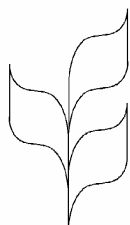




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CONFERENCE OF THE PARTIES TO THE  
CONVENTION ON BIOLOGICAL DIVERSITY  
SERVING AS THE MEETING OF THE PARTIES TO  
THE CARTAGENA PROTOCOL ON BIOSAFETY

First meeting

Kuala Lumpur, 23-27 February 2004

Item 6.3 of the provisional agenda\*

**GEF SUPPORT FOR CAPACITY-BUILDING**

*Note by the Executive Secretary*

1. The Executive Secretary is circulating herewith, for the information of participants in the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, an information document prepared by the Global Environment Facility providing information on the activities that have been undertaken and lessons learned with a view to contributing to the Parties' deliberations on further work to strengthen the capacity of eligible countries to implement the Cartagena Protocol.
2. The document is being issued in the form and languages in which it was received by the Secretariat of the Convention on Biological Diversity.

\* UNEP/CBD/COP-MOP/1/1.

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# Global Environment Facility

February 2, 2004

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## GEF SUPPORT FOR CAPACITY BUILDING IN BIOSAFETY

**An information document prepared by the GEF Secretariat and  
Implementing Agencies (UNDP, UNEP and World Bank) for the first  
meeting of the Conference of the Parties serving as the meeting of the  
Parties to the Cartagena Protocol on Biosafety**

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## INTRODUCTION

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

2. 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.*”<sup>1</sup> As the financial mechanism of the Convention on Biological Diversity, the GEF was also called upon to serve as the financial mechanism of the protocol and in particular to assist in capacity building in biosafety.<sup>2</sup>

3. The GEF has made substantive progress in financing capacity building efforts for the effective implementation of the Cartagena Protocol on Biosafety. This document provides information on the activities that have been undertaken and lessons learned with a view to contributing to the Parties’ deliberations on further work to strengthen the capacity of eligible countries to implement the Cartagena Protocol.

### *Guidance of the Conference of the Parties to the GEF on Biosafety*

4. Prior to the adoption of the Cartagena Protocol, the Parties to the Convention on Biological Diversity at the third meeting of the Conference of the Parties in 1997 approved the following as a component of the guidance to the financial mechanism:

“...[T]he GEF shall provide financial resources to developing countries for country-driven activities and programs, consistent with national priorities and objectives, recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries:

- (a) For capacity-building in biosafety, including for the implementation by developing countries of the UNEP International Technical Guidelines on Safety in Biotechnology.”<sup>3</sup>

5. At the fifth meeting of the Conference of the Parties in 2000 the Parties “[w]elcome[d] the decision of the Council of the Global Environment Facility requesting its secretariat, in consultation with the Implementing Agencies and the secretariat of the Convention on Biological Diversity, to develop an

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<sup>1</sup> *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, Article 1

<sup>2</sup> *Ibid.*, Article 28

<sup>3</sup> Decision III/5 paragraph 2 (a), Decisions from the Third Meeting of the Conference of the Parties to the Convention on Biological Diversity (Buenos Aires, Argentina, 4-15 November 1996)

initial strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety.”<sup>4</sup>

6. In 2002, the sixth meeting of the Conference of the Parties requested “...[T]he GEF [to] provide financial resources to developing countries for country-driven activities and programs, consistent with national priorities and objectives, recognizing that economic and social development and poverty eradication are the first and overriding priorities of developing countries,...for national capacity-building on biosafety, in particular for enabling effective participation in the Biosafety Clearing-House and in the implementation of the Action Plan for Building Capacities for the Effective Implementation of the Cartagena Protocol on Biosafety proposed by the Intergovernmental Committee on Cartagena Protocol at its second meeting, and for other needs identified in the recommendations of the Intergovernmental Committee at its second meeting for assisting developing countries to prepare for the entry into force of the Protocol.”<sup>5</sup>

## **RESPONSE OF THE GEF TO THE GUIDANCE OF THE COP**

### **Pilot Project**

7. In response to the decision of the third meeting of the Conference of the Parties, the Council approved a pilot biosafety enabling activity project. The objective of the project was to assess the types of needs that recipient countries might have in this area, and the level and range of financial support for activities to address those needs, in order to pilot activities with a view to generating experience and lessons to assist the GEF to put together an appropriate program in the area of biosafety.

