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Agenda Item 5(c)

INITIAL STRATEGY FOR ASSISTING COUNTRIES TO PREPARE FOR THE ENTRY INTO FORCE OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Recommended Council Decision

The Council, having reviewed the proposed *Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety*, approves the strategy as a basis for guiding GEF action and requests the GEF Secretariat, in collaboration with the Implementing Agencies, to work with interested countries to assist them. The Secretariat is requested to report to the Council regularly on the implementation of the strategy, including the project entitled, *Development of National Biosafety Frameworks*, for which UNEP is the Implementing Agency.

The GEF Secretariat is requested to coordinate with bilateral and other multilateral organizations with a view to facilitating better collaboration and coordination among them for the provision of assistance to interested countries and to explore opportunities to strengthen partnerships for the provision of capacity building activities related to the strategy.

The GEF Secretariat is requested to inform the Intergovernmental Committee on the Cartagena Protocol (ICCP) of this strategy and the efforts that are underway through the GEF to build the capacity of countries to address the objective of the Protocol.

EXECUTIVE SUMMARY

1. The Council at its meeting in May 2000, requested the GEF as the financial mechanism for the Cartagena Protocol to prepare an initial strategy for assisting countries to prepare for the entry into force of the Protocol. The decision was welcomed by the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity. The strategy in pursuance of these decisions proposes activities for the GEF to undertake in the period leading up to the entry into force of the Protocol based on GEF's experience in implementing the Convention, including its pilot project on biosafety.
2. The main objectives of this initial strategy are to: a) assist countries in the establishment of national biosafety frameworks, b) promote information sharing and collaboration, especially at the regional and subregional level, and c) promote collaboration with other organizations to assist capacity-building for the Protocol.
3. The proposed activities that contribute to the achievement of the objectives are: a) a project to assist in establishing national biosafety frameworks in interested countries signatory to the Protocol; b) a limited number of demonstration projects to assist in implementing the national biosafety frameworks; c) coordination with other organizations to provide biosafety-related assistance; d) when timely, support for countries to participate in the biosafety clearing-house; and e) enhancement of the scientific and technical advice to the GEF on biosafety issues.
4. The Council is invited to consider this strategy and to approve it as a basis for GEF action.

INTRODUCTION

5. 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 24 May 2000. As of September 15, 2000, 75 countries have signed the Protocol. It will remain open for signature in New York from 5 June 2000 to 4 June 2001.

6. 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 focussing on transboundary movements.*”¹ 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.² The mandate envisaged is consistent with the GEF’s general approach of assisting action that is beneficial to the global environment, since national action on biosafety will yield global benefits in terms of conservation and sustainable use of biological resources. The GEF can also build on the specific experience that it has acquired through assisting countries to implement the Convention.

DECISION OF THE GEF COUNCIL

7. At its meeting in May 2000, the GEF Council adopted the following decision with respect to the Protocol:

“The Council welcomes 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 requests 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. The Council also requests UNDP and the GEF Secretariat to take into account the provisions of the Cartagena Protocol in the on-going work of the Capacity Development Initiative.”³

¹ *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, Article 1

² *Ibid.*, Article 28

³ *Joint Summary of the Chairs – GEF Council Meeting (May 9-11, 2000)*, paragraph 18

GUIDANCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY TO THE FINANCIAL MECHANISM RELATED TO BIOSAFETY

8. Prior to the adoption of the Cartagena Protocol, the Parties to the Convention on Biological Diversity designated capacity-building for biosafety as a priority for GEF assistance. Specially, at the third meeting of the Conference of the Parties to the CBD, the Parties approved the following decision as part 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.”⁴

9. At the recent fifth meeting of the Conference of the Parties, the Parties welcomed the decision of the GEF Council to develop an initial strategy for assisting countries to prepare for the entry into force of the Protocol.

“The Conference of the Parties...[w]elcomes 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 initial strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety.”⁵

PILOT PROJECT ON BIOSAFETY

10. In response to the decision of the third meeting of the Conference of the Parties, the GEF financed a pilot biosafety enabling activity project. The objective of this 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 enable the GEF to put together an appropriate program in the area of biosafety. The project had a country level component in 18 representative countries around the world, and a global/ regional component for consultations. The results of the project have been evaluated by UNEP and the Steering Committee of the project. The pilot project has given the GEF important experience on which to draw in determining the funding needs of countries for capacity-building. A brief description of the pilot project and its evaluation are contained in Annex A.

⁴ 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)

⁵ 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)

11. 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.

EVALUATION OF THE PROJECT

12. An expert evaluation of the pilot project commissioned by UNEP finds that it was successful in assisting the participant countries in establishing national biosafety frameworks, to the extent that a majority of the countries involved have adopted new legislation or other regulatory mechanisms for biosafety. The level of stakeholder participation was high although it differed substantially from country to country. The eight regional workshops were successfully conducted and provided valuable insights to the kind of assistance that countries require with regard to biosafety. Although the project was successfully concluded, the evaluation also notes that the timeframe was unrealistically short in view of the ambitious objectives.

SCIENTIFIC AND TECHNICAL ADVISORY PANEL (STAP) REVIEW OF THE PROJECT

13. The project was also subjected to a selective STAP review in order to obtain scientific and technical advice based on experiences gained through the project. The review points out that the provisions of the Cartagena Protocol should be used to identify the issues that countries will need to address, within the broader scope of biosafety issues. A clearer definition of scientific and technical issues is recommended in the formulation of national biosafety frameworks. Similarly, national decisions will be needed for the kind of institutional arrangement that suits a country best. On issues such as risk level classification for environmental release, regional/ sub-regional coordination is recommended. The review agrees that the time frame was a limiting factor in the project's achievements.

