

# EVALUATION OF GEF SUPPORT FOR BIOSAFETY

EXECUTIVE VERSION

## 2006



GLOBAL ENVIRONMENT FACILITY  
EVALUATION OFFICE



**Global Environment Facility  
Evaluation Office**

# **Evaluation of GEF Support for Biosafety**

**Executive Version  
January 2006**

Evaluation Report No. 28

© 2006 Global Environment Facility Evaluation Office  
1818 H Street, NW  
Washington, DC 20433  
Internet: [www.thegef.org](http://www.thegef.org)  
E-mail: [gefevaluation@thegef.org](mailto:gefevaluation@thegef.org)

All rights reserved.

The findings, interpretations, and conclusions expressed herein are those of the author(s) and do not necessarily reflect the views of the GEF Council or the governments they represent.

The GEF Evaluation Office does not guarantee the accuracy of the data included in this work. The boundaries, colors, denominations, and other information shown on any map in this work do not imply any judgment on the part of the GEF concerning the legal status of any territory or the endorsement or acceptance of such boundaries.

#### **Rights and Permissions**

The material in this work is copyrighted. Copying and/or transmitting portions or all of this work without permission may be a violation of applicable law. The GEF encourages dissemination of its work and will normally grant permission promptly.

ISBN: 1-884122-46-9

#### **Global Environment Facility**

Director of the GEF Evaluation Office: Robert D. van den Berg  
Task Manager, GEF Evaluation Office: Jarle Harstad

Biosafety Evaluation Team:

Donald J. MacKenzie, Co-Chair, Consultant

Jeffrey A. McNeely, Co-Chair, Consultant

E. Jane Morris, Consultant

Harold Roy-Macauley, Consultant

Tomme R. Young, Consultant

Joshua E. Brann, GEF Evaluation Office

Dora Nsuwa Cudjoe, Administrative Consultant

Editing and layout: Nita Congress

Printing: Graphic Communications

Cover photo: Anvar Ilyasov

Evaluation Report No. 28

A FREE PUBLICATION

# Contents

<b>Foreword.....</b>	<b>v</b>
<b>1. Main Conclusions and Recommendations .....</b>	<b>1</b>
1.1 Conclusions .....	1
1.2 Recommendations .....	3
<b>2. Background, Scope, and Methodology.....</b>	<b>5</b>
2.1 Background .....	5
2.2 Evaluation of GEF Biosafety Support .....	5
2.3 Initial LMO Country Capacity (National Baselines) .....	6
<b>3. GEF Support for Biosafety .....</b>	<b>7</b>
3.1 Development of NBFs.....	7
3.2 Implementation of NBFs.....	8
3.3 Capacity Building for BCH Participation .....	8
<b>4. Modalities of GEF Support .....</b>	<b>9</b>
4.1 NBF Development Project .....	9
4.2 Individual NBF Implementation Projects.....	10
4.3 Agency Fee Levels .....	10
4.4 Comparative Advantages of the Implementing Agencies .....	12
<b>5. Regional Collaboration, Harmonization, and Coordination .....</b>	<b>13</b>
5.1 Regional and Subregional Workshops.....	13
5.2 Regional Cooperation .....	14
5.3 Coordination with Other Bilateral and Multilateral Organizations .....	15
5.4 Conclusions .....	26
<b>6. Awareness Raising, Public Involvement, and Stakeholder Participation .....</b>	<b>17</b>
6.1 Awareness Raising and Public Involvement .....	17
6.2 Stakeholder Participation in the NCCs.....	18
6.3 Conclusions .....	18

<b>7. Capacity Development in Risk Assessment and Risk Management .....</b>	<b>19</b>
7.1 Risk Assessment in NBF Development Projects .....	19
7.2 Risk Assessment in NBF Implementation Projects .....	20
7.3 Capacity Building in Risk Management .....	20
7.4 Conclusions .....	20
<b>8. Biosafety Policy and Regulatory Development .....</b>	<b>21</b>
8.1 Indicators for Evaluating Policy and Regulatory Outputs .....	21
8.2. Conclusions .....	23
<b>9. Databases and Information: The Biosafety Clearing-House.....</b>	<b>25</b>
9.1 Information Sharing and the BCH.....	25
9.2 Conclusions .....	26
<b>10. Effectiveness of Quality Assurance Tools and Mechanisms .....</b>	<b>27</b>
10.1 Technical Advice from Implementing Agencies .....	27
10.2 Review of the UNEP Toolkit .....	28
10.3 Advice Provided by External Experts .....	29
10.4 Effectiveness of the Global NBF Development Project Umbrella Approach.....	30
10.5 Conclusions .....	30
<b>11. The GEF's Contribution to Progress in Implementing the CPB .....</b>	<b>31</b>
11.1 Speed of Ratification of the Cartagena Protocol .....	31
11.2 Progress in Countries Related to Various Articles of the CPB.....	31
11.3 Advancement toward Compliance and Implementation of CPB.....	33
<b>Acronyms.....</b>	<b>35</b>
Box 5.1: Regional and Subregional Workshops .....	13
Figure 4.1: Suggested Flowchart for Development of a National Biosafety Framework.....	11
Table 3.1: Allocations under the GEF Initial Strategy.....	7
Table 3.2: Implementation Countries by Implementing Agency .....	8
Table 4.1: Total Allocation under the GEF Initial Strategy for Biosafety .....	12
Table 6.1: Level of Public Involvement .....	17
Table 6.2: Inclusiveness of Country NCCs.....	18
Table 9.1: Information Elements in the BCH (as of August 28, 2005).....	26
Table 10.1: Quality, Usefulness, and Timeliness of Technical Advice.....	28
Table 10.2: Assessment of Toolkit Utility in NBF Development Countries.....	29
Table 11.1: Overall Progress Made in Countries to Implement the CPB .....	33

## Foreword

Biotechnology is probably as old as civilization itself. Special methods of food preparation, such as developing drinks from fermenting wheat or fruit, or making cheese, were known in prehistoric times. In recent decades, this old science has seen dramatic new developments. With the recent development of “new” biotechnologies, such as living modified organisms (LMOs), hope was raised that these would contribute greatly to an increase in world agricultural production and thereby help reduce hunger and diseases. However, the emergence of LMOs has also led to concerns about potential harmful effects on the environment and human health. These concerns were addressed through the Convention on Biological Diversity (CBD), which provided a framework to negotiate the Cartagena Protocol on Biosafety, which regulates international transfers of LMOs and aims to reduce risks for human health and the environment. The Protocol has only recently come into force and its provisions have not yet been fully implemented. Concern about the safety of new biotechnologies and their products continues and has led to heated debates among many stakeholders.