8. The project had two main components:

- (a) assistance for the establishment of national biosafety frameworks in 18 countries, including a survey of capacity for both biotechnology and safety assessment, and
- (b) the organization of eight regional workshops that explored both risk analysis and management and transboundary movement of living modified organisms.

9. The pilot project gave the GEF important experience to better understand the needs of countries for capacity-building

### **Initial Strategy to assist countries to prepare for the entry into force of the Protocol**

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<sup>4</sup> Decision V/13, paragraph 1 Decisions from the Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity (Nairobi, Kenya, 15-26 May 2000)

<sup>5</sup> Decision VI/17, paragraph 10(b) Decisions from the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity (The Hague, Netherlands, 7-19 April 2002)

10. After the adoption of the Cartagena Protocol, the GEF Council, at its meeting in May 2000, “welcome[d] the adoption of the Cartagena Protocol on Biosafety, including Article 28 of the Protocol which provides that “the financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.” The Council request[ed] the secretariat, in consultation with the Implementing Agencies and the secretariat of the Convention on Biological Diversity, to inform the Council at its next meeting of its initial strategy for assisting countries to prepare for the entry into force of the Protocol<sup>6</sup>.

11. At its meeting in November 2000, the Council approved an initial strategy to assist countries to prepare for the entry into force of the Cartagena Protocol. This strategy proposed activities that the GEF could usefully undertake in the period leading up to the entry into force of the Protocol, recognizing that once the Protocol entered into force, the Conference of the Parties to the Convention on Biological Diversity will provide guidance to the GEF on the priorities and policies to be followed in providing subsequent GEF assistance to countries to assist them to implement the Protocol.

12. The activities proposed in this 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.

13. The following activities were proposed to meet the objectives referred to above:

- (a) A project to assist interested signatories to the Cartagena Protocol in establishing national biosafety frameworks;
- (b) A limited number of individual, country-based demonstration projects to pilot activities to address capacity-building needs to implement national biosafety frameworks;
- (c) coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;
- (d) support to enable countries to participate in the biosafety clearing-house, once the clearing-house terms of reference were agreed upon by the Parties; and

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<sup>6</sup> *Joint Summary of the Chairs – GEF Council Meeting (May 9-11, 2000)*, paragraph 18

- (e) enhancement of the scientific and technical advice to the GEF on biosafety issues.

## **Implementation of the Initial Strategy**

### *Global Project on the Development of National Biosafety Frameworks*

14. In order to provide assistance to countries in an expeditious manner, the Council approved a global project on the “Development of National Biosafety Frameworks” (NBF project). UNEP is the implementing agency managing the project. The project began implementation in June 2001 and is currently assisting 120 participating countries to set up their national framework for the management of living modified organisms (LMOs), allowing them to meet the requirements of the Cartagena Protocol.

15. The total cost of the UNEP-GEF Biosafety Project is \$38.4 million. This is funded by a contribution of \$26.1 million from the Global Environmental Facility (GEF), with co-financing of \$12.3 million from participating countries and UNEP. Countries are contributing one third of the costs of their national projects, in cash and/or in kind.

16. Countries participating in the project are currently developing their own national biosafety frameworks (NBF) in a four-phase process: (a) setting up the required project management structures; (b) gathering of baseline information in inventories and surveys; (c) analysis of the information in consultation with stakeholders; and (d) drafting of the NBF.

### Review of Experience in Preparing Inventories and Surveys

17. In order to develop legal, administrative, decision-making and public participation systems for biosafety, each country needs a comprehensive picture of the state of biotechnology and biosafety, and of the relevant systems of law to see which, if any, systems of law or regulations are relevant to biosafety. The NBF project asked countries to collect this baseline information in order for them to answer the following questions, “Why do we need a National Biosafety Framework (NBF)?” and “What do we include in our NBF, who should we involve, and how do we go about drafting our NBF?” The information collected will also help countries to meet their obligations and information requirements under the Protocol for the Biosafety Clearing House (BCH).

18. Countries have taken a variety of approaches in carrying out their surveys. In large countries, consultants, government staff, academia, and the National Coordination Committee (NCC) have worked together to collect information to produce a cohesive, complete analysis and report to be used at the national level for informed choices and decision-making. In smaller countries, a single consultant or even the National Project Coordinator (NPC) carried out the surveys and came up with a comprehensive synthesis report. The surveys also helped countries to identify capacities, resources and opportunities that exist and gaps and constraints that they need to address.

