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Agenda Item 15

STRATEGY FOR FINANCING BIOSAFETY

RECOMMENDED COUNCIL DECISION

The Council reviewed the proposed *Strategy for Financing Biosafety* (GEF/C.30/8/Rev.1) and approves it as an interim basis for the development of projects for implementation of the Cartagena Protocol on Biosafety until such time as the focal area strategies are approved by the Council. The Council invites the Implementing and Executing Agencies, under the coordination of the GEF Secretariat and based on their comparative advantages, to collaborate with the GEF to provide assistance to countries for the implementation of the Protocol.

I. INTRODUCTION

1. The Cartagena Protocol in Biosafety (CPB) was adopted by the resumed first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity in Montreal, Canada, on January 29, 2000. It was opened for signature in Nairobi, Kenya, on May 24, 2000 and entered into force on September 11, 2003. As of October 2006, the CPB has 135 Parties.

2. The objective of the CPB is “to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on transboundary movements”.

3. In accordance with Article 28 of the CPB, as the financial mechanism of the Convention on Biological Diversity, the Global Environment Facility (GEF) also serves as the financial mechanism of the CPB. As stated in Article 28 of the CPB, the GEF largely supports developing countries, in particular the least developed country Parties and the small island developing States among them, and the Parties with economies in transition, in their efforts to identify and implement their capacity- building requirements for the purpose of the implementation of the Protocol.

II. OBJECTIVE OF THE GEF BIOSAFETY STRATEGY

4. The main objective of this proposed GEF Strategy is to help build the capacity of eligible countries¹ to implement the Cartagena Protocol on biosafety through activities at the national, sub-regional and regional levels.

5. The proposed strategy takes into account the guidance from the Conference of the Parties with respect to the CPB (Annex A), GEF’s mandate, as well as the lessons and experiences emerging from the following processes:

- (a) Experience to date with the implementation of the projects funded under the GEF’s Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety (see Annex B I);
- (b) Results of the independent evaluation of GEF’s support to the Cartagena Protocol on Biosafety, prepared by the GEF Office of Monitoring and Evaluation² (see Annex B III);
- (c) Inputs received from the GEF Council on the Elements for a Biosafety Strategy paper³ presented and discussed at the November 2005 Council meeting;

¹ CBD COP Decision VII/20

²http://www.thegef.org/MonitoringandEvaluation/METThemesTopics/METBiodiversity/documents/Publications_BiosafetyExecVer-ENGLISH-lowres_000.pdf

- (d) Inputs received at a consultative session⁴ held in conjunction with the COP/MOP-3 in Curitiba (Brazil), March 13-17, 2006; and
- (e) Inputs received from the GEF Council on the proposed GEF Strategy for Financing Biosafety Activities⁵, during the June 2006 Council meeting.

III. STRATEGIC FOCUS

6. The following elements⁶ constitute the foundations of this Strategy:

- (a) emphasize regional and sub-regional approaches when suitable to the group of participating countries;
- (b) tailor support to demonstrated country needs;
- (c) focus on in-country coordination and stakeholder involvement;
- (d) involve a broader range of Implementing and Executing Agencies than during the Initial Strategy;
- (e) enhance awareness raising and public participation; and
- (f) foster long-term sustainability of the capacity built through countries' support after project completion.

IV. OPERATIONAL GUIDANCE

Scope and Eligible Activities

7. Priority will be given to activities for the implementation of the CPB, that are specified in the COP guidance to the GEF with respect to biosafety, in particular the key elements in the *Updated Action Plan for Building Capacities for the Effective Implementation of the CPB*⁷, agreed at the third Conference of the Parties serving as the meeting of the Parties to the CPB (COP-MOP-3), and identified in a country's stock-taking analysis. Activities will be developed using both regional and national approaches. Regional approaches will have flexibility to target specific needs of countries within a region.