The Global Environment Facility (GEF) is the designated financial mechanism for the Cartagena Protocol. The GEF’s initial financing of capacity-building activities in biosafety began in 1997, but increased considerably after the GEF Council’s approval in 2000 of the GEF’s Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety. Given the heated debate on biotechnology in many countries, it is not surprising that opposing voices were also heard regarding the GEF’s support, which was—according to these voices—“not neutral” but then either perceived to be against the biotech-

nology industry or against the opponents of this industry. Not surprisingly in these circumstances, given the amounts of money involved, the GEF Council at its November 2004 meeting requested the GEF Evaluation Office to initiate an evaluation of the biosafety activities financed under the GEF’s Initial Strategy. This report presents the results of this evaluation.

The evaluation found that the GEF’s support was consistent with the Cartagena Protocol. As such it was “neutral” in its approach. This will not mean that the debate on how to approach biosafety and living modified organisms will disappear—it means that the effort can continue to bring more transparency and scientific know-how to these issues, while at the same time allowing stakeholders to express their interests in a clear way. It means that the Cartagena Protocol can continue to grow as the mechanism for international cooperation on this highly controversial issue.

The evaluation contains many valuable findings that will allow the GEF to improve and adapt its support. For example, it was found that countries that already had considerable experience with biosafety issues were better able to utilize the support. The needs of countries with little prior biosafety experience were not as well addressed. The GEF has contributed to building scientific and management capacities in biosafety in all countries evaluated, although the effectiveness of the work varied. A majority of countries had achieved notable stakeholder involvement. The progress regarding regional collaboration had fallen short of the initial planned level of achievement. Nevertheless, the GEF’s support has on the whole had a considerable effect toward preparing countries for ratification and implementation of

the Protocol. The draft evaluation report was discussed in the November 2005 GEF Council meeting, as well as the elements for a new GEF biosafety strategy provided by the GEF Secretariat. This final version of the evaluation will be formally submitted to the Council and will hopefully provide “food for thought” for the new biosafety strategy of the GEF. This means that the management response to this evaluation will be included in the new strategy document and will not be included as an annex to this report.

The manager of the evaluation team was Jarle Harstad of the GEF Evaluation Office. Other members of the evaluation team were Donald MacKenzie of Agbios; and Jeff McNeely of IUCN as evaluation co-chairs; Jane Morris of the African Centre for Gene Technologies; Harold Roy-Macauley of the West and Central African Centre for Agricultural Research and Development; Tomme Young of the IUCN Law Centre; and Joshua E. Brann from the GEF Evaluation Office. Dora Cudjoe assisted the team on administrative and organizational matters.

Special mention should be made of the Athena Institute of the Vrije Universiteit Amsterdam, which undertook a Delphi study of the consistency, usefulness, and professional quality of the United Nations Environment Programme (UNEP) Toolkit that was prepared to support countries in

preparing a national biosafety framework. The complete study is accessible on the website of the Evaluation Office.

The GEF Secretariat, the Implementing Agencies, and the CBD Secretariat gave valuable comments as the evaluation proceeded. Useful inputs were also received from the Global Industry Coalition on the perspectives of the biotechnology industry and the Third World Network on nongovernmental organization perspectives. Thanks for their sincere cooperation are especially due to the many individuals in the 18 countries that were visited or interviewed telephonically. Likewise, the management and staff of the UNEP/GEF Biosafety Office in Geneva were always very forthcoming in providing key documents, data, and information throughout the whole process. Thanks are also due to the 11 national consultants who greatly helped the organization and implementation of the country field visits.

Besides this executive report, which is available in hard copy in English, and in electronic versions in English, Spanish, and French, the full report is available in English on the Evaluation Office’s website and on a CD-ROM.



Rob D. van den Berg  
Director, Evaluation Office



# 1. Main Conclusions and Recommendations

## 1.1 Conclusions

### **Conclusion 1: GEF support has been consistent with the Cartagena Protocol.**

The Global Environment Facility (GEF) has responded very expeditiously and systematically to the request from the Convention on Biological Diversity (CBD) for support to the Cartagena Protocol on Biosafety (CPB). GEF support has at times operated in a sensitive policy environment. Questions have been raised regarding whether the GEF support was neutral and in line with the Protocol. The evaluation team concluded that the United Nations Environment Programme (UNEP), United Nations Development Programme (UNDP), and World Bank have taken pains to remain neutral in this dynamic debate among the various interest groups, and have succeeded in doing so.

A separate Delphi study, carried out by Vrije Universiteit, Amsterdam, shows that 78 percent of the respondents stated that the Toolkit, which was prepared by UNEP as guidance material for the countries, was very consistent/consistent with the Cartagena Protocol. The Toolkit was judged by 79 percent of country participants to be very useful/useful to their country. However, several of the Toolkit modules were not sufficiently timely to be as useful to all countries as they could have been.

### **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. In view of this, it is notable that the Cartagena Protocol's ratifica-

tion 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 contributed to considerable progress toward implementation of the Protocol by enhancing capacity on scientific, administrative, legal, and information management matters, as well as promoting cross-sectoral collaboration and collaboration between the public and private sectors as well as the civil society.

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

For each of the 100 National Biosafety Framework (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 at least 28 to 30 months, even if one of the key indicators on country project achievements had to be scaled down. This was partly due to over-optimistic planning and insufficient supervision resources provided by the GEF.

There was a general recognition in the supported countries that the UNEP regional coordinators and support team were highly committed and hardworking. However, their large subproject portfolios meant that the level of administrative and technical backstopping was too low relative to the complex task of preparing, initially, 100 NBFs. UNEP was not in a position to become 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. In spite of delays and weaknesses in some instances, there has been noteworthy progress in the subprojects. Although there are variations in quality, the completed NBF reports generally provide a good basis for further efforts by the countries.

In contrast, 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.

**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 Biosafety Clearing-House has increased general access to information, even if the data-sharing obligations have not been fully met.**

Nearly all countries have appointed national coordination committees (NCCs) comprising on average 10 to 15 members, with representation from most of the relevant government departments and other institutions/organizations. However, in nearly half the countries, representation on the NCCs is not as broad as advised. At the NCC level, stakeholder participation and involvement were highly variable. In a few cases, some committee members had an inflexible attitude, making cooperation difficult. On the whole, the NBF development projects have strengthened public participation. The evaluation of the 38 NBF reports completed to date showed that 82 percent of the countries have included provisions for public participation mechanisms in their national frameworks.

