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## REPORT OF THE STAP SELECTIVE REVIEW OF “PILOT BIOSAFETY ENABLING ACTIVITY PROJECT”

(Prepared by the Scientific and Technical Advisory Panel)

**Report of the  
STAP Selective Review of  
"Pilot Biosafety Enabling Activity Project"**

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

October, 2000

**STAP Secretariat  
United Nations Environment Programme**

## **Preface**

It is a pleasure to present the final report of the STAP Selective Review on the “UNEP/GEF Pilot Biosafety Enabling Activity Project” to you. The Selective Review was undertaken by STAP as directed by the GEF Council at its meeting of November, 1997.

The STAP Review Team consisted of Dr. Jose Sarukhan and Dr. Setijati Sastrapradja.

This report was prepared by the Selective Review Team with input from the STAP Secretariat.

Madhav Gadgil  
STAP Chairman

## **Executive Summary**

The STAP Selective Review of the “UNEP/GEF Pilot Biosafety Enabling Activity Project” was undertaken at the request of the GEF Council at its meeting of November 1997. The Terms of Reference of the Selective Review was agreed after wide consultation with the Consultative Meeting of the Participating Countries and the Steering Committee for the project.

The STAP Selective Review which was essentially a desk study and focused on the scientific and technical issues arising from the implementation of the activities of the Pilot Project; assessment of the scientific and technical issues that need to be addressed in the context of the implementation of National Biosafety Frameworks; ways and means to enhance the scientific and technical capacity of the participating countries in terms of risk assessment and risk management; scientific and technical issues that need to be addressed by contemplated regional/subregional centres of expertise and specific recommendations in the follow-up action to the Pilot Phase.

For each of these issues a number of specific suggestions are made by STAP. In considering the follow-up action of the Pilot Phase project, STAP is recommending that consideration be given to a number of issues including, broadening and deepening of future interventions; biodiversity policy should be cross-sectoral in orientation and not sectoral; clarity of institutional set up to implement the framework; training to enhance human resources capability on this subject is most appropriate so that assessment on scientific and technical issues can be conducted properly; national and regional dialogues to strengthen national capacity; the inclusion of biodiversity aspect in the biosafety framework; the creation of greater awareness on this subject outside the scientific community.

In addition, STAP is recommending that a scientific and technical meeting be convened by the GEF to address issues such as the critical mass of the scientists that are needed to implement the framework; the institutional issues to implement the framework, since many countries lack institutional mechanism to mobilize the existing scattered scientists; the development of scientific and technological competence in biotechnological/ biosafety; and to develop closer collaboration with the existing biotechnology agencies.

## 1. Background

The UNEP/GEF Pilot Biosafety Enabling Activity Project was approved by the GEF Council at its November 1997 meeting. The overall goals of the project are outlined in the project brief<sup>1</sup> as follows:

- (i) Strengthen national capacity in order to implement biosafety procedures and maximise the potential of biotechnology;
- (ii) Apply biosafety procedures to enhance environmental management;
- (iii) To investigate modalities for applying the UNEP International Technical Guidelines for Safety in Biotechnology, and other guidelines under the Convention on Biological Diversity;
- (iv) Harmonize regional and international legal instruments in order to simplify the process of applying and conforming to regulations;
- (v) Raise public awareness of the issues involved in release of living modified organisms, and their products, to promote informed debate;
- (vi) Carry out an assessment of technological capacity, its effect on implementation of national biosafety frameworks and means to improve it;
- (vii) Increase the overall safety to biotechnology so that citizens may reap the benefits with minimum adverse effects on health and environment.

The project comprises two main elements:

- (i) **National Component** which entails the Preparation of National Biosafety Frameworks by eighteen (18) countries<sup>2</sup> 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 workshops<sup>3</sup> 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 Biotechnology<sup>4</sup>.

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

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<sup>1</sup> UNEP/GEF Pilot Biosafety Enabling Activity Project, 1997

<sup>2</sup> 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.

<sup>3</sup> Two workshops were conducted in each of the following 4 regions: Africa; Asia/Pacific; Latin America and Caribbean; and Central and Eastern Europe regions

<sup>4</sup> 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.

review undertaken by STAP to the 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 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 is composed of Prof. José Sarukhan (STAP); Dr. Setijati Sastrapradja (STAP) and Dr. Jorge Larsana, Biosafety/Biotechnology specialist.

## **2. 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 LMO's - will benefit future efforts (regional and national) that specifically address the environmental issues especially the impact on conservation and sustainable use of biological diversity 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 LMO's 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 NBFs suggest creating a specific LMO register (or similar concepts), it is very important to include minimum standards for information management. Many countries have developed Geographical International System (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 LMO's 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 systematic), ecology (population ecology and genetics, evolutionary ecology, interactions and reproductive systems) and molecular biology with those related to capacity to produce and manage LMO's such as biotechnology, agronomy, etc. This balance will help both the understanding potential risks of LMO's 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 LMO's to human health (e.g. living vaccines or direct consumption of LMO's),

consumption of purified derivatives of LMO's 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 centres of expertise**

A risk level classification for environmental releases is required? 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.

### **3. 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 one<sup>5</sup> 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:

- (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

Through 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

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<sup>5</sup> Pakistan



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 (IA); 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 should not be restructured only to the environment sector but also cross sectoral issues.
  - (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 from UNEP-GEF. Considering this recommendation, STAP is in the opinion that, there is a need for a scientific and technical meeting(s) to be convened by the GEF to address issues such as, but not limited to;
- (a) The critical mass of the scientists that are needed 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”**

**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.