

BIOSAFETY PROTOCOL NEWS

JULY 2011 ● Issue 9

National Administrative Systems for Biosafety

Experiences and Lessons Learned from Africa, Asia, the European Union and Latin America and the Caribbean



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JULY 2011 ● Issue 9

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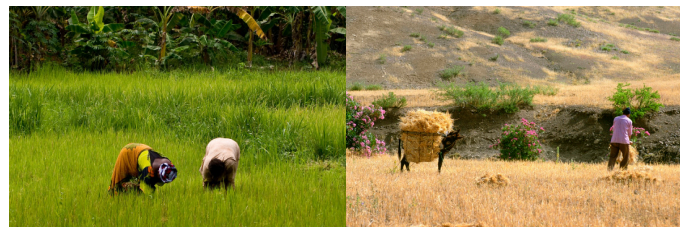
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Introduction

by Ahmed Djoghlafl ●

Executive Secretary of the Convention on Biological Diversity



Dear Reader,

I am pleased to introduce the ninth issue of the Biosafety Protocol News. This issue focuses on experiences and lessons learned in establishing and implementing national administrative systems for biosafety. The Cartagena Protocol on Biosafety requires Parties to take appropriate legal, administrative and other measures to implement their obligations under the Protocol. It also specifically requires each Party to designate one or more competent national authorities to perform the administrative functions required by the Protocol.

National administrative systems for biosafety are cornerstones for the effective implementation of the Protocol. They provide mechanisms and procedures for handling applications and facilitating decision-making regarding the import or release of living modified organisms (LMOs). They also provide mechanisms for monitoring and enforcement to ensure the safety of the LMOs once they are approved.

To date, most Parties to the Protocol have to set up administrative systems for biosafety as part of their national biosafety frameworks. The articles in this issue highlight the experiences and lessons learned in the establishment and implementation of national administrative systems in Cuba, Kenya, Malaysia, Mexico and the European Union.

The nature and scope of the biosafety administrative systems vary from country to country. Some countries, such as Cuba, Kenya and Malaysia have established centralised systems whereby a single institution is designated to handle all the applications, coordinate public input and provide administrative support for the risk assessment and decision making processes, in collaboration with other relevant government agencies. Others, such as Mexico, have placed administrative responsibilities for biosafety in various government departments depending on the type or intended use of the LMOs in question.

All the administrative systems described in this issue have established multidisciplinary advisory bodies to provide independent scientific and technical advice to the decision makers and risk managers in an objective and transparent manner. All of them have also incorporated mechanisms for public access to information and stakeholder consultation to foster transparency and public confidence in the decision-making process. Furthermore, all the systems described in this issue have mechanisms for coordination and exchange of information between relevant regulatory agencies.

While progress has been made in establishing biosafety administrative systems in most countries, major challenges still remain in fully operationalising those systems. As noted in the articles from Cuba, Kenya and Malaysia, there is a need to strengthen the institutional and human resources capacities, improve coordination among relevant government agencies and ensure harmonization of the biosafety regulatory frameworks with other related legislation. There is also a need to build public awareness, support and confidence in the biosafety regulatory systems as noted in the articles from Mexico and Malaysia.

I wish to thank all the contributors to this issue for sharing their valuable and insightful experiences. I call upon all Parties and other stakeholders to use this newsletter to share information and news regarding their experiences and lessons learned in the implementation of the Protocol.



Administrative Systems for Handling Biosafety Issues in Cuba



EMERGING EXPERIENCES AND LESSONS LEARNED

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Introduction

Cuba's biosafety system was initiated in the year 1996 with the establishment of the National Centre for Biological Safety (CBS¹) as the institutional structure responsible for controlling biological risks. The early establishment of the CBS, and its facilitation with a State budget aimed exclusively at implementing regulatory functions in biosafety, is a clear demonstration of the political will and commitment of the Cuban government to address the nation's biosafety problems in a specialized manner and on a permanent basis. Over the last 15 years, the biosafety system in Cuba has evolved and considerable experience has been gained. This article describes some of the main emerging experiences and lessons learned.

Regulatory Framework for Biosafety

Cuba relies on a set of legal instruments in the fields of biodiversity and biotechnology to provide protection to the environment and human health. There are a total of seven specific regulations that provide the technical and procedural basis for authorization, inspection and monitoring of biological agents (including LMOs). The legal instruments include: (i) Decree No.190 on Biological Safety and Resolution 67/96 of the CITMA which created the CBS; (ii) Resolution 76/2000 (Regulation for the Granting of Biosafety Authorizations) which establishes the procedures for granting biosafety authorizations linked to the development, use, handling and transboundary movement of LMOs; (iii) Resolution 8 on General Biosafety Regulation for Facilities where Biological Agents and their Byproducts, Organisms and Fragments thereof with Genetic Information are Handled; (iv) Resolution 103 (Regulation Establishing the Biosafety Requirements and Procedures for Facilities that Use Biological Agents and their Byproducts, Organisms and Fragments thereof with Genetic Information) and (v) Resolution 112 (Regulation Establishing the Biosafety Requirements and Procedures for Facilities that Work with Plants and Animals that Represent a Biological Risk). The legislation facilitates the implementation of the Cartagena Protocol on Biosafety and other relevant international agreements. Cuba chose to follow a wider approach to biological safety which also addresses alien species and biological agents. Accordingly, the implementation of the Protocol cannot be viewed in isolation from the rest of Cuba's biosafety legislation. This wider approach to biosafety distinguishes the Cuban biosafety framework from those of other countries of the region.

The Government of Cuba has also adopted technical standards and guidelines. These include the guidelines for LMO risk assessment and risk management applicable to (i) confined use and (ii) release into the

¹ The Spanish acronym for National Center for Biological Safety of Cuba is CNSB (Centro Nacional de Seguridad Biológica).

environment of plants and aquatic and non-aquatic animals resulting from modern biotechnology.

National Competent Authority

The CBS, which is part of the Office for Environmental Regulation and Nuclear Safety (ORASEN in Spanish) in the Ministry of Science, Technology and the Environment (CITMA), is the central body in the country responsible for coordinating activities aimed at ensuring efficient control of biological agents, including genetically modified organisms. A control mechanism has been created based on national legislation which provides the CBS with the legal tools needed to exercise its state functions.

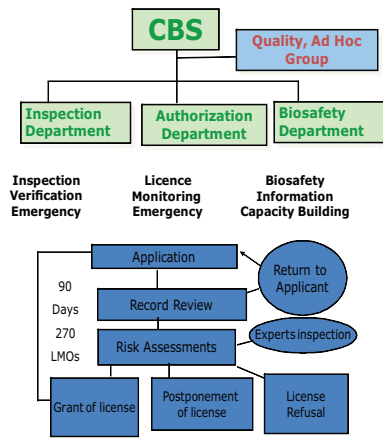
As a regulatory body and Competent National Authority under the Cartagena Protocol on Biosafety, the CBS performs the administrative functions required by the Protocol. Its main functions include: (i) development of legal instruments and technical standards necessary for the implementation and strengthening of biosafety measures in the country; (ii) conducting inspections of the facilities where biological agents are handled and areas where exotic species and LMOs are released; (iii) monitoring the enforcement of biosafety legislation; and (iv) granting of biological safety authorizations for those activities where there is a potential risk to the environment and human health. Applications for activities involving LMOs are handled in the context of the last function.

Although the CBS is located in Havana, Cuba's capital, it is represented in all of the provinces by biosafety specialists based in the territorial offices of the Ministry of Science, Technology and the Environment. The CITMA territorial delegations play important regulatory and control functions in the respective territories. They assume and authorize processes, carry out inspections and participate in surveillance and monitoring activities. The information collected is provided periodically to the CBS head office in Havana and follow-ups are made to verify the safety conditions under which the activities are performed.

The decision-making process for LMOs activities

Decision-making on activities involving LMOs follows a procedure established in the biosafety legislation. This process is shown graphically in figure 1 below. Resolution 76/00 stipulates that the applicant must submit to the CBS a written request for authorization. This must be accompanied by relevant technical documents including the elements required to carry out risk assessments and the proposed measures to manage the risks involved for the purpose of preventing adverse effects. Upon receipt of the application, the CBS: (i) screens the technical information provided for completeness (may request any additional information, if necessary); (ii) carries out a risk assessment within 90 days from the date of receipt of the documents; (iii) makes a decision and submits the information for publication in the Biosafety Clearing-House (BCH). CITMA has the authority to suspend and revoke authorizations for any activity related to the use, research, production and release of GMOs.

Figure 1: Decision-making process regarding LMO activities



From 1999 up until the present, a total of ninety-six (96) authorizations for activities involving LMOs have been granted. These include the establishment of facilities where research and production activities and greenhouse assays are performed as well as small and large scale releases in the human, animal and vegetal spheres.

The cultivated plants are: sugar cane (*Sacharum spp.*), papaya (*Carica papaya*), potato (*Solanum tuberosum*), banana (*Musa spp.*), pineapple (*Ananas comosus*), rice (*Oryza sativa*), tomato (*Solanum lycopersicum*), sweet potato (*Ipomoea batata*), tobacco (*Nicotiana tabacum*), maize (*Zea mays*) and soy bean (*Glycine max*).

Notwithstanding the governance of CITMA over biosafety matters, there are other regulatory authorities that, from different viewpoints, are relevant and competent to address LMO issues. These include:

- The Ministry of Agriculture (MINAG), which is responsible for setting the national agricultural policy, and taking into account the national and international competitiveness of the agricultural sector, to the benefit of Cuban society.
- The Ministry of Public Health (MINSAP), which is responsible for setting standards for the preservation of human health as well as establishing measures for the fight against epidemics, state sanitary inspections, hygiene-epidemiological prophylaxis and education on health and food safety.
- The Institute of Nourishment and Food Hygiene (INHA) in MINSAP, which is responsible for the implementation of the Sanitation Registry. It has the authority to approve or reject food, raw materials, food additives and other products resulting from biotechnology destined for human consumption or otherwise in contact with food.
- The Institute of Veterinary Medicine (IMV), which is in charge of regulating all animal health-related aspects including sanitary controls and the management of a national network of veterinary diagnostics.
- The National Center of Plant Health (CNSV) in MINAG is responsible for establishing a plant health system that protects national territory from the introduction of invasive species that damage plants. It aims to sustain plant health by means of prevention, localization, control and eradication of plant pests. It also addresses (i) state plant service, (ii) the determination and control of pesticides, (iii) biological means of export, import and internal circulation, (iv) livestock and forest production and (v) biological means.

The CBS is required to coordinate with these and other regulatory authorities in order to achieve a harmonious, yet expeditious, decision-making process.

Main challenges

Cuba has faced several challenges since biosafety measures were introduced in the country. The majority of these have been due to financial constraints, weaknesses in the current national biosafety framework and lack of training due to the blockade that has prevailed for decades. Other challenges have been due to the limited coordination among the relevant authorities whose mandates and decision management have an impact upon biosafety. Technological constraints have also limited the participation of Cuba in the BCH. There is a need to develop greater technological capacity to connect to and access the BCH's Central Portal and to eventually develop a national BCH node. Some of these challenges have been addressed through the projects funded by the Global Environment Facility (GEF) which have enabled the development and implementation of the current national biosafety framework.

Other major challenges include poor institutional coordination and the lack of capacity in several fields. Greater coordination and harmonization are needed in order to facilitate effective implementation of the Protocol, and biosafety issues in general, by the various relevant national authorities.

Furthermore, there is a need to: (i) harmonise the decision-making process to make it more coordinated and expeditious; (ii) synchronize the needs for capacity-building into a single mechanism to avoid duplication of projects and other efforts; (iii) mobilize adequate financial resources for biosafety activities; (iv) identify and address the gaps related to the implementation of the Protocol; and (v) further integrate biosafety issues into border control systems and the import and export mechanisms.

With regard to training, even though a great deal of work has been done over the past fifteen years, there is a need to develop a unique centralized national training program. This should involve all levels, from undergraduate to post-graduate levels, and involve all relevant stakeholders, from higher technical officials to the local population. Once achieved, Cuba will have the capacity needed for extending its training activities potentially up to the Latin-America and Caribbean regional levels.

Conclusions

Cuba has a relatively comprehensive and integrated national biosafety system which is managed by highly skilled and trained specialists. It is supported up by a legal framework that meets the requirements of the Cartagena Protocol on Biosafety and also addresses the priorities the country has established for biosafety. Furthermore, Cuba has established comprehensive control mechanisms, such as the systems of inspection and authorization that allow for the accomplishment of regulatory activities. Biosafety is also being incorporated into other relevant sectoral and cross-sectoral plans and strategies developed. Notably, biosafety issues are prominent in the Cuban Environment Strategy which constitutes one of the paramount policy documents for governing actions of the Central State Agencies. Nevertheless, there are a number of constraints and challenges affecting the implementation of the Protocol which must be addressed over the coming years.

Administrative Systems for GMO Safety Assessments in the EU



BUILDING ON EUROPEAN-WIDE EXPERTISE

by Per Bergman ● Mr. Per Bergman is the Head of the GMO-Unit at the European Food Safety Authority, European Union. He can be contacted at: Per.BERGMAN@efsa.europa.eu

Introduction

Under the European Union (EU) Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (GMOs) and Regulation (EC) No 1829/2003 on genetically modified (GM) food and feed, GMOs and derived food and feed products are subject to a risk analysis before they can be placed on the market or released into the environment in the EU. In this risk analysis process, the European Food Safety Authority (EFSA) is mandated to assess submitted evidence and provide scientific advice to risk managers (including the European Commission (EC) and EU Member States) on any possible risks of GMOs to human and animal health and the environment. This scientific advice is elaborated by EFSA's GMO Panel as: (i) scientific opinions on the applications for GMO market access, (ii) specific safety issues or requests, or as (iii) guidance documents for risk assessment of GMOs. This article describes EFSA's role and experience in the EU's GMO regulatory process, i.e. handling of GMO safety assessments provision of scientific advice on GMOs in the EU.

Mission of the European Food Safety Authority

By providing independent, objective and transparent scientific advice, EFSA aims to ensure a high level of consumer protection and to restore and maintain confidence in the safety of the EU food chain. The risk managers, based on EFSA's scientific advice and other legitimate factors, decide whether a GMO or a derived product can be placed on the EU internal market.

EFSA provides scientific opinions on the safety of (i) GMOs such as plants, microorganisms and animals, on the basis of Directive 2001/18/EC and (ii) genetically modified (GM) food and feed products, on the basis of Regulation (EC) No 1829/2003. EFSA's scientific opinion on the safety assessment of GMOs is given through its Panel on GMOs. The GMO Panel consists of 21 scientific experts who are selected in their personal capacity based on scientific excellence after an open call for interest for its 3 year mandate. It is supported by several Working Groups of experts, covering a broad range of relevant expertises, and the GMO Unit which provides administrative and scientific support to the work of the Panel. Experts mostly come from EU research institutes, universities or national risk assessment authorities.

The GMO Panel has issued scientific opinions on (1) EU market access applications, (2) guidance for risk assessment, (3) national safeguard clauses, and (4) specific safety issues. All scientific advice of the GMO Panel is published and made available in the EFSA Journal¹. Here only

¹ The EFSA Journal is accessible at: <http://www.efsa.europa.eu/en/efsajournal.htm>.

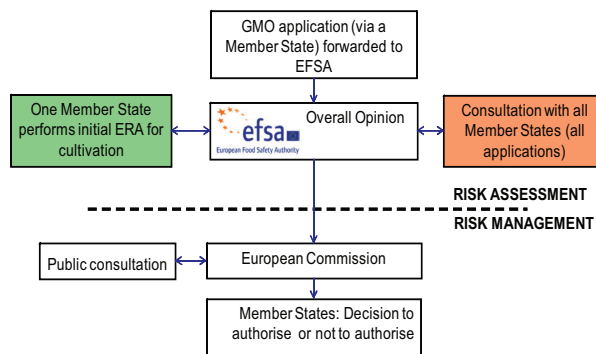
scientific opinions on GMO market access applications and guidance are described.

The GMO authorization procedures in the EU

There are two different GMO authorisation procedures provided for in EU legislative frameworks for GMOs, namely Directive 2001/18/EC on the deliberate release into the environment of GMOs and Regulation (EC) No 1829/2003 on GM food and feed. Applicants submitting applications for GM food and feed use under Regulation (EC) No 1829/2003 may also include deliberate release into the environment, i.e. cultivation in the scope of use. If so the environmental risk assessment criteria as laid down in Directive 2001/18/EC will be used for the part of the assessment relating to cultivation of the GMO.

Regulation (EC) No 1829/2003 establishes a centralised procedure for approval of GM food and feed in the EU (see Figure 1 below). Under this procedure, the GMO application is sent to a Member State that immediately forwards the application to EFSA which then carries out a risk assessment. All Member States have full access to all parts of all submitted applications via EFSA's dedicated extranet and have the possibility to raise questions and comments during a commenting period on each application. If the application includes the scope cultivation of the GMO one Member States is delegated to perform the environmental risk assessment. EFSA finalises the full scientific risk assessment of the application and delivers a scientific opinion to the EC along with all other information required under Regulation (EC) No 1829/2003 within 6 months. The EC consults the public on the overall opinion over a 30 day period. Based on EFSA's scientific opinion and the public comments, the EC and Member States are then responsible for taking a decision on the applicant's request.

Figure 1: GMO Authorisation Procedure under Regulation (EC) No 1829/2003



EFSA GMO Panel assessment of market access applications

Scientific assessment of applications

For EU market access applications the GMO Panel evaluates information from several sources: (1) EU legislation prescribes that applicants shall provide an application with all relevant information needed to conclude on the risk assessment and in accordance with issued guidance documents, (2) environmental risk assessment reports and information received from EU Member States, (3) any relevant scientific literature. After deliberations of the GMO Panel, EFSA publishes an overall opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. The opinion contains the following elements: (i) the scientific opinion of the GMO Panel, (ii) information relating to the Cartagena Protocol as submitted by the applicant, (iii) proposal regarding labelling of the product as submitted by the applicant, (iv) the validation report and a validated detection method as submitted by the EU Reference Laboratory, (v) information related to certified reference materials as submitted by the EU Reference Laboratory, (vi) the monitoring plan as submitted by the applicant, (vii) Member States comments including information on how EFSA addressed these comments, and (viii) the initial environmental risk assessment report from a Member State in cases the GMO is intended for cultivation in the EU. To date, approximately 110 applications for GM plants have been submitted to EFSA under the Regulation (EC) No 1829/2003. These applications cover a diversity of crops (mostly maize, followed by cotton and soybean) and traits (herbicide tolerance, insect resistance, or both). Other traits include: drought tolerance in maize; altered oleic acid content in soybean; or reduced amylose content in potato. Most GM plant applications are for import and processing for food and feed uses. Presently 17 GM plant applications submitted under the Regulation (EC) No 1829/2003 cover cultivation in the EU.

Approximately 30 applications involving GM microorganisms (GMMs) have been assessed, or are under assessment. Five of these are for feed materials submitted under Regulation (EC) No 1829/2003 whereas other applications cover feed additives or food ingredients produced from GMMs. At present no GM animal applications for market access have been submitted to EFSA.

Guidance documents

In the evaluation of GMO applications for market access, potential direct and indirect effects, as well as immediate, delayed and cumulative long-term adverse effects are considered and assessed on a case-by-case basis. In this respect the GMO Panel publishes scientific opinions with guidance that may assist applicants in the preparation and presentation of GMO applications. The guidance documents describe, inter alia, principles, concepts, data requirements and issues to be considered in the risk assessment². Scientific opinions giving risk assessment guidance are