Stocktaking

³ http://thegef.org/Documents/Council_Documents/GEF_C27/C.27.12_Elements_for_a_Biosafety_Strategy.pdf

⁴ During the margins of COP/MOP-3 two consultation sessions took place, on lessons learnt from the Implementation projects carried out under the GEF initial strategy and on the proposed elements for a biosafety strategy. Both events had a significant participation from IAs, CPB Parties and observers.

⁵ http://www.thegef.org/Documents/Council_Documents/GEF_C28/documents/C.28.5FinancingBiosafetyActivities.pdf

⁶ Strategic Focus reflects the substantive elements of the strategy document *Elements for a Biosafety Strategy* presented to Council in November 2005.

⁷ <http://www.biodiv.org/decisions/default.aspx?id=11059&m=MOP-03>

8. A stocktaking assessment of participating countries will be a first step in project design. The stocktaking phase could comprise an independent⁸ identification and assessment of the following aspects: national policies regarding biotechnology and biosafety, activity regarding the transfer, handling and use of LMOs, regulatory development in the country, status of biotechnology development, existing technical capacity on biosafety issues including risk assessment and risk management, monitoring and enforcement, public information and public participation, possibility of common approaches and synergies at regional or sub-regional levels, among others.

9. The stocktaking assessment will be funded as the first component of the project proposals.

10. The stocktaking exercise should result in targets that are measurable and clearly defined.

Regional and Sub-regional CPB Implementation Projects

11. Providing support to eligible countries through regional or sub-regional projects will be pursued when there are opportunities for cost-effective sharing of limited resources, and for coordination between biosafety frameworks. Regional and sub-regional approaches will be pursued where stocktaking assessments support the potential for coordinating biosafety frameworks, for interchange of regional expertise, and common priority areas for capacity building.

12. Regional and sub-regional projects will have components for implementation of the CPB at national level and components for its implementation at regional and sub-regional levels. Eligible activities at both levels will be those identified in the stock-taking analysis and are contained in the COP guidance to the GEF with respect to biosafety, in particular those indicative tasks suggested in the *Updated Action Plan for Building Capacities for the Effective Implementation of the CPB*, to be undertaken at different levels to implement its key elements.

13. Regional and sub-regional support for the implementation of the CPB will usually be provided through full sized projects. Funds for regional and sub-regional projects will be drawn from country allocations⁹ for biodiversity under the Resource Allocation Framework (RAF). Such projects should produce high potential for leveraging additional funding, high replication potential, and/or high cost-effectiveness.

Country-Level CPB Implementation Projects

⁸ Independent in this context means that the assessment is undertaken by experts /organizations that are not directly involved in subsequent project execution. Experts/organizations will have outstanding biosafety knowledge and will be proposed by the participating countries.

⁹ http://thegef.org/Operational_Policies/Resource_Allocation_Framework.html

14. Single-country projects will be implemented when the characteristics of the eligible country, as assessed in the stock-taking analysis, and the design of existing or planned future regional or sub-regional efforts in the area, recommend a national approach for the implementation of the CPB in that country.

15. Eligible activities will be determined by a stock-taking assessment, among those tasks considered in the *Updated Action Plan* for the implementation of the CPB at national level.

16. Support to country-level CPB implementation projects will usually be provided by medium-sized projects and funded from country allocations in the biodiversity focal area under the RAF.

Issue-Specific Multi-country or Regional Projects

17. An issue-specific approach can be an effective way to support groups of countries lacking competence in particular fields and assist them to build their capacities in that field. This multi-country approach will be pursued where stocktaking assessments support the needs of eligible countries and on the basis that this approach would foster the pooling of resources, economies of scale and international coordination.

18. Issues and activities supported will be any of those foreseen in the *Updated Action Plan* that target specific needs of the group of countries and could benefit from an issue-specific approach.

19. Support will be provided through full or medium sized projects, depending on the number of countries, their needs and the selected issue. Funds will be drawn from country allocations for biodiversity under the RAF.

Avoiding Duplication

20. In reviewing project proposal for biosafety projects, the Secretariat will work with the agencies to ensure that there is no duplication of financing for any country that may participate in more than one type of project (regional, sub-regional, national or issue specific.)

