. Once it is authorised by the Body or Agency in question, it will appoint the personnel.

Article 12: The inspection of biological safety has the objective of checking the fulfilment of current laws on the matter and will include, among others, the following aspects:

a) Verification of containment barriers,
b) Fulfilment of proper practices;
c) Implementation of the plans to prepare and update the personnel regarding biological safety;
d) Organisation, receipt and final destination of samples and biological agents;
e) Checking of the standards and procedures for the use of biological agents and their products, organisms and their fragments with genetic information, their release into the environment, as well as the verification of their fulfilment;
f) Checking the records and control of biological agents and their products, organisms and their fragments with genetic information existing in the facilities;
g) Checking the safety program in the facility, as well as its physical protection and safety plan and its implementation,
h) Checking if the conditions for the authorisation of biological safety granted remain the same;
i) Fulfilment of the country agreements in virtue of International Agreements and Conventions regarding or related to biological safety, to which Cuba is a State Party.

CHAPTER VI
ABOUT AUTHORISATIONS OF BIOLOGICAL SAFETY

Article 13: The execution of the activities listed in this Article will require the authorisation granted by the Ministry of Science, Technology and Environment for each activity without detriment of those that should be granted by other Bodies or Agencies of the Central Administration of the State:

a) The siting, design, project, condition, remodelling, starting, operation and closing of facilities where biological agents and their products, organisms and their fragments with genetic information are used;
b) Receipt or sending, transfer with advance request and assessment by the corresponding agencies of biological agents and toxins as well as organisms from risk groups previously agreed; equipment, technologies and materials in general among local facilities that use them or between Cuba and other States so as to avoid they are used to carry out prohibited activities at national or international levels;
c) The procedures for the destruction or disabling of biological agents and toxins, when for their volume, characteristics and location they are considered dangerous or can violate international agreements to which Cuba is a Party;
d) The research, production and field testing that involve biological agents and their products, organisms and their fragments with genetic information;

e) The environmental release of biological agents and their products, organisms and their fragments with genetic information;
f) The import and export of biological agents and their products, organisms and their fragments with genetic information;
g) Transport of dangerous biological wastes; and
h) Others related to the fulfilment of the agreements contracted by the Republic of Cuba in international legal instruments on this matter or related to it.

Article 14: the Ministry of Science, Technology and Environment will propose to competent Bodies and Agencies the conditions and requirements of knowledge, including the establishment of official courses on this subject. The personnel that work in facilities requiring a high level of biological safety for the risk they pose should receive these.

CHAPTER VII
ABOUT DANGEROUS BIOLOGICAL WASTES

Article 15: The holders of the agencies in charge of facilities and release areas whose operations may originate dangerous biological wastes, that is, those containing biological agents, organisms and their fragments with genetic information that pose a real or potential threat for the human health and the environment in general will be responsible for the use, treatment, and disposal under safe conditions and in keeping with current environmental provisions so as to guarantee the protection of the environment and, in particular, of the population and the workers;

Article 16: The authorities mentioned in the above article, who are responsible for the use, treatment, transport and waste disposal, will make provision in its budget for the monetary appropriations necessary to meet the costs generated by such operations.

CHAPTER VIII
ABOUT BIOLOGICAL EMERGENCIES

Article 17: The Ministry of Science, Technology and Environment, in co-ordination with the National General Staff of the Civil Defence will participate in the drafting, execution and control of a National Plan for Emergencies or any other situation caused by events that may originate a damage with immediate or delayed negative effects to the environment, the population and the workers in particular due to the escape or release of organisms. Moreover, it will advise technically the Civil Defence from a biosafety point of view as well as in the assessment of the existing situations.

Article 18: The holders of the agencies in charge of facilities that manipulate biological agents and their products, organisms and their fragments with genetic information as well as the areas where they are released into the environment, will be responsible for the drafting, organisation and preparation of emergency plans that will be implemented in their respective facilities and areas.

TRANSITORY PROVISION

UNIQUE: The Centres, institutions and the bodies and agencies of the Central Administration of the State will submit the Ministry of Science, Technology and Environment, in a term of 90 days from the publication of this Decree Law, an information regarding the releases of organisms into the environment carried out in the country in the last five years for the corresponding risk assessment and prepare their record. The information will include:

- Scientific and common name;
- Designation;
- Treated or sowed hectares;
- Quantities released for years; and
- Risk assessment for the workers and the environment.

