

# **Evaluation of GEF's Support to the Cartagena Protocol on Biosafety**

**GEF Office of Monitoring & Evaluation**

*Final Draft*

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# **Chapter 1. Main Conclusions and Recommendations**

## **1.1 Introduction**

The Global Environment Facility (GEF) is designated as the financial mechanism of the Convention on Biological Diversity (CBD) as well as of the Cartagena Protocol on Biosafety (CPB) under the CBD. The CPB's objective is to help ensure an adequate level of protection in the field of safe transfer, handling, and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health, and specifically focusing on transboundary movements.

The GEF began its initial financing of capacity-building activities for biosafety in 1997 when the GEF Council approved allocations to 18 countries under a pilot phase. In 2000, the council approved the GEF Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Protocol. In accordance with the strategy, the council approved an umbrella-type global project, including up to 100 countries, for the development of national biosafety frameworks (NBFs) and individual projects in 12 countries for the implementation of such frameworks.

During the period 2003–05, the GEF Council approved allocations for the development of NBFs in 30 additional countries and support for building capacity in countries to participate in the Biosafety Clearing-House (BCH) mechanism in 139 countries.

The GEF Council tasked the GEF Office of Monitoring and Evaluation with carrying out the present evaluation. Four key questions were identified in the Terms of Reference:

1. Is GEF support consistent with the Cartagena Protocol conducted in a way that takes into account the needs of the recipient countries, and is it of sufficient professional quality?
2. Is GEF support to capacity development efforts, including stakeholder involvement and regional collaboration, relevant and effective?
3. What progress has been made in countries on building the requisite capacities toward their ratification and implementation of the Cartagena Protocol?
4. Are the modalities and approaches of GEF support effective and efficient compared to similar projects?

## **1.2 Study Design, Analytical Framework, and Methodology**

A team of seven members undertook the evaluation. Data collection included interviews with relevant global-level stakeholders: the GEF Secretariat, the CBD Secretariat, the World Bank, the United Nations Development Programme (UNDP), and, especially, the United Nations Environment Programme (UNEP), which has major responsibility for implementation of the projects. Further, interviews and viewpoints were sought from the Global Industry Coalition on Biotechnology, the Third World Network, and representatives of other bilateral and multilateral agencies.

In all eleven NBF development and NBF implementation countries were selected for field visits, and interviews were conducted by telephone with representatives from another eight countries. The countries were chosen to provide geographic representation, cover projects at various stages of implementation, and illustrate the work of the three GEF Implementing Agencies: UNEP, UNDP, and the World Bank. The evaluation team also undertook in-depth reviews of the 38 NBFs that had been completed as of June 10, 2005.

A component of the evaluation was carried out by the Free University of Amsterdam, whose team conducted a review of the UNEP Toolkit used by countries as the primary guidance material for the Development of National Biosafety Framework Project. Questionnaires were sent to 500 people in 30 countries; of these, 102 individuals in 29 countries responded.

### **1.3 Conclusions**

The main body of the evaluation report contains detailed answers to the questions raised in the Terms of Reference. In this chapter, the main conclusions and recommendations are highlighted for consideration by the GEF Council.

<b>Conclusion 1: GEF support has been consistent with the Cartagena Protocol.</b>
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The GEF has, on the whole, responded very expeditiously and systematically to the request from the CBD for support to the Cartagena Protocol. Only a few months after adoption of the CPB, the GEF had a fully fledged support program in place, which to date has reached 142 countries. GEF assistance has operated in a sensitive political environment, with often diametrically opposite positions expressed by the biotechnology industry and advocacy nongovernmental organizations (NGOs). At times, there have also been different positions pursued by various government departments. In sometimes heated public discussions about the modality, form, and substance of GEF support, questions were raised regarding whether GEF support was neutral and in line with the Cartagena Protocol.

The separate Delphi study carried out by the Free University of Amsterdam shows that 78 percent of the respondents stated that the Toolkit was very consistent with the Cartagena Protocol. Only one respondent felt it was not consistent with the CPB; the remainder had no opinion or did not know. Further, the Toolkit was judged by 79 percent of country participants to be very useful and/or useful to their country. However, several of the modules were not sufficiently timely to be as useful to all countries as they could have been. In most cases, the modules were used by the national project coordinator (NPC) and some members of the national coordinating committee (NCC). This study found that utility for stakeholders beyond key project staff was not high.

There has been criticism that UNEP has provided insufficient space at awareness-raising workshops for private sector and civil society participants to make presentations of their respective views and perspectives. However, the evaluation team concludes that generally

acceptable rules for giving access to the podium for organizations with observer status have been followed. The evaluation team has also concluded that UNEP, UNDP, and the World Bank have taken pains to remain neutral in this dynamic debate among the various interest groups.

**Conclusion 2: The GEF has contributed to speeding up ratification and has promoted implementation processes of the Cartagena Protocol.**

There have been serious controversies about the Cartagena Protocol, especially among Organisation for Economic Co-operation and Development (OECD) countries. This has created a level of insecurity in other countries regarding the political impact of their potential ratification. In view of this, it is notable that the Cartagena Protocol's ratification has been relatively rapid. The ratification process has been directly influenced by the initiation, and especially the completion, of the GEF projects. Besides promoting ratification, the GEF has, through the development and implementation of NBFs, contributed to considerable progress toward compliance with the protocol, first, by supporting capacity development on scientific, administrative, legal, and information management matters; and second, by promoting cross-sectoral and public-private collaboration at the country level. However, the allocated funds for some areas were only sufficient for capacity development at a general or introductory level.

**Conclusion 3: The NBF development project was not adequately designed and funded to fully take the complexities of local conditions and needs into account.**

For each of the 100 NBF development projects in the various countries, the initial time allocation of 18 months and their budget frames did not match the complexity and high ambitions of the project document with regard, for example, to regional cooperation, capacity building, public participation, and preparation of the framework itself. It is likely that the countries on average will require 28 to 30 months. The key indicators on subproject achievements also had to be scaled down. This too is in part due to an insufficient supervision fee allocated by the GEF for this complex task.

There was a general recognition in the supported countries that the UNEP regional coordinators were highly committed and hardworking. However, their large subproject portfolios meant that the level of administrative and technical backstopping was lower than expected by most of the countries, especially those that had little prior experience with the topic. UNEP's role was quite limited in some of the key assignments of the countries. The stocktaking of initial country conditions were carried out by national consultants, while the peer reviews were carried out by international consultants hired by the countries, or by UNEP with the use of project funds. This meant that UNEP was not fully acquainted with the baseline condition of the countries, which weakened its ability to give detailed technical advice under the NBF development project. Insufficient legal expertise among the UNEP NBF project staff was also a contributing factor. However, in spite of delays and weaknesses, there has been noteworthy progress in the subprojects, and it is expected that 80 NBFs will be completed by the end of 2005. Although there are

variations in quality, the completed NBF reports generally provide a good basis for further efforts by the countries.

The UNEP-administered NBF implementation projects had more realistic objectives and were better funded. The same applies to the four World Bank- and UNDP-administered implementation projects. Despite some initial delays, one of the four projects has been completed, two are now on a promising track, while one has not started.

**Conclusion 4: Awareness-raising and participation efforts by different stakeholders have not been as broad as required by the Cartagena Protocol and advised by the GEF project documents. Support for capacity building under the BCH has increased general access to information.**

Nearly all countries have appointed national coordination committees comprising on average 10 to 15 members, with representation from most of the relevant government departments and other institutions/organizations. A range of stakeholders have been involved with the objective of contributing toward formulating the NBF and building support within the respective countries. However, in nearly half the countries, representation on the NCCs is not as broad as advised, since some key government departments, academic institutions, the private sector, or civil society are not represented.

The NCCs have held substantive workshops and sought initial inputs and final comments into the NBF or legal documents. At the NCC level, stakeholder participation and involvement were highly variable. In a few cases, the positions by some representatives were sometimes quite inflexible, making collaboration difficult. The evaluation of the 38 completed NBF reports showed that 82 percent of the countries have included provisions for public participation mechanisms, with reference to article 23.2 of the Cartagena Protocol.

Efforts aimed at participation and public awareness have been broader in national and sometimes subnational workshops. However, the funds for this initiative were insufficient relative to the overall needs expressed by the countries. In the NBF implementation projects, awareness-raising and participation efforts varied, but were in relative terms more limited than in the development projects.

Significant amounts have been allocated by the GEF to capacity building in information handling and the creation of databases for participation in the BCH. By September 2005, all the NBF implementation countries and nearly a third of the NBF development countries had established national project websites. The posting of relevant information on the national websites has at times provided useful information within and outside the country, as well as for the CBD, even in cases where countries were formally required to submit this information directly to the BCH's central portal.

**Conclusion 5: Capacity development in risk assessment and risk management has primarily been of a general or introductory nature.**

As planned, most NBF development projects have organized general introductory courses in risk assessment and risk management. The NBF implementation projects have organized one week of intensive specialist training. Fewer efforts have been directed at building corresponding administrative, inspection, enforcement, and monitoring capacities.

Coordination of roles and responsibilities among existing regulatory bodies in countries is in the process of being resolved, but often remains a thorny issue and a significant impediment. Most countries already have some level of risk assessment and risk management procedures in place for dealing with other issues and commodities (for example, sanitary and phytosanitary systems, environmental impact analysis, and so on). There have been relatively few efforts to explore how capacities under these existing systems can be extended to support risk assessment and risk management of LMOs.

**Conclusion 6: Subregional cooperation with the objective of information sharing has been satisfactory, but no subregional harmonization of scientific, legal, and regulatory instruments has taken place, except in the European Union (EU) accession countries.**

Under the NBF development project, UNEP organized 16 regional and subregional workshops. These had two objectives: information sharing and harmonization of scientific, legal, and regulatory instruments. The workshops succeeded well in terms of sharing information and establishing networks and communication lines among key individuals and institutions in the region, either on a direct country-to-country basis or through existing regional entities.

However, there has been hardly any progress on formal regional intergovernmental collaboration or harmonization of scientific, legal, and regulatory instruments, which in the GEF Strategy and GEF NBF development project design were seen as crucial for effective management of transfer of LMOs across borders.

**Conclusion 7: The umbrella modality for the NBF development project has been effective in countries with prior biosafety experience and a minimum level of existing competence, but not as satisfactory in countries with less prior experience and competence.**

The GEF employed an umbrella project modality for the 100 NBF development subprojects. In all countries, the project established a full-time NPC and national coordinating or steering committee, conducted national awareness or capacity-building workshops, developed risk management and regulatory systems, and prepared websites for public information and participation in the BCH. The umbrella approach was, under

the circumstances, a necessary tool to deliver assistance expeditiously to the large number of countries requesting assistance, and it entailed economies of scale. The alternative of organizing 100 individual projects without a single coherent system would have been much more demanding both in terms of time and resources. GEF has previously had positive experience with its global Climate Change Support Program, which represented a similar modality.

The umbrella approach was especially effective in countries that could easily incorporate the support into their own biosafety systems; it was much less effective where the need for support was greater, and/or the initial conditions were less receptive. On the whole, the approach was too ambitious in terms of high goals within limited time schedules, and it did not have a sufficient flexibility to adapt the level of funding and the measures of required technical assistance to the needs of each country.

**Conclusion 8: Consultation and coordination by the GEF Secretariat at the global level have been weak. There has been little consideration as to whether biosafety could be better linked to other related aspects of the GEF's biodiversity portfolio.**

Since 1999, the GEF has allocated \$59.4 million, or about 55 percent of total recorded allocations, to biosafety efforts in developing countries and countries with economies in transition. There is limited cooperation and collaboration between the donors, presumably due to differences in donor policies and the engagement of special interests in project execution, but also due to few initiatives having the objective of coordinating use of scarce funds. Relatively little is known about complementarity or duplication among various actors in the donor community. UNEP has been considerably engaged in information exchange with other donors. The CBD Secretariat has held two Coordination Meetings for Governments and Organizations Implementing or Funding Biosafety Capacity Building Activities.

While most donors and participating countries have treated biosafety separately from related biodiversity matters, several countries have considered it in conjunction with the wider issues of biosecurity, agrobiodiversity, alien invasive species, or illegal transboundary movement of endangered species. In the context of biosafety, however, the significant investments needed in developing expertise, physical capacity, and institutions suggests that it will be important to consider potential options relating to integration with basically identical control mechanisms.

The GEF Initial Strategy pointed to the need for the GEF to engage the scientific community in considering opportunities for sharing lessons and building synergies. This has not taken place to any significant extent.

#### **1.4 Recommendations**

Assuming that the GEF will continue to support the Cartagena Protocol, the conclusions of this evaluation lead to the following recommendations for future support.

**Recommendation 1: Future assistance should be better planned and customized to each participating country.**

The GEF has initiated important work on developing NBFs in 130 countries. Future assistance should be based on a better understanding of the needs and priorities of each country. In customizing new support, the GEF should also actively seek to integrate national support with regional collaboration where appropriate.

**Recommendation 2: The GEF should consider providing longer term training for building and sustaining specialist capacity in risk assessment and risk management.**

Biosafety is a highly technical and specialized area. The required competence for the full implementation of the Cartagena Protocol requires systematic and longer term training of relevant specialists.

**Recommendation 3: The GEF should continue to emphasize awareness-raising and public participation issues, including support to the BCH.**

Public consultation and information sharing are important elements in satisfactory functioning of the Cartagena Protocol. At the country level there is also a strong expression of further needs in this area.

**Recommendation 4: The GEF should work toward a higher degree of donor and partner collaboration and other cost-sharing schemes at the global and national levels.**

Future requests to GEF and other donors or partners for funding in the biosafety area are likely to increase. A large number of countries now expect to move from the NBF development phase to the implementation phase, which will entail investments in, for example, the upgrading and equipping of relevant laboratories and other facilities at the national, multicountry, or regional level. GEF should seek a broader level of collaboration with donors and other partners in order to meet the demand in a satisfactory way.

**Recommendation 5: The GEF should seek advice from its Scientific and Technical Advisory Panel of the GEF and other scientists as to whether and how biosafety could be better integrated strategically and programmatically into the GEF biodiversity portfolio.**

The number of related international environmental agreements is high, and is continuing to increase. The potentials for integration and synergies between the agreements should be explored both within GEF and at country level.

## **Chapter 2. Background, Scope, and Methodology**

### **2.1 Background**

The GEF is designated as the financial mechanism for the Convention on Biological Diversity, as well as for the Cartagena Protocol on Biosafety which falls under the CBD. The Cartagena Protocol was adopted by the Conference of the Parties (COP) in January 2000, and entered into force on September 11, 2003.

The GEF began its initial financing of capacity-building activities for biosafety in 1997, when the GEF Council approved pilot projects in 18 countries. Following the completion of these projects, an evaluation of this pilot phase was conducted, which contributed to the development of the GEF's Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Protocol (GEF 2000; herein referred to as the "GEF Strategy").

The GEF Council subsequently approved funding for the global Development of National Biosafety Frameworks Project, to be implemented by UNEP, which was intended to cover the development of frameworks for 100 countries. The GEF Council also approved projects in 12 countries for the implementation of the NBFs.

Additional GEF-financed initiatives included two add-on projects to the initial Development of National Biosafety Frameworks Project (one for 20 countries, the other for 10; approved by the GEF Council in January 2004 and June 2005, respectively), and a project to support the development of the Biosafety Clearing-House mechanism in 50 countries, with a subsequent add-on for 89 countries. See Table 3.1 for a complete breakdown of GEF-funded activities for biosafety capacity building.

### **2.2 GEF Council Request for and Timing of Evaluation**

At its November 2004 meeting, the GEF Council requested that the GEF Office of Monitoring and Evaluation undertake an evaluation of the activities financed under the initial strategy approved by the Council in May 2000 for helping countries prepare for the entry into force of the Cartagena Protocol. The GEF Office of Monitoring and Evaluation planned for the evaluation to be completed in time to serve as an input to the council's December 2005 meeting. Following the planning stages of the evaluation, the GEF Council's December 2005 meeting was moved to November 2005. Given the complex character of the evaluation, the final completion date could not be brought forward. Instead, a draft version of this report will be made available to the council meeting in November. The timing of the evaluation will allow the GEF Council to decide on elements for future GEF financing for capacity building in biosafety activities as the GEF moves into its fourth replenishment phase.

The evaluation is taking place at a time when a significant part of the work under the initial Development of National Biosafety Frameworks Project has been completed. More than 40 countries have posted their completed NBFs; there should be around 80 completed NBFs in all by the end of 2005.

The GEF Strategy was originally expected to be in effect only until the Cartagena Protocol entered into force, which occurred on September 11, 2003. In this respect, this evaluation could have taken place one year earlier. However, the evaluation is timed to coincide with the final phase of the majority of activities supported under the GEF Strategy, rather than the termination of the strategy document itself. One consequence of this schedule is that an operational gap between the time that many countries complete their NBFs and when they undertake the next phase of GEF-supported activities may cause significant discontinuities in the work of the national executing agency (NEA).

### **2.3 Terms of Reference**

The final Terms of Reference for the evaluation were approved by the director of the Office of Monitoring and Evaluation on April 20, 2005. The main objective of the evaluation is to evaluate the efficiency, effectiveness, and relevance of the GEF Strategy.

Four key questions were identified in the evaluation's Terms of Reference:

1. Is GEF support consistent with the Cartagena Protocol conducted in a way that takes into account the needs of the recipient countries, and is it of sufficient professional quality?
2. Is GEF support to capacity development efforts, including stakeholder involvement and regional collaboration, relevant and effective?
3. What progress has been made in countries on building the requisite capacities toward their ratification and implementation of the Cartagena Protocol?
4. Are the modalities and approaches of GEF support effective and efficient compared to similar projects?

This evaluation seeks to answer these questions as objectively and in the most balanced manner possible, given the data available. The evaluation covers the following GEF-supported biosafety capacity-building activities:

- Development of National Biosafety Frameworks Project (100 countries),
- Development of National Biosafety Frameworks Project add-on (20 countries),
- Projects for implementation of NBFs (12 countries),
- Certain aspects of GEF support for implementation of BCH mechanisms (50 countries).

The evaluation does not cover:

- pilot phase projects,
- the second add-on to the Development of National Biosafety Frameworks Project (10 countries),
- the first add-on to the BCH mechanism project (89 countries).

The pilot phase projects were completed before the GEF Strategy was developed, and an evaluation of these projects has already been conducted. The two add-on projects that are

not covered had not begun at the time that this evaluation was initiated. The focus of the evaluation is shown in Table 2.1 below.

**Table 2.1: Focus of the Evaluation**

Issue	NBF development projects	NBF implementation projects	BCH support
GEF support and UNEP Toolkit are consistent with the Cartagena Protocol and country needs	Main focus	Reduced attention	Not included
Support for capacity assessment and strengthening, including stakeholder participation and regional cooperation	Yes	Yes	Yes
Progress toward attainment of protocol goals	Yes	Reduced attention	Not included
Effectiveness/efficiency of GEF support	Yes	Yes	Reduced attention

It is important to keep in mind throughout this evaluation report that the team’s objective was not to review the performance of countries per se. At the same time, national institutions were and are responsible for the activities of the development and implementation projects within each respective country. In some particular country circumstances—political power shifts following elections, civil unrest, natural disasters—country-level activities had to be delayed or were incomplete. Therefore, the evaluation team reviewed countries’ progress toward implementation of the Cartagena Protocol in order to evaluate the relevance, effectiveness, and efficiency of the GEF’s support to countries. Multiple data collection strategies were used by the evaluation team; these are described below.

## 2.4 Global Stakeholder Interviews

The evaluation team conducted interviews with relevant global stakeholders. These included the GEF Secretariat, UNEP, UNDP, the World Bank, the CBD Secretariat, the Global Industry Coalition on Biotechnology, the Third World Network, and representatives of other bilateral and multilateral agencies on a more informal basis. The evaluation team conducted several in-depth interviews with the UNEP development project team based in Geneva, since UNEP is responsible for the majority of activities related to the GEF biosafety strategy. Three group interviews were carried out with the UNEP NBF development project coordinator and the regional coordinators. For a complete list of persons interviewed, see annex 6.

In addition to actively seeking input from the above-mentioned stakeholders, the evaluation team sought to ensure the possibility for input from all interested parties. To this end, the Terms of Reference of the evaluation were published on the GEF Office of Monitoring and Evaluation website, and comments were solicited from any stakeholders wanting to provide feedback to the evaluation.

## 2.5 Field Visits

The primary component of the evaluation was a series of field visits, each conducted by two members of the evaluation team. The field visits took place between May 22 and July 16, 2005. The duration of each field visit was one week, and the two-person team

assigned to a country was supported by a local country-based consultant. The local consultant assisted in arranging the team's agenda for the week based on a generic outline and stakeholder list provided by the team. The consultant also provided valuable insight and knowledge into the particular country situation and context, and served as a translator when necessary. The field visits were the evaluation team's main opportunity to gain detailed information and data about project activities and execution at the country level. During each visit, team members interviewed as wide a variety of relevant stakeholders as possible, typically interviewing 20 to 40 persons in the course of a week.

Eleven countries were selected for field visits. These countries were chosen to provide geographic representation, as well as to provide a view of projects at various stages in the process of undertaking GEF-supported activities: namely, those participating in the Development of National Biosafety Frameworks Project but not yet finished; those participating in the Development of National Biosafety Frameworks Project and finished with their NBF; and those participating in an NBF implementation project. Countries were also selected in order to provide examples of projects implemented by each of the Implementing Agencies; they were also selected on the basis of size, to include especially large countries and small island developing states (SIDS). Countries selected for field visits are listed in Table 2.2.

**Table 2.2: Countries Selected for Field Visits**

Country	Region	Project stage (at start of evaluation)	Implementing Agency	Size
Bahamas, The	Latin America and the Caribbean	Development	UNEP	SIDS
Burkina Faso <sup>a</sup>	Africa	Development	UNEP	
China	Asia and Pacific	Implementation	UNEP	Large
Croatia <sup>a</sup>	Central and Eastern Europe	Development	UNEP	
Ethiopia	Africa	Development	UNEP	
Guatemala	Latin America and the Caribbean	Development project completed	UNEP	
India	Asia and Pacific	Implementation	World Bank	Large
Mexico	Latin America and the Caribbean	Implementation	UNDP	Large
Morocco	Africa	Development	UNEP	
Tajikistan	Asia and Pacific	Development project complete	UNEP	
Uganda	Africa	Implementation	UNEP	

a. These countries completed their NBF project during the course of the evaluation.

During the field visits, the categories of stakeholders the evaluation team sought to interview included: national project coordinator; members of the national coordinating or steering committee; NEA; biosafety focal point; GEF focal point; national competent authority; parliamentarians; relevant ministries and government agencies (environment, agriculture, health, trade, and so forth); scientific research institutions; academia; the private sector, local, national, and international NGOs or other civil society groups; consumer rights organizations; farmers associations; indigenous and local community groups; bilateral and multilateral organizations; and any other relevant stakeholder groups in a given country.

## 2.6 Non-Field Reviews

To complement the field visits, the evaluation team also planned to review an additional 10 countries in detail through telephone interviews with relevant stakeholders in the country. Due to logistic issues, the team was only able to review eight countries. The goal of these reviews was to expand the sample of countries examined in detail for the evaluation, while recognizing that the time and resources available for the evaluation were limited. These non-field reviews, although less detailed than the field visits, allowed the evaluation team members a more comprehensive picture of GEF support to the respective countries than would have been possible through basic desk reviews.

The non-field reviews were conducted from late July to early September 2005. Again, two team members were assigned to each country and participated in phone interviews with two to four persons in the selected country who had experience with and knowledge of GEF-supported biosafety capacity-building activities. The stakeholders interviewed generally included the NPC, technical experts directly involved in the project, NGO representatives, other members of the NCC, the biosafety focal point, and NEA representatives. These countries were selected based on similar considerations to those used in selecting countries for field visits. The countries selected for non-field reviews are listed in Table 2.3.

**Table 2.3: Countries Selected for Non-Field Reviews**

Country	Region	Project stage (at start of evaluation)	Implementing Agency	Size
Botswana	Africa	Development	UNEP	
Bulgaria	Central and Eastern Europe	Implementation	UNEP	
Chile	Latin America and the Caribbean	Development	UNEP	
Colombia	Latin America and the Caribbean	Implementation	World Bank	
Cuba	Latin America and the Caribbean	Implementation	UNEP	SIDS
Lao PDR <sup>a</sup>	Asia and Pacific	Development project complete	UNEP	
Lebanon	Asia and Pacific	Development	UNEP	
Malaysia	Asia and Pacific	Implementation	UNDP	
Samoa <sup>a</sup>	Asia and Pacific	Development project complete	UNEP	SIDS
Turkey <sup>b</sup>	Central and Eastern Europe	Development	UNEP	

- a. Country was initially selected for inclusion, but logistic issues resulted in the evaluation team's being unable to evaluate these countries in depth as originally planned.
- b. Country completed its NBF project during the course of the evaluation.

In total, the regional balance of the sample is five countries from Africa, seven countries from Asia and Pacific (including Samoa as a SIDS representative), three countries from Central and Eastern Europe (the region with the fewest countries), and six countries from Latin America and the Caribbean (including The Bahamas as a SIDS representative). There were nine countries selected that were participating in the NBF development project but that had not yet finished, four countries that had completed their NBF, and eight countries that were participating in NBF implementation projects. Regarding Implementing Agencies, 17 projects implemented by UNEP were selected, and 2 each by

UNDP and the World Bank. Two of the countries evaluated are SIDS; three are large countries.

## **2.7 Desk Reviews of National Biosafety Framework Reports**

The evaluation team undertook in-depth reviews of the 38 NBFs that had been completed as of June 10, 2005. Examining the completed NBFs, which are the primary output for each country participating in the Development of National Biosafety Frameworks Project, provided the evaluation team with a consistent means to review each country's progress toward preparation for implementation of the Cartagena Protocol. Review protocols were developed to ensure that standardized review procedures were followed by each team member. Each team member reviewed five to six NBFs. For a full list of countries with completed frameworks that were reviewed, see annex 4.

Several of the countries with completed NBFs were also the subject of field visits or non-field reviews. Therefore, the evaluation team reviewed a total of 53 countries at some level; this is approximately 40 percent of the 132 countries involved in the NBF development and implementation projects.

## **2.8 Toolkit Review**

A subsidiary component of the evaluation was carried out by the Free University of Amsterdam. A review of the UNEP Toolkit used by countries as the primary input for the Development of National Biosafety Frameworks Project was conducted through a questionnaire sent to 500 persons in 30 countries participating in the project, as well as other stakeholder groups. The questionnaires were sent out in late June 2005; by late July 2005, about 100 responses had been received for a 20 percent return rate. The results from this review have been used to supplement other data described in this report.

## Chapter 3. GEF Funding for Biosafety

Biotechnology and related biosafety aspects are important features of the Convention on Biological Diversity. Article 8(g) provides that each contracting party shall, as far as possible, establish or maintain means to regulate, manage, and control the risks associated with the use and release of living modified organisms resulting from biotechnology. Beyond this specific objective under the protocol, all protocol parties (as contracting parties under the CBD) are further expected to

directly or by requiring any natural or legal person under its jurisdiction providing the [living modified] organisms..., provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.<sup>1</sup>

The third meeting of the Conference of the Parties of the CBD (COP-MOP 3) requested the GEF to provide financial resources for capacity building in biosafety.

### 3.1 Experiences of the Pilot Phase

At its November 1997 meeting, the GEF Council allocated \$2.7 million for the development of NBFs in 18 countries in developing countries and countries with economies in transition.<sup>2</sup> UNEP was the Implementing Agency for this project, under which each country received a grant of approximately \$100,000. A second component of the pilot phase project constituted support to four regional seminars on biosafety.

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<sup>1</sup> CBD Article 19.4. The convention also requires that national actions relating to the development of LMOs should benefit both the country and entity developing the LMO, as well as the countries that are the sources of the genetic resources used in the biotechnology work. The latter objectives are to be accomplished through the requirement that users must ensure that source countries are allowed to “effectively participate in biotechnological research” utilizing their genetic resources, and that each source country should have “priority access on a fair and equitable basis...to the results and benefits arising from biotechnologies based upon genetic resources” they provide (CBD articles 19.2 and 19.3, respectively). These provisions link the development and utilization of LMOs with the obligations to share benefits under articles 15, 16, 17, 20, and 21. Hence, the reference to “access to the results and benefits” is generally believed to include both the social and livelihood benefits of the new organism and the financial benefits arising from its commercialization.

<sup>2</sup> All dollars cited in this report are U.S. dollars.

In each country, the pilot phase was designed to last for 12 months, which proved to be far too ambitious. All projects were extended to 18 months. An evaluation of the pilot phase project concluded that the regional workshops were successfully conducted, productive, and worthwhile. Box 3.1 summarizes the lessons learned from the pilot phase evaluation. It was recognized that both national and subregional capacities needed to be strengthened. The evaluation emphasized strongly that realistic time scales were of great importance for the NBF development phase. The tight schedule for the pilot phase limited the attainment of the objectives, since most countries were not able to pass the legislation that had been drafted. The evaluator also recommended

#### **Box 3.1: Pilot Phase Key Lessons Learned**

- This was an ambitious project that was successfully executed.
- The regional workshops provided a good understanding and appreciation of the type of assistance that countries might need to ensure the transparent and safe consideration of the use of products of modern biotechnology.
- The time scale of the project was severely limiting. In an extended/expanded future program/project, more realistic time scales need to be adopted.
- The degree of public participation and involvement in the project at the national level differed substantially among countries, largely reflecting differing traditions, difficulties caused by country size and geographical conditions, number of languages, and educational deficiencies.
- There is a strong need for strengthening national capacities and an urgent need for establishing and/or strengthening subregional centers of expertise with relevant capacities, facilities, and human resources to support national-level risk assessment and risk management activities.

*Adapted from UNEP-GEF 2000, Executive Summary.*

a further review of the 1995 *UNEP International Technical Guidelines for Safety in Biotechnology*, which provides direction for implementation of the pilot phase.

The evaluation report recommended five areas of assistance for continued support:

- National projects for the development of NBFs in 60 countries;
- National projects for the implementation of NBFs in 25 countries, including the 18 that had gone through the pilot phase;
- Regional and subregional awareness-raising workshops;
- Establishment/strengthening of regional/subregional centers of excellence;
- Integrated multi-pronged global, regional, or subregional workshops.

In its subsequent projects, the GEF broadly accepted the first three recommendations, but not the last two. These latter were aimed at capacity developing at the subregional and regional levels.

### **3.2 GEF Strategy**

The GEF Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Protocol (GEF 2000) was based on a decision in the Conference of the Parties to the

CBD that designated capacity building as a priority for GEF assistance (CBD 1996). Further guidance has been provided by CBD-COP especially in decisions V/3, VI/17, and VII/20.

For ease of cross referencing, the list below is formatted in accordance with the original GEF initial strategy (GEF 2000). The GEF Strategy aims to:

- A. Assist countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks, including strengthening capacities for risk assessment and management with a wide degree of stakeholder participation;
- B. Promote information sharing and collaboration at the regional and sub-regional level and among countries that share the same biomes/ecosystems; and
- C. 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.

The following activities were proposed:

- I. Assist countries to establish national biosafety frameworks;
- II. Individual country projects to implement national biosafety frameworks;
- III. Coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;
- IV. Support for country participation in the Biosafety Clearing-House (BCH); and
- V. Enhancement of scientific and technical advice to the GEF on biosafety issues.

The preparation of NBFs would, according to the GEF Strategy, include:

- (a) assessment/stocktaking to provide information on the status of existing biosafety practices;
- (b) assessment of any existing legal instrument or guidelines that might impact on the use, import or export of LMOs;
- (c) identification and involvement of all relevant stakeholders to the extent possible;
- (d) identification of actions needed to enable countries to implement the Protocol, and options and priorities for filling such gaps;
- (e) preparation of a legal framework and/or guidelines for the implementation of the Protocol;
- (f) establishment of a roster of experts and means of including them in regional networks;
- (g) assessment of options for implementation of various elements of the biosafety frameworks, for example at the regional level;
- (h) identification of opportunities for harmonization at the regional and subregional level; and
- (i) additional features that may be identified.

All developing countries and countries with economies in transition that are parties to the Cartagena Protocol were considered eligible for funding on biosafety from the GEF. Following CBD-COP decision 7/20, parties to the CBD that were not yet parties to the protocol but had provided a clear political commitment toward becoming parties were also considered eligible. The allocations made by the GEF under its initial strategy are shown below in Table 3.1.

**Table 3.1: Allocations under the GEF Initial Strategy**

Project	Number of countries	Allocation (\$ millions)
Pilot Phase <sup>a</sup>	17	2.7
NBF Development	100	26.1
NBF Development add-on 1	20	5.2
NBF Development add-on 2 <sup>a</sup>	10	2.6
Implementation projects	12	9.2
BCH Mechanism	50	4.6
BCH Mechanism add-on 1 <sup>a</sup>	89	8.9
Total <sup>b</sup>		59.4

a. Not covered by this evaluation.

b. Details may not sum to total because of rounding.

