

# Biosafety Protocol News

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## In this issue:

### Introductory Message

by Ahmed Djoghlaif, SCBD Executive Secretary

One of the key driving forces of the 21st century is information. The Cartagena Protocol on Biosafety, the first major environmental treaty of the 21st century recognizes the crucial role of information-sharing, gathering and dissemination in the successful implementation of the Protocol. Article 23 of the Protocol, on public awareness and participation, and decision BS-II/13 of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) emphasize the need and importance for Parties to engage in the promotion and facilitation of public awareness, education and participation regarding the safe transfer, handling and use of living modified organisms.

I am pleased to present the inaugural issue of *Biosafety Protocol News (BPN)*, which has been developed as part of the Secretariat's awareness and outreach efforts under its outreach strategy for the Cartagena Protocol on Biosafety and the Global Initiative on Communication, Education and Public Awareness of the Convention on Biological Diversity. Its publication coincides with the third anniversary of the entry into force of the Protocol, which was marked on 11 September.

The purpose of this newsletter is to provide Parties, other Governments, relevant agencies and other stakeholders with a medium to exchange information and news regarding their efforts to implement and promote awareness of the Protocol. The newsletter will also serve as an important platform for Governments and relevant stakeholders to share experiences and lessons learned, highlight ongoing partnerships and cooperation, and showcase their capacity-building projects and activities.

In this first issue of *BPN*, particular attention has been given to the work of the Global Environment Facility (GEF) and its implementing agencies, including the support provided to Parties and other governments for the development and implementation of national biosafety frameworks (NBFs).

The article by Monique Barbut, the new Chief Executive Officer (CEO) of the GEF, underscores the need for collective efforts and renewed commitment to mobilize resources to implement the Convention on Biological Diversity and the Cartagena Protocol. It highlights the role that the GEF has played in supporting activities aimed at building capacities for the effective implementation of the Protocol. The articles submitted by UNEP-GEF provide an overview of some of the GEF-funded activities and points out the achievements made especially towards the development and implementation of national biosafety frameworks in more than 130 developing countries as well as building capacities for effective participation in the BCH. Likewise, the article by the World Bank describes the ongoing effort in supporting capacity-building projects in Colombia, India and the multi-country projects in Latin America and West Africa. This issue also provides an overview of the main outcomes of the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 3), which was held from 13 to 17 March 2006 in Curitiba, Brazil. In addition, it describes areas where progress has been made in developing tools and capacities for supporting the implementation of the Protocol.

The article by Worku provides a checklist of various submissions from governments and relevant organizations as requested by COP-MOP 3 for the purpose of facilitating the consideration of the respective issues at COP-MOP 4. The article by Erie highlights what has so far been accomplished with respect to capacity-building and outlines the major gaps

that need to be addressed. In addition, the article by Kirsty describes some of the innovative tools and the on-going efforts to further improve the operation and use of the BCH.

The newsletter also features personal perspectives on the Protocol and broader biosafety issues. In that context, the article by Cyrie Sendashonga, former Senior Programme Officer, Biosafety Division at the Secretariat, provides some reflections on the negotiation process for the Protocol and also points out some issues that she feels might pose difficulties to its implementation.

*BPN* will be published on a bi-annual basis. I invite and encourage all Governments, relevant agencies and stakeholders to contribute articles to future issues of the newsletter. I would like to express my personal gratitude to the GEF Secretariat, UNEP-GEF, the World Bank, and to Cyrie Sendashonga for contributing articles to this first issue.

I hope that this newsletter will serve as a valuable information tool in the advancement of the objectives and effective implementation of the Protocol.

Ahmed Djoghlaif  
Executive Secretary,  
Convention on Biological Diversity

## **Message from Monique Barbut, CEO, Global Environment Facility (GEF)**

Dear Colleagues:

I am pleased to contribute to the inaugural issue of the Biosafety newsletter being launched by the Convention on Biological Diversity.

As the newly-appointed CEO of the Global Environment Facility (GEF), I am committed to building on the GEF's core strengths, and increasing its impact with respect to the implementation of international environmental agreements including the Convention on Biological Diversity.

The time is opportune to renew our efforts in strengthening the implementation of the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB).

### **GEF replenishment**

Readers will be pleased to know that the fourth replenishment of the GEF was successful, topping US\$3.13 billion for global environment protection over the next four years. For this robust replenishment, we owe thanks to 32 donors. Furthermore, the Third GEF Assembly hosted by the Government of South Africa in Cape Town, August 29-30, strengthened the role of GEF as the, or a, financing mechanism of the global environmental conventions.

### **GEF's role in capacity-building for biosafety**

The twentieth century was an industrial one, and it is clear that the twenty-first will be a biological century. The GEF is fully committed to implementing the Cartagena Protocol on Biosafety which seeks to protect biological diversity from the potential risks posed by living modified organisms (LMOs) resulting from modern biotechnology.