Focus on in-country coordination and stakeholder involvement

21. Special attention will be paid to ensuring in-country coordination of roles and responsibilities, and stakeholder involvement, in the development and implementation of project activities. To this end, projects will clearly define the role of a national coordination mechanism, including the promotion of synchronized and synergistic implementation of capacity building activities and the synergetic use of donor assistance.

22. The extension of existing national capacities for risk assessment and risk management, such as those for customs and trade, to support risk assessment and risk management of living

modified organisms will be explored by the GEF Secretariat in consultation with STAP and pursued where appropriate.

Involvement of a broad range of Implementing and Executing Agencies

23. The implementation of this strategy requires advantages and skills provided by different Agencies. The flexibility in project design and contents envisaged in this strategy will create the necessary conditions for a wide participation of Implementing and Executing Agencies, under the coordination of the GEF Secretariat and based on their comparative advantages, in the GEF support for the implementation of the CPB.

24. Coordination of biosafety capacity building efforts supported by the GEF will be enhanced through the establishment of a steering committee to ensure that biosafety projects are executed in alignment with the GEF Strategy. The steering committee will include relevant GEF Agencies, CBD Secretariat representatives and will be chaired by the GEF Secretariat.

25. Proposals to be funded will be implemented by Implementing and Executing Agencies based on each agency's comparative advantage.

Awareness raising, public participation and information sharing

26. Activities such as awareness raising, education on biosafety, access to information and public participation on decision making will be fully incorporated in project design.

27. The role of the Biosafety Clearing House (BCH) is essential as an information sharing mechanism. In this context, further efforts will be made to support the full participation of eligible countries in the BCH.

Long-term training in risk assessment and risk management

28. Long-term training in risk assessment and risk management will be incorporated into project design where stock taking assessments indicate there is a need.

Sustainability

29. GEF will only support project proposals that demonstrate ways in which participating countries will promote the continuation of activities to implement the CPB after the end of the GEF support.

30. Sustainability will be reflected in:

- (a) Development of a national biosafety strategy, which includes a national biosafety capacity-building strategy and action plan, will support biosafety activities over the long-term.

- (b) Designation of competent authorities and the creation of a national coordination mechanism, recognized in the regulatory framework, will support the necessary institutional sustainability.
- (c) Biosafety management costs will be incorporated into the national accounts and budgets to provide financial sustainability for the biosafety policy.
- (d) Environmental sustainability will be supported through the development of national regulatory systems that incorporate principles and requirements of the CPB into the national legislation and national sustainable development policy.
- (e) National implementation and operation of NBFs will be supported through capacity building (institutional and human resources).
- (f) Regional cooperation and south-south cooperation, where this approach has been promoted. Such cooperation can help build a critical mass of scientific and other expertise in each region for the benefit of the region as a whole.
- (g) Whenever expressed by the participating countries, participation of political/economic regional and sub-regional organizations will be sought to promote mainstreaming and sustainability.

International coordination

31. Coordination of efforts at the international level will be enhanced through the exchange of information, by collaboration, and working through the *Coordination Mechanism for the Implementation of the Action Plan for Building Capacities for the Effective Implementation of the CPB* (annex IV to Decision BS-I/5¹⁰). Complementarity with other existing biosafety capacity building initiatives will be stressed to ensure maximum synergy among different efforts. Wherever possible, GEF-funded biosafety capacity building projects will be linked¹¹ to existing bilateral and multilateral biosafety projects that implement the CPB to ensure maximum synergy.

IV. MONITORING AND EVALUATION

32. The monitoring plan of this strategy will provide information to any subsequent evaluation, especially with regard to effectiveness and efficiency.

33. Decision BS-I/5¹² of the COP-MOP, contains a set of criteria and indicators for monitoring implementation of the CPB capacity building Action Plan. In paragraphs 27 and 28 of the decision, Parties, other Governments and relevant organizations are invited to use them, as appropriate, to monitor their biosafety capacity-building initiatives being implemented in support of the Action Plan (see Annex C).

