



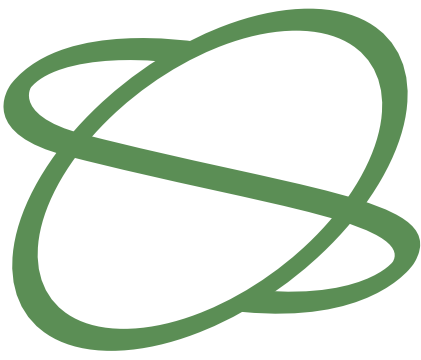
GEF

UNEP/GEF
Building Capacity
for the
Implementation
of the
Cartagena
Protocol
on
Biosafety



UNEP

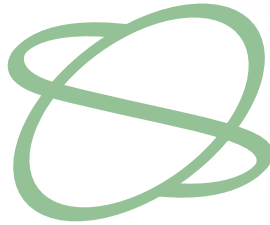
United Nations Environment Programme



GEF



UNEP



GEF



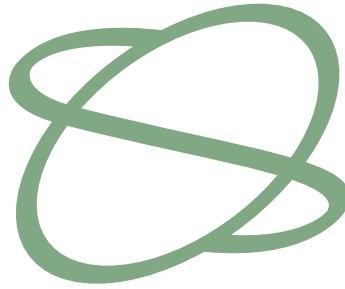
UNEP



GEF



UNEP



GEF



UNEP



GEF



UNEP

UNEP/GEF
Building Capacity
for the
Implementation
of the
Cartagena
Protocol
on
Biosafety

March 2002



Preface

The Cartagena Protocol on Biosafety, being the first international legal instrument of the 21st century, has caught the enthusiastic attention of the world environment community since its adoption on 29th January 2000. This enthusiasm must be sustained. Accordingly, UNEP as one of the three Implementing Agencies of the Global Environment Facility (GEF) is taking the lead in promoting one of the most important initiatives undertaken by the GEF. That is to build the capacity of developing countries and countries with economies in transition to address the challenges of the implementation phase of the Protocol.



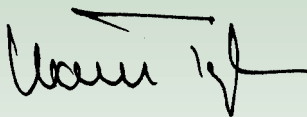
Since the beginning of the 1990s, UNEP has made a major contribution in promoting the biosafety agenda. In 1995, UNEP's International Technical Guidelines on Biosafety were adopted. Between 1997 and 2000, UNEP successfully implemented, with GEF resources of US\$ 2.7 million, a pilot biosafety project that assisted 18 countries prepare National Biosafety Frameworks and promoted regional cooperation.

Based on the success of the pilot project, and following the designation of the GEF as the financial mechanism of the Cartagena Protocol on Biosafety, UNEP is now implementing, with GEF financing, a US\$ 39 million project that will assist up

to 100 countries, worldwide, prepare their National Biosafety Frameworks as well as promoting regional and sub-regional cooperation. To this end, more than 20 regional and sub-regional workshops will be convened during the three year duration of this project, unique in the history of the GEF.

In addition, and in accordance with the Initial Strategy on Biosafety adopted by the GEF Council, UNEP is assisting eight countries that participated in the pilot project to implement their National Biosafety Frameworks. The experience gained through these demonstration projects will be of great assistance in meeting the challenge of making operational the biosafety frameworks developed through the global project.

The activities presented in this brochure clearly indicate the significant contribution that UNEP is providing in assisting countries to prepare themselves for the entry into force of the Protocol and implement its innovative provisions.



Klaus Töpfer
Executive Director
UNEP



Contents

Preface

List of Acronyms

1. Introduction	2
2. The Biosafety Protocol and The GEF Initial Strategy	8
3. UNEP/GEF Action in Biosafety	10
3.1. The Pilot Biosafety Enabling Activity	12
3.2. The Global Project for the Development of National Biosafety Frameworks in up to 100 Countries	16
3.3. Implementation of National Biosafety Frameworks	22
4. Participatory Approach and Lessons Learned	26
5. Conclusion	30
Terminology	32
Further Information	34
Contact Persons at UNEP/GEF	35

List of Figures and Boxes

Figure 1: The development of international agreements on biosafety and UNEP/GEF supportive action	7
Figure 2: UNEP/GEF Support to the Development and implementation of National Biosafety Frameworks	11
Figure 3: Development of the Pilot Biosafety Enabling Activity	13
Figure 4: Development of the Global Project	17
Figure 5: Development of demonstration projects for the implementation of National Biosafety Frameworks	23
Box 1: Article 22 of the Cartagena Protocol: Capacity-Building	5
Box 2: National Biosafety Frameworks	15

List of Acronyms

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
COP	Conference of the Parties
CP	Cartagena Protocol
FAO	Food and Agriculture Organisation
GEF	Global Environment Facility
ICCP	Intergovernmental Committee of the Cartagena Protocol
ICGEB	International Centre for Genetic Engineering and Biotechnology
LMO	Living Modified Organism
NBF	National Biosafety Framework
NBSAP	National Biodiversity Strategies and Action Plan
NGO	Non Governmental Organisation
SC	Steering Committee
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNIDO	United Nations Industrial Development Organisation

1. Introduction

Agenda 21, adopted at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in June 1992, makes specific provision for the "Environmentally Sound Management of Biotechnology". In the introduction to chapter 16, it is recognised that, although biotechnology cannot provide solutions to all the fundamental problems of environment and development, it could, nonetheless, contribute substantially to sustainable development:

"Biotechnology promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. It offers new opportunities for global partnerships."