FINAL PROVISION

FIRST: The Bodies and Agencies of the Central Administration of the State, having heard in each case the opinion of the Ministry of Science, Technology and Environment, will guarantee the existence of organising, advisory and consult structures that allow the fulfilment of what this Decree Law establishes.

SECOND: The Ministry of Science, Technology and Environment will issue as many provisions as it consider necessary for the best implementation of this Decree Law.

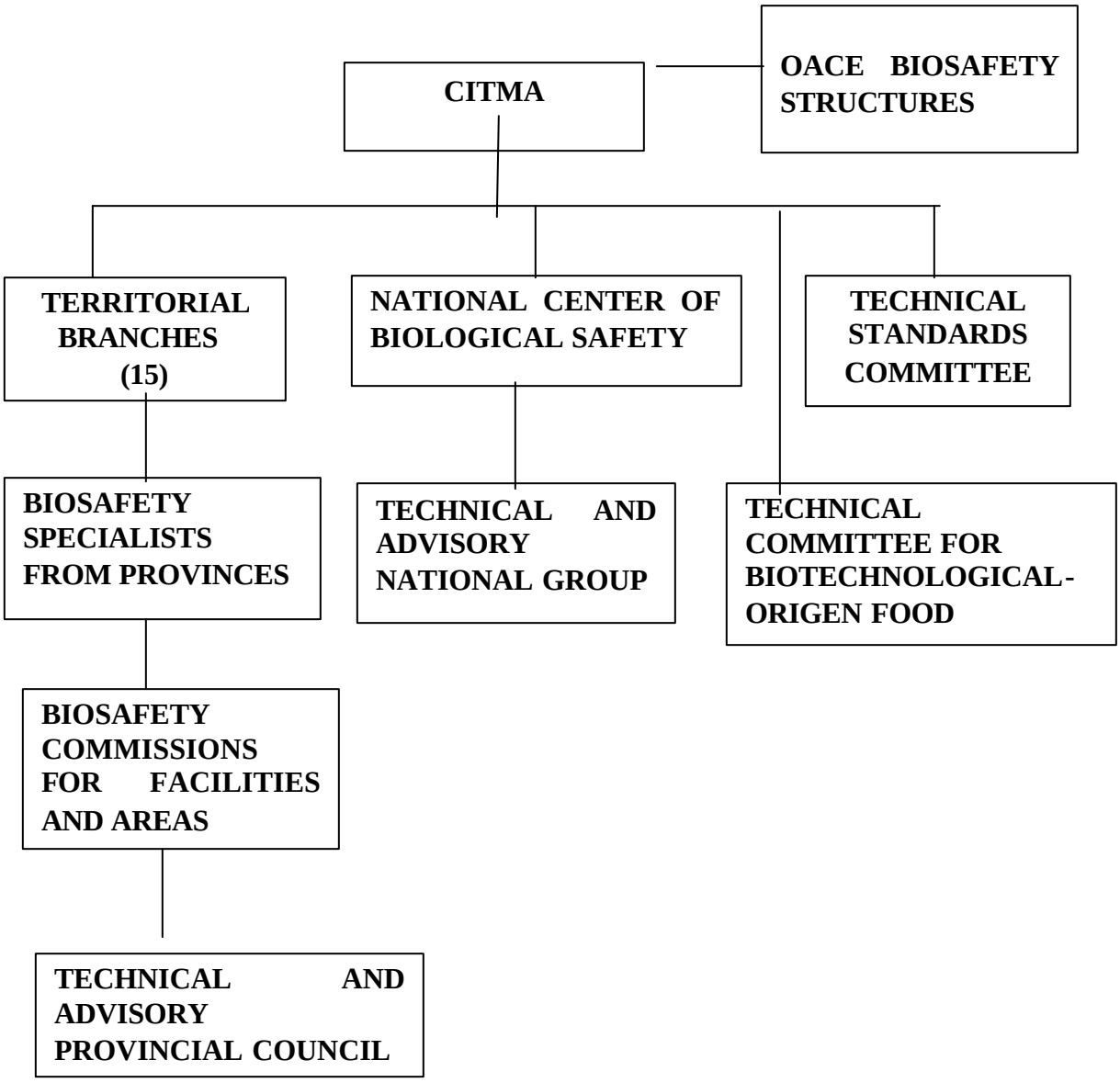
THIRD: This Decree Law will take effect when published in the Official Gazette of the Cuban Republic.