### Review of Experience on Results of Data Analysis

19. The Inventory and survey phase merges with the data analysis phase, and the question for countries changes to “where do we want to go from here?” The collected data enables a country to make the decision of changing legislation and making future choices for regulation.

20. The results of public consultations and analyses have helped countries to achieve:

- (a) an increased national awareness of biosafety, specifically on the present status of biotechnology and biosafety in the country;
- (b) an improved understanding of the needs for capacity building and institutional mechanisms for the management of biosafety;
- (c) an improved understanding of the needs and priorities of different stakeholders so that different views and priorities are taken into consideration in developing the NBF;
- (d) a clearer picture of NBF priorities and components, including regulatory regimes and administrative systems;
- (e) a review of their existing systems for biosafety in order to ensure that they are both consistent with the requirements of the protocol and are able to meet national needs and priorities;
- (f) improved access to biosafety information through the development of databases and websites;
- (g) a firm foundation for sub-regional cooperation based on identification of shared needs and priorities between countries in the sub-region.; and
- (h) an improved ability to design an NBF that meets the specific needs of each country.

21. In many countries, national workshops have enabled different stakeholders to debate issues of biosafety and to increase their understanding of the risks and benefits associated with biotechnology. Countries have also utilized leaflets, radio and TV programmes, websites and other educational materials to reach the public.

#### Review of Experience in Stakeholder Involvement

22. All countries participating in the NBF development project have been encouraged to identify stakeholders who will be involved as partners in the development of the NBF. Those involved in the NBF development include national government agencies, national or international NGOs, community based organizations, academic and research institutions, schools, the media, the private sector, and local government.



23. Workshops have been held at national and subregional level in order to assist countries in developing a system to involve the stakeholders in decision making for the development and implementation of the NBF.

#### Review of Experience in Drafting National Biosafety Frameworks

24. Experience of the project has underscored the need to undertake a critical analysis and review of the current situation in a country in terms of existing regulatory regimes relevant to biosafety and biotechnology together with review of existing decision-making structures and then to revise or establish administrative systems for biosafety.

25. The project and its workshops have helped countries to identify available options in terms of regulatory regimes. These options include:

- (a) the development of a new and comprehensive law on biosafety that covers all aspects of biosafety;
- (b) a framework or umbrella law that sets up the necessary institutional and regulatory structure at the national level with amendments or additions to existing legislation or regulations; and
- (c) the drafting or revision of a Decree or Executive Order, with specific regulation for each sector.

#### *Country-based demonstration projects to assist in capacity-building to implement national biosafety frameworks*

26. In the interest of gaining further experience and developing good practices so as to promptly and effectively assist Parties after the entry into force of the Protocol, the GEF Council agreed that the GEF should finance a limited number of pilot country-based demonstration projects in countries with sufficient capacity that they did not require assistance under the global project to develop a national biosafety framework. The purpose of these projects is to pilot more in-depth and country specific capacity building efforts aimed at the implementation of the country's national biosafety framework.

27. The GEF Council has approved 12 demonstration projects to support countries in the implementation of their national biosafety frameworks. Two projects (Malaysia and Mexico) are implemented by UNDP, eight projects are being implemented by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda) and two projects (India and Colombia) are being implemented by the World Bank.

*Projects on Implementation of National Biosafety Frameworks managed by UNDP (Malaysia and Mexico)*

28. Although implementation of the project in Malaysia is only now commencing, the project in Mexico has been under implementation for about eight months. One of the early lessons from this project concerns information sharing. The project has found that an intensive investment in design of an information sharing system pays dividends, as it has resulted in all government agencies involved in the project following the same objectives, contributing to the formation of a task force. The main focus for shared information has been on how different government agencies carry out risk assessment and how they interact with decision makers in agriculture and environment in a coordinated fashion to release LMO's into the environment. This coordination is reflected in the biosafety law. Risk assessment methodologies have been reviewed by all the government agencies with responsibilities related to biosafety in order to promote a coordinated approach.