Potential for partnership was foreseen especially between countries with developed expertise in biotechnology and countries rich in biological (and hence genetic) resources but lacking biotechnological expertise and capital needed to transform these resources to serve the needs of sustainable development.

Chapter 16 of Agenda 21 also stresses that the community at large can only derive full benefit from biotechnology if it is developed and applied judiciously. The use and release into the environment of living modified organisms (LMO) resulting from modern biotechnology could have adverse impacts on the conservation and sustainable use of biological diversity. Agenda 21, therefore, seeks to ensure safety in the development, application, exchange and transfer of biotechnology, through international agreement on principles of risk assessment and management.

The safe use of modern biotechnology has also featured prominently in the Convention on Biological Diversity (CBD). The CBD recognises that, if developed and used with adequate safety measures for the environment and human health, biotechnology can contribute towards achieving the Convention objectives, which are:

"the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources."

The CBD calls on Parties to:

"Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms, resulting from biotechnology which are likely to have adverse environmental impacts, that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health" (Article 8 (g)).

"Consider the need and modalities of a protocol setting out appropriate procedures, including, in particular advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity" (Article 19.3).



Annelies Van Brink

Capacity Building

The Cartagena Protocol on Biosafety, adopted in January 2000, is the result of this call. In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of the Protocol is

"to contribute to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focussing on transboundary movement."

The importance, in order to achieve this objective, for all Parties to co-operate to build capacity in biosafety in developing countries and countries with economies in transition was underlined. While developed countries have established domestic biosafety regimes, many developing countries and countries with economies in transition have limited capabilities to cope with the nature and scale of known and potential risks associated with the use of modern biotechnology and are only now starting to establish their own National Biosafety Frameworks. Article 22 of the Protocol specifically addresses the issue of co-operation and capacity-building (Box 1).

Throughout this process, the Global Environment Facility (GEF), as the financial mechanism of the CBD and of the Cartagena Protocol, and the United Nations Environment Programme (UNEP), as one of the three Implementing Agencies of the GEF, have responded to the international calls to build capacity in biosafety.

In adopting its decision, COP II/5, at its second meeting (Jakarta, Indonesia, 6-15 November 1995), the Conference of the Parties to the CBD stressed the importance of urgently finalising and applying the UNEP International Technical Guidelines for Safety in Biotechnology, to facilitate the development of national capacities to assess and manage biotechnology risks, establish adequate information systems, and develop human resources and expertise relevant to issues of biosafety at national and regional levels.

Article 22, Cartagena Protocol

CAPACITY BUILDING

- 1. The Parties shall co-operate 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, sub-regional and national institutions and organisations and, as appropriate, through facilitating private sector involvement.*
- 2. For the purposes of implementing paragraph 1 above, in relation to co-operation, 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. Co-operation in capacity-building shall, subject to the different situation, capabilities and requirements of each 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*

Box 1: Article 22 of the Cartagena Protocol: Capacity-Building

Capacity Building

In December 1995, after an extensive consultative process involving regional and global workshops, UNEP finalised the International Guidelines for Safety in Biotechnology, designed to serve as an interim measure during the development of the Protocol.

In response to the Conference of the Parties request to the GEF to provide financial resources to developing country parties for capacity-building in biosafety, the 10th meeting of the GEF Council in November 1997 approved the UNEP/GEF US\$ 2.7 million Biosafety Pilot Enabling Activity to assist eighteen eligible countries prepare National Biosafety Frameworks and promote regional collaboration.

Following the adoption of the Cartagena Protocol in January 2000, the GEF Council, in November 2000, adopted an *"Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"* (GEF/C.16/4). The strategy outlines activities that the GEF shall undertake in the period leading up to the entry into force of the Protocol, and is based on GEF's experience in implementing the CBD. At the same meeting, the Council also adopted the US\$ 39 million project prepared by UNEP for the Development of National Biosafety Frameworks in up to 100 countries.

In accordance with the Initial Strategy, UNEP has continued to work with participating countries of the pilot project to support the implementation of the National Biosafety Frameworks developed in the earlier project. The GEF Council, in December 2001, approved eight UNEP/GEF medium sized projects with this purpose.