SET FORTH at Palacio de la Revolución, in the city of Havana, on the twenty-eighth day of January, 1999.

FIDEL CASTRO RUZ

Note:
This translation was completed at the National Centre for Biological Safety. Every effort was made to have an accurate, consistent and readable translation. Nevertheless, the original Spanish text remains the official version of the Decree Law and any interpretations of critical importance should continue to rely on it.

2.2 - GRAPHICAL STRUCTURE OF THE NATIONAL SYSTEM OF BIOLOGICAL SAFETY



2.3 - MAIN FUNCTIONS OF THE NATIONAL CENTER OF BIOLOGICAL SAFETY

- To organize, conduct, perform, supervise, and control, as it corresponds to, the National System of Biological Safety.
- To be involved in the regulation and supervision of the activities associated with the physic protection of biological and toxinic agents as well as the organisms released into the environment along with the competent bodies, state agencies, and institutions.
- To work out and propose the integral program of development and the research lines about biological safety in coordination with the competent bodies, organizations, and specialized institutions.
- To perform risk assessments for human health and the environment in relation with the investment projects and other working activities with potential risks together with the proposal about the necessary measures to be taken in each case. All of the above should be done in coordination with the corresponding bodies, state agencies, entities, and institutions.
- To organize and conduct the inspections to be done to the biomedical, biotechnological facilities, to any entity that handle biological agents, and to the areas where organisms are released into the environment in order to verify the dispositions and standards established regarding biological safety.
- To propose the legal instruments and technical standards that allow establishing and complementing the measures for biological safety.
- To work out recommendations related to the inclusion of these topics in the syllabus for intermediate-and-advanced-level specialists whose profile is related to Biosafety. In addition, to promote the technical and professional specialization and upgrading of the personnel devoted to biological safety.
- 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 toxinic agents and organisms released into the environment in coordination with the corresponding bodies, state agencies, and entities.
- To organize and perform the procedures for granting licenses to those facilities where biological agents are handled, as well as authorizations, and other permits for the activities associated with design, construction, research, releases into the environment, and others, related to the agreements assumed by the country in international instruments.
- To sort out in risk groups the biological and toxiic agents that have adverse effects on man, plants and animals.

ANNEX 3

MATRIX SHOWING THE RELATION BETWEEN THE PROJECT ACTIVITIES, THE CARTAGENA PROTOCOL AND THE NATIONAL BIOSAFETY FRAMEWORK

PROTOCOL ACTIVITIES	PROJECT ACTIVITIES	NBF and associated MAIN FUNCTIONS OF THE NATIONAL CENTER OF BIOLOGICAL SAFETY
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.	➢ **To support the implementation of the regulatory and administrative biosafety system as per Decree Law N.190/99 on Biological Safety 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 Cuba, and meet the obligations foreseen under the Cartagena Protocol**	➢ To organise, conduct, perform, supervise, and control, as it corresponds to, the National System of Biological Safety. ➢ To be involved in the regulation and supervision of the activities associated with the physic protection of biological and toxinic agents as well as the organisms released into the environment along with the competent bodies, state agencies, and institutions. Decree Law 190. ***Article 4***: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions: n) Evaluate, guide the risk management and approve field trials or research and releases into the environment of biological agents and their products, organisms and their fragments with genetic information, independently of the risk group to which they may belong; o) Organise, direct and fulfil inspections to facilities and all national area where biological

		agents and their products, organisms and their fragments with genetic information are used or released, p) Grant, suspend and revoke authorisations for carrying out activities related to the use, research, test, production, release, import and export of biological agents and their products, organisms and their fragments with genetic information; q) Establish proper procedures in the transfer, handling and use of organisms that may have negative effects for the conservation and sustainable use of biological diversity, particularly agriculture products;
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	**The strengthening of the National Biosafety System.** **Working on legal instruments and technical documents on biosafety.** 1) Finalised the Rules that are part of Decree-Law 190/99 of Biological Safety and submit them for approval. They are: - Rule of Licenses of Biological Safety approved. - Rule of Biological Safety for facilities handling biological agents at small and large scale that may affect animals, man, and plants approved. - Rule for the State Environmental Inspection of Biological Safety approved. 2) Established a Standardisation Committee for biosafety standards. Identification and working out technical on Biosafety and their publication. 3) To Work out and implement the National Strategy of Biosafety.	➢ To organise and conduct the inspections to be done to the biomedical, biotechnological facilities, to any entity that handle biological agents, and to the areas where organisms are released into the environment in order to verify the dispositions and standards established regarding biological safety. ➢ To propose the legal instruments and technical standards that allow establishing and complementing the measures for biological safety. ➢ To organise and perform the procedures for granting licenses to those facilities where biological agents are handled, as well as authorisations, and other permits for the activities associated with design, construction, research, releases into the environment, and others, related to the agreements assumed by the country in international instruments. Decree Law 190.

