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Environment Programme

UNEP-GEF Biosafety Projects on Implementation of National Biosafety Frameworks

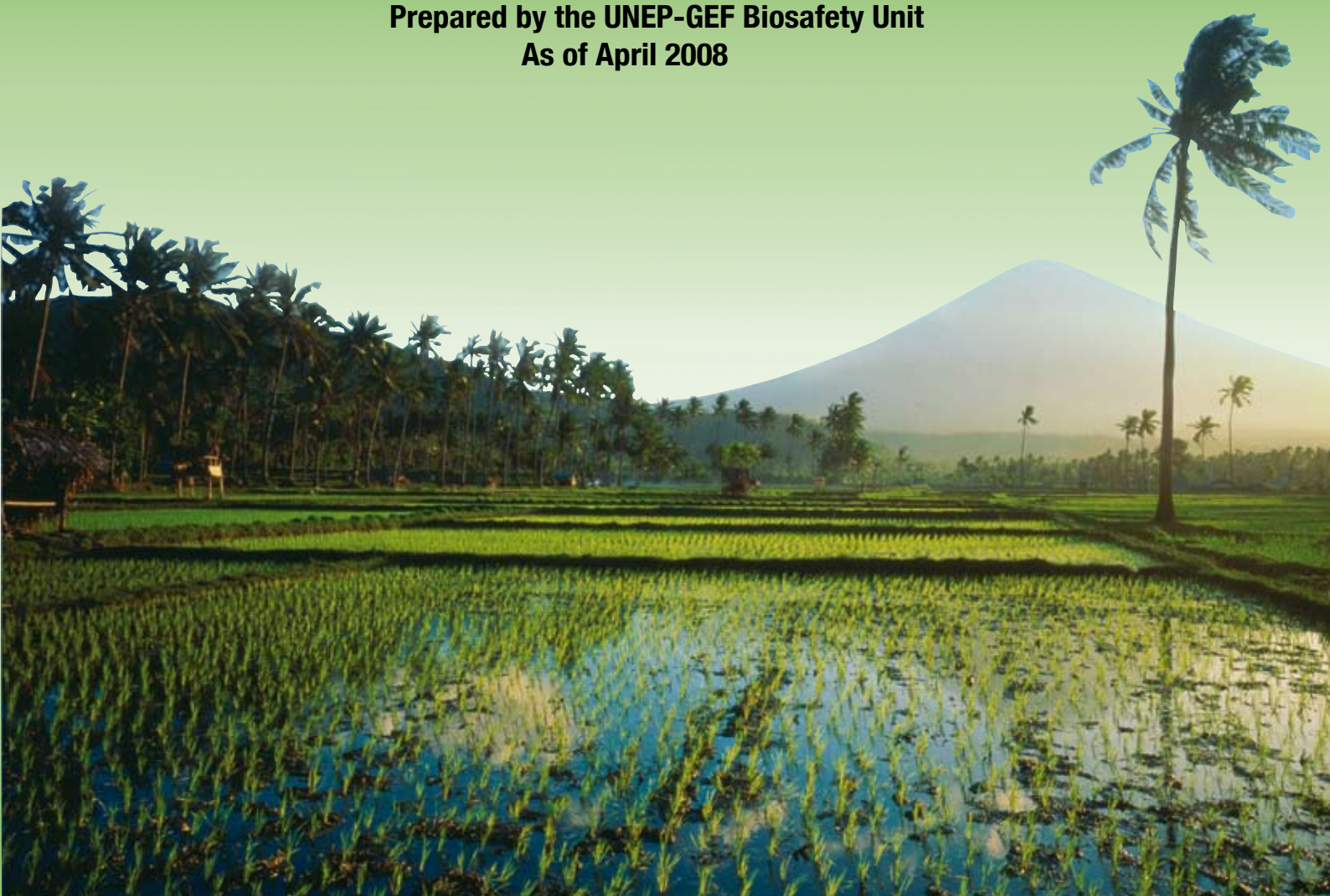


Global Environment
Facility

Guidance towards Implementation of National Biosafety Frameworks:

Lessons Learned from the UNEP Demonstration Projects

**Prepared by the UNEP-GEF Biosafety Unit
As of April 2008**



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Foreword

The Cartagena Protocol on Biosafety marked a significant milestone in how countries cooperate towards the safe transfer, handling and use of living modified organisms that come from modern biotechnology. However, the ultimate success of this international agreement depends on the capacity of Parties to fully implement this landmark agreement. The Cartagena Protocol on Biosafety (CPB), adopted in 2000, entered into force on September 11 2003. Since then, a total of 147 countries have either ratified or acceded to the CPB. The speed of its ratification bears testimony to the importance countries attach to this legal instrument.

The Global Environment Facility (GEF), as the financial mechanism to both the Convention on Biological Diversity and its Cartagena Protocol on Biosafety, has played an important role in building the necessary capacity in biosafety since the adoption of the Protocol. The GEF, together with UNEP, UNDP and the World Bank, assists countries in developing and implementing national biosafety frameworks (NBFs), and participating in the Biosafety Clearing House (BCH).

The eight demonstration UNEP-GEF projects for assisting countries to implement their NBFs has been enabling countries to successfully meet their obligations as Parties to the Protocol. This has been done by building scientific and technical capacity and helping to translate draft NBFs into a workable and effective roadmap to manage a comprehensive biosafety system in the countries.

Guidance towards Implementation of National Biosafety Frameworks: Lessons Learned from the UNEP Demonstration Projects is an analysis of eight UNEP managed demonstration projects for the implementation of national biosafety frameworks between 2002 and 2006. The findings and recommendations offer valuable lessons to countries moving towards the implementation of similar projects.