### 3.3 GEF Biodiversity Strategic Priorities

As part of the third GEF replenishment (GEF-3),<sup>3</sup> the biodiversity program of the GEF Secretariat developed a series of four strategic priorities to help sharpen the focus of the GEF's investment in biodiversity conservation (GEF 2003). The third of these priorities is Capacity Building for the Implementation of the UN Convention on Biological Diversity Cartagena Protocol on Biosafety. This strategic priority is general in its focus and is framed as a separate pillar, unlinked to the rest of the GEF's biodiversity portfolio. The stated rationale for the strategic priority is that "There is recognition of the potential risks posed by modified living organisms and therefore biosafety constitutes a high priority for recipient countries. This priority also responds to the guidance from the CBD and it is consistent with the decisions of the Intergovernmental Committee for the Cartagena Protocol" (GEF 2003).

The generality of the focus on biosafety in the strategic priorities document can be interpreted as reflective of the GEF waiting to receive additional guidance from a meeting of the parties to the CPB, since the protocol had not entered into force at the time the document was developed. According to the strategic priorities document, the protocol was expected to enter into force early in GEF-3. Also by this time, the GEF Council had approved the Development of National Biosafety Frameworks Project for 100 countries, based on the experience from the pilot phase.

Under the biodiversity strategic priorities being developed for GEF-4, the biosafety priority is pending and will be modified once the results from this evaluation are

<sup>3</sup> GEF-3 covers GEF fiscal years 2003–06; GEF-4 will cover fiscal years 2007–10.

published. It is anticipated that the GEF Secretariat will develop a revised strategy for biosafety taking into consideration the decisions and viewpoints expressed by the GEF Council.

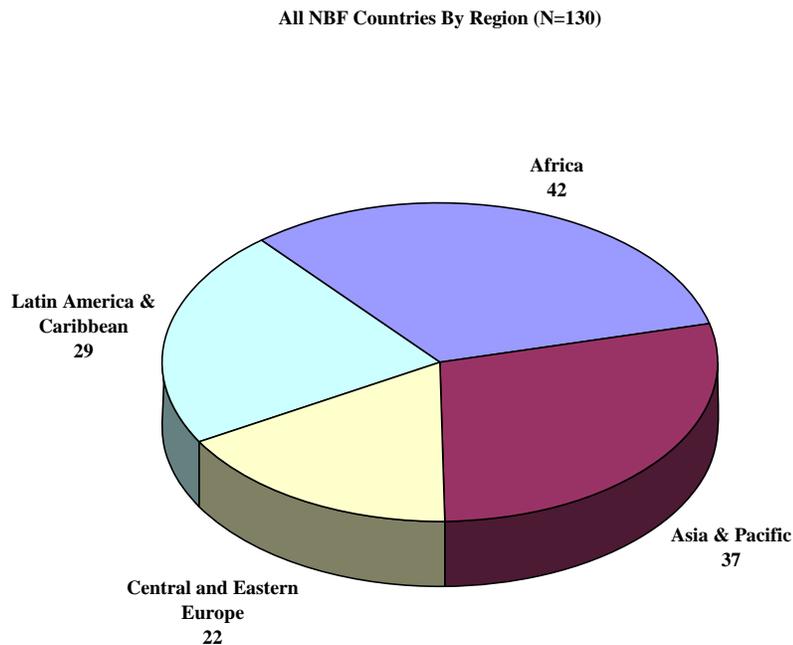
### 3.4 Development of NBFs

At its November 2000 meeting, the GEF Council allocated \$26.1 million to support up to 100 countries in developing NBFs and arranging for regional and subregional workshops. Another \$5.2 million was allocated in November 2003 for the development of NBFs in 20 additional countries; \$2.6 million was allocated in 2005 for another 10 countries. UNEP is the sole Implementing Agency for NBFs.

The GEF's total allocation to capacity building for implementation of the Cartagena Protocol is shown in Table 3.1. Of the total investment of \$59.4 million, \$45.1 million of the allocation is covered by this evaluation. This does not include the pilot phase, the second NBF development add-on project, and the BCH add-on project.

Figure 3.1 shows the number of countries participating in the NBF development project for each region, including countries participating as part of the second add-on project.

**Figure 3.1: Participation in the NBF Development Project**



The main components of the NBF projects are:

- Development of frameworks through information gathering, analysis, consultation, training, and preparation of a draft NBF, including legal instruments,

administrative systems, risk assessment procedures, and systems for public participation and information;

- Arrangement of regional workshops that aim to increase understanding of the CPB and impart knowledge on the implications for risk assessment and decision making at national levels;
- Arrangement of subregional workshops focusing on capacity building, cross-national opportunities for collaboration, mechanisms for sharing of risk assessment and management experiences, coordination of capacity-building activities, and networking to share lessons and experiences.

Table 3.2 shows the range of funding for NBF development projects at the individual country level in each region. Overall, the lowest allocation to any individual country was \$91,500; the highest allocation was \$220,000.

**Table 3.2: GEF Individual Country Funding Range for the NBF Development Project, by Region**

Region	Lowest country allocation	Highest country allocation
Africa	\$118,000	\$220,000
Asia and Pacific	\$91,500	\$203,000
Central and Eastern Europe	\$100,000	\$200,000
Latin America and the Caribbean	\$91,800	\$200,000
All countries	\$91,500	\$220,000

The majority of countries provided co-financing of 50 percent of the GEF budget, but there were exceptions; country co-financing ranged from \$18,000 (15 percent) to \$244,000 (122 percent). The global average for GEF funding was \$145,184, and the global average for co-financing was \$74,762 (52 percent).

### 3.5 Implementation of NBFs

In 2001, the GEF approved 12 individual country demonstration projects on NBF implementation (see Table 3.3). The project period was typically three years, and the GEF allocation to each country ranged between \$500,000 and \$1 million. The NBF implementation projects have been adapted to country-specific conditions, with the generic activities including the following:

- Reviewing NBFs and drafting regulations and guidelines to support its implementation;
- Making operational a regulatory and administrative system for handling applications and related biosafety matters
- Setting up decision-making mechanisms to handle applications for releases and transboundary movements of LMOs;
- Development and publishing of technical guidelines for risk assessment and risk management, monitoring and enforcement;

- Strengthening capacity of risk assessment/management, including as needed, setting up and/or improving and equipping special laboratories for this purpose;
- Strengthening information systems on LMOs;
- Enhancing public awareness, public education, and participation; and
- Setting up of biosafety databases for the purpose of the BCH (GEF 2001).

UNEP's implementation project participants are all countries that participated in the pilot phase as well. Although these countries made progress during that phase, it is acknowledged that many had to carry out more detailed stocktaking of national policies and relevant competencies and to train personnel at a basic level in risk assessment, risk management, public awareness, and participation.

**Table 3.3: Implementation Countries by Implementing Agency**

Implementing Agency	Implementation Countries
UNDP	Malaysia, Mexico
UNEP	Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland, Uganda
World Bank	Colombia, India

Four countries were included in the NBF implementation phase that had not participated in previous GEF-supported biosafety activities. These were Malaysia and Mexico, assisted by UNDP; and India and Colombia, assisted by the World Bank. These four NBF implementation projects are the only components of the GEF-supported biosafety activities not implemented by UNEP.

### **3.6 Capacity Building for BCH Participation**

At its November 2003 meeting, the GEF Council allocated \$4.6 million through UNEP for assistance to 50 countries to participate in the Biosafety Clearing-House of the Cartagena Protocol. The central web-based BCH portal is administered by the CBD Secretariat, but national-level components are to be developed by individual countries. The objective is complementary to the overall biosafety program's objectives, but aims more specifically at developing core human and technical resources to establish the appropriate BCH infrastructure to readily access scientific, technical, environmental, and legal information on LMOs to ensure adequate protection in the safe transfer, handling, and use of LMOs. Whereas the CBD Secretariat is focusing its work on the establishment of a central portal, the GEF is supporting development of national BCH components and capacities to access and use the BCH. About three-fourths of the funds were assigned for training country officials in managing and operating the mechanism; the remaining one-fourth was allocated to procuring equipment. In May 2005, the GEF allocated \$8.9 million to an additional 89 countries to promote their participation in the BCH.

## **Chapter 4. Modalities of GEF Support**

### **4.1 The GEF's Quick Start and Responsiveness to the CBD**

UNEP was chosen as the sole Implementing Agency for the 100 initial NBF development projects as well as for the subsequent 30 projects approved in 2004–05. This was primarily due to UNEP's long-term interest and involvement in biosafety issues. At the same time, the other Implementing Agencies did not demonstrate interest in addressing the apparent demand for capacity building in biosafety identified by the COP-MOP.

Compared to its previous support of enabling activities in climate change, biodiversity, and persistent organic pollutants, the GEF responded expeditiously to the request by the CBD to support biosafety by allocating funding to 142 countries. Recent reviews have shown that "regular" GEF projects take between two and five years to be developed and approved (GEFOME 2005). By contrast, in spite of the bureaucratic routines under which the multilateral organizations are required to operate, UNEP-GEF had a fully fledged support system in place for executing the NBF development phase in the majority of the initial 100 countries by June 2001. This was five months after the adoption of the CPB, and more than two years before its ratification.

This achievement seems in large part to be due to UNEP's long involvement in biosafety matters during CBD meetings and otherwise, as well as the drafting of UNEP's initial guidelines. UNEP played a very decisive role in initiating the pilot project and formulating both the GEF Strategy and its subsequent proposal to support NBF development in up to 100 countries. It is rare in the GEF's history to carry out a pilot project and approve an initial strategy before the relevant convention is adopted. Even countries that had not acceded to the protocol, but that gave assurances that they would do so, were eligible to receive GEF funding. This may have been due to the high level of international attention and concern surrounding biotechnology, as well as a clear recognition that this technology is developing at an extremely rapid rate which is expected to increase in coming years in selected countries. For example, India gave its first approval for commercial release of LMOs (for Bt cotton) in 2002. In 2003, the country received fewer than 10 applications; but by 2004, there were 30 applications, and so far in 2005, India has received well over 200 applications for field trials.

### **4.2 National Baselines**

One aspect of this evaluation is an assessment of the initial (baseline) level of preparation for entry into force and implementation of the Cartagena Protocol at the individual country level. It is recognized that countries participating in the project represent a broad spectrum of pre-existing baseline preparations for project work.

The countries visited or interviewed in the course of this evaluation were generally grouped into three baseline categories, depending on the information available for review in terms of the extent of LMO-related activities within the country and the extent to which current regulatory frameworks and administration were available and operating to address issues and concerns covered by the protocol:

- “High” baseline countries were those that are actively and significantly involved in the development of LMOs and have regulatory systems that are at least partially effective in addressing primary biosafety issues.
- “Medium” baseline status refers to those countries that are undertaking a low level of domestic research or field trials, but whose safety systems relating to biotechnology are not as yet fully or mostly functional.
- “Low” baseline status refers to countries whose primary current expectation with regard to LMOs will be their possible importation as food or feed, or for processing, with relatively limited expectation of formal LMO introduction in agriculture and no current system or ability to consider control of “informal” or illegal introduction.

The results of this initial categorization of the 18 countries visited or telephoned in this evaluation are tabulated in Table 4.1.

**Table 4.1: Baseline Levels of Countries Visited or Interviewed**

Type of Project	Baseline level		
	High	Medium	Low
Countries with Development projects (12)	1	3	8
Countries with Implementation projects (6)	4	1	1

These statistics suggest some very fundamental differences among the countries. A country with a high baseline state of development (significant agricultural or activities involving LMOs ongoing and regulated at project inception) would need, and be capable of, implementing a far more ambitious and higher level of action than one whose baseline level was low (primary LMO activities being food importation and/or a few trials or introductions). Baseline data provides a useful yardstick for much of the analysis to follow, as the expected outcomes of project activities will be significantly different among countries depending on their baseline conditions.

### 4.3 NBF Development Project

#### *Organizational Set-up at Country Level*

In the first module of the UNEP Biosafety Framework Development Toolkit (Phase 0 – Starting the Project), which was provided to nearly all countries when they began their national NBF project, UNEP spelled out the key principles and operational and management implications for NBF development projects. Beyond ensuring safety and building professional and institutional capacity, UNEP’s primary programmatic documents also emphasize the need for sustaining capacity, promoting participation by all stakeholders, and enabling a country to make an informed choice on whether or not it wants to import and use LMOs. The Toolkit provides for the designation of a national executing agency to be the legal entity of the government responsible for executing the national project. The NEA is next required to establish a national coordinating committee to advise and guide the preparation of the NBF. In the countries evaluated, the NCC varied greatly in size between 7 to more than 25 members. A typical NCC comprises representatives from the ministries of agriculture, environment, trade, foreign affairs,

economy, planning, health, education, transportation, and justice, and includes various government institutions and departments under the ministries, such as the customs service. In addition, one or two members are generally from the academic community, the biotechnology industry, and NGOs such as consumer and farmer associations; in rare cases, committees also include advocacy NGOs. The NCCs were assigned key roles—to develop a common understanding of the country’s path forward, provide policy and professional advice, provide a discussion forum, mobilize data, approve workplans, ensure information flow, and approve various reports and the final NBF.

The NCC is an essential component of the national organization and ensures at least some level of involvement and “buy in” for the project by key stakeholders in the country. It also ensures a relatively broad sign-off to the NBF, especially by government departments. As shown in the more detailed analysis in Chapter 6, there are considerable variations in the breadth of NCC composition, member competencies, and frequency of meetings.

The NPCs were chosen by the NEA in consultation with UNEP. They were often a lynchpin in the complex cooperation and coordination structures and instrumental in keeping together the large number of participants both from within and outside government. Given that NPCs are recipients of a large fraction of the total benefit and capacity development under the NBF development project, UNEP strongly encouraged the selection of NPCs who would stay with the issue after project completion and made efforts to ensure this by keeping NPCs in a relevant full-time government position after project closure. In the cases evaluated, the NPCs stayed on for the duration of the project. Retention of NPCs following project completion is more difficult to evaluate. The extent of this continuity may be a key determinant of the progress that countries will make following project completion and may also enhance the potential sustainability of project results. UNEP influence on such national-level decisions, however, is limited.

The NPCs have played a key role in the execution of the NBF development projects. They have often had difficult tasks, given the novelty, complexity, time pressure, and political sensitivity of the issues involved, with frequent turf battles among various ministries. However, as the NPCs themselves represented almost the only communication channel with UNEP’s regional coordinator, some key points of concern may not have been identified, particularly where the NPC did not function well. This illustrates the frailty of UNEP’s less intensive approach—to be less directly involved in oversight of substantive project activities—although (as noted above) this approach was welcomed by some NEAs, especially those in high baseline countries.

The proposed time frame for the NBF development projects was 18 months, with three phases comprising six months each. During the first phase, a country was expected to prepare inventories and surveys of current uses of biotechnology, relevant existing legislation and regulation in the country, and potentials and mechanisms for cooperation and harmonization of risk assessment and risk management systems on a regional and/or subregional basis. The second phase comprised further analyses of surveys and inventories, development of national databases, and the planning and implementation of

wider awareness-raising campaigns and stakeholder involvement both within and outside government institutions. The last phase included the drafting of national policies, legal instruments, risk assessment guidelines and mechanisms, and publication of the final NBF report, together with inventories and guidelines.

An analysis of the pilot phase evaluation reveals some inherent weaknesses in the approach and design of the NBF development project. First, the time frame for completion of the national projects was much too short. In review of the pilot phase, it was determined that the countries needed 50 percent more time than initially allocated. In planning for the NBF development project, however, it appears that the lessons of the pilot phase were not heeded. To date, the average duration of NBF development projects has been 28 months among countries that have finished the project thus far. To some extent, it must be assumed that these are the “best performers” and that the remaining projects may require additional time. See Table 4.2 for the timeframes in which countries finished as of August 31<sup>st</sup>, 2005 had completed their NBF development project.

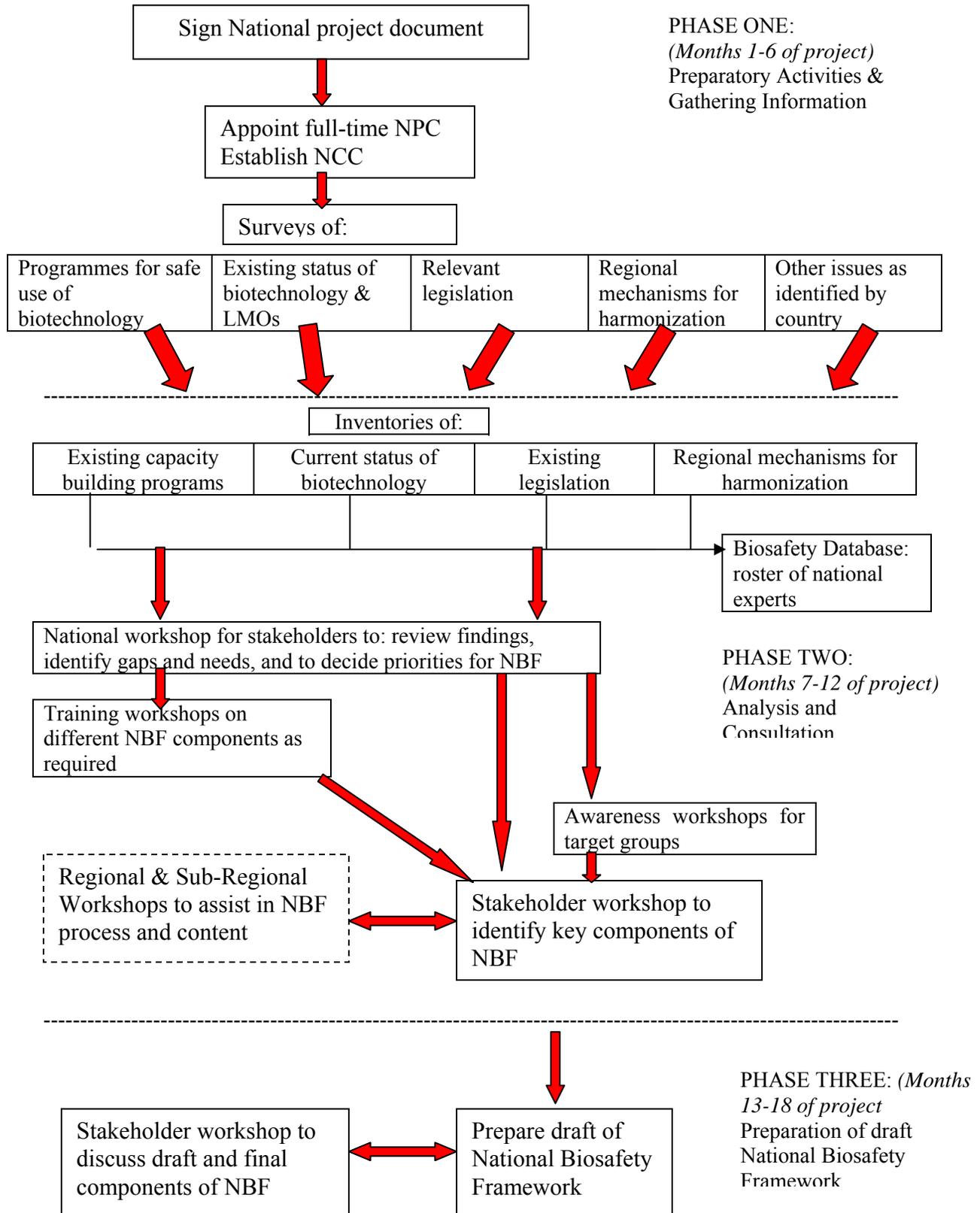
The time requirement is not surprising and was in fact predicted, as noted above. In addition to factors discussed later (complexity, low baseline capacity, and the need to develop internal cooperation), the relaxation of the project qualification requirements (allowing non-signatory countries to be eligible for support)—while perhaps encouraging quicker ratification and securing preliminary national endorsement of the CPB—extended the project to a group of countries that were even less certain about national priorities and less informed about biosafety matters. For the countries included in the NBF add-on project, the anticipated time frame has been extended to 24 months.

**Table 4.2: Number of Countries Completing NBFs by Number of Months**

Number of months	Number of countries
0–18	3
19–21	5
22–24	10
25–27	6
28–30	7
31–33	5
More than 33	6

As in the pilot phase, the primary goal of the NBF development and implementation projects has proven to be too ambitious even with the extensions provided. As noted in a GEF project brief (GEF 2001, annex III), the “objectively verifiable success indicator of the NBF development project was that legislation, regulation and/or guidelines will be in place to allow for the assessment and management of risk associated with the use of modern biotechnology” During the course of the project, the goal was scaled down and aimed only at completing preparation of the draft NBF, not at having the actual mechanisms in place.

**Figure 4.1: Suggested Flowchart for Development of a National Biosafety Framework**



Source: GEF 2001.

As of August 31, 2005, 45 NBF projects were completed, with the average duration for all projects being 28.4 months. Viewing the NBF projects from a regional perspective, projects in Africa have taken the longest to complete, requiring an average of 32 months. Although countries in Latin America and the Caribbean have the shortest average completion time at 24 months, there are only two completed projects in this region. It is likely that the average required project time for the region will be much higher once more countries have completed their projects. In the Asia and Pacific region, the average project completion time is 28 months. In Central and Eastern Europe—the region with the largest percentage of countries reaching completion—the average project completion time has been 25 months. According to figures provided by the UNEP project team it is estimated that the actual average completion time for countries in this region will be 30 months, once all currently existing projects have been completed.

#### **4.4 Individual NBF Implementation Projects**

Unlike the NBF development project, which operated through a set of similarly created and mandated national subprojects, the NBF implementation projects initiative consisted of a series of 12 separately created national interventions. Of these, eight were UNEP-executed and -operated as a follow-up to the pilot projects. The projects were designed more individually for countries that had already completed NBFs (in this case, referring to establishing a national legislative/administrative framework, often including a draft legal framework, rather than simply a plan for later creation of that framework). The World Bank and UNDP each executed two projects in countries that had not participated in the pilot but that had some experience with LMOs.

In practice, although UNEP pilot countries had completed significant work, most had not fully drafted all relevant instruments needed in order to have a functional national legal framework in place. Many of these projects thus include substantial legislative drafting components. In at least one country, legislation developed in the pilot phase has been abandoned and a new primary legislative drafting process is being undertaken.

UNDP and World Bank implementation projects were directed at countries that had developed national frameworks without project assistance and were deemed ready for the NBF implementation phase. In some cases, national political and other factors have later proven to be obstacles; for example, two projects have undertaken little work toward completion of their Terms of Reference.

The UNEP NBF implementation projects have received significantly more direct assistance (substantive as well as administrative) from their UNEP coordinator than was provided to the NBF development projects. The UNDP and World Bank projects, where operational, have been approached very differently. UNDP limited its role to administrative oversight in the two implementation countries for which it was responsible. By contrast, the World Bank has provided both administrative oversight and technical backstopping, including sending initial and mid-term expert missions to address substantive issues and decisions.

## 4.5 Agency Fee Levels

Contrary to the normal GEF fee level of 9 percent, the GEF Secretariat negotiated the fee down to 3 percent for the 100 initial NBF development countries. However, in addition to this fee, the project budget included salaries and travel expenses for four regional program coordinators. This indicates that UNEP's resources for implementation and execution of the projects were around 17 percent of the total project cost, which would be quite generous in a normal development project, but may be inadequate considering the novelty of the subject matter, the breadth and scope of project objectives, the lack of agreement on the science, the dispersed geography of the projects, and the great diversity of opinions among countries—and especially among the nongovernmental organizations and institutions—invited to participate.

The distribution of direct oversight responsibility varied over the course of the NBF development project. Initially, each regional coordinator recruited by UNEP was responsible for managing and supervising a large number of projects. One coordinator had responsibility for 39 countries, although not all of these had active projects at the same time.

Later, the GEF Secretariat provided additional administrative resources, some of which were used to increase the number of regional coordinators. For the 30 additional NBF projects, the normal fee level of 9 percent was reinstated. UNEP oversees 93 percent of the GEF's support for biosafety, while the World Bank and UNDP implement much smaller percentages—3 percent and 4 percent, respectively.

Table 4.3 shows the actual dollar amounts handled by each of the Implementing Agencies, as well as the respective administrative fee received to support administration and oversight of the respective projects. The table also shows the ratio of the fee received relative to the total size of each agency's biosafety portfolio. On the whole, UNEP's share of fees received has been proportionally less than that of the other agencies. Overall, the Implementing Agencies have received fees representing 7 percent of the total GEF investment.

**Table 4.3: Total Allocation under the GEF Initial Strategy for Biosafety**

Implementing Agency	Total GEF (\$ millions)	Total fees (\$ millions)	Fee percentage
UNDP	\$2.4	\$0.4	16
UNEP	\$55.0	\$3.4	6 <sup>a</sup>
World Bank	\$2.0	\$0.3	15
Total	\$59.4	\$4.1	7 <sup>b</sup>

*Note:* The fee percentage calculated here includes only the official agency fee. The percentage does not, in the case of UNEP, include any additional agreed-upon resources.

- a. In addition, UNEP received compensation for the positions of four regional coordinators.
- b. Not adjusted to reflect the four regional coordinators cited above.

#### **4.6 Comparative Advantage of the Implementing Agencies**

While UNEP, UNDP, and the World Bank are all implementing GEF biosafety projects, UNEP has by far the largest portfolio. UNEP has developed substantial capacity in its project management office in Geneva, with two regional coordinators posted in Africa and a subregional coordinator posted in both the Pacific and Latin American regions. UNEP has developed considerable professional expertise in many aspects of biosafety, although its legal expertise in this area remains weak. In contrast, biosafety has been a minor part of the World Bank and UNDP portfolios, and these two Implementing Agencies have not developed expertise equivalent to that of UNEP. Some participating countries indicated that they would find it advantageous for an Implementing Agency to have an in-country presence, which UNEP, for the most part, does not have. The UNEP biosafety project team has partially offset a lack of country presence by being highly available and responsive by phone and electronic communication.

The World Bank has begun to develop its biosafety portfolio (with a project proposal under way for a regional center of excellence in Latin America), and has indicated that it anticipates that its biotechnology/biosafety portfolio will grow in the near future. The World Bank also points to its comparative advantage emanating from its extensive engagement in agriculture and agricultural research. Regarding country presence, even though the World Bank has a large office in India, its staff in Delhi has little direct involvement with or oversight of the biosafety implementation project, which is instead managed from World Bank headquarters in Washington, D.C. In this sense, then, there is relatively little advantage taken from the World Bank's country presence.

Of the two UNDP NBF-implemented projects, one (Malaysia) has yet to commence project start-up. In the other project (Mexico), UNDP has limited itself to an administrative project oversight role and drawn on the substantive capacity of the UNEP team for substantive technical backstopping. While one or two of its country offices have articulated a strong interest in handling client country demands regarding biosafety issues, UNDP centrally decided to draw on the strong technical capacity of UNEP rather than attempt to duplicate such technical capacity itself. Through its decentralized structure, UNDP does have a strong in-country presence, which could play an important part in administrative backstopping. This has been advantageously made use of by UNEP in some countries.

## Chapter 5. Regional Harmonization, Coordination, and Collaboration

### 5.1 Background and Rationale

#### *Regional Opportunities under the Cartagena Protocol*

Given the Cartagena Protocol's overall objective of managing the transboundary movement of LMOs—coupled with the fact that many countries may lack the technical and financial ability to develop, staff, and operate the full range of administrative institutions and mechanisms generally thought necessary to fully comply with the protocol—the CPB supports and encourages regional cooperation, coordination, and harmonization on biosafety issues. The protocol text touches on this aspect in numerous places. For example, article 14, Bilateral, Regional and Multilateral Agreements and Arrangements, specifically discusses aspects of regional cooperation, stating that parties may enter into these types of agreements regarding the international transboundary movement of LMOs, as long as such agreements do not result in a lower level of protection than is consistent with the protocol.<sup>4</sup> For purposes of national implementation, however, the primary provision is article 22.1, Capacity Building. In this provision, the protocol specifically *requires* the parties to “cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety...including through existing global, regional, sub-regional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.” The protocol's provisions regarding illegal and unintentional transboundary movement of LMOs create a positive obligation for inter-country cooperation, although they specifically do not require any formal or informal collaborative action. Inter-country cooperation is strongly mandated in provisions that require the posting of information regarding LMO introductions and use in the Biosafety Clearing-House discussed below.

#### *Pilot Phase Experience*

With regard to regional action, the pilot phase demonstrated the real and potential benefits of collaboration through regional activities such as awareness-raising workshops. It presented two workshops each in the Africa, Asia and Pacific, Latin America and the Caribbean, and Central and Eastern Europe regions. The activities of the pilot phase are further described in section 5.2.

The evaluation of the GEF-funded pilot phase activities recognized the value of these workshops (UNEP-GEF 2000, Executive Summary), stating, “The workshops provided a good understanding and appreciation of the type of assistance that the countries might need to ensure the transparent and safe consideration of the use of products of modern

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<sup>4</sup> This provision does not enable, nor does it constitute permission for, all sovereign nations to have the right to enter into agreements subject to good faith requirements of consistency among them. Rather it is a mechanism for “smoothing the road” in the case of frequent import-export arrangements among countries whether within a region or more generally. Although it might be thought to enable the development of harmonized standards within a region, such development requires formal international negotiations and the creation of a separate legal instrument. As such, it is not a mechanism of the protocol.

biotechnology.” The evaluation concluded that “[the project] has stimulated regional cooperation.”

### ***GEF Approach to Regional Aspects***

The activities of the pilot phase, and their subsequent evaluation (as well as a review of pilot phase activities by the GEF Scientific and Technical Advisory Panel), provided a significant portion of the basis for the GEF Strategy on biosafety, which was adopted by the GEF Council in November 2000. The strategy strongly emphasizes regional and subregional objectives and activities, stating that:

National biosafety decisions and activities need to take into account legislative measures and biosafety regulatory systems of adjacent countries. Sub-regional cooperation in information sharing and harmonizing legal and regulatory instruments is crucial for effective management of transfer of LMOs across borders. Information to assist countries in decision making is not necessarily available within a single country. Maximizing the use of institutional, financial, technical and human resources within a region will enhance a country’s ability to implement the Protocol and will facilitate an exchange of best practices and experiences (GEF 2000).

One of the three main objectives of the GEF Strategy is the promotion of “information sharing and collaboration at the regional and subregional level and among countries that share the same biomes/ecosystems” (GEF 2000). Set out in more detail (GEF 2000), specific regionally and subregionally focused activities planned for GEF support could include the following:

- Establishment of a roster of experts in a transparent manner and modalities for including them in national, sub-regional and/or regional networks;
- Assessment of options for implementation of various elements of the biosafety frameworks, for example at the regional level;
- Identification of sub-regional and regional opportunities for harmonizing regulatory frameworks, identifying regional expertise, and exchanging information on initiatives, collaboration and priority areas for capacity building.

The GEF Strategy largely focuses on activities and opportunities for communication and cooperation. Its references to harmonization of regulatory mechanisms, especially risk assessment guidelines, are appropriately limited in scope—calling only for “identification of opportunities in this regard”—a wise choice, given the political disparities that may exist among countries in a region and given the fact that many developing countries are still not entirely fixed in their policy choices on LMOs. Emphasis on actual legal harmonization among countries is relatively modest. Legal harmonization can take significant amounts of time, since it necessarily involves international negotiations among sovereign nations, and, in some cases, delegation of national authority to a regional or subregional body. Moreover, few countries even had legislation relating to LMOs at the time the GEF Strategy was developed.

Given the strong priority of regional objectives and the significant needs encountered, the NBF project documents include a survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data, and data validation, as one of the specified activities at the national level. Therefore, it can be expected that countries

participating in the NBF project have conducted some exploration regarding the possibility of collaboration through less formal mechanisms and through the medium of existing regional cooperation structures.

## **5.2 Regional and Subregional Workshops**

Following the model of the pilot phase project, the first component of the Development of National Biosafety Frameworks Project is Promoting Regional and Subregional Collaboration and Exchange of Experience, to be achieved through a series of regional workshops. According to the project document (GEF 2001, pp. 3–6), “The expected outcome of the workshops will be a clear understanding by participating countries of the obligations placed upon them by the protocol. This will require an understanding of the risk analysis and management procedures that are needed to ensure the safe use of relevant living modified organisms.”

The project document further elucidates the expected outcomes of both the regional and subregional workshops, respectively. The regional workshops will be held to:

- Identify the tasks required of countries that have signed the Protocol;
- Decide on those issues that may be addressed at a regional, sub-regional or national level and the methods that are to be used to address each of these issues;
- Identify key players in each country, and the way in which expertise and experience may be used across the region;
- Designate sub-regions and decide on those issues to be referred to sub-regional meetings (GEF 2001).