The international process and UNEP/GEF activities that have, and continue, to support the process are described in detail in the sections that follow. ■

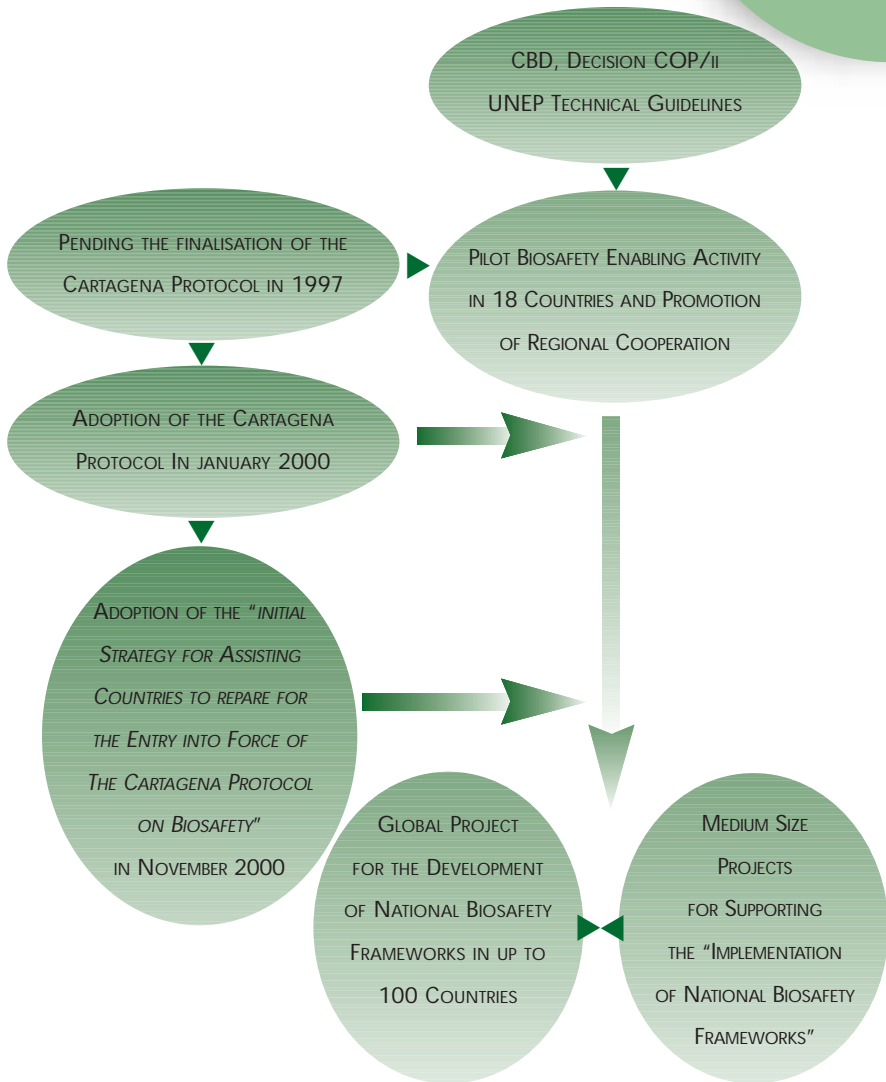


Figure 1: The development of international agreements on biosafety and UNEP-GEF supportive action

2. The Biosafety Protocol

and the GEF Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol

The Cartagena Protocol on Biosafety was adopted in January 2000, at the resumed session of the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity held in Montreal. The Protocol was opened for signature at the 5th Meeting of the Conference of the Parties (CBD COP5) held in Nairobi in May 2000. By December 2001, more than 100 countries had signed the Protocol. The legal and regulatory structures required to implement it need now to be developed.

The CBD COP5 included a Ministerial Round Table on *"Capacity-building in Developing Countries to Facilitate the Implementation of the Protocol"*. Decision V/13, on *"Further guidance to the financial mechanism"* and Decision V/1, on the Biosafety Protocol, 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 need for capacity-building was also emphasised at a GEF workshop on the UNEP/GEF Pilot Biosafety Enabling Activity held at the margins of CBD COP5 with the participation of more than 150 delegates.

In November 2000, the GEF Council adopted an *"Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety"* (GEF/C.16/4). The main objectives outlined in the strategy are:

- (a) to assist countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of National Biosafety Frameworks, including strengthening

capacity for risk assessment and management with a wide degree of stakeholder participation,

- (b) to promote information sharing and collaboration at the regional and sub-regional level and among countries that share the same biomes/ ecosystems, and
- (c) to promote identification, collaboration and coordination among other bilateral and multilateral organizations to assist capacity-building for the Protocol and explore the optimization of partnerships with such organizations.

Specific activities proposed to meet these objectives were:

- (a) A project to assist interested signatories to the Cartagena Protocol in establishing National Biosafety Frameworks;
- (b) Individual, country-based demonstration projects, through any of the GEF Implementing Agencies, to assist in building-capacity to implement National Biosafety Frameworks;
- (c) Co-ordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;
- (d) Support to enable countries to participate in the biosafety clearing-house, once the clearing-house terms of reference are agreed upon by the Parties; and
- (e) Enhancement of the scientific and technical advice to the GEF on biosafety issues.

The Initial Strategy and the results of the Pilot Biosafety Enabling Activity were presented and discussed during the First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP-1), held in Montpellier on 11-15 December 2000. The ICCP-1 stressed the need for capacity building and strengthening of human and institutional resources of developing countries, especially in least developed and Small Island Developing States, and countries with economies in transition. The meeting also stressed the importance of a regional approach. ■

3. UNEP/GEF Action in Biosafety

The United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF) have a proven track record in responding to international calls for assistance in the field of biosafety. The CBD has designated the GEF as its overall financial mechanism, as well as the financial mechanism of the Cartagena Protocol on Biosafety. Meanwhile, UNEP, as one of the Implementing Agencies of the GEF, has taken an active role in Biosafety capacity-building since the beginning of the 1990s. This includes its participation in the conception of the UNIDO/UNEP/WHO/FAO *ad hoc* Working Group on Biosafety in 1990 and a series of consultative processes culminating in the finalisation of the UNEP International Technical Guidelines for Safety in Biotechnology in 1995.