INITIAL STRATEGY

14. The decision of the Council at its meeting in May 2000 that was welcomed by the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity, requested the GEF to prepare a strategy "for assisting countries to prepare for the entry into force of the Protocol." This paper, therefore, proposes activities that the GEF could usefully undertake in the period leading up to the entry into force of the Protocol. It recognizes that once the Protocol enters 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.

15. The activities to be undertaken in the period leading to the entry into force of the Protocol should assist Parties in identifying their needs for further capacity-building and should provide a good foundation on which to build further capacity pursuant to the guidance of the Parties.

16. This paper takes into account the guidance of the Conference of the Parties to the Convention on Biological Diversity on biosafety as well as the provisions of the Cartagena Protocol. In particular, the strategy has been prepared drawing upon the provisions of the Protocol concerning the financial mechanism and capacity-building (Articles 22 and 28)⁶, and the lessons learned and experience of the pilot project. The strategy has been prepared in

⁶ Two articles of the Protocol are particularly relevant to the GEF. Article 28 gives the GEF a role as the financial mechanism of the Protocol, and in particular, assigns priority to provision of financial assistance for capacity-building referred to in Article 22. The text of the articles specifically provides:

Article 22: Capacity-building

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organisations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 28: Financial Mechanism and Resources

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.

2. 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.

3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.

5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.

6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

consultation with the Implementing Agencies and the Secretariat to the Convention on Biological Diversity.

17. In developing activities pursuant to this strategy, the GEF will seek consistency with the decisions of the Conference of the Parties to the Convention on Biological Diversity, national priorities and sustainable development. The GEF will encourage the participation of a wide range of interested stakeholders at the national level, including NGOs and the private sector. The GEF will also ensure that the activities complement national, bilateral and multilateral activities in the area of biosafety, and it will work towards promoting partnerships with interested multilateral and bilateral organizations.

18. The work plan for the Intergovernmental Committee on the Cartagena Protocol (ICCP), adopted by decision V/1 of the Conference of the Parties to the Convention on Biological Diversity, includes capacity-building as a significant feature. It is understood that the Convention Secretariat is preparing an indicative framework for capacity-building under the Protocol, for consideration by the ICCP in its meeting in December, 2000. The GEF strategy will ensure close collaboration and complementarity with the development of this framework, in consultation with the Convention Secretariat.

19. The strategy will focus primarily on assistance to developing countries and countries with economies in transition that are signatories to the Cartagena Protocol with a view to facilitating and encouraging effective efforts to prepare for the entry into force of the Protocol. Provision will also be made to promote regional and sub-regional cooperation and exchange of information and experience as a way of further strengthening the capacity of the Parties.

OBJECTIVES OF THE INITIAL STRATEGY

20. The activities that are proposed in this strategy are 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.

PROPOSED ACTIVITIES

21. The following activities are 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) individual, country-based demonstration projects, through any of the GEF Implementing Agencies, to assist in capacity-building 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 are agreed upon by the Parties; and
 - (e) enhancement of the scientific and technical advice to the GEF on biosafety issues.

Assistance to countries for the establishment of national biosafety frameworks

22. Prior to the entry into force of the Protocol, and building upon the experience of the pilot project, the GEF will finance a project under which the activities of the pilot project will be extended to all interested eligible Parties. (See Work Program submitted for Council approval: GEF/C.16/7). This will enable interested eligible Parties to establish national biosafety frameworks, to gain a clearer understanding of their country priorities and capacity-building needs, and through sub-regional and regional consultations and information sharing, to strengthen networks and institutions that will assist in implementing the Protocol.

23. The pilot project has shown that for a Party to meet its commitments under the Protocol, it should develop a comprehensive framework for biosafety and put in place appropriate legal/regulatory and administrative systems to assess any possible impact on its environment. The development of national frameworks for biosafety should include risk assessment and risk management modalities, including scientific skills that might be required. The process for the development of such a framework should also seek to promote information dissemination, public awareness, education and participation.

24. Based on the experience of the pilot phase and the provisions of the Protocol, preparation of national biosafety frameworks will include:

- (a) assessment/stocktaking to provide information on the status of existing biosafety practices;
- (b) assessment of any existing legal instruments or guidelines that might

impact on the use, import or export of living modified organisms (LMOs);

- (c) identification and involvement of all stakeholders relevant to implementation of the Protocol, to the degree possible;
- (d) identification of actions that need to be undertaken to enable countries to implement the Protocol as well as options and priorities for filling such gaps;
- (e) preparation of a legal framework and/or guidelines necessary for the implementation of the Protocol, including strengthening capacity for risk assessments and risk management, monitoring and inspection services;
- (f) establishment of a roster of experts in a transparent manner and modalities for including them in national, sub-regional and/or regional networks;
- (g) assessment of options for implementation of various elements of the biosafety frameworks, for example at the regional level; and
- (h) identification of sub-regional and regional opportunities for harmonizing regulatory frameworks, identifying regional expertise, and exchanging information on initiatives, collaboration and priority areas for capacity-building; and
- (i) additional features that may be identified by the ICCP.