*Projects on Implementation of National Biosafety Frameworks managed by UNEP (Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda).*

29. The eight demonstration projects being managed by UNEP started in 2002 and are expected to be completed in 2005. The projects are 'driven' by the countries. The participating Governments are also expected to ensure coordination with other relevant capacity building projects in their country to avoid duplication and ensure synergy.

30. The role of UNEP focuses on providing expert assistance and guidance, ensuring accountability through adequate and transparent reporting, and promoting adequate coordination with other biosafety capacity building projects.

31. At the end of each project, each participating country will have:

- (a) a workable and transparent regulatory regime for biosafety that is consistent with the Biosafety Protocol and other relevant international obligations; and
- (b) implementing systems for handling of notifications or requests for approvals (including administrative processing, risk assessment and decision making), enforcement and monitoring, as well as public information and public participation.

32. The activities carried out to date under these projects are the following:

- (a) a detailed picture of the state of development of the national biosafety frameworks of the participating countries has been obtained;
- (b) reviews of draft legislation by panels of experts from international organizations, governments, academia, NGOs and the private sector have been undertaken in Bulgaria, Cameroon, Kenya, Namibia and Uganda; and

- (c) 4-5 day 'start up' workshops were held in Bulgaria, Namibia, Cameroon, Kenya, Uganda, Cuba and China which address in detail the main components of national biosafety frameworks, i.e. regulatory regimes, systems to handle notifications or requests, enforcement and monitoring, public information and public participation. In several cases these 'start up' workshops were preceded by a one-day introductory seminar for parliamentarians. These workshops were open to observers from NGOs, the private sector, media and other countries. In the workshops, resource persons included experts from international organizations, such as the CBD Secretariat, ISNAR and OECD, countries where biosafety frameworks have been in place for several years, as well as from academia, NGOs and the private sector.

33. Continued expert support to the countries in the execution of the project's work plans is being provided. Assistance has been provided in:

- (a) reviewing and/or drafting enabling legislation and interim measures for biosafety;
- (b) drafting implementing regulations and complementing guidelines on technical topics such as information requirements and risk assessment;
- (c) drafting operational manuals that are aimed at providing internal guidance to officials and experts involved in the implementation of national biosafety frameworks;
- (d) drafting plans for enforcement;
- (e) the legal and practical aspects of public information and public participation;
- (f) the legal aspects and practice of the Biosafety Clearing House of the Biosafety Protocol;
- (g) organization of workshops on a variety of topics, such as risk assessment; and
- (h) collecting and making available examples of biosafety policies as well as of public information and participation approaches used all over the world.

34. A meeting of the national coordinators of the UNEP projects was held in early 2004, with the following objectives:

- (a) to gain insight into the day to day practice of a number of countries where biosafety frameworks have been in place for many years;
- (b) to exchange updates and experiences on the progress of the projects;
- (c) to provide 'one to one' expert assistance on topics identified by the national coordinators; and

- (d) to assist the national coordinators in complying with the formalities of the projects, such as reporting. This meeting was open to observers from other countries and other implementing agencies.

35. The summaries of the state of developments in each participating country at the start of the project, the reports of the workshops, the fine tuned work plans and other documents resulting from these projects are published on the UNEP-GEF Biosafety web site ([www.unep.ch/biosafety](http://www.unep.ch/biosafety)) under 'Implementation projects'.

36. To promote synergy and harmonization as much as possible, the team involved in these projects and the team involved in the UNEP GEF Global Project on the Development of National Biosafety Frameworks are working closely together to promote consistency between these two phases of the GEF Initial Strategy.

37. In implementing all these projects, close cooperation has been sought with international organizations and governments involved in biosafety capacity building.

*Projects on Implementation of National Biosafety Frameworks managed by the World Bank (Colombia and India)*

38. Two GEF demonstration projects on capacity building for the implementation of the Cartagena Protocol are currently under implementation in India and Colombia with the World Bank as the implementing agency.

39. Both projects became effective in the fall of 2003 and are expected to have a three year duration. The overall objective is to strengthen national biosafety frameworks in each country through the improvement of capacity and coordination for decision-making among ministries and relevant institutions, and for risk evaluation and management. This will, in turn, allow Colombia and India to effectively implement and fulfill their obligations under the Cartagena Protocol on Biosafety.