¹⁰ <http://www.biodiv.org/doc/meetings/bs/mop-01/official/mop-01-06-add2-en.pdf>

¹¹ The linkage will not entail shared financing of individual projects but rather complementarity of activities within an intervention.

¹² <http://www.biodiv.org/decisions/default.aspx?id=8287&m=MOP-01>

34. In addition to the indicators contained in Decision BS-I/5, the following indicators will be undertaken at the program level:

	Indicators	Targets	Sources of Verification
Outcome: Operational national biosafety decision-making systems that contribute to the safe use of biotechnology in conformity with the provisions and decisions of the Cartagena Protocol on Biosafety.	Percentage of participating countries with regulatory and policy framework in place	75%	Project reports, final evaluations
	Percentage of participating countries that have established a National Coordination Mechanism.	75%	Project reports, final evaluations
	Percentage of participating countries with administrative frameworks in place	75%	Project reports, final evaluations
	Percentage of participating countries with risk assessment and risk management strategies for the safe transfer, handling and use of LMOs, specifically focused on transboundary movements.	75%	Project reports, final evaluations
	Percentage of participating countries that have carried out risk assessments	75%	Project reports, final evaluations
	Percentage of participating countries that fully participate and share information on the BCH	75%	BCH Central Portal Statistics
Output 1. Support provided for biosafety implementation to all GEF eligible countries	Number of countries successfully completing CPB implementation projects as a proportion of the participating countries.	75%	Project documents, GEF project database
Output 2. Targeted support to build capacity on thematic issues of importance at the regional level.	Number of countries successfully completing regional biosafety projects as a proportion of the participating countries.	75%	Project documents, GEF project database

V. RESOURCE ENVELOPE

35. Under the Resource Allocation Framework, each country will decide the amount it wants to dedicate from its biodiversity allocation to biosafety capacity building and this will decide the final amount that GEF invests in biosafety during GEF-4. The envelope set aside to implement

this strategy and meet country demand during GEF-4 is \$90 million. (Doc. GEF/C.29/3: *Summary of Negotiations on the Fourth Replenishment of the GEF Trust Fund*)¹³.

¹³ http://www.thegef.org/Documents/Council_Documents/GEF_29/documents/C.29.3SummaryofNegotiations.pdf

36. **Annex A: EXISTING GUIDANCE FROM THE COP**

The seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (COP7) approved Decision VII/20 on further guidance to the financial mechanism. This Decision incorporates decisions prepared by COP/MOP1 regarding support for biosafety activities.

The Conference of the Parties serving as the meeting of the Parties to the CPB, at its second meeting held in May-June 2005, approved Decision BS-II/5, encouraging the GEF and the Executive Secretary of the Convention to continue their strong collaboration in advancing support to the implementation of the Protocol and to further develop its funding modalities for organizing its support to the Protocol in a systematic and flexible manner.

The Conference of the Parties, serving as the Meeting of the Parties to the CPB, at its third meeting held in March 2006, approved Decision BS-III/3 on Capacity-Building that includes the Updated Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety.

The Updated Action Plan considers the following key elements requiring concrete action:

Key elements requiring concrete action:

1. *The following key elements are meant to be considered in a flexible manner, taking into account the different situations, capabilities and stages of development in each country.*

- *Institutional capacity-building:*
 - (i) *Legislative and regulatory framework;*
 - (ii) *Administrative framework;*
 - (iii) *Technical, scientific and telecommunications infrastructures;*
 - (iv) *Funding and resource management;*
 - (v) *Mechanisms for follow-up, monitoring and assessment;*
- *Human-resources development and training;*
- *Risk assessment and other scientific and technical expertise;*
- *Risk management*
- *Awareness, participation and education at all levels, including for decision makers, stakeholders and the general public;*
- *Information exchange and data management, including full participation in the Biosafety Clearing-House;*

- *Scientific, technical and institutional collaboration at sub regional, regional and international levels;*
- *Technology transfer;*
- *Identification of living modified organisms, including their detection;*
- *Socio-economic considerations;*
- *Implementation of the documentation requirements under Article 18.2 of the Protocol*
- *Handling of confidential information*
- *Measures to address unintentional and/or illegal transboundary movements of living modified organisms;*
- *Scientific biosafety research relating to living modified organisms;*
- *The taking into account risks to human health.*

The Conference of the Parties to the CBD, at its eighth meeting held in March 2006 in Curitiba (Brazil), approved Decision VIII/18 on Guidance to the Financial Mechanism. This Decision incorporates decisions prepared by COP/MOP3 regarding support to biosafety activities.