Following the call for initiatives of the *Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety*, two sets of activities are currently being implemented by UNEP:

1. A global project for the Development of National Biosafety Frameworks in up to 100 countries;
2. Demonstration projects to support the implementation of National Biosafety Frameworks.

Both build upon the successful conclusion in 2000 of the Pilot Biosafety Enabling Activity.



Robert Holmgren

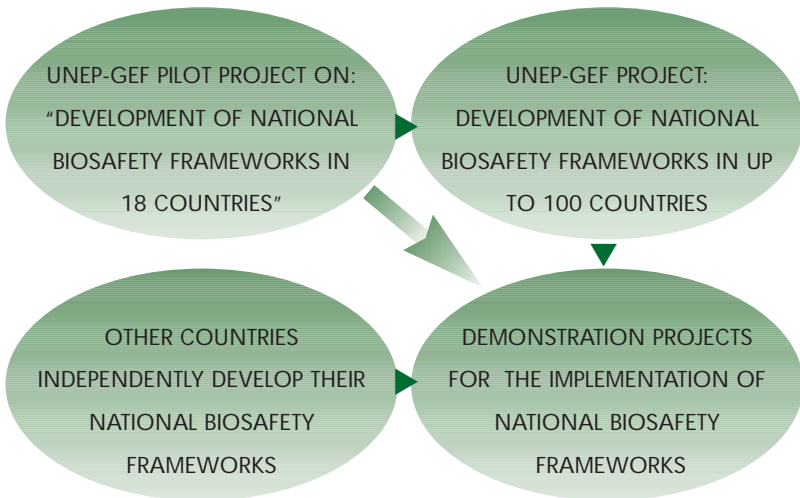


Figure 2: UNEP/GEF Support to the development and implementation of National Biosafety Frameworks

3.1 The Pilot Biosafety Enabling Activity

In 1996, prior to finalization of the negotiation of the Cartagena Protocol, the third meeting of the Conference of the Parties to the Convention on Biological Diversity requested the GEF, as the financial mechanism of the CBD, to provide financial resources to developing country Parties for building capacity in biosafety (Decision COP/III/5).

In response to this request and to the UNEP Governing Council Decision 19/16 on Biosafety, the 10th meeting of the GEF Council, held in Washington, DC in November 1997, approved a Pilot Biosafety Enabling Activity project of US\$ 2.7 million submitted by UNEP acting as one of the three Implementing Agency of the GEF. The overall aims of the Pilot Biosafety Enabling Activity project were:

- To carry out an assessment of technological capacity, its effect on implementation of National Biosafety Frameworks and the means to improve it;
- To strengthen national capacity to implement biosafety procedures;
- To harmonise regional and international legal instruments;
- To raise public awareness of the issues involved in release of living modified organisms

The project, involving participation of 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, the Russian Federation, Tunisia, Uganda, and Zambia) had two components:

- a. *National Level Component* aiming at assisting eighteen eligible countries to prepare National Biosafety Frameworks (US\$ 1.9 million), and
- b. *Global Level Component* aiming at facilitating the exchange of experience at regional levels through the convening of 2 workshops in each of four regions (US\$ 0.8 million).

Stage 1

UNEP/GEF Pilot Biosafety Enabling Activity 1997 - 2000

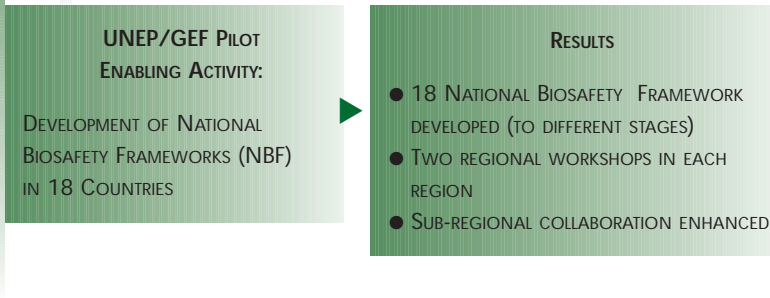


Figure 3: Development of the Pilot Biosafety Enabling Activity

The National Component

The objective of the national component was to develop, promote and strengthen national instruments for environmental management and methods for implementation of National Biosafety Frameworks. This called for harmonisation of biosafety management systems at sub-regional, regional and global levels as well as development of greater awareness of potential benefits and possible risks resulting from modern biotechnology, among a wide spectrum of stakeholders at sub-regional, regional and global levels.

As part of this work, national surveys were carried out to identify existing applications of modern biotechnology, the extent and impact of releases of LMOs, biosafety, risk assessment and risk management systems, and review existing legislation relevant to biosafety. The participating countries varied in size, geographical location, and their level of economic development. They were at different stages in developing modern biotechnology and apply-

Capacity Building

ing biotechnology products, and at different stages in preparing their National Biodiversity Strategies and Action Plans (NBSAPs). Some countries, for example the Russian Federation, already had elements of a National Biosafety Framework in place. In those instances, funding was directed to improving and expanding the existing structure and to integrating the UNEP International Technical Guidelines into the national framework.