Following this, the expected outcomes of the subregional workshops are:

- Identify sub-regional priorities to enhance existing capacities and expertise;
- Discuss ways to collaborate in utilizing human resources and relevant expertise and to provide mechanisms for sharing national experience;
- Provide information leading to the harmonization of procedures for the assessment and management of risks and benefits of living modified organisms and review of applications for field trials and field releases;
- Ensure complementarity and coordination with the capacity building efforts of individual governments and other international, bilateral and multi-lateral agencies (GEF 2001).

The regional and subregional workshops were anticipated to have two functions: (1) to represent an efficient way of communicating and imparting knowledge to, and exchange experience among, a large number of country participants; and (2) to promote regional and subregional collaboration and harmonization of scientific, legal, and regulatory instruments, which could be a positive contribution for effective management of transfer of LMOs across borders. The full description of the planned activities and outcomes of the workshops can be found in the NBF development project document (GEF 2001). According to this document, \$1.14 million of GEF funds were budgeted for promotion of regional and subregional collaboration and exchange of experience, with an additional \$0.89 million budgeted for country in-kind support.

### ***Workshop Organization and Outputs***

Overall, three series of regional and subregional workshops were held (see Box 5.1), for a total of 16 workshops in all. There were more than 800 individual participants, and some were able to attend two or three of the workshops. These were usually representatives from the national executing agencies or were the national project coordinators. Although both the number of workshops and number of participants is significant when taken as a whole, the total number of participants per country was relatively limited. The majority of participants were government representatives, covering a range of ministries and agencies. Regional organizations, NGOs, the private sector, and academia were also represented.

The first series of four regional workshops aimed at a general introduction of the CPB, the NBF development project, and the main elements of work in the preparation of an NBF. The second series of six workshops were held at the subregional level; these aimed at providing insights into systems and methodologies for risk assessment and public participation. These workshops also facilitated the exchange of practices, experiences, and lessons among the countries in the subregion.

The objective of the third series of six workshops was to help participants acquire a better understanding of the different options for regulatory regimes and administrative systems for biosafety, as well as the legal and administrative requirements of the Cartagena Protocol, and potentials for regional and/or subregional collaboration and harmonization. It was emphasized particularly at the joint workshop for the Pacific and Caribbean SIDS that mechanisms for closer collaboration on a subregional level (one in the Pacific and one in the Caribbean) would significantly increase the potential of individual small countries to pool resources and enhance the development of policies, laws, science, regulatory systems, and institutional capacities. A report was produced after each workshop, which provided a summary of workshop activities; annexes to the workshop reports include the results of the workshop evaluation questionnaires.

### ***Workshop Outcomes and Other Results***

As a whole, the regional and subregional workshops were viewed positively by the participants, as indicated both by the post-workshop evaluations conducted by UNEP and feedback received directly by the evaluation team. Participants in the first series of regional workshops indicated that these were “very useful” for those from countries

#### **Box 5.1: Regional and Subregional Workshops**

##### First Series (Regional Workshops)

Nairobi, Kenya; January 16–19, 2002  
Nitra, Slovak Republic; February 5–7, 2002  
Beijing, China; March 4–8, 2002  
Buenos Aires, Argentina; May 8–10, 2002

##### Second Series (Subregional Workshops)

Windhoek, Namibia; November 12–15, 2002  
Mexico City, Mexico; December 10–13, 2002  
Kuala Lumpur, Malaysia; January 21–24, 2003  
Nadi, Fiji; February 18–22, 2003  
Vilnius, Lithuania; May 27–30, 2003  
Dakar, Senegal; April 22–25, 2003

##### Third Series (Subregional Workshops)

Shiraz, Islamic Republic of Iran; October 19–22, 2003  
Santiago, Chile; November 25–28, 2003  
Antalya, Turkey; December 9–12, 2003  
Dar-es-Salaam, Tanzania; March 9–12, 2004  
Ouagadougou, Burkina Faso; April 20–23, 2004  
Port of Spain, Trinidad and Tobago; May 11–14, 2004

where the NBF project had not begun at the time of the workshop. The workshops provided a good understanding of how to undertake the NBF process and produce an acceptable NBF document. Feedback gathered by the evaluation team through country visits, non-field reviews, and reviews of NBFs indicated that nearly all countries involved in the project were able to participate in at least one workshop.

Another important aspect of the workshops was the facilitation of network building and information sharing. Many participants indicated that this was achieved, and shared their appreciation for this aspect as one of the key outcomes of the workshops. One participant of the workshop held in Tanzania stated that simply knowing people in other countries who were going through or who had gone through a similar process was very helpful because then there were people to contact when questions arose about how to deal with some aspect of the NBF development project.

The workshops also played an important role in raising awareness and understanding of the issues surrounding LMOs and biosafety among workshop participants.

### ***Challenges of the Workshop Approach***

While the workshops were considered useful or helpful in the development of NBFs, it is unclear whether they were the most effective means of building the extensive regional cooperation on biosafety called for in the GEF Strategy and NBF development project document. Budget resources only allowed for a few people from each country to attend the workshops; these were mostly NPCs and NEA representatives. Given that the workshops were only for three or four days, there was little potential for meaningful dialogue on regional collaboration or harmonization, or the development of regional approaches to implementing biosafety. This was not surprising, given the level of funding available for this activity and the very low level of initial awareness, knowledge, and capacity in most countries.

On the other hand, some difficulties were encountered by the UNEP project team in identifying individuals with sufficient capacity to attend the workshops. In planning the workshops, UNEP set strict guidelines about which individuals were qualified to represent their respective country so as to ensure that the training would have the greatest benefit at the country level when the participants returned home. These stringent criteria sometimes made it difficult to ensure participation by the desired number of people, especially for workshops in Africa. Furthermore, given the low level of initial awareness and capacity of the majority of workshop participants, the short time frame of the workshops was insufficient for participants to develop a good understanding of complex scientific issues such as risk assessment and risk management of LMOs.

As previously described, workshops did provide participants with a valuable opportunity for informal information exchange and networking. However, to achieve the level of activity implied in the GEF Strategy and NBF development project document, efforts to facilitate true bi- or multilateral collaboration and harmonization among institutions and high-level officials at the national level will require a much longer term and more resource-intensive investment. The UNEP project team members indicated that, based on

their experience, countries are unlikely to begin thinking about subregional cooperation until they have a clear understanding of what biosafety means in their national context, have achieved consensus among diverse interests at the national level, and have developed their own NBF document. It is also noteworthy that the potential for regional cooperation and harmonization is only mentioned in a small subchapter in UNEP's Toolkit.

The limited utility of the workshops in terms of addressing regional aspects was also reflected in the participant feedback received by UNEP. In the first series of regional workshops, respondents indicated that the workshops were only marginally useful on the issue of regional and subregional resources and priorities. Focusing on regional aspects was a specific goal of the third series of workshops, and this component received a slightly higher rating from those participants, thereby indicating improvement over the first series of workshops. The third series dealt with regulatory regimes and legal and administrative systems, addressing much more directly the practical options for subregional cooperation. But rather than discussing direct cooperation among countries, the participants saw the solution in using existing subregional organizations and institutions, which had mostly not been formally involved in the project. This series of workshops took place in the fourth quarter of 2003 and first half of 2004—somewhat late in the NBF development process.

It is unclear how much knowledge transfer occurred from workshop participants to in-country nonparticipants once participants had returned to their home country. In the majority of workshops, a maximum of four persons from any given country could attend. This small number limited the effects the workshops could have at the country level. Some interviewees indicated that direct bilateral exchanges of technical experts between both developed and developing countries could be a useful mechanism for building more extensive capacity at the national level and encouraging bilateral or regional cooperation. Other activities that have been identified as potentially useful include information and experience exchange workshops conducted on a bilateral basis, training of trainers in technical aspects of biosafety, and joint training of border control and customs officers among countries sharing borders. These approaches could possibly be addressed through existing mechanisms such as the Southern Africa Customs Union, the Andean Community Customs Union, or other such agreements related to the transboundary movement of goods.

Capacity retention was another challenge faced in the execution of the workshops. This challenge is faced by all such capacity-building mechanisms. Participants who have gained knowledge sometimes do not stay in their current position within government or may leave their home country altogether to pursue educational or other professional opportunities abroad. It is difficult to quantify the degree to which capacity is retained in a country following workshops such as the ones conducted for this project. One indication is the movement of NPCs to other positions inside or out of government. UNEP has recognized this as an ongoing challenge faced by the project, and has encouraged countries to find ways to keep their NPCs on staff following project conclusion.

The budget for the regional component was quite small, constituting only \$2.1 million out of the total allocation of \$26.1 million, or about 8 percent of total GEF project costs. The evaluation of the pilot phase recommended an allocation of about \$27 million for regional and global collaboration.

### **5.3 Multi-Country Cooperation**

As noted above, it was expected that the NBF development project would contribute to potential regional and subregional interaction. In particular, the project was supposed to foster two critical actions cited as expected outcomes of country projects (GEF 2001):

- establish the systems needed for risk assessment, audit of risk assessments and risk management, taking into account national and subregional/regional needs;
- provide appropriate mechanisms for sharing scientific assessments at subregional levels (while allowing for decisions at the national level, if necessary).

These activities were expected to be funded at a level of \$15,000 per country participating in the NBF development project; it is unclear to what extent this provision was actually funded within the country subproject documents.

Regional activities were not included as part of the workplan for countries participating in implementation projects. UNEP had originally included this component in implementation project planning, as well as activities supporting curriculum development on biosafety-related issues. However, the GEF Secretariat decided that these activities should not be included in the implementation projects, and no budget allocation was made to support these aspects. According to the GEF Secretariat, the rationale behind this decision was that having only two implementation projects in each region offered little scope for regional cooperation. This logic ignores the fact that other biosafety-related activities were taking place in many countries, including the Development of National Biosafety Frameworks Project in countries in every region. In some cases, the relative inequality among countries (which may have been increased by the designation of only one country for pilot and implementation project funding) is frequently a factor in preventing such cooperation. Even in situations where implementation projects were ongoing in neighboring countries, there was no evidence of bilateral coordination.

#### ***Achievements in Cooperation among Countries***

Direct bilateral or regional activities took a number of different forms in the NBF project. All EU accession countries (countries that have already acceded or are planning to do so sometime in the future) are harmonizing regulations to EU standards, creating de facto regional harmonization; the EU countries specifically analyzed as part of this review are Bulgaria, Croatia, Czech Republic, Estonia, Latvia, Lithuania, former Yugoslav Republic of Macedonia, Moldova, Slovak Republic, Slovenia, and Turkey. Although some of these countries are not yet part of the EU, they have all made efforts to harmonize their national biosafety policies, legislation, and regulations to EU standards. On the other hand, while the focus on EU harmonization has helped set a minimum level of regulation

among countries, this does not mean that countries not yet acceded to the EU are necessarily collaborating and communicating with other EU or non-EU countries. This evaluation saw relatively little evidence of in-depth, meaningful discussions among these countries on biosafety issues. The evaluation did not inquire in detail into intra-European cooperation, but did learn of EU-based peer review services and the involvement of many countries in the Aarhus Convention (the United Nations Economic Committee for Europe's Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, adopted in 1998), which has important applications for the biosafety protocol.

Another example of regional cooperation in biosafety was in central Asia, where, in October 2004, six Central Asia countries met in Dushanbe and shared experiences on the development of NBFs and formulated a resolution on biosafety collaboration in the region. This resolution was presented at the meeting of the Commonwealth of Independent States International Committee on Sustainable Development. In Latin America, countries have established an annual symposium on transgenic products, with the fourth session held in late September 2005 in Porto Alegre, Brazil. UNEP participated in this meeting, which discussed the approaches countries were taking on biosafety issues and a comparison of laws, regulations, and communication strategies.

As part of the NBF development project, most countries obtained and reviewed the laws of both neighboring and distant countries. The primary purpose of this activity, however, appears to have been to study them as potential models for legislative development rather than as a first step to harmonization or even development of coordination. When gathered from within the region, much of this information was relevant to two other specific activities listed in the suggested workplan of the national project documents—a survey on existing NBFs in the countries of the subregion and a survey on existing mechanisms for harmonization of risk assessment/risk management, mutual acceptance of data, and data validation. These activities were carried out in a rather sporadic manner. At least eight (21 percent) of the completed NBFs reviewed under this evaluation reported that one or both of these surveys was completed within their national projects. Within the completed NBF documents, discussions or analysis of regional collaboration and harmonization are largely absent. Approximately three-quarters of the completed NBFs did not include any discussion of regional aspects of biosafety. In Central and Eastern European country NBFs, regional analysis was easier than in other areas and was considered more essential, since their primary regional cooperation related to integration with EU directives on LMOs and biosafety.

One possible future means of collaboration in various subregions could be through the development of regional “centers of excellence” for biosafety. A proposal is under development by the World Bank for this type of mechanism in northern Amazonian countries, through the International Center for Tropical Agriculture, which is one of the regional centers of the Consultative Group on International Agricultural Research. Regionally based approaches involving other such subregional organizations are discussed in section 5.4.

### ***Challenges to Future Progress***

There have been a few positive examples of bilateral or regional discussions in Central Asia and Eastern Europe, but considering the national project budget allocation for this type of activity, there was relatively little scope for direct bilateral discussions. NPCs or other member of the NEA could use national project funds to visit neighboring countries, but UNEP had no budget provision to support this type of activity outside of the funding for the national project. The time frame for the national projects was also highly compressed, and some NEAs indicated that the project was so focused on meeting the requirements of the NBF within the allotted time frame there was not sufficient time to deal with other aspects such as regional cooperation. Agencies in many countries have expressed interest in exploring regional cooperation, and the GEF should be in a position to help facilitate this process when conditions are appropriate.

Countries face many challenges when attempting to address regional cooperation and collaboration on issues of biosafety. Inter-country dialogue on biosafety issues is currently difficult, at best, due to the preliminary nature of national policy decision making on these issues in the vast majority of countries reviewed in this analysis. One significant difficulty is language barriers, which were seen as a particular problem in eastern Asia. China is one of the more advanced countries with regard to the level of biotechnology activity being undertaken. Individuals interviewed as part of this evaluation expressed concern that China's ability to cooperate and share information on biosafety with other countries in the region was consistently hampered by language barriers. Despite these challenges, in the future the national Biosafety Clearing-House mechanism should help facilitate some degree of regional cooperation.

## **5.4 Cooperation through Regional Organizations**

The GEF Strategy calls on the NBF development project to explore and maximize possibilities for working with regional and subregional organizations to enhance implementation through regional cooperation on biosafety. This conclusion arises from provisions of the GEF Strategy (1) requiring that the regional and subregional workshops should enable and encourage the development of opportunities for regional collaboration, and (2) calling upon the NBF development project to work with multilateral and bilateral institutions to further the goals of the strategy (GEF 2000, paras. 20 and 26).

Regional cooperation could be especially important for SIDS regions such as the Caribbean and the Pacific. While many SIDS are concerned about the potential effects of LMOs on their isolated and fragile ecological systems, the limited capacity of individual countries makes it difficult for any single nation to establish and maintain a cost-effective national regulatory system for biosafety. The potential for SIDS and other similarly positioned nations to ensure effective implementation of the CPB is dependent on their ability to address manpower and expertise deficiencies through collective action and shared capacity.

Notable developments toward regional collaboration involving subregional organizations include the following:

- UNEP-GEF support contributed to the development of regional approaches to biosafety in two regional meetings held in collaboration with the Caribbean Community, with support from the Caribbean Agricultural Research and Development Institute, the primary body within the community related to biosafety. In addition, as an output of the NBF project in Dominica, a formal proposal for Regional Coordination of Biosafety in the Context of the CPB was developed. This proposal has been circulated to other Caribbean Community member states for possible approval.
- In the Pacific, the project formed an agreement with the Secretariat of the Pacific Regional Environment Programme to host a regional node of the BCH mechanism for Pacific island nations.
- A meeting for the South Asia subregion was held in Kathmandu in November 2004 to open preliminary discussions on the establishment of a regional cooperative framework for biosafety. These preliminary discussions were held under the auspices of the South Asian Association for Regional Cooperation, which organized this meeting, and are documented in SAARC 2004.
- A second regional meeting organized by the government of Sri Lanka on completion of its NBF project was held in April 2005. The aim of this meeting was to exchange information on NBFs in the region and to work out areas for inclusion in the regional agreement on biosafety, including cooperation on sharing and exchange of information.
- Working with the Association for South Eastern Asian Nations Secretariat, the NBF project brought together the association's 10 member states in June 2004 in Manila to discuss their experiences in developing their NBFs and to explore areas for cooperation. The possible areas for collaboration identified included cooperation on development of regulations, sharing of information on biosafety through the BCH, and a regional information network on biodiversity.
- The UNEP project team is working with the Economic and Social Commission for West Asia and the International Center for Agricultural Research in the Dry Areas on promoting regional cooperation on biotechnology and biosafety. The initial activities in this area include an e-forum on biotechnology and biosafety in West Asia and North Africa; this will be followed by a regional meeting in early 2006.

In addition to these formal activities, the staff of the UNEP-GEF projects, as well individual countries participating in the NBF project, have had informal information exchanges and discussions with a few other relevant regional organizations, such as the Economic Community of West African States, the Association for Strengthening Agricultural Research in Eastern and Central Africa, and the Association of Southeast Asian Nations.

Although there are some regional biosafety-related activities under way, there is room for much more progress to be made in this area in the future. Numerous organizations in many regions could play important roles in facilitating regional activities; these include the centers of the Consultative Group on International Agricultural Research, the West and Central African Council for Agricultural Research and Development, and the Southern Africa Development Community. Many of these organizations are focused on agricultural technology and research, including biotechnology. Some organizations, such as the Southern Africa Development Community, are beginning to consider how to deal with biosafety. Although addressing biosafety is an additional level of activity, there may be important synergies achieved through the integration of biosafety measures directly into nascent programs for the promotion of biotechnology research.

An important question moving forward will be to what degree GEF support for biosafety-related activities can catalyze or encourage initiatives within regional bodies, and the most effective mechanisms for engaging them. Additionally, some regionally focused institutions may not be appropriately positioned to achieve buy-in by all stakeholders.

## **5.5 Coordination with Other Bilateral and Multilateral Organizations**

The third objective of the GEF's initial strategy on support to the CPB is "promoting 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" (GEF 2000). This goal seems to have been prompted by statements by several donors about their intention to provide financial support to the CPB at the Ministerial Round Table in Nairobi in May 2000. The GEF Strategy proposes that the GEF Secretariat, in conjunction with the Implementing Agencies and the CBD Secretariat, convene annual meetings of interested organizations to build synergies and establish complementarities in capacity building. Pursuant to a request by the Intergovernmental Committee for the Cartagena Protocol, the first such meeting was held in December 2000. It was agreed that the CBD Secretariat would establish a database directly addressing biosafety capacity building—a process that has been completed and is posted in the BCH. In addition to information from agencies and organizations providing capacity-building projects and support, about 50 countries have submitted data about their capacity-building needs. Practically all respondents expressed the need for enhanced institutional capacity building in risk assessment, risk management, regulatory systems, awareness raising, education, and public participation.

A second meeting, Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Building Activities, was held in 2004. At this meeting, participants prepared operational procedures and guidelines for coordination of biosafety activities, which were subsequently approved at COP-MOP 2. It is expected that further coordination meetings will be held whenever necessary, at least once a year. In preparation for the next meeting and COP-MOP 3, the CBD Secretariat will carry out a comprehensive review and possible revision of the action plan for capacity building (CBD 2005).

An ongoing study by the United Nations University Institute of Advanced Study has compiled data on all funding by donors and co-funding by governments of biosafety capacity-building projects (UNU forthcoming). According to the current information available, total allocations since 1999 amount to about \$157 million, of which GEF funding and government co-funding represents about 55 percent combined. The remainder is allocated by about 16 multilateral and bilateral agencies. The areas addressed in projects by agencies that have contributed in excess of \$1 million are biosafety regulatory implementation and capacity building (U.S. Agency for International Development—USAID); training in biosciences (Canadian International Development Agency); capacity building in biotechnology, biosafety, and biotech policy, research, and education (Swedish International Development Agency, Department of Research Development), biosafety policy, awareness raising, participation (German Federal Ministry for Economic Cooperation and Development); holistic biosafety assessment and master of science course (Norwegian Agency for International Development); biosafety systems in Poland (European Union); 19 assorted biotechnology and biosafety initiatives (Rockefeller Foundation); strengthening capacity building in Asia, Bolivia, and Grenada (Food and Agriculture Organization of the United Nations—FAO); and a global training course in genetic engineering, biotechnology, and biosafety (International Centre for Genetic Engineering and Biotechnology).

Many countries with implementation projects are also recipients of other bilateral or multilateral biosafety projects with the same or similar objectives, often working with the same in-country partner institutions. For example, Uganda and Kenya are also participating in USAID's Program for Biosafety Systems; Namibia has participated in the Southern Africa Regional Biosafety program; India is a participant in USAID's South Asia Biosafety Program; and Bulgaria and Poland have both benefited from the Dutch government's Matra project on implementation of biosafety frameworks. Poland has also been supported through an EU twinning program.

The GEF Strategy's requirements for coordination and collaboration with other multilateral and bilateral projects is important because, in its absence, there is the risk of promoting competing subnational priorities or creating confusion and/or misunderstanding regarding the relative roles of different projects within the national strategy. In this context, coordination and collaboration imply more than merely sharing information on respective project activities. As indicated in the NBF development project document (GEF 2001), one of the objectives of the regional workshops was to "ensure that activities undertaken under this project are implemented in coordination with other biosafety capacity-building efforts of individual governments and other international bilateral and multilateral agencies."

## **5.6 Conclusions**

Regional workshops were the primary tool by which the project addressed the regional component of its mandate. Based on the stage of national policy development and technical capacity, it was appropriately determined that the workshops would focus on the cooperative/collaborative elements of that mandate, rather than expending significant

efforts in promoting the development of regionally harmonized legislation and standards—a process for which the countries were not yet ready.

The workshops were intended as a cost-efficient way of imparting essential information to the national project coordinator and key members of the NCC, and of establishing useful contacts. Given the low level of initial awareness and capacity of many workshop participants, the workshops functioned as a mechanism for primary awareness-raising—a much less cost-effective result. In general, the workshops' main positive contribution was the creation and education of a small node of experts and interested officials in each country—the kernels from which an entire biosafety framework will ultimately grow.

The limitations of the regional workshops were recognized in the mid-term evaluation of the NBF development project (Navajas and Seyami 2003): “the programmed funds and events are insufficient to attend the strong demand—and potential—for subregional cooperation, let alone for in-depth training.” Disregarding demand and potential, it also appears as though the programmed funds and events were too limited to meet the ambitious objectives to facilitate regional cooperation on biosafety among parties as outlined in the project document and the GEF Strategy.

The various subregions are at different stages of development with regard to regional collaboration and cooperation, and may need different types of support to create effective regional mechanisms. Although there may be some consistent types of technical or other support that can be provided among all regions, a uniform approach to regional cooperation, collaboration, and harmonization is not likely to be an effective way forward for all regions. Capacity-building activities, such as regional workshops, are most effective when targeted toward a group of stakeholders with similar levels of capacity and technical skills.

In the process of NBF development, the national subprojects appear (based on reports submitted) to have given little attention to bilateral or subregional aspects. Given the baseline levels of knowledge, awareness, and capacity in many countries at the beginning of the NBF development project, it was likely premature to call for high levels of regional integration in the GEF Strategy—despite the obvious need for longer term activities in this direction. It was important to recognize the potential benefits and synergies from regional coordination, collaboration, and harmonization with regard to biosafety and the Cartagena Protocol, but at the time the Development of National Biosafety Frameworks Project was conceived, many countries had yet to even ratify the protocol. In this context, the envisioned level of activity under the GEF Strategy and NBF development project was ambitious to a fault. Yet the potential for regional collaboration exists at the stage when countries begin moving into implementation; to limit this aspect in the NBF implementation phase projects was possibly a missed opportunity.

The NBF development project's work on developing coordination at a global level among bilateral and multilateral organizations embodies only an initial foray, in coordination with other international initiatives for such coordination. While further work is clearly necessary, initial efforts have been notable.

GEF support for biosafety capacity building, including the regional workshops and other activities dealing with regional aspects of biosafety, have had positive outcomes. However, the limited budget for these activities has also limited the potential benefits. In the future, it will be important to promote the sustainability of the benefits gained thus far, including addressing the problem of capacity retention.

Donor coordination at a global level has been quite weak. Some reasons for this are differences in policies, special country interests, and variations in focus among various donor agencies. Other reasons are engagement of institutions in the donor and recipient countries that are not closely involved in the GEF-supported projects. The Secretariat of the CBD and the GEF Secretariat are the two bodies that could play a larger role in this context.

At the country level donor coordination has also been limited in some cases. In some countries, the evaluation noted a lack of concerted cooperation or collaboration with other similar projects. In others, there are examples of coordination among some projects, although certainly not all. In Asia, the NBF project has worked closely with the FAO regional project for capacity building for biotechnology and biosafety.

## Chapter 6. Awareness Raising and Stakeholder Participation

### 6.1 Awareness Raising

Article 23 of the CPB states that 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; (and) endeavor to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported (CBD 2000b).

The article also expects the parties to “consult the public in the decision-making process, make the results of such decisions available to the public.” In addition, parties are called upon to inform the public about the means of public access to the BCH.

The NBF development project seeks to achieve two primary objectives—NBF development and the promotion of regional cooperation through, among others, “[r]aising public awareness...on the issues involved in the release of living modified organisms to promote informed debate and to ensure that where any use of modern biotechnology is permitted, it is done in an open and transparent way” (GEF 2000). Specifically, the subproject activities were to encompass “(in cooperation with the relevant international industry organizations, NGOs and consumer associations), neutral and objective information material for the public, [including]... provi[sion of] information on media coverage to the project management” (CBD 2000b). A newsletter and other publications (including video and electronic materials) were also suggested. Several other project activities described in this report (including public workshops, the BCH, and a website) are also undertaken partly for public awareness purposes.

The estimated budget allocated to each country to support public participation included \$15,000 for tools to raise public awareness and information on media coverage and \$20,000 for developing methods to involve the public and private sectors at all stages of the project. The actual allocations decided in consultation with each country were slightly higher.

A factor reported in virtually all countries visited (and in most of the draft NBF reports reviewed), including those that had completed all public awareness-raising activities under their national subprojects or implementation projects, was the ongoing need to raise public awareness regarding biosafety issues. In many cases, the lack of awareness also extended to parliamentarians, relevant government officials, and even academics.

There were a variety of perspectives on the nature of awareness needed. Many NPCs and NCC members indicated simply a need for heightened political awareness and public consciousness of LMO issues so that they could engage in the political process on either side of the issue. Some have suggested a need to build acceptance among consumers, building a clearer knowledge of the market for LMO food products, for example. In some

cases, the need was stated in terms of awareness of the advocacy perspectives of various interest groups—whether a desire to heighten perceptions of potential dangers of LMOs to various sectors or to better understand their benefits. For these purposes, biosafety is not simply a scientific concern, but involves significant cultural, social, and political components.

As the subprojects progressed, an additional awareness objective often arose: to ensure that the public is sufficiently informed about biotechnology policies and practices and the biosafety measures being proposed for public comment.

In furtherance of this mandate, virtually all projects presented workshops, which often consumed a large number of person-days of training and awareness raising, considering the very limited resources available. In most cases the public awareness workshops were open to government officials, special interest groups, and the general public. In a majority of national subprojects, the workshops were arranged in the capital; several countries also made efforts to reach out at least to the main provincial centers. Beyond these primary tools, many projects prepared video and audio materials, training packets, and other awareness-raising measures.

The limited funding available within the subproject budgets has meant that these activities typically amounted to only a small contribution in a larger body of awareness-oriented work within each country. Often, these efforts could not compare in number or impact to efforts by other groups. For this reason, a few projects took a longer term view—directing their energies to the creation of a plan for awareness raising, rather than simply presenting workshops and creating materials with a shorter useful life.

Based on interviews and country visits, the evaluation results suggest that awareness raising was a complex challenge, and the project results were self-evaluated by subproject staff in virtually every country to be insufficient to achieve the ambitious goals. The public awareness component of the national subproject documents has often been the basis for a project's primary interaction with the social sciences, and with experts and activists working in these issues. Despite anticipated difficulties in this area, the NBF development project design appears to focus on the scientific, technical, and institutional aspects of biosafety, with less direct connection to issues of greatest interest to the public.

## **6.2 Stakeholder Participation in Projects**

The interest in public participation as a mandatory component of international agreements arises out of a combination of international emphasis on democratic governance, along with the continuing evolution and growth of national legislative and administrative practice. As the distance increases between primary parliamentary (democratically controlled) bodies and the administrative bodies they are charged with overseeing, public involvement takes on increasing importance. Effective public involvement consists of three components:

- *Access to information:* Public involvement in governance can only be meaningful when the public is able to be fully informed. This may require more than just availability of documents. To enable true access to information, governments may need to provide other kinds of assistance (for example, independently created summaries of key documents, and ombudsman programs).<sup>5</sup>
- *Transparency:* Decision making must happen through open, noticed, and reported meetings and decision processes to ensure that government functions by rule of law rather than at one official's or agency's discretion.
- *Public participation:* Direct public input (public hearing or comment processes, representative commissions, or working groups) are often necessary to ensure that those most affected have a right to be heard in decision making. National legislation sets standards and procedures for ensuring appropriate participation, and for government response to such input. Where affected groups are rural, indigenous, remote, or disadvantaged, special action may be needed to actively promote and enable the participation of these persons.

Paragraph 23.2 of the Cartagena Protocol requires public involvement in LMO-related decision making, stating that “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.” Other provisions clarify that parties must provide access to information and transparency as a component of this responsibility.<sup>6</sup>

The GEF Strategy and project documents include an intrinsic and primary mandate to ensure the development and application of appropriate measures for ensuring public participation in the regulatory and decision-making processes relating to LMOs and biotechnology, including participation in the primarily governmental process of NBF development through the national subprojects.

Participation is distinguished from the majority of the protocol's numerous specific requirements, however, by the fact that it is also a separately mentioned objective of the NBF development project. The GEF Strategy underscores this requirement, noting the expectation that the projects will “improve public participation on the issues involved in the release of living modified organisms to promote informed debate and to ensure that

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<sup>5</sup> In commercial legislation, access to information is part of a triple balance: Applicants often must retain a right to keep some information confidential; governments need to review all relevant information; and the public needs access and the ability to ensure that government lives up to its mandates.

<sup>6</sup> Recognizing that access to information and transparency are essential components that make public participation meaningful, other provisions of article 23 require the parties to “promote and facilitate...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”; “endeavor to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported”; and “endeavor to inform its public about the means of public access to the Biosafety Clearing-House.”

where any use of modern biotechnology is permitted, it is done in an open and transparent way” (GEF 2000, para. 17(v)). The national subproject documents similarly single out these requirements, calling on the countries to create “mechanisms for public participation and information” (GEF 2000, para 3.1.2). The UNEP Toolkit also identifies participation mechanisms as a separate requirement of the completion of a satisfactory NBF, in addition to the legislative framework (UNEP 2004b).

### 6.3 Public Involvement and Participation

The NBF development projects incorporated concepts of public involvement and participation in two primary ways—participation in the work of the national subprojects themselves, and the provisions and procedures implementing the public involvement requirement of the Cartagena Protocol.

The evaluation team addressed both aspects of participation during the country interviews. In general, these data indicate that public participation objectives were only partially achieved through the project (see Table 6.1).

**Table 6.1: Level of Public Involvement**

Participation	Level of public involvement		
	High	Medium	Low
Development projects (7)	2	5	5
Implementation projects (4)	1	3	2

While an overwhelming majority of countries complied with project requirements (creating an NCC, holding substantive workshops, seeking comments on relevant documents), the actual “participation impact” of these structural components was less than the project designers may have expected. Participation challenges arose both from lack of appropriate stakeholder representation on the NCC (or implementation project steering committee) and from systematic practices limiting stakeholder participation in certain activities.

Given that biotechnology and biosafety are both controversial and relatively new in many countries, public involvement offers an important element—promoting both buy-in and awareness. Practices that limited stakeholder participation, or failed to take legitimately provided stakeholder comments into account (for example, printing a document in final book form before providing it to stakeholders for comment), can negate some of these potential benefits of the national projects.

At the same time, however, in some countries it was felt that the national projects created an unnecessarily high profile for predrafting legislation—an activity that is usually undertaken in a less participatory manner—particularly where the resulting document will be submitted to parliament, and there face democratic scrutiny. Some of the involved persons who commented during the course of the in-country and telephone reviews stated that the project may have actually stirred up controversy where it had not previously existed.