Decision VIII/18, on Guidance to the Financial Mechanism, states:

Cartagena Protocol on Biosafety

9. *Requests the Global Environment Facility to provide an assurance that the introduction of the Resource Allocation Framework will not in any way jeopardize eligible Parties' access to funding for biosafety-related activities including regional activities where appropriate;*

10. *Requests the Global Environment Facility to base their allocation of resources to support the implementation of the Protocol on country needs and priorities, and as a priority to support the establishment of a base level of capacity in all eligible developing country Parties, in particular the least developed and the small island developing States, and Parties with economies in transition;*

11. *Urges the Global Environment Facility to support in-country, regional and sub-regional stock-taking studies to enable:*

(a) *The better planning and customizing of future assistance to the respective needs of eligible countries, given the fact that a "one-size-fits-all" approach to biosafety has been demonstrated to be inappropriate;*

(b) *The identification of clear and realistic targets;*

(c) *The identification and provision of technical and adequately experienced expertise for the implementation of national biosafety frameworks;*

(d) *The development of effective coordination which facilitates the support, ownership and involvement of all relevant national ministries and authorities, to ensure synergy and continuity;*

12. *Requests the Global Environment Facility to support:*

(a) *The provision of longer-term support for building, consolidating and enhancing sustainable human resource capacity in risk assessment and risk management, and also in developing detection techniques for identifying living modified organisms;*

(b) *Awareness-raising, public participation and information sharing, including through the Biosafety Clearing-House;*

(c) *Coordination and harmonization of national biosafety frameworks at regional and sub-regional levels, where appropriate;*

(d) *Sustainable national participation in the Biosafety Clearing-House, including capacity building, to take into account the need for Parties to be able to provide summary information in the common formats for reporting information (particularly keywords for categorizing records) in an official language of the United Nations to enable registration of such information with the Central Portal;*

(e) *Transfer and joint development of technology in risk assessment, risk management, monitoring and detection of living modified organisms;*

(f) *Development and implementation of national biosafety frameworks;*

(g) *Development of technical, financial, and human capacity including postgraduate education, biosafety-related laboratories and relevant equipment;*

(h) *Implementation of the revised Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety;*

(i) *Facilitation of the consultative information-gathering process leading to the preparation of national reports under the Protocol for those developing country Parties, in particular the least developed and small island developing States, and Parties with economies in transition, which lack sufficient capacity in this regard;*

13. *Invites the Global Environmental Facility, developed country Parties and Governments, as well as relevant organizations to take into account the revised Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety and increase their financial and technical support to developing countries and countries with economies in transition for its implementation;*

Annex B: GEF BIOSAFETY SUPPORT TO DATE

I. Initial GEF Strategy on Biosafety

After the adoption of the CPB, the GEF Council, at its meeting in November 2000, approved an Initial strategy to assist countries to prepare for the entry into force of the Cartagena Protocol.

The activities proposed in the strategy were aimed at:

- (a) assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national Biosafety frameworks, including strengthening capacity for risk assessment and management with a wide degree of stakeholder participation;
- (b) promoting information sharing and collaboration at the regional and subregional level and among countries that share the same biomes/ecosystems, and
- (c) 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.