Efforts aimed at participation and public awareness have been broader in national and sometimes subnational workshops. The funds for this initiative were insufficient relative to the overall needs expressed by the countries.

Significant funds have been allocated by the GEF to promote awareness raising and national participation in the

Biosafety Clearing-House (BCH). The participation has been initiated, even if most countries' data-sharing obligations under the Protocol have not been fully met at this stage. By September 2005, all the NBF implementation countries and nearly a third of the NBF development countries had established national project websites, which could be a useful step toward greater participation in the BCH.

**Conclusion 5: Capacity development in risk assessment and risk management has primarily been of a general and introductory nature. Few countries have as yet effectively integrated biosafety matters with other existing relevant risk management structures.**

As planned, most NBF development projects have organized general introductory courses in risk assessment and risk management. The NBF implementation projects have mostly organized one week of intensive specialists' training.

Progress has been made on coordination of roles and responsibilities among existing regulatory bodies in countries, but this 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 few efforts to explore how capacities under existing systems, such as those for customs and trade, can be extended to support risk assessment and risk management of living modified organisms (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 accession countries.**

Under the NBF development project, UNEP organized 16 regional and subregional workshops to promote information sharing and subregional harmonization. The workshops succeeded well in terms of sharing information and establishing networks and communication lines among key individuals and institutions in the region. However, there

has been little if any progress on formal regional intergovernmental collaboration or harmonization of scientific, legal, and regulatory instruments.

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

The umbrella approach entailed using a uniform coherent approach for all participating countries. Under the circumstances, it greatly facilitated the delivery of assistance expeditiously to the large number of countries requesting assistance, and it entailed economies of scale.

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.

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

Since 1999, total donor funding and government co-funding in biosafety projects in developing countries and countries with economies in transition has amounted to about \$157 million,<sup>1</sup> of which GEF project funding and government co-funding to these projects represents about 55 percent. The remainder has been allocated by about 16 multilateral and bilateral agencies. Cooperation and collaboration among the donors is limited. Relatively little is known about complementarity or duplication among various actors in the donor community. The CBD Secretariat has taken some leadership in information sharing among some key actors at the global level. UNEP has been engaged to some extent in information exchange with other donors, mostly at the country level.

While most donors have treated biosafety separately from related biodiversity, environment, and health matters,

---

<sup>1</sup>All dollar figures in this report are U.S. current dollars.

several countries have considered it in conjunction with the wider issues of biosecurity, agrobiodiversity, alien invasive species, or illegal transboundary movement of endangered species.

## 1.2 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 and implementing NBFs in 142 countries. Future support should be better customized to the respective country conditions and national support better integrated 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 staff than has taken place till now.

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

There is wide support for increased emphasis on awareness raising, public consultation, and information sharing.

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

Future requests 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, multi-country, or regional level.

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

As the GEF role as the financial mechanism for environmental conventions and the number of focal areas expand, further efforts need to be made for integration and the building of synergies among various areas and programs.

## 2. Background, Scope, and Methodology

### 2.1 Background

The GEF is the designated financial mechanism for the Convention on Biological Diversity, as well as for the Cartagena Protocol on Biosafety which falls under the CBD 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. The evaluation of this pilot phase contributed to the development in 2000 of the GEF's Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Protocol.

The Council subsequently approved funding for the global project, Development of National Biosafety Frameworks, which initially covered development of frameworks for 100 countries; it also approved projects in 12 countries for NBF implementation. In 2004 and 2005, the Council expanded NBF development to first an additional 20 countries, and then 10 more countries; it also allocated support for the development of the Biosafety Clearing-House mechanism in 50 countries, with a subsequent add-on for 89 countries. Table 3.1 provides a breakdown of all GEF-funded activities for biosafety capacity building.

### 2.2 Evaluation of GEF Biosafety Support

At its November 2004 meeting, the GEF Council requested the GEF Office for Monitoring and Evaluation (since renamed the GEF Evaluation Office) to undertake an evaluation of the biosafety activities financed under the GEF Initial Strategy.

The final Terms of Reference for the evaluation were approved by the Director of the GEF Evaluation Office on April 20, 2005. 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 the pilot phase projects, the second add-on (10 countries) to the Development of National Biosafety Frameworks Project, or the first add-on (89 countries) to the BCH mechanism project.

The evaluation was accomplished through several tasks:

- **Global Stakeholder Interviews.** The evaluation team conducted interviews with relevant global stakeholders, including the GEF Secretariat, UNEP, UNDP, World Bank, Convention of Biological Diversity Secretariat, Global Industry Coalition on Biotechnology, and Third World Network; representatives of other bilateral and multilateral agencies were also interviewed. The team conducted several in-depth interviews with the UNEP development project team based in Geneva.
- **Field Visits.** The primary component of the evaluation was a series of field visits, each of which was conducted by two members of the evaluation team. Eleven countries—the Bahamas, Burkina Faso, China, Croatia, Ethiopia, Guatemala, India, Mexico, Morocco, Tajikistan, and Uganda—were visited. These countries were chosen to provide a geographic range, as well as a range of project stages and country sizes, and include all three GEF Implementing Agencies.
- **Non-Field Reviews.** To complement its field visits, the evaluation team reviewed eight additional countries—Botswana, Bulgaria, Chile, Colombia, Cuba, Lebanon, Malaysia, and Turkey—mostly through three to five telephone interviews with relevant stakeholders in each country. Although less detailed than the field visits, these reviews gave the team members a more comprehensive picture of the GEF’s overall support.
- **Desk Reviews of NBF Reports.** The evaluation team reviewed the 38 NBFs that had been completed as of June 10, 2005. This in-depth review gave the team a consistent means of evaluating each country’s progress

toward preparation for implementation of the Cartagena Protocol.

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. Of the 19 countries visited or reviewed, 15 had projects implemented by UNEP, and 2 each by UNDP and the World Bank. Two of the countries evaluated are Small Island Developing States (SIDS); three are large countries.

Vrije Universiteit of Amsterdam undertook a subsidiary component of the evaluation by reviewing the UNEP Toolkit used by countries as the primary input for developing their NBFs. The reviewers conducted this evaluation using a questionnaire sent to 500 persons in 30 countries participating in the project as well as other stakeholder groups.

