



A Comparative Analysis of Experiences and Lessons From the UNEP-GEF Biosafety Projects

Prepared by the UNEP-GEF Biosafety Unit
As of December 2006



Acknowledgement

The UNEP-GEF Biosafety Unit (2006) acknowledges the financial support provided by the Global Environment Facility which enabled UNEP to assist countries to develop and implement their National Biosafety Frameworks, and also to the national biosafety project teams in more than 140 countries and stakeholders whose hard work we hope we have reflected, at least partially, in this document.



Foreword

On 11 September 2003, the Cartagena Protocol on Biosafety of the Convention on Biological Diversity (CBD) entered into force. By 31 December 2006, 137 countries had ratified or acceded to the Protocol, signalling the importance that countries attach to the issue of biosafety.

For many countries, participation in the Cartagena Protocol has been a challenge, due to a lack of capacity for biosafety activity at the national level. In response, the Conference of the Parties of the CBD, working with the Global Environment Facility (GEF) has made resources available to build capacity for the Protocol's implementation.



In its capacity as an Implementing Agency of the GEF, UNEP has been providing administrative and technical assistance to countries participating in a global development project, within which 124 countries have developed National Biosafety Frameworks. In addition, UNEP has assisted eight countries to successfully implement their National Biosafety Frameworks, and is also assisting more than 139 countries to use and participate in the Biosafety Clearing House.

Much of the experience of this capacity building has been captured in the Comparative Analysis, produced by the staff of the UNEP Biosafety Unit who developed and managed these multi-country activities. There are many lessons to be learned from it, particularly on how over 130 countries have worked with UNEP to build – from nothing in many cases – sustainable systems for the safe use of biotechnology. The lessons learned in working with a diverse range of developmental, socio-economic and technological conditions are also apparent, as are the multiple methods that the UNEP Biosafety Unit has developed to meet the challenges in biosafety and biotechnology.

Under the Bali Strategic Plan on Technology support and capacity building, adopted by the UNEP Governing Council in 2005, UNEP is mandated to provide more coherent, coordinated and effective delivery of environmental capacity building and technical support at all levels in response to well-defined country priorities and needs. The work analyzed in the publication provides an excellent example of how this mandate can, and should, be fulfilled. I commend it as a valuable addition to a growing body of work that demonstrates how targeted partnerships can support equitable and sustainable development.

Achim Steiner
United Nations Under-Secretary-General and
Executive Director, United Nations Environment Programme



Foreword

The Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects, which sets out the path toward implementation of the Cartagena Protocol, can serve as an important synthesis tool in demonstrating the collaborative efforts of participants in the National Biosafety Framework Development Project, including the engaged countries, the GEF, and the Convention on Biological Diversity Secretariat.



The creation of capacity in the area of biosafety is critical, and remains today a priority for the GEF. At the GEF, as part of this priority, we have engaged in a continual evolution and expansion of support to countries for implementing the Protocol. After the Protocol's adoption, the GEF Council approved an initial strategy to help countries prepare for its entry into force by providing assistance to more than 120 countries to develop their national biosafety frameworks (NBFs). Since then, GEF has supported 139 countries in the Biosafety Clearing House (BCH) and 12 countries which are participating in implementation projects for the Protocol. The total amount allocated to these projects exceeds \$56 million.

After the Protocol entered into force in September 2003, the GEF Council extended its support to 11 countries to move forward in implementing their NBFs; and two regions, Latin America and West Africa, have received support to strengthen regional centers of excellence to assist their countries to implement the CPB. Total funding for these activities has been close to \$18 million.

Further to a successful fourth replenishment of the GEF in August 2006, the GEF Council approved a renewed Strategy for Financing Biosafety, as a framework for projects designed to implement the CPB. We have invited our partners to collaborate with us to provide assistance to countries to continue our role in biosafety capacity building.

This work is urgent. I am pleased that this publication helps clarify the benchmarks and lessons from which we can draw so that, with the effort of all stakeholders, we will achieve our goal of helping countries to implement the CPB for the better protection of biological diversity.