Under the biosafety initial strategy the following projects have been approved by the GEF Council:

- (a) A global project on the “Development of National Biosafety Frameworks” (NBF project). The project is being managed by UNEP and is currently assisting more than 120 countries to establish their NBFs.
- (b) A global project on “Building Capacity for the effective participation of Parties in the Biosafety Clearing House” (BCH). This project, implemented by UNEP, is assisting 139 countries to participate in the BCH.
- (c) Twelve demonstration projects on “Implementation of National Biosafety Frameworks”. Two projects are managed by UNDP (Malaysia and Mexico), eight projects are managed by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and two projects (India and Colombia) are managed by the World Bank.

The total amount allocated to these projects is 56,466,908 USD.

It was agreed that, based on the experience gained through the undertaking of activities proposed in the initial strategy, the results of the Capacity Development Initiative, and the guidance of the Conference of the Parties to the Convention on Biological Diversity once the Protocol entered into force, the GEF would present to the Council for its consideration a strategy for advancing and building upon the activities undertaken in the initial strategy.

II. Cartagena Protocol on Biosafety Entering into Force

On September 11, 2003, the CPB entered into force and the first meeting of the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP1) was held on February 2004.

The GEF Council, at its meeting in May 2004, welcomed the guidance of the Conference of the Parties to the CBD inviting the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries.

At the November 2004 Council meeting, the GEF Council requested the Office of Monitoring and Evaluation (OME) to undertake an evaluation of the activities financed under the Initial Strategy. The evaluation, to be finished by November 2005, was expected to provide valuable information and lessons for future GEF support aimed at building capacity to implement national biosafety frameworks at the country level.

The Council, at its June 2005 meeting, approved an interim approach to the financing of biosafety capacity building activities, pending the completion of the evaluation. The Council also requested the Secretariat to prepare, in consultation with the Implementing Agencies and having into account the results of the evaluation, a proposed strategy on the most efficient and effective means to provide additional support to countries to strengthen their capacity to implement national biosafety frameworks, as called for in the guidance of the Convention.

The approved interim approach seeks to support countries with urgent needs to move forward in implementing their NBFs through 10 to 15 medium sized projects, similar in scope, activities and financing to the demonstration projects implemented under the initial strategy. In addition, it was agreed that support would be provided through one to two projects aimed at strengthening developing country regional centers of excellence to enable those centers to assist countries in the region in implementing their NBFs.

III. Office of Monitoring and Evaluation (OME) Evaluation of the GEF Initial Strategy on Biosafety.

At its November 2004 meeting, the GEF Council requested that the GEF Office of Monitoring and Evaluation undertake an evaluation of the activities financed under the initial strategy approved by the Council in May 2000 for helping countries prepare for the entry into force of the Cartagena Protocol. The GEF Office of Monitoring and Evaluation presented a draft of the evaluation on GEF's support to the Cartagena Protocol on Biosafety (Doc. GEF/ME/C.27/Inf.1/Rev.1) to the GEF Council, during its meeting held on November 2005.

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)

A. Objectives

The main objective of the evaluation is to evaluate the efficiency, effectiveness and relevance of the GEF Initial Strategy on Biosafety. The evaluation has focused on four key questions:

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

B. Main conclusions of the evaluation

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 with the Cartagena Protocol. The Toolkit was judged by 79 percent of country participants to be very 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 Organization for Economic Co-operation and Development (OECD) countries. In view of this, it is notable that the Cartagena Protocol's ratification has been relatively rapid. The ratification process has been directly influenced by the initiation, and especially the completion, of the GEF projects.

Besides promoting ratification, the GEF has 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 sub-national 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, 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, several countries have considered it in conjunction with the wider issues of biosecurity, agrobiodiversity, alien invasive species, or illegal transboundary movement of endangered species.

C. Recommendations

The conclusions of the 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.

D. Incorporation of Recommendations in the Present Biosafety Strategy

The evaluation carried out by the OME has provided valuable information and lessons for future GEF support aimed at building capacity to implement national biosafety frameworks, as requested by the Conference of the Parties.

The proposed GEF strategy for financing biosafety activities takes into account the conclusions gathered from the OME of the GEF Initial Strategy on Biosafety and has been designed building upon the recommendations of the report.

A management response to the evaluation has been prepared by the GEF Secretariat in collaboration with the Implementing Agencies and is before the Council as document GEF/C.30/8.