The Global Component

The global component incorporated two back-to-back UNEP/GEF Regional Workshops on Biosafety in each region. The first workshop covered issues related to risk assessment and risk management of LMOs. The topics addressed included organisms with novel traits resulting from modern biotechnology for enhancement of biosafety. The analysis allowed for a full environmental impact assessment.

The second workshop focused on issues related to transboundary transfer of LMOs, including appropriate mechanisms and methods for supply and exchange of information regarding biosafety.

The UNEP/GEF Regional Workshops on Biosafety brought together more than 267 government designated experts from different countries of the regions, with representatives from the scientific community, UN bodies, bio-industry, NGOs and other organisations. The participants discussed and exchanged views on a wide range of issues related to safety in modern biotechnology. These ranged from issues related to risk assessment and risk management of LMOs, to issues related to transboundary transfer of LMOs, including appropriate mechanisms and methods for supply and exchange of information regarding biosafety. The regional workshops were held in: Havana, Cuba, 26-30 October 1998 (Latin America and the Caribbean); Bled, Slovenia, 11-15 November 1998 (Central and Eastern Europe); Nairobi, Kenya, 23-27 November 1998 (Africa); New-Delhi, India, 7-11 December 1998 (Asia and the Pacific).

What is a National Biosafety Framework?

A National Biosafety Framework is a system of legal, technical and administrative mechanisms set in place to address safety in the field of modern biotechnology. Although biosafety frameworks vary from country to country, their main elements would be:

- a regulatory system set in place to address safety in the field of modern biotechnology
- an administrative system to handle requests for permits for certain activities, such as releases of LMOs
- a decision making system that includes risk assessment and management for the release of LMOs
- mechanisms for public participation and information

Box 2: National Biosafety Frameworks

3.2. The Global Project for the Development of National Biosafety Frameworks in up to 100 Countries

In February 2001, the Governing Council, at its 21st session held in Nairobi, “noted with appreciation the successful completion of the United Nations Environment Programme/Global Environment Facility Pilot Biosafety Enabling Activity Project implemented by national executing agencies of 18 Global Environment Facility-eligible countries” and strongly supported further and more extensive actions in the field, “commending the GEF approval of the UNEP/GEF Development of National Biosafety Frameworks Project to benefit up to 100 Global Environment Facility-eligible developing countries and countries with economies in transition.”

The global project for assisting up to 100 countries develop their National Biosafety Frameworks (NBF) began operation in June 2001. At the Second meeting of the Intergovernmental Committee of the Cartagena Protocol (ICCP-2), held in Nairobi, Kenya, from 1-5 October 2001, a status report on the implementation of this project was presented at the plenary of the meeting and further discussed during a side event held on 2nd of October, co-chaired by the Executive Director of UNEP and the chairman of ICCP with the participation of more than 300 delegates.

The US\$ 39 million project, including a \$26 million grant from the GEF, aims at:

- i. Assisting up to 100 GEF eligible countries that have signed the Cartagena Protocol on Biosafety to prepare their National Biosafety Frameworks, and
- ii. Promoting regional and sub-regional co-operation through the convening of regional and sub-regional workshops.

Stage 2

Building Capacity For The Biosafety Protocol: Development Phase 2001-2004

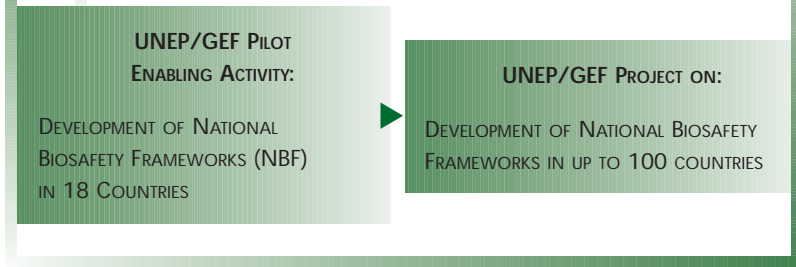


Figure 4: Development of the Global Project

The overall objective of the UNEP/GEF global project is to prepare countries for the entry into force of the Protocol, by assisting in the following activities among others:

1. Carrying out an assessment of current technological capacity to manage Biosafety issues, and the implications of this on the implementation of a National Biosafety Framework;
2. Strengthening national capacity to develop national regulatory biosafety frameworks;
3. Strengthening national capacity for competent decision-making on notifications and requests related to LMOs, including the establishment of administrative systems to assist with:

Capacity Building

- Screening, for completeness, notifications and requests
 - Risk assessment, including, where appropriate, the consideration of risk management,
 - Decision-making within the time limits specified in the regulatory framework and in accordance with the provisions of involvement of stakeholders, and
 - A mechanism for feed-back between these different steps.
4. Applying other measures according to the Protocol taking into account the work of the Inter-governmental Committee for the Cartagena Protocol on Biosafety (ICCP);
 5. Supporting regional and sub-regional collaboration, including harmonisation of the implementation of national regulations;
 6. Raising public awareness and improving information flow to the public on the issues involved around the release of LMOs to promote informed debate and to ensure transparency with respect to the regulation of LMOs.
 7. Providing all stakeholders with an opportunity to be involved in the design and implementation of a National Biosafety Framework.