Three biosafety publications are being launched at the fourth Conference of the Parties serving as the Meeting of the Parties in Bonn, Germany in May 2008. We hope that countries will find these lessons useful as they build their capacity to implement the Cartagena Protocol on Biosafety for the better protection of biological diversity now and into the future.



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Executive Summary

The UNEP-GEF Biosafety Unit recently started an analysis of lessons learned from the 8 UNEP-managed demonstration projects for the implementation of National Biosafety Frameworks. These projects were approved by GEF Council in November 2001, for Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland, and Uganda. The 3-year projects started in September 2002 and were completed in the period 2005-2007.



The present report provides a synthesis and analysis of lessons learned from the 8 implementation projects. The findings and recommendations offer valuable lessons to countries moving towards the implementation of similar projects. Early 2006, the GEF council approved another round of 11 UNEP-managed biosafety implementation projects for countries in Africa, Asia and Central/Eastern Europe. By the time of writing this report, these new implementation projects had just been launched.

The report was developed during May-August 2007, and has been drawn from the following activities:

- (1) A review of relevant documents and reports, including:
 - Results of a survey among National Project Coordinators (NPCs) conducted by UNEP in 2005,
 - Reports of NPC meetings, held in 2004 and 2005,
 - Selected quarterly progress reports as submitted to UNEP,
 - Summary of lessons learned, extracted from project terminal reports.
- (2) Consultations with NPCs, via telephone and e-mail, to review specific findings from individual countries.
- (3) Joint review of the preliminary report, developed in collaboration with the UNEP Biosafety Unit team members, summarizing main findings and recommendations.
- (4) Peer review by two international experts in biosafety.

The experiences and lessons learned reported by NPCs have been analyzed in combination with the experience gained by UNEP in the management and coordination of the same projects. Based on the above, the results of the analysis are expected to contribute to improved preparation and execution of future biosafety implementation projects.

It should be emphasized that the analysis does not represent a formal, external project evaluation, but rather an internal review of lessons learned and emerging issues during the life of the implementation projects, and ways in which they were addressed.



The report is structured around the following main topics:

(1) Project objectives and achievements

- National policies on biotechnology and biosafety
- Regulatory regime – laws and regulations
- System to handle notifications
- Monitoring and inspections
- Public information and awareness, and the Biosafety Clearing-House (BCH)

(2) Project management and implementation

- Management team and NCC
- Coordination between government agencies
- Adoption of policies, laws, regulations
- Regional / international collaboration and sharing experiences
- Technical support and backstopping

Summary of Recommendations

Recommendations to enhance project achievements:

1. The agreed project period turned out to be too short for most countries. As a result, the expected duration of the present set of implementation projects is 4 years instead of 3. However, taking into account that considerable time might be needed to evaluate the workability and effectiveness of the NBF by confronting it with a real application, a project duration of 5 years is more realistic.
2. A national biosafety policy or strategy is essential to provide guiding principles for the subsequent development and implementation of a biosafety legal framework, and mechanisms for policy coordination across government departments. Policies and laws should be dynamic and flexible to allow for the integration of outcomes and obligations from ongoing national and international dialogues.
3. In the development of policies, laws and regulations, the process is equally important as the resulting policy or legal document. Consultative approaches are indispensable even though it builds in time-consuming rounds of review and revisions.
4. Devising a strategy for getting a policy or legal document through, and investing in raising awareness and familiarity among policy makers, may limit the time required from draft to adoption. The NCC can play a valuable role in this process.
5. External review of draft policies and laws contributed to their practicality and consistency with the Cartagena Protocol on Biosafety and other relevant obligations.
6. Detailed implementing regulations are an equally essential element of a biosafety framework, as they clarify matters over which government agency (-ies) regulate what, and how.



7. Technical guidelines for reviewing and assessing notifications were introduced through training programs for specific audiences, which often benefited from the involvement of foreign experts.
8. Progress on establishing national BCHs and contributing to the central BCH was very uneven across countries, and sometimes hampered by national laws governing the distribution of official government documents. This issue must be addressed upfront in the current cycle of implementation projects, and be made a more explicit component of national biosafety frameworks.
9. Recurrent technical training on topics such as risk assessment, GMO detection, and others, was identified as a priority for future support, and frequently mentioned as a candidate for cross-country (sub-regional) collaboration. Sub-regional collaboration and the sharing of expertise and information were done on an informal basis; this should become a regular feature in future support programs.
10. A complete “library” should be developed of technical outputs from the implementation projects, and make them accessible to other countries. In some cases, this would include support for translations.
11. It will be essential that the GMO detection laboratories, established with UNEP-GEF support, seek international accreditation so that they can act as reference laboratories in the sub-region.
12. A separate in-depth study should be carried out among those countries (e.g. Bulgaria, China and Cuba) which have released biotechnology products, to document their experience in how their NBF was used with regards to monitoring and inspection. This will provide an insight into the strength and weakness of their regulatory and/or administrative system. This analysis will help other countries which are carrying out similar NBF implementation projects to design a more robust monitoring and inspection system.
13. Establishing a national program or strategy for public awareness should be considered, in order to best reach out to different stakeholder groups, and to avoid unintended effects such as unnecessary public controversy.
14. The inclusion of a wide range of stakeholder representatives in the NCC proved an effective approach to public involvement in biosafety framework development, review and adoption.

Recommendations to enhance project management:

1. A potentially valuable guidance document to implementation project teams is the UNEP

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