## 6.4 Stakeholder Participation in the NCCs

As discussed in section 4.1 above, the national subproject documents (which are essentially contracts between the countries and UNEP) committed the NEAs to establishing an oversight committee (NCCs) consisting of a mix of government officials and “likely...representations from the private and civil society sectors” (UNEP 2003d). The UNEP Toolkit provides a much stronger mandate for inclusion of representatives of all relevant government agencies as well as representatives from civil society and the private sector (UNEP 2001). This kind of formulation obviously seems intended to enable the NCC to liaise with all government departments with interests in and information about biotechnology and with stakeholder groups (including farmer organizations and NGOs, as well as scientists). An important role of the NCC could be to ensure that each subproject was driven from an inter-ministerial (cross-sectoral) and national perspective rather than from the perspective of a single ministry or organization.

In response to this requirement, nearly all NBF development projects reviewed in this evaluation set up an NCC. Within NBF implementation projects, there is a greater variety in organization, given that some of these projects are implemented by UNDP and the World Bank. Regardless of which Implementing Agency was involved, all implementation projects included some kind of nationally created project steering committee. In projects implemented by the World Bank and UNDP, however, the civil society stakeholders involved have not included the full range of organizations concerned with biosafety issues.

### **Box 6.1: Tajikistan: A Dynamic Participation Process**

Tajikistan’s NCC was a dynamic body involving a full range of stakeholders. The NCC met once a week for six months, with a different member giving an expert presentation on a topic of relevance each week. The individuals involved found the process to be very useful and beneficial, not only for the country, but also for their own professional development and capacity.

The current level of LMO and biotechnology activity in Tajikistan is very low, with no varieties approved for field trials or commercial release. Because of the low level of domestic activity, the country’s primary concern regarding LMOs is the labeling of imported LMOs or products that contain LM components. It is expected that biotech activity in the country will expand in the future, but there is also a significant concern that the country’s unique biodiversity resources be safeguarded from the influence of LMOs.

One of the main tasks of the NCC is to represent key government and nongovernmental stakeholder groups and ensure that NBF reports and other documents, including laws, reflect contributions from all government sectors as well as nongovernmental stakeholders.

The UNEP Toolkit recommended representation of the key ministries, academic institutions, the private sector, producer and consumer interests and/or other NGOs aiming for a total membership of 10-15 individuals. The evaluation focused primarily on adequate representation of each of the most active governmental sectors (environment, agriculture, health, and economy/trade). In most cases, representation was found to be well balanced, but there were variations in NCC representation from just a few ministries (Belarus, Estonia) to 11 ministerial-level bodies (Mexico). In a few cases, such as in Tajikistan (see Box 6.1), dynamic processes of stakeholder participation evolved through

the NCC. Where fewer ministries were included, this might have been because of lack of appropriate capacity in the country. However the apparent absence, in some cases, of representation from the ministries of health (Niger, Senegal), agriculture (Lao PDR, Uganda) and trade (Latvia, Slovak Republic, Lithuania) is curious. An appropriate balance among the various ministries would be an indicator that a diversity of viewpoints was taken into account.

The evaluation examined NCC composition, giving a general rating that assessed compliance with elements of NCC membership—with particular attention to the inclusion of relevant government departments and nongovernmental stakeholder groups. Table 6.2 below summarizes the data. Most of the ratings are either high or low, with few at the medium level.

**Table 6.2: Inclusiveness of Country NCCs**

NCC representation	Inclusiveness of NCC		
	High	Medium	Low
<i>In-country reviews:</i>			
Development projects (7)	3	0	4
Implementation projects (2)	1	0	1
<i>Non-field reviews</i>			
Development projects (5)	2	3	0
Implementation projects (2)	0	0	2
	<b>Good</b>		<b>Poor</b>
<i>Document reviews (development projects only)</i>	13		13

*Note:* These results include only UNEP-implemented projects reviewed by this evaluation.

In the case of the implementation projects managed by the World Bank and UNDP, there were wide differences in representation. In India (a World Bank project), a project steering committee was formed but it had only met only once by July 2005 and is not a cohesive body as yet. The Colombia project (also World Bank) is managed by an inter-ministerial coordination committee containing representatives of many government and intergovernmental institutions, but with an imbalance among ministries in that most representatives are from agencies and boards under the agriculture ministry, and there is little representation of civil society. There was sufficient inter-ministerial contention in that case that long negotiations were needed to even establish voting rules. Mexico (a UNDP-managed project) has only a small and relatively inactive managing committee. This level of oversight was all that was needed in view of the strength of the country's NEA—the Inter-ministerial Commission on Biosecurity and Genetically Modified Organisms (CIBIOGEM).<sup>7</sup> This body, which is also Mexico's national biosafety focal point, brings together 11 ministerial-level bodies for the purpose of national biosafety oversight. To some extent, CIBIOGEM has been cited as a role model for intra-governmental collaboration, particularly in countries with significant existing LMO activities, experts, and regulatory bodies.

<sup>7</sup> CIBIOGEM was formed by presidential decree in 1999 and was recently formally codified in Mexican law as part of the country's new Biosafety Act, which was adopted in March 2005.

Only one of the countries reviewed in depth (Colombia) addressed ministry representation questions procedurally—that is, developed formal voting procedures that were written in a way that ensured that ministries with a low level of representation could not be outvoted by a more numerous ministry group. None of the other countries visited or interviewed had, or indicated a need for, a formal voting system.

In some countries, it may be idealistic to expect all relevant stakeholder ministries to collaborate in a collegial manner. In many cases, ministries are competing for resources, and cooperation is not necessarily high on their respective agendas. Involving civil society can also raise potential challenges to consensus—for example, in countries where NGOs are so strongly against the objectives of the project that they effectively prevent significant progress from being made. In some cases, NGOs known to hold strong positions were excluded from the process.

## **6.5 Legislative Provisions for Participation in Biosafety Decision Making**

The evaluation considered the actual project outputs with regard to participation in formal governance for biosafety. Specifically, in its review of all completed NBF reports, it noted that about three-quarters (28 of the 38 completed NBFs examined) included complete public participation requirements for the country; several others included specific measures addressing part of the participation issue.

Actual performance may be higher than suggested by this survey, however, since most countries already recognize participation as a primary tool of democratic governance. Some countries have already passed general legislation legitimizing public participation in all administrative decision-making processes within the country. Many European countries are also parties to the Aarhus Convention, for example, and noted that the national implementation of that convention is directly applicable to their biosafety frameworks. Other countries (for example, Cuba) include public involvement rights, responsibilities, and procedures in laws of general applicability and higher priority than their biosafety law, so new legislative instruments cannot supersede or contradict these primary responsibilities.

The prominence of participation in the GEF Strategy and project documents may well have been intended to focus special attention on participation and indicate the GEF's desire to strongly promote compliance with this critical component of modern governance. As a consequence, omissions relating to the development of participation mechanisms in project documents should probably have triggered special attention.

Public participation was less prominent in implementation project activities. In three of eight implementation projects examined by this evaluation, neither the legislative aspect of participation nor provisions for representation in steering committees were included in project design.

## 6.6 Conclusions

Project performance with regard to public awareness raising and participation mandates has been mixed, with few countries achieving a high rating on this factor—both in regard to project operations and in the development of participation mechanisms for the implementation of biosafety legislation.

Given the low level of funding available for public awareness activities, performance of this element was likely to be limited. With regard to public awareness and participation, development projects could have been more closely tailored to country needs.

In several countries, NGOs and the private sector provided feedback that their views were not adequately considered in project outputs and activities. This is not surprising, given the highly polarizing and scientifically uncertain nature of the issues surrounding biosafety.

Multi-stakeholder processes on a topic as controversial as biotechnology are inherently difficult, leading some country project managers to exclude controversial views from the NCC altogether; however, the national workshops did seem to involve a wider range of views. Inclusion of holders of opposing viewpoints, although often increasing the difficulty in the short term, can also increase buy-in and support over the longer term of post-project activities.

## Chapter 7. Capacity Development

Capacity building is one of the prime elements expected to facilitate effective and efficient implementation of the Cartagena Protocol in developing countries and countries with economies in transition.<sup>8</sup> As discussed earlier in section 5.5, an international framework for capacity building has been agreed upon and adopted under the CPB that will guide the implementation of the GEF Strategy (ICCP 2000, para. 2). On a complex issue such as biosafety, the human element of capacity building involves the transfer of know-how, and the provision of training, in sciences related to safety in biotechnology and in the use of risk assessment and risk management techniques. In addition, physical capacity in biosafety implementation will often require the development of appropriate facilities (UNEP 1995). Elements of capacity building, which may contribute to effectiveness, include systematic assessment of needs and identification of options, development and strengthening of relevant institutions, development of skills and expertise in human resources, and establishment of necessary scientific and information management facilities, including transfer of technology.

Various capacity-building tasks are addressed differently under the NBF development and implementation projects:

- NBF development projects were intended to identify existing capacity gaps with regard to drafting of legal documents, administrative systems, risk assessment procedures, and systems for public participation. All the NBF development countries visited by the team gave a medium to low rating of the GEF support to capacity assessment; they gave a higher rating to support in actual capacity building.
- NBF implementation projects were assumed to have some prior basic capacity and were more selective in strengthening specific areas of human capacity, as well as establishing needed infrastructure in terms of laboratories and databases for participation in the BCH.

### 7.1 Capacity Development in Risk Assessment

The need to ensure biosafety through national systems of risk assessment and risk management was recognized as an international priority within the 1992 Convention on Biological Diversity, signed in Rio de Janeiro at the UN Conference on Environment and Development. It was also explicitly addressed in Chapter 16 of Agenda 21 (UNCED 1992). Article 15 of the Cartagena Protocol requires that scientifically sound risk assessment be performed for every decision taken under the protocol, and that the purpose of such assessments shall be “to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological

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<sup>8</sup> Ministerial Round Table on “Capacity-Building in Developing Countries to Facilitate the Implementation of the Protocol” held in Nairobi 23 May, 2000, during the 5<sup>th</sup> Conference of the Parties to the CBD; the GEF Workshop on the UNEP/GEF Pilot Biosafety Enabling Activity, held 24 May, 2000 in the margins of the CBD COP5.

diversity, taking also into account risks to human health.” Although intentionally not imposing rigid international standards for risk analysis, the protocol stresses that “recognized risk assessment techniques” shall be taken into account, including guidelines developed by relevant international organizations. For small countries, which may have limited institutional capacity, the ability to access external expertise and information and/or make use of regional or subregional mechanisms for risk assessment and risk management may be crucial for implementing the protocol.

Annex III of the Cartagena Protocol provides guidance and basic principles and objectives for a scientifically sound risk assessment. While a country’s risk analysis procedures need not follow or adopt the contents of the annex, they must be “consistent” with it. The GEF support was intended to help the participating countries achieve the required consistency through the development and implementation of their own risk assessment capacity, guidelines, and modalities for creation of expert committee(s) that would be responsible for this aspect.

The NBF development projects are somewhat different from the implementation projects with respect to their role and activities to promote functioning systems for risk assessment and risk management.

#### ***NBF Development Projects***

Within the NBF development project document, the objectives and activities related to risk assessment and risk management include the following, in addition to the regional and subregional workshops and efforts to develop regional collaboration as discussed above:

- the identification of national and/or subregional expertise for risk assessment and developing appropriate roster(s) of experts;
- the establishment of systems needed for risk assessment and the audit of risk assessments and risk management to ensure the safe use of modern biotechnology, taking into account national and subregional needs.

At the NBF development stage, the national subprojects were not expected to focus on providing detailed technical training in risk assessment and management, as this would be a priority during the subsequent implementation phase. Similarly, many development phase projects were not yet ready to develop and adopt specific risk assessment guidelines and procedures, since they first needed to complete their primary biosafety legislation. A few countries, such as Ethiopia, did undertake such development, and all appeared to discuss it. Based on feedback from project personnel in countries visited or interviewed by telephone, it appears that the project was not very helpful in providing examples of risk assessment and management, although this had been expected by some countries. (Ten countries rated UNEP support as medium in this respect; seven rated it as low.) As evaluated in section 10.1, Toolkit Module 3 outlines the risk assessment criteria (UNEP 2004c).

Based on telephone and in-country interviews with NPCs, members of the NCC, and other stakeholders, and desk reviews of various NBF documents, it is apparent that most countries have given consideration to establishing a national committee for risk assessment. In nearly all countries, the mechanism for risk assessment takes the form of an expert committee, such as a multi-stakeholder national biosafety committee, sometimes with more technically oriented subcommittees for conducting product-specific reviews. For many countries, staffing of this committee alone will be a challenge, and, at project completion, the risk assessment and risk management structures are often just a plan on paper or are in the formative stages. For example, Burkina Faso has created a new national biosecurity agency with a legal mandate for coordination and monitoring of all activities pertaining to the implementation of biosafety, but budgetary and technical capacity constraints currently limit its effectiveness.

The creation of national biosafety committees in countries with low baselines is expected to be very difficult, both in terms of staffing and financing. Alternatives to this approach do not appear to have been considered in the NBF development projects. The GEF support in the development project was not intended to build the capacity to undertake subsequent implementation of risk assessment systems. As surveyed in the evaluation visits to development project countries, five out of seven countries (71 percent) received a low rating on the survey evaluation of support for risk assessment capacity strengthening.

As implemented through the NBFs to date, nearly all national implementation of systems for risk assessment and management require the creation or restructuring of expert committees. Analysis of national stocktaking regarding the level and location of capacity in risk assessment (which varied greatly from country to country) should logically have been a primary input into the development of this element of the NBF.

The project also called for networking; this required, among other things, creation of a roster of experts. This task was undertaken by 17 (50 percent) of the 34 projects with completed NBFs, although analysis of these rosters indicates that they were not always developed systematically or subjected to evaluative criteria or peer review.

The second series of subregional workshops (discussed in section 5.2) introduced the topics of risk assessment and risk management. Given their focus on the creation of NBF risk assessment components (a regulatory drafting task), they were not structured to give participants hands-on experience of risk assessment—which, in any case, could not likely have been meaningfully addressed in the short time frame of the workshops. In addition, workshop discussions did not distinguish the risk assessment and management systems necessary for handling general broad-scale releases of LMOs from those required to deal with much more limited confined field tests. These two are very different, both in content and in the degree to which they are needed, especially in low baseline countries.

### ***NBF Implementation Projects***

The countries participating in the NBF implementation projects were generally further advanced, with most having established systems for risk assessment and risk

management. Some of these countries had significant experience in dealing with biosafety prior to the start of the implementation projects.

India, Mexico, Cuba, and China have substantial technical capacity in both biotechnology and biosafety, and have experience with introductions of LMOs both in experimental field trials and in more general agricultural contexts. Colombia, Bulgaria, Poland, and Kenya also have some experience in dealing with experimental field trial introductions of LMOs; while Uganda, Cameroon, and Namibia have not yet had this experience. For countries with limited experience, risk assessment and management systems created by the project have yet to be put into practice and tested with real applications.

The GEF contribution to capacity building in risk assessment and the development of guidelines or manuals varied considerably from country to country. For example, Mexico's project document indicates a budget of \$575,000 for capacity building in risk assessment, compared with a budget of \$180,000 for all aspects of training (including risk assessment) in Kenya. Some countries (for example, Cuba, Bulgaria, Mexico, China, and India) included the publication of risk assessment manuals in their project documents, while this aspect did not feature in the project documents from Uganda, Kenya, or Namibia.

The GEF support to capacity building in risk assessment and management has been primarily implemented through the usual approach of short-term (three- to five-day) workshops, although some countries (for example, Mexico) held longer (two-week seminars) sometimes working directly in laboratories. The utility of shorter workshops, while positive in the context of raising awareness, is minimal as a tool for establishing sustainable institutional capability and the confidence for sound regulatory decision making.

Many countries with implementation projects are also recipients of other bilateral or multilateral biosafety projects with the same or similar objectives; these initiatives often work with the same in-country partner institutions as the GEF-supported project (see section 5.5).

## **7.2 Capacity Building in Risk Management**

Risk management includes not only the application of relevant national laws and regulatory standards, but also the imposition of appropriate risk mitigation measures (for example, crop-specific isolation distances to minimize pollen-mediated gene flow in the case of experimental field trials, or requirements for post-commercial monitoring or the imposition of insect-resistance management plans) and requirements for inspection and controls at ports of entry. These activities are normally embodied in an administrative system that includes one or more competent authorities with specified jurisdiction (for example, import, export, domestic use, commercialization, field trials, contained use), mechanism(s) for processing requests or applications, mechanism(s) for risk assessment (for example, via national expert committees or by risk evaluators within the competent authorities), and mechanism(s) for enforcement of LMO-related laws and decisions. Well-functioning administrative systems have a number of qualities, including clarity,

transparency, consistency, practicality, authority, participation, predictability, enforceability, and adaptability (UNEP 2004c).

One important question raised in several aspects of the evaluation was the integration of biosafety-related risk management with other risk management measures related to introduced crops and other plant varieties and the introduction of animal species. Long before the LMO issue was prominent, the commercial introductions of conventionally created species (hybrids, cross-bred species) and natural species from other locations, placed commercial agriculture and food security issues within the realm of potential risks to environmental health, species conservation, and human health. International instruments addressing these issues (including the International Plant Protection Convention, the FAO Codex Alimentarius, the WHO's *International Health Regulations*, the standards set by the Office International des Epizooties, and the CBD's *Guiding Principles for the Prevention, Introduction and Mitigation of Impacts of Invasive Alien Species*) have generally not been addressed or referred to under this project.

Here also, there were significant differences between the development and implementation projects.

#### ***NBF Development Projects***

The GEF Strategy specifically proposes to help countries strengthen capacity for risk management, monitoring, and inspection services. Within the NBF development project document, the objectives related to risk management and administrative systems were tightly linked to risk assessment, and, in addition to the activities described in the previous section, would be achieved by:

- strengthening national capacity in order to implement biosafety procedures and take competent decisions through establishing systems needed for risk assessment, audit of risk assessment, and risk management, to ensure the safe use of modern biotechnology taking into account national and subregional/regional needs;
- applying biosafety procedures to enhance environmental management.

Issues related to the establishment of risk management and administrative systems for implementing an NBF were addressed during the third series of subregional workshops, discussed in section 5.2.

The workshops intentionally did not address, or only partially addressed, several other points, including:

- how to develop specific risk assessment guidelines;
- mechanisms for risk management;
- post-release monitoring of LMOs;
- how best to make use of data generated in other countries;
- coordination among different national institutions;
- systems for handling LMOs in transit;

- national capacities for implementation, including strengthening of customs, quarantine, and environmental assessment systems.

Although many NBF development countries have identified how administrative and decision-making systems would work in the NBF, at this stage of development low baseline countries have not put theory into practice. Higher baseline countries, of course, have experience in dealing with environmental introductions of LMOs under existing systems.

The final selection of responsible agency remains a matter of political discussion in many countries. As indicated during the third Latin America subregional workshop, “the main conflict identified at the moment of implementing NBF is the coordination of the administrative tasks and competencies of the institutions involved in them” (UNEP 2003c, para. 118). This was also stressed in the Asia subregional workshop, wherein it was “noted that much of the administrative system seemed to be in place in many countries, and that coordination was the major challenge where different agencies were working separately” (UNEP 2003b, para. 62). For the majority of countries, internal issues regarding the designation of regulatory authority and coordination among competent authorities once designated remains a significant issue yet to be addressed; this was cited as a concern.

While many countries have identified that existing regulatory institutions (for example, customs officials, phytosanitary or seed certification bodies) would be utilized for biosafety inspection, enforcement, and monitoring, few have undertaken a systematic training needs assessment for these organizations. Five of the countries whose NBFs were reviewed above indicated that they had undertaken some systematic training needs assessment; a few have identified front-line regulatory inspectors or customs officials for training.

### ***NBF Implementation Projects***

Among implementation projects, there is a wide range of differing experience and capacity. Project objectives with respect to the establishment and strengthening of administrative and risk management systems differ across countries.

For example, in India, which has long-established systems for risk assessment and decision making, the support for inspection and monitoring has, to date, been limited to building laboratory infrastructure (that is, the purchase of new equipment) for detection and traceability. India is currently undertaking a comprehensive training needs assessment, which is scheduled for completion during fall 2005. Mexico has used its project both to increase coordination mechanisms for risk assessment and to provide training for officials implementing risk management requirements (specifically, training field officials and assisting in the development of the national database that is used in these processes). Cuba focused on training of inspection officials, as well as drafting of regulatory standards to which such inspections will apply.

In Uganda, project staff are currently working on mechanisms for handling requests. With respect to inspection, monitoring, and enforcement, the needs are still emerging, and existing mechanisms will be used. The project is focusing on developing standard operating procedures, guidelines, and manuals for this purpose. In Namibia, the project trained the relevant inspectorates and provided them with model standard operating procedures for biosafety inspection and monitoring, although the system has yet to be put into practice because of a lack of applications.

### **7.3 Conclusions**

The final selection of responsible national agencies is still a matter of political discussion in many countries. The main conflict identified at the moment of implementing an NBF is the coordination of the administrative tasks and competencies of the institutions involved. Most NBF development countries have only arranged general introductory courses in risk assessment and management. Most of the NBF implementation projects had only provided a week of intensive training in risk assessment, at best. Few efforts seem to have been directed to building a corresponding administrative, inspection, enforcement, or monitoring capacity. Some country scientists have undergone longer term in-depth practical training in risk assessment and decision making; this may be helpful in building sustainable capacity within regulatory agencies and expert committees. Many countries need more time to make decisions about risk assessment guidelines and conduct more in-depth training for the staff that will carry out these tasks.

Although synergistic national implementation of international agreements is generally seen as an increasingly important objective, the practice has proven difficult for many countries, particularly where specific international agreements have trade impacts or are not accepted by all of the enacting country's trade partners. In the context of biosafety, however, the significant investments needed in developing expertise, physical capacity, and institutions suggests that it will be important to consider potential options relating to integration with basically identical control mechanisms.

## Chapter 8. Biosafety Policy and Regulatory Development

### 8.1 The Legal Context

The Cartagena Protocol is generally neutral on the topic of LMO introduction—that is, it neither encourages introductions nor opposes them. Rather, it is designed to increase public confidence in the safety of proposed introductions and marketed products, while providing the public and private sectors that are involved in the LMO industry or markets, as well as the farmers that use LMOs, with a *commercially valuable legal right*—a legally valid permit to import, introduce, transport, or develop LMOs. In choosing a permit mechanism as the primary method of creating and mandating biosafety, the protocol negotiators expected to provide a strong commercial law basis for addressing biosafety. This basis can be created, however, only where the resulting permit system provides “legal certainty.”

For purposes of this evaluation, legal certainty might be described as “commercially reasonable expectations” and explained as follows: Where a legal system is clear and based on standards rather than unlimited discretion, a company is able to make commercially rational decisions regarding matters governed by that legal system. In a system that provides LMO-related legal certainty, for example, a company that demonstrably complies with its permit and relevant law will be legally protected or subject to limited liability (or be free from all liability), in the event of an accident or oversight arising from the introduction of LMOs. On the other hand, a company that introduces LMOs without first obtaining or complying with its permit can be subject to penalties, forfeitures, and potentially limitless liability, even if there has been no accident.

To this end, the protocol requires parties to adopt a number of legislative provisions that are more specific (both in content and operation) than normally found in international instruments. In particular, these provisions impose very specific requirements on national decision-making processes, setting time limits on the process, specifying the nature and limits on national rights to alter permissions after they are obtained, and generally attempting to create a level of commercial predictability in the process. These specific provisions (CBD 2004a), requiring national implementation, envision a broad complex of integrated legal instruments and institutions in countries that engage in significant LMO-related activities. In countries with less LMO activity and lower expectation of such involvement in the near term (referred to here as low baseline countries), only a limited number of these legislative tasks are urgently needed to be accomplished within the next few years. The protocol text provides special assistance for these countries as an alternative to immediate development of fuller legislation:

- As an alternative to immediate development of a law addressing the “introduction of LMOs,”<sup>9</sup> parties may decide to directly use article 10 of the protocol, adopting it by reference as an interim measure for implementing the protocol.<sup>10</sup>

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<sup>9</sup> The protocol of course limits its provisions to the first international introduction, but there is no legal reason why these provisions cannot be applied to later introductions or to introductions by domestic entities. See articles 2.1–2.4.

- As an alternative, to develop a streamlined decision-making process to address LMOs used as food, feed, or for processing (LMO-FFPs),<sup>11</sup> parties may decide to directly utilize the provisions of article 11.6 of the protocol in the same way.

While attempting to sort out their concerns regarding biosafety legislation in a comprehensive manner, parties may adopt a narrower range of interim measures to solve their immediate needs. Other step-by-step approaches could be used to issue legally certain permits, slowly building up to a full national decision-making system.

The CPB provides further tools and options to help developing countries. Of these, the BCH is most notable. By requiring official (government-authorized only) posting of LMO introduction decisions, the protocol enables countries with limited scientific capacity to apply scientific analysis developed and governmentally tested elsewhere in their risk analysis and as inputs into other aspects of decisions.<sup>12</sup>

The Evaluation studied 40 draft country NBF reports prepared as part of the NBF development project. All of these produced at least some draft legislation.<sup>13</sup> The analysis in this evaluation focused on two factors: the quality/acceptability of the legislation developed and the readiness of the countries to engage in a legislative process addressing these issues. This report considers and describes the results of the evaluation by considering several indicators of the effectiveness and quality of that process and its outputs.

## **8.2 Lessons from the Pilot Phase**

The pilot phase used a team of internationally known experts in biosafety law to review every law created under the pilot project. The resulting laws were consequently competently drafted. It is not clear whether any stocktaking information was provided to the reviewers; thus, it may not have been possible as a general matter for the external review process to determine whether the laws were particularly appropriate and/or implementable. These issues were left for legislative backstopping by legal experts staffing the pilot project at the global level and national experts, where available. This multi-expert and multi-stage peer review process was found to have yielded generally positive results.

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<sup>10</sup> The assumption underlying this provision is that the CBD Secretariat or some other body will adopt interim risk analysis and decision-making standards to assist countries using this authority. See article 9.

<sup>11</sup> The same assumption noted above underlies this provision.

<sup>12</sup> In this way, Country A, when considering the utilization of Country B's decisions or decision-inputs in Country A's decisions on the same LMO, may determine whether and how Country B's standards and policies accord with its own and utilize the information accordingly.

<sup>13</sup> The evaluation team concluded that all projects reviewed adopted some form of legislative instruments, whether new law, regulations, subregulations, appendices, or amendments to existing instruments. Not all legislation appears to have been submitted in full text version to the UNEP NBF project team. Many final NBF reports provide brief summaries of general objectives of legislation; some only note that it exists and was created as part of the NBF development project.

This report does not attempt to evaluate the pilot phase, but has compiled information from several sources on the operational work and some outputs of those projects. Several of the implementation countries reviewed in this evaluation had been supported in the pilot phase. Their NBF implementation projects appear to have drafted legislation, but in most cases (for example, Cuba and Bulgaria), this legislation was focused and designed to promote and/or enable biosafety implementation. This result was not universal, however, as at least one NBF implementation project wrote an entire framework law, despite having a very complete existing framework. In this evaluation's review of that country's implementation project, it was noted that there is little expectation that this law will ever be adopted. In another case of legislative drafting during the pilot phase, a law was produced that reportedly did not address local needs and institutions, so the NBF implementation project found it necessary to recommence the drafting process at a later stage of the project.

### **8.3 National Preparation and Readiness**

It was apparent throughout this evaluation—particularly in interviews and field visits—that the national subprojects (and regional coordinators) generally believed that the production of legislation was a mandatory requirement of completion of the national NBF development project. These perceptions were not directly created by the global project documents, but may have been derived from them. For example, the global project specifically described its activities as the “drafting of legal instruments, including regulatory frameworks and guidelines as appropriate” (GEF 2001, para. 29).

Toolkit 3i, for example, initially states that its goal is not to decide any elements of national legislation in advance (UNEP 2004b). It notes specifically that “different countries will use a diversity of approaches, legal instruments, and terminology that are best suited to their own situation.” On this basis, the Toolkit identifies many primary tasks for the legislative drafters, and ultimately for decision makers. However, the manner in which these tasks are stated suggests the need for legislative drafting, and in fact, expresses all of its suggestions and recommendations in the context of the creation of comprehensive national biosafety legislation. It notes, for example, that the countries' primary task under the project is “to draft their NBF, and particularly the regulatory regime, which forms the central pillar of the NBF” (UNEP 2004cb, para. 1.2.1). It goes on to define “national biosafety framework”<sup>14</sup> as “a combination of policy, legal, administrative and technical instruments that are developed to ensure an adequate level of protection” (UNEP 2004b, para. 1.3).

These documents and statements, and their implications for national subproject staff, may have combined with the low level of technical support from the global project to create an impression among NPCs and NEAs, as well as some regional coordinators. Low baseline countries, in particular, appear to have adopted relatively comprehensive framework laws. These are often similar in coverage and content—necessitating

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<sup>14</sup> The term “national biosafety framework” does not appear in the Cartagena Protocol and appears to have been used as a generic term in its early appearance in the GEF Strategy. In the context of the NBF development project, however, it is a defined term.

relatively high levels of further administrative development (regulations operational structures, and other legal needs) and detailed institutional and regulatory requirements for risk assessment. In a sample of 17 NBF reports containing legislation, nine countries self-reported that they have relatively low baselines in LMO issues.<sup>15</sup> All nine created comprehensive framework legislation calling for more than one committee, at least one of which should be composed of LMO-specialized scientists, and should meet very frequently (in many cases, monthly).

In the course of interviews and in-country reviews relating to 17 national subprojects, there were indications that some countries may not yet have been ready for comprehensive legislative development. A number of other reasons have been suggested to explain the national desire to develop comprehensive legislation immediately, including the possibility that some NEAs might have perceived the project as an opportunity to increase their portfolio/mandate in the biosafety area. It remains probable that a more “hands-on” approach could have enabled the presence of more constructive options at an early point, increasing the project’s effectiveness by ensuring that the work done in each country was directed to actual needs and ability to implement.

Among high and medium baseline countries, there was more diversity of approach. Although three of the eight such countries whose legislation was surveyed in this evaluation developed comprehensive frameworks duplicating and/or overlapping with existing national laws regulating biotechnology development and activities, the other five engaged in more focused legislative development processes. They adjusted existing systems to consider relevant issues, and to reconfigure or revise relevant documentation so that it could more easily support and conform to CPB requirements; or they developed specific mechanisms for integration or coordination among existing legal instruments, mandates, processes, and agencies.

#### **8.4 Contributions of Specialized Capacity and Expertise**

The project’s legislation work was intended to address many needs—research, legislative drafting, and—especially—sustainably building awareness and capacity to address biosafety issues beyond the 18 months of subproject operations. Capacity development in biosafety policy and legislation proved to be an unexpectedly difficult task, for three reasons:

- As commercial permit legislation, biosafety law is qualitatively different from normal types of biodiversity-oriented legislation and policy, particularly in that its primary objective is the creation of legal certainty—a task that requires very complex legislative and legal expertise.
- Many countries were still in the throes of significant controversy relating to biotechnology and biosafety issues during the term of their subproject. These

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<sup>15</sup> NBF reports selected for this part of the analysis were from Argentina, The Bahamas, Bulgaria, Cambodia, China, Cuba, Georgia, Ghana, Guatemala, the Islamic Republic of Iran, Jordan, DPR Korea, Madagascar, Mozambique, the Philippines, Samoa, and Slovenia.

countries (as well as some where such controversy did not exist or where it had been debated and generally resolved) were not ready to consider difficult issues, options, and challenges regarding legal implementation.

- Most of the NPCs did not have significant experience with law and legislative development issues and processes. Often, where legislative experts were identified by the subprojects, those experts had no prior experience with biosafety or, more generally, with the national implementation of technical international objectives.

Accordingly, in many countries, the national subproject's most significant contributions to national legislative development were as follows:

- initiation of relevant discussions on biosafety policies in key forums and among key officials unfamiliar with biosafety policies and principles;
- highlighting the practical and legal issues of how national biosafety policies could be implemented in a fair, legally defensible, and commercially justifiable way;
- in particular, developing an initial core (NPCs and NCCs) of biosafety implementation expertise, and connecting that group to relevant decision makers, technical experts, regional counterparts, and international sources of information and assistance.

This last contribution was particularly important, given that, in most countries, neither this core group nor the key individuals and agencies most active in the field had considered legal or legislative issues or been sensitized to the needs of legislative development.