In the area of biosafety, after the adoption of the Cartagena Protocol, the GEF Council approved an initial strategy to assist countries to prepare for its entry into force. Under that initial strategy, GEF provided assistance to more than 120 countries to develop their national biosafety frameworks (NBFs). Since then, GEF has supported the participation of 139 countries in the Biosafety Clearing House (BCH), and 12 countries are participating in implementation projects for the Protocol. The total amount allocated to these projects exceeds \$56 million.

After the Protocol entered into force in September 2003, the GEF Council welcomed the guidance of the Conference of the Parties inviting the GEF to extend support for implementation projects and requested the GEF Evaluation Office to conduct an evaluation of the activities financed under the initial strategy. The evaluation is expected to provide valuable information and lessons for future GEF support.

Pending the completion of the evaluation, the Council approved an interim approach to the financing of biosafety capacity-building activities. Under the interim approach, 11 countries that were in urgent need of moving forward in implementing their national biosafety frameworks received support. In addition, two regional projects—in Latin America and West Africa, aimed at strengthening regional centres of excellence to enable those centres to assist countries in the region—have been funded. Total funding for these activities is close to \$18 million.

Based on the guidance from the Convention on Biological Diversity, and building on the results of the evaluation carried out, the GEF Secretariat, in collaboration with the Implementing Agencies, submitted to the GEF Council a paper on “Elements for a Biosafety Strategy”. This document was reviewed and the substantive elements welcomed as a basis for developing a strategy to guide the provision of GEF assistance to support the implementation of the Cartagena Protocol. The GEF Secretariat is currently drafting a GEF Strategy for Financing Biosafety Activities for review and approval by the GEF Council in December 2006.

We look forward to strengthening our collective efforts to implement the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, which are so essential for achieving sustainable development.

With best wishes,

Monique Barbut  
CEO, Global Environment Facility

## **Overview of COP-MOP 3 Outcomes and Follow-up Actions for the Inter-Sessional Period** by Worku Damena Yifru, Biosafety Division, SCBD

The third meeting of the Conference of the Parties serving as the meeting of the Parties to the Biosafety Protocol (COP-MOP 3) took place in March 2006. The meeting adopted several decisions. Some of the decisions brought in improved approaches or new elements to the Protocol process. Decisions such as those on: (i) compliance related issues; (ii) the operation of the Biosafety Clearing-House; (iii) capacity-building, including the adoption of an updated version of the Action Plan; (iv) a revised format for national reporting; and (v) risk assessment and risk management, would go a long way in helping Parties better implement the requirements of the Protocol.

The core focus of COP-MOP 3 was on reaching agreement on detailed documentation requirements for shipments of living modified organisms that are intended for direct use as food or feed, or for processing (paragraph 2 (a) of Article 18 of the Protocol). The intense negotiations finally came to fruition when Parties reached consensus at the final hours of the meeting. The compromise package, which is contained now in decision BS-III/10, requests Parties and urges other Governments to take measures to ensure that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing is in compliance with the requirements of the country of import and clearly state the information specified in paragraph 4 of the decision. According to the decision, in cases where the identity of the living modified organism is known through means such as identity preservation systems, the documentation is required to state that the shipment contains living modified organisms, and in cases where the identity of the living modified organisms is not known through means such as identity preservation systems, it has to state that the shipment may contain one or more living modified organisms that are intended for direct use as food, or feed, or for processing.

Since more attention was directed towards resolving the outstanding issue under paragraph 2 (a) of Article 18, discussions on other agenda items remained relatively limited, and in many instances, substantive decision taking

postponed pending further review. Quite a number of decisions simply call for views and information from Parties and other stakeholders in order to facilitate future consideration of the items concerned.

Therefore, in the two-year inter-sessional period prior to the next meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, Parties and other stakeholders are expected to engage in the Protocol process with a view to laying the groundwork necessary for future decision taking with respect to several items. The items or issues, which need attention, reflection, and appropriate action during the inter-sessional period include:

- (a) *Handling, transport, packaging and identification.* In connection with this item, Parties are requested and other Governments are invited or urged to submit:
  - (i) Information on experience gained with the use of existing documents. (decision BS-III/8, paragraph 1) This information is important to review the adequacy of existing documentation systems in fulfilling the requirements of identification of transboundary movements of living modified organisms for contained use and those for intentional introduction into the environment, and to consider the need for a stand-alone document;
  - (ii) Views and information on the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances to address concerns relating to the transboundary movement of living modified organisms, and on gaps that may exist and that may justify a need to develop new rules and standards or to adjust existing ones. (decision BS-III/9, paragraph 1);
  - (iii) Information on experience gained with the use of living modified organism sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques. (decision BS-III/10, paragraph 11).

