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**GUIDANCE TOWARDS IMPLEMENTATION OF
NATIONAL BIOSAFETY FRAMEWORKS:**

**LESSONS LEARNED FROM THE UNEP DEMONSTRATION
PROJECTS**

(Prepared by UNEP)

Guidance towards implementation of National Biosafety Frameworks:

Lessons learned from the UNEP demonstration projects

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UNEP-GEF Project on Implementation
of National Biosafety Frameworks



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 team members, summarizing main findings and recommendations.

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.
2. A national biosafety policy or strategy is essential to provide guiding principles for the subsequent development and implementation of a biosafety legal framework. 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 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.
10. A complete inventory 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. 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.
13. 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. 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 training needs assessment.
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.