Four regional workshops, one each for Africa, Latin America and the Caribbean, Asia and the Pacific and Eastern Europe, will be held during the early stages of the project. Fifteen sub-regional workshops will be convened to allow countries to work together to identify common ground for collaboration. The following sub-regions have been identified: North Africa, West Africa, Central Africa, Eastern Africa, Southern Africa, Caribbean region, South America, Central America, West Asia, South East Asia, South Asia, Central Asia, Pacific Islands, Eastern Europe, and the Baltic.

The implementation of the project is guided by the "Indicative framework for capacity building under the Cartagena Protocol on Biosafety" (UNEP/CBD/ICCP/1/4), as well as the guidance of the Intergovernmental Committee on the Cartagena Protocol.



Pham Tung Nguyen/UNEP

Capacity Building

The project is also guided by a technical Steering Committee set up by UNEP and the GEF Secretariat. The Steering Committee is composed of representatives of the GEF Secretariat, UNEP, the Scientific and Technical Advisory Panel of the GEF (STAP), the United Nations Development Programme (UNDP), the World Bank, the United Nations Industrial Development Organization (UNIDO), the UN Food and Agriculture Organisation (FAO), the International Centre for Genetic Engineering and Biotechnology (ICGEB), and the ICCP Secretariat. Quarterly meetings are held to review progress of the project and to ensure that the experiences are made available to a wider audience.

A biosafety toolkit is being developed as part of the project. The toolkit will serve as a practical manual to assist countries develop a draft NBF to guide national decisions on the safe transfer, handling and use of living modified LMOs and to meet the requirements of the Cartagena Protocol.

The toolkit is primarily intended for use by those responsible for designing a NBF: the National Executing Agency (NEA), the National Project Co-ordinator (NPC), and the National Coordinating Committee (NCC). It will also provide practical advice for stakeholders who will be involved in the preparation of the NBF.

The toolkit is a flexible document that can be tailored to meet the diverse needs of different countries, and that will allow countries to select those tools and ideas that are most useful to them. It utilises experiences and expertise from a diversity of sources including the project team, international and national experts and pilot projects from Phase I. It is an evolving document, continuously under review in light of experiences of countries participating in the Global NBF project. It also provides answers to frequently asked questions in order to provide guidance to countries on tackling problems and constraints that they encounter in designing and implementing their national projects.



W. Kikuts/UNEP

The toolkit is divided into four modules, each addressing one of the phases listed in the national project document:

- Phase 0* - The vision (or rationale) of the project design, its guiding principles, and the institutional and management structures
- Phase 1* - Surveys and the preparation of inventories in the different sectors pertaining to biosafety within the country.
- Phase 2* - The identification of stakeholders and the related consultation, analysis, and training activities to priorities and parameters for the drafting of the NBF.
- Phase 3* - The drafting of the NBF including a final consultation with stakeholders for their endorsement of the NBF.

3.3. Implementation of National Biosafety Frameworks

In order to gain experience and develop good practices that may promptly and effectively be used to assist Parties once the Protocol enters into force, GEF is currently financing country-based demonstration projects to assist in the implementation of National Biosafety Frameworks. According to the Initial Strategy for the Entry into Force of the Cartagena Protocol, this type of assistance is provided to countries that have participated in the pilot project, or that do not request assistance to develop a National Biosafety Framework. This assistance might best be provided to countries that have already ratified the Protocol.

During 2001, UNEP worked with several of the participant countries of the Pilot Biosafety Enabling Activity, to develop national programmes that support the implementation of the National Biosafety Frameworks developed during the earlier project. In each case these supportive programmes have been developed as GEF medium-sized projects (requiring not more than \$1 million GEF financing). The first set of eight projects, approved by the GEF Council at its meeting held in December 2001, includes projects for Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda.

The common objective of the projects is to strengthen national capacity in order to support implementation of the National Biosafety Framework. While the projects have been developed by each country to address their own specific needs, they focus broadly on the following activities:

Finalization of the legislative/administrative framework. Depending on the country situation, this activity involves finalizing and submitting for approval the draft national biosafety legislation as well as completing the administrative arrangements needed to implement the biosafety management mechanism as required by the Protocol.

Stage 3

Building Capacity For The Biosafety Protocol: Implementation Phase 2002-2005

UNEP/GEF PILOT PROJECT ON: "DEVELOPMENT OF NATIONAL BIOSAFETY FRAMEWORKS IN 18 COUNTRIES"

GEF ELIGIBLE COUNTRIES DEVELOP THEIR OWN NATIONAL BIOSAFETY FRAMEWORKS

8 DEMONSTRATION PROJECTS TO SUPPORT THE IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORKS

Figure 5: Development of demonstration projects for the implementation of National Biosafety Frameworks

Strengthening and, when needed, building capacity, mainly through training courses and training workshops on biosafety legal aspects, handling requests for releases of LMOs into the environment, risk assessment and management.

Strengthening national facilities such as existing reference laboratories for inspection purposes.

