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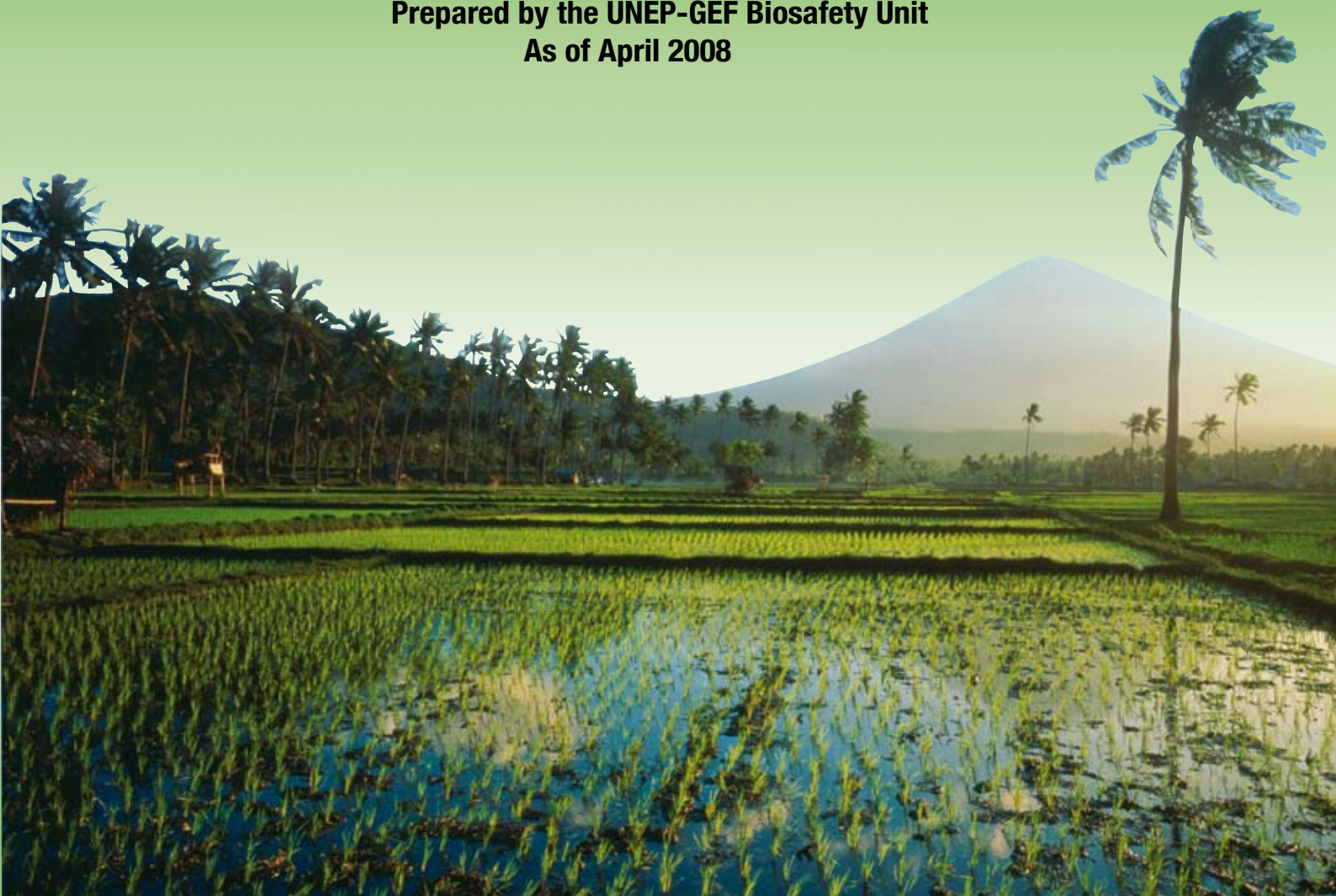
Global Environment
Facility



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 “Guide for implementation of national biosafety frameworks”, which should be made available in its final version to all participating countries.
2. Stocktaking workshops at project inception are an important tool to review the project’s objectives and proposed activities, and to identify any necessary adjustments early on.
3. The coordination function for implementation project requires substantial investments in terms of staff time. The projects require an NPC who acts as an “ambassador” towards policy makers, stakeholder groups and the donor agency. Appointing a skilled and experienced assistant NPC helps ensuring continuity in times of staff turnover.
4. Finance managers should be considered as full members of the project teams. Legal experts should be involved early on in projects emphasizing the development of laws and regulations.



5. NCCs play an important role not only in guiding the project team but also in the formulation and adoption of policies and laws. They are also instrumental in promoting coordination among government agencies. This function should be spelled out in their terms of reference.
6. (Sub-regional) Collaboration across countries should be encouraged, as a regular feature of biosafety implementation projects. Areas for collaboration must be carefully determined but would include, as an initial step, joint work on technical guidelines and technical training.
7. Collating and providing access to (translated) materials developed under the implementation projects would also encourage cross-country collaboration.
8. As noted above, project teams benefited from interaction with foreign experts. Though external technical support can be a sensitive issue in essentially country-driven projects, biosafety expertise is relevant across countries, and exchange of information and experiences should be encouraged.
9. Project teams should identify areas for external technical support early on the project; for example, by conducting a needs assessment on training.
10. Based on experience gained with external experts, UNEP should compile a roster of experts who can support implementation projects in specific areas. It will be important to establish clear criteria and a peer-review committee for this purpose.
11. Technical support by the UNEP biosafety team was well received, but demand clearly exceeded supply. UNEP should seek formal collaboration with specialized agencies in order to better address technical assistance needs.

Recommendations to enhance project sustainability:

1. Biosafety should be developed hand-in-hand with biotechnology development. This is to emphasize and demonstrate that the Cartagena Protocol was not established to serve as an anti-biotech instrument and that implementation of NBF is the only way to find out whether the NBF developed to ensure the safe use of biotechnology is indeed effective and workable.
2. Biosafety management should be integrated into national development plans, institutional structure and budget to ensure sustainability beyond the project cycle.
3. Building capacity of a *team* rather than an individual at the national level should be emphasized to ensure continuous biosafety implementation despite staff attrition.
4. Regional collaboration in sharing resources and biosafety information, and possibly providing financial support should be a cost effective method for continued biosafety capacity development in countries in the region.



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I. Introduction

The present report provides an analysis of lessons learned from 8 demonstration projects for the implementation of National Biosafety Frameworks (NBFs). These projects were approved by the GEF¹ Council in November 2001, for Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland, and Uganda. These, on average, 3-year projects started in September 2002 and were all but one completed by December 2006.

The findings and recommendations from completed implementation projects present valuable lessons to countries moving towards the implementation of similar projects. Early 2006, the GEF council approved another cycle 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 present report was developed during May-July 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 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.

1 GEF: Global Environment Facility



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, including the Biosafety Clearing-House (BCH)
 - Monitoring and inspections
 - Public information and awareness
- (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

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, as well as ways in which they were addressed. The GEF Office of Monitoring and Evaluation commissioned an external evaluation of its support to the implementation of the Cartagena Protocol on Biosafety in 2005², which should be considered in conjunction with this report. In addition, the recent UNEP publication³ analyzing experiences and lessons from 124 completed National Biosafety Framework (NBF) development projects complements the findings from this report.