A set of detailed technical responses prepared by UNEP was provided as Information document GEF/C.28/Inf.9 to the June 2006 Council meeting¹⁴.

IV. Elements of the GEF Biosafety Strategy for the Implementation of the Cartagena Protocol on Biosafety.

The GEF Secretariat, in consultation with the Implementing and Executing Agencies, and based on (i) CBD COP Guidance, (ii) GEF's mandate, operational strategy, Council decisions, and procedures, (iii) the findings of the OME Evaluation, and (iv) the GEF-4 Programming Document, presented to the Council document GEF/C.27/12, Elements for a Biosafety Strategy.

During its meeting in November 2005, the Council reviewed the proposed Elements for a Biosafety Strategy and welcomed the substantive elements (recognizing that funding is a

¹⁴ http://www.thegef.org/Documents/Council_Documents/GEF_C28/documents/C.28Inf.9UNEPResponse.pdf

separate issue) as a basis for developing a strategy to guide the provision of GEF assistance to support the Cartagena Protocol on Biosafety, taking into account the comments made at the Council meeting. The GEF Secretariat was invited to prepare, in consultation with the Implementing and Executing Agencies, a draft biosafety strategy for Council review and comment in early 2006. On the basis of the comments received, and taking into account the outcomes of COP/MOP-3 in March 2006, the Secretariat would prepare a proposed strategy for Council review and approval by mail prior to the Council meeting in June 2006.

Council members comments made on this issue are recorded in the Joint Summary of the Chairs of GEF Council Meeting held in November 8-10, 2006¹⁵.

¹⁵ http://www.thegef.org/Documents/Council_Documents/documents/JointSummaryofChairs-RevisedNovember30_000.pdf

Annex C:

SET OF INDICATORS FOR MONITORING IMPLEMENTATION OF THE ACTION PLAN FOR BUILDING CAPACITIES FOR THE EFFECTIVE IMPLEMENTATION OF THE PROTOCOL

1. The set of indicators presented below is intended for use in tracking the overall progress in implementing the Action Plan, encompassing the overall cumulative contribution of different capacity-building projects and other activities. The indicators are not intended for use in measuring the results of specific individual capacity-building projects. Such indicators would need to be developed on a case-specific basis.

2. In the set of indicators outlined below, four main types can be identified, namely: "indicators of existence", "indicators of status", "indicators of change" and "indicators of progress towards an endpoint". The first type includes indicators that show whether something exists or not (i.e. yes/no), e.g. existence of laws and regulations. Status indicators include actual values/ levels of a given parameter, either quantitatively (e.g. number of people, percentage of people) or qualitatively (e.g., low/medium/high). The "indicators of change" show variation in the level of a given parameter, either increase/decrease or positive/negative. Indicators of change are measured in comparison to a starting point in time or in terms of progress towards and endpoint. In some cases, the measurement may be quantitative (e.g. change in number of staff), and in other cases it may be qualitative (e.g. change in level of satisfaction). They may also show overall trends or pattern of change.

Desired outcome (based on Action Plan elements)

Criteria and indicators

A. Improved institutional capacity

(i) Effective legislative and policy frameworks in place

1. a) Existence of biosafety frameworks (e.g. policies, laws and regulations)
- b) Level of harmonization of national biosafety frameworks with other national policy frameworks and programmes
- c) Level of consistency of national biosafety frameworks with the Protocol
- d) Level of stakeholder satisfaction with the national biosafety frameworks

(ii) Appropriate administrative frameworks in place

1. a) Existence of clearly defined institutional mechanisms for administering biosafety, including designation of competent national authorities and responsibilities among agencies
- b) Change in the quantity and quality of staffing in national institutions dealing with biosafety

- c) Percentage of notifications handled and decisions taken within the timeframes specified in the Protocol
 - d) Existence of systems for managing biosafety records and for maintaining institutional memory
 - e) Existence of mechanisms for inter-institutional coordination (e.g. steering committees or intranets), and change in the level of activity of such mechanisms
- (iii) Improved technical, scientific, and telecommunications infrastructures***
- 1. a) Change in the quantity and reliability of office equipment and facilities in institutions dealing with biosafety
 - b) Number and variety of facilities (e.g. laboratories) available for biosafety research work
 - c) Change in the level of reliability of telecommunication infrastructure
- (iv) Enhanced funding and resource management***
- 1. a) Amount of funding for biosafety activities received or provided
 - b) Percentage of funding for biosafety coming from national budgetary allocation
 - c) Rate at which resources earmarked for biosafety are used for the intended activities and in a cost-effective manner
- (v) Enhanced mechanisms for follow-up, monitoring and assessment***
- 1. a) Existence of national mechanisms for monitoring and reporting of implementation of the Protocol
- B. Improved human resources capacity development and training***
- 1. a) Number of national experts trained in diverse specialized biosafety-related fields
 - b) Frequency at which local experts are used in undertaking or reviewing risk assessments and other activities relating to the implementation of the Protocol
 - c) Frequency at which expertise from the roster of experts is accessible whenever required by countries
- C. Improved capacity for risk assessment and other scientific and technical expertise***
- 1. a) Amount of biosafety research and proportion of risk assessments carried out locally
 - b) Frequency at which local expertise is used in undertaking or

reviewing risk assessments

D. Improved capacity in risk management

1. a) Existence of risk management strategies for LMOs with identified risks
- b) Rate at which risk management strategies and measures developed to prevent or mitigate identified risks are actually implemented

E. Improved public awareness, participation and education in biosafety at all levels

1. a) Change in level of public awareness of the Protocol
- b) Change in the number, scope and variety of measures taken to promote awareness of the biosafety and the Protocol
- c) Rate of involvement of relevant stakeholders in decision-making and in the development and implementation of national biodiversity frameworks
- d) Change in frequency of public access to relevant biosafety information, including through the Biosafety Clearing-House

F. Improved information exchange and data management including full participation in the Biosafety Clearing-House

1. a) Change in level of exchange of relevant biosafety data and information
- b) Extent to which information required under the Protocol is provided to the Biosafety Clearing-House
- c) Existence of national systems for data management and information exchange
- d) Existence of appropriate national infrastructure and capability to access the Biosafety Clearing-House
- e) Degree to which the Biosafety Clearing-House responds to the information needs of different stakeholders
- f) Level of stakeholder satisfaction with the Biosafety Clearing-House (including its accessibility, user-friendliness and content)
- g) Change in number, frequency and regional distribution of Governments and organizations accessing and retrieving information from the Biosafety Clearing-House
- h) Change in number and regional distribution of Governments and organizations contributing information to the Biosafety Clearing-House

Desired outcome (based on Action Plan elements)

Criteria and indicators

G. Increased scientific, technical and institutional collaboration at sub regional, regional and international levels

1. a) Existence of various mechanisms for regional and international collaboration in biosafety
- b) Change in number of bilateral and multilateral collaborative initiatives in biosafety underway
- c) Change in level of participation in regional and international collaborative mechanisms and initiatives
- d) Existence of, and level of participation in, regional/ sub-regional advisory mechanisms and centers of excellence
- e) Existence of regional and sub-regional websites and databases
- f) Existence of mechanisms for regional and sub-regional coordination and harmonization of biosafety regulatory frameworks
- g) Existence of, and level of participation in, mechanisms for promoting south-south cooperation in biosafety issues
- h) Change in amount and availability of international technical guidance for implementation of the Protocol
- i) Existence of mechanisms for promoting common approaches

H. Improved access to and transfer of technology and know-how

1. a) Existence of enabling frameworks for technology transfer
- b) Change in number of relevant technologies transferred

I. Improved identification of LMO shipments as required by the Protocol

1. a) Existence of national measures for identification of LMO shipments
- b) Change in level of use of modern LMO identification techniques
- c) Change in level of effectiveness of identification systems and measures in ensuring safe handling, transport and packaging of LMOs