40. The India Biosafety Capacity Building Project commenced implementation with a two-day project launch workshop that included key stakeholders and several experts in biosafety. The workshop focused on the project's overall objectives in relation to the implementation plan, as well as more generally on the conceptual framework for the capacity building approach. Project components were also reviewed including the preparation of annual plans, procurement and financial management and monitoring and evaluation. The next immediate steps are to set up the steering committee – a key component to a sustainable project outcome, assess training needs and finalize the annual work plan. The Colombia Biosafety Capacity Building Project is scheduled to begin with a project launch workshop in early 2004 for all stakeholders.

41. Although it is a little early to glean lessons learned from the two projects, experience from completed or ongoing projects for other global environmental issues involving capacity building might be

useful to underscore the importance of sustained coordination and cooperation between various government agencies and other stakeholders. One important lesson learned from projects under the Multilateral Fund for the Implementation of the Montreal Protocol, for example, is that on-the-ground results translate to a country's meeting its protocol obligations when they are linked to an overall strategy that has the buy-in of all relevant agencies and stakeholders. Dialogue through stakeholder workshops, steering committees and memoranda of agreement on common goals become important tools for achieving cooperation and coordination and can be used as milestones to gauge the degree that objectives are being met.

42. The underpinning of the biosafety projects in Colombia and India is the building up of capacities in all relevant institutions. Both projects will place a strong focus on building relationships between stakeholders and keeping them engaged through out implementation.

#### *Building Capacity for the effective participation of Parties in the Biosafety Clearing House*

43. The GEF Council, in November 2003, approved an additional project aimed at building capacity for the effective participation of Parties in the Biosafety Clearing House of the Cartagena Protocol. This project is an add-on project to the current UNEP-GEF project for Development of National Biosafety Frameworks.

44. The project will assist those countries that have ratified or acceded to the Cartagena Protocol by the time of the first Conference of the Parties serving as the meeting of the Parties to the Protocol (COP/MOP), and that are not already beneficiaries of similar assistance through a GEF project to participate in the Biosafety Clearing House (BCH).

45. The specific objectives of the UNEP-GEF project are to:

- (a) strengthen capacity in eligible countries through support for capacity building including training activities for key stakeholders;
- (b) create an enabling environment for Parties to meet the obligations for implementation of the Protocol; and
- (c) support further capacity building activities through the development and dissemination of an interactive computer-based training package including the BCH toolkit.

46. GEF financing for this project totals US\$4.6m and in-kind contributions from governments total US\$0.35m for total project costs of US\$4.9m. Associated funding from the US is \$0.13m.

47. The following summarizes the capacities that are expected to be built under the various project activities approved by the GEF Council in accordance with the Initial Strategy.

- (a) Capacity expected to be built under the umbrella project for the development of National Biosafety Frameworks
  - (i) Capacity to make informed choices on national regulatory regime for biosafety and to draft the NBF.
  - (ii) Capacity to draft risk assessment management and public participation elements of the NBF.
  - (iii) Capacity to draft administrative and regulatory regimes for NBF.
  - (iv) Better understanding of administrative systems for implementing the different components of the regulatory regime (including managing notifications, decisions and information.).
  - (v) Capacity to manage project financial reporting.
  - (vi) Increased national understanding of biosafety and the Cartagena Protocol and related topics.
  - (vii) Technical capacity to collect and analyze data to manage bio safety information at the national level (this will complement future training for BCH project).
- (b) Capacity expected to be built through pilot projects aimed at assisting countries to implement the National Biosafety Frameworks
  - (i) Approval and implementation of a workable and transparent regulatory regime consisting of enabling legislation, implementing regulations and complementing guidelines that are consistent with the Biosafety Protocol and other relevant international obligations.
  - (ii) Implementing systems for handling of notifications or requests for approvals (including systems for administrative processing, risk assessment and decision making), enforcement and monitoring, public information and public participation will be established in each country.
  - (iii) Guidance on regulatory regimes, administrative processing of notifications and requests, risk assessment, decision making, enforcement, monitoring, public information, public participation and international information exchange available in each country.