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

26. Regional and sub-regional workshops will be convened to promote information exchange and cooperation. Such workshops may also be used to identify opportunities for strengthening regional and sub-regional organizations, institutions and centers of excellence to assist Parties in implementing the Protocol. Key areas for regional and sub-regional cooperation include:

- (a) human resources and relevant expertise,
- (b) risk assessment, management, monitoring and inspection, including guidelines, methodologies and procedures,

- (c) review of applications for field trials, field releases, and contained use, and
- (d) exchange of information, including lessons learned and good practices.

Country-based projects to identify and demonstrate capacity-building to implement national biosafety frameworks to be piloted (two per region)

27. In countries that do not request assistance to develop a national biosafety framework or have participated in the pilot project, it is proposed that the GEF undertake country-based demonstration projects to assist in the implementation of a country's national biosafety framework.

28. This type of assistance might best be provided to countries that have already ratified the Protocol, in much the same way that assistance through the financial mechanism of the Convention on Biological Diversity is to be provided to Parties to the Convention. However, in the interest of gaining experience and developing good practices that may promptly and effectively be provided to assist Parties once the Protocol enters into force, it is proposed that the GEF finance a limited number of country-based demonstration projects (maximum of eight countries - two per region for Africa, Asia, Eastern Europe, and Latin America and the Caribbean).

29. Any such country project will be presented to the GEF Council for approval. All three GEF Implementing Agencies have expressed an interest in assisting countries in such capacity-building projects, and countries may work with any of the Implementing Agencies to develop individual proposals to the GEF Council.

30. The experience gained through these demonstration projects should assist the Parties in determining guidance to the financial mechanism once the Protocol enters into force. The GEF Secretariat will ensure that lessons learned will be shared and that methodologies and experiences are transferred to other Parties as they later receive assistance pursuant to the guidance of the Parties to the Protocol.

Coordination with other multilateral and bilateral organizations working and providing assistance in the area of biosafety

31. At the Ministerial Round Table on Capacity-building in Developing Countries to Facilitate the Implementation of the Cartagena Protocol on Biosafety held in Nairobi on May 24, 2000, many donor countries indicated their intention to provide financial support to developing countries for capacity-building related to the Protocol. In consultations with the Secretariat of the Convention on Biological Diversity, it has been noted that a wide range of organizations are interested in the field of biosafety, including bilateral, regional, and international organizations, foundations and the private sector.

32. In order to promote greater information exchange on the activities that are being financed with a view to facilitating openness among donors, an exchange of lessons learned, and an effective and efficient delivery of assistance to developing countries, it is proposed that the GEF

Secretariat, in cooperation with the Implementing Agencies and the Convention Secretariat, convene an annual meeting of interested organizations to review activities and assistance being provided to developing countries in the area of biosafety.⁷ The minutes of these meetings will be made publicly available through the GEF website.

33. Through these meetings and other consultations, the GEF will attempt to build synergies and establish complementarity, share lessons learned, and identify institutions, in both developed and developing countries, with which the GEF can seek partnerships for implementation of the initial strategy, optimize resources and increase the potential for success.

Support to enable countries to participate in the biosafety clearing-house, once the terms of reference of the clearing-house are agreed upon by the Parties

34. Decision V/1 of the fifth meeting of the Conference of the Parties to the Convention on Biological Diversity outlines the work plan for the Intergovernmental Committee for the Cartagena Protocol on Biosafety. In the preamble to the decision, the Conference of the Parties emphasized “the priority of launching the biosafety clearing-house no later than the entry into force of the Protocol, and also the need to engage in capacity-building as soon as possible.”

35. It will be recalled that the GEF provided assistance to developing countries to enable them to participate in the clearing-house mechanism of the Convention within the framework of enabling activities for biodiversity. An evaluation presented to the fifth meeting of the Conference of the Parties concluded that GEF support for participation in the clearing-house mechanism has proved effective in enabling a large number of countries to begin sharing information related to Convention implementation and to benefit from information available through the clearing-house.

36. From experience in providing assistance for purposes of the Convention’s clearing-house, it is clear that GEF assistance can facilitate participation by developing countries in a biosafety clearing-house. It is also clear from the Protocol that the biosafety clearing-house is central to the implementation of the Protocol. Nevertheless, before the GEF can determine what assistance is required by developing countries, there must be agreement as to the terms of reference and structure of the biosafety clearing-house. These issues were addressed by a meeting of technical experts to be convened by the Convention Secretariat in September 2000. The proposals of the experts will be reviewed by the Intergovernmental Committee for the Cartagena Protocol on Biosafety, the first meeting of which will be convened in December 2000.

37. Once the biosafety clearing-house is established, the GEF could be available to provide prompt assistance to the national competent authority to enable participation in the clearing-house. This would require countries to identify a national competent authority responsible for the biosafety clearing-house before support could be provided.

38. Should the Intergovernmental Committee for the Cartagena Protocol propose a time frame for launching the biosafety clearing-house prior to the entry into force of the Protocol, the GEF Secretariat will inform the Council of the type and modality of assistance that it

⁷ If possible, such a meeting could be organized in the margins of a GEF Council meeting or a CBD meeting.

recommends be provided to countries to assist them to participate in the biosafety clearing-house. In preparing its recommendations, the GEF will draw upon its experience in providing assistance to countries for the Convention's clearing-house mechanism. One issue that will need to be determined is whether GEF assistance for the biosafety clearing-house should only be made available to interested countries that have ratified the Protocol or whether signature of the Protocol is a sufficient criterion.

Enhancement of scientific and technical advice to the GEF on biosafety issues.