observation that is commensurate with its life-cycle or generation time before it is put to its intended use.	4) To organise the following workshops: • 2 National workshop on the implementation of legal documents, technical rules and methodologies; (5 days, 100 participants) • 3 Local workshops for defining, analysing and approving the National Biosafety Strategy (3 days, 30 participants) • 1 National workshop for adopting the National Strategy of Biological safety. (3 days, 100 participants)	*Article 10*: Objects of state environmental inspection of biological safety are: entities with facilities that handle biological agents and their products, organisms and their fragments with genetic information that may affect the man, animals and plants, and the areas where they are released into the environment.
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.	**Develop methodologies to 1) assess, manage and monitor the risks associated to LMOs handling, transport, use, transfer and release and 2) produce and validate the related data at national level.** 1) To develop a methodology for risk management. .2) To start methodology for monitoring of LMOs released into the environment	Decree Law 190. ***Article 4***: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions: e) Establish mechanisms for the study, assessment and management of the risks of the release into the environment of biological agents and their fragments with genetic information and the procedures to control, mitigate and treat dangerous biological wastes. f) Establish the National System of Accountancy and Control of biological and toxin agents and organisms that will be released into the environment; ***Article 7***: The entities in charge of release areas will undergo a process of risk assessment and management that comprises a multiple analysis, on scientific basis, to characterise and identify the nature and the magnitude of hypothetical situations of danger, if they existed, their probability of occurrence and the possible extent of the damages caused by the activities related to the use and release of biological agents and their products, organisms and their fragments with genetic
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.		
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.** 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 on measures that it has taken to implement the Protocol.		information and the measures aimed at guaranteeing that such a release be carried out in safe conditions. ***Article 4***: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions: i) Study, assess, organise, co-ordinate, promote, participate and perform, as the case may be, all activity derived from the responsibilities and functions assigned to Cuba as State Party of International Conventions on the matter or related to it; ***Article 12***: The inspection of biological safety has the objective of checking the fulfilment of current laws on the matter and will include, among others, the following aspects: i) Fulfilment of the country agreements in virtue of International Agreements and Conventions regarding or related to biological safety, to which Cuba is a State Party.
Article 15. 1. Risk assessment undertaken pursuant to this	**Develop methodologies to 1) assess, manage and**	To perform risk assessments for human health and

Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognised risk assessment techniques.	**monitor the risks associated to LMOs handling, transport, use, transfer and release and 2) produce and validate the related data at national level** 1) To develop a methodology for risk assessment	the environment in relation with the investment projects and other working activities with potential risks together with the proposal about the necessary measures to be taken in each case. All of the above should be done in co-ordination with the corresponding bodies, state agencies, entities, and institutions. To sort out in risk groups the biological and toxinic agents that have adverse effects on man, plants and animals. Decree Law 190. ***Article 4***. The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions: r) Establish classifications regarding: • The organisms that are released into the environment taking into account their origin and the risk they pose for human health and the environment, • The biological agents that affect the man, animals and plants and their distribution in risk groups, • The facilities that use biological agents and their products, organisms and their products with genetic information. ***Article 13:*** The execution of the activities listed in this Article will require the authorisation granted by the Ministry of Science, Technology and Environment for each activity without detriment of those that should be granted by other Bodies or