Parties are also requested, and other Governments and relevant international organizations, are urged to take urgent measures to strengthen capacity-building efforts in developing countries, in order to assist them in the implementation of and benefit from documentation and identification requirements for living modified organisms intended for direct use as food or feed, or for processing. (decision BS-III/10, paragraph 12);

(b) *Risk assessment and risk management.* Parties, other Governments and donor organizations are called upon to make funds available as soon as possible to enable the regional workshops on capacity-building and exchange of experiences on risk assessment and risk management envisaged in decision BS-I/9, paragraph 2, to be held in advance of the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. Those with relevant experience in risk assessment and risk management to offer are also invited to share their experiences and expertise at the regional workshops. (decision BS-III/11, section B, paragraph 10)

(c) *Liability and redress.* The Conference of the Parties serving as the meeting of the Parties to the Protocol agreed that three five-day meetings of the Ad Hoc Open-Ended Working Group of Legal and Technical Experts on Liability and Redress should be convened before its fourth meeting and urged donors to provide voluntary financial contributions that would enable the organization of these meetings (one of the three meetings has no funds allocated from the core budget), and to ensure participation by all Parties. (decision BS-III/12)

(d) *Monitoring and reporting.* Parties are requested to submit their first regular national report, covering the period between entry into force of the Protocol for each Party and the reporting date, 12 months prior to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to allow consideration of the reports at that meeting. (decision BS-III/14, paragraph 3). The first national regular reports will be due on 11 September 2007. In order to adhere, to the extent possible, to the 12-month timeframe prior to the meeting that reviews the reports, and also to allow sufficient time for processing, only reports received by 11 September 2007 will be included in the analysis that the Secretariat is to prepare for the consideration of the Parties at their fourth meeting (decision BS-III/14, paragraph 7);

(e) *Assessment and review.* Parties, other governments as well as relevant intergovernmental and non governmental organizations and other stakeholders are invited to submit their views that should:

- (i) Evaluate the effectiveness of the Protocol, including an assessment of procedures and annexes, taking into account the items specified in paragraph 6 (b) of the medium-term programme of work contained in the annex to decision BS-I/12;
- (ii) Assess the procedures and annexes under the Protocol, with a view to identifying difficulties arising from implementation as well as suggestions for appropriate indicators and/or criteria for evaluating effectiveness and ideas on the modalities of the evaluation. (decision BS-III/15);

Parties may include their views on assessment and review and any information that may be relevant to the evaluation of the effectiveness of the Protocol in their first national reports.

(f) *Socio-economic considerations.* Parties, other Governments and relevant international organizations are requested to provide their views and case studies, where available, concerning socio-economic impacts of living modified organisms. (decision BS-II/12, paragraph 5).

Finally, it should be noted that all the submissions referred to above have to reach the Secretariat at least six months prior to the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol. In order to avoid delay in the preparation and circulation of the relevant documents, the Secretariat appreciates a timely submission of the views and information highlighted above. □

## **Building Capacities for the Effective Implementation of the Biosafety Protocol: What Have We Accomplished in the Last Six Years?**

by Erie Tamale , Biosafety Division, SCBD

### **Introduction**

When the Protocol was adopted in January 2000, it was acknowledged then that its successful implementation hinged on building national capacities, especially in developing country Parties and Parties with economies in transition. Six years on since its adoption, a number of capacity-building initiatives in biosafety have been undertaken at the global, regional and national levels and many lessons have been learned. This article gives a general overview of what has been accomplished and outlines the unmet needs and gaps and what still remain to be done.

### **The Context**

Article 22 of the Biosafety Protocol requires Parties to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety. It states that such cooperation shall, subject to the different situations, capabilities and requirements of each Party, include scientific and technical training and the enhancement of technological and institutional capacities in biosafety.

Following adoption of the Protocol, governments decided to give high priority to capacity-building. Accordingly it was one of the main issues that was addressed during the preparatory phase prior to the entry into force of the Protocol in September 2003, which was spearheaded by the Intergovernmental Committee on the Cartagena Protocol (ICCP). The ICCP developed a number of tools, which were subsequently adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) at its first meeting. COP-MOP 1 also decided to make capacity-building one of the standing items on its medium-term programme of work.

At its three previous meetings, the COP-MOP has adopted a number of decisions related to capacity-building, including decisions: BS-I/4, BS-I/5, BS-II/3, BS-III/3 and BS-III/11 (paragraphs 14-18). Those decisions provide useful tools and guidance to Parties, other Governments, relevant organizations and the Executive Secretary regarding specific

measures and actions that may be undertaken to advance the building of capacities for the effective implementation of the Protocol. Some of the key tools and mechanisms adopted include the following:

- The “Action Plan for Building Capacities for the Effective Implementation of the Protocol”, which was adopted at MOP/1 and updated by MOP/3, provides a useful framework that assists governments and organizations to better address priority capacity-building elements in a strategic, systematic and integrated manner.
- A Coordination Mechanism, adopted at MOP 1 and further enhanced in decisions taken at MOP 2 and 3, has provided an important mechanism to facilitate coherent and collaborative implementation of the Action Plan and to ensure mutual supportiveness among different initiatives. As part of the Coordination mechanism, four important capacity-building databases have been developed in the Biosafety Clearing-House (BCH) to allow exchange of information on on-going activities, identification of gaps and to facilitate improved targeting of available resources and opportunities to meet specific country needs and priorities. These include databases on capacity-building projects, short-term opportunities and country needs; the compendium of biosafety education and training courses; and the Biosafety Information Resource Centre, which contains a wide array of useful resource materials. It is now possible to find in one place a summary of, and links to, the various ongoing or planned biosafety projects, short-term opportunities (such as funding, seminars, scholarships or internships) and training courses as well as existing resource materials. As well, three Coordination Meetings and three Liaison Group meetings have been organized.
- A roster of experts has been established through the BCH to provide advice and other support, as appropriate and upon request, to developing country Parties and Parties with economies in transition, to conduct risk assessment, make informed decisions, develop national human resources and promote institutional strengthening, associated with the transboundary movements of living modified organisms. Currently, more than 600 experts are registered in the Roster.

### **What have we achieved since the adoption of the Protocol?**

Over the last six years since the adoption of the Protocol, several initiatives have been implemented at various levels to support countries to meet their capacity-building requirements under the Protocol. Considerable investment has been made and a number of achievements have been realised. According to an assessment undertaken by the United Nations University Institute of Advanced Studies, close to US\$ 180 million has been invested in biosafety-related capacity-building initiatives. Examples of some of the specific major achievements include the following:

- As described in the articles by Monique Barbut and UNEP-GEF, more than 120 countries have, with assistance from the global UNEP-GEF project, developed their national biosafety frameworks (NBFs) and at least 12 other countries have embarked on implementing theirs. At the time of the adoption of the Protocol, only very few of developing countries had biosafety policies and regulatory frameworks in place and most of them did not have administrative systems for handling requests for LMO imports or field releases.
- Many countries have established institutional mechanisms for administering biosafety, including strengthening of institutions responsible for biosafety and establishment of national biosafety committees.
- A number of short-term training workshops and a few long-term courses on biosafety have been organised. According to the information in the BCH, there are more than 55 reported regular biosafety-related courses, both short-term and long-term. As well at least 95 projects have specifically contributed to human-resources development and training in various biosafety related fields through training workshops and international biosafety courses, on-job training and staff exchanges and, provision of scholarships and fellowships.
- Some progress has been made in building capacity for risk assessment and risk management but there is still a major gap in this area. There is a need to build long-term human resource and infrastructure capacity in many countries in order to enable them to effectively implement the risk assessment and risk management provisions

of the Protocol.

- Considerable awareness of the Protocol and biosafety in general has been built over the last six years, at least among the major stakeholders, especially policymakers and relevant private sector players. In many countries, biosafety and the existence of the Protocol is now known and many stakeholders are increasing becoming aware of the issues involved.
- Since the adoption of the Action Plan, the level of exchange of biosafety information and data has dramatically increased, largely as a result of the progress made in operationalizing the Biosafety Clearing-House. And as described in the article by UNEP-GEF, more than 130 countries are now being assisted through the BCH project to build their capacity to participate effectively in the BCH, including through training and establishment of national nodes of the BCH or national biosafety websites and databases.

### **What are the main gaps?**

Clearly, some progress has been made in the area of capacity-building over the last six years, as outlined above. Nevertheless, a lot more still needs to be done. According to the survey carried out by the Secretariat in 2005, major capacity-building gaps still exist especially in the areas of: technology transfer, identification of living modified organisms (LMOs), risk assessment and risk management, and the handling of socio-economic considerations. A lack of adequate funding for biosafety remains the biggest constraint. Several countries have also highlighted a lack adequate human resources and institutional capacities, including appropriate infrastructures and limited access to technologies and technical know-how. Other specific major unmet needs and gaps mentioned include a lack of: laboratories for the detection and quantitative analysis of living modified organisms (LMOs); systems for inspection and post-release monitoring of the environmental impacts of LMOs; skills and know-how of implementing the documentation systems for LMO shipments in the context of Article 18 of the Protocol, facilities for biosafety research as well as tools and guidance materials on risk assessment and risk management.

### **Conclusion**

A lack of capacity remains one of the biggest challenges for the effective implementation of the Protocol. There is a need to consolidate and build upon the achievements made so far in order to enable developing countries and countries with economies in transition to build the human resource and institutional capacities. In doing so, it is important to take into account the fact that capacity-building is not only a matter of imparting new knowledge and skills but also providing the environment and opportunities for people to utilize them. It is also important to identify, mobilize and make effective use of existing capacities and resources. As emphasized by the decisions of the Conference of the Parties serving as the meeting of the Parties to the Protocol, capacity-building initiatives should be demand-driven, responsive to the needs and priorities of the recipient countries and should be implemented in an adaptive and incremental manner. Moreover, it is imperative to adopt a coordinated approach in order to maximize synergies among different initiatives and funding sources as a precursor to ensuring the long-term sustainability of capacity-building efforts.