It should also be noted that, at this point, it would be premature to assess the workability and effectiveness of the still evolving national biosafety frameworks. The majority of the projects analyzed were completed very recently, and the resulting NBFs have not yet been seriously tested in terms of receiving actual applications. In some countries, NBF development was taken over by political events such as government decisions to declare a moratorium on releases of genetically modified organisms (GMOs).



- 2 GEF. 2005. Evaluation of GEF's Support to the Cartagena Protocol on Biosafety. Prepared by the GEF Office for Monitoring & Evaluation. GEF/ME/C.27/Inf.1/Rev.1. Washington, D.C.: Global Environment Facility.
- 3 UNEP. 2006. A Comparative Analysis of Experiences and Lessons from the UNEP-GEF Biosafety Projects. Prepared by the UNEP-GEF Biosafety Unit. Geneva: United Nations Environment Programme.

II.

The UNEP-GEF supported biosafety implementation projects

This section provides a brief introduction to the 8 UNEP-GEF supported biosafety implementation projects. In November 2001, GEF approved funding for 12 “demonstration” projects for biosafety implementation, of which 8 were to be managed by the UNEP Biosafety Unit. The demonstration projects were financed under the GEF’s “Initial Strategy for Assisting Countries to Prepare for the Entry into Force of the Cartagena Protocol on Biosafety (CPB)”.⁴ Countries eligible for implementation support under the Initial Strategy were selected on the basis of two criteria: (i) their governments had ratified, or had acceded to the CPB; (ii) countries had already a draft NBF, prepared either under the previous UNEP/GEF Pilot Biosafety Enabling Activity in 1998-1999 or with national resources. All these 8 countries implemented by UNEP participated in the UNEP/GEF Pilot Biosafety Enabling Activity.

By July 2007, all of the 8 projects were completed. Countries involved were, in alphabetical order:

1. Bulgaria
2. Cameroon
3. China
4. Cuba
5. Kenya
6. Namibia
7. Poland
8. Uganda

Generally, the goal of an implementation project is to enable a country to convert its draft National Biosafety Framework (NBF) into a workable, effective, and transparent regulatory regime, in line with national priorities and international obligations. The projects also assist countries to create administrative mechanisms for handling all aspects of biosafety decision making. This means that by the end of the projects, the participating countries should have:

- (1) A workable and transparent regulatory regime consisting of enabling legislation, implementing regulations and complementing guidelines that are consistent with the Biosafety Protocol and other relevant international obligations;
- (2) Implementing systems for:
 - handling of notifications or requests for approvals (including systems for administrative processing, risk assessment and decision making)
 - enforcement and monitoring
 - public information and public participation

⁴ For details on the GEF initial strategy, see URL: http://www.gefweb.org/Documents/Council_Documents/GEF_C16/GEF_C.16_4_Rev.1.pdf



II.a. Implementation projects: Common objectives

Based on the broad goals defined for the biosafety implementation projects, each of them are very similar in terms of project objectives. Table 1 (next page) shows an overview of project objectives by country, and associated budgets. Common objectives for country projects included:

- (1) Formulating a national policy on biotechnology and biosafety, in countries where this was deemed relevant;
- (2) Developing and implementing a regulatory and administrative regime: law(-s), enabling regulations, technical guidelines;
- (3) Building capacity and human skills in the areas of risk assessment, risk management, LMO⁵ identification, monitoring and enforcement;
- (4) Setting up national information systems on biosafety, including the development of a national biosafety clearing-house (BCH)
- (5) Promoting public information and awareness on issues related to modern biotechnology and biosafety.

Despite having common objectives, the biosafety implementation projects differed greatly in content as they involved a very diverse group of countries. Some countries already had a legal framework for biosafety in place, which needed amendment as a consequence of ratifying the Cartagena Protocol on Biosafety (CPB), and had extensive experience in handling of LMO notifications and biosafety assessments. A number of countries had gone through multiple assessments for confined field trials, while a few (e.g., Poland, China) had already approved commercial releases of LMOs in their country. And, some countries received assistance for biosafety capacity development from multiple sources, while others mostly relied on UNEP-GEF support. On the other hand, some implementation countries could still be considered to be at the early stages of capacity development in biosafety regulation and decision-making.

Consequently, as a result of this highly diverse baseline situation at the start of each project, the actual project activities and outputs make up a mixed picture, which will be analyzed in section III below. Given the comprehensive and ambitious scope across countries, the agreed project period (3 years on average) turned out to be too short for most (except one) countries. UNEP-GEF showed adequate flexibility in this respect by extending the project periods as necessary. As a result, the expected duration of the present set of recently GEF-approved implementation projects is 4 years instead of 3.



5 LMO = living modified organism. An LMO is defined in the Cartagena Protocol on Biosafety as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.

Table 1. UNEP-GEF biosafety implementation projects: Overview of objectives and outputs

Country	Project period	Budget	Objectives (from project proposals, abridged by author)	Main outputs reported (from progress reports and project terminal reports)
Bulgaria	September 2002 – February 2006	GEF: US\$ 407,879 Country co-financing: US\$ 96,380	<ul style="list-style-type: none"> Set up a regulatory and administrative basis for the safe transfer, handling and use of LMOs Publish technical guidelines for risk assessment and monitoring Strengthen capacity on risk assessment and risk management; testing and monitoring; legal issues; identification of LMOs Biosafety Database System to be connected to the Biosafety Clearing House Mechanism Enhance public awareness 	<ul style="list-style-type: none"> LMO Act (June 2005) Regulations enacted for contained use, environmental releases and placing on the market Enforcement manual Biosafety guidelines for R&D organizations LMO testing and detection units at ABI Environmental impact studies related to GM potato, tomato, alfalfa, strawberry; Bulgaria botanical files database Technical training on risk assessment / risk management, inspection and enforcement Pilot Biosafety Clearing-House Workshops and conference for policy makers, NGOs, scientists and the media Newsletters, brochures, press releases
Cameroon	September 2002 – March 2006	GEF: US\$ 560,300 Country co-financing: US\$ 111,100	<ul style="list-style-type: none"> Support the establishment of the legal and administrative biosafety management system Strengthen capacity at legislative, administrative and scientific level decision-makers, officers of key government Ministries and other main stakeholders Strengthen national capacities and facilities for improving LMOs risk assessment, management and monitoring Strengthen the national information system by setting up a data system, Biosafety National Clearing House Portal and NGOs involvement Enhance national capacity for public awareness 	<ul style="list-style-type: none"> Adoption of biosafety law (April 2003) <i>Draft</i> implementation decree to the biosafety law⁶ Technical training on LMO identification; risk assessment / risk management; inspections Manuals on risk assessment / risk management Two reference labs for LMO identification and detection National portal for BCH Training for scientists on GM foods, feeds and processing Workshops for journalists, information officers; NGOs and community-based organizations Workshops for Parliamentarians; farmers; educational officers
China	September 2002 – December 2005	GEF: US\$ 997,400 Country co-financing: US\$ 269,000	<ul style="list-style-type: none"> Formulate relevant laws and regulations, and establish appropriate mechanisms to effectively assess, monitor, control and regulate the transboundary movement, environmental release of (LMOs) Produce and promulgate technical guidelines and develop techniques to improve national ability in risk assessment and risk management in connection with the storage, transportation, environmental release, use and transboundary movement of LMOs Develop a proper monitoring system and devise methods to improve the ability to monitor environmental release of LMOs Develop and set up a biosafety database system and establish a BCH to facilitate information sharing Organize a series of RA/RM training courses and workshops to train decision-makers, customs officials, inspectors, scientists and technicians 	<ul style="list-style-type: none"> Report on biosafety policy, legislation and management system in China <i>Draft</i> "Transgenic Biosafety Law" Technical guidelines for RA / RM for GM fish, plants, bacteria, viruses and food products Methodology and indicators to monitor the environmental impacts of GM cotton, rice, soybean Equipped "National Key Laboratory on Biosafety" Biosafety databases and national BCH in Chinese and English Technical training materials and courses on biotechnology, biosafety, risk assessment, monitoring Internet dialogues, seminars and awareness-raising events on biosafety policies, science and regulation