Strengthening the information system ([link to the Biosafety Clearing House](#)). In collaboration with the BCH Team and the CBD Secretariat, this involves strengthening a Biosafety database system that serves the purpose of the Biosafety Clearing House and contains all the information required by the Cartagena Protocol (Article 20 and Articles 6, 10, 11, 12, 13, 14, 17, 19, 23, 24 and 25) as follows:

Capacity Building

- Applications for permits,
- Laboratory and field trials,
- Permits for the release of GMO to environment/market,
- Products containing GMO,
- Transboundary movement of LMO (import and export),
- LMO risk assessment, monitoring and control.

Strengthening national capacity for public awareness and public participation, involving development and dissemination of appropriate material, national strategy and training of personnel for public awareness and public participation purposes.

Activities will be carried out over three years. Each national project will be guided by a national steering committee but, in addition, an over-arching steering committee will provide advice and guidance during the implementation of the projects and facilitate sharing of experiences between the participating countries. Experience gained, best practices, and lessons learnt will be discussed during the development of the projects and disseminated internationally for replication in other countries.

Further steps in relation to the implementation phase of the process will be decided during ICCP-3 to be held in the Hague in April 2002 in parallel with COP6 of the CBD. ■



4. Participatory Approach

and Lessons Learned in the UNEP/GEF Biosafety Activities

The GEF initial strategy for biosafety emphasizes the necessity for an enhanced participatory approach:

"In developing activities pursuant to this strategy, UNEP/GEF will seek consistency with the decisions of the Conference of the Parties to the Convention on Biological Diversity, national priorities and sustainable development. The GEF will encourage the participation of a wide range of interested stakeholders at the national level, including NGOs and the private sector. The GEF will also ensure that the activities complement national, bilateral and multilateral activities in the area of biosafety, and it will work towards promoting partnerships with interested multilateral and bilateral organizations." (par. 17).

The implementation of the UNEP/GEF activities is therefore undertaken in close co-operation and consultation with the related biosafety intergovernmental processes.

In this respect, a workshop was organised on the 24th May 2000 at the margins of the Fifth Meeting of the Conference of the Parties with the participation of more than 200 delegates. The need for capacity building was further stressed as a key requirement for the early entry into force and effective implementation of the Protocol. In addition, an indicative framework for capacity-building under the Protocol was prepared for consideration by the ICCP at its first meeting.



Ake Taka/UNEP

A workshop was also held at the First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP-1), held in Montpellier on 11-15 December 2000. The workshop discussed the UNEP/GEF projects, including the Pilot Biosafety Enabling Activity; the need for capacity building and strengthening of human and institutional resources of developing countries, especially in least developed and small island developing states and countries with economies in transition; and the importance of a regional approach. Among other recommendations, the ICCP-1 invited Parties and Governments, non-governmental, private sector and scientific organisations to submit information regarding capacity-building needs, priorities and existing initiatives as well as suggestions on capacity-building for the implementation of the Protocol. Furthermore, ICCP-1 called for an open-ended meeting of experts to be held prior to the second meeting of the Committee to develop further the capacity-building provisions of the Protocol. It called also for a workshop on financial support for National Biosafety Frameworks.

Capacity Building

The open-ended expert meeting on capacity building for the Cartagena Protocol on Biosafety was held in Havana on 11-13 July 2001. A presentation was made at the plenary session on the development of the UNEP/GEF global project, Development of National Biosafety Frameworks.

The open-ended meeting was followed by a one day international workshop on "Financial support for the creation and implementation of the National Biosafety Frameworks" held on 14th July. Arising from a specific request made at this workshop, an exercise to identify complementarity and synergy between different capacity-building programmes on biosafety was initiated as part of the UNEP/GEF Global Project for the Development of National Biosafety Frameworks. The results of this exercise will be circulated to the Donors and other international agencies and the project will ensure that the details of any developing programmes are shared within the international community.

The outcomes and recommendations of the Havana meeting, including a "Draft Action Plan for building capacities for the effective implementation of the Protocol", were presented to the ICCP at its second meeting (ICCP-2) in Nairobi in October 2001. ICCP-2 endorsed the Action Plan. During ICCP-2, a side-event was staged with the participation of 300 delegates, to present the progress of the global project and introduce the demonstration projects and their main components. ■



5. Conclusion

In its capacity as one of the three implementing Agencies of the GEF, UNEP has taken the lead in assisting GEF eligible countries in the field of biosafety, fulfilling the role of the GEF as the financial mechanism of the Cartagena Protocol on Biosafety. Being the first international legal instrument for the environment of the 21st century, Mr. Klaus Toepfer, the Executive Director of UNEP, has stressed the importance to the world environment of ensuring the successful implementation of the Cartagena Protocol. Through the UNEP/GEF global project, Development of National Biosafety Frameworks, and the demonstration projects supporting implementation of National Biosafety Frameworks, UNEP is determined to play its role in ensuring the successful implementation of the Cartagena Protocol. ■







Terminology

BIOSAFETY: is a term used to describe efforts to reduce and eliminate the potential risks resulting from biotechnology and its products. For the purposes of the Biosafety Protocol, this is based on the precautionary approach, whereby the lack of full scientific certainty should not be used as an excuse to postpone action when there is a threat of serious or irreversible damage (see “What is the precautionary approach?”). While developed countries that are at the center of the global biotechnology industry have established domestic biosafety regimes, many developing countries are only now starting to establish their own national systems (source: CBD Frequently Asked Questions about the Cartagena Protocol on Biosafety, <http://www.biodiv.org>)