### 2.3 Initial LMO Country Capacity (National Baselines)

The GEF biosafety project documents reveal that there were great variations among countries at project inception with regard to the initial level of LMO activities, as well as availability of policies, institutions, and capacities (national baselines). For the purpose of assessing the progress the GEF had contributed to with regard to implementation of the Cartagena Protocol, the evaluation team made an initial classification of the countries’ initial situation with regard to “high,” “medium,” or “low” baselines. The “high baseline” countries were those that were actively involved in the development and regulation of LMOs at the outset; the “medium baseline” countries were those with some research and field trials; “low baseline” countries were those with little or no LMO involvement. Of the 18 countries that the evaluation team visited or interviewed telephonically, the numbers of countries assigned to the high, medium, and low categories were 5, 4, and 9, respectively.

## 3. GEF Support for Biosafety

The GEF Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Protocol was based on a decision in the Conference of the Parties (COP) to the CBD that designated capacity building as a priority for GEF assistance. Further guidance has been provided by the CBD-COP, especially in decisions V/3, VI/17, and VII/20.

The original GEF Initial 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.

In addition to supporting activities in countries to develop or implement NBFs, the GEF also set out to support country participation in the BCH, promote coordination with other donor organizations, and enhance scientific and technical advice on biosafety matters.

The GEF's total allocation to capacity building for implementation of the Cartagena Protocol is shown 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.

### 3.1 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 NBF projects. The main components of the NBF projects are:

- Development of frameworks through information gathering (stocktaking), 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 decisionmaking 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.

The range of funding for NBF development projects at the individual country level was between \$91,500 and \$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 to \$244,000. The global average for the GEF funding was \$145,184, and the global average for co-financing was \$74,762 (52 percent).

### 3.2 Implementation of NBFs

In 2001, the GEF approved 12 individual country demonstration projects on NBF implementation (see Table 3.2).

**Table 3.2: 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

The project period was typically three years, and the GEF allocation to each country ranged between \$500,000 and \$1 million.

UNEP’s implementation project participants are all countries that had previously participated in the pilot phase. 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.

### 3.3 Capacity Building for BCH Participation

In November 2003 and 2005, the GEF Council allocated \$13.5 million through UNEP for assistance to 139 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.



## 4. Modalities of GEF Support

### 4.1 NBF Development Project

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 (NEA) 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 nongovernmental organizations (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, mobi-

lize 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. There are considerable variations in the breadth of NCC composition, member competencies, and frequency of meetings.

The national project coordinators (NPCs) were chosen by the NEA in consultation with UNEP. They were often a linchpin in the complex cooperation and coordination structures and instrumental in keeping together the large number of participants both from within and outside government. 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.

The proposed time frame for the NBF development projects was 18 months, with three phases comprising 6 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 potential 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.

The evaluation has identified 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. To date, the average duration of NBF development projects has been 28 months among countries that have finished the project thus far. These countries seem to be the “best performers”; the remaining projects will most likely require even more time, even if the scope of one of the key indicators has been reduced.

The UNEP Toolkits prepared a suggested flowchart for the scoping and scheduling of an NBF. This is shown in Figure 4.1.

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. Countries in Latin America and the Caribbean have the shortest average completion time of 24 months, but there were only two completed projects in this region.

## 4.2 Individual NBF Implementation Projects

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 World Bank and UNDP each executed two projects in countries that had not participated in the pilot but that had some experience with LMOs.

The UNEP NBF implementation projects have received more direct assistance (substantive as well as administra-

tive) from the UNEP coordinators 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.

## 4.3 Agency Fee Levels

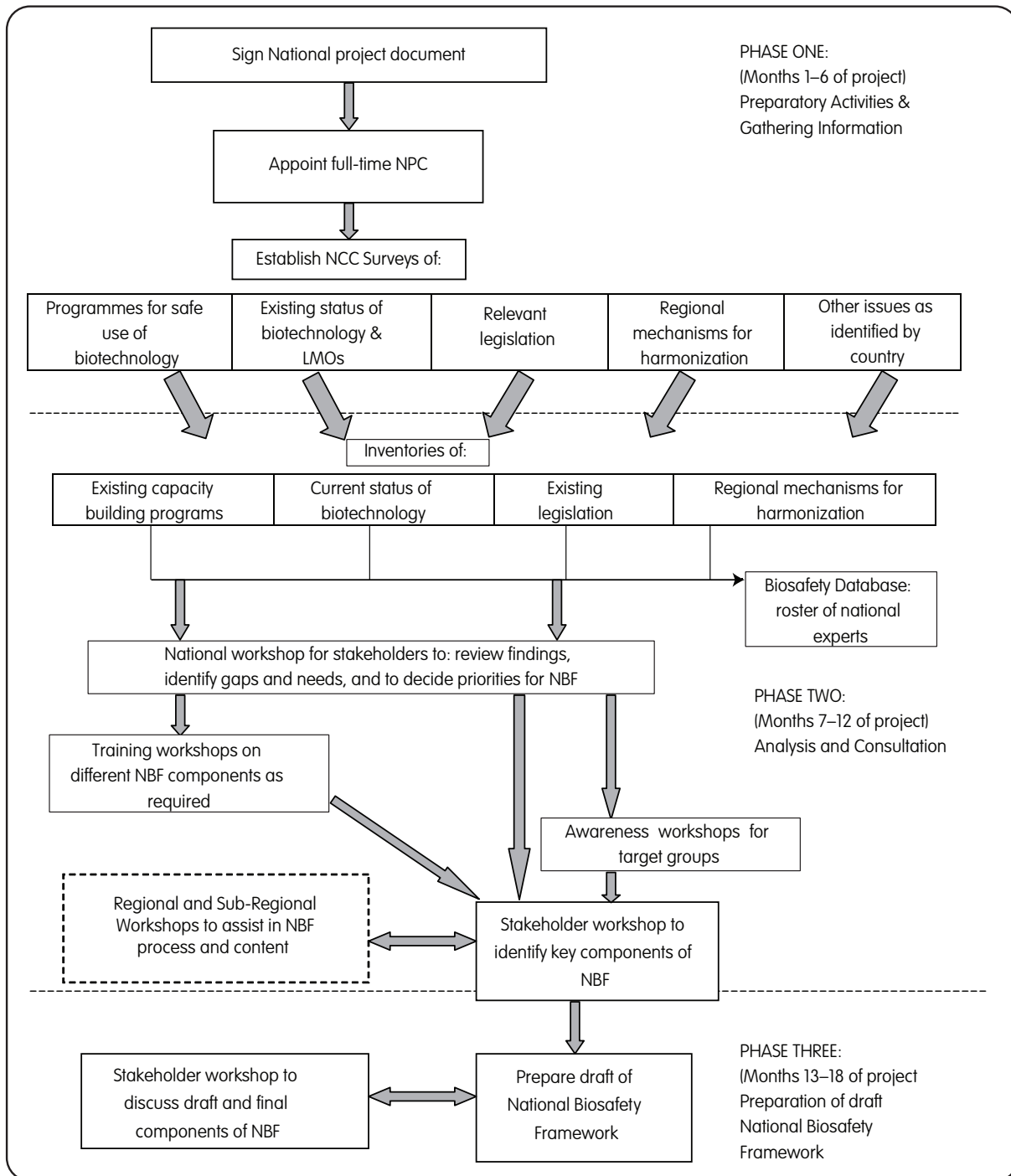
Contrary to the normal GEF fee level of 9 percent, the GEF Secretariat negotiated a fee of 3 percent for the 100 initial NBF development countries. However, in addition to this fee, the project budget included salaries and travel expenses for four regional program coordinators. This indicates that UNEP’s 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 have been 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.