- (iv) Operational manuals aimed at providing internal guidance to officials and experts involved in the implementation of national biosafety frameworks will be prepared and disseminated.
  - (v) “Gene Files” with relevant information about genes that are frequently used in genetic modification will be developed.
  - (vi) Establishment national BCH with link to the central BCH.
  - (vii) Capacity to coordinate and collaborate with Governments and with other organizations involved in biosafety and biosafety capacity building projects.
  - (viii) Strengthening of laboratories to evaluate and mitigate risks and capacity building in monitoring.
  - (ix) Support to centers of excellence and networks for research, risk assessment, and monitoring.
  - (x) Operational systems for risk assessment and management, and monitoring will be established.
  - (xi) Inter-sectoral/inter-ministerial mechanism for formulating national policies and coordinating decision-making on biosafety issues will be established.
  - (xii) Established relations between stakeholders and sustained engagement in implementation.
- (c) Capacity expected to be built through the umbrella project for the Biosafety Clearing House Mechanism.
- (i) Establishment of national BCH with link to the central BCH.
  - (ii) Sustained capacity to use and access the BCH established in country.
  - (iii) Capacity to store data, access and register information in the BCH.
  - (iv) Decision makers with capacity to identify and access information required for decision making under the Cartagena Protocol.
  - (v) Capacity to publish information on BCH.
  - (vi) Physical infrastructure of national BCH (both hardware and software) to be provided).

- (vii) National and regional experts capable of training others at national level on the use of the BCH will be identified and trained.

## **LESSONS AND BEST PRACTICE**

48. Although the experience with the NBF development project and even more so with the NBF Implementation projects and Biosafety Clearing-House is quite new, some interesting lessons are beginning to appear.

### **Country Ownership**

49. Adequate assessment of capacity-building needs should be conducted early during the process.

50. Given the differing level of awareness and capacity of various countries the process is not owned to the same extent by all national actors. Greater national efforts and commitment in countries that are less advanced and/or economically concerned by biosafety issues will be needed, backed up by strong support from the international community.

51. Higher levels of engagement with individual countries are required in order to build and maintain commitment. In order to do so, awareness and education are fundamental in biosafety activities as these are highly technical and of highly specific nature.

52. On the public sector side, commitment on funding recurrent costs from government budgets should be strengthened. The potential to utilize market measures and structures to contribute to financial sustainability of the planning and decision making structures should be fully taken into account.

53. In view of differing country capacities across the world, flexibility at the design and execution levels and in terms of time span is important to ensure full country ownership.

### **Sustainability**

54. Key building blocks of sustainability such as institutional, policy and regulatory, financial and social sustainability have to be addressed early in the process. The lack of attention to those aspects may reduce the potential for successful implementation of activities afterwards.

55. The more aware people are about the importance of the subject and the impact of biotechnology on their life (food, health, trade.) the more likely it will be sustained.

### **Enabling environment**

56. National level efforts must be substantial to create a sound enabling environment. The discussion and clarification of biosafety issues that are of concern to governments and key stakeholders should be facilitated as much as possible.



57. National level efforts must be substantive to create and or strengthen a sound enabling environment.

### **Stakeholder Involvement**

58. The breadth and scope of stakeholder participation during the design stage promotes greater country ownership. The more inclusive the process, the greater is its social sustainability. Furthermore, the breadth, scope, and quality of participation of range of stakeholders is fundamental for the long-term impact on the implementation of the resulting NBFs. However, it is difficult, expensive and time consuming to ensure full participation and special efforts will be needed on this issue.

59. In terms of key social issues, there is a real need to address concerns of farmers and the private sector, as well as the public more generally, on the potential impact of the Protocol and the NBF on trade and economic related issues. This perception will be crucial in building longer-term support for the formal approval and implementation of the NBFs.

60. The private sector should be a key operator in biosafety issues and its full involvement in the development and implementation of the NBFs is crucial to make it viable over the long-term.

61. Keeping open lines of communication with all stakeholders is fundamental to synergize and synchronize effort and reduce wastage.

### **Technical Issues**

62. Although national biosafety frameworks vary from country to country, they usually contain a number of common components:

- (a) biosafety policy, which is usually part of a broader policy on biotechnology;
- (b) a regulatory regime on biosafety, which usually consists of enabling legislation and implementing regulations;
- (c) a system to handle requests (including administrative processing, risk assessment & management, decision making);
- (d) follow up actions (monitoring and enforcement); and
- (e) public information, awareness and participation.