6 The draft implementation decree was subsequently adopted by the government of Cameroon in May 2007.



Country	Project period	Budget	Objectives (from project proposals, abridged by author)	Main outputs reported (from progress reports and project terminal reports)
Cuba	September 2002 – December 2005	GEF: US\$ 646,500 Country co-financing: US\$ 284,142	<ul style="list-style-type: none"> Support the implementation of Decree Law N.190/99 on Biological Safety by drafting and enacting additional relevant regulations Improve the ability to 1) assess, manage and monitor the risks associated to LMOs handling, transport, use, transfer and release and 2) produce and validate the related data Strengthen national capacities by carrying out training activities and providing facilities for capacity building purposes Strengthen the information system by setting up a database to be linked to the Biosafety Clearing House Strengthen capacity building for public awareness on biosafety related issues 	<ul style="list-style-type: none"> <i>Draft</i> National Action Plan on Biological Safety <i>Draft</i> State regulation on environmental inspection on biological safety Methodologies for LMO risk assessment and monitoring (plants and animals) Checklist for obtaining data and data validation for LMO risk assessment and risk management <i>Draft</i> procedures / manual for inspections; inspection program established Course developed on "Accreditation of Biological Safety Inspectors" Program for public education established, including National Course on Biosafety, virtual course on biosafety, training for journalists, seminars and workshops
Kenya	September 2002 – June 2006	GEF: US\$ 510,879 Country co-financing: US\$ 108,658	<ul style="list-style-type: none"> Support the establishment of the regulatory and administrative basis for the implementation of the biosafety management and monitoring system Strengthen capacity building on biosafety policy, management, administration and risk assessment / management Strengthen national facilities for LMOs managing, handling and monitoring activities Strengthen the national information system to serve as well for the purposes of the BCH Strengthen national capacity to enhance public awareness and promote information sharing on biosafety related issues 	<ul style="list-style-type: none"> National policy on biotechnology and biosafety <i>Draft</i> Biosafety Bill Manual for handling LMO applications Manual / checklists for monitoring and inspections Training workshops on risk assessment, monitoring and inspections Public awareness events, brochures and other information materials Strategy for public awareness creations under development Kenya BCH established Enhancement of 2 laboratories
Namibia	September 2002 – June 2007	GEF: US\$ 672,000 Country co-financing: US\$ 239,000	<ul style="list-style-type: none"> Support the establishment of the legal and administrative basis to meet the obligations foreseen under the Cartagena Protocol Improve the ability to screen LMOs in order to monitor and manage the risks associated to their handling, transport, use, transfer and release Strengthen capacity building of main stakeholders through training courses and workshops Strengthen information sharing Enhance public awareness on biosafety issues 	<ul style="list-style-type: none"> Enactment of the Biosafety Bill (December 2006) Biosafety regulations (2007) <i>Draft</i> manual for Biosafety Act Administrative procedures for the Biosafety Unit Technical guidelines for contained use, field trials, general release, transport and transit GMO testing, training and research laboratory <i>Draft</i> papers on: Socio-economic consideration; public hearing and public participation; transport and transit in relation to other mechanisms within the country <i>Draft</i> manual for Inspection and Monitoring Training workshops on risk assessment and risk management, inspectors training Application forms, check lists Brochures on biosafety, disseminated in local languages Awareness events for farmers, media, schools in different regions

Country	Project period	Budget	Objectives (from project proposals, abridged by author)	Main outputs reported (from progress reports and project terminal reports)
Poland	September 2002 – September 2005	GEF: US\$ 460,000 Country co-financing: US\$ 88,100 Associated financing (EU-PHARE): US\$ 2,616,550	<ul style="list-style-type: none"> Strengthen the national infrastructure for risk assessment and monitoring of LMOs Strengthen capacity on biosafety issues, especially in the areas of: risk assessment and risk management; testing and monitoring; legal issues; administrative arrangements. Strengthen information sharing by developing integrated databases to be linked to the BCH Enhance national capacity for public awareness on biosafety 	<ul style="list-style-type: none"> <i>Draft</i> "Biosafety Strategy" <i>Draft</i> GMO Act (revising GMO Act of 2001) Administrative manual for GMO Bureau Manual for risk assessment 3 LMO detection laboratories equipped Training workshops for scientists, customs officers Guidelines for laboratories dealing with GMOs National biosafety website and BCH Book on "Biosafety of Biotechnology", disseminated through seminars and conferences Documentary on "Genes in menu" Public opinion poll on biotechnology and biosafety
Uganda	September 2002 – December 2005	GEF: US\$ 560,000 Country co-financing: US\$ 82,000	<ul style="list-style-type: none"> Set up a regulatory and administrative system to meet the obligations foreseen under the Cartagena Protocol Strengthening effective scientific human capacity in risk assessment / risk management and monitoring capabilities through training Strengthening national infrastructure for LMOs testing Strengthening the information system to be linked to the BCH Enhance public awareness and promote dissemination among the relevant stakeholders 	<ul style="list-style-type: none"> National policy on biotechnology and biosafety" <i>Draft</i> Biosafety Bill and associated regulations Training of legal specialists Manual on procedures for notifications LMO testing laboratory Training of agricultural inspectors Communication strategy for biotechnology and biosafety

Source: (i) Approved project documents, accessed through GEF project database. URL: <http://gefonline.org/home.cfm> ; (ii) Progress reports posted on UNEP-GEF biosafety projects website. URL: <http://www.unep.ch/biosafety/parcountrieslist.htm>

7 Approved by the Government of Uganda in April 2008.



III. Project objectives and achievements

As mentioned above, and as seen in Table 1, the objectives and scope of the biosafety implementation projects were comprehensive and ambitious. In fact, some countries even put in additional components soon after projects had started, in order to respond to emerging priorities; e.g., on developing a national policy on biotechnology and biosafety, or, commissioning risk assessment research. This has resulted in an impressive range of activities and outputs of which only selected examples will be used in this report. At the same time, it should be noted that much work is still in progress. It is therefore too early to fully assess the results from completed implementation projects, and this may have to be revisited at a later stage.