CONFERENCE OF THE PARTIES: means the Conference of the Parties to the Convention (source: Cartagena Protocol on Biosafety)

CONTAINED USE: means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment (source: Cartagena Protocol on Biosafety)

EXPORT: means intentional transboundary movement from one Party to another Party (source: Cartagena Protocol on Biosafety)

EXPORTER: means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported (source: Cartagena Protocol on Biosafety)

IMPORT: means intentional transboundary movement into one Party from another Party (source: Cartagena Protocol on Biosafety)

IMPORTER: means any legal or natural person, under the jurisdiction of the Party of import, who

arranges for a living modified organism to be imported (source: Cartagena Protocol on Biosafety)

LIVING MODIFIED ORGANISM: means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (source: Cartagena Protocol on Biosafety)

LIVING ORGANISM: means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids (source: Cartagena Protocol on Biosafety)

MODERN BIOTECHNOLOGY: means the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family,

that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (source: Cartagena Protocol on Biosafety)

REGIONAL ECONOMIC INTEGRATION ORGANISATION: means an organisation constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorised, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it (source: Cartagena Protocol on Biosafety)

TRANSBOUNDARY MOVEMENT: means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties (source: Cartagena Protocol on Biosafety)





Further Information

COP Decisions on issues related to biosafety

- Decision V/1, Nairobi, 2000:
Workplan of the Intergovernmental Committee on the Cartagena Protocol
- Decision EM-I/3, Montreal, 2000:
Adoption of the Cartagena Protocol and interim arrangements
- Decision EM-I/2, Cartagena, 1999:
Tribute to the Government and people of Colombia
- Decision EM-I/1, Cartagena, 1999:
Decision on the continuation of the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity
- Decision IV/3, Bratislava, 1998:
Issues related to biosafety
- Decision III/20, Buenos Aires, 1996:
Issues related to biosafety
Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms
- Decision I/9, Nassau, 1994:
Medium-term programme of work of the Conference of the Parties

WEB SITES:

www.gefweb.org

www.unep.ch/biosafety

www.biodiv.org/biosafety/

Contact Persons at UNEP/GEF

Ahmed Djoghlaf

Director

Division of GEF Co-ordination

United Nations Environment Programme

P.O. Box 30552, Nairobi, Kenya

Tel. +254 2 624165

Fax. +254 2 624041

Ahmed.Djoghlaf@unep.org

UNEP-GEF GLOBAL Project on Development of National Biosafety Frameworks**Chris Briggs**

Programme Manager,

UNEP-GEF Global Project for the Development of National Biosafety Frameworks

International Environment House,

15, Chemin des Anemones,

CH-1219 Chatelaine, Geneva, Switzerland

Tel. (+41) (0)22 9178400

Fax: (+41) (0)22 9178070

Chris.Briggs@unep.ch

Charles Gbedemah

Regional Coordinator for Africa

UNEP-GEF Global Project for the Development of National Biosafety Frameworks

Division of GEF Co-ordination, UNEP

P.O. Box 30552, Nairobi, Kenya

Tel. +254 2 624066,

Fax. +254 2 624041

Charles.Gbedemah@unep.org

Giovanni Ferraiolo

Regional Coordinator for Latin America and Caribbean

UNEP-GEF Global Project for the Development of National Biosafety Frameworks

International Environment House,

15, Chemin des Anemones,

CH-1219 Chatelaine, Geneva, Switzerland

Tel. (+41) (0)22 9178400

Fax: (+41) (0)22 9178070

Giovanni.Ferraiolo@unep.ch

Nizar Mohamed

Regional Coordinator for Asia and Pacific

UNEP-GEF Global Project for the Development of National Biosafety Frameworks

International Environment House,

15, Chemin des Anemones,

CH-1219 Chatelaine, Geneva, Switzerland

Tel. (+41) (0)22 9178400

Fax: (+41) (0)22 9178070

Nizar.Mohamed@unep.ch

UNEP-GEF Projects on the Implementation of National Biosafety Frameworks**Alessandra Sensi**

Task Manager, Biosafety

Division of GEF Co-ordination

United Nations Environment Programme

P.O. Box 30552, Nairobi, Kenya

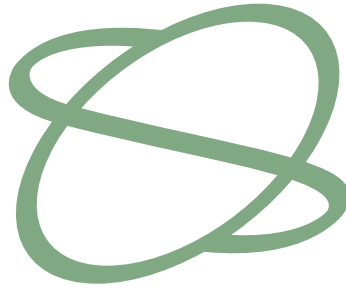
Tel. +254 2 623676,

Fax. +254 2 624041

Alessandra.Sensi@unep.org



UNEP



GEF



UNEP



GEF



UNEP



www.unep.org

United Nations Environment Programme
Division of GEF Coordination
P.O. Box 30552 - Nairobi, Kenya
Tel: [254 2] 624165 - Fax: [254 2] 624041
E-mail: gefinfo@unep.org
www.unep.org/gef