39. Recognizing the diverse perspectives and interests in the field of biosafety, the GEF will solicit the views of experts chosen for their regional diversity and diversity of perspective on issues relating to the implementation of this strategy. The roster of experts being developed by the CBD Secretariat will be a very useful resource for identifying experts from whom to solicit advice on biosafety issues.

40. UNEP has indicated that in proposing a third reconstitution of STAP, the Executive Director will take into account gaps that may be identified in the expertise of STAP, including gaps in expertise on the emerging area of biosafety.

FOLLOW-UP TO COUNCIL CONSIDERATION OF THE INITIAL STRATEGY

41. The Council is invited to consider this proposed strategy and to approve it as a basis for GEF assistance in the field of biosafety pending the entry into force of the Protocol. Subject to the Council's comments and approval, the following actions will be implemented:

- (a) A project proposal to assist countries to establish national biosafety frameworks, with UNEP as the Implementing and executing agency, is before the Council for approval at this meeting (See Work Program submitted for Council approval: GEF/C.16/7). If the Council approves the work program, it is expected that the project will be fully operational in early 2001.
- (b) In order to gain experience related to more in-depth capacity building activities, a maximum of eight country-driven demonstration projects will be submitted for Council approval. Countries may develop these projects in collaboration with any of the Implementing Agencies.
- (c) The GEF Secretariat, in collaboration with the Implementing Agencies and the Convention Secretariat, will organize the first consultation of interested bilateral and multilateral organizations in the first half of 2001.

(d) The GEF will inform the ICCP of its strategy. The GEF will follow the work of the ICCP and will keep the Council informed of the progress that is achieved so that the Council may determine whether the deliberations of the ICCP necessitate any modifications to this initial strategy. This will include consideration of assistance that might be provided with respect to the biosafety clearing-house.

42. Based on the experience gained through the undertaking of activities proposed in this 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 enters into force, the GEF will present to the Council for its consideration a strategy for advancing and building upon the activities undertaken in the initial strategy.

EVALUATION REPORT

EXECUTIVE SUMMARY

Background

1. This evaluation was undertaken by Dr. Julian Kinderlerer of the University of Sheffield, U.K. during the period November/December 1999. It covers the two components of the project:
 - (i) Support to the preparation of National Biosafety frameworks by 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russia, Tunisia, Uganda and Zambia).
 - (ii) Organisation of a series of awareness-raising regional workshops on issues related to biosafety/biotechnology. These were held in Havana, Cuba; Bled, Slovenia; Nairobi, Kenya; and New Delhi, India.
2. The evaluation of the project involved:
 - (i) An examination of all country reports submitted to UNEP in relation to the development of National Biosafety Frameworks;
 - (ii) Visits to Bulgaria, China, Kenya and Mauritius and discussion with officials responsible for the projects in Poland, Russian Federation while at a meeting of the Central and Eastern European Countries in Bulgaria, December 1999.
 - (iii) An examination of the reports emanating from all the workshops held in the four regions, plus reports of the Consultative Meeting of the Countries participating in the Pilot Project and the 2nd Steering Committee meeting held in Cairo, Egypt, 24-26 May 1999.
 - (iv) The evaluator also gives a brief explanation of the appropriateness of the project in relation to relevant provisions of the Convention on Biological Diversity (such as Article 8g) and relevant aspects of Chapter 16 of Agenda 21 (Environmentally sound management of biotechnology).

Project Implementation

3. The project was implemented by UNEP in association with National Executing Agencies (NEAs) of the respective countries (for the national level component).

The three primary stages in the implementation of the project in each individual country were as follows:

- (i) The current use of modern biotechnology within the borders of the country, collecting information on what was being done in national institutions, whether Government, university or private industry, and the level of awareness of biosafety within the institutions;
- (ii) The structures required for a risk assessment and audit of these assessments in order to ensure the safe use of modern biotechnology;
- (iii) The means by which the safe use of modern biotechnology could be promoted. This was often interpreted as the promotion of use of biotechnology, tempered by a need to involve the public in the development of strategies to ensure biosafety.

UNEP also collaborated with IRRO/MSDN and four institutions designated by respective host governments for the organisation of regional workshops.

Evaluation

- 4. This was an ambitious project that was successfully executed over a period of 16 months (originally planned for 12 months). Seventeen (17) out of eighteen (18) countries in the pilot project prepared National Biosafety Frameworks. The evaluator is satisfied that the countries have identified the national systems needed to ensure the safe adoption and application of products of modern biotechnology. However, many had not separated their role in promoting the technology from that of audit and safety assessment. The report suggests that it is important, in order to maintain public acceptance of a Government's objectivity, that a clear separation of duties/activities is maintained and the consequential necessary national capacities developed for the execution of the respective roles. These countries now require further support for capacity building initiatives that would enable them to implement the biosafety frameworks in the light of the provisions of the Protocol on biosafety. The UNEP International Technical Guidelines for Safety in Biotechnology (which were used by the participating countries as a guide) may also need updating/reviewing to take into account the Biosafety Protocol Provisions.
- 5. The evaluator observes that all the regional workshops were held and that a wide spectrum of stakeholders was involved. The regional workshops were successfully conducted, productive and worthwhile. The workshops provided a good understanding and appreciation of the type of assistance that the countries might need to ensure the transparent and safe consideration of the use of products of modern biotechnology. All the workshops concluded that strong regulatory authorities and efficient systems are needed to give users confidence in the safety of products on the market. It was recognised that there is a need for development and/or strengthening of national as well as sub-regional capacities, including the development of human resource infrastructure to attempt risk assessment, management and monitoring of LMOs at national, sub-regional/regional levels.