The main findings and lessons learned from the **project components** are presented in this section, while a similar summary on **project management** can be found in section IV.

Table 2. UNEP-GEF implementation projects: Summary of achievements across countries

Project component	Summary of achievements
1. National policy	<ul style="list-style-type: none"> • 2 national policy adopted (Kenya, Uganda) • 2 national policies drafted (Cuba, Poland)
2. Regulatory regime	<ul style="list-style-type: none"> • 3 biosafety acts / laws adopted (Bulgaria, Cameroon, Namibia) • 4 biosafety acts / laws drafted (China, Kenya, Poland, Uganda) • Implementing regulations enacted in 4 countries (Bulgaria, Cameroon, Cuba, Namibia)
3. Handling of notifications	<ul style="list-style-type: none"> • Administrative procedures established (<i>all countries</i>) • Guidelines, manuals developed for risk assessment, risk management (<i>all countries</i>) • BCH launched in 5 countries (Bulgaria, China, Kenya, Namibia, Poland) • Technical training conducted on risk assessment, risk management (<i>all countries</i>)
4. Monitoring and inspections	<ul style="list-style-type: none"> • LMO testing and detection units equipped in 7 countries (Bulgaria, Cameroon, China, Kenya, Namibia, Poland, Uganda) • Environmental impact studies conducted in 2 countries (Bulgaria, China) • Guidelines, manuals developed for environmental monitoring and inspections (<i>all countries</i>) • Technical training conducted on monitoring and inspections (<i>all countries</i>)
5. Public information and awareness	<ul style="list-style-type: none"> • <i>Strategies</i> for biosafety communication, awareness developed in 3 countries (Cuba, Kenya, Uganda) • Awareness and outreach materials published (<i>all countries</i>) • Awareness-raising workshops conducted for policy makers, journalists, farmers and other stakeholders (<i>all countries</i>)

Source: Data extracted from Table 1 above.



III.a. Developing and adopting a national policy

While developing a national guiding policy on biotechnology and biosafety was not included in the original project objectives in any country, this element was added in some countries such as Cuba, Kenya, Poland and Uganda. National policies were adopted in Cuba and Kenya by the end of the implementation project, while the policy process in Poland and Uganda continues, with government approval in Uganda in early 2008.

A national biosafety policy or strategy is essential as it provides a set of principles to guide subsequent development and implementation of a biosafety legal framework and associated regulations. A critical element of a national policy is a clear definition of a country's goals and priorities for biosafety and associated capacity development. In addition, it serves to build long-term government support and inclusion of biosafety capacity development into national budgets. In many countries, formulating a national policy for biosafety is a pre-requisite, before any laws or regulations can be promulgated. Namibia, for example, adopted a national policy on biotechnology and biosafety as early as 1999. The importance of national policy or strategy formulation is acknowledged in the current round of biosafety implementation projects, in which it has become a distinct component for most countries.

Lessons learned and best practices

In policy development, the policy development process appeared to be equally important as the resulting policy. Broad stakeholder involvement in the drafting process, including civil society organizations and members of Parliament, helped building broad understanding and agreement on a country's goals for biosafety, and political support for policy approval. Equally important, policy development on biosafety allowed for, or should have allowed for early interaction and coordination across relevant branches of government, as in most countries biosafety decision-making involves multiple Ministries and agencies.

Adopting a consultative process was considered indispensable even though it builds in time-consuming rounds of review and revisions. This was confounded by turnover of policy makers and politicians, leading to repeated efforts to build awareness on the importance of adopting a national policy.

In order to limit the time required from draft to adoption, project teams devised a detailed strategy for getting a policy through. In Kenya, for example, this included early involvement of, and outreach activities to the relevant Parliamentary committees and individual members of Parliament who could act as "champions" for the policy. In some cases, NGOs were called upon to support steady progress of the policy process and to lobby for the policy's adoption. At this stage of the project, it was found that a high-level, broadly constituted National Coordinating Committee (NCC), set up as part of the implementation projects, can play a key role in policy advocacy and avoiding delays within the responsible Ministry or Government Cabinet.

In Cuba, the process followed for developing the National Biosafety Strategy included the following steps: (i) preparation of a draft document by a technical team; (ii) a series of small-group review meetings; (iii) review by the project's NCC; (iv) discussion at a broad national workshop; (v) incorporation as an action plan under the National Environmental Strategy.



The biosafety strategy covers the following topics:

- Global and national context of the Strategy
- Evolution of biosafety in Cuba and current status
- Problem identification and justification for a strategy
- General and specific objectives
- Instruments to implement the strategy
- Strategy assessment indicators, implementation and follow-up schedule

III.b. Implementing a regulatory regime

Defining the legal framework for biosafety decision-making was emphasized in all projects. Most countries involved in implementation projects already had a functional legal framework for biosafety, which in some cases needed amendment as a result of ratifying the CPB and other emerging needs – for example, imminent accession to the European Union (i.e., Bulgaria and Poland) – in other cases, project teams concentrated on developing regulations to foster implementation of previously enforced biosafety legislation (e.g., Cuba).

By the end of the projects, most countries had a discrete biosafety law regulating modern biotechnology, with the exception of Uganda where initially biosafety regulations were drafted for adoption under the Science and Technology Act. Later on, it was decided to develop a distinct biosafety law. This process is still ongoing.

In addition, efforts in all projects were directed towards the development of implementing regulations, and technical guidelines for applicants and regulators. Implementing regulations make up an essential element of the national biosafety framework, providing details on how an Act is implemented in practice and spelling out the roles and responsibilities of the various regulatory agencies in a country.

Lessons learned and best practices

In all cases, particularly in the drafting of biosafety laws, a consultative approach was adopted, as was the case in policy development. This approach proved to be useful in securing broad consensus regarding the objectives and scope of national biosafety laws.

In addition, most draft laws benefited from external review by legal experts abroad, who provided inputs on the practicality of a proposed law and its consistency with the CPB and other international standards and agreements.

Similar to the policy development process, the road from drafting a law to its adoption generally turned out to be long and circuitous. Consultations with relevant government departments and agencies, and diverse stakeholder groups, and reviews of draft laws helped building awareness and agreement on the proposed laws but also necessitated many rounds of revisions. In countries where proposed laws had to pass parliamentary approval, significant investments were required in order to achieve the necessary level of understanding and support from relevant Ministries and members of Parliament.

As the process was becoming more drawn out, political changes occurred in project countries forcing project teams to repeat their efforts in educating new members of Parliament and decision makers. In anticipation of a new or amended legislative framework,



it appeared that biosafety decision-making (e.g., for LMO field trial applications) slowed down under the existing “interim” framework.

In Poland the project team’s initial efforts focused on drafting a new GMO Act, building on the current Act of 2001, which would respond to the requirements from the Cartagena Protocol and relevant EU Directives. Deliberations on issues such as co-existence of GM crops with conventional and organically produced crops, delayed the process. Following general elections in 2005, a new government declared Poland “GM Free” and put the new GMO Act on hold. The 2001 Act is therefore still in force but no approvals are granted for any type of GMO releases. Also in China, a comprehensive “Transgenic Biosafety Law” was drafted as part of the implementation project; however, to date, the law has not been adopted and GMO releases continue to be managed through a set of government decrees.