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.

For the 30 additional NBF projects, the normal fee level of 9 percent was reinstated.

Table 4.1 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.

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



Source: UNEP.

**Table 4.1: 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.

#### 4.4 Comparative Advantages 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. Although UNEP now has considerable professional expertise in many aspects of biosafety, 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 World Bank 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 had 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, relatively little advantage is taken of the World Bank's country presence.

UNDP has limited itself to an administrative project oversight role and has drawn on the capacity of the UNEP team for substantive technical backstopping. UNDP centrally decided not to develop as strong a technical capacity as UNEP, and opted for a modest role in the GEF's biosafety program. Through its decentralized structure, UNDP has a strong in-country presence, which has been advantageously used by UNEP in some countries.

## 5. Regional Collaboration, Harmonization, and Coordination

The CPB supports and encourages regional cooperation, coordination, and harmonization on biosafety issues. Such an approach is critical to achieving the Cartagena Protocol's overall objective of managing the transboundary movement of LMOs, particularly given 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.

### 5.1 Regional and Subregional Workshops

The regional and subregional workshops were expected to (1) represent an efficient way of communicating and imparting knowledge to, and exchanging experience among, a large number of country participants; and (2) promote regional and subregional collaboration and harmonization of scientific, legal, and regulatory instruments, which could be a positive contribution to effective management of transfer of LMOs across borders.

#### Workshop Organization and Outputs

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 NEAs and the NPCs. 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.

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 was held at the subregional level and 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

#### 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

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.

### **Workshop Outcomes**

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

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. 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**

Despite the positive feedback from participants, it is unclear whether these workshops 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; moreover, their short duration (only three or four days long) did not provide much 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.

It is unclear how much knowledge transfer occurred once participants 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.

Capacity retention was another challenge faced. Participants who have gained knowledge sometimes do not stay in their current position within government or may leave their home country altogether to pursue opportunities abroad. 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.

## **5.2 Regional Cooperation**

The NBF development project was expected to contribute to potential regional and subregional interaction. In particular, it was supposed to:

- Establish the systems needed for risk assessment, audit of risk assessments and risk management, taking into account national and subregional/regional needs; and
- 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.

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

Direct bilateral or regional activities took a number of different forms in the NBF project. All European Union (EU) accession countries are harmonizing regulations to EU standards; this does not, however, mean that countries not yet acceded to the EU are necessarily collaborating and communicating with other countries.

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, given the preliminary nature of national policy decisionmaking on these issues in the vast majority of countries reviewed in this analysis.

### **Cooperation through Regional Organizations**

The GEF Initial Strategy calls on the NBF Development Projects to explore and maximize possibilities for cooperation through regional organizations, both in order to exchange information and lessons, and to share the costs and burdens of every country creating an operational national system. 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.

Considerable efforts have been made toward exploring options for more regional collaboration under the auspices of subregional organizations in the Caribbean, the Pacific, South Asia, Central Asia, West Asia, West Africa, Southern Africa, and Latin America. However, the initiatives have mostly been made by science institutions or individuals, and most have not led to formal country commitments.

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

The third objective of the GEF 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.

Pursuant to a request by the Intergovernmental Committee for the Cartagena Protocol, the first coordinating meeting was held in December 2000, at which 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.

The CBD Secretariat has further organized two Coordination Meetings for Governments and Organizations Implementing or Funding Biosafety Building Activities, in 2004 and 2005. The meetings have addressed 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.

An ongoing study by the United Nations University had, by June 2005, identified allocations since 1999 to biosafety projects in developing countries and countries with economies in transition to the tune of about \$157 million, of which GEF funding and government co-funding combined represented about 55 percent. The remainder had been allocated by some 16 multilateral and bilateral agencies.

The GEF Initial Strategy's requirements for coordination and collaboration with other multilateral and bilateral proj-

ects is important because, in their 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. The GEF has not yet played an active role in promoting collaboration and cooperation with other organizations assisting the implementation of the Protocol.

## 5.4 Conclusions

The regional and subregional workshops provided participants with valuable opportunities for informal information exchange and networking. To achieve the level of activity called for in the GEF Initial 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 limitations of the regional workshops were recognized already in 2003 in the mid-term evaluation of the NBF development project, which stated: “the programmed funds and events are insufficient to attend the strong demand—

and potential—for subregional cooperation, let alone for in-depth training.”

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 some consistent types of technical or other support could 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.

Although some regional biosafety-related activities are under way, much more progress could be made in this area in the future. A number of organizations and multi-country agreements could play important roles in facilitating regional activities, and important synergies can be achieved through the integration of biosafety measures directly into nascent programs for the promotion of biotechnology research.

Donor coordination at a global level has been quite weak; the objectives of the GEF Initial Strategy in this regard have not been reached.



## 6. Awareness Raising, Public Involvement, and Stakeholder Participation

### 6.1 Awareness Raising and Public Involvement

A factor reported in virtually all the countries visited (and in most of the draft NBF reports reviewed) was the ongoing need to raise public awareness regarding biosafety issues. In many cases, the lack of awareness extended to parliamentarians, relevant government officials, and 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. Others suggested a need to build acceptance among consumers. In still other 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.