# **Biosafety Clearing-House News**

## **Living Modified Organisms Registry**

by Kirsty Galloway McLean, Biosafety Division, SCBD

### **Launch of the LMO registry**

In July 2006, an easily accessible central registry of all living modified organisms (LMOs) for which decisions have been taken was launched in the Biosafety Clearing-House (BCH). The registry provides summary information for each LMO, including the transformation event, gene insert and characteristics of the modification, and its unique identification code

(if available). Links to all decisions that refer to one of these organisms are provided at the bottom of each LMO record accessible through the registry.

## **What is in the LMO registry?**

The LMO registry contains all LMOs for which: (a) companies have applied for a unique identifier; and/or (b) there are decisions taken under the Protocol that have either been registered with the BCH, or where the Secretariat has been advised such decisions will be registered shortly. The organism will appear in the BCH no later than at the time of registration of a decision, although full details in the registry may not be supplied until the Secretariat has conducted a literature search and/or confirmed technical information with the registrant or developer.

The registry also contains information on organisms that may have been approved for release even though the developer decided not to proceed with commercialization (i.e., the LMOs were never commercially released). Where the Secretariat has been able to determine commercialization status from the developers, that information is also included in the database.

## **What is the difference between the LMO registry and the LMO database?**

The LMO registry contains a single entry for each unique organism or transformation event, and includes detailed information about the organism. The registry presents this information summarized in table format, where each record may be selected for further details.

However, multiple records may exist for each unique organism elsewhere in the BCH, since Governments may create their own record for a LMO if they wish. (For example, a Government may choose to create its own record if it wishes to report more information than is included in the registry, or for technical reasons.) The LMO database contains all LMO records, including such duplicates, and can be searched using keywords and the BCH controlled vocabulary.

## **How do I access the LMO registry and database?**

The LMO registry (list of organisms) and the searchable LMO database are available on-line in the “organisms” section of the BCH at <http://bch.biodiv.org/organisms/>.

# **Unique Identification of Living Modified Organisms**

by Kirsty Galloway McLean

## **What is the unique identification code?**

The BCH uses unique identification systems for living modified organisms to facilitate searching and retrieval of information. Currently, the only existing unique identification system in international use is the OECD Unique Identifier for Transgenic Plants<sup>1</sup>. The OECD Unique Identifier is a simple alphanumeric code that is given to each living modified plant that is approved for commercial use, including for use as food or feed, similar to the ISBN codes used to identify books. The OECD naming system has been designed so that developers of a new transgenic plant can generate an identifier and include it in the dossiers that they forward to national authorities during the safety assessment process.

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<sup>1</sup> ENV/JM/MONO/2002/7 Guidance for the Designation of a Unique Identifier for Transgenic Plants, Organisation for Economic Development and Co-operation (OECD), October 2004

Once approved, national authorities can then forward the unique identifier to the OECD Secretariat for inclusion in the OECD's product database, from which the information is automatically shared with the Biosafety Clearing-House.

The unique identifier is a nine-digit code, composed of three elements that are separated by dashes (-). These elements are outlined below:

2 or 3 alphanumeric digits to designate the applicant

5 or 6 alphanumeric digits to designate the transformation event

1 numerical digit for verification (this is intended to reduce errors by ensuring the integrity of the alphanumeric code)

A fictional example could be:

CBD-ABØ12-6, where

CBD is the applicant code (e.g. Convention on Biological Diversity);

ABØ12 is the transformation event (each applicant has their own internal mechanism for allocating unique transformation events); and

6 is the verification code (calculated by adding together the other letters and numbers in the unique identifier (alphabetical characters are designated as A=1, B=2, Z=26, etc). If the total sum is made up of several numerical digits, those digits are added together until the total sum is a single digit. In this case, 3+2+4+1+2+0+1+2=15, 1+5=6)

Two approaches are possible for products created with more than one transformation event (often referred to as "stacked" transformation events), where these transformation events have been previously approved for commercialization. An applicant may choose to generate a novel unique identifier for such products, or they may choose to use a combination of the unique identifiers from products previously approved for commercialization.

## What organisms have a unique identifier?

Under the Protocol, provision of any unique identification information is expected for living modified organisms intended for direct use as food or feed, or for processing (i.e. decisions taken under Article 11), since it is assumed that most of these will have been approved for commercial use. The third meeting of the Parties to the Protocol also requested governments to provide information relating to unique identification when registering decisions under the Advance Informed Agreement procedure, where available.