A handwritten signature in dark ink, appearing to read 'Barbut'.

Monique Barbut,
CEO and Chairperson,
Global Environment Facility (GEF)



Foreword

This comparative analysis study on the 124 countries in the National Biosafety Frameworks (NBF) development project, and the eight demonstration implementation projects, encompasses valuable experiences, lessons learned and best practices that will further enrich the development of the processes of implementation, specifically with regard to the Cartagena Protocol on Biosafety. The analysis will also serve to augment the knowledge base for processes of implementing other Multilateral Environment Agreements.



It is no exaggeration to say that the study has made a major contribution towards exploiting modern biotechnology in a safe manner. It will enrich the country processes in putting in place their NFB in a cohesive fashion, and in the process ensure the maximum use of their resources.

Indeed, the adoption in January 2000 of the Cartagena Protocol on Biosafety, and its subsequent entry into force on 11 September 2003, are major landmarks in the sustainable development agenda. However, the main challenge currently facing Parties is the development of NBFs to implement the Protocol. The sheer diversity of this study has come at the right time to assist countries with their national processes.

Since its adoption the Protocol has received remarkable support from all partners. The number of Parties to the Protocol continues to grow, and currently stands at 135. This is a clear sign of the confidence the global community places in the Protocol. It is also a recognition of the need for international cooperation in ensuring the safe transfer, handling and use of Living Modified Organisms resulting from modern biotechnology.

The biggest challenge facing many developing countries in implementing the Protocol and other Conference of the Parties-Meeting of the Parties (COP-MOP) decisions is the lack of human resource, institutional and technological capacities in biosafety. In Curitiba, at the third MOP a new spirit of consensus and cooperation on issues related to biosafety was born opening a new era for the implementation of the objective of the Cartagena Protocol on Biosafety. This new phase in the implementation of this innovative unique legal instrument calls for a new era in the cooperation of the Convention and its financial mechanism.

The recent historic COP-MOP decision on the detailed requirements for documentation accompanying shipments of Living Modified Organisms (LMOs) intended for direct use as food or feed, or for processing to foster transparency and predictability in the international trade of genetically modified commodities and boost public confidence in the international biosafety system can only become operational if the necessary capacity-building activities are put in place. Capacity-building experiences, as documented by the United Nations Environment Programme (UNEP)-Global Environment Facility (GEF) projects, can help countries to acquire the necessary experiences and use them effectively.



The development and implementation of NBF projects have made an immense contribution to the development process at the national level to sustain the Cartagena Protocol. Our deep appreciation goes to our development partners through the GEF for the support given to:

- More than 130 countries that have completed or are about to complete developing their NBF;
- 12 countries that are in the process of implementing their NBFs with support provided through UNEP, the United Nations Development Programme, and the World Bank; and
- More than 139 countries are being assisted, through UNEP-GEF, to build their capacities in order to effectively participate in the Biosafety Clearing-House.

I would like to thank the Global Environment Facility and its implementing agencies for their support. The GEF is currently the single largest donor for biosafety capacity-building activities. According to the recent survey carried out by the United Nations University Institute of Advanced Studies, the GEF has, over the last five years, invested close to US\$60 million in biosafety capacity-building projects. This accounts for more than 40% of the total bilateral and multilateral funding assistance for biosafety. It is also gratifying to note that of the US\$3.13 billion for the fourth GEF replenishment over the next four years, more than US\$80 million will be spent on biosafety projects. I welcome this renewed support and commitment from the GEF under the leadership of the new CEO and Chairman to establish a vibrant partnership with the Convention on Biological Diversity and its Protocol. This will go a long way in assisting Parties to build the capacities necessary to enable them to fulfill their obligations under the Protocol.

In my capacity as the Executive Secretary I look forward to an enhanced phase of collaboration between the Secretariat and its financial mechanism during the new phase of the GEF.