		Agencies of the Central Administration of the State: s) The research, production and field testing that involve biological agents and their products, organisms and their fragments with genetic information; t) The environmental release of biological agents and their products, organisms and their fragments with genetic information; u) The import and export of biological agents and their products, organisms and their fragments with genetic information;
Article 22 1. 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 organizations and, as appropriate, through facilitating private sector involvement. 2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each	**Strengthen and develop national capacities at human and infrastructural level** C.1) Strengthened National Biosafety Centre with the needed equipment for capacity building purposes (C.2) Run national training courses on Biosafety. (C.3) Organise 2 Workshops on biosafety	➢ To work out recommendations related to the inclusion of these topics in the syllabus for intermediate-and-advanced-level specialists whose profile is related to Biosafety. In addition, to promote the technical and professional specialization and upgrading of the personnel devoted to biological safety. Decree Law. 190. ***Article 5***: The Bodies and Agencies of the Central Administration of the State and, in particular, those in charge of facilities and release areas, will have the following duties, rights and functions without detriment of the ruling action of the Ministry of Science, Technology and Environment: b) Add the aspects regarding biological safety in its programs of research and development, inspections, investments and internal regulations, assigning the necessary resources for that, and promoting pure research regarding biological safety;

Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.		
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.	**Develop a National System for Information Exchange and set up the related network to be linked to the BCH.** 1) To develop a National Database System for Information Exchange based on a national database on facilities, micro-organisms, negative impacts, transgenic organisms, environmental releases, experts, and others. 2) To set up a network within the country, and an Intranet for the Centre. 3) To organise 2 national workshops on the use, handling of database and the evaluation of a national system for Information Exchange on Biosafety (5 days, 45 participants).	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 toxinic 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 and to develop a national database system for information exchange. Decree Law 190. ***Article 4***: The Ministry of Science, Technology and Environment is the agency of the Central Administration of the State in charge of setting up, fulfil and control the policy of the State and the Government regarding biological safety. To this purpose, in co-ordination with the bodies and competent state agencies it will have the following functions and attributions: v) Guide and carry out checking to containment barriers existing in the facilities that handle biological agents and organisms; *Article 17*: The Ministry of Science, Technology and Environment, in co-ordination with the

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.		National General Staff of the Civil Defence will participate in the drafting, execution and control of a National Plan for Emergencies or any other situation caused by events that may originate a damage with immediate or delayed negative effects to the environment, the population and the workers in particular due to the escape or release of organisms. Moreover, it will advise technically the Civil Defence from a biosafety point of view as well as in the assessment of the existing situations**.**
Article 22 The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations and, as appropriate, through facilitating private sector involvement. **Article 23** 1. The Parties shall: Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies; Endeavour to ensure that public awareness and	**Strengthen and develop the upgrading and the technical and professional training of human resources for risk assessment and management** **Develop of human resources for risk assessment and management.** **Executing the upgrading and the technical and professional training.** 1) To run Mastery, postgraduate course, and integral course on Biosafety and a distance course (courses 40 – 60 hours, mastery 1200 hours, people 30) 2) Co-ordinate the participation of national specialists in courses and scientific events in the country or abroad in Biosafety and other sciences related to it. 3) To perform two national meetings of specialists each year of the project so as to evaluate the organisation and management of biosafety in the provinces, exchange experiences, state new tasks, study and discuss new instruments and procedures. (3 days, 45 participants) 4) To develop teaching material on Biosafety.	To work out and propose the integral program of development and the research lines about biological safety in co-ordination with the competent bodies, organisations, and specialised institutions. To work out recommendations related to the inclusion of these topics in the syllabus for intermediate-and-advanced-level specialists whose profile is related to Biosafety. In addition, to promote the technical and professional specialisation and upgrading of the personnel devoted to biological safety. Decree Law 190. ***Article 5***: The Bodies and Agencies of the Central Administration of the State and, in particular, those in charge of facilities and release areas, will have the following duties, rights and functions without detriment of the ruling action of the Ministry of Science, Technology and Environment: c) Carry out a proper information of the public before any release into the environment of biological agents and their products, organisms and their fragments with genetic information;

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. 3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House.	5) To work out and publicise teaching materials. 6) To work out and publicise magazine on Biosafety on a 3-4 time -a-year basis. 7) To co-ordinate, work out and execute a program for public education. 8) To organise 2 National workshops on Biosafety. (3–5 days, 100 participants)	***Article 9***: The representatives of the Bodies and Agencies from the Central Administration of the State, the entities, and the researchers, in what they are concerned and once the view from the Ministry of Science, Technology and Environment is heard, are in the obligation of developing a proper information and preparation of the public. In one way or another, it will have the direct or indirect relation with the release once it is approved. For that, they should base on the services of the National System of Health, the political and mass organisations and the mass media.

ANNEX 4

UNEP Response to the STAP Technical Review

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

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

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

Country's Specific Issues

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

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

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

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