6. A recurrent theme of the participants at the regional workshops and of the officials and experts in the 17 countries participating in the national level component, was their genuine and honest commendation of UNEP for conceptualising and executing the project and the Global Environment Facility (GEF) for funding it. Both the regional workshops and the Consultative Meeting of the Participating countries as well as the Steering Committee members of the Pilot Project underlined the importance of extending further UNEP/GEF financial and technical support beyond the pilot project and to include additional eligible countries.
7. It is observed that the time scale for the project was severely limiting, and most countries were not able to complete the full legislative process of getting their national biosafety frameworks legally adopted by their Parliaments. However, the preliminary work done towards producing legal systems for safe biotechnology applications demonstrated a commitment to the project and towards ensuring that modern biotechnology is (so far as is possible) conducted in a safe manner.
8. The impetus of the project provided countries with the possibility of establishing a regulatory framework and of kick-starting the use of biotechnological techniques and options in those countries since research and development (R&D) in the area of biotechnology was “lagging”, relative to industrialised countries.
9. Accordingly and most commendably, a majority of the countries involved in the project have passed or drafted new legislation to control the use of LMOs/GMOs within their borders. This type of exercise may extend to other areas of biodiversity and protection of the environment – a very important and welcome development.
10. The level of public participation and involvement in the project in respect of the national level component, differed substantially among the countries, largely reflecting differing traditions, difficulties caused by the size and geographical conditions of the countries, the number of languages and educational deficiencies.
11. Having been an ambitious project, attempting much within a very short timeframe, the achievements attained indicate a well-managed project. The sub-Project documents and the UNEP biosafety guidelines provided a framework for the work involved in this project and the individual participating countries were provided timetables and detailed guidance for delivery of various aspects of the project. The evaluator was impressed that the structures instituted by UNEP ensured that where countries failed to meet their obligations, the system was flexible enough to ensure that money was withheld. In some circumstances small amounts of extra finance were required, and again, countries were impressed with the flexibility of the system. Task managers at UNEP were clearly willing to talk with country representatives and provide the flexibility in interpreting the needs of countries within the framework set by the project.
12. In an extended/expanded future programme/project, timescales that are more realistic need to be identified. If need be, the terms of reference could be scaled down or drafted

to ensure that countries are fully aware of what is readily achievable within the set time-frames, and within the funds that may be provided.

Framework for Cost Norms

13. The identification of cost norms was one of the goals of the project. This has turned out to be very complex (perhaps virtually impossible). Variety in climate, physical and social geography, the number of local languages needed to bring on awareness of the benefits and risks of biotechnology to all stakeholders should be taken into account in the design of the biosafety systems to be implemented in the respective countries and in deciding on a level of funding support to be provided to the countries.
14. The rate of adoption of modern biotechnology applications may differ considerably and significantly from country to country. Whereas the adoption of technology itself may be cheap, and could be readily implemented at the laboratory stage by many countries, it is not the case with respect to risk assessment and risk management. Consideration of the potential hazards of any new LMO to human health or environment may be very expensive, and the investments required for the commercial exploitation of these novel LMOs may be substantial.
15. Fortunately, in the wake of the project activities at national level, and consequent awareness raised during both the regional workshops and the biosafety protocol negotiations, a majority of countries would not be starting from scratch i.e. from a complete absence of environmental legislation or total lack of some capacity for assessment of the impact of LMOs. However, there is strong need for strengthening national capacities and urgent need for establishing and/or strengthening sub-regional centers of expertise with the relevant capacities, facilities and human resources to support national level risk assessment and risk management initiatives.
16. From the experience gained and lessons learned in the pilot project, five types of broad assistance may be identified namely:
 - (i) Support to the development of National Biosafety Frameworks by approximately 60 countries through a consultative and participatory process involving a wide spectrum of stakeholders nation-wide (US\$ 18 million).
 - (ii) Support to the implementation of National Biosafety Frameworks by 25 countries, including those that participated in the UNEP/GEF Pilot Biosafety Enabling Activity Project, and other countries that are at various stages of finalisation of their National Biosafety Frameworks prepared on their own initiatives (US\$ 14,840,000).
 - (iii) Support to sub-regional/regional awareness raising workshops on issues related to biosafety and biotechnology (US\$ 5.2 million).
 - (iv) Support to establishment/strengthening of sub-regional/regional centres of excellence for biosafety and biotechnology (US\$ 7,780,000).
 - (v) Support to Integrated, Multi-pronged Global/Regional/Sub-regional Medium-sized Projects on Biosafety (US\$ 20 million).

17. Accordingly, a crude estimate of funding needs required for accelerated capacity building initiatives in the immediate short-term (2 years) in respect of the critical mass of target countries may be given as US\$ 65,820,000 starting from the July 2000. This would facilitate enhancement of biosafety at the national, sub-regional and regional levels in the identified critical mass of 85 countries, as further outlined below.