Almost all the projects organized workshops, which often consumed a large number of person-days given the very limited resources available (approximately \$15,000 per project). Most of these 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. Many projects also prepared video and audio materials, training packets, and other awareness-raising measures.

Effective public involvement comprises public access to information, transparent decisionmaking by authorities/agencies and public participation, including direct pub-

lic input in decisionmaking. Public participation is distinguished from the majority of the Protocol’s numerous specific requirements by the fact that it is also a separately mentioned objective of the NBF development project. The GEF Initial Strategy underscores this requirement, noting (para. 17[v]) 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 where any use of modern biotechnology is permitted, it is done in an open and transparent way.

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.

In reviewing both aspects of participation during the country interviews, the evaluation team found that public participation objectives were only partially achieved (see Table 6.1).

**Table 6.1: Level of Public Involvement**

Participation	Level of Public Involvement		
	High	Medium	Low
Development projects (12)	2	5	5
Implementation projects (6)	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.

## 6.2 Stakeholder Participation in the NCCs

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 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 summarizes the data. Most of the ratings are either high or low, with few at the medium level. In most cases, representation was found to be well balanced; in a few particularly successful cases, dynamic processes of stakeholder participation actually evolved through the NCC.

**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>
Document reviews (development projects only)	13		13

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

Wide differences in representation were found in the implementation projects managed by the World Bank and UNDP.

The inclusion in some countries of fewer ministries on the NCC could indicate a lack of appropriate capacity in the particular country. However, the apparent absence, in some cases, of representation from the ministries of health, agriculture, and trade is curious. In some countries it may be idealistic to expect all relevant stakeholder ministries to collaborate in a highly effective manner. Ministries are frequently competing for resources, and cooperation is not necessarily high on their respective agendas. Involving civil society can also raise potential challenges to consensus; in some cases, NGOs known to hold strong positions were excluded from the process.

The evaluation considered the actual project outputs with regard to participation in formal governance for biosafety. The team found 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.

## 6.3 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, and high needs at the country level, 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.

Multi-stakeholder cooperation processes on a topic as controversial as biosafety have at times been difficult. Nevertheless, the strong commitment on this matter by the Protocol, as well as the GEF, seems to have brought about a better recognition of its importance. It is noteworthy that most of the completed NBF reports have taken the issues further to institutionalize and propose specific measures for implementation.

## 7. Capacity Development in Risk Assessment and Risk Management

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. On the complex issue of biosafety, 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.

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 evaluation 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 Risk Assessment in NBF Development Projects

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 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.

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.

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 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 that had completed this aspect of the NBFs, although analysis of these rosters indicates that they were not always developed systematically or subjected to evaluative criteria or peer review.

## **7.2 Risk Assessment in NBF Implementation Projects**

The evaluation shows that at least 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.

## **7.3 Capacity Building in Risk Management**

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 (alien invasive species) placed commercial agriculture and food security issues within the realm of potential risks to environmental health, species conservation, and human health. The biosafety projects were rarely connected to other international agreements/instruments under the Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO), or CBD addressing these issues. Although many NBF development countries have identified how administrative and

decisionmaking systems would work in the NBF, the plans have not been put into practice in low baseline countries.

For the majority of countries, internal issues regarding the designation of competent national authority/authorities and coordination among competent authorities once designated, remain yet to be satisfactorily resolved.

## **7.4 Conclusions**

The final selection of national agencies responsible for biosafety 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 have provided a week of intensive training in risk assessment. Few efforts seem to have been directed at building a corresponding administrative, inspection, enforcement, or monitoring capacity. Some country scientists, in both the public and private sectors, have undergone longer term, in-depth practical training in risk assessment and decisionmaking; 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 be assigned to 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 suggest that it will be important to consider potential options relating to integration with risk management procedures having basically identical control mechanisms connected to other international agreements under the FAO, WHO, and CBD.

## 8. Biosafety Policy and Regulatory Development

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.”

To this end, the Protocol requires parties to adopt a number of legislative provisions that are more specific (both in content and operation) than those normally found in international instruments. 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.

The evaluation team studied 38 draft country NBF reports prepared as part of the NBF development project. All of these produced at least some draft legislation. The 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.

### 8.1 Indicators for Evaluating Policy and Regulatory Outputs

To evaluate national legislative implementation, 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. To this end, the following four indicators were identified.

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

This analysis was conducted through desk review of 38 NBF reports, analyzing the inclusion and completeness of specific requirements and provisions mandated in the Protocol. It should be noted that some NBF reports did not address all of these issues. In fact, more than 13 percent were completely 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.

The most basic Protocol requirements—the decisionmaking systems for regular introduction decisions (and, where included, for food, feed, and processing [FFP] decisions)—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).

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

Response to national need is a very broad question; this evaluation specifically looked at the following aspects, which are potentially reflective of response to national need:

1. The inclusion or exclusion of separate processes for FFP; and
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. This point was evaluated by a more in-depth review of completed NBF reports in a single super-regional area—Africa (14 countries). Ten (71 percent) of the African countries whose legislation was specifically reviewed did include some level of special and streamlined decisionmaking for FFPs, while four did not. None of the reviewed NBFs that omitted FFP provisions addressed that omission through any of these other provisions.

**Element b-2: New Law or Law Revision.** This practice of “regulating over” existing laws (either by providing generi-

cally that the current law supersedes 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**

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 judged to be sufficient in terms of primary legal requirements.

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.

Operative omissions (errors that would be sufficient to render the legislation inoperable on its face) were not found in any of the documents reviewed.

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

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.

## **8.2. Conclusions**

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 objective of the GEF projects was to provide technical and legal assistance to that process, to enable countries to apply biosafety principles and obligations in an effective manner that neither unduly restricts LMO activity nor

enables action without appropriate levels of scrutiny and competent risk analysis. The development of insufficient, flawed, invalid, or questionable legislation can be problematic where it gives the unjustified impression of a rigorous system that can create legal certainty.

Overall, the process of legislative development in national subprojects and the provision of technical assistance to that process were found to have mixed results. In high baseline countries, where sufficient legal and legislative experience with biosafety and previous legislative development existed, the projects appeared to provide a forum for further discussions and development. Where baselines were lower, however, the countries' needs for more specific legal advice and assistance were less completely met.