The NBF development project's legislative efforts can be seen as beneficial, even where the project's draft legislation and other specific legislative proposals prove unsuitable to the primary needs of a biosafety framework (legal certainty). Quite apart from the specific professional outputs of the project, its commencement of key capacity building, discussion, and sensitization processes with regard to the various relevant legal issues within a field formerly focused entirely on scientific concerns is recognized as a key contribution. In this connection, it is noted that the legislative stocktaking process is a critical and important element of national legislative development, particularly in countries with ongoing technical and commercial regulatory activities relating to biotechnology and/or biosafety. Where stocktaking processes and reviews were participatory, or were used in detail in later work of the project, the resulting focus on integration and cooperation among relevant agencies may lead to more productive work in future—despite the fact that, during the project, stocktaking efforts were often not fully utilized or professionally evaluated.

## **8.5 Policy and Regulatory Outputs**

National legislative implementation in the area of biosafety must necessarily address commercial objectives. As such, it must use particular types of legislative tools and mechanisms that are not normally thought of as environmental law, and which are thus

unfamiliar to many environmental law practitioners. The ability to convey legal certainty arises primarily through the creation of legislative instruments that are of unquestionable legal validity and that are put into practice in a consistent and legally defensible way.

To evaluate this process, it was necessary to define a set of indicators that could provide a basis for analyzing whether particular subprojects' legislative outputs provide relevant, nonbiased, and professionally adequate draft legislation implementing the CPB. Based on the objectives of the GEF Strategy, the mandates of this evaluation, the sources available (primarily document review, supplemented by in-country and telephone reviews), and the specific objectives of the convention, the following four indicators were identified:

- a. Draft legislative outputs are consistent with and would at least satisfy the minimum requirements under the CPB.
- b. Draft legislative outputs respond to the national needs in a country.
- c. Draft legislative outputs are legally valid and professionally adequate.
- d. If adopted, the draft legislative outputs would be practically implementable in that country's legal system.

These four indicators are briefly examined below.

***Indicator a: Draft Legislation Is Consistent with and Sufficient under the CPB***

Consistency with the protocol is an essential requirement under the NBF development project and every national subproject. However, consistency is a relatively minimal set of requirements, in light of article 2.4 of the protocol, which specifically allows parties to enact legislation that is stricter than the protocol.

Analysis of this issue occurred through desk review of 38 NBF reports, analyzing the inclusion and completeness of specific requirements and provisions mandated in the protocol. Table 8.1 provides the result of that initial determination—whether the minimum coverage of the draft law is the same as, or stricter than, the national actions required by the relevant provisions under the protocol. It should be noted that some NBF reports did not address all of these issues. More than 13 percent of the NBF reports were silent on some questions. It is not possible to conclude with certainty the meaning of these omissions. In some cases, they may relate to an area that was not addressed by the project because it is already covered in the general law of the country; however, lacking any reference, it is not clear that the subproject and/or regional coordinators considered the issue.

**Table 8.1: Selection of Protocol-Required Provisions Addressed in NBF Reports (percentages)**

Selection of required provisions	Reports addressing this issue	Generally sufficient coverage <sup>a</sup>	Reports not addressing this issue
Risk assessment (article 15)	38	92	0
Decision procedure on import (article 10)	38	87	0
Public participation mechanisms (article 23.2)	36	82	5
Risk management (article 16)	38	82	0
Application of advanced informed agreement (articles 7, 8, 10, 11, 15 )	37	79	3
Review of decisions (article 12)	33	59	11
Handling, transport, packaging, identification (article 18)	33	50	13
Exporter notification (article 8)	33	45	13
Unintentional movements (article 17)	36	45	5
Illegal transboundary movements (article 25)	34	34	11

a. The survey called for reviewers to rate national legislative framework as reflected in the NBF report. Ratings for each item were full coverage, partial coverage, rudimentary coverage (mention), no coverage. A few reviewers did not answer some questions. The above table provides the percentage of NBFs that were rated as having full or partial coverage for each type of provision.

The most basic protocol requirements—the decision-making systems for regular introduction decisions (and, where included, for FFP decisions<sup>16</sup>)—are generally addressed in all legislative outputs reviewed, whether in new legislative proposals or in existing law summarized in the NBF reports as already consistent with the protocol. In general, the text of new draft legislation also addresses the requirements of an advanced informed agreement process, including risk assessment procedures and scientific advisory bodies.

A few issues were more frequently omitted from the draft legislation. For example, less than 40 percent of the draft NBFs reviewed address or propose measures “preventing and...penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol” (article 25.1), and only 45 percent address unintentional transboundary movement (article 17). While many countries are aware that they cannot fully police these matters, the lack of a provision could prevent them (or other governments) from applying penalties in the event that a violation is found (despite limited or nonexistent formal policing). This statistic, however, may be unduly negative, given that in many countries, relevant penal provisions are contained in a separate code and may have addressed these matters. The failure to mention these provisions in draft NBF reports suggests that this is not the case.

***Indicator b: Legislation Responds to National Needs***

As noted above, the question of legal need and readiness to adopt legislation appears to be an important indicator of the value of investing project funds in legislative implementation in a country. As noted in section 4.2, national readiness levels, capacity, and perceived needs varied greatly among countries participating in the NBF development project. However, at the time that national subprojects were created, specific information on need-related issues was very limited and did not figure into the

<sup>16</sup> The issue of separate FFP provisions is discussed under indicator b-1.

negotiation of subproject activities, schedules, and Terms of Reference. It was often left to consultants and others involved in a project's legislative drafting processes to determine each country's needs.<sup>17</sup> The ability of legislative instruments to provide legal certainty is partially dependent on both how well they reflect national needs and how clearly they provide mandates for national implementation.

Response to national need is a very broad question, and best answered through national technical assistance, backstopping, and careful creation and use of stocktaking analyses. To gain an indication of this factor, however, this evaluation considered two aspects, which are potentially reflective of response to national need:

1. the inclusion or exclusion of separate processes for food, feed, and processing;
2. the choice between adoption of a single new legislative framework and the more focused approach of amending and integrating existing legislation.

**Element b-1: Food, Feed, and Processing.** In low baseline countries, one element of national need relates to FFP issues. These may need to be addressed at an early stage in each project, in light of both the high priority given to food and livelihood issues in these countries, and because these countries' most immediate use of the legislation will be the importation of food, often in the form of aid packages. The Cartagena Protocol specifically addresses the different needs and objectives that may apply to food products, and contains a separate set of special provisions (article 11) enabling a more streamlined decision-making system for imports of LMO-FFPs.

Analysis of this element occurred in stages. In the first stage, reviewers did not examine FFP provisions per se, instead looking only to see if food and/or feed were mentioned in the draft. As a second step, it was necessary to look more closely at what these provisions actually provide, and consider the reasons underlying the creation of this streamlined process for addressing food imports—to enable food transactions to occur in a more expedited way. This point was examined by a more in-depth review of completed NBF reports in a single super-regional area—Africa (14 countries). In evaluating this issue, it was important to look for other potential sources of FFP streamlining. In this connection, the UNEP project team suggested that where FFP provisions were omitted, these matters might be covered in other provisions—particularly emergency measures, labeling, and, as noted in article 18, “placing on the market.”

On the basis of this analysis, it appeared that 10 (71 percent) of the African countries whose legislation was specifically reviewed did include some level of special and streamlined decision making for FFPs, while 4 did not. None of the reviewed NBFs that omitted FFP provisions addressed that omission through any of these other provisions.

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<sup>17</sup> Primary legislative drafting decisions are not typically left to externally funded projects. Where such projects are created to draft legislation, the primary decision would usually have been made earlier, at a more appropriate level of government.

This factor is clearly not an indicator of inconsistency with the protocol. The omission of article 11's FFP provisions is not a violation of the protocol, as there is no legal requirement for countries to adopt FFP provisions, so long as FFPs are included within the basic coverage of the primary provisions adopted to satisfy the article 10 decision process—"stricter legislation" under article 2.4 is always permitted. Rather, the question to be considered is whether this "simplification" operates in the best interests of the country. One objective of article 11—to enable low baseline countries to process decisions on necessary or desired FFPs in a more expeditious manner—would appear important enough to warrant the effort involved in creating and applying separate provision.

**Element b-2: New Law or Law Revision.** Another key point relating to responsiveness to national need relates to each country's choice of legislative activities, particularly in countries already possessing some level of national biosafety legislation. The decision between adopting entirely new legislation or integrating biosafety requirements into existing institutions and processes may have a critical impact on the effectiveness of legislation. The practice of adopting a broad new law covering matters subject to regulation in other sectors, agencies, or ministries can be legally problematic. Without significant legal and legislative research and policy development, this approach results in multiple laws addressing the same points, and can create legal uncertainty both within government and applicants seeking a valid and defensibly legal permit.

This point demonstrates the critical importance of legislative stocktaking. This process must include not only a compilation of information on existing provisions, but also a rigorously detailed analysis of their functioning, to ensure that the proper choice is made and effectively undertaken. Beyond a simple listing of relevant laws, a very detailed identification of all provisions and processes that address or partly duplicate biosafety procedural requirements, as well as an analysis of how they can be revised, repealed, or integrated into a new system, is essential.

This practice of "regulating over" existing laws (either by providing generically that the current law controls over all other provisions, or that it generically does not supersede any) was found to some extent in 9 of the 17 laws examined. It may be more prevalent, however, as 12 out of the 17 created entire frameworks without specifically identifying the extent to which other legislation might apply and/or conflict.

***Indicator c: Legislation Is Legally Valid and Professionally Adequate***

A legal framework does not acquire legal certainty through the adoption of a checklist of provisions. A biosafety framework is comprised of a complex of legislative approaches, systematic analysis, and creativity, focused by the need to achieve a specific kind of objective: a system of permits and oversight mechanisms that is legally valid and protected, consistent, and defensible. As such, it must meet high professional standards—that is, it must be:

- unambiguous and specific in primary provisions,
- internally consistent in operative provisions,

- appropriately inclusive of all necessary operative language.

Inexpertly drafted legislation that does not meet these basic requirements—that creates insufficient or legally uncertain permits and processes, for example—may deter external investors and importers from future attempts to act within the country. It may fail to provide users with appropriate levels of confidence that their acquired rights will protect them.

Analysis of this issue was necessarily a task for legal experts. Consequently, the breadth of this evaluation’s analysis of the professional quality of legal and legislative documents under the project was limited by the number of experts on the team. In addition, a full analysis of these issues is not easily quantifiable, owing to the range of potentially serious errors or flaws that might affect a law’s validity or professional quality. To address these constraints, this evaluation focuses only on the three critical factors listed above, rather than considering the full range of points that might be suggested. It is based on two primary sources of information:

- evaluations obtained through in-country and telephone interviews of national subproject staff, NCC members, and other participants in 17 national subprojects;
- detailed expert legal evaluation of a random selection of draft national legislative documents from 17 of the countries reviewed during the evaluation.<sup>18</sup>

For half (nine) of the countries visited and interviewed, the national interviewees and the evaluation team members conducting the national review, reported that national legislative procedures and processes were fully sufficient. Similarly, the technical review of a separate selection of 17 countries’ NBF reports also resulted in 9 that were generally adjudged to be sufficient in terms of primary legal requirements.

The latter review also provided more detailed information and analysis of the three factors:

- Limited *primary ambiguities* appeared in five of the national legislative documents reviewed, but proliferated only in two of them. The most serious ambiguities involved:
  - The development of a clear and consistent scoping system (for defining which actions require permits of each type) and then adding additional terms (undefined both at law and in normal use), which make it impossible to know with legal certainty whether a permit is needed and when it expires, or to make other determinations.
  - The definitions of key terms used in a standard setting with reference to the “probability of harm,” or by setting a case-by-case standard that permits are required for any introduction “which is likely to cause environmental damage

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<sup>18</sup> The random selection resulted in the evaluation of legislation from three countries executing UNEP implementation projects, and 14 executing development projects; these included four African, four Asian, three Central and Eastern European, three Latin American, and three SIDS countries.

or an irreversible change to ecological balance.” If relying on such legislation, the applicant can only know for certain if a permit is required by applying for one.

- Creating specific mandatory language that states the precautionary principle’s application as “not restricting government from refusing or conditioning a permit, where there is not yet sufficient scientific information regarding potential risks” on the one hand, but stating that a permit is required for LMOs “whose dangerous nature...is scientifically proven” on the other.
- *Functional inconsistencies* were apparent in eight countries’ legislative documents (47 percent of the sample). However, the majority of these could be relatively easily alleviated through technical editing of the draft, or, if it has already been adopted, through statutory construction and remedial drafting in implementing regulations where laws are already adopted. Examples include drafts that called for:
  - regulation of “LMOs and derivatives”—there is no objective way to identify LMO derivatives, except where they are LMOs themselves;
  - failure to develop a clear legal/procedural basis for repeal of portions of other ministries’ legislation;
  - apparent creation of separate permit requirements that must be obtained at essentially the same time from the same agency;
  - enabling the issuance of “generic permits” (not limited to a particular area), but stating that permits cannot be issued where abutting land is used for organic agriculture;
  - failure to make it clear which agency is authorized to receive applications.
- *Operative omissions* (errors that would be sufficient to render the legislation inoperable on its face) were not found in any of the documents reviewed.

Professional adequacy is also measurable by examining the use of examples. Legislative drafting that meets a checklist or follows a model act is rarely a positive contribution to national development. Although copies of other countries’ legislative documents may be more useful, this approach too can backfire if not overseen by expert backstopping.

This evaluation discerned a spectrum of responses regarding the provision and use of models and other legislation in the interviewed/visited countries. A few countries received specific models, or considered the Toolkit to be a model. Approximately half of the countries claimed to have reviewed the legislation of several other countries, although most acquired these documents themselves and expressed a wish that UNEP had provided more help with this (about one-third claimed to have received little or no other legislation or assistance with obtaining examples of other laws).

In addition to selecting and providing useful samples of other legislation, backstopping could have provided guidance on their use. For example, Guatemala’s draft legislation includes many organizational provisions “borrowed” from Mexico’s recently adopted legislation. This system is excellently functional in Mexico, where it grew organically as

a means of coordinating the already active LMO regulatory activities from more than 11 different government agencies and ministries, each of which is staffed with (or supported by) several highly qualified scientists and other biosafety experts. It is not clear that it will function as effectively when imported without this background.

***Indicator d: Legislation Would Be Practically Implementable***

Perhaps the most important element of legislation is its adaptation to the institutional needs and capacities within the country. Decisions can only provide legal certainty when made in an institutional framework, and thus be more firmly anchored in the rule of law. Many factors may affect implementability in the context of biosafety; the most obvious limiting factor is the availability of persons with scientific and technical expertise as well as the existence of laboratory facilities and other kinds of equipment. In many countries, more general limitations of manpower and financial support may also restrict options.

The question of implementability is sometimes misunderstood. Adopting legislation beyond a country's ability to implement is not merely wishful thinking, it creates serious problems of legal uncertainty. In this connection, it is noted that nearly every project-developed draft law or proposal for the creation of a primary biosafety framework calls for an advanced informed agreement to be based on a risk assessment conducted by a fully staffed scientific advisory committee, specifying the scientific competencies that must be included on that committee. Many of the low baseline countries examined in this evaluation are unlikely to be able to create and staff such a committee. A decision made under the biosafety law may raise primary validity issues, since a critical component of the process cannot be completed in the manner required by law.

The project's legislative activities demonstrate their lowest level of effectiveness with respect to implementability—the matching of national legislative proposals to the national resources and capability to put them into practice. This lower showing is probably a result of the fact that the question of implementability was not addressed in project toolkits or national analyses.

Evaluation of implementability must depend on factual information regarding capabilities and obstacles within the country. To evaluate this indicator, information was collected from country visits and telephone reviews concerning the basic capabilities of government and other resource persons in 17 countries. In 62 percent of these countries, limitations of scientific capacity and equipment are severe enough to seriously limit the country's ability to staff significant scientific bodies or engage in certain kinds of risk management activities. Where the country's primary expectation relates to food imports, or where LMO development is unlikely in the short term, a more streamlined law focused on the most needed provisions may be more appropriate. New project-created draft framework legislation and proposals uniformly call for a full scientific advisory committee and development of new institutions and mandates.

In participating countries with only a limited expectation of LMO activities, an elaborate system may also create a more long-term implementability problem—continuing capacity. In interviews with UNEP staff, it was noted that two implementation project

countries that have completed comprehensive biosafety frameworks have not yet had any applications to process. If ever called on to make biosafety decisions, decision makers and advisors may require significant retraining at the time such applications are received.

## **8.6 Conclusions**

The project design and legislative module of the Toolkit provided a useful approach to investigate national needs and options—particularly through their comprehensive treatment of the need for and scope of stocktaking. The national subprojects' legislative activities met with varying levels of success in terms of meeting these primary activities.

Many primary actors in national subprojects as well as regional coordinators perceived that the development of policy, law, and regulatory instruments was expected for all countries where significant biosafety regulations did not already exist. Although this perception was not strictly correct, based on the specific contractual provisions and the objectives identified in the global strategy, it was understandable in light of the low level of technical backstopping from the project. The legislative drafting process may have been premature in many cases, suggesting that this perception may have led to a less than optimal expenditure of project funds.

Although most legal stocktaking documents could not be reviewed, the stocktaking tool remains the primary instrument for developing legally effective and appropriate biosafety frameworks. Regardless of the fate of project-created legislative documents and proposals, the underlying research embodied in national stocktaking efforts may serve as the beginning for more technically appropriate efforts in future.

The objective of national legislation under the CPB is the creation of a commercially valuable permit system that conveys legal certainty to applicants and permit holders. The development of insufficient, flawed, invalid, or questionable legislation can be problematic where it gives the impression of a rigorous system that can create legal certainty, with that impression later shown to have been false. Based on four primary indicators, the potential effectiveness of legislative instruments prepared under the project is mixed. In particular:

- The draft legislation and proposals generally address the majority of requirements under the CPB; however, a few key issues are insufficiently addressed. The primary areas of deficiency relate to illegal transboundary movement of LMOs and unintentional movement of LMOs.
- There are some instances in which proposed legislation does not adequately address or reflect the national needs in a country.
- While the projects contain few fatal legal flaws that would make them invalid on their face if adopted, a number of inadequacies were discerned that would affect the ability of those laws to function as a commercially certain system.
- There are some instances of “legislating over” existing legislation, without addressing whether and how other/pre-existing legislation will apply.

- Most telling, in many situations, the drafted legislative outputs in many countries are not sensitive to the countries' ability to implement detailed technical regulatory systems, and would face problems of implementation if adopted.

The project's low level of technical backstopping, as further described in Chapter 9, minimized the NBF development project's ability to help NPCs and NEAs ensure the high legislative standards necessary to create a system of legally certain commercial permits. Brief examination of the approach taken and results achieved by the pilot projects suggests that the latter may have been more effective.

## Chapter 9. Databases and Information: The Biosafety Clearing-House

### 9.1 Introduction

Information collection, collation, analysis, and sharing are major components of the Cartagena Protocol and primary mechanisms for achievement of its objectives. Through the Biosafety Clearing-House, the protocol is able to provide a source of official records of national decisions and experience. This information is critical to the functioning of the protocol, especially in developing countries with limited ability to fully develop relevant information and/or evaluate individual varieties themselves. In addition to its role as a primary decision-making input, the BCH is intended to have other roles relating to international information sharing (articles 6, 10, 11, 12, 13, 17, and 20), domestic participation, (article 23.2), and public awareness (article 23.3).<sup>19</sup> It is also important for maintaining a national regulatory memory—another key to ensuring that the primary mechanisms of the NBF function sustainably. Accordingly, the CBD COP identified the creation of the BCH as one of its immediate priorities on the date that the protocol's final text was adopted; this recommendation was reiterated in the following COP meeting, and in decisions of the COP-MOP (CBD 2000a, para. 13; CBD 2000c, para. 3, CBD 2004b, para. 3).

As the BCH is a major implementation tool for the protocol, the specific information that must be posted on it is found in several different provisions. Many of these relate to the posting of various kinds of decisions and notifications on LMO importation—provisions that are (or should become) indicative of the level of LMO activity in the country, but whose use will only be immediately required of countries already active in LMOs (these provisions are given in articles 6.1, 10.3, 12, 13, 17.1, 17.2, 20.3c, 20.3d, and 25.3. In addition, however, all parties are required (and non-parties are allowed) to post more general information, including existing laws, regulations, and guidelines applicable to LMOs (as per articles 11.5 and 20.3a); bilateral, regional, and multilateral instruments of relevance (article 20.3b); and decisions to rely on the general provisions of article 11.6, in lieu of a national framework, for LMOs for food, feed, or processing. The protocol also authorizes (and the BCH contains) a list of relevant specialists in biosafety.

The mechanisms of the BCH were mandated in very general terms, and later clarified by the parties to be implemented through the creation of a central node, which may be surrounded by a distributed network of national nodes, and all of which together shall be considered the mechanism.<sup>20</sup> Each party is required to provide a range of very specific information in a program-compatible format. This format is specified by the BCH unit of the Protocol Secretariat, whose data provision guidelines include four options for integration into the BCH (Secretariat of the Convention on Biological Diversity 2003):

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<sup>19</sup> National implementation of the protocol requires public participation in biosafety issues generally as well as of particular applications and proposals. Additionally, the protocol specifies rights of public access to information on LMOs—a separate requirement that is specifically tied to the BCH.

<sup>20</sup> See COP-MOP decisions BS I/3 and II/2, and CBD 2004a. These decisions recognize that many countries will not be able to create national nodes and provide other options.

- “Register data in the central portal using the Management Centre”—that is, enter information directly through an Internet connection with the central node.
- “Register data locally using database templates and send data to the central portal”—that is, provide information by sending an e-mail, diskette, or CD-ROM copy to the central portal. (Countries that cannot provide electronic outputs may provide hard copies of their materials.)
- “Make data available through a local website and allow the central portal to crawl to retrieve metadata” (enabled by applying specific parameters in posting material on national websites).
- “Store data on national BCH databases, and actively make those data available through the central portal using BCH interoperability protocols”—the creation of a national (or presumably regional)<sup>21</sup> node of the BCH that can seamlessly interconnect with the central node.<sup>22</sup>

The objective of this approach is that all parts of the BCH will be available and interoperable—that is, they can be searched by any party through a single search. To minimize the need for intensive technical database training, the Secretariat has prepared a modular system for entering information into a BCH-compatible database, which can be modified for countries with limited capability to use electronic communication or data input tools (see Secretariat of the Convention on Biological Diversity 2003).

Although national biosafety websites are not required in the protocol, they form another key component of national information systems and can provide a major contribution to national public outreach efforts (and serve as a source of information for public participation), as required under article 23 of the protocol. While the creation of national websites does not in itself satisfy the protocol’s BCH requirements—even if they are populated by all of the necessary information—it is expected that the UNEP-GEF’s technology/training-focused BCH project will enable countries to conform their websites to the criteria of the second option for BCH data entry cited above.

## 9.2 Information and the BCH

Design of the NBF development project recognized the importance of the BCH, the urgency of populating it with relevant data, and the fact that the initial development of a country’s biosafety database (and website) can require a one-time development of capacity and commitment of personnel that may be very difficult for many developing countries. The NBD Development sub-project document (UNEP 2003d) includes an indicative allocation of \$15,000 per country for the funding of databases and information

<sup>21</sup> While regional action is not specifically authorized in the CBD or protocol, article 14.a of the protocol specifically allows regional and bilateral cooperation, “regarding intentional transboundary movements of living modified organisms.” According to interviews with the UNEP-GEF project team, the project is supporting the creation of regional nodes of the BCH.

<sup>22</sup> At present, there are six interoperable nodes functioning in conjunction with the BCH, presented by two international bodies (the OECD and the International Centre for Genetic Engineering and Biotechnology), three parties (Switzerland, Belgium, and Republic of Korea) and one non-party (the United States).

technology. This allocation is used in the national subprojects to address specific performance requirements related to the goal of database development and linkage to the BCH:

- “Identify how information should be stored and managed for input in the BCH and for promoting public participation.”<sup>23</sup>
- “Create a database listing national experts in fields related to biotechnology and biosafety...risk assessment and risk management of LMOs.”<sup>24</sup>
- “Create a database detailing relevant outputs of the national surveys” (UNEP 2003d).

The council also set forth a more general requirement that countries should, through their national projects, “develop...a National Biosafety Database and link [it] to the Biosafety Clearing House,” (UNEP 2003d, para. 3.2). but did not specify the contents of such a database. The Phase 1 Toolkit module, however, is specifically based on the Protocol Secretariat’s guidance for entering data into the BCH (UNEP 2002). Subprojects are also called on to develop national websites for public awareness and other purposes, as reflected in the GEF Council document as well as in the national subprojects agreed upon between UNEP and the countries. As noted above, national websites can be used as a means of uploading information to the central node of the BCH, so long as the database of information for the BCH conforms to special technical standards in the Secretariat’s guidance. Through these provisions, the project sought to address the most urgent component of the protocol’s information and BCH requirements—the collation of information and documents, and assurance of the availability of necessary information.

The 12 NBF implementation projects had higher goals related to the creation and use of electronic databases, information sharing by country stakeholders and the general public, as well as better and more secure access to and use of the central portal. With GEF funding and country co-funding, each had in excess of \$100,000 at its disposal for this purpose.

In NBF development countries, the perceived demand for more sophisticated capacity in electronic communications beyond the initial allocation has been increasing. At its November 2003 meeting, the GEF Council allocated \$4.6 million to 50 NBF development countries, with the following specific objectives:

- to strengthen capacity in eligible parties through support for capacity building including training activities for key stakeholders; these programs will cover data management, identification and access to information required for decision

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<sup>23</sup> The project and its Toolkit do not focus particular attention on the role of electronic tools for “promoting public participation.” See UNEP 2003a, box 1; and general references to articles 23 (public awareness and participation) and 21 (confidential information).

<sup>24</sup> Although there is no provision in the Cartagena Protocol regarding the creation of a roster of experts, this tool is recognized in the GEF Strategy, which specifically lists the development and sharing of such a roster among the components of NBF development; see GEF 2000, para. 24(f).

- making under the CPB, and access to and registration of information in the BCH;
- to create an enabling environment for parties to meet the obligations for protocol implementation by providing participating countries with appropriate computer hardware and software (at a cost of \$25,000 per country), as well as appropriate software for the storage and exchange of data with the BCH through Internet connectivity or other means;
- to support further capacity-building activities through the development and dissemination of an interactive computer-based training package, including the BCH Toolkit, which will be developed at the global level and used for training as well as distributed in participating countries (at a cost of \$29,000 per country).

UNEP carried out a survey of needs for support in this area. Based on guidance from COP VII/20, UNEP submitted a proposal to the November 2004 council meeting to extend assistance for capacity building in relation to the BCH to an additional 89 countries, with a GEF contribution of \$9.9 million. Some initial objections were raised by council members about the level of support, but approval was finally given to this allocation in May 2005.

The BCH project has, to date, developed training manuals and modules, and recently began training processes. At this stage in its operations, it is far too early to assess its effectiveness and impact, particularly since it is designed to provide detailed technical and equipment capacity in BCH focal points—a process that has only begun.

The database and information requirements of the national subprojects represent an example of the manner in which project design and project actualization were markedly different. The national subprojects did not address most of the immediate data-related issues that have been identified as critical to bringing the protocol into operation.

### **9.3 Cooperation with the Biosafety Clearing-House**

The performance of the NBF development and implementation projects with regard to the BCH and information development offers an example of the manner in which the over-optimistic project design affected its implementation. In the face of a need to produce many significant outputs with relatively limited funding and with time limit of 18 months per country, the database and data-sharing requirements of the project were accorded relatively low priority, despite strong COP and COP-MOP emphasis on the urgent need to bring the BCH into full operation.

Two relevant information sources were available to the team. First, although it may not accurately describe the national subprojects' performance, one set of informative statistics was obtained by review of the BCH itself.<sup>25</sup> Table 9.1 examines some information elements in the BCH for the 53 countries reviewed.

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<sup>25</sup> The accessible portions of the BCH do not provide detailed data about the specific source or date of many records.

**Table 9.1: Information Elements in the BCH (as of August 28, 2005)**

Country	Roster of experts <sup>a</sup>	Legislation	Risk assessments	Introduction decisions	FFP decisions <sup>b</sup>	Other decisions <sup>c</sup>
Completed development project (39 reviewed)	21	18	-	-	4	-
Development project in progress (6 reviewed)	5	3	-	-	-	-
Implementation project completed (3 reviewed)	2	3	-	-	1	2
Implementation project in progress (5 reviewed)	3	3	-	-	-	1
Total number entering data (of 53 countries reviewed)	31	27	-	-	5	3
Total number of countries (parties, signatories, and non-parties) providing records <sup>d</sup>	74	61	4	-	13	9

- Roster of experts listing are not centrally vetted. Some countries that the review found to be very low in technical capacity listed dozens of experts; other countries of extremely high capacity (India, Malaysia) did not have any listings in the BCH.
- The five evaluated countries reviewed that have already posted decisions are Mexico (35 decisions under article 11), Argentina (8), Lesotho (1), Czech Republic (3), and Republic of Korea (33). The fact that other countries within the evaluation have not posted decisions might be evidence of a limited level of decision activity, rather than failure to comply.
- This includes general notices, moratoriums, and a variety of other nonstandard notifications.
- There were a total of 189 potentially contributing countries: 125 parties, 63 countries that are parties to the CBD but not to the protocol, and 1 country that is an active observer in both.

The foregoing statistics indicate weak, or at best mixed, performance regarding fulfillment of BCH requirements. Specifically, the first two columns of Table 9.1 represent information that must be published, whether by CPB or project requirement. As noted above, every country was required to undertake at least two activities that guarantee that they will have material to post on the BCH, and those same documents required that this information be compiled and posted. Although many countries have not completed their development or implementation projects and have not formally adopted the legislation drafted under their projects, all have, at a minimum, compiled a list of existing national legislation or legislative information relevant to biosafety (the national stocktaking). Yet only 21 (less than 50 percent) of countries with completed projects have posted anything in the legislation section of the BCH. Similarly, although not required under the protocol, every national subproject was called upon to create a roster of experts. A review of 36 of the draft NBFs submitted by completed projects to date shows that 16 (44 percent) of these countries not only completed such rosters, but affirmatively vetted and evaluated the individuals listed. Of the full 53 countries examined, 31 countries (58 percent) have posted either type of information on the BCH.

Even countries that have met these basic posting requirements have not posted any decisions; this suggests that there has been no action within these countries relating to LMO introduction in at least the past two years (the posting of pre-protocol decisions is

allowed but not required).<sup>26</sup> If this assumption is correct, it may have significant relevance to other questions examined within this report relating to the level of activity countries will engage in under this protocol.

The control data (the last row of the table) suggest that this situation is not limited to the project, as only 48 percent of CPB parties appear to have posted legislation as required. The project was arguably expected to promote better performance than could be expected without GEF assistance; however, this overall statistic suggests that compliance with the protocol's BCH may require more than the provision of additional funding for information development. Hence, the GEF has funded a more focused project relating to providing technical training, support, and equipment to further encourage BCH compliance.

The UNEP development project team reports that further progress in this area, including the development of regional BCHs (either regional nodes, as described above or regional websites meeting the BCH technical requirements) is ongoing, and will be posted and accessible soon. The current project staff has significant expertise in database development and information-sharing technologies and approaches.

A second source utilized in this evaluation is national biosafety websites. In nearly all countries evaluated, project staffs have interpreted the database components to be satisfied by their work under other project components in establishment of national websites. In many of these, the website produced to date is a "project website"—posted to provide information about project activities, but not necessarily serving as the source of official information on biosafety, which would make the website satisfy BCH requirements. Although most of the national biosafety websites do not yet appear to be interoperable with the BCH (due to language, accessibility, and other problems), the most complete of these sites may serve as precursor or interim mechanisms through which the countries can compile relevant data that will eventually be entered in the BCH, while also addressing the public awareness and participation elements of the protocol. Consequently, review of these national websites may be a useful indicator of progress toward database development and information sharing.

Table 9.2 summarizes information collected from national websites in the course of this review.

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<sup>26</sup> Project staff reports that only two of the completed implementation projects have not yet used the decision-making processes under their NBFs; neither of these were investigated in this evaluation. This suggests that decisions may have been made that are not yet recorded in the BCH.

**Table 9.2: Information Provided by National Websites**

Country	Website available in accessible language <sup>a</sup>	Website exists, but not posted, not reviewable due to technical problems, or not in an accessible language <sup>a</sup>	No website reported in NBF or BCH
Development project completed (39 reviewed)	7	8	24
Development project in progress (6 reviewed)	2	0	4
Implementation project (8 reviewed) <sup>b</sup>	3	2	3
Total (53 reviewed)	12	10	31

a. Accessible language refers to English, French, or Spanish.

b. Given the prerequisites of implementation projects, they are comparable to completed development projects for purposes of this table.

For this analysis, only national biosafety websites (as opposed to project-focused websites) identified by the evaluation team, as well as all websites for any of the 53 evaluated countries listed under the “national contacts” section of the BCH were examined. The specific contents provided in these websites are relevant in demonstrating the level of utilization of websites for the compilation of data required, in addition to the public awareness purposes on which the website requirements were focused in the national subprojects.