Conclusions and Recommendations

18. There can be no doubt of the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives believed that this was the type of project that the countries would have had to undertake. However, if left entirely to Governments for funding, it would have been greatly delayed, much slower and less effective. Certainly, a majority of the project activities at national level would not have taken place without the UNEP/GEF support. While limited funds are available in some of the countries for fundamental research, or applied research and development, most developing countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. Establishment of sub-regional/regional centres of expertise and nodes for supply and exchange of information, the training of scientists to use the technology safely, and to think about the consequences of their work, were seen to be of extreme importance and urgency.
19. The need expressed by those participating in this project for the funds allocated to them, and the impetus that they have experienced from its implementation, has been clearly demonstrated in this project. The countries involved in the project are fearful of being unable to complete the process started. They believe that much has been accomplished, but that there is much to accomplish in the area of biosafety and biotechnology in relation to biodiversity. If they are to set up strict regulatory systems, there needs to be enforcement and laboratory and field facilities that are capable of testing and validating the presence or absence of modified organisms. It is acknowledged that the project has stimulated a new approach to biotechnology by national and international organisations and that it has stimulated regional cooperation. It would be a great pity if these 17 countries were unable to continue the good work started in the course of a single year.
20. In the evaluator's view, it is crucial for the future of biotechnology that a project similar to this one is funded in those countries that have yet to develop a consistent framework for the safe use of this science. If at all possible, as many as possible of those countries involved in this project should continue to be involved, acting in some ways as mentors to newly involved countries so as to allow the rapid build-up of expertise in this area. The experience gained and expertise developed as well as lessons learned should not be lost. Many more countries should benefit from similar input of funds and expertise as that available through this project. Many of these countries have applied for funding for their own National Biosafety Frameworks.

21. The follow-up project for new countries would then be similar to that already achieved, requiring a survey of the expertise and use of both biotechnology and of biosafety. An assessment of the need for an overall biosafety framework would then follow.
22. In order to effectively fulfil its functions as a complement to the Protocol on Biosafety, and to further guide the countries in the preparation of the National Biosafety Framework in the light of the provisions of the Protocol on Biosafety Frameworks in the light of the provisions of the Protocol on Biosafety, it is strongly recommended that consideration be given to the review of the UNEP International Technical Guidelines for Safety in Biotechnology.

**REPORT OF THE STAP SELECTIVE REVIEW OF
"PILOT BIOSAFETY ENABLING ACTIVITY PROJECT"¹**

Prepared by
The Scientific and Technical Advisory Panel (STAP)
of the Global Environment Facility (GEF)

STAP Secretariat
United Nations Environment Programme
Background

The UNEP/GEF Pilot Biosafety Enabling Activity Project was approved by the GEF Council at its November 1997 meeting. It is intended to promote a comprehensive understanding and approach by countries, within a regional/sub-regional context, to safeguarding biological diversity under *in-situ* conservation against possible adverse impacts from living modified organisms (LMOs)/organisms with novel traits (ONTs) resulting from biotechnology, by enhancing safety in biotechnology. The project comprises two main elements:

- (i) **National Component** which entails the Preparation of National Biosafety Frameworks by eighteen (18) countries² of variable sizes, geographical locations, level of socio-economic development, as well as different stages of biotechnology development and application of biotechnology products; and
- (ii) **Global Component** which caters for the convening of 8 regional workshops³ with the main aim of providing a better understanding and appreciation of biosafety issues pertinent to the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology⁴.

At the adoption of the project by the GEF Council in November 1997, STAP was requested to undertake a Selective Review, on completion of the project. The purpose of the independent technical review undertaken by the Scientific and Technical Advisory Panel (STAP) to the Global Environment Facility (GEF) is to broadly to (i) review the scientific and technical issues arising from the implementation of the activities of the Pilot Project; (ii) assessment of the scientific and technical issues that need to be addressed in the context of the implementation of

¹ This is a preliminary report prepared for the Inter-Agency Task Force Meeting. The final report will be considered and adopted at the Seventh Meeting of STAP to be convened in September, 2000.

² The countries participating in this component include: Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russian Federation, Tunisia, Uganda and Zambia.

³ i.e. two workshops to be conducted in each of the following 4 regions: Africa; Asia/Pacific; Latin America and Caribbean; and Central and Eastern Europe regions

⁴ UNEP International Technical Guidelines for Safety in Biotechnology was adopted by the Global Consultation of Government-designated experts in 1995. The Conference of the Parties (COP) to the Convention of Biological Diversity (CBD) in its decision II/5, 1995 stated that, during the development of a Protocol on Biosafety of the CBD, internationally agreed guidelines such as that of UNEP's may serve as an interim mechanism.

National Biosafety Frameworks (iii) advise on ways and means to enhance the scientific and technical capacity of the participating countries in terms of risk assessment and risk management (iv) advise on the scientific and technical issues that need to be addressed by contemplated regional/subregional centres of expertise and (v) highlight pertinent issues in the context of follow-up action to the Pilot Phase.

The selective review undertaken by STAP, consists essentially, of a desk study of the available document produced as part of the project activities. The STAP Selective review team composed of Prof. José Sarukhan (STAP); Dr. Setijati Sastrapradja (STAP) and Dr. Jorge Larsana, Biosafety/Biotechnology specialist.

1. Review of the Scientific and Technical Aspects of the Project

Based upon the outputs of the projects, the following comments and conclusions are made in accordance with the terms of reference of the selective review.

2.1 Scientific and technical issues arising from the implementation of the activities of the Pilot Project

The issue of scope of the biosafety frameworks is both a policy decision and a scientific and technical issue. A clear definition in this regard will benefit all national Frameworks and their future articulation with multilateral biosafety frameworks. Biosafety in its general sense involves practices relating to many fields of expertise and various sectoral authorities. However, within the Cartagena Protocol on Biosafety a clear emphasis is given to the evaluation and management of the potential risks to biological diversity associated to the release of Living Modified Organisms to the environment. Accordingly, GEF funds designated to biosafety should prioritize the biodiversity-related component of the National Frameworks.