Project performance in legislative/policy development in these countries was inexorably linked to issues of capacity building; peer review; and the creation, review, and utilization of stocktaking processes.





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

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 particularly critical to developing countries with limited ability to fully generate relevant information and/or evaluate individual varieties themselves. Additionally, the BCH is intended to have other roles relating to international information sharing, domestic participation, and public awareness. It is also important for maintaining a national regulatory memory—another key to ensuring that the primary mechanisms of the NBF function sustainably.

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. 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.

The evaluation included field or desk reviews of achievements related to BCH in 53 countries. Of these, 12 countries had created national biosafety websites available in at least one of the three GEF official languages (English, Spanish, and French). 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 and participation efforts.

### 9.1 Information Sharing and the BCH

The NBF development project document includes an indicative allocation of \$15,000 per country for the funding of databases and information technology. 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 country 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. In 2003 and 2005, the GEF Council allocated \$13.5 million for BCH development in 139 countries.

The evaluation team analyzed the amount of data posted on the BCH by the 53 countries reviewed. This included 39 countries that had completed, and 6 countries that had not completed, their NBF development projects, as well as 8 NBF implementation countries.

The number of postings by the 53 countries appears in Table 9.1. The posted data were compared with the total number of entries in the BCH by the 189 potentially contributing countries (“control group”; see footnotes under Table 9.1).

**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>
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

- Rosters of experts 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 data suggest that neither the 53 countries that have received assistance from the GEF in the context of the CPB nor the control group have posted all the data that are required. The low level of posting applies both to countries supported by the GEF as well as those not supported. This suggests that compliance with the Protocol's BCH posting may require more than the provision of additional funding for information development.

The UNEP development project team reports that further progress in this area, including the development of regional BCHs (either regional nodes or regional websites meeting the BCH technical requirements), is ongoing, and will be posted and made accessible soon.

## 9.2 Conclusions

As yet, the information and data-sharing obligations under the Protocol have not been sufficiently addressed, neither generally by parties to the CPB as a whole nor by the work under the projects, to enable the BCH to function. Although not completely addressing many functional needs of the BCH, national websites do demonstrate progress in the collection of some 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 have not been harvested into the BCH, it appears that subproject-created websites have not yet met the requirements for direct use by the BCH.

# 10. Effectiveness of Quality Assurance Tools and Mechanisms

The participating countries and the GEF Implementing Agencies engage in a partnership and have a combined responsibility to ensure project quality and effectiveness. In this endeavor, the partners have a number of tools and mechanisms. This includes recruitment of long-term and short-term staff, preparation and use of guidance materials, organization of surveys and workshops, project planning and reporting, procurement of long-term and ad hoc technical advice, and organization of peer review of final documents.

The evaluation team analyzed the effectiveness of some of the intervention tools and mechanisms available to the two partners (GEF's Implementing Agencies as well as the national executing agencies). The UNEP Toolkit was one of the principal mechanisms for providing both administrative and substantive guidance to participating countries. Given the limitations to direct in-country interaction between UNEP regional coordinators and NPCs, the Toolkit was anticipated, at least partially, to fill the gap.

## 10.1 Technical Advice from Implementing Agencies

A comparison of the quality of advice given by each of the three GEF Implementing Agencies (UNEP, UNDP, and the World Bank) must by necessity be restricted to NBF implementation projects, which were the only common project modality. Since UNDP and the World Bank only managed two projects each, a scientific analysis of relative effectiveness is not possible. Based on general feedback provided by the NPCs and other key project personnel, the evaluation cannot point to statistically significant differences in the

usefulness of the assistance advice provided by each of the GEF's three Implementing Agencies, partly because they operated quite differently and under very different circumstances. The main differences among the three are, first, that UNEP has had a much longer term engagement in biosafety matters and has a much wider professional experience and competence; second, the two other agencies provided assistance mostly to high baseline (and larger) countries, which received higher GEF allocations, while UNEP covered all the low baseline countries.

The World Bank supervised biosafety 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. The approach appeared to be relatively suitable to its partner countries, India and Colombia.

UNDP has made no efforts to build specialist biosafety competence among its regular staff, which consequently provided very limited substantive input to its only ongoing project in Mexico, except through the NPC. Since Mexico is a high baseline country, the approach was quite suitable in this case. A second UNDP project in Malaysia has not started yet, partly due to a change of government, but also partly due to poor communication between the two partners.

Since UNEP implemented the bulk of the biosafety portfolio, this assessment of agency performance is mainly based on its performance. The data are not very comprehensive and do not take some important issues into full account; for instance, whether specific assistance was rendered at the

request of the country or through generic support—for example, at regional workshops.

The quality, usefulness, and timeliness of the technical advice provided to the countries were rarely rated “high.” The scores were especially low in the low baseline countries, while the high baseline countries generally stated that the advice and backstopping were 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 provides the ratings with regard to UNEP’s technical advice, given by participants interviewed in 17 countries visited or interviewed telephonically. (Note that some countries did not respond to all questions.)

The 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—these were primarily countries 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. Available project resources dictated that,

in general, UNEP had to take a low-intensity oversight and feedback approach.

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 was no one with a legal background. The UNEP project team is well regarded for its commitment and hard work.

Concerning UNEP’s involvement on subprojects, two activities to note in particular are the national stocktaking and the peer review system. 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. 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.

## 10.2 Review of the UNEP Toolkit

Between May and August 2005, an email survey of the UNEP Toolkit was carried out by Vrije Universiteit of Amsterdam. A questionnaire was distributed to 500 key stakeholders in 30 countries, plus an additional 40 persons

**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

at the global level, representing academia, other biosafety donors, the biotechnology industry, and NGOs. 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 results show that 78 percent of the 102 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 decisionmaking (38); designing a regulatory regime (36); illegal introduction of LMOs into the country (53); and systems for monitoring, inspections, and law enforce-

ment (50). The last two topics were singled out as requiring most attention.

The main evaluation team assessed the use and utility of the Toolkit through structured interviews with a wider group of potential users in the seven NBF development countries visited. The assessment included the Toolkit’s consistency with country needs, its availability to stakeholders, and level of use in the country. The two surveys are not directly comparable because the issues raised and the selection of respondents were different. Table 10.2 sums up the evaluation team’s assessment of selected 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.

In conclusion, it is the view of the evaluation team that the Toolkit was primarily used by, and proved to be quite useful for, the NPC and some key members of the NCC. It was not widely disseminated and scarcely used by the wider stakeholder groups in the countries.