It has become apparent that in order to get a law from draft to adoption, a detailed strategy is needed at project inception, developed in collaboration not only with responsible Ministries but also with the relevant national legal department such as the Attorney General’s Chambers or Ministry of Justice. In projects where the development of laws and regulations was a major challenge, project teams secured the necessary legal expertise early on in the process.

Coordination among the different regulatory agencies and clarifying the roles and responsibilities for government agencies involved in biosafety decision-making remains a challenge in many countries, as reported in several project terminal reports. This has to be addressed early on in the development of national policies (see section III.a above) and also by elaborating detailed implementing regulations in parallel with the drafting of an overarching law. A multi-agency, consultative approach to developing regulations will help clarify matters of who regulates what, and how. However, not all countries had completed work on implementing regulations at the end of the project and this should be a priority for follow-up efforts.

Experiences in Kenya as described by Shibalira (2007)⁷ are illustrative of lessons learned and strategies across countries, towards getting laws drafted and adopted. She concludes that

“... it was absolutely necessary to build consensus so as not to scuttle the law-making process. We held various stakeholders meetings, shared information and collected and collated the stakeholders’ views. These views later helped shape the draft law. [...] In the process of finding a home for the agreed legislation, various government departments tussled over which department was best suited to host the law. Part of the consensus building was to ensure that the departments put the national interest before their self-interest.”

III.c. Handling notifications

While progress on the political aspects of biosafety (policies, laws) was sometimes slow, strong progress was made on matters that are of a technical-administrative nature, and less controversial, such as the development of technical guidelines and associated technical training. By the end of the implementation projects, all countries involved had a clear system for handling LMO notifications, including designated competent authorities for granting licenses and permits, biosafety offices and national biosafety advisory committees.

⁷ Shibalira, R.O. 2007. Drafting a Biosafety Law: My Experience. *Biosafety Protocol News*, vol.2 no.1., p.6. June 2007.



A Biosafety Clearing-House (BCH) represents a specific component of the system for handling notifications. The Cartagena Protocol on Biosafety established a global Biosafety Clearing-House (BCH) to facilitate exchange of information and as a mechanism to assist Parties to implement the Protocol. A functional national BCH, linked to the central BCH is an essential part of the information exchange required as countries engage in the notification, assessment and decision-making on GMOs. As a compliance requirement under the Protocol, establishing a BCH was included as an objective in all implementation projects.

Lessons learned and best practices

The administrative system sketched above needs underpinning with detailed technical guidelines, for assessing different types of applications (such as contained use, field trials, commercial release, etc.), and associated application forms. In addition, detailed manuals / checklists are needed, dealing with practical aspects of, for example, conducting confined field trials, or monitoring for environmental impact. As summarized in Table 1, the implementation projects generated a good number of technical guidelines relevant to their national biosafety frameworks.

Namibia, for instance, developed a manual for administrative procedures for the Biosafety Unit under the Biosafety Act, and a detailed manual for monitoring and inspections. Experts in South Africa were consulted in reviewing the draft manuals.

Technical guidelines were introduced through training programs, which is a proper way to explain and disseminate them. Such training programs benefited from the involvement of foreign experts in most countries. Most project teams, in their terminal reports, identified the need for recurrent, longer term training on a continuous basis in order to build up a broader biosafety skills base in their countries and to deal with the usual staff turnover and attrition.

NPCs identified the development of technical guidelines and conducting technical training programs as suitable candidates for stronger cross-country collaboration. Particularly for countries located in the same (sub-) region such collaboration would result in economies of scale such as the sharing of external experts and (draft) guidelines, and, in the long run, compatible biosafety frameworks at the technical level. NPCs reported the sharing of technical guidelines on an informal basis; clearly, this could have been a more regular feature within the life of the projects.

In order to improve access to the body of technical outputs generated by the first wave of implementation projects, there is a need to take stock of what has been published so far, analyze their utility to other project teams and to make them easily accessible through, for example, the Internet or CD-ROM. Some materials have been published in local languages and provisions will have to be made to have them translated.

As regards the BCH, results from these activities are very mixed. Some countries managed to set up user-friendly, instructive BCH websites⁸ containing relevant information and guidance on national policies, regulations and biosafety decisions, and are actively contributing to the central BCH hosted by the CBD Secretariat. China's National Biosafety Clearing-House, managed by the National Biosafety Office at SEPA⁹, provides a central access point to essential biosafety information such as:

8 See, for example, the China Biosafety Clearing-House at URL: <http://english.biosafety.gov.cn/>

9 SEPA: State Environmental Protection Administration



- Implementing regulations on GMO releases, import / export, labeling;
- Technical guidelines for performing risk assessments of various GM applications;
- Application forms;
- A database of decisions on field trial applications and commercial releases;
- Links to external sources of biosafety information.

On the other hand, progress remained limited in a number of implementation countries. They clearly would have benefited from targeted support in this area as provided through the current, UNEP-managed BCH project. However, the 8 country projects analyzed in this report were not eligible for support under the BCH project and were already under way at the time the BCH project was conceived¹⁰.

In some countries, the lack of information deposited is a result of national laws governing the distribution of information. Laws in some countries generally forbid draft laws, regulations and decision to be placed in the public domain. One way of overcoming this issue is to make the BCH part of the national law or regulation governing biosafety. This will spell out the type of information that should be placed on the national and central BCH, and will ensure the allocation of resources (human, financial) to set up and maintain an information system. An example in this regard is provided by Brazil, where the national Biosafety Information System was established by law and an associated Ministerial decree.

It should be noted that BCH efforts in countries that take part in the current cycle of 11 implementation projects are benefiting from targeted BCH support from UNEP, and generally have made BCH efforts a stronger component of their projects.

III.d. Monitoring and inspections

Similar to the technical component described under III.c, strong progress was made in developing the framework for monitoring and inspections. Work focused primarily on the development of manuals or checklists for monitoring and inspection activities, and associated technical training. In addition, a major area of investment for the projects comprised the upgrading of laboratories and purchasing of equipment to established LMO detection units.

In relatively advanced countries such as Bulgaria and China, a number of academic risk assessment studies were commissioned as part of the implementation project, which will eventually be of use to monitoring for environmental impacts. Box 1 (below) illustrates this point, listing the outputs generated as part of these biosafety studies in Bulgaria. In China, similar work resulted in guidelines and indicators to monitor the environmental impacts of GM cotton, rice and soybean.

10 For further details on the BCH project, see URL: <http://www.unep.ch/biosafety/BCH.htm>



Under the Kenya project, a “Manual for Inspection and Monitoring of Genetically Modified Organisms in Kenya” was published in May 2006, spelling out the purpose, procedures and standards for monitoring and inspections in the country. A series of checklists is included as annexes to the manual. The document was developed in consultation with regulatory agencies and introduced through training workshops for regulators and field inspectors.

Lessons learned and best practices

As in the case of outputs generated for handling notifications, it will be important to develop a complete inventory of such outputs and ensure they become available to current and future implementation countries. The utility of monitoring and inspection guidelines across countries was confirmed by the fact that such materials were frequently shared among the implementation project coordinators.