The OECD unique identification system examined here applies only to living modified plants. Work is ongoing to develop a unique identification naming convention for other types of organisms.

# Point of View

## The Cartagena Protocol on Biosafety:

### from where to where - A personal perspective from Cyrie Sendashonga

On 22 May 1992 in Nairobi, the text of the Convention on Biological Diversity was adopted. It was my initiation to international treaty-making, as I was then just six months into the job at UNEP as a Programme Officer in the Biodiversity and Biotechnology Unit of what was then called the Terrestrial Ecosystems Branch of UNEP. The subject of living modified organisms (which is the term the Convention used rather than the term "genetically modified organisms" used in everyday language) had come up during the negotiations of the Convention, and a number of negotiators had called for the inclusion in the Convention of some provisions to regulate the use and especially the movement of LMOs from one country to another. In the end, realizing the complexity of the task, Governments opted for a "saving" clause leaving the development of a protocol at a later stage, as reflected in paragraph 3 of Article 19 of the Convention.

In November 1995 in Jakarta, the Conference of the Parties at its second meeting gave a mandate to a working group of legal and technical experts on biosafety to develop a protocol on biosafety focusing specifically on transboundary movement of any LMO that may have adverse effect on the conservation and sustainable use of biodiversity.

On 29 January 2000 in Montreal, the Cartagena Protocol on Biosafety finally came to life.

I would like to share some personal perspectives and a few anecdotes on the long road that led to the Protocol and how I see its future. Between the adoption of the text of the Convention in Nairobi (22 May 1992) and the second meeting of the Conference of the Parties, which launched the negotiations on a protocol, there were several others meetings related to the topic of biosafety, such as : the meetings of Panel IV established by the Executive Director of UNEP in the aftermath of the adoption of the Convention; an informal consultation with a group of experts on biosafety held in Geneva in July 1993 at the request of the Executive Director; the development of UNEP technical guidelines on biosafety; the expert group meetings in Cairo (May 1995) and Madrid (July 1995) which formulated the recommendations which were considered by the Conference of the Parties in Jakarta.

I was personally in charge of the informal expert consultation held in Geneva in November 1993. It brought together a dozen experts from academia, the industry and the government sector, all acting in their personal capacity. I recommended which experts to be invited by the Executive Director of UNEP, proposed the agenda for the meeting and served as facilitator and rapporteur for the meeting. I remember the recommendations made by the experts present at that meeting with respect to what they considered as the minimum requirements that a protocol on biosafety would need to fulfill in order to be what they referred to as a “win-win” instrument: it would have to address substance as well as perceptions, it would have to be flexible enough to take into account new scientific developments, and it would have to provide a framework for capacity-building in order to create confidence and build trust on the issue of GMOs.

I believe that the Cartagena Protocol on Biosafety that was adopted seven years after that informal meeting in Geneva essentially fulfils those basic requirements: its core provisions (advance informed agreement procedure; procedure for LMOs intended for direct use as food or feed, or for processing (LMOs-FFPs); the BCH; handling, transport, packaging and identification; compliance; liability and redress; public awareness and participation) do address both substance and perceptions; its scientific provisions relating to risk assessment and risk management (Articles 15, 16, Annex III) were constructed to take into account the evolving nature of scientific developments; finally, the Protocol makes a strong case for capacity-building and capacity strengthening for the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety (Articles 22 and 28).

So, is the picture all rosy for the Protocol and its future? I wish I could emphatically say YES, but I am afraid that would be being too optimistic. Like all human endeavours, the Protocol does have some weaknesses. In my view, its Achilles' heel lies in Article 26 (socio-economic considerations): because Article 26 introduces a political element in the decision-making process with regard to import of LMOs, it opens the door to potential conflicts between those who would want to see the implementation of the Protocol guided only by science—especially as regards the import and other transboundary movements of LMO—and those who are of the view that nothing should impede on the sovereign right of any nation to take decisions which it feels are in the best interest of its people, including prohibiting the import of LMOs on socio-economic considerations.

There are people who are of the view that the fundamental weakness of the Protocol (its original sin) lies in its endorsement of the precautionary approach. I personally do not look at it that way: the precautionary approach as elaborated in the Protocol is not inconsistent or in contradiction with the risk assessment and risk management provisions of the Protocol to be carried out in a scientifically sound manner. The weakness of the Protocol will be in the way Parties and non-Parties will want to interpret and apply Article 26, i.e., reaching decisions on import taking into account socio-economic considerations and consistent with their international obligations. Should conflicts arise, it will remain to be seen whether the matter will be dealt with in the framework of the cooperative procedures and institutional mechanisms on compliance established by the COP-MOP (e.g. the Compliance Committee), or whether some

Governments, especially non-Parties, will prefer to head to the World Trade Organization (WTO) right away. Only time will tell. Long life to the Protocol!