As a further step beyond this evaluation, the 12 websites identified in Table 9.2 as being accessible and available were examined to determine how much of their current content satisfies the CPB’s requirements for the BCH. This information is provided in Table 9.3.

**Table 9.3: Contents of National Biosafety Websites for 12 Countries**

Website components	Number of websites that include component
Roster of experts	9
List of LMO-connected institutions	6
Legislation	10
Introduction decisions	4
FFP decisions	5

*Note:* For the purposes of this table, a website was considered to have posted information on a topic if it contains a reporting site for that subject, even if the report was, for example, “to date there have been no [introduction decisions made under this system] in this country.”

These results suggest that some projects have collected some relevant information in electronic form that they will ultimately post on the BCH. The low performance levels on posting risk assessments and various decisions may not be an indication of non-performance, but rather an indicator that many countries have not yet processed an application for LMO introduction or other activity that is supposed to be regulated under the protocol.

As noted, the low levels of performance in preparing and posting biosafety data may be explained in many cases by a lack of technical capacity and confidence. Although the Secretariat has provided a user’s tool to enable initial data entry into the BCH, project staff may have lacked confidence to enter data into the system. As discussed above, a

separately funded project is in its initial phases of providing equipment and training for BCH implementation.

#### **9.4 Conclusions**

Given the integral role of the BCH in the international functioning of the protocol, as well as its domestic functions relating to public participation and awareness, the BCH was designated for immediate priority by the CBD COP and the COP-MOP. As yet, however, the information and data-sharing obligations under the protocol have not been sufficiently addressed, neither generally nor by the work under the projects, to enable the BCH to function.

The NBF development project was designed to directly facilitate initial progress in BCH implementation through the development of national databases. Ultimately, however, the national subprojects focused instead on the creation of national websites.

Although not completely addressing many functional needs of the BCH, websites demonstrate progress in the collection of some of the relevant data. If posted in a specified format, national websites can be the means by which information is uploaded by the Protocol Secretariat into the BCH's central node. Based on external evaluation of the websites, and the fact that data from them has not been harvested into the BCH, it appears that subproject-created websites have not yet met the requirements for direct use by the BCH. Although less than half of the national subprojects reviewed have posted a website, this may reflect a de-prioritization of database development and data-sharing issues, in light of scarce time and professional resources, and the hope that the BCH projects (which are primarily directed at increasing human capacity and providing equipment and support) will also contribute to the population of the BCH and national databases, using information compiled by the NBF development subprojects.

## **Chapter 10. Effectiveness of Guidance and Quality Assurance in Country Projects**

The GEF's overall guidance is provided by the Conference of the Parties to the Convention of Biological Diversity and the CPB. This guidance is operationalized in the GEF Strategy and GEF Council allocation documents. The overall objectives, operational principles, and budgets are integrated into specific country level project documents, mostly accompanied by memoranda of understandings, and administrative and technical guidelines. The Implementing Agencies have provided detailed guidance and quality assurance through reporting and supervision tools, including contents, schedules, and sharing of responsibilities among the GEF Implementing Agencies and the national executing agencies. The documents also spell out the responsibility for technical advice/backstopping, as well as criteria and procedures for recruitment of internal and external expertise. The effectiveness of these tools and mechanisms used by the Implementing Agencies at the country level is analyzed in this chapter.

### **10.1 Technical Advice and Backstopping to National Subprojects by the Implementing Agencies**

In a new, complex, and controversial regulatory area, the need for expert assistance is obvious. Technical advice is either provided by the regional coordinators or specialists of the Implementing Agencies, or by consultants hired by the Implementing Agencies or the countries, using GEF and counterpart funds. The evaluation obtained two kinds of information regarding technical advice and expert assistance:

- evaluation in the 17 countries, based on in-country and telephone interviews, primarily reflecting national satisfaction with the quality of technical inputs into NBF processes by the Implementing Agencies;
- primary review of the quality of external peer reviews of the final draft NBF development reports and the qualifications of the peer reviewers commissioned or recommended by UNEP.

The results of the evaluation's review of technical inputs in the 17 countries are summarized in Table 10.1 below. This summary is based on feedback provided by the NPCs and other key project personnel during in-country visits and telephone interviews. The data below are necessarily subjective, and do not take some important issues into full account; for instance, whether information was supplied at the request of the country or through generic support (for example, at subregional workshops). The evaluation shows that there are no significant differences in the quality and usefulness of the technical advice provided by any of the GEF's three Implementing Agencies. The table shows that the quality, usefulness, and timeliness of their technical advice were rarely rated "high." The scores were especially low in the low baseline countries (see section 2.4), while the high baseline countries generally stated that the advice and backstopping was adequate. This suggests first that the level of advice was better suited to countries with a high baseline than those with a low baseline. It does not necessarily mean that the advice was

of low or medium quality in the majority of countries, but rather that good advice was mostly not readily available in a form that was adapted to the country's situation at a time when it was needed. The scores on advice on risk assessment/risk management and interim measures are very low; scores are markedly higher on legal aspects and public participation.

**Table 10.1: Quality, Usefulness, and Timeliness of Technical Advice**

Area of Implementing Agency advice	Quality, usefulness, and timeliness		
	High	Medium	Low
Scientific, risk assessment, and enforcement aspects	1	6	10
Legal aspects	5	4	7
Public awareness programs	4	7	6
Provision of relevant documentation	2	5	4
Provision of examples of laws and regulations from other countries	4	5	7
Provision of examples of risk assessment and management procedures	0	10	7
Provision of examples of interim measures that could be adopted	1	0	11

The three GEF Implementing Agencies managed the NBF development projects and implementation projects in different ways. The team has made a separate assessment of UNEP's performance in this regard since it implemented the majority of all projects.

The World Bank supervised biosafety two projects out of its headquarters in Washington, D.C., and sent relatively strong teams of specialists to provide technical advice during semi-annual supervision missions, which resulted in aid memoranda with clear recommendations. There was little technical advice offered in the intervening periods.

UNDP has made no efforts to build specialist biosafety competence among its regular staff, choosing instead to ensure contact between its projects and UNEP's strong technical Biosafety unit for providing of substantive input to its only ongoing project in Mexico. The second UNDP project in Malaysia has not started yet, partly due to a change of government, but partly also due to poor communication between the two partners.

## **10.2 Effectiveness of UNEP's Organizational and Technical Support**

As elaborated in section 4.1, UNEP quickly developed a fully fledged management and operating system for the NBF development subprojects, spelling out in great detail the administrative requirements countries were advised to follow. The countries were required to select a national executing agency as the entity responsible for executing the NBF, and to appoint an intergovernmental and intra-country national coordinating committee to guide and coordinate the work. UNEP required that it be consulted on the hiring of the national project coordinator, who is responsible for management, coordination, oversight, monitoring, and reporting. UNEP's main operational and technical responsibilities during the project cycle were agreed to be as follows:

1. consultation on the appointment of the NPC;
2. approval of the quarterly technical and financial reports and workplans (five to eight per project);

3. consultation on organization of national workshops to present the findings of the stocktaking surveys (see Figure 4.1).
4. consultation on national workshops in risk assessment and public awareness, and consultation on the NBF report;
5. receipt, forwarding and discussion of peer reviews in most cases.

Apart from the mandatory management system and guidance of the Toolkit—which at times provided relatively clear suggestions on how countries were to proceed, and at other times listed possible options—UNEP chose generally a low-intensity oversight and feedback approach. This worked well for high baseline countries, but not so well in countries with little or no prior experience. The UNEP project team was not able to visit and provide hands-on guidance to all 120 countries involved. According to UNEP’s records, as of August 31, 2005, 23 countries had not been visited by UNEP project staff—mostly, those included for allocations by the GEF Council in November 2003. In all, 62 countries had been visited once, 27 countries had been visited twice, and 8 had been visited more than twice. Apart from consultations during country visits, the advice and guidance had taken place primarily by e-mail and phone communication, at regional workshops, and during CBD COP-MOPs. Management problems in some countries would often have necessitated significantly more time-consuming responses and actions, at times almost on a daily basis. This was particularly the case in Africa, which had the greatest needs and the least UNEP supervisory resources per country in the initial period.

There are many examples of the UNEP project team making every effort to be of help and giving measured assistance directed toward countries with the greatest needs. The UNEP regional coordinators primarily had a scientific background and were strong in project management, but for a considerable period there were none with a legal background. Despite the logistical and other weaknesses, the UNEP project team is well regarded for its commitment and hard work.

**Table 10.2: Travel of UNEP Project Team to Countries, as of August 31, 2005**

Country	Average visits per country	Total missions
Development project	1.2	145
Implementation project	3.5 <sup>a</sup>	38

a. This includes missions to implementation project countries during the time they were participating in the pilot phase of the GEF-supported activities. This average is also calculated by replacing the outlier of Kenya (13 visits) with the average of all the other countries.

In general, the regional coordinators had to budget their time between general administration and professional backstopping, and necessarily had to prioritize the former. In a number of countries, NPCs remarked on the lack of UNEP feedback on issues of substance highlighted in the quarterly reports. Other times, UNEP staff complained that quarterly reports were often very sketchy and lacking in sufficient detail for a proper evaluation of progress to be made. UNEP’s complaints about lack of adherence to agreed-upon standards and criteria are apparently accessible only in informal and personal communication and not recorded in publicly accessible documents, such as aid memoranda, as is the case for the World Bank.

Concerning UNEP's involvement on subprojects, two activities to note in particular are the national stocktaking and the peer review system (the latter is dealt with in section 10.4). The stocktaking exercises could have provided an opportunity for the regional coordinators or Implementing Agency specialists to acquaint themselves with the national situation and improve their ability to provide guidance. However, this was neither planned, nor financed, as a separate activity in the NBF development projects. The regional coordinators did not always receive nor systematically review the stocktaking reports. Similarly, the inability to undertake backstopping visits at decisive stages in the substantive data-gathering period of the subprojects also limited the quantity and value of inputs from agency staff. Further, it reduced the possibilities for pointing out potentials for collaboration and harmonization within the subregion as well as national legislative choices that could be the most suitable to each country's needs and capacity.

### **10.3 The UNEP Toolkit**

The UNEP Toolkit was one of the principal mechanisms for providing both administrative and substantive guidance to participating countries. As stated in UNEP's introductory letter to the publication of the first Toolkit module in December 2001, the aim of this toolkit is to provide a practical 'how-to' guide for countries to assist them in developing their draft National Biosafety Framework.

The Toolkit product was not originally identified or budgeted, but was independently developed by the UNEP biosafety team as a means of responding to frequently asked questions from countries and to assist them in structuring project execution. For UNEP, the Toolkit provided a mechanism to formalize and generally share advice that was provided on an ad hoc basis by regional coordinators or outside experts through e-mail and other communications with NPCs. Given the limitations to direct in-country interaction between UNEP regional coordinators and NPCs, the Toolkit was expected, at least partially, to fill the gap.

The development of the Toolkit was viewed as a priority activity within the NBF development project at the first meeting of the steering committee in February 2002. The overall structure, as described in the first module released on December 20, 2001, was organized as a series of individual modules, each addressing a particular phase listed in the national project document. A brief description of the various Toolkit modules is provided in annex 3.

#### ***Toolkit Timeliness***

The development of the various Toolkit modules occurred over a 35-month period. The following table presents the status of the national subprojects at the time of publication of the various modules.<sup>27</sup>

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<sup>27</sup> At the time of the midterm evaluation of the global project in August 2003 (Navajas and Seyani 2003).

**Table 10.3: Comparison of Toolkit Module Publication Dates and NBF Subproject Status**

Toolkit module	Publication date <sup>a</sup>	NBF subprojects started at publication date <sup>b</sup>	NBF subprojects completed at publication date <sup>b</sup>
Phase 0 – Starting the Project	December 20, 2001	1	0
Phase 1 – Taking Stock	May 17, 2002	12	0
Phase 2 – Consultation and Analysis	September 26, 2003	99	0
Phase 3(i) – Regulatory Regime	September 11, 2004	114	17
Phase 3(ii) – Administrative Systems	November 30, 2004	118	18

- a. Publication dates were provided by UNEP.
- b. For the purposes of this evaluation, the project start date was defined as the effective date of the double-signed national project document as provided by UNEP.
- c. The date of project completion was defined as the date the draft NBF was posted to the UNEP website, as provided by UNEP.

By UNEP’s estimation, 34 (29 percent) of the 118 participating countries had begun drafting their NBF prior to the final publication of the last Toolkit module. According to the evaluation team’s assessment, of the 46 countries that had posted draft NBFs by July 21, 2005, 17 (37 percent) had completed this activity prior to the publication of the first Phase 3 module. This information may not convey the full story, however, given that “final publication” is not equivalent to “first unveiling.” Earlier drafts of the Phase 2 module were circulated November 2002 and May 2003, and drafts of the Phase 3(i) and 3(ii) module were circulated by their primary author in the 2003 workshops. Moreover, the contents of the Phase 3(i) and 3(ii) module relate to substantive drafting, and can theoretically be used as additional input throughout the drafting and review of key NBF documents.

The late availability of Toolkit modules was identified as a concern in the 2003 midterm review, where it was noted that “toolkits began to appear after many countries were already well into the project” and the “absence of the phase 2 Toolkit was cited as a big drawback by many countries, since they lacked guidelines for carrying out phase 2 activities” (Navajas and Seyami 2003). This comment, however, underscores the value countries were expecting from the final modules, further suggesting strong positive reactions to the first two modules. Although the Phase 0 module dealing with project startup and organization discussed why a country needs an NBF and dealt at some length with the participatory process in developing one, there was no factual description of what an NBF was. This description of the various components of an NBF was not addressed until the Phase 3(i) module, which was published almost three years later. Similarly, the description of rights and obligations of parties to the Cartagena Protocol that was provided in the Phase 3(i) module would have been a valuable component of the Phase 0 module, where this topic was afforded only cursory treatment.

### ***Delphi Review of the Toolkit***

Between May and August 2005, a review of the Toolkit was carried out by Vrije Universiteit of Amsterdam. The purpose of the review was to assess whether the Toolkit was consistent with the Cartagena Protocol, responsive to country needs, and of sufficient professional quality. The university used a questionnaire, which was distributed to 500

respondents in 30 countries plus an additional 40 respondents representing global actors: the biotechnology industry, other donor organizations, NGOs, and academic institutions. Responses were received from 102 individuals from 29 participating countries. Some of the reasons for the low response rate were i) the university did not have as much time to carry out the study as it had wanted; ii) the study was conducted partly during vacation time for many respondent; iii) some respondents had insufficient internet connections; iv) language problems (the questionnaire was available only in English, French and Spanish; v) some of the global actors had not very thorough experience with the Toolkit. Even if the response rate was on the low side, a systematic data gathering approach was used. However, of those who responded, 91 percent stated that they were well informed about the Cartagena Protocol and 78 percent stated they were well informed about the Toolkit.

The Delphi study addressed the consistency of the project with the Cartagena Protocol through seven separate questions. The results show that 78 percent of the respondents answered that the Toolkit was “very consistent” or “consistent” with the protocol. Only one respondent answered “not so consistent,” while the remainder gave no answer. There were also several questions related to “responsiveness to country needs”; 79 percent stated that the Toolkit had been or is useful/very useful for their country, while most of the remainder gave no clear answer. On the question of whether the Toolkit was sensitive with regard to countries’ available scientific expertise, 65 percent gave a positive answer, 15 percent a negative, and 20 percent gave no answer or did not know. Nine questions were related to the professional quality of the Toolkit. More than 70 percent of the respondents indicated that they were satisfied/very satisfied with the clarity of aims, the selection of topics, and the depth and comprehensiveness of guidance on selected topics.

Another aspect of quality surveyed was coverage of topics. There were seven topics on which between 36 and 53 percent of the respondents wanted more emphasis: protection of biodiversity and human health (39); public awareness programs (37); risk assessment (37); organizing procedures for decision making (38); designing a regulatory regime (36); illegal introduction of LMOs into the country (53); and systems for monitoring, inspections, and enforcement (50). The two last topics were singled out as requiring most attention.

The Delphi review also incorporated some open questions about advantages, disadvantages, and challenges that respondents experienced with the Toolkits. Especially the problem of timeliness was seen as a challenge. More than half of the National Project Coordinators who responded to the Delphi study saw timeliness of Toolkits availability as the most important constraint. Other issues that were identified by all respondents included lack of country specifics taken into account; too narrow focus; no attention given to issues of NBF implementation; and not enough focus on science/LMO development. In addition to these critical remarks there were also different and opposing positive views about the Toolkits: a guiding step-by-step approach; flexibility to specific conditions; clear explanations; information on harmonization of LMO legislation and procedures; and better awareness of biosafety issues.

The Delphi review also identified some of the same challenges noted by the evaluation team, especially with regard to timeliness. More than half of the NPCs who responded to the Delphi study saw timeliness of Toolkit availability as its most important constraint. Other issues identified included lack of country specifics taken into account, too narrow a focus, no attention given to issues of NBF implementation, and not enough focus on science/LMO development. Balancing these were a number of positive views on Toolkit strengths: a guiding step-by-step approach, flexibility to specific conditions, clear explanations, information on harmonization of LMO legislation and procedures, and better awareness of biosafety issues.

### ***Review of the Toolkit by the Evaluation Team***

The evaluation team assessed the Toolkit also, but had a considerably smaller sample of countries; even though it interviewed a much wider group of potential users in each country (e.g. most members of the NCC). The evaluation team focused essentially on the use of the Toolkit. This may explain that there are some divergences between the two reviews. During its interviews in 7 countries, the evaluation team made assessments of toolkit consistency with country needs, its availability to participants, level of use in the country, and dissemination of the Toolkit to relevant stakeholders, as well as level of guidance it offered on particular issues.

There were no responses indicating that the Toolkit was inconsistent with the Cartagena Protocol, incorrect, or confusing, or that it possessed other negative qualities. The users of the toolkits generally provided two responses; these were either:

- (1) strong appreciation—the Toolkit was found to be very useful and well used;
- (2) generally positive comments about the Toolkit, but admission that it was not used, whether because the respondent did not need or want it, or for other reasons.

In general, the most positive reviews came from NPCs, many of whom (especially in small countries and SIDS) were practically alone in completing or ensuring the completion of many elements of the project design and substantive outputs. Several of these made such comments as “I wish all projects provided this kind of assistance.” Usually the strongest praise was reserved for the Phase 0 module, which provided very detailed assistance on how the project should operate and be administered. Other key participants, such as members of the NCC, and other stakeholders claim to have seen the Toolkit, but to have rarely applied it. The overall utility of the Toolkit to the countries visited was therefore judged as mostly medium to low.

Apart from the Phase 0 module, the remaining modules were less utilized; the reasons for this may range from timing (discussed above), distribution, or the fact that the Toolkit—geared as it was for the “average” national project—was either too sophisticated or too simple to address a specific need. Although many respondents were comfortable with the complexity level of the Toolkit, some felt that they had received insufficient explanation in its use. While the Toolkit modules were disseminated to members of the NCC in most cases, there was generally no awareness of them among the broader stakeholder group.

UNEP made the Toolkit available in English, French and Spanish, and the Toolkit was translated into Russian by the Tajikistan NBF development project.

Table 10.4 sums up the evaluations team’s assessment of various aspects of the Toolkit. Issue 1 was raised in countries both visited and interviewed by telephone and received 11 responses. The other issues were only raised in the seven NBF development countries visited.

**Table 10.4: Assessment of Toolkit Utility in NBF Development Phase Countries**

Issue	Low	Medium	High
1. Consistency with country needs	7	1	3
2. Explanation of how to use Toolkit	3	3	1
3. Relevance to country process	5	1	1
4. Level of use	4	2	1
5. Efforts of dissemination to various stakeholders	6	1	0

*Note:* The countries visited were The Bahamas, Burkina Faso, Croatia, Ethiopia, Guatemala, Morocco, and Tajikistan. Countries interviewed by telephone were Botswana, Chile, Lebanon, and Turkey. At the time of the on-site interviews, four of the countries visited had completed their NBFs; three were still in process.

## 10.4 Advice Provided by External Experts

Within each national subproject, about \$50,000 was budgeted for engagement of professional advice or other expertise. The amounts were expected to cover five stocktaking reports, as well as advice through the drafting process and peer review of the draft final NBF report. For the stocktaking phase UNEP encouraged the countries to use national, and in some cases regional, experts, with the aim of building national capacity. A number of countries requested assistance from UNEP for peer reviews of the draft NBFs, which led to the engagement of peer reviewers in 40 of the 54 draft final NBFs, according to project staff tabulations.

By August 2005, peer reviews had been carried out for all completed reports in Africa, and for about two-thirds of the reports completed in Asia and Eastern Europe, but only two countries in Latin America. The peer reviewers were sometimes NPCs from other countries in the region; other times, they were international experts.

The evaluation team examined eight of the UNEP-funded peer reviews with regard to the technical competence of these reviews, and the technical quality of the reviewers themselves. In three cases, the reviewers’ qualifications and the quality of the reviews were found to be technically unsatisfactory. Peer review quality was analyzed in terms of the contents of the review focusing on correctness, completeness, relevance, and usability. This evaluation concluded that the level of expertise of peer reviewers varied.

## 10.5 Effectiveness of the Global NBF Development Project Umbrella Approach

At the overall level, the GEF has used two allocation models: 12 individual medium-sized country project allocations; and one umbrella-type allocation, which initially included NBF development projects in 100 countries, to which 30 were later added. The support to create capacity for participation in the BCH is also of the umbrella type, since

the project initially included 50 countries, to which 89 countries were added. This evaluation does not fully assess the capacity building for participation in the BCH, since this project is only in its initial stage.

The GEF has previously employed a global project allocation type in similar areas of GEF enabling activities. Although the individual project approach was chosen from 1996 to 2000 as the main modality in the GEF support to enabling activities in biodiversity and climate change, UNDP—and partly UNEP—were also tasked with giving additional assistance to the same countries through global support programs, especially based on regional and global networking, websites, and help desks.

For the NBF development initiative, the umbrella project modality employed essentially the same approach to all countries: execution by the NEA, recruitment of a full-time NPC, overall guidance and coordination by an NCC, national awareness raising and capacity-building workshops, development of risk management and regulatory systems, and preparation of websites for public information and participation in the BCH. The umbrella approach was, under the circumstances, a necessary tool to deliver assistance expeditiously to the large number of countries requesting assistance, and it entailed economies of scale. The alternative of organizing 100 individual projects without a single coherent system would have been much more demanding both in terms of time and resources. The objective of economizing on GEF funds by employing economies of scale was an important contributing factor to the choice.

The approach was especially effective in countries that could easily incorporate the support into their own biosafety systems, but much less effective in countries where the need for support was greater and/or the initial conditions were less receptive. On the whole, the approach was too ambitious in terms of high goals within limited time schedules, and it did not have a sufficient inbuilt flexibility to adapt the level of funding and the measures of required technical assistance to the needs of each country. Due to resource constraints, UNEP was forced to employ a low-intensity follow-up and supervision strategy in each country. This reduced the ability for extra support to low baseline countries. However, such follow-up was not necessarily an inherent feature of the umbrella approach, which might have had an inbuilt flexibility and also included sufficient professional back-up and supervision and specific country features.

## **10.6 Conclusions**

In general, the UNEP Toolkit modules have been found satisfactory in terms of consistency with the Cartagena Protocol and professional quality, although less responsive to country needs. The main problem was tardiness relative to project execution in a great many countries, and the lack of access to and use of the modules by the broader stakeholder groups at the country level.

For a project as complex and contentious as developing a national regulatory framework for LMOs, a toolkit approach may have limitations when compared with more direct mechanisms of providing guidance. Given limited funding and time constraints, however,

the toolkit approach may have been a cost-effective, although not entirely satisfactory means, of providing basic guidance to a large number of countries working toward the same or similar goals.

The quality, usefulness, and timeliness of the technical advice and backstopping by Implementing Agency staff and external expertise were rated mostly at a medium to low level. This does not necessarily mean that the advice itself was of low quality, but rather that good advice was not readily available in a form that could be adapted to the country situation at a time when it was needed.

The umbrella approach was, under the circumstances, a necessary tool to deliver assistance expeditiously under a single project to 100 countries, although the approach was too ambitious, and was much better adapted to “high baseline” than “low baseline” countries.

## **Chapter 11. The GEF's Contribution to Progress in Implementing the CPB**

The final step in this evaluation calls for an analysis of the third question in the evaluation's Terms of Reference: What progress has been made in countries on building the requisite capacities toward their ratification and implementation of the Cartagena Protocol? In general, each of the activities discussed in the previous chapters was undertaken with the object of promoting the objectives of the Cartagena Protocol in developing countries and countries in transition. This chapter considers the overall effect of those activities on national and international progress toward implementation.

Analysis of this issue requires the consideration of both the effectiveness of the national subprojects and global activities in achieving progress, and also a more general look beyond the specific outputs of the project—documents created, workshops and other materials presented, and interviews conducted—to consider wider indicators of the extent of changes in governance, policy, public opinion, and priorities in supported countries.

This chapter examines five primary indicators of change and development in regard to the objectives of international action on biosafety and of the GEF's influence on such change:

- speed of ratification/accession to the protocol;
- the significance of the GEF's support for NBF development, NBF implementation, and capacity building for participation in the BCH;
- the degree to which the GEF-funded projects have contributed to compliance with, and full implementation of, the CPB;
- consistency and neutrality of the GEF's role and support;
- breadth of coverage of GEF support.

### **11.1 Speed of Ratification of the Cartagena Protocol**

One overall indicator relates to the status of ratifications of the protocol. In addition to being a question of this analysis, and an objective of the GEF Strategy, the extent and speed of ratification may provide a measure of the effectiveness of GEF support, particularly when compared to the status of similar international agreements.

Regardless of the difficulty and length of negotiations necessary to create an international instrument, one key factor evidencing its acceptance, value, and effectiveness is the number of affected countries that agree to become party to it. A country's consent to adopt or sign a protocol is not as reliable an indicator as ratification, which embodies its full and formal commitment to become party. As such, the process of ratification, accession, or other acceptance of party status in an environmental convention or protocol is sometimes quite slow. A commitment of (and possible restraint on) a country's national sovereignty, this process usually requires the approval of the highest national body or bodies in the country. These formalities can take time, in light of the role of

relevant documents, their execution, and their formal delivery to the international depository both as legal processes and as political/public relations opportunities.

One way of evaluating the speed of the ratification process is by comparing it to other international agreements (see Table 11.1).

**Table 11.1: Comparing CPB to Similar International Agreements**

Factor	CPB	CITES <sup>a</sup>	Kyoto Protocol	Montreal Protocol	POPs Convention
Current number of parties	125	169	156	189	110
Date of adoption	Jan. 29, 2000	March 3, 1973	Dec. 11, 1997	Sept. 16, 1987	May 22, 2001
Date of 50 <sup>th</sup> accession <sup>b</sup>	Sept. 2003	June 1979	Feb. 2005	Dec. 1989	May 2004
Months from adoption to 50 <sup>th</sup> accession <sup>1</sup>	43	63	62	27	36
Ratifications in year 1	2	1	5	10	5
Ratifications in year 2	10	7	16	37	25
Ratifications in year 3	28	13	10	16	30
Ratifications in year 4	42	10	15	9	37
Ratifications in year 5	29	10	54	12	13
Ratifications in years 6–10	14	37	56	77	
Ratifications in years 11–15		14		22	
Ratifications in years 16–present		77		6	

- a. The four other instruments listed above—Convention on International Trade in Endangered Species of Flora and Fauna (CITES), the Kyoto Protocol to the UN Framework Convention on Climate Change; the Montreal Protocol to the Vienna Convention for the Protection of the Ozone Layer, and the Stockholm Convention on Persistent Organic Pollutants (POPs Convention)—are included because each is similar to the CPB in terms of the kinds of compliance required (development of national legislation designed to control transboundary movement of specific environmental species and subspecies that may be difficult to identify), although none demands a level of detailed compliance equal to the CPB.
- b. Each international instrument requires a different number of parties in order to enter into force. For example, the Montreal Protocol called for only 11 parties (although with some special requirements), and was in force 15 months after adoption. By contrast, the Kyoto Protocol needed 55 and was subject to some special requirements, so more than 86 months elapsed before it entered into force. For comparison, this table notes the amount of time it took each of these instruments to garner 50 ratification/accessions.

Both the Cartagena and Kyoto Protocols have been topics of serious controversy among OECD countries, although arguably the Cartagena Protocol has been more directly politically sensitive of the two. Such controversy between or among OECD countries can sometimes create a high level of insecurity in other countries regarding the political effects of their own ratification. Consequently, it is notable that the Cartagena Protocol's ratification has been relatively rapid, in comparison with other controversial instruments (in this case, the Kyoto Protocol), and with CITES whose ratification was delayed by other political factors.

Another measure of the effect of GEF support on ratification can be based on review of the protocol status of countries that were non-parties when they received GEF funds. When the decision was made to allocate funding to such countries, a proviso was added that such countries must be parties to the CBD, and that they must deposit with the GEF chair and the Secretary General of the CBD a signed declaration that they "intended to ratify the protocol before the completion of the GEF project." Table 11.2 describes the status of this subgroup of countries.

**Table 11.2: Current Status of Countries Not Party to the Cartagena Protocol at Start of NBF Development Project**

Countries not party to CPB at NBF project commencement (total 38)	Now CPB Party	Not yet CPB party
...which have now completed NBFs (31):	26 (84%)	5 (16%)
...with projects still in progress (7):	4 (57%)	3 (43%)

These data indicate that completion of the project bears a strong relationship to ratification of the protocol. This relationship was borne out in incidental cases throughout the evaluations. In some of the countries visited or interviewed, the NPCs indicated that they had devoted significant amounts of project time, and especially of post-project time, to interacting with government officials and encouraging ratifications, often with positive results. Although several countries have not yet taken action on their commitment to swift ratification, such post-project efforts may still be ongoing. At present, 81 percent (31 of 38) of countries with completed NBFs have ratified the protocol; ratification in countries with projects still in progress has been slower. It seems reasonable to conclude that project participation enhanced awareness of the protocol at administrative and political levels, and gave officials sufficient assurance in their protocol-related capability that they could more confidently recommend ratification.

In general, the national political situation with regard to accession to the protocol was not discussed in the NBF reports, and, as noted above, the process may be lengthy. Preparing the NBF and implementation of the protocol are relatively complex processes, requiring significant human and financial resources. As international law, a decision to ratify the protocol would create a national obligation to incur these costs. In a decade of shrinking national budgets, two of the most frequently trimmed budget items are those of the environment and agriculture ministries. The choice among competing priorities within these ministries may also be delaying or sidelining necessary intra-governmental efforts to promote ratification.

## **11.2 Significance and Results of Nationally Oriented Support**

As detailed in Chapter 1, the GEF support was largely directed to providing assistance to the development of national legal frameworks, and the development of institutions and capacity for their implementation. This section does not repeat the report's earlier analysis of GEF support in these areas, but considers the international significance of that work.

### ***Development of Biosafety Policies, Systems, and Regulations***

As explained in Chapter 1, the development of the instruments and internal institutional agreements comprising the country's overall biosafety framework is a large and difficult task. In attempting to address this aspect of the GEF Strategy, specific choices were made directed at maximizing the amount of work to be undertaken with the minimum cost and most immediate results.

As demonstrated in Table 8.1 and discussed in section 8.4, evaluation of the legal instruments and NBF reports demonstrated that, at minimum, most NBFs have

specifically addressed most protocol-required legislative and regulatory provisions. In many cases, issues not directly covered in legislation developed through the project may have been omitted because they were addressed in other existing law. However, these outputs are generally still in the form of interim drafts; in many cases, the countries still require significant professional assistance to make them sufficiently functional and effective in form and content to be put forward as legislative or regulatory proposals. In many instances, national legislative development has insufficiently integrated or addressed issues of national need, institutions, and capacity, so existing legislation may not fit comfortably into national systems. In the worst case, if such legislation were adopted without further technical assistance and advice, it would result in “paper compliance”—where the law exists on the books but is generally not implemented.

In all cases evaluated, the project’s work has created a functional basis for further work, including reconsideration of the problems identified above. Regardless of the extent of direct legislative drafting undertaken by a national subproject, its NBF report includes a plan describing additional legislative work needed and identifying and prioritizing next steps for the country. Relatively few countries have indicated how they intend to support and fund these activities—perhaps owing to the frequently expressed expectation that there would be a subsequent phase of the project, in which countries could take further steps toward full implementation of the protocol.

In evaluating the significance of these results as a contribution to progress in implementing the Cartagena Protocol, it is reasonable to consider the progress experienced by similar multilateral environmental agreements that require parties to adopt and implement technical regulatory frameworks.