### 10.3 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.

**Table 10.2: Assessment of Toolkit Utility in NBF Development 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.

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

#### **10.4 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 main umbrella-type allocation, which initially included NBF development projects in 100 countries; 30 more countries were later added.

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 in administrative and financial management of subprojects on a global scale in the GEF's rapid response. 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 umbrella 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 built-in 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 could have had more flexibility for adaptation at the national level, and also included sufficient professional back-up and supervision for country-specific issues.

#### **10.5 Conclusions**

In general, the UNEP Toolkit modules have been found satisfactory by the primary users (project staff and coordinating committee members) 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 various 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 was 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 in all cases, 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.

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

The final step in this evaluation called for an analysis of the following question: What progress has been made in countries in building the requisite capacities toward their ratification and implementation of the Cartagena Protocol? This section summarizes the evaluation team's assessment of the primary indicators of progress toward these goals and the GEF's contribution in this regard.

## 11.1 Speed of Ratification of the Cartagena Protocol

One way of evaluating the speed of the ratification process is by comparing it to other international agreements. Both the Cartagena and Kyoto Protocols have been topics of serious controversy among OECD countries. Such controversy between or among OECD countries is likely to 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 by 125 countries has been relatively rapid, in comparison with other controversial instruments (in this case, the Kyoto Protocol), and with the Convention on International Trade in Endangered Species of Flora and Fauna, 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. At the time of the evaluation, 81 percent (31 of 38) of countries with completed NBFs had ratified the Protocol, while ratification in countries with national subprojects still in progress had been slower.

Based on these facts and other information, the evaluation concludes that participation in the GEF biosafety efforts enhanced awareness of the Protocol at administrative and political levels, and contributed to a speedier ratification by many countries than would otherwise have been the case.

## 11.2 Progress in Countries Related to Various Articles of the CPB

Another indicator is the GEF's support and coverage related to various articles of the CPB.

### Legislative and Regulatory Provisions

Most NBFs have specifically addressed nearly all protocol-required legislative and regulatory provisions. In many cases, issues not directly covered in legislation by the countries 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 GEF efforts have created a functional basis for further work, including reconsideration of

the problems identified above. Viewed in this context, the NBF development project may be seen to represent a significant contribution. At a minimum, 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, and have developed a plan (reflected in each national NBF report) for further regulatory development. This status is significantly more advanced than for other conventions and protocols which have been in existence far longer.

### **Regional Harmonization and Cooperation**

Although the GEF Initial Strategy recognizes that it is early in most regions to expect formal harmonization of legislative and regulatory provisions, the countries did not undertake significant efforts toward investigating options for regional cooperation and harmonization, frequently omitting consideration of this aspect from NBF development processes. The more immediate goal of building a base of regional and subregional networks that could enable the sharing of expertise and information was attained to a much higher extent. This might constitute an intermediate step toward building formal regional institutional structures.

### **Public Participation**

Public participation was strongly promoted by the UNEP project team, and through the Toolkit and other Implementing Agency documents. There have been some significant achievements in this regard, 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. However, the evaluation shows that there is a wider acceptance of awareness raising and more interest in broader public participation in a number of countries, especially in Eastern Europe and Latin America.

### **Capacity Development**

The level of and need for capacity development were often insufficiently assessed in countries. At the global level, significant capacity-building efforts were directed at sensitizing a small core group of actors in each participating country.

Ultimately, more specialized types of collegiate and post-graduate training will be needed in many countries. Pending that, however, other objectives, including efforts to develop regional and other networks among national actors, fill a critical capacity development role.

### **Progress Related to National Coordination and Cooperation**

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 do so for some years.

Practically, in a number of low baseline countries, the need for such capacity is not currently recognized, since LMO development and introduction are not primary issues in their national agendas. Although clearly the GEF has enabled these countries to develop individual and institutional experience at some level, through the networking, sensitization, and informational resources provided, further attention to capacity issues will be necessary in order them to implement the Protocol.

An important institutional component of the GEF efforts was the development of the national coordination committees, created to provide primary domestic oversight and guidance to operations. In many countries, the NCC was both an effective steering committee and a nascent network of key biosafety-related officials and other actors, which provided important tools and experiences for cross-sectoral and public-private partnerships. 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 the GEF project activities.



### 11.3 Advancement toward Compliance and Implementation of CPB

The evaluation identified national baselines of the initial situation regarding LMOs in the sampled countries at the outset of the project and assessed the rate of progress that has been achieved during project implementation.

Various aspects of the achievements have been described and analyzed above. The evaluation concludes that important achievements have been reached by the GEF projects, even if the results vary considerably among countries. The majority of countries have achieved either a high or low rate of progress, while a smaller number of countries have been

given a medium rating. This is shown in Table 11.1; in the sample of 17 countries, 6 attained a high level of progress, 4 a medium level and 7 a low level.

**Table 11.1: Overall Progress Made in Countries to Implement the CPB**

Item	Country	High	Medium	Low
Overall progress made on requisite capacities to implement the protocol	Development projects (11) <sup>a</sup>	3	3	5
	Implementation projects (6)	3	1	2

- a. The level for one country has not been determined due to lack of data.



## Acronyms

<b>BCH</b>	Biosafety Clearing-House	<b>LMO</b>	Living Modified Organism
<b>CBD</b>	Convention on Biological Diversity	<b>NBF</b>	National Biosafety Framework
<b>COP</b>	Conference of the Parties	<b>NCC</b>	National Coordinating Committee
<b>COP-MOP</b>	Conference of the Parties to the Convention on Biological Diversity Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety	<b>NEA</b>	National Executing Agency
<b>CPB</b>	Cartagena Protocol on Biosafety to the Convention on Biological Diversity	<b>NGO</b>	Nongovernmental Organization
<b>EU</b>	European Union	<b>NPC</b>	National Project Coordinator
<b>FAO</b>	Food and Agriculture Organization of the United Nations	<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>FFP</b>	Food, Feed, and Processing	<b>SIDS</b>	Small Island Developing States
<b>GEF</b>	Global Environment Facility	<b>UNDP</b>	United Nations Development Programme
		<b>UNEP</b>	United Nations Environment Programme
		<b>WHO</b>	World Health Organization







Global Environment Facility  
Evaluation Office  
1818 H Street, NW  
Washington, DC 20433  
USA

[www.theGEF.org](http://www.theGEF.org)