Ahmed Djoghla
Executive Secretary
Secretariat of the Convention on Biological Diversity



I. Executive Summary

- i. This study looks at the 124 countries that participated in the UNEP-GEF Project for Development of National Biosafety Frameworks (NBF), hereinafter referred to as the NBF development project, as well as the 8 countries that participated in the UNEP-GEF demonstration projects for the implementation of the NBFs, hereinafter referred to as the 8 demonstration implementation projects, focussing on a comparative analysis of their experiences in order to draw out lessons and best practices applicable to other global initiatives for implementation of MEAs. These projects are implemented by UNEP under the GEF Initial Strategy for assisting countries to prepare for entry into force of the CPB.
- ii. The NBF Development Project started in June 2001 and by June 2006 124 countries had joined the project. By 31 December 2006, 84 countries had completed their draft NBF; the remaining countries are expected to complete their NBFs by the end of the project in December 2007. All the eight demonstration projects were completed by the end of 2006.

The process of developing an NBF

- iii. This paper looks at how each country participating in the NBF project used a process of knowledge mapping, adapted to its own particular social, political, environmental and development situation. Using an iterative learning process, countries collected and analysed information on biotechnology and biosafety within the context of their development priorities, and refined and developed their ideas about the different components of the NBF. This iterative process led to a map of the NBF that is dynamic, and evolves in light of experience as systems are established and become operational. The actual NBF produced by each country is therefore tailored to their own special needs and priorities.

Why did countries develop an NBF

- iv. The 132 countries around the world that joined the UNEP-GEF NBF Projects in order to develop and implement their national biosafety frameworks did so for reasons that included both national development priorities and international obligations. Many countries saw biotechnology and biosafety as being integral to their national development planning priorities, particularly for sustainable development. For some countries, the primary reason for joining the project was to have access to funds from UNEP-GEF for capacity building activities. In most of these countries, the process of developing the NBF resulted in an increased awareness of the importance of biosafety and the potential of biotechnology for development. Thus these countries were able to integrate biosafety into their national development planning processes. Similarly, in those countries where the initial impetus for joining the NBF development project was to enable them to comply with the CPB, the process of collecting and analysing information helped to highlight the importance of biosafety as a sustainable development issue.



NBF: the policy context

- v. Participating countries chose to develop national policies that address biosafety in a variety of forms, depending on a country's national priorities. Some chose to develop a stand-alone policy on biosafety, whilst others formulated a combined policy on biotechnology and biosafety. Some policies were part of wider policies on biodiversity conservation and environmental protection, trade related issues, biosecurity and quarantine, or within the overall context of sustainable development or Agenda 21.

NBF: the regulatory regime

- vi. A number of countries had some form of regulatory regime (i.e. either primary or secondary instruments) in place before they started their NBF projects. However, most countries that started work on their NBF did so without any pre-existing regulatory regime for biosafety. Many of these countries without a pre-existing biosafety regime decided to select a level 3 primary legal instrument, created under delegated authority. The choice of a level 3 primary legal instrument enabled countries to build on existing and functional legal systems in order to promulgate a legal basis for regulating GMOs within a short time-frame, allowing them to work with a legal instrument that could be reviewed and revised easily.
- vii. Other countries without a pre-existing biosafety regime decided to adopt a level 1 biosafety law as the primary legal instrument for a variety of reasons. These included lack of a suitable existing law that could serve as a 'home' for a level 3 biosafety legal instrument; political support that enabled a level 1 law to be approved relatively quickly; And a lack of existing laws that adequately address or recognise the importance of biotechnology and biosafety.

NBF: the institutional set-up

- viii. The proposed institutional setups for the **National Competent Authority (NCA)** in the different NBFs include: a single NCA receiving and processing applications; or more than one NCA, each with Sectoral responsibilities and with either a single window or multiple windows for receipt of applications for GMOs. In the draft NBFs in all regions, the proposals for the **risk assessment** setup usually assign that responsibility to the NCA or overall biosafety body, with advice from either an ad-hoc scientific advisory body, or an established advisory committee.

NBF: Addressing Article 23 of the CPB

- ix. Countries have addressed Article 23 of the Cartagena Protocol on public awareness,

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