Within the National Frameworks a sound delimitation of scope - either including or excluding health issues and/or products derived from LMOs - will benefit future efforts (regional and national) that specifically address the environmental issues or the release of LMO. Thus, the recommendation is to promote and support clear definitions of scope, regardless of their amplitude or specificity, which is a sovereign decision. Whatever the final national decisions on scope, it is important to have clearly defined attributions to facilitate articulation with regional and global biosafety instruments.

During the time of implementation of the Pilot Project the Cartagena Protocol has been agreed upon. Its aspects of risk evaluation and risk management, including the annexes, are very useful for identifying the scientific and technical issues that will need to be addressed by countries.

2.2 Scientific and technical issues that need to be addressed in the context of the implementation of the National Biosafety Frameworks.

Clarity in scope definition needs scientific and technical expertise to understand clearly the differences between releasing living modified organisms to the environment, the production and/or commercialization of their living products (e.g. seeds, tuber) and the use and commercialization of non living derived or purified products. Although UNEP has provided

guidelines that have proven useful, more on site training and capacity building might be needed to ensure clarity in definitions of scope within National Frameworks.

Intent of use of the LMO or its products should also be carefully considered because this will also be useful in clear definitions of scope.

Finally, the process of building and implementing the NBF's should be viewed as an aid in the political-administrative decisions that will further help in defining the scope of the biosafety framework in each country.

Depending on national capacity and existing institutions, a centralized authority dealing with all aspects related to biotechnology or a specific authority dealing exclusively with modern biotechnology and the release of LMOs to the environment are the two extremes of a full range of possibilities. These national decisions should be taken with sound scientific and technical understanding of their consequences in order to facilitate the articulation between National Frameworks and multilateral agreements.

2.3 Ways and means to enhance the scientific and technical capacity of the activities of the participating countries in terms of risk assessment and risk management

Although most NBF suggest creating a specific LMO register (or similar concepts), it is very important to include minimum standards for information management. Many countries have developed GIS and biological inventories capacities, many with GEF support, that should be articulated with biosafety information. This is crucial if monitoring is going to be implemented in the medium term.

Biosafety databases (including information of LMOs and their uses) should not be isolated from biodiversity information management. In fact, resources from biosafety procedures (risk evaluation and management) should positively benefit biodiversity information management through the support of baseline inventories of pollinators). Precise geographical information will also prove very useful in risk evaluation - including modeling - and management, as well as in monitoring.

There are many databases and GIS utilities that have developed specific biodiversity applications. Such software and database should be extended - as needed in each country - to include information specific to risk evaluation (e.g. distribution of wild relatives and landraces or their reproductive systems). These efforts will profit if viewed within the context of projects related to the implementation of the obligations of inventorying and monitoring in the CBD and its Annex 1.

The efforts in capacity building should balance the disciplines related to risk assessment and management such as biological inventories (taxonomy and molecular systematics), ecology (population ecology and genetics, evolutionary ecology, interactions and reproductive systems) and molecular biology with those related to capacity to produce and manage LMOs such as biotechnology, agronomy, etc. This balance will help both the understanding potential risks of LMOs and also the production of biological information needed for risk assessments in local

environments. This will foster a scientifically sound application of the precautionary principle, its approaches and practices. The importance of this balance between areas of expertise is fundamental for sound environmental risk assessments.

At national level, it would be very useful to clarify the differences between the direct potential hazards posed by LMOs to human health (e.g. living vaccines or direct consumption of LMOs), consumption of purified derivatives of LMOs and the potential indirect risks to human health through damage to biodiversity and the environment. This has long been a problematic issue of interpretation and it would be important to promote a common understanding of the issue. This problem is also illustrated by the tendency to use risk level classifications that have been developed with human health considerations. These levels of risk do not apply to many of the biotechnological applications foreseen in the short or middle term to be used or imported to developing countries.

Recommendations in part 3 can be applied to part 4 in some instances but viewed at the regional/subregional level.

2.4 Scientific and technical issue that need to be addressed by the contemplated regional/subregional centers of expertise

Will we need a risk level classification for environmental releases? This is a specific scientific and technical issue to be addressed at the regional/subregional level of coordination.

Similar to the scientific and technical capacity comment (see 2.3), STAP is of the view that not only agricultural biotechnology centre should be envisioned, but also strong networking between global agricultural facilities and biodiversity libraries (e.g. herbaria, collections and germplasm bank) and national research institutions. The repatriation of information needed for risk assessments in tropical and developing areas is deposited in developed countries. Much of this already exists, what is lacking is a formal linkage of this efforts on biodiversity information with the biotechnology and biosafety oriented efforts.

It would be very useful to start developing a conceptual framework that will eventually lead us to some form of classification of environmental risk levels, particularly those related to biodiversity. This will benefit all countries and multilateral agreements in the long run.