- *The Convention on International Trade in Endangered Species of Flora and Fauna.*<sup>28</sup> In the most recent analyses of national implementation, it was found that only 41 percent of parties are fully in compliance with CITES legislative requirements, after 30 years since adoption (CITES 2004). Forty-seven parties have been required to develop or improve legislation, and/or to provide a legislative plan describing how and when they will address deficiencies in their legislative framework.
- *The Convention on Biological Diversity.* Although covering a very broad range of issues, the CBD requires legislative measures in very few, of which only the provisions regarding access to genetic resources and equitable benefit sharing relate to trans-border activities.<sup>29</sup> To date, only 35 of the 188 CBD parties have posted any legislation or references to it, and only about 18 countries (10 percent

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<sup>28</sup> CITES is similar to the protocol in that its primary mandate relates to the control of biological materials moving among countries; it requires formal permits from both the exporting and importing countries; and it requires the adoption of national legislation (although at a much lower level than the CPB—it has only four primary requirements).

<sup>29</sup> In this connection, the convention requires parties to adopt 10 different kinds of “legal, administrative, or other measures,” primarily in article 15, but also in articles 16, 17, 19, 20, and 21.

of CBD parties) have yet adopted substantial national legislation implementing Access and Benefit Sharing (see Cabrera 2004).

- *The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal.*<sup>30</sup> This convention is beginning, in its 16th year of operations, its first systematic examination of national implementation. As of the date of this report, only about 86 countries (52 percent of parties) have so far responded to the call to provide or summarize their existing legislation relevant to hazardous wastes. No analysis has yet been completed to determine whether and to what extent these laws comply with the convention.

Viewed in this context, the project's work in NBF development may be seen to represent a significant contribution. At a minimum, through the project, 93 percent of developing country parties (and many countries that have not yet ratified the protocol) have made at least some progress toward achieving their legislative and institutional objectives,<sup>31</sup> and have developed a plan (reflected in each national subproject's NBF report) for further regulatory development. This status is significantly more advanced than other instruments mentioned above which have been in existence far longer.

Within the primary objectives of the project, one further critical contribution relates to the development of sources of expertise and information sharing at the governmental and implementation levels. Although the GEF Strategy recognizes that it is early in most regions to consider formal harmonization, the project did not engage in significant efforts toward investigating options for regional cooperation, frequently omitting consideration of this aspect from NBF development processes, and limiting global efforts to the cultivation of limited contacts with a random selection of existing regional and subregional intergovernmental bodies. The project performed well on the more immediate goal of building a base of regional and subregional networking that will enable the sharing of expertise and information, even before regional structures can be agreed upon.

### ***Awareness and Participation***

As noted in Chapter 1, the project and GEF Strategy gave priority to three key factors relating to public consciousness of and participation in LMO-related activities: public awareness raising, cross-sectoral and stakeholder participation in project decisions and activities, and the development of legislative provisions for public participation in decisions made under the NBF.

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<sup>30</sup> The Basel Convention is similarly directed at controlling the commercial movement of substances across boundaries. Its objectives are environmental protection and safety. Its primary legislative requirements call for measures implementing controls of the movement in customs and penalties. Unlike biosafety, the scientific issues and standards underlying the Basel Convention are clear and well accepted internationally, and the governmental mandates for pollution control already existed very generally.

<sup>31</sup> It was assumed that a country is making "at least some progress" once it has an NEA, NPC, and NCC in place and is clearly moving forward on the project.

The level of public awareness on biosafety issues, and public awareness of the project, could not be reliably assessed within the scope of this evaluation. Significant efforts were directed in national subprojects at public awareness raising, sometimes at the most general level, and in other cases more focused on particular activities and issues relevant to the project. This work included not only direct awareness raising and participation, but the building of long-term mechanisms for public information, including national biosafety websites and the BCH.

While the achievements on public participation in project activities were mixed, the national subprojects clearly expressed a desire to broaden their activities to include a cross-sectoral mix of agencies and perspectives. Public participation was strongly promoted by the UNEP project team, and through the Toolkit and other project documents. Yet, in many cases, national efforts at inclusiveness and cross-sectoral operations were evaluated to have been inadequate to the task, and many processes insufficiently open and responsive to the breadth of necessary perspectives, institutions, and stakeholder groups.

The primary impetus behind the protocol's creation was the need to build confidence among governments and their citizens that LMO-related decisions were taken on a sound and precautionary basis. If it succeeds in this mission, the protocol may make an important contribution to building acceptance of LMOs and acceptance by the LMO industry of the value of publicly recognized compliance with these standards. As such, public awareness and participation are a critical element of the work of the project.

The extremely limited budgetary allocation to these issues suggested that the project was not intended to create full media campaigns and awareness activities. In a few cases, countries focused their efforts on designing strategies for longer term efforts to develop awareness and participation.

### ***Capacity Development***

The majority of countries had a low initial level of biosafety capacity. Capacity building was therefore an essential element of all GEF biosafety projects. The level of and need for capacity development, however, were often insufficiently assessed in the course of national subproject development and operations. At the global level, significant capacity-building efforts were directed at sensitizing a small core group of actors in each participating country. This kind of development, while certainly insufficient to provide the full level of capacity each country will need to have or access to implement the protocol, does represent a first step in that process.

Given the complex technical specialties involved, it is not a short process to truly raise capacity in this area. Ultimately, more specialized types of collegiate and postgraduate training will be needed in many countries. Pending that, however, other project mandates, including efforts to develop regional and other networks among national actors, fill a critical capacity-development role.

### **11.3 Scientific and Administrative Tools for Implementing the Protocol**

Given the variance among countries' baseline level of preparation in implementing the protocol at the start of their projects and subprojects, it is perhaps not surprising that fully operational risk assessment processes and risk management systems are not yet available in the majority of countries involved. Despite very detailed information regarding these processes in the protocol and its annexes, the fact remains that risk assessment decision making is dependent to a large extent on governmental decisions regarding the level of risk that will be considered acceptable and how that determination is to be made.

Consequently, in many countries, project work in developing implementation bodies, standards, and protocols was primarily focused on building awareness and initial understanding of the relevant issues and the nature of the decisions and technical support needed in order to bring them into functional existence when the national situation and capacity are ready to do so. For many countries, it is evident that the envisioned scientific and technical capacity required to implement the NBF does not exist, and is not likely to for some years. Still, however, the countries have gained important value through the networking, sensitization, and informational resources provided by the project.

As noted above, based on the on-site and telephone evaluations of 17 countries, the evaluation team concluded that six have made a high degree of progress toward implementation of the protocol, four a medium degree, and seven a low degree. The countries with the greatest initial capacity have made the greatest progress, suggesting that on-the-ground progress is most likely in countries that begin with a high level of national capacity and involvement in LMO issues, and (resulting in) governmental commitment to moving forward.

An important institutional component of the project was the development of the national coordination committees, created to provide primary domestic oversight and guidance to project operations. In many countries, the NCC was both an effective project steering committee and a nascent network of key biosafety-related officials and other actors. This process has at times proven so effective that the NCC has been restructured with a direct governmental mandate to operate as its national biosafety committee following the end of project activities.

### **11.4 Support for Participating Countries to Advance toward Compliance**

In the course of this evaluation, an analysis was conducted in 18 countries providing a variety of statistical and evaluative results. As a concluding factor in each national review, the evaluation team members were asked to rate the countries reviewed on their level of preparation for entry into force of the protocol and on the overall progress made toward building capacity to implement the protocol; see Table 11.3.

**Table 11.3: Overall Progress Made in Countries to Implement the CPB**

Item	Country	High	Medium	Low
Current level of preparation for entry into force and implementation of the protocol	Development projects (10)	1	5	4
	Implementation projects (6)	3	1	2
Overall progress made on requisite capacities to implement the protocol	Development projects (11)	3	3	5
	Implementation projects (6)	3	1	2

In analyzing these data, it should be noted that 6 of the 12 NBF development project countries, and four of the six implementation project countries, visited or interviewed for this evaluation had not yet completed their projects. With this caveat, it is apparent that these evaluations compare to the baseline evaluation described in section 4.2, which showed that 8 of the 12 NBF development project countries evaluated began at a low baseline, 3 began at a medium baseline, and only one was considered to be high baseline. The influence of the project can thus be seen to have been relatively positive, with two countries advancing to a medium level of preparation, and half the countries being seen to have made medium or high levels of progress, despite the overwhelmingly low baselines at the beginning.

These data clearly indicate that project progress was most effective in high baseline countries. Comparing these results to the evaluations of project outputs and outcomes supports this point. Among NBF implementation projects, those that were at a high baseline level of involvement in LMO activities and regulation were found to have the best performing projects, scoring almost exclusively in the medium and high ranges in evaluation of project outputs, outcomes, and impacts. Those identified as having a medium or low baseline level performed relatively inadequately, generally receiving low (or infrequently medium) scores on evaluations of project outputs, outcomes, and impacts. In NBF development projects, ratings of outputs were correspondingly higher for countries starting with a high or medium baseline than for those with medium or low baseline levels. The incidence of negative findings regarding project results (for example, that one or more of a subproject's outputs were ineffective, of unacceptable professional quality, lacking in some elements of consistency with the protocol, or of questionable implementability) was significantly greater for countries with low initial baseline ratings.

The effectiveness of the GEF support may have been diminished by decisions to use generally identical requirements, capacity-building processes, support services, and oversight mechanisms for all national subprojects regardless of the baseline levels of the countries involved, and without any in-depth pre-project analysis of the specific needs and capacity in each case.

### **11.5 Consistency and Breadth of GEF Support to the CPB**

As detailed in Chapter 1, GEF support was generally rated highly with regard to consistency with the protocol and its objectives. As discussed in section 10.3, the project Toolkit was evaluated for consistency with the protocol in several different ways, receiving a generally high rating in the assessment survey and a more mixed rating from

the wider group of participants interviewed in the evaluation visits, as well as notable praise from particular interviewees with regard to protocol consistency and value.

In light of the overall neutrality of the protocol on questions of biotechnology and LMO introductions generally, the issues of sectoral or other bias constitute a further element of the consistency analysis. One of the most difficult challenges perceived by the UNEP project team arose from the need to maintain neutrality with regard to the highly controversial issues that surround and often interact with the question of biosafety implementation. The project team was aware of the need to avoid taking a substantive position on these issues in order to maintain their ability to provide services to countries that may in some cases have been firmly committed to one side or the other, or in others resistant to taking advice from strong proponents of either side.

In the end, although the UNEP project team was challenged at times by advocacy groups claiming bias, the nature of those opposing claims may actually demonstrate general impartiality. Both strong biotechnology proponents and strong opponents have submitted such complaints, often addressed at the same project components (workshops or Toolkit). This fact suggests that UNEP's work was balanced and unbiased in either direction.

## **11.6 Conclusions**

National progress toward implementation of the Cartagena Protocol has been a very difficult task, in part because of the time involved between commencement of these activities and concrete formal results (national ratification, adoption of policy and legislative frameworks, and creation and operation of implementing institutions and standards). It is important to recognize the significantly different potential time horizons for countries to be able to fully implement the protocol. Some countries may be able to implement their NBFs, as envisioned, within three to five years. For other countries, however, 10 years or longer may be necessary. As noted in earlier chapters, this fact is not inherently problematic. The actual biosafety requirements of many countries with little capacity may be relatively low. By contrast, countries that have the capacity necessary to implement their NBFs quickly are also much more likely to engage in significant biotechnology activities, and therefore have a greater need to have a fully operational biosafety framework in place.

These differences among countries aside, it is clear that most countries are, at a minimum, more aware of biosafety and biotechnology issues and farther along the path to addressing them than they were at the time of protocol adoption in 2000. The GEF, by far the world's largest provider of support for biosafety implementation in developing countries, has clearly made an important contribution to the international effort toward implementation of the Cartagena Protocol, moving quickly and effectively to bring prompt assistance to the largest possible number of countries.

Future progress will turn on enhancing cooperation with regional and subregional initiatives, intergovernmental and bilateral donors, and spontaneous national and regional proposals that derive from specific needs and demands rather than external recommendations. To ensure implementability and appropriateness, activities to address

biosafety need to move forward in a logical progression, at a rate that makes sense for countries based on their level of capacity and degree of need. The attempt to provide support to so many countries within a compacted timeline, in a consistent and substantive manner, represents an unprecedented effort for the GEF—and perhaps for any organization in the world.

## Annexes

## Annex 1. Acronyms

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CIBIOGEM	Mexico's Inter-ministerial Commission on Biosecurity and Genetically Modified Organisms (Comisión Mexicana Intersecretarial sobre Bioseguridad y Organismos Genéticamente Modificados)
CITES	Convention on International Trade in Endangered Species of Flora and Fauna
COP	Conference of the Parties
COP-MOP	Meeting of the Parties of the Cartagena Protocol
CPB	Cartagena Protocol on Biosafety to the Convention on Biological Diversity
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FFP	Food, Feed, or Processing
GEF	Global Environment Facility
GEFSEC	Secretariat of the Global Environment Facility
GMO	Genetically Modified Organism
LMO	Living Modified Organism
NBF	National Biosafety Framework
NCC	National Coordinating Committee (as organized through one of the national subprojects under the UNEP GEF, WB-GEF or UNDP-GEF Projects)
NEA	National Executing Agency (organization administering one of the national subprojects under the UNEP GEF, WB-GEF or UNDP-GEF Biosafety Projects)
NGO	Nongovernmental Organization
NIA	National Implementing Agency (organization administering one the national subprojects under the UNEP GEF, WB-GEF or UNDP-GEF Biosafety Projects)
NPC	National Project Coordinator (nationally designated person with primary responsibility for implementing one the national subprojects under the UNEP GEF, WB-GEF or UNDP-GEF Biosafety Projects)
OECD	Organisation for Economic Co-operation and Development
SIDS	Small Island Developing States
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
USAID	U.S. Agency for International Development
WB	World Bank

## **Annex 2. Terms of Reference of the Evaluation of GEF's Support to the Cartagena Protocol on Biosafety**

### Background and GEF's Strategy

At its November 2004 meeting, the GEF Council requested the GEF Office of Monitoring and Evaluation (OME) to undertake an evaluation of the activities financed under the initial strategy approved by the Council in May 2000 for assisting countries to prepare for the entry into force of the Cartagena Protocol.

The Cartagena Protocol for Biosafety under the Convention of Biological Diversity (CBD) was adopted in January 2000 and the Global Environment Facility (GEF) became its Financial Mechanism. The objective of this Protocol (see Article 1) is “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) 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 trans-boundary movements”<sup>32</sup>.

The GEF strategy for assisting countries to prepare for the entry into force of the Protocol (GEF/C.16/4/Rev.1) was based on a decision in the Conferences of the Parties (COP) to the Convention on Biodiversity (CBD), which designated capacity-building as a priority for GEF assistance (decision III/5 paragraph 2 (a), 1996). Further guidance has been provided by COP-CBD especially in decisions V/3, VI/17 and VII/20. The GEF strategy aims at:

- D. Assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks, including strengthening capacities for risk assessment and management with a wide degree of stakeholder participation,
- E. Promoting information sharing and collaboration at the regional and sub-regional level and among countries that share the same biomes/ecosystems, and
- F. Promoting 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.

The following activities were proposed:

- VI. A project to assist interested signatories to the Cartagena Protocol in establishing national biosafety frameworks;

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<sup>32</sup> “Living modified organisms” means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology (Protocol Article 3). The Protocol entered into force on in September 2003.

- VII. Individual, country-based demonstration projects through any of the GEF Implementing Agencies, to assist in capacity-building to implement national biosafety frameworks;
- VIII. Coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;
- IX. Support to enable countries to participate in the Biosafety Clearing House (BCH), once the terms of reference are agreed upon by the Parties; and
- X. Enhancement of the scientific and technical advice to the GEF on biosafety issues.

The GEF Council, at its November 1997 meeting, approved a Pilot Biosafety Enabling Activity project of US\$ 2.7 million, aimed mainly at assisting eighteen eligible countries to prepare National Biosafety Frameworks (NBFs). Based on the experience of the pilot phase and the provisions of the Protocol, the preparations of national biosafety frameworks would, according the GEF's initial strategy, include:

- (j) assessment/stocktaking to provide information on the status of existing biosafety practices;
- (k) assessment of any existing legal instrument or guidelines that might impact on the use, import or export of living modified organisms (LMOs);
- (l) identification and involvement of all stakeholders relevant to the implementation of the Protocol, to the extent possible;
- (m) identification of actions that need to be undertaken to enable countries to implement the Protocol as well as options and priorities for filling such gaps;
- (n) preparation of a legal framework and/or guidelines necessary for the implementation of the Protocol, including strengthening capacity for risk assessment and risk management, monitoring and inspection services;
- (o) establishment of a roster of experts in a transparent manner and modalities for including them in national, sub-regional and/or regional networks;
- (p) assessment of options for implementation of various elements of the biosafety frameworks, for example at the regional level, and
- (q) identification of sub-regional and regional opportunities for harmonization of regulatory frameworks, identifying regional expertise, and exchanging information on initiatives, collaboration and priority areas for capacity-building; and
- (r) additional features that may be identified by the Intergovernmental Committee for the Cartagena Protocol (ICCP).

All developing countries and countries with economies in transition, which are parties to the Cartagena Protocol, are eligible for funding from GEF—and following the CBD-COP decision 7/20—also parties to the Convention on Biodiversity which were not yet parties to the Protocol, but had provided a clear political commitment towards becoming parties.

## II. Program Components

### *Preparation of National Biosafety Frameworks (NBFs)*

At its November 2000 meeting the GEF Council allocated US\$ 26 million to support about 100 countries to develop NBFs. Another US\$ 5.2 million was allocated in November 2003 for the development of NBFs in 20 additional countries. UNEP is the sole Implementing Agency (IA) for NBFs. Their main project components are:

- a) Development of frameworks through information gathering, analysis, consultation, training and preparation of a draft NBF, including legal instruments, administrative systems, risk assessment procedures, systems for public participation and information;
- b) Arrangements of regional workshops, which aims at increasing the understanding of the Cartagena Protocol on Biosafety and imparting knowledge on the assessment of implications for risk assessment and decision-making at national levels; and
- c) Arrangements of sub-regional workshops focusing on capacity building, cross-national opportunities for collaboration, mechanisms for sharing of risk assessment and management experiences, the coordination of capacity building activities and networking to share lessons and experiences.

### *Implementation of National Biosafety Frameworks*

In 2001 GEF approved 12 individual country demonstration projects on implementation of the NBFs. The project periods are usually three years. The GEF allocation to each country is mostly in the range of US\$ 500,000 to 1 mill. The **“Implementation Projects”** are to be adapted to the country specific situation. The generic activities include:

- (a) Reviewing NBFs and drafting regulations and guidelines to support its implementation;
- (b) Making operational a regulatory and administrative system for handling applications and related biosafety matters
- (c) Setting up decision making mechanisms to handle applications for releases and transboundary movements of LMOs;
- (d) Development and publishing of technical guidelines for risk assessment and risk management, monitoring and enforcement;
- (e) Strengthening capacity of risk assessment/management, including as needed, setting up and/or improving and equipping special laboratories for this purpose;
- (f) Strengthening information systems on LMOs;
- (g) Enhancing public awareness, public education and participation; and
- (h) Setting up of biosafety databases for the purpose of the BCH.

UNEP has the responsibility for the NBF Implementation Projects in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. UNDP has the responsibility for the Implementation Projects in Malaysia and Mexico. The World Bank is responsible for NBF Implementation Projects in India and Colombia.

### **CAPACITY BUILDING FOR PARTICIPATION IN BIOSAFETY CLEARING HOUSE (BCH)**

At its November 2003 meeting the GEF Council allocated US\$ 4.6 million through UNEP for assistance to 50 countries to effectively participate in the BCH of the Cartagena Protocol, whose central portal is administered by the CBD Secretariat. The objective is complementary to the overall biosafety program's objectives, but aims more specifically at developing core human resources to establish the appropriate BCH infrastructure to readily access scientific, technical, environmental and legal information on LMOs to ensure adequate protection in the field of safe transfer, handling and use of LMOs. Whereas the CBD Secretariat is focusing its work on the establishment of a central portal, GEF has supported the development of national BCH components and capacities in the countries to access and use the BCH. About three fourth of the funds were assigned for the training of country officials in managing and operating the mechanism, while one fourth was assigned for procuring equipment (i.a. computers). A proposal by UNEP to extend assistance to an additional 89 countries in the BCH is currently being revised before it will be re-submitted to the GEF Council for comments and the GEF/CEO for endorsement.

### **I. Objective and Key Questions of the Evaluation**

The main objective is to evaluate the efficiency, effectiveness and relevance of the GEF's initial support strategy. The evaluation aims first and foremost to enable decision making in the GEF Council on biosafety activities. The focus will be on four key questions:

- 1) Is the GEF support consistent with the Cartagena Protocol, conducted in a way that takes into account the needs of the recipient countries and is it of sufficient professional quality?
- 2) Is the GEF support to capacity development efforts, including stakeholder involvement and regional collaboration, relevant and effective?
- 3) What progress has been made in countries on building the requisite capacities towards their ratification and implementation of the Cartagena Protocol?
- 4) Are the modalities and approaches of the GEF support effective and efficient compared to similar projects?

The four key questions will guide the choice of methodology for the evaluation as well as selection of countries for desk and field review.

## II. Scope of the Evaluation

The first key issue will focus mainly on the support given to enable recipient countries to develop draft National Biosafety Frameworks (umbrella project for more than 100 countries). The second issue on capacity development will be studied for all three program components. The third issue on results relative to the project objectives will focus mainly on the NBF development project, since the NBF Implementation and BCH projects are not yet sufficiently advanced. The question concerning the cost-effectiveness will compare both NBF development and NBF Implementation approaches with similar approaches in other international efforts to support recipient countries. The focus of the evaluation is shown in the following table.

<b>Issues</b>	<b>NBF development projects</b>	<b>NBF Implementation projects</b>	<b>Biosafety Clearing House support</b>
Are GEF/UNEP toolkits consistent with the Cartagena Protocol and country needs?	Main focus	Reduced attention	Not included
Support for capacity assessment and strengthening, including stakeholder participation and regional cooperation.	Yes	Yes	Yes
Progress towards attainment of the goals of the Protocol	Yes	Reduced attention	Not included
Effectiveness/efficiency of GEF support	Yes	Yes	Reduced attention

The following schematic presentation of the logic of intervention of the three program areas will be used to further develop concrete sub-questions under each key question.

	<b>NBF Development projects</b>	<b>NBF Implementation projects</b>	<b>Biosafety Clearing House support</b>
Inputs	GEF/UNEP's toolkits, regional and sub-regional seminars. technical advice/backstopping	Training, advice, national seminars, etc.	Training
Outputs	Capacity in place to draft NBFs	Capacity in place to implement NBFs	Capacity to access and use the BCH
Outcomes	NBFs	NBF in force and implemented	Effective use of the BCH
Impact	Countries well prepared for entry into force of the Protocol.	Countries have the capacity to fulfill the requirements under the Protocol	Countries are able to exchange information and experience with LMOs and fulfill the information provision requirements under the Protocol.

An initial list of sub-questions of the evaluation is contained in Annex 1. The issues will be further refined and operationalized in subsequent inception reports in an early phase of the evaluation.

### **III. Approach and Methodology**

The Evaluation will be carried out in two parts. The first part will be based on the *Delphi method*, which is a review method for mapping various opinions and exploring further the attitudes of the respondents to specific issues related to the TOR of the evaluation (Annex I, 1.1.). After a first research phase—mainly consisting of a facilitator sending a questionnaire to a group of about 10 selected experts—the facilitator will seek feedback from a bigger group of 50-150 respondents. On the basis of the responses, the facilitator will prepare a synthesis, which he/she sends back to the respondents and asks them to indicate the extent to which they agree with the synthesis, and to make changes –if any– in their own response to the previous questionnaire. After several research and feedback rounds (usually three) the final responses will be edited and reported.

Traditional evaluation methods will be employed by the evaluation team to address the three remaining issues: capacity development; progress towards compliance and cost-effectiveness. The issues of capacity building will be addressed both through desk reviews and field visits. It is estimated that more than 30 NBFs will be available for review by the team. The team will also assess mid-term reviews, progress reports and reports from the regional workshops. The team will select a representative sample of about 20 countries which are in the process of preparing their NBF and some which have reached the next stage and are engaged in the Implementation Projects. About half of these countries will be visited by the evaluation team, while the other half will be interviewed via telephone and mail. The selection of countries for field visits will be made on the basis of a careful analysis of the existing portfolio. The main selection criteria will be geographical coverage, country size, stage of implementation. The evaluation will cover the overall GEF follow up of its initial strategy as well as efforts at the country level implemented by all the three IAs. The evaluation team will address the issue of effectiveness/efficiency of project approaches/modalities partly through the desk and field reviews and partly through comparisons with similar enabling activity projects within and outside the GEF (e.g. enabling activities in climate change and biodiversity).

Both the facilitators of the Delphi approach and the evaluation team will prepare inception reports, which will give further details of approaches and methodology within a period of 4 weeks. The evaluation team will prepare a combined draft final and final report of the whole evaluation.

### **IV. Organization**

The Delphi Review will be tendered to a competent institution. The other parts of the evaluation may be tendered or be managed by the Office of Monitoring and Evaluation. The team members will have a relevant scientific background, evaluation experience as well as work experience in the countries/regions to be covered.

The required competencies of the evaluation consultants are:

- Masters degree or higher qualification in relevant subjects in the social and/or natural sciences;
- Minimum 10 years of experience in evaluation and research in the areas of environment and development;
- Documented experience in the areas of biological diversity and biosafety.;
- Work experience in developing countries and countries with economies in transition;
- Good analytic and writing skills and interpersonal communication skills;
- No conflict of interest with planning or implementation of any GEF support for biosafety.
- Fluency in English; knowledge of Spanish or French is desirable; and

Both the participants in the Delphi methodology and the evaluation team will be vetted on their independent position and to prevent conflict of interest with any GEF support in biosafety or otherwise. Comments to the draft TOR will be solicited from the GEF Secretariat, GEF IAs, the Convention for Biological Diversity, and all other interested parties and groups. The draft TOR will be posted on the website for the Office of Monitoring and Evaluation.

#### **V. Sample of Countries for Field and Non-field Visits**

The criteria for country selection are the following, in order of importance:

1. Geographic representation
2. IA representation
3. Stage of implementation
4. Country size
5. Logistical considerations.

The following countries will be covered in the evaluation:

<b>FIELD VISITS</b>							
<b>Country</b>	<b>Region</b>	<b>IA</b>	<b>Pilot</b>	<b>Development</b>	<b>NBF Complete</b>	<b>Implementation</b>	<b>Country size</b>
Uganda	AFR	UNEP	X			X	
Burkina Faso	AFR	UNEP		X			
China	Asia	UNEP	X			X	Large
India	Asia	WB				X	Large
Croatia	ECA	UNEP		X			
Tajikistan	ECA	UNEP		X	X		
Ethiopia	AFR	UNEP		X			
Morocco	MENA	UNEP		X			
Mexico	LAC	UNDP				X	
Guatemala	LAC	UNEP		X	X		
Bahamas	LAC	UNEP		X			SIDS
<b>NON-FIELD REVIEWS</b>							
Colombia	LAC	WB				X	
Malaysia	LAC	UNDP				X	
Lao PDR	Asia	UNEP		X	X		
Botswana	AFR	UNEP		X			
Bulgaria	ECA	UNEP	X			X	
Chile	LAC	UNEP		X			
Lebanon	MENA	UNEP		X			
Cuba	LAC	UNEP	X			X	
Turkey	ECA	UNEP		X			
Samoa	Pacific	UNEP		X	X		SIDS

## **Appendix 1.**

### ***LIST OF SUB-QUESTIONS.***

The sub-questions are organized in accordance with the two above-mentioned evaluation methods, the three biosafety programs to be evaluated, and a concluding issue which addresses the overall effectiveness and efficiency of the programs.

#### **1. Adequacy of GEF/UNEP Toolkits**

Through the use of Delphi method:

Assess the degree to which the UNEP/GEF toolkits used for the development of national biosafety frameworks are consistent with the Cartagena Protocol, responsive to country needs, and of sufficient professional quality

#### **2. Development of National Biosafety Frameworks**

The evaluation team will assess progress made in selected countries, as well as the adequacy of UNEP's guidance and backstopping efforts. It will especially assess the efforts for:

- 2.1 stocktaking of initial technical and legal capacities and identification of actions necessary for the implementation of the Protocol and the filling of capacity gaps;
- 2.2 general awareness raising of the relevant issues and an enhancement of stakeholders' involvement in the decision-making processes by public and private sector actors, including producers, consumers, academia, NGOs, etc;
- 2.3 strengthening of national capacity for decision-making and implementation of biosafety procedures, including legal and regulatory frameworks, and systems for risk assessments and risk management, monitoring and enforcement;
- 2.4 harmonizing guidelines, regulations or laws through sub-regional agreements, where relevant.

#### **3. Implementation of National Biosafety Frameworks**

The evaluation team will review the overall project progress in the 12 projects currently implemented by UNDP, UNEP and the World Bank, including:

- 3.1 Assess the effectiveness and efficiency of the support provided by the Implementing Agencies and the achievements till now by the countries, in terms of capacity development and other efforts for:

- drafting supportive policies and regulations—in the short and/or long term;
  - setting up of regulatory, institutional and administrative systems for handling of applications and other biosafety matters;
  - development, dissemination and use of technical guidelines for risk assessment, risk management, monitoring and enforcement;
  - achievements in strengthening capacities of risk assessment/management, including setting up and equipping special laboratories, including (prospects for) their use;
  - setting up of information databases to benefit in-country coordination and the BCH.
- 3.2 Assess achievements with regard to strengthening information systems on LMOs and increased public awareness of biosafety issues, and establishment of systems for participation by relevant stakeholders in the various tasks, including public and private sector actors: producers, consumers, academia, NGOs, etc.

#### **4. Biosafety Clearing House of the Cartagena Protocol**

In selected countries the evaluation team shall review initial efforts by UNEP in establishing national systems and capacities for the BCH, including:

- 4.1 Consider UNEP's stocktaking efforts (i.a. the questionnaire survey);
- 4.2. Assess efforts to integrate and coordinate GEF support to the BCH with existing biodiversity and environmental communication and management capacities and tools.
- 4.3. Assess coordination efforts between BCH capacity building efforts in countries and the central portal operated by the CBD Secretariat.

#### **5. Overall Effectiveness and Efficiency of Program Approaches**

The evaluation team shall:

- 5.1. Assess the overall progress made in the implementation of GEF's initial strategy;
- 5.2. Assess complementarity and synergy between GEF's efforts and related activities by other multilateral and bilateral organizations, and whether opportunities for joint actions and/or the pooling of resources have been utilized, as well as GEF's achievements in facilitating collaboration and coordination;
- 5.3. Assess coordination and complementarity between GEF support at the sub-regional, regional and national levels, and achievements in promoting information sharing and collaboration;
- 5.4. Assess timeliness and cost-effectiveness of the Implementing Agencies' efforts, including efforts for delivering co-funding by the three IAs;

- 5.5. Assess systems for financial management, budgeting and accounting and the division of expenditures and costs at the national, regional and overall levels.
- 5.6. Consider the effectiveness of evaluation, monitoring and other feed-back mechanisms;
- 5.7. Analyze the comparative advantage of organizing GEF's assistance as global umbrella projects vs. more limited national or regional programs.
- 5.8. Assess efforts for the enhancement of scientific and technical advice to the GEF on biosafety issues.

## 6. Issues for Follow-up

The evaluation team shall identify key issues for further follow-up by the GEF.