Particularly the methodologies and indicators developed as part of risk assessment research in countries such as Bulgaria and China would be relevant to other countries. Adapting the findings from these studies to practical policy advice, for example, the monitoring indicators derived in China, should be pursued. Support will be needed for translating much of this work into other languages in order to become better accessible.

Collaboration across countries should also be supported in the area of GMO detection. The laboratory facilities equipped as part of the implementation projects could serve as reference laboratories for countries in the sub-region. This way, the need for significant investments in each individual country could be minimized by making full use of existing testing facilities. In addition, countries would be encouraged to collaborate on developing testing guidelines and sampling guidelines rather than each one developing its own standards and methods. 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.

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 to 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.



Box 1. Publications and related outputs from biosafety studies conducted in Bulgaria

1. Kalushkov P. L. Dimitrova & O. Nedved, 2003. Bt-genetically engineered potatoes preserve aphidophagous coccinellids. – *Acta Entomol. Bulgarica*, 9, 12-15 (in Bulgarian).
2. Kalushkov P., 2004. The abundance of epigeic arthropods in Bt and standard potato fields. – *Sci. Conf. St. Zagora - 2004, V.II, Agrarian sciences*, 329-333 (in Bulgarian).
3. Kalushkov P., B. Gueorgiev & L. Spitzer, 2004. Biodiversity of ground beetles (Coleoptera: Carabidae) in Bt and standard potato fields. – *Sci. Conf. St. Zagora - 2004, Volume II, Agrarian sciences*, 329-333.
4. Kalushkov P. & R. Batchvarova, 2005. Effectiveness of Bt Newleaf potato to control *Leptinotarsa decemlineata* (Say) (Coleoptera: Chrysomelidae) in Bulgaria. – *Biotechnol. & Biotechnol. Eq.* 19, 28-34.
5. Kalushkov P., 2005. Can the genetically modified crops change the environment? – (ed. N. Chipev & V. Bogoev) “*Biodiversity, ecosystems, global changes*” 363-368 (in Bulgarian).
6. Kalushkov P. & G. Blagoev, 2005. The effect of experimental plot design of Bt and non-Bt potato fields on the results of epigeic fauna. – (ed. N. Chipev & V. Bogoev) “*Biodiversity, ecosystems, global changes*” 369-374 (in Bulgarian).
7. Kalushkov P. & I. Hodek, 2005. The effect of six species of aphids on some life history parameters of the ladybird *Propylea quatuordecimpunctata* (Coleoptera: Coccinellidae). – *European J. Entomol.* 102, 449-452.
8. Kalushkov P. & O. Nedved, 2005. Genetically modified potatoes expressing Cry 3A protein do not affect aphidophagous coccinellids. – *Journal of Appl. Entomol.* 129, 401-406.
9. Nedved O, P. Kalushkov & G. Blagoev, 2006. Spiders in Bt and non-Bt potato fields in Bulgaria. – *Bull. IOBC wprs Bull.* 29(5), 103-110.
10. Kalushkov P., R. Tzankova, P. Stoeva, R. Batchvarova, M. Vlahova, S. Slavov & M. Radkova, 2006. Ecological investigations on the effect of Bulgarian GM plants on the arthropod fauna. – *Bull. IOBC wprs Bull.* 29(5), 85-90.
11. Kalushkov P., G. Blagoev & H. Deltchev, (in press). Biodiversity of epigeic spiders in genetically modified (Bt) and conventional (non-Bt) potato fields in Bulgaria. – *Acta zool. Bulgarica*
12. **Poster:** Nevena Alexandrova, Mariana Vlahova, Mariana Radkova, Violeta Kondakova, Rossitza Buchvarova, Plamen Kalushkov, Atanas Atanassov (2006). Environmental Risk Assessment case studies in Bulgaria.
13. Kalushkov P., Tzankova R., Stoeva P., Batchvarova R., Vlahova M., Slavov S., Radkova M. 2006 Ecological investigations on the effect of Bulgarian GM plants on the arthropod fauna. *IOBC/wprs Bulletin* 29, pp 83-90.
14. Popov T., R. Batchvarova, S. Slavov, P. Christova, M. Alexandrova, A. Atanassov, I. Yamaguchi, H. Anzai. 2004. Gene Dispersal from Genetically Modified Tobacco in the Field. *Transgenics*, Vol. 4, pp. 189-195.
15. Kapchina V., G. Milanov, A. Zankov, D. Stefanov, S. Slavov, V. Goltsev and R. Batchvarova. 2004. The Changes in Some Photosynthetic Characteristics of Transgenic Tobacco Plants, Resistant to Bacteria *Pseudomonas syringae pv. tabaci*. *Biotechnol. & Biotechnol. Equipment*, 3/18, pp. 74-84. IF 0.056



III.e. Public information and awareness

All implementation projects included as one of their objectives the promotion of public awareness on matters related to modern biotechnology and biosafety. The emphasis on building public awareness stems from the fact that, in general, familiarity with the key issues involved was limited at the projects' start, while the UNEP-GEF projects as well as the Cartagena Protocol call for public consultation in biosafety decision-making. As a result, national biosafety frameworks and related laws and regulations contain provisions for public consultation and involvement.

The implementation projects aimed at raising public awareness and knowledge about biosafety issues, so that different groups can contribute to decision-making effectively. Information and awareness activities were undertaken by (i) involving NGOs and other stakeholder groups in NCCs, and in developing policies and laws; (ii) developing awareness materials and organizing public awareness events.

Awareness materials produced under the implementation projects ranged from brochures and stickers in local languages (e.g., in Kenya) to, for example, a documentary "Genes in the Menu" and book on "Biosafety of Biotechnology" launched in Poland.

Lessons learned and best practices

Activities and outputs related to public awareness are numerous and wide-ranging, reflecting the range of stakeholder groups – politicians, farmers, consumers, etc. – and associated information needs. While it can be safely assumed that all activities were relevant given the general lack of information on biosafety issues, it is not always clear if and how these contributed to NBF implementation. In some cases, awareness activities had unintended effects such as creating public controversy around, for example, the development of a national biosafety law.

An effective approach to public involvement was the inclusion of stakeholder representatives as members of the NCC, established at project inception. This contributed to consensus-building around major outputs such as national policies and laws. Another effective way of structuring public involvement and outreach would be the development of national programs or strategies on the subject, as took place in, e.g., Cuba, Kenya and Uganda. A more strategic approach to public awareness ensures that the right audience is reached and that ways and means are identified to continue public awareness activities beyond the life of the project.

In Bulgaria and Poland, public awareness and information activities received additional support from EU-funded initiatives such as the Phare program, which supports countries in preparing for accession to the European Union. Project teams succeeded in coordinating activities between those supported by UNEP-GEF and by other organizations, enabling them to reach much wider audiences. As a result, public awareness activities in these countries are continuing beyond the life of the implementation project. In Bulgaria, outreach mechanisms were established, which are still active, such as the Bulgarian Association of Biotechnologies and the Black Sea Biotechnology Association.