Cyrie Sendashonga was a Senior Programme Officer for Biosafety at the CBD Secretariat. She led the biosafety programme for seven years before moving to the Centre for International Forestry Research (CIFOR) in 2006 as Regional Coordinator for Central Africa. You can reach Ms. Sendashonga at [c.sendashonga@cgiar.org](mailto:c.sendashonga@cgiar.org)

## UNEP-GEF Activities

### The Global Project for Development of National Biosafety Frameworks (NBFs)

The UNEP-GEF Global Project for Development of National Biosafety Frameworks is now in its fifth year of implementation and now includes 126 countries. The last country to join the project was Bosnia & Herzegovina in June 2006. To date, 68 countries have posted their draft national biosafety frameworks on the UNEP biosafety website – see list at <http://www.unep.ch/biosafety/news.htm#nbf>. Each project includes the following main activities:

- Surveys and inventories of current biosafety practices, existing policy/legal frameworks and available expertise,
- Harmonization of legal and regulatory instruments,
- Strengthening of risk assessment/management capabilities,
- Strengthening of public awareness and mechanisms for public participation, and
- Design and publication of the national biosafety framework.

The project has developed support toolkits for each of the major phases in the development of an NBF, and has also coordinated 4 regional and 12 subregional workshops to promote collaborations and exchanges of experience on biosafety. It is expected that all countries will have completed their draft NBFs by the end of December 2007. UNEP Biosafety has begun to compile some of its experience with NBF development with a preliminary case study “Building Biosafety Capacity in Developing Countries: Experiences of the UNEP-GEF Project on Development of National Biosafety Frameworks”. □

### Projects for the Implementation of National Biosafety Frameworks

The UNEP-GEF Biosafety Unit manages eight of the twelve GEF-funded demonstration projects on implementation of national biosafety frameworks (NBFs), in Bulgaria, Cameroon, China, Cuba, Kenya, Namibia, Poland and Uganda. These eight countries finished their pilot projects, which resulted in draft NBFs, in 1999. The demonstration projects started in September 2002 and were set to last about three years, with budgets ranging up to US\$ 1 million. Five of the eight projects were completed by the end of mid-2006, and the remaining three will be completed by the end of the 2006. By the end of the project, the participating countries will have in place:

- A policy on biosafety, either as a comprehensive policy in itself, or as parts of other relevant national policies;
- An operational regulatory regime for biosafety, which is in line with the Cartagena Protocol on Biosafety and other relevant international obligations, as well as consistent with existing national sectoral laws;
- Workable and transparent systems for handling applications for GMO release (including systems for administrative handling, risk assessment and decision making);
- Workable and transparent systems for public information and public participation in decision making;
- A functional system for enforcement and post-release monitoring; and
- A national website and/or a national Biosafety Clearing-House (BCH).

Lessons learned from the eight demonstration projects will be applied to the new implementation projects. Twelve of the 15 countries, which have submitted implementation projects for GEF-funding under the Interim approach, completed their draft NBFs under the development project. The other 3 countries were from the Pilot Projects. Eleven have been approved (Cambodia, Czech Republic, Egypt, Estonia, Lithuania, Mauritius, Moldova, Slovakia, Tunisia, United Republic

of Tanzania, and Viet Nam), and four are awaiting final endorsement and funding (Ghana, Latvia, Liberia, and the Democratic People's Republic of Korea). A larger number of other countries are preparing draft project proposals for NBF Implementation with UNEP, either as stand alone national projects or as part of (sub)regional projects. These proposals will be submitted to GEF for approval after the new GEF strategy has been agreed in November 2006. □

## **Project for Building Capacity for Effective Participation in the Biosafety Clearing-House (BCH)**

The UNEP-GEF Project for Building Capacity for Effective Participation in the BCH can now work with up to 139 eligible countries. Currently, 100 countries have committed themselves to participate in the project. The BCH Capacity-building Project will strengthen capacity by providing training to key stakeholders and also via an equipment component, which will provide computer hardware and software for data storage and exchange. UNEP-GEF Biosafety Unit with the assistance of the CBD Secretariat has trained Regional Advisors to provide advice and support to countries. 34 BCH Regional Advisors have been contracted to date. Participating countries can select Advisors to visit and support their national projects. The Canadian, Swiss and United States governments have been collaborating with the project by contributing software to assist countries in setting up national BCH components. Canada has also been providing support to the establishment of the regional Pacific node of the BCH for the Pacific Island States, and may provide similar support to the Caribbean region. An Operational Handbook to help countries participate in the project can be downloaded from <http://www.unep.ch/biosafety>, and all BCH training materials are available online. □

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## **World Bank and GEF Biosafety Activities**

The World Bank first became involved in GEF biosafety work when two countries sought its assistance in implementing national biosafety frameworks (NBFs). The Bank-GEF projects in Colombia and India to build capacity for implementing the Cartagena Protocol on Biosafety (CPB) became effective in 2003 and are now nearly completed. India and Colombia each received US\$1 million in GEF funds (in addition to US\$3.5 and US\$2 million in co-financing respectively) out of a total of US\$9.2 million provided for an initial twelve demonstration projects focused on NBF implementation under UNEP, UNDP and the Bank.