## Appendix II

### Timetable for Biosafety Evaluation

April 4-7, 2005	First team meeting to prepare draft Inception Report, including protocols for interviews, formats for responses and final choice of 20 countries for desk and field reviews.
April 25	Finalization of interview protocols/questionnaires to be sent to GEFSEC/IAs for comments
April 15-30	Interview with the GEF Secretariat, Implementing Agencies, CBD Secretariat, selected other donors
May 2-July 15	Teleconferences with 10 countries
May 2-July 15	Field visits to 10 countries; each country studied by two team members and one local consultants
August 10	All field reports completed
August 22-25-	Full team meeting to decide on report outline and main issues/discussion points/tentative conclusions
September 30	First draft report to be sent to GEFSEC and IAs for comments. Sections on specific countries to be viewed by countries
October 15	Deadline for comments
Oct. 15–Nov. 4	Redrafting and submission of final draft report to Council
January 15, 2006	Final report for printing

### Annex 3. Contents of the UNEP Toolkit

In response to an unmet demand for technical and operational guidance at the country level, UNEP decided it was advantageous to develop a Toolkit. The Toolkit comprises five modules which were completed between December 2001 and November 2004. The contents are as follows:

- **Phase 0 – Starting the Project (*December 20, 2001*):** This first module provides guidance to key project participants (NEA, NPC, NCC) regarding how the project should be managed, including their respective roles, and hiring and/or composition of the NPC/NCC. It also addresses basic questions of government and stakeholder participation in formulation of the NBF.
- **Phase 1 – Taking Stock (*May 17, 2002*):** The second module is intended to provide guidance on completing the various national surveys and preparation of inventories in the different sectors pertaining to biosafety and biotechnology.
- **Phase 2 – Consultation and Analysis (*September 26, 2003*):** This module provides guidance on the identification of stakeholders, the consultation process and analysis of survey findings, and training activities needed to identify the priorities and parameters for drafting the NBF. The module also provides brief advice on priority setting for NBF development, on and identifying and filling gaps from survey finding analyses.
- **Phase 3(i) – Developing the Regulatory Regime (*September 11, 2004*):** This module describes the components of an NBF and presents a number of illustrative examples of various approaches to biosafety regulation. The module also examines broader questions of regulatory decision making and the role of nonsafety considerations, approaches to transparency and public participation, labeling, and inspection and enforcement.
- **Phase 3(ii) – Administrative Systems (*November 30, 2004*):** This module describes establishment of an administrative system to handle applications, locating the risk assessment function, decision-making procedures, public involvement, and other administrative duties of the competent authority(ies). The module also provides examples from different countries related to monitoring, inspection, and enforcement, and explains the common attributes of well-functioning regulatory systems.

## Annex 4. Countries with Completed NBFs Reviewed by the Evaluation Team

	COUNTRY		COUNTRY
1	Argentina	20	Lao People's Democratic Republic
2	Armenia	21	Latvia
3	Belarus	22	Lesotho
4	Burkina Faso	23	Liberia
5	Cambodia	24	Lithuania
6	Republic of Congo	25	Former Yugoslav Republic of Macedonia
7	Côte d'Ivoire	26	Mali
8	Croatia	27	Moldova
9	Czech Republic	28	Niger
10	Estonia	29	The Philippines
11	Georgia	30	Samoa
12	Ghana	31	Senegal
13	Guatemala	32	Slovak Republic
14	Indonesia	33	Slovenia
15	Islamic Republic of Iran	34	Tajikistan
16	Jordan	35	Tanzania
17	Kazakhstan	36	Togo
18	Democratic People's Republic of Korea	37	Tonga
19	Republic of Korea	38	Vietnam

## **Annex 5. Evaluation Team Members**

### **Jarle Harstad, Evaluation Manager, GEF Evaluation Office**

Jarle Harstad, lead monitoring and evaluation specialist in the GEF's Office of Monitoring and Evaluation is the manager of, and a participant in, this evaluation. After graduate studies in geography and economics, he served as a research assistant and assistant lecturer at the University of Oslo, Norway. He has conducted longer term research work in Kenya and Botswana and has also worked for the Kenyan and Ugandan governments. Mr. Harstad has been a senior planning officer and a research and evaluation officer in the Norwegian Agency for International Development and was head of the evaluation division in the Norwegian Ministry of Foreign Affairs, before he joined the GEF in 1996 to establish its monitoring and evaluation unit. Among his other duties are coordination and drafting of monitoring and evaluation policies and methodologies, and management of program, cross-cutting, and GEF-wide organizational evaluations.

### **Donald MacKenzie, Evaluation Co-Chair, Consultant**

Donald MacKenzie is the executive vice president of AGBIOS, a private consulting firm dedicated to providing biotechnology policy, regulatory, and risk assessment expertise. Before joining AGBIOS, Dr. MacKenzie was head of the Science Policy Division within Health Canada and was responsible for the development and coordination of biotechnology policy within the Health Products and Foods Branch. He has also worked in the Canadian Food Inspection Agency as associate director of the Program Issues Coordination Office, where he was responsible for the management of high-visibility issues in the areas of animal and plant health and production, food safety, and consumer protection. Earlier, Dr. MacKenzie had a productive research career spanning the disciplines of biochemistry, plant virology, and plant molecular biology within Agriculture and Agri-Food Canada's Research Branch. He was among the first Canadian researchers to apply plant transformation techniques for the production of transgenic crop species with resistance to plant virus infection. From 1992 to 1997, Dr. MacKenzie was chief of the Biotechnology Section at the Plant Protection Division's Centre for Plant Health.

### **Jeffrey A. McNeely, Evaluation Co-Chair, Consultant**

Jeffrey A. McNeely is chief scientist at IUCN, based in Gland, Switzerland, where he has worked since 1980. He has been deeply involved in the Convention on Biological Diversity from the earliest days, helping to draft the first concept of the convention and attending most of its meetings until the present. He was a co-founder of the Global Biodiversity Forum, which sought to enable civil society to contribute to the work of the CBD. He is the author or editor of over a dozen books on biodiversity, and has recently been working on enhancing the relationship between biodiversity and other fields such as agriculture, human health, and energy. His 2003 book (with Sara Scherr), *Ecoagriculture*, identifies research priorities for linking agriculture with wild biodiversity. He is on the Scientific and Technical Council of the International Risk Governance Council, a member of the Advisory Board of the Sustainable Agriculture Initiative, and a member of the Bureau of the International Assessment of Agricultural Research and Technology for

Sustainable Development. He is also on the editorial advisory board of eight international journals. He has done field work or provided technical advice in over 70 countries.

### **Joshua E. Brann, GEF Evaluation Office**

Joshua Brann has worked with the Global Environment Facility for more than three years, first as a member of the GEF Secretariat biodiversity team, and then as a member of the GEF Office of Monitoring and Evaluation. Prior to becoming involved in the evaluation of GEF biosafety activities, Mr. Brann was a primary contributor to the Biodiversity Program Study and the Overall Performance Study of the GEF. He has also been involved in the GEF Office of Monitoring and Evaluation's annual performance review, and evaluations of the GEF project cycle and the GEF Operational Program on Integrated Ecosystem Management.

Before joining the GEF, Mr. Brann worked for numerous NGOs, including the World Wildlife Fund. He received his M.A. in international relations and economics from the Johns Hopkins University School of Advanced International Studies.

### **Jane Morris, Consultant**

Jane Morris gained her training in biochemistry in Scotland. She worked in the CSIR in South Africa for several years before moving to the University of British Columbia in Canada. On returning to South Africa, she joined a large chemical company, AECI Ltd, where she took responsibility for biotechnology R&D in an industrial environment. She rejoined the CSIR in 1999 and managed its Strategic Technology Group in the division of Food, Biological, and Chemical Technologies before taking on her current role as director of the African Centre for Gene Technologies, a joint initiative of the CSIR and the University of Pretoria to establish a platform in gene discovery.

Ms. Morris has a long association with biotechnology and biosafety in South Africa, having chaired SAGENE, the advisory committee on genetically modified organisms (GMOs) before the GMO Act was passed. In this role, she was actively involved in the drafting of the GMO Act. She assists the South African Department of Agriculture in reviewing applications for use or release of GMOs under the GMO Act, and was recently a member of an appeal board constituted under the act. She has acted as a resource person in various international training activities involving biotechnology and biosafety. She has also served on the national board of the International Council for Science, and has participated in various South African government delegations involved in establishing biotechnology links with other countries.

### **Harold Roy-Macauley, Consultant**

Harold Ransford Roy-Macauley, a native of Sierra Leone, has over 15 years' experience in scientific leadership and has contributed to enhancing the scientific capacity of national agricultural research systems of developing countries—mainly in Africa—in the areas of plant biodiversity improvement and agricultural development. He has work experience with public and private research, training and development institutions/organizations, farmers, and civil society organizations at the Africa-wide and international levels. He is involved in several coordination, planning, and evaluation

processes for the application of modern biotechnology in agricultural research in West and Central Africa. He is also coordinating the Forum for Agricultural Research in Africa initiative for improving and accelerating the development and implementation of biosafety systems for modern agricultural biotechnology. Dr. Roy-Macauley is bilingual in English and French.

**Tomme Rozanne Young, Consultant**

Tomme R. Young is senior legal officer at the IUCN Environmental Law Center in Bonn, Germany. Throughout her 23 years as a lawyer, she has developed a specialized expertise in environmental law and policy, with a focus on natural resource management and integration of environmental legislation with other legislation addressing social policy and commercial objectives. In the field of biosafety, she has focused on issues of national policy and decision making, and the special needs of development of technologically, environmentally, and commercially appropriate legislation in this complex and technical area. Ms. Young has served as a special advisor on environmental and sustainable development issues to foreign governments, under the auspices of several UN agencies. She has advised the governments of more than 30 countries in Europe, Africa, Asia, Oceania, and the Americas on legislative drafting and negotiations and regulatory development. She has participated in the negotiation of international and regional agreements, and has served on the IUCN delegation to several of them. She has prepared advisory white papers on key elements of the Biodiversity Convention and its implementation, as well as on sustainable development, invasive species, environmental protection, resource development, conservation finance, certification, environmental liability/enforcement, and coastal zone management. Prior to entering international work, she represented numerous multinational corporate clients while in private practice.

**Dora Nsuwa Cudjoe, Administrative Consultant**

Dora Cudjoe joined the GEF Monitoring and Evaluation Office as a consultant with the biosafety evaluation team. Prior to this appointment, she gained experience in monitoring and evaluation with the energy and environment unit of the UNDP country office in Ghana, where she undertook mid-term tripartite review of UNDP-sponsored projects. Earlier, Ms. Cudjoe worked with the Environmental Protection Agency in Ghana monitoring health and socioeconomic impacts of certain industrial activities. She reviewed environmental impact assessments for projects.

Ms. Cudjoe holds a master's degree from the Yale University School of Forestry and Environmental Studies in environmental management, focusing on the science and policy of cross-cutting environmental issues. She is Ghanaian.

## **REVIEW FOR THE DELPHI STUDY OF THE UNEP TOOLKIT**

### **Review Team, Vrije Universiteit, Amsterdam:**

Professor T. de Cock Buning, PhD  
F. Haker, MSc  
Professor P. Bereano (University of Washington)  
Dr. J. de Boer, PhD  
Professor J. Bunders, PhD

### **Advisory Panel to the Research Team:**

Dr. J. Cohen	International Food Policy Research Institute, USA
Dr. G. Fuller	Croplife Asia (China)
Dr. O.M. El-Tayeb	University of Cairo
Dr. T. Young	World Conservation Union, Germany
Dr. K. Chnon Lek	Nanyang Technological University, Singapore
D. Mackenzie	Agbios, Canada
J. Mayr	Former Minister of Environmental Affairs, Colombia
P. Phifer	U.S. Fish and Wildlife Service, USA
Dr. E. Bravo	Red por una Americana Latina Libre de Transgenicos, Ecuador

## **Annex 6. Interviewees**

### **A. GLOBAL ENVIRONMENT FACILITY SECRETARIAT**

1. Gonzalo Castro, Team Leader, Biodiversity
2. Patricia Bliss Guest, Deputy Chief Executive Officer
3. Paz Valiente, Senior Environmental Specialist

### **B. UNEP/GEF BIOSAFETY UNIT**

1. Christopher Briggs, Global Development Program Manager, UNEP/GEF Biosafety Unit, Switzerland
2. David Duthie, Information Officer, UNEP/GEF Biosafety Unit, Switzerland
3. Liina Eek, Assistant Regional Coordinator for Central and Eastern Europe, UNEP/GEF Biosafety Unit, Switzerland
4. Giovanni Ferraiolo, Regional Coordinator for Latin American and Caribbean Region, UNEP/GEF Biosafety Unit, Switzerland
5. Charles Gbedemah, Regional Coordinator for African Region, UNEP/GEF Biosafety Unit, Kenya
6. Nizar Mohamed, Regional Coordinator for Asia Pacific Region, UNEP/GEF Biosafety Unit, Switzerland
7. Fee Chon Low, Implementation Project Manager, UNEP/GEF Biosafety Unit, Switzerland

### **C. UNDP**

1. John Hough, UNDP Senior Technical Advisor for Biodiversity, New York, USA

### **D. WORLD BANK**

1. Matthew A. McMahon, Lead Agriculturist
2. Mary Ellen Foley, Task Manager, Biosafety Projects
3. Indira Janaki Ekanayake, Lead Agriculturist
4. Eija Pehu, Adviser, Agriculture and Rural Development
5. Morven Mclean, Consultant to the World Bank, AGBIOS, President

### **E. CBD SECRETARIAT, MONTREAL, CANADA**

1. Cyrie Sendashonga, Head of Biosafety Programme
2. Kirsty McLean, Programme Officer
3. Ryan Hill, Programme Officer
4. Erie Tamale, Programme Officer

## **STAKEHOLDER GROUPS**

### **F. GLOBAL INDUSTRY COALITION ON BIOTECHNOLOGY, USA**

1. Sarah Lukie, Senior Advisor

### **G. THIRD WORLD NETWORK**

1. Lim Li Lin, Researcher

## **H. GLOBAL BIOSAFETY CONSULTANTS**

1. Julian Kinderlerer, Evaluator of the Pilot Phase
2. Pietvander Meer, Biosafety Consultant

## **I. REGIONAL CONSULTANTS**

1. **Mexico, and Guatemala:** Maria Amanda Galvez Mariscal, Professor, Department of Food Science and Biotechnology, Faculty of Chemistry; Coordinator, University Food Science Program, National Autonomous University of Mexico
2. **Croatia:** Jasmina Nicola Ginovska, Local Coordinator, Agriconsulting, Europe S.A Brussels, Macedonia

## **J. NATIONAL CONSULTANTS**

1. **Bahamas:** Sharrah T. Moss, Environmental Education Officer, Exuma Education Resource Centre, Exuma
2. **Burkina Faso:** Jeremy Tinga Ouedraogo, Researcher, Institut de l'Environnement et Recherches Agricoles
3. **China:** Yan Xie, Associate Research Professor, Institute of Zoology, Chinese Academy of Sciences
4. **Croatia:** Meira Bosnić, (formerly) National Project Coordinator for the UNEP/GEF Project
5. **India:** Pushpam Kumar, Lecturer/ Department of Environmental Biology, University of Delhi; Associate Professor, Institute of Economic Growth, Dehli
6. **Morocco:** Ismail El Hadrami, Researcher, Faculte de Sciences Semnalia, Unversite Cadi Ayyad Marrakech, Morocco
7. **Tajikistan:** Shavkat Ismailov, Water and Sanitation Program Manager, International Society of Red Cross and red Crescent Society
8. **Uganda:** Patrick Rutimbanzigu Rubaihayo, Professor, Makerere University

## **FIELD VISITS**

### **I. BAHAMAS**

1. Stacey Moultrie, National Project Coordinator
2. Marcus Bethel, Minister, Health and Environment
3. Elma Garroway, Permanent Secretary, Health and Environment
4. Kenneth Richardson, Chair, National Coordinating Commission (BEST)
5. Donald Cooper, Undersecretary, GEF Operational Focal Point
6. John Hammerton, (retired) Chief Scientist, BEST
7. Maurice Isaacs, Veterinary Officer, Department of Agriculture
8. Ramould Ferreira, Attorney in private practice; Consultant
9. Lynne Gape, Director, Education and Communications, Bahamas National Trust

### **II. BURKINA FASO**

1. Bertrand Zida, Secretary General, Ministry of Environment
2. Samuel Yeye, The Project Coordinator
3. Lompo Zourata, Director Biosafety National Agency

4. Bancé Soumaila, Focal Point, Cartagena Protocol on Biosafety
5. Lambert Ouedraogo, Member, National Coordinating Committee
6. Kabore Marguerite, Member, National Coordinating Committee
7. Albert Ouedraogo Member, National Coordinating Committee
8. Zangré Roger, Consultant
9. Francis Massimbo, Consultant
10. Sourabié Ibrahim, Technical Adviser of the Ministry of Agriculture
11. Zongo Jean Didier, University of Ouagadougou
12. Basile Guissou, Director General, CNRST
13. Boly Hamidou, Director, INERA
14. J. D. Zogo, Coalition veille OGM
15. François Traoré, UNPCB/CPF ; Farmer and Producer Organisations
16. Toguieni, Consumer Organizations

### **III. CHINA**

1. Guangqing Zhu, National Coordinator, GEF Project; Director, Biodiversity and Biosafety Project, State Environmental Protection Agency (SEPA)
2. Andrew Laurie, CTA, GEF-UNDP China Wetland Biodiversity Project
3. Beiwei Zeng, (retired) Hunan Environmental Protection Bureau
4. Bentai Wan, Director General, Department of Natural Protection and Ecology Conservation, SEPA
5. Bill Bleisch, Director, China Program, Fauna and Flora International (FFI)
6. Bin Li, Officer, IUCN, China
7. Biqing Li, Director, Department of Science and Technology, Ministry of Commerce
8. Changju Yang, Professor, College of Environmental Sciences, People's University, China
9. Chaode Ma, Program Manager, Project Management Division, Foreign Economic Cooperation Office, SEPA
10. Dayuan Xue, Researcher, Nanjing Institute of Environmental Sciences, SEPA
11. Dongsheng Liu, Officer, GTZ Project Office, Division of Agro-Resources and Environment, Department of Science, Education and Rural Environment, Ministry of Agriculture
12. Fei Xie, Director of the GEF China Office
13. Guiling Wang, Deputy Director, Project Management Office, UNDP/GEF Conservation and Greenhouse Gas Emissions Reduction in Chinese Township and Village Enterprises, Ministry of Agriculture
14. Haibin Xu, Professor, National Institute for Nutrition and Food Safety, Chinese Center for Disease Control and Prevention
15. Haigen Xu, Researcher, Nanjing Institute of Environmental Sciences, SEPA
16. Haijun Zhao, Program Officer, Project Management Division, Foreign Economic Cooperation Office, SEPA
17. Jianzhi Zhang , Contact person, GEF Project; Officer, Biodiversity and Biosafety Office, SEPA
18. Jie Gong, Project Coordinator, German Technical Cooperation (GTZ)
19. Keping Ma, Deputy Director, Institute of Botany, Chinese Academy of Sciences

20. Kongming Wu, Executive Director, Institute of Plant Protection, Chinese Academy of Agricultural Sciences
21. Lu Yan, Program Officer, Fauna and Flora International
22. Ninan Wu, Program Officer, Project Management Division IV, Foreign Economic Cooperation Office, SEPA
23. Qin Wang, Program Officer, Project Management Division, Foreign Economic Cooperation Office, SEPA
24. Qin Wang, Translator, Program Officer, Project Management Division IV, Foreign Economic Cooperation Office, SEPA
25. Seth Cook, Director, IUCN, China
26. Shuang Gao, Project Assistant, Project Management Office, UNDP/GEF CBD Implementation, Ministry of Agriculture
27. Shuifang Zhu, Deputy Director General, Institute of Animal and Plant Quarantine, Chinese Academy of Quality Inspection and Quarantine
28. Sung Wang, Professor, Institute of Zoology, Chinese Academy of Sciences
29. Sze Pang Cheneung, Campaign Manager, Greenpeace
30. Wang Canfa, Professor, University of Political Science and Law, China
31. Wenjuan Zhang, Executive Assistant, UNEP Office in Beijing, UNEP
32. Wenxuan Yu, Volunteer, Center for Legal Assistance to Pollution Victims
33. Xin Zhi, Division of Transgenic Safety Department, Centre for Science and Technology Development, State Forestry Administration
34. Xingguo Han, Director, Institute of Botany, Chinese Academy of Sciences
35. Xinwu Wang, Deputy Director, Biosecurity Division, Department for Supervision on Animal and Plant Quarantine, General Administration of Quality Supervision, Inspection and Quarantine
36. Xuefeng Sun, Director, Project Management Division IV, Foreign Economic Cooperation Office, SEPA
37. Xuemin Shao, UNEP/GEF Coordinator, UNEP China Office, UNEP
38. Yexu Wang, Senior Program Officer, Foreign Economic Cooperation Office, SEPA
39. Yexu Wang, Senior Program Officer, Project Management Division IV, Foreign Economic Cooperation Office, SEPA
40. Yingfeng Guo, Senior Program Officer, Project Management Division IV, Foreign Economic Cooperation Office, SEPA
41. Zhang Jianzhi, Senior Project Officer, Biodiversity and Biosafety Office, SEPA
42. Zhuyun Wang, Director, Office for Management of Invasive Alien Species, Division of Agro-Resources and Environment, Department of Science, Education and Rural Environment, Ministry of Agriculture
43. Rusong Li, Program Officer, Energy and Environment Cluster, UNDP
44. Ning Li, Director, Biosafety Office of Agricultural GMO, Development Centre for Science and Technology, Ministry of Agriculture
45. Jiancheng Shao, Deputy Director, Biosafety Office of Agricultural GMO, Development Centre for Science and Technology, Ministry of Agriculture
46. Kai Wei, Officer, Biosafety Office of Agricultural GMO, Development Centre for Science and Technology, Ministry of Agriculture

47. Andres Liebenthal, Sector Coordinator, Environment and Social Development Sector, World Bank, Beijing, China

#### **IV. CROATIA**

##### **NCC Members**

1. Davorin Markovic, National Focal Point for Cartagena Protocol on Biosafety
2. Irina Zupan, State Institute, State Institute of Nature Protection
3. Meira Bosnić, National Project Coordinator, National Executing Agency
4. Sanela Ljubenko Mihelj, Croatian National Institute for Public Health
5. Srecko Jelenic, Faculty of Science, University of Zagreb
6. Vida Posavec, Project Assistant, State Institute for Nature Protection
7. Vinko Kozumplik, Faculty of Agriculture, University of Zagreb
8. Vladimir Lay, Institute of Social Sciences Ivo Pilar
9. Zoran Zgaga, Faculty of Food Technology and Biotechnology, University of Zagreb

##### **NGO Members**

10. Helen Lipanovic, Green Istria
11. Irena Brnada, REC Country Office for Croatia
12. Jadranka Pelikan, Eko Zadar
13. Jagoda Munic, Green Action
14. Ksenija Pavlekovic, Society IQL – BIOVEGA Company
15. Nediljko Landeka, Green Istria
16. Sonja Karoglan Todorovic, Ecologica
17. Zdenka Kocmur, Croatian Association for Consumers Protection
18. Zlatko Pejic, Society for Improvement Quality of Living

##### **NEA and Ministry Representatives**

19. Jasminka Radovic, Head, Expertise Division and BFP for CBD, State Institute for Nature Protection
20. Zoran Sikic, Assistant Minister, Minister of Culture

##### **Industry Representatives**

21. Damir Janic, Manager, Biotechnology Products, PLIVA HRVATSKA-Pharmaceutical Company
22. Ita Juros, Croatian Chamber of Economy
23. Maja Zecevic, PODRAVKA d.d.
24. Slaven Racki, Investments Specialist; Environment Protection, PLIVA HRVATSKA- Pharmaceutical Company

##### **Representatives from Croatian Food Agency**

25. Domagoj Simic, Member, Institute for Agriculture, University of Osijek
26. Gordan Lauc, Member of the Panel, Faculty of Medicine, University of Osijek
27. Jelena Zafran Novak, Member, Croatian National Institute for Public Health
28. Krunoslav Capak, President, National Coordinating Committee
29. Sanja Milos, Coordinator, Croatian Food Agency
30. Srecko Jelenic, Member, Faculty of Agriculture, University of Zagreb

##### **Members of the Committee for drafting by-laws for contained use of GMO**

31. Duska Vujaklija, Rudzer Boskovic Institute
32. Gordan Lauc, Faculty of Medicine, University of Osijek

33. Hrvoje Fulgosi, Member, National Coordinating Committee
34. Hrvoje Zorc, Deputy Minister, Ministry of Science, Education and Sport
35. Vladimir Delic, Faculty of Science, University of Zagreb
36. Zoran Zgaga, Faculty of Food Technology and Biotechnology, University of Zagreb

**Representatives of the Ministry of Health and Social Welfare**

37. Ivana Vrhovec, Sanitary Inspector
38. Ivo Africh, Deputy Minister
39. Natasha Fischbach, Sanitary Inspector
40. Ptichek, Sanitary Inspector
41. Zeljko Slemenshek, Sanitary Inspector

There are seven additional sanitary inspectors who's names are not known.

**Ruder Boskovic Institute**

42. Duska Vujaklija, Division of Molecular Biology
43. Hrvoje Fulgosi, Division of Molecular Biology
44. Magdalena Grce, Division of Molecular Biology
45. Mladen Zunic, Director

**GEF Focal Point:**

**Ministry of Environment Protection, Physical Planning and Construction**

46. Nikola Ruzinski, State Secretary, GEF Political Focal Point
47. Gordana Ruklic, GEF Operational Focal Point

**Ministry of Agriculture, Forestry and Water Management (MAFWM)**

48. Branka Bukovic Susic, Veterinary Department, MAFWM
49. Darka Hanel, Institute for Plant Protection, Zagreb
50. Davor Samota, Member of NCC, BIOPA-Osijek
51. Delfa Rados, Forestry Department, MAFWM
52. Djuka marik, Agricultural Inspector, MAFWM
53. Jadranka Micka, Department for Food Industry, MAFWM
54. Miljenko Deskovic, Forestry Department, MAFWM
55. Miljenko Rakic, Division of Agriculture, MAFWM
56. Robert Smolec, Section of Phytosanitary Inspection, MAFWM
57. Snjezana Keresha, Faculty of Agriculture
58. Stanislav Volenik, State Institute for Seed and Seedlings

**Members of Parliament**

59. Boris Varga, External Member, Agriculture and Forestry Committee
60. Miljenko Doric, Member, European Integration Committee
61. Silvano Hrelja, Member, Committee on Labor, Social Policy and Health
62. Zeljko Kurtov, Member, Agriculture and Forestry Committee

**Vegetable Producers and Traders at the Green Market, Zitnjak**

63. Drazen Cacic, Consultant – Head, Vegetable Growers Association, Agricultural Extension Institute

**UNDP Representative**

64. Sandra Balent, Department of Environment Protection

**V. ETHIOPIA**

**Members of the National Administration and National Competent Authority**

1. Tewolde Berhan G. Egziabher
2. Desalegn Mesfin
3. Solomon Kebede
4. Wondweson Sintayehu
5. Belete Geda
6. Mahlet Teshome
7. Tarik Kassa

**Members of the National Coordinating Committee**

8. Hailu Tefera
9. Berhe G. Egziabher

**Technical Experts**

10. Zerihun Woldu, Addis Ababa University

**Members of the National Coordinating Committee**

11. Eshetu Lemma
12. Tsegaye Kidane Mariam
13. Negusu Aklilu
14. Ayele Kebede

**Members of the National Coordinating Committee**

15. Girma Yosef, Ethiopian Science and Technology Commission
16. Mered Kumsa, Ministry of Agriculture & Rural Development
17. Million Habte, International Law
18. G. Medhin Birega, MoARD
19. Alemu Jote, MoARD
20. Ato Desalegn Mesfin, Environmental Protection Authority

**VI. GUATEMALA**

**National Coordinating Committee**

1. Roberto Cobaquil, Chair, National Coordinating Committee
2. Ana Luisa Noguera SE- Consejo Nacional de Áreas Protegidas
3. ( National Executing Agency)
4. Juan Mario Dary, Ministerio de Ambiente y Recursos Naturales
5. Alvaro Orellana, Agricultural Research Institute
6. Nicolás Alfredo Pelíco, Centro de Acción Legal Ambiente y Social de Guatemala
7. Juan de Dios Calle, Vice Ministro del Ambiente y Recursos Naturales
8. Ana del Rosario Aragón, Ministerio de Economía
9. Pablo Eduardo Calderón, (Consejo Nacional de Áreas Protegidas);
10. Consejo de Investigación para el Desarrollo de Ciencias Agrícolas
11. Ana Lucia Orozco, Consultant
12. Joana Cabrera, Liga Del Consumidor (**not a member of the NCC**)

**Instituto de Ciencia y Tecnología Agrícola**

13. Luis Gerardo Molina, Director, Instituto de Ciencia y Tecnología Agrícola
14. Aura Elena Suchini, President, Comité de Biotecnología

**Risk Assessment Focus Group**

15. Ricardo Avila, Technical University, CONAP
16. Hiram Aragones
17. Cesar Azurdia, Consultant

18. Guillermo Godínez, CONOCyT

**Law and Risk Management Focus Group**

19. Alexandra Sobenes, Consultant

20. Juan de Dios Calle, Vice Ministro Recursos Naturales (MARN)

21. Milton Cabrera, MARN

22. Catalina López-Gálvez, National Project Coordinator

**Laboratorio de Fitopatología, Universidad de Valle**

23. Margarita Palmieri, Profesora, Department Head

24. Carlos Rolz, Dean

**Industry representatives and others**

25. Ingrid Barillas, Ministerio de Economía

26. Cristina Rodas, MAGA

27. Fidel Us, Academia de Lenguas Mayas

28. Ricardo Avila, Technical University/CONAP

29. Manuel Rivas, Monsanto

30. Laureando Figueroa, Syngenta

31. Joventino Flores, CONAGRAB

32. Horacio Villavicencio, Algodones Maya

33. Donal Rogozinski, SEMECA

**Delegation of Central American NGOs – *Red de Coordinación en Biodiversidad***

34. Julio Sanches, Friends of the Earth, Nicaragua

35. Fabian Pacheco, Alianza Centroamericano de Protegida a la Biodiversidad, Costa Rica

36. Mario Godínez, Asoc. Ceiba. Guate (also working in El Salvador)

37. Juvencio Chom, *Alianza de Protrgida a Biodiv* (U. San Carlos) Guatemala

38. Representative from *Madreselva*, Honduras

**VII. INDIA**

1. Suman Sahai ,Gene Campaign

2. Tilak R. Sharma, Senior Scientist, National Research Centre on Plant Biotechnology, Indian Agricultural Research Institute

3. V. P. Sharma Meghnad Saha, Distinguished Fellow, The National Academy of Sciences

4. Manju Sharma, Board Member, United Nations University-Institute of Advanced Studies, Japan

5. Prodipto Ghosh, Secretary, Ministry of Enlivenment and Forests

6. Ashok Khosla, President, Development Alternatives

7. K. Vijaya Lakshmi , Manager, Environment Systems Branch, Development Alternatives

8. K. Bhan, Secretary, Department of Biotechnology Ministry of Science & Technology

9. George C. Varughese, Vice-President, Development Alternatives

10. Rachid Benmessaoud Operations Adviser, The World Bank, India

11. Vibha Dhawan, Vice-Chancellor, Teri School of Advanced Studies

12. Sachin Chaturvedi, Fellow, Research and Information System for Developing Countries

13. Bilal H. Rahill, Lead Environmental Specialist, The World Bank, India
14. Manoranjan Hota, Additional Director, Ministry of Environment and Forests
15. M.S. Swaminathan, Chairman, National Commission on Farmers, Ministry of Agriculture
16. G. Kalloo, Deputy Director General, Horticulture and Crop Science
17. C. R. Babu, Vice Chancellor, University of Delhi
18. Suresh Babu, Research Scholar, Centre of Environmental Management of Degraded Ecosystem, University of Delhi
19. Inderjit, Professor, Centre of Environmental Management of Degraded Ecosystem, University of Delhi
20. Meena Gupta, Additional Secretary, Ministry of Environment and Forests
21. R. S. Sharma, Scientist, Centre of Environmental Management of Degraded Ecosystem, University of Delhi
22. D. D. Verma Jt. Secretary, Additional Secretary, Ministry of Environment and Forests
23. Amit Love, Research Scholar, Centre of Environmental Management of Degraded Ecosystem, University of Delhi
24. Prem Narayan Jt. Secretary, Ministry of Agriculture
25. Samar Singh, Executive Director General, WWF India
26. K. Kahrialoo, National Bureau of Plant Genetic Resources, Indian Agricultural Institute
27. Raju Barwale, Managing Director, Mahyco Industries, Mumbai
28. R. K. Sinha Coordinator, All India Crop Biotechnology, New Delhi

## **VIII. MEXICO**

1. Agustín Lopez, National Project Coordinator
2. Omar Trujillo Vazques, Assistant to the National Project Coordinator
3. Manuel Robert, Executive Director, National Biosafety Focal Point
4. Perla Pineda, UNDP Focal Program Officer
5. Jonathan Ryan, UNDP liaison, SEMARNAT
6. Manuel Robert, Executive Director, CIBIOGEM
7. Jose Luis Solleiro, CCADET, Mexico
8. Juan Manuel de la Fuente, Monsanto
9. Francisca Acevedo, Comisión Nacional para el Conocimiento y Uso de Biodiversidad (CONABIO)
10. Johathan Ryan, UNDP/SEMARNAT
11. Concepción Rodriguez, UNAM
12. Maria Colin, Greenpeace
13. Cati Mirelle, GEA
14. Marcelo Signorini Porchietto, Subdirector Ejecutivo de Efectos Poblacionales, Comisión de Evidencia y Manejo de Riesgos Sanitarios, Secretaria de Salud
15. Rocío Madrid, Secretaria de Salud
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