IV. Project management and execution

The biosafety implementation projects, as pioneering efforts in the area of biosafety capacity building, yield a good number of lessons regarding project management and execution. Most project teams reported that project management itself was a challenge, largely resulting from the ambitious scope of the projects and the management of political, multi-stakeholder processes involved in formulating policies and laws. This section summarizes the main findings and lessons with regard to project management and implementation.

IV.a. Project team

Each implementation project involved a small project management team, usually made up of a National Project Coordinator (NPC) and assistant NPC. Administrative and financial management support was provided through the National Executing Agency (NEA), which was based within government agencies in some countries, and scientific institutes in others. Selection of the NEA and NPC was made on basis of their prior experience in biosafety capacity development. National Coordinating Committees (NCCs) were appointed to provide guidance to the project team.

Lessons learned and best practices

The coordination function for implementation projects clearly requires a substantial investment in terms of staff time. A few projects were affected by NPC turnover and lacked adequate support by the NEA. This had an effect on the quality and timeliness of reporting to UNEP, and obviously on the project's performance in general.

Working with diverse stakeholder groups, often with opposing views on biosafety, and fostering the development of policies, laws and regulations requires an NPC who can act as an "ambassador" for the project towards policy makers, interest groups, and the donor agency. In cases where a part-time NPC is appointed, having a full-time assistant NPC becomes essential, combining project-management skills with extensive knowledge of the subject matter. Appointing an experienced assistant NPC would also ensure continuity of the project in times of staff turnover.

As all project budgets involved a combination of GEF funding with matching in-kind and in-cash contributions by the implementation country, consistent financial management and reporting (both on GEF funding and co-financing) is essential to the project's success. Finance managers involved in project administration were increasingly considered as full members of the project teams.

NCCs varied in numbers and composition, depending on the size and situation in each country. All NCCs involved representatives from the relevant regulatory Ministries or agencies. Such inter-sectoral committees can play an important role not only in guiding the project team, but also in the formulation and eventual adoption of policies and laws, particularly in ensuring that the political processes are not blocked. Some project teams reported that the NCC has indeed fulfilled this oversight function.

The value of having a coordinating / advisory body such as the NCC is confirmed by the fact that they continued functioning in some countries after the project had ended. In Cameroon, the NCC members were appointed to the National Biosafety Inter-Ministerial



Committee (NABIC), which was created by the biosafety law. In the case of Kenya, the NCC continued functioning after project completion and acts as an advisory committee to other ongoing biosafety capacity development programs. This way, the NCC was instrumental in building bridges between the UNEP-GEF supported project and other bilateral or multilateral biosafety support programs, such as the USAID-supported Program for Biosafety Systems (PBS).

IV.b. Coordination among government agencies

A second challenge reported on project management relates to the difficulties encountered in engaging and coordinating the various government bodies involved in biosafety regulation, and for that reason in the execution of the implementation projects. This challenge is connected to the questions faced in the development of national policies and laws on biosafety, as to which department should function as the National Competent Authority, and what products or applications are regulated by which agency. Obviously, perspectives on the likely environmental and human health impact of LMOs are different between agencies from the Environment or Public Health sectors, as compared to agencies from Agriculture and Science & Technology. Although this will remain an issue in biosafety decision-making, several initiatives were taken to build stronger consensus across regulatory bodies.

Lessons learned and best practices

The first approach to achieving stronger coordination among government agencies was to secure their representation at the NCC. The NCCs were valuable as a means to addressing any conflicts at an early stage, and to establish good rapport between the project team and various government agencies. However, this did not prevent the occurrence of delays and coordination difficulties as noted above. Formal high-level policy consultations will be required prior to the start, and during the execution of projects.

NCC discussions on biosafety policies and laws were in some cases broadened to more formal inter-agency consultations on the national biosafety framework. For example, Namibia established an inter-ministerial committee to address any emerging issues at high political levels. In all countries, work on detailed implementing regulations for biosafety decision-making processes greatly helped clarifying each Ministry's regulatory role and will contribute to avoiding conflicts in future.

As a result of these activities, project teams cited the enhanced collaboration and consensus among government agencies as one of the major outcomes, while recognizing the fact that continued efforts will be required.

IV.c. Sub-regional collaboration and sharing experiences

In most project terminal reports, emphasis was placed on sub-regional collaboration as one area deserving more attention in future projects. While developing a biosafety framework and compliance to the Cartagena Protocol is essentially a national responsibility, there is clearly scope for collaboration across countries. First, experience gained in, e.g., environmental risk assessment and management, and materials developed in one country should be relevant to other countries. Secondly, resources such as technical experts and laboratory facilities could be used more efficiently and cost-effectively if shared by countries in the same sub-region. Finally, in the longer term, countries in a specific sub-region could work towards common biosafety guidelines on transboundary aspects of LMOs.



Lessons learned and best practices

Informal collaboration among countries was encouraged on an informal basis, as the implementation projects did not have any provisions for (sub-regional) cross-country collaboration.

The annual NPC meetings were reported to be a very useful mechanism for sharing experiences and materials across implementation countries. Several project teams recommended increasing the frequency for NPC meetings to twice a year. In addition, creating a “library” or depository of key outputs such as technical guidelines, e.g., for risk assessment or monitoring, and making them available in common languages would encourage sharing materials.

NPCs of implementation projects acted as resource persons in regional workshops organized under the UNEP-managed NBF development project. This was a valuable approach in preparing development-project countries for the challenges faced in implementation projects. Continuation of this type of interaction would be encouraged by keeping the NPCs of completed implementation projects engaged as regional advisors, available to support countries in the same sub-region as need arises.

More formal sub-regional collaboration is expected to be supported under the current round of GEF support to biosafety. It will be important to determine upfront where such collaboration would add value to ongoing country-level efforts, and to have it focused on a set of well-defined strategic objectives.

IV.d. Technical support

In projects that are essentially country-driven, as in the case of the implementation projects, external technical support can be a sensitive issue as it may be perceived as unduly influencing in-country policy processes. However, for a subject such as biosafety, for which considerable experience has been gained worldwide that is of immediate relevance to countries developing or implementing their NBFs, providing technical support and advice is indispensable. The UNEP biosafety team organized technical support through its own staff and by making arrangements for the involvement of external technical experts as resource persons in specific activities such as training.

Lessons learned and best practices

All project teams reported that the UNEP biosafety team has done an impressive job in providing guidance and technical support, and that more technical support was needed. Obviously, with initially 2 and later on 1 technical officer/Task Manager overseeing progress in 8 implementation countries, there are limitations as to what can be achieved. Nevertheless, the UNEP team actively supported the development of legal and technical documents, and training methods and materials. Staff members acted as technical resource persons in training events in project countries. In particular, project teams valued the stocktaking workshops organized with UNEP at project inception.

A potentially important mechanism to providing guidance to implementation projects is the “Guide for implementation of national biosafety frameworks”¹¹, drafted in 2003 but not yet available in its final version. This guide complements the UNEP toolkit for the

11 Available at URL: http://www.unep.ch/biosafety/impdocs.htm#A_draft_guide



NBF development projects, and could serve as a useful checklist and reference document for implementation project teams. The current group of countries carrying out implementation projects would benefit from having such a guide.