Achievement of Project Objectives and Issues for Project Follow-up

The project was undertaken between April 1998 and September 1999, during which the two main components of the project were implemented, namely;

3.1 National component: Of the 18 countries selected to participate in the project one⁵ was not able to continue its participation in the pilot phase. Most countries accomplished the tasks as outlined in the Term of Reference of the project, which among others are:

⁵ Pakistan

- (a) The status of biotechnology capacity in the country
- (b) The Task Force on Biosafety established
- (c) The National Biosafety Framework formulated
- (d) The awareness of the importance of biosafety framework Multidisciplinary team on biotechnology/biosafety formed

Thorough survey and national workshop in each country data on activities, infrastructures, and human resources engaged in biotechnology research and development was gathered. Moreover, awareness on the need to develop biosafety measures was enhanced among different disciplines of scientific community and the different sectors in the government. In most countries, before the project, there was no legal framework to assess and manage the risk. Through the project, these countries were able to formulate the National Biosafety Framework. In conclusion, STAP was pleased to observe that countries participating in the project appreciated the efforts of the project to provide them with opportunity to developing and enhancing their capacity in biosafety.

3.2 Regional/International Component: A total of 8 regional workshops were organized in Latin America and the Caribbean, Central and Eastern Europe, Africa, and Asia-Pacific. The main issues discussed in the workshops were:

- (a) Issues related to risk assessment and risk management of living modified organisms (LMOs) or organisms with novel traits (ONTs).
- (b) Issues related to transboundary transfer of LMOs and ONTs.

The workshops brought together biosafety experts from different countries and sectors and provided them with a forum to exchange views and information on the above issues. In this way, awareness on the issues related to biosafety and biotechnology of the participants who represented governments, the scientific community, United Nation Bodies, non-government organizations, and private sectors was arisen. Moreover, the workshops facilitated the development of national regulatory frameworks, particularly for those countries participating in the project.

The workshops also provided participants with the opportunity to learn from each other on the state of the art of biotechnology in various countries. This in turn reflected the state of the art of biotechnology in particular regions. The workshops were also able to identify the trends in commercialization and international trade of biotechnology products. A major conclusion arising from those discussions is that regulatory and efficient systems are needed to provide safety to the users of biotechnology products. As for the transboundary movement of LMOs and ONTs; legal issues, including advance informed agreement (AIA); and compensation and labeling were also addressed. It becomes obvious that such legal issues are related to the national capacity for establishing a strong regulatory system.

The need to develop and increase capacities including human resources, infrastructure and mechanisms for information supply and exchange was identified as prerequisites to implement the UNEP Guidelines for Safety in Biotechnology and Protocol of Biosafety

after its completion. International cooperation was considered as not only essential for the development of capacities in biotechnology and biosafety but also for the harmonization of efforts between national and regional level.

The need to enhance national capacity for biosafety biotechnology was stressed.

3.3 Issues highlighted in the context of follow-up actions to the Pilot Phase Project

Based upon the content of the various reports, the following issues are being highlighted in the context of any follow-up action to Pilot Phase Project.

- (i) **Time Factor:** Based on the reports submitted at the completion of the project it is obvious that the project has promoted awareness among the participating countries on the need of establishing legal framework to assess and manage the risk of the products of biotechnology, in particular LMOs and ONTs. However, from the list of constraints, STAP stresses the importance of the time factor for the project implementation.
- (ii) **The continuation of the project:** All participating countries expressed the desire to continue with the project implementation considering the elements of biosafety framework is now in place. They stressed the need to enhance the capacity building to conduct the risk assessment and risk management. STAP is of the opinion that legal frameworks/regulation/law should be accompanied by the competence of human resources. Therefore, for those participating countries, if and when the project will be continued, the following aspects need further consideration:
 - (a) The scope of the project needs to be broadened and deepened.
 - (b) Biotechnology policy: to cover not only in environment sector but cross sectoral issues as well.
 - (c) Clarity of institutional set up to implement the framework.
 - (d) Training to enhance human resources capability on this subject is most appropriate so that assessment on scientific and technical issues can be conducted properly.
 - (e) National and regional dialogues to strengthen national capacity.
 - (f) Biodiversity aspect is included in the biosafety framework not only health and environment.
 - (g) Awareness on this subject of community outside the scientific community
 - (h) The active involvement of the Steering committee on the project Implementation.
- (iii) **The Project Expansion:** The regional workshops recommended that the project should be expanded to countries which need assistance form UNEP-GEF. Considering this recommendation, STAP is in the opinion that before the first meeting of the ICCP of the CBD is convened, a scientific and technical meeting should be convened by UNEP/GEF to address issues such as, but not limited to;
 - (a) The critical mass of the scientists that are need to implement the framework
 - (b) The institutional issues to implement the framework, since many countries lack institutional mechanism to mobilize the existing scattered scientists.
 - (c) The development of scientific and technological competence in biotechnological/ biosafety.
 - (d) To develop closer collaboration with the existing biotechnology agencies.

STAP Selective Review of the Pilot Biosafety Enabling Activity Project

Annex 1

Terms of Reference

1. Review the scientific and technical issues arising from the implementation of the activities of the Pilot Project
2. Assess the scientific and technical issues that need to be addressed in the context of the implementation of the National Biosafety Frameworks
3. Advise on the ways and means to enhance the scientific and technical capacity of the participating countries in terms of risk assessment and risk management
4. Advise on the scientific and technical issues that need to be addressed by the contemplated regional/subregional centres of expertise.
5. Assess the usefulness of the project outputs, and how they contribute to the overall objectives of the project.
6. Based upon (1-4) and taking into consideration the recommendations of the Regional workshops advise on the desirability of expanding the Pilot Biosafety Enabling Activity Project bearing in mind:
 - (a) The level of additional support needed, for the future implementation of the National Biosafety Frameworks already prepared, and
 - (b) The future actions and types of assistance required to facilitate the preparation of NBFs for other developing countries and countries with economies in transition.