63. On complex technical issues such as biosafety and especially in aspects such as risk assessment, monitoring and enforcement, consideration should also be given to strengthening regional and sub-regional centers of excellence as individual countries are likely to have difficulty in assembling a cadre of specialists on a number of topics. If such technical assistance units are strengthened, their long-term sustainability would have to be assured.

64. Many countries do not have sufficient resources to carry out all work nationally and so sub-regional cooperation needs to be fostered and supported in order to allow sharing of resources. It is essential to devote considerable time to setting up an atmosphere of trust for exchange of information and experts between countries. All other forms of cooperation have to be based on this relationship of trust.

65. Consideration should also be given to increasing cooperation with economic actors (e.g. WTO, private sector) and with those related to intellectual property (e.g., WIPO).

### **EMERGING ISSUES**

66. The above quick review identified a number of key issues that need to be addressed to facilitate the proper implementation of the Protocol. Among the most important, the following are key.

#### **The magnitude of the tasks related to capacity building**

67. The amount of capacity building expected is very substantive ranging from the very basic elements of a framework to policy and regulatory issues, technical and scientific aspects, information exchange, and inter-sectoral coordination including sectors rarely associated with biological issues such as trade. Considering the substantive amount of financial resources needed for capacity building on this and other themes under the CBD, the COP may want to consider, in cooperation with the GEF, further ways and means of involving multilateral institutions, regional banks, and other relevant funding bodies to assist Parties in their efforts to implement the Protocol.

#### **Limited absorptive capacity**

68. Countries developing and implementing their National Biosafety Frameworks (NBFs) are at different stages of capacity, ranging from those that have almost nothing to those that are more advanced. Some countries may have capable and well-developed institutions, with highly qualified staff and adequate policies to respond to key challenges posed by the Protocol and its implementation. However, the great majority are at fairly early stages in their capacity development, assessing needs, taking stock, identifying options, and seeking to complete or implement their NBFs. Considering this, the COP/MOP may want to request the GEF to continue its step-wise approach, identifying and building institutional and human capacity according to the absorptive capacity of the countries involved.

### **Country-drivenness**

69. The issue of country-drivenness is fundamental. Capacity building activities must be placed in the context of national priorities and policy and regulatory considerations, long-term financing schemes, and formal follow-up..<sup>7</sup>

### **National institutional set-up**

70. Institutional structures in terms of staff, experts and systems need to be in place, fully trained and well coordinated. All key stakeholders need to be fully involved, including Custom and Trade Departments which are often rarely associated with biodiversity issues. The development of abilities within the countries requires institutional structures that need to be defined as simply as possible and typically are likely to include, at a minimum, the National Competent Authority (ies) the CBD Focal Point and the BCH Focal Point. Countries should recognize early on the need to have multi-stakeholder approaches in their structures managing biosafety issues in order for this to be as sustainable as possible.

### **Regional and sub-regional technical and scientific expertise**

71. Recently, there have been indications that some collaborating organizations are starting to assume costs of organizing regional events to further promote such regional cooperation. The comparatively developed countries also recognize this need and could be interested in subcontracting expertise, training facilities and infrastructure. In addition, feeding national experiences into the global learning process is necessary and should be strengthened through the BCH. Countries must be helped to develop networking mechanisms at all levels and supported in setting up formalized systems for collaboration with other countries in order to share resources and reduce costs.

72. More emphasis should also be put on increased cooperation at sub-regional and regional levels in all the technical areas and with economic actors.

### **Sustainability of capacity built**

73. One of the major issues eligible Parties face in addressing capacity-building efforts is to consider its long-term sustainability as these efforts are not only costly but time consuming and often typically difficult to assess their impacts. True sustainability depends on cross-sectoral integration and commitment, and such commitment is neither generated of its own accord nor results simply from participation in meetings/workshops. Long-term political will, financing, and sound policies and regulations are all fundamental for this to happen. Market approaches could help to strengthen financial sustainability nationally.

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<sup>7</sup> Refer to GEF guidance under Decision III/5, paragraph 2, Decision IV/13, preambular paragraph, Decision V/13, paragraph 2, and Decision VI/17, paragraph 10.

## **GEF catalytic role**

74. The GEF is committed to playing a key role in facilitating and promoting international cooperation recognizing its role to catalyze greater financing for biosafety activities. This will require:

- (a) greater integration of GEF work programs with the regular work programs of the GEF Implementing Agencies;
- (b) outreach to key stakeholders such as governments, non-governmental organizations, the private sector;
- (c) active encouragement of bilateral, regional, and other multilateral organizations and foundations to contribute financing;
- (d) facilitation of information dissemination and knowledge management; and
- (e) financing of innovative approaches to ensure that recurrent costs of funded activities can be met.