In addition to UNEP team members, external experts were involved as needed. Their involvement particularly focused on (i) review of draft laws and other legal documents; (ii) technical training on risk assessment / risk management, and monitoring and inspection. This again confirms that biosafety expertise is relevant across countries, and exchange of experiences should be encouraged. In order to make full use of available expertise, it is recommended that project teams identify areas for external technical support early on in the project. For instance, a Training Needs Assessment could be conducted to determine the needs for technical training.

Based on experiences gained with external experts, UNEP would be able to compile a roster of experts who can support implementation projects in specific areas. Compiling such a roster and making it available to project teams would help advance planning for involvement of external experts, and may alleviate the workload faced by the UNEP biosafety team. This type of mechanism appears to be working well for the BCH project. As external technical support can be a sensitive issue, it will be important to establish clear criteria and a peer-review committee for endorsing external experts, and to regularly review their performance in UNEP-supported projects.

Considering that the UNEP biosafety team lacks adequate legal expertise, UNEP could collaborate with other agencies, such as IUCN, who have experience in developing regulatory regimes for biosafety. In addition, in-house legal expertise within UNEP and DGEF could be tapped, which would also help to mainstream biosafety in UNEP's programs. In a similar fashion, UNEP should collaborate with the CBD Secretariat and inter-governmental organizations such as ICGEB¹² in providing technical training in risk assessment and risk management.



12 ICGEB = International Centre for Genetic Engineering and Biotechnology

V. Summary and Recommendations

As noted in the preceding sections, the analysis of lessons learned and best practices across countries yields a wide range of findings and recommendations, which will be valuable to current and future biosafety implementation projects. This section will endeavour summarizing the key recommendations, and add suggestions on maintaining the sustainability of efforts over time.

V.a. 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. Critical elements of a national policy are a clear definition of a country's goals and priorities for biosafety and associated capacity development, and a division of responsibilities across government agencies. 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 multi-stakeholder 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 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. The sharing of expertise and



information was done on an informal basis; this should become a more regular feature in future support programs. Sub-regional collaboration and sharing of experiences must be encouraged now that a growing number of countries have a functional biosafety framework in place.

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.

V.b. Recommendations to enhance project management

1. A potentially valuable guidance document to implementation project teams is the UNEP “Guide for implementation of national biosafety frameworks”, which should be made available in its final version to all participating countries.
2. Stocktaking workshops at project inception are an important tool to review the project’s objectives and proposed activities, and to identify any necessary adjustments early on.
3. The coordination function for implementation project requires substantial investments in terms of staff time. The projects require an NPC who acts as an “ambassador” towards policy makers, stakeholder groups and the donor agency. Appointing a skilled and experienced assistant NPC helps ensuring continuity in times of staff turnover.
4. Finance managers should be considered as full members of the project teams. Legal experts should be involved early on in projects emphasizing the development of laws and regulations.
5. NCCs play an important role not only in guiding the project team but also in the formulation and adoption of policies and laws. They are also instrumental in promoting coordination among government agencies. This function should be spelled out in their terms of reference.
6. Collaboration across countries should be encouraged, as a regular feature of biosafety implementation projects, in order to implement national biosafety frameworks in an efficient and cost-effective manner. Areas for collaboration must be carefully determined but would include, as an initial step, joint work on technical guidelines and technical training.
7. Collating and providing access to (translated) materials developed under the implementation projects would also encourage cross-country collaboration and learning from prior experiences.



8. Project teams benefited from interaction with foreign experts. Though external technical support can be a sensitive issue in essentially country-driven projects, biosafety expertise is relevant across countries, and exchange of information and experiences should be encouraged.
9. Project teams should identify areas for external technical support early on the project; for example, by conducting a needs assessment on training.
10. Based on experience gained with external experts, UNEP should compile a roster of experts who can support implementation projects in specific areas. It will be important to establish clear criteria and a peer-review committee for this purpose.
11. Technical support by the UNEP biosafety team was well received, but demand clearly exceeded supply. UNEP should seek formal collaboration with specialized agencies in order to better address technical assistance needs.

V.c. Sustainability of the biosafety frameworks

While formally not part of this study's scope, the key question remains whether the national biosafety frameworks developed, or under development as a result of the UNEP-GEF supported projects, demonstrate their sustainability and effectiveness over time. Obviously, the question on effectiveness and workability can only be answered in 2 to 3 years from now and UNEP may wish to re-visit the projects at that point. It would be premature to assess the workability and effectiveness of the still evolving national biosafety frameworks. The majority of the projects analyzed were completed very recently, and the resulting NBFs have not yet been seriously tested in terms of receiving actual applications. In some countries, NBF development was taken over by political events such as government decisions to declare a moratorium on GMO releases (e.g., in Bulgaria and Poland), which prevent their NBFs from becoming fully functional.

Based on the analysis and interactions with NPCs, a number of measures can be reported that will contribute to the frameworks' sustainability, including:

1. Project teams have successfully lobbied for inclusion of biosafety management in national environmental policies and associated budgets; and, where relevant, in important mechanisms for donor support such as national strategies for poverty reduction or programs to address the Millennium Development Goals. This has been an essential step in ensuring continuity in terms of hiring staff to manage biosafety offices and laboratories, and moving to a professional regulatory system. In EU countries such as Bulgaria and Poland, the need to comply with EU Directives on biosafety provides strong incentives for continued government efforts and funding to strengthen the national biosafety framework. These efforts are also supported by EU organizations and programs.
2. Mechanisms created under the implementation projects may continue functioning beyond the life of the project. In a number of countries the NCC continues to function as an informal or formal biosafety advisory committee. As noted above, the Kenya NCC still functions as an advisory body to other biosafety technical assistance programs. In Cameroon, NCC the members have been appointed to the NABIC, which was created by the biosafety law.



3. Particularly in Africa, a number of regional political and trade organizations have developed a strong interest in biosafety, and NPCs are actively involved in these discussions. Cases in point include NEPAD¹³, CILLS¹⁴, COMESA¹⁵, the EAC¹⁶ and the AU¹⁷. Such regional initiatives could become a conduit to promoting collaboration among countries, sharing resources and biosafety information, and possibly providing financial support for continued biosafety capacity development.
4. Project teams are actively engaged in new national and regional initiatives to strengthen biosafety capacity. In addition to existing regional bodies, networks have been formed to establish sub-regional biosafety initiatives supported by GEF. These initiatives are emerging in Latin America (GEF approved); West Africa (GEF approved) and East and Central Africa (under development). These sub-regional initiatives build on earlier GEF biosafety support and aim at closer collaboration among countries in biosafety framework development and decision making.

In summary, as demonstrated in this report, all countries involved in the UNEP-GEF supported implementation projects have made a number of important steps towards establishing a national biosafety framework that is functional and in compliance with the Cartagena Protocol. In a majority of implementation countries, more work is needed to achieve a fully functional NBF. In those cases, priorities for government and donor-agency follow-up support have been clearly identified as a result of the implementation projects.



13. NEPAD = New Partnership for Africa's Development
14. CILLS = Le Comité Permanent Inter Etats de lutte contre la Sécheresse dans le Sahel
15. COMESA = Common Market for Eastern and Southern Africa
16. EAC = East African Community
17. AU = African Union



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