Global Environment Facility

GEF/C.30/Inf.7
November 14, 2006

GEF Council Meeting
December 5-8, 2006

BUILDING BIOSAFETY CAPACITY: THE ROLE OF UNEP AND THE BIOSAFETY UNIT

(Prepared by UNEP)

AUGUST 2006

Building Biosafety Capacity: The Role of UNEP and the Biosafety Unit

Timeline

December 1995
Finalization of UNEP "Technical Guidelines for Safety in Biotechnology"

November 1996
COP3 of the CBD requested the GEF to provide financial resources for capacity-building in biosafety

January 29, 2000
Adoption of the Cartagena Protocol on Biosafety (CPB)

November 2000
GEF Council approved the "Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety".

November 2000
GEF Council approved UNEP-GEF project for "Development of NBFs"

2002
GEF Council approved 12 demonstration implementation projects

September 11, 2003
CPB came into force

November 2003
GEF Council approved a UNEP-GEF project for assisting countries to use and access the BCH

November 2005
GEF Council approved an interim approach on biosafety

2006
CEO approved 11 new demonstration projects

The UNEP-GEF Biosafety Unit

The UNEP-GEF Biosafety Unit works in collaboration with many international, regional, and national partners. The Unit's portfolio under the GEF Initial Strategy—currently valued at more than US$ 70 million (see table below)—consists of:

- helping up to 130 countries to develop National Biosafety Frameworks (NBFs) (34.1 M US $ from GEF plus 13.1 M US$ in cofinancing),
- implementing NBFs in a set of 8 demonstration countries, (4.8 M US $ from GEF plus 1.2M US$ in cofinancing), and
- ensuring widespread access to the Biosafety Clearing-House for up to 139 countries (13.5 M US $ from GEF plus 1.4 M US$ in cofinancing).

Building on UNEP's ten-year track in the emerging field of biosafety, the UNEP-GEF Biosafety Unit has taken a leading role in implementing the GEF Biosafety Strategy through three key activities. All these projects are enabling some 140 developing and transition countries to develop a basic capacity in dealing with biosafety issues. These activities are bringing the Cartagena Protocol to life and yielding important lessons in how to improve biosafety systems everywhere.

The Cartagena Protocol on Biosafety

The Cartagena Protocol was adopted in January 2000 as a supplementary agreement to the 1992 Convention on Biological Diversity (CBD). It establishes rules and procedures for the handling, transfer, and use of living modified organisms (LMOs)—whether for intentional introduction into the environment or for use directly as food or feed or for processing. Under the Protocol, countries must adopt measures to reduce and manage risk and be prepared to take necessary steps in the event of accidental release of LMOs. The Protocol emphasizes public awareness, participation of the public in decision making, and capacity building.

GEF, which is the financial mechanism for implementing the Protocol, adopted an Initial Strategy for assisting countries to prepare for the Protocol's entry into force and provided funding for UNEP to undertake projects toward that end. UNEP already had a substantial body of experience on which to build. It had developed "Technical Guidelines for Biosafety," which were adopted by the international community in 1995 as an interim measure while the Protocol was being negotiated, and in the late 1990s had successfully implemented a GEF-funded biosafety pilot project.

Building Capacity through National Biosafety Frameworks (NBFs)

The global NBF Development Project has two major components: working with up to 130 individual countries to develop National Biosafety Frameworks and promoting regional and sub-regional collaboration on biosafety issues.

A National Biosafety Framework is a system of legal, technical, and administrative mechanisms to address safety issues related to modern biotechnology. The NBF Development Project developed a set of core activities and created a Toolkit (available in four languages) to help countries develop draft NBFs, which generally include plans for the following: a government policy on biosafety, a regulatory framework, administrative structures to handle requests or applications for decisions on LMO handling and transfer, a system for increasing public awareness and promoting public participation in decision making, and enforcement and monitoring systems.

As of August 2006, 124 countries were participating in the NBF Development Project. Of these, 71 countries had completed draft NBFs and posted them to the Biosafety Unit website (14 in Central and Eastern Europe, 23 in Africa, 22 in Asia, and 12 in Latin America and Caribbean). By December 2007, when the Project is scheduled to end, more than 90 percent of participating countries are expected to have completed the process.