## **Technical and scientific expertise**

75. Very few countries have all the capacity to address the levels of complexity to successfully carry out all agreed tasks under the Protocol. Many would need substantive technical backstopping. Given the limited capacity in place and the high level of skills needed, ranging from the policy and regulatory aspects to technical and scientific issues, Parties, governments and other key stakeholders should strengthen regional and subregional cooperation in biosafety and support centers of excellence which can provide the necessary backstopping to eligible Parties. Most countries are interested in sub-regional technical cooperation and may be interested in a more structured sharing of information, experts and facilities.

76. The technical and scientific fields in the area of biotechnology have progressed substantively during the last few years. These advances however, are highly localized, mostly in developed countries and in some advanced developing countries. There is an urgency to strengthen national efforts on these matters. Countries should explore strategies to deal with this issue as the more technical expertise countries have on the subject, the more likely their efforts will be sustained.

## **Long-term Commitment and follow-up**

77. The development of NBFs will be meaningless if they are not implemented in a workable and transparent manner. National follow-up, and where possible regionally supported is crucial. Strong national political and financial commitment as well as multilateral and bilateral institutions, regional banks, and relevant funding bodies will be required in the process.

## **Role of Private Sector**

78. Commercial biotechnology development has already been substantial in areas such as agriculture and health. The private sector has had more substantive development in biotechnology than the public sector due to the high cost of research and development. The private sector could contribute to supporting and deepening the debate by providing tools, practices and training necessary to manage potential risks to biodiversity, humans and the environment. The COP/MOP may consider developing mechanisms to tap the resources of the private sector for the further development of biosafety.

## **Synergies**

79. Issues of biosafety and, more broadly, biotechnology have substantive synergies with other key issues such as trade, intellectual property, access and benefit sharing provisions under the Convention. Economic interests, can have both important positive and negative incentives (depending on the country) to participate in the Protocol. There are also concerns regarding the trade repercussions of the Protocol's ratification on agricultural exports. The intellectual property aspects and negotiation of an ABS international regime to regulate these issues will all need to identify the level of potential synergies among them and with regional and global economic actors.

## **Coordination between the different biosafety capacity building initiatives**

80. There are a number of global, regional and sub-regional initiatives that seek to assist eligible Parties to develop and/or strengthen their national capacity in biosafety. In order to be cost-effective, GEF project review criteria will continue to include close coordination with ongoing and planned activities to avoid duplication and overlap. Given the magnitude of the tasks and the time frame required to build capacity on biosafety, coordination is essential for long-term success.

## **CONCLUSIONS**

81. In considering guidance to the GEF, the Conference of the Parties may wish to consider the following issues.

82. The GEF has made substantive progress in financing capacity building for the effective implementation of the Cartagena Protocol on Biosafety. To date, it has funded the activities foreseen under its Initial Strategy, by supporting the implementation of key capacity-building activities, and there are some initial lessons and best practice that would contribute substantively to knowledge management on this important topic.

83. The GEF Council has also authorized funding aimed at development of National Biosafety Frameworks (NBFs), for funding the initial startup of the BCH in eligible countries that are party to the Protocol, and building capacities to enable them to implement their NBFs.

84. Considering the substantive amount of financial resources needed for capacity building on this and other themes under the CBD, the COP may want to consider, in cooperation with the GEF, further ways and means of involving multilateral institutions, regional banks, and other relevant funding bodies in supporting the work of the Protocol.

85. Strong national political commitment on this theme is fundamental. Parties and governments should be encouraged to include identify biosafety as a key national priority. They will also need to address recurrent costs issues and to maintain and strengthen the sustainability of the capacity built.

86. Regular assessment of experience in the area of biosafety should be conducted to assist countries to benefit from lesson learnt and best practice. Further, appropriate structures for knowledge management and dissemination should be established. Monitoring and evaluation of the activities are highly beneficial, and are essential to the application of adaptive management approaches. Programs and projects will needed to ensure that useful lessons for the iterative planning and implementation processes are captured and acted upon.