These two projects aim to build capacities in relevant country institutions towards national biosafety frameworks that allow countries assess, monitor and manage the potential risks posed by the transfer, handling and use of living modified organisms (LMOs) while meeting CPB obligations. The projects have generated useful lessons, along with other biosafety projects in the GEF portfolio that were highlighted in the Evaluation of GEF Support for Biosafety and reflected in GEF's draft Strategy for Financing Biosafety Activities.

The Bank recently submitted, on behalf of countries in Latin America and West Africa, two GEF project proposals that introduce a multi-country approach, draw on some of the lessons learned from the GEF's Initial Strategy and propose measures to safely manage and control the trade and use of GMOs, in line with CPB objectives. Countries chose a multi-

country approach to better coordinate and share experiences; take advantage of shared concerns on biodiversity, biosafety and related issues; and, pool expertise and resources to avoid duplicating efforts – given scarce resources and capacity.

The Latin America multi-country capacity-building project – worth nearly US\$18 million (with US\$5 million in GEF financing) – is designed to complement and reinforce national biosafety initiatives through scientific, technical, and institutional cooperation. The West Africa Regional Biosafety Project, worth an estimated US\$24 million (including US\$5.4 million in GEF funding) aims to protect biodiversity from potential risks associated with LMOs within the West African Economic and Monetary Union through member state cooperation. Both projects emphasize sustainable biosafety capacity-building by maximizing expertise that exists across countries and by tailoring project design to articulated needs and circumstances of each country in a region.

□

## **EDUCATION AND OUTREACH**

As part of its ongoing outreach efforts, the CBD Secretariat welcomed students from Université de Montreal's (UdM) annual training course on European, Comparative and International Environmental Law accompanied by its coordinator Françoise Maniet and Prof. Veit Koester (Denmark). The training course covered topics of European and International law, with a special emphasis on practical enforcement and comparative law. Prof. Koester's training session was on Biodiversity and Nature Conservation with a focus on biodiversity-related multilateral environmental agreements (MEAs). It was a request from Prof. Koester that brought these students to the Secretariat in order for them to receive a first hand account of the operations of the Convention and to learn from presentations given by SCBD staff members Olivier Jalbert and Worku Damena Yifru.

Olivier Jalbert gave an historical overview of the Convention as well as outlined its objectives, institutional structure and programmes of work. He also noted the value of conservation and the protection of ecosystems in the overall effort to save biodiversity.

Worku Damena Yifru presented a brief history of the Cartagena Protocol on Biosafety as well as highlighted key issues, concerns and major controversial areas in the negotiations of the Protocol. He cited scope, precautionary approach, biosafety and trade and labelling as major contentious issues within the Protocol.

The training course takes place every summer and registrations from civil servants working in environmental policies, NGOs and industry professionals are encouraged. Information regarding the course for 2007 will be available at the start of next year and can be found at the following website: <http://www.monnet.umontreal.ca>

## **PASSAGES: In Memory of Mario Ramos**

We at CBD Secretariat were shocked and saddened by the sudden death of our friend and colleague Mario Ramos, GEF.

Mario was a senior biodiversity specialist and acting team leader for biodiversity in the GEF. He joined the GEF at its inception, and had been instrumental in the development and implementation of GEF biodiversity strategies, operational programs and policy frameworks in response to guidance from the Conference of the Parties to the Convention on Biological Diversity and its Protocol, as well as in the promotion of improved effectiveness of GEF as the financial mechanism of the two legal instruments.

Mario was a firm believer in the global biodiversity agenda, and knew that full cooperation between the Convention and its financial mechanism was essential to advancing that cause. With incomparable command of the issues, and an unerring political sense, he made important contributions over the course of personifying the Global Environment Facility especially within the framework of the Convention and its Protocol. He was a trusted source of information, expertise and knowledge for many colleagues at the CBD Secretariat.

Mario was known for his kindness, warmth of heart and concern for his friends and colleagues. He was admired from Washington, D.C., to Montreal, from New York to Nairobi, indeed in all corners of the world, lives were touched by him. He is mourned with deep affection and will be greatly missed by his friends and colleagues at the Secretariat.  
□

## Biosafety Protocol News

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DNA double helix graphics courtesy of the U.S. National Library of Medicine

Photos from ENB/IISD and UNEP-GEF

We would like to hear from you:

We are encouraging governments, particularly those that are Party to the Protocol and relevant stakeholders to send articles and digital photos on their implementation, awareness and outreach activities. Please send your contributions to [BPN@biodiv.org](mailto:BPN@biodiv.org)

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