The second component involves promoting collaboration and exchange of experiences on biosafety among countries. The Project has convened sixteen regional and sub-regional workshops, and smaller meetings focusing on sub-regional collaboration. These meetings and workshops help national project staff to increase their knowledge and learning from one another. They promote south-south collaboration and networking, with countries increasingly requesting technical assistance from other developing countries that have done similar work.

Implementing NBFs in Demonstration Countries

Countries that have ratified the Cartagena Protocol are eligible to apply for support in implementing their draft NBFs. In November 2001, GEF approved funding for twelve demonstration projects, of which eight were to be managed by the Biosafety Unit. As of August 2006, five (Bulgaria, Cameroon, China, Kenya, and Poland) are completed; the remaining three (Cuba, Namibia, and Uganda) will be completed by the end of the year.

The goal of an implementation project is to enable a country to convert its draft NBF into a workable, effective, and transparent regulatory regime, in line with national priorities and international obligations. It also assists countries to create mechanisms for handling all aspects of biosafety. Outcomes in each participating country would be likely to include:

- a policy on biosafety;
- an operational regulatory regime;
- workable and transparent administrative system;
- workable and transparent systems for public information, public participation, and enforcement and monitoring;
- enhanced technical and laboratory capacity for LMO detection; and
- a national website and/or national Biosafety Clearing-House.

Access to the Biosafety Clearing-House

Ensuring Use and Access to the BCH

The Cartagena Protocol established the Biosafety Clearing-House (BCH) to help countries exchange information on living modified organisms and to assist them in implementing the Protocol. With GEF support, the Biosafety Unit helps countries both to develop national BCH components and access and use the resources available through the global BCH. The project provides advice, training, and computer hardware and software.

As of June 2006, over 100 countries were participating in the BCH Project. The Biosafety Unit has produced an operational handbook, training modules, and case studies and has established a pool of Regional Advisors to whom participating countries can turn for help in making BCH participation decisions. In collaboration with the governments of Canada, Switzerland, and the USA, the BCH Project is providing software to help countries set up national BCH components.

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The Record to Date and Looking Forward

The recent evaluation of GEF support for biosafety projects concluded that the projects contributed to speedy ratification and implementation of the Protocol. In fact, there are now 112 developing country Parties to the CPB out of the total of 142 developing countries (79 percent) being assisted by UNEP-GEF, compared to two Parties at projects' start. The evaluation also found that the projects enhanced scientific, administrative, legal, and information management capacity; promoted collaboration across sectors within countries as well as among countries; and that the support provided to countries has been consistent with the Cartagena Protocol.

The Biosafety Unit has implemented over 90 percent of the GEF Initial Strategy. It has developed a full complement of tools, experiences, lessons, trained advisors, and collaborators with which to continue to undertake both national-level and regional capacity building. As the activities under the GEF Initial Strategy come to a close, the Biosafety Unit is developing plans to use the resources developed and the lessons learned in future activities—particularly in NBF implementation and in promoting use of the Biosafety Clearing-House.

The work of NBF implementation is just beginning. Over one hundred countries are developing NBFs and still need resources and guidance to implement them. Following up on the eight demonstration projects, the Biosafety Unit has received GEF approval for 12 more biosafety implementation projects. The new projects were approved under an 'Interim Approach' that lasts until the GEF Council agrees on the new Strategy for Biosafety.

The methodology developed by the Biosafety Unit for implementation (see Box 1) and the lessons learned from demonstration projects (Box 2) provide a strong base from which to proceed with future NBF implementation. In addition, the Unit will work on promoting regional coordination and cooperation, as requested by countries, perhaps through hybrid national-regional concepts. Increased networking and exchange of experiences will be a major focus of this work.

In each of the projects under the Initial Strategy, the Biosafety Unit emphasized awareness raising and public participation, and the Unit remains committed to this principle, and to working with an ever wider range of partners, both as collaborators and as additional sources of funding.

Box 1

Implementation Methodology

The Biosafety Unit has developed a body of materials, resources, and expertise that enable it to work effectively in helping countries to implement their draft NBFs. It provides the following services:

- administrative support;
- support, training and advice on technical, legal, and scientific aspects of biosafety;
- development of technical and training materials;
- information gathering, translation, and exchange of relevant documents;
- development of mechanisms for exchange of information and experience, for networking within and between countries, and for sub-regional cooperation; and
- facilitation of a learning environment for acquiring experience and disseminating lessons.

Key Steps Required to implement a National Biosafety Framework Nationally

Box 2

Implementing NBFs: Key Lessons Learned

The initial eight implementation national-level demonstration projects had an average cost of $0.76 million, about 18 percent of which was contributed by the participating countries. Some lessons emerging from the projects:

- Implementing a draft NBF in developing countries takes about four years, but can be done because of all the experiences accumulated and the Biosafety Unit's collaboration with numerous international partners.
- High-quality scientific and technical support throughout the project cycle was essential for success. Increased support for training in risk assessment and risk management is of high priority.
- Availability of, and access to, high-quality, up-to-date materials in appropriate languages are key necessities.
- Mechanisms, such as meetings and study tours, which help countries learn from one another as well as from countries with established biosafety mechanisms, are a great help to countries.
- Where formal approval of laws/regulations is pending, putting in place functional interim measures to handle applications for LMOs is an important step.
- Emphasizing inclusiveness and participation by major stakeholders contributes to ongoing sustainability of the system set up.

Example 1: Jordan

Comprehensive Initial Inventory Identified Need for New Law

Jordan began its NBF development process in a context in which interest in biotechnology was high; university research programs were trying to catch up with the biotechnology expertise of other countries in the areas of agriculture and medicine in particular, and numerous related laws were already in place. One of the early steps for the National Coordinating Committee for the project was to undertake a comprehensive survey of national laws, by-laws, regulations, and decisions related to biotechnology and biosafety. The survey identified a considerable body of legal mechanisms that were relevant but none that directly addressed the transportation, handling, and use of living modified organisms as required by the Cartagena Protocol. A working group consisting of academics, lawyers, and scientists was convened to develop a draft by-law, which was vetted by stakeholders in two national workshops and then submitted to the Environment Ministry for formal adoption. The by-law establishes a national Biosafety Committee whose job is to do risk assessment, monitor labeling, and generally oversee enforcement of the law.

Example 2: Ghana

Ensuring Stakeholder Participation by Key Ministries

Even prior to the NBF Development Project, modern biotechnology was widely viewed in Ghana as a promising technology for improving living conditions, increasing food production, and improving health. A number of steps had already been taken to increase biosafety capacity. Nevertheless, the UNEP-GEF team faced considerable difficulty in trying to set up a broad-based, inclusive, and consultative process to developing a National Biosafety Framework. Bureaucratic procedures threatened the goal of involving technical as well as high-level participation from various ministries. Careful attention to explaining the importance of the project, its role in preparing the country for participation in the Cartagena Protocol, and the need for shared ownership of the NBF enabled the team to get around bureaucratic protocol procedures and gain access to key personnel. Their involvement in turn helped to create and maintain a high level of interest and commitment to the NBF development process.

Example 3: Kenya

Implementation: Moving from draft to operational NBF

Kenya is one of the eight demonstration countries implementing their National Biosafety Frameworks after developing a draft NBF under the UNEP-GEF Pilot project (1997-2000). The 45-month implementation project, which has just completed, is seen as timely and highly relevant to the country's needs and priorities. Kenya is one of the African countries that has a high level of scientific capacity in biotechnology, including several biotechnology products in the laboratories. Despite the recognition that biotechnology can address many of the country's needs, Government approval of the Biosafety Bill has been delayed. This is partly because the Government has decided that approval of a Biotechnology and Biosafety Policy should precede the Biosafety Bill. Notwithstanding that, interim measures for handling requests for use of LMOs for research and development (R&D) as well as for special field-testing have been in operation. To date, five approvals for R&D and six approvals for confined field-testing have been granted. The Biosafety Bill was approved by the Cabinet Committee in July 2006 and forwarded to the Parliament for adoption.

Example 4: The Biosafety Clearing-House

Think Globally, Work Nationally

The BCH Project's initial step of training 34 specialists, living and working in developing and economies-in-transition countries, quickly proved to be an important step. Individuals with expertise in either the Cartagena Protocol or information technology received training in the Biosafety Clearing-House biosafety issues and now provide targeted and region-specific guidance and assistance to countries. This has helped countries participating in the project to receive advice from people facing similar situations and conundrums. After a mission of a BCH Regional Advisor to Peru, country representatives explained that for the first time they did not have to clarify cultural attitudes or justify their way of working. Similarly, in the Caribbean, a Regional Advisor who is highly regarded as an expert in the region has helped countries speed up their participation in the BCH.

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