



# Global Environment Facility

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GEF Council  
November 8-10, 2005

Agenda Item 12

## ELEMENTS FOR A BIOSAFETY STRATEGY

**Recommended Council Decision**

The Council reviewed the elements for a GEF biosafety strategy (document GEF/C.27/12) and approves the elements as a basis for developing a strategy to guide the provision of GEF assistance to support the Cartagena Protocol on Biosafety. The GEF Secretariat is invited to prepare, in consultation with the Implementing and Executing Agencies, a proposed biosafety strategy for Council review and approval by mail in early 2006.

## **I. INTRODUCTION**

1. The purpose of this paper is to identify basic elements that would form the foundations of a GEF Strategy in Biosafety. After Council discussion and comment on the proposed elements, it is proposed that a full GEF Strategy on Biosafety be prepared for Council approval by mail early 2006.
2. The overall objective of the strategy will be to ensure that the GEF provides cost-effective and timely support for implementation of national biosafety frameworks in order to promote the contribution of the safe use of biotechnology to national sustainable development policies.

## **II. BACKGROUND**

3. The Cartagena Protocol on 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 on May 24, 2000.
4. The objective of the Protocol 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”. As the financial mechanism of the Convention on Biological Diversity, the GEF is also called upon to serve as the financial mechanism of the Protocol.

## **III. GEF STRATEGY ON BIOSAFETY TO DATE**

5. 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.
6. 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.

7. 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.

8. 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.

#### **IV. CARTAGENA PROTOCOL ON BIOSAFETY ENTERING INTO FORCE**

9. 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.

10. 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.

11. Decision VII/20, on Further Guidance to the financial mechanism states:

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*24. Invites the GEF to extend support for demonstration projects on implementation of the national biosafety frameworks to other eligible countries;*

*25. Urges the GEF to ensure a rapid implementation of its initial strategy for assisting countries to prepare for the ratification and implementation of the Protocol, and to support capacity-building for the establishment of national components of the BCH in a flexible manner, and to provide additional support for the development and/or strengthening of existing national and regional centers for training; regulatory institutions; risk assessment and risk management; infrastructure for the detection,*

*testing, identification and long-term monitoring of living modified organisms; legal advice; decision-making; handling of socio-economic considerations; awareness-raising and technology transfer for biosafety.*

26. *Notes that the role of the GEF, in accordance with its mandate, in the Action Plan for Building Capacities for the Effective Implementation of the Protocol, adopted by the COP/MOP1, includes:*

- (a) *Providing funding and other assistance to build necessary legislative and administrative frameworks, and for training in risk assessment and risk management;*
- (b) *Deciding on further areas for financial support for capacity-building in accordance with the identified priority needs of developing countries and countries with economies in transition, responses to the questionnaires, the outcomes of inter-sessional workshops, and its previous pilot project on biosafety;*
- (c) *Implementing the GEF Strategy to Assist Countries to Ratify and Implement the CPB;*
- (d) *Facilitating the provision of technical support; and*
- (e) *Facilitating the use of existing and developing regional networks.*

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

## **V. OFFICE OF MONITORING AND EVALUATION (OME) EVALUATION OF THE GEF INITIAL STRATEGY ON BIOSAFETY.**

### **A. Objectives**

17. 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?

18. A draft report by the Office of Monitoring and Evaluation with main results and findings is presented to the Council as document GEF/ME/C.27/Inf.1.

### **B. Results**

19. The evaluation carried out by the OME provides 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.

20. Currently, the project “Development of NBFs” is being implemented in more than 120 countries, aimed at building up the necessary basis for the Parties to initiate a more in-depth and comprehensive implementation of the Cartagena Protocol. At the same time, the project “Building Capacity for the effective participation of Parties in the Biosafety Clearing House (BCH)” complements this effort by providing useful tools for the full participation in the Cartagena Protocol Clearing House to the participating countries.

21. The evaluation finds that the implementation of these two projects has had a positive effect at different levels, building up a momentum that would facilitate further advances in the implementation of the Cartagena Protocol. Some of the most significant achievements, highlighted by the evaluators, are the following:

- (a) activities directed towards drafting new legislation and regulations for the implementation of the Protocol have started, providing a basis of the national regulatory frameworks.
- (b) increase in awareness of biosafety issues has been created among key project participants, such as government, private sector and civil society.
- (c) dialogue and interaction have been facilitated among government entities and academia, frequently including industry and civil society too.
- (d) at regional and sub-regional levels, meetings have been held, providing opportunities for discussion, information sharing and exchange of views among participating countries.

22. The evaluation also uncovered areas where there is room for improvement and/or need for change of approach in GEF support to countries for the implementation of the CPB:

- (a) clear and realistic targets need to be identified based on an analysis and evaluation of the stock taking study.
- (b) financial support has to be estimated based on country needs and should cover adequately the fields where support is needed according with the findings of the stocktaking study in the country. Funding needs vary depending on the number of issues addressed by the proposed project and their complexity, as well as by the national or regional approach recommended.
- (c) regional cooperation and harmonization needs more attention.
- (d) adequate support to countries requires a “hands-on” approach by people with adequate and substantial experience in implementing national biosafety frameworks.
- (e) need for in-country coordination and “ownership” of the projects by all involved ministries, to ensure synergy and continuity.
- (f) there is a broad range of differences among countries interested in receiving support in terms of approaches, degree of implementation, needs and concerns about different issues addressed by the Protocol and therefore a “one-size-fits-all” approach does not work.

## **VI. PROPOSED ELEMENTS OF THE GEF BIOSAFETY STRATEGY FOR THE IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY.**

23. The issue of capacity building for the implementation of the CPB is the proposed third strategic objective of the biodiversity focal area in the Programming Document for GEF-4 currently under discussion. The proposal recognizes that 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 also into account risks to human health, and specifically focusing on trans-boundary movements, constitutes a high priority for recipient countries. In GEF-3 the focus was on helping countries prepare for the coming into force of the CPB and, in the process, to develop a draft for a national biosafety framework. During GEF-4, it is proposed that this support will continue, but with an increasing focus on capacity building to assist the implementation of national biosafety frameworks.

24. 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, it is proposed that the following elements will form the foundations of a GEF Biosafety Strategy for the Implementation of the Protocol:

- (a) Emphasize regional approaches when suitable to the group of participating countries. Regional cooperation will allow for the pooling of resources of countries, can ease the resource demands of each one and will promote harmonization. Regional approaches will have flexibility in terms of issues addressed to target specific needs of countries within a region. Under some circumstances, and based on clear criteria, single-country projects, will be allowed.
- (b) Capacity building activities through, to the extent possible, existing Regional Centers of Excellence, to promote the strength of longer term capacity building assistance to countries. This approach provides high sustainability of the capacity built, while enhancing South-South collaboration in biosafety issues and a more efficient use of scarce resources.
- (c) Tailor support to demonstrated country needs. As there is a broad range of differences among countries interested in receiving support in terms of approaches, technical capacity, degree of implementation, needs and concerns about different issues addressed by the Protocol, a stocktaking assessment of participating countries should be a first step of project design when needed. That stocktaking phase should comprise an independent expert identification and assessment of the following aspects: national 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. The stock taking exercise should result in clearly defined, measurable targets.
- (d) Focus on in-country Coordination and stakeholder involvement. The existence of different ministries or administrative departments involved in biosafety and biotechnology issues in the countries, sometimes with different concerns and priorities, makes it necessary to ensure in-country coordination of roles and



responsibilities. In this context, future projects have to clearly define the role and stress the importance of a national coordination mechanism.

- (e) Involvement of a broader range of Implementing and Executing Agencies than during the Initial Strategy. UNEP managed the largest number of biosafety projects during the implementation of the initial strategy. A balanced portfolio requires the involvement of additional IAs and EAs, in particular those with comparative advantages in biosafety-related issues (i.e., agriculture, biotechnology, development, trade, capacity building, etc). Wherever possible, biosafety capacity building projects should be linked to existing bilateral and multilateral biosafety and biotechnology projects to ensure maximum synergy.
- (f) Awareness raising and public participation. There is a need to continue supporting awareness raising, education on biosafety, access to information and public participation on decision making. This is an important aspect of the CPB and builds the basis for support over the long term of post-project activities.
- (g) Co-financing and incremental costs. Implementation of NBFs raises the question as to the role of the GEF in supporting the CPB in its broadest sense, since its implementation also provides countries with benefits that impact not only biodiversity conservation but other sectors such as health and food safety. Project proposals should demonstrate that sufficient funding will be made available by the participating country for the continuation of the implementation.

25. An envelope of US\$80 Million has been proposed in the Programming Document for these activities (refer to strategic objective 3 under the biodiversity focal area).

## **VII. IMPLICATIONS OF THE RESOURCES ALLOCATION FRAMEWORK (RAF) ON THE PROPOSED BIOSAFETY STRATEGY FOR GEF-4**

26. The proposed strategy relies heavily on regional and sub-regional approaches for implementation. The proposed envelope of US\$80 million, however, exceeds the 5% ceiling that has been adopted for global and regional projects in the biodiversity focal area under the RAF (i.e., US\$44 Million under a flat scenario of US\$880 million for biodiversity during GEF-4).

27. The combination of these two factors implies that a significant proportion of the resources needed to implement the biosafety strategy will need to be derived from country allocations (whether for countries with individual allocations or for countries in the group allocation model). It is an open question whether countries be willing to “contribute” a portion of their allocations to support regional implementation projects for biosafety.

28. The answer will depend on whether the proposed regional projects support country efforts in ways that compete favorably with alternative national-level projects, as well as with the relative importance that countries give to biosafety as opposed to other issues within the biodiversity focal area. In order to be make the proposed regional projects competitive, the Implementing and Executing Agencies will need to demonstrate that such projects generate

significant leverage in terms of: (i) additional resources in the form of co-financing, (ii) gains in economies of scale for the technical assistance to be provided, (iii) opportunities for learning and technology transfer, (iv) South-South cooperation, and (iv) opportunities for harmonization of country-level approaches within regional groups.

29. It is expected that countries will analyze such issues at the time of providing project endorsements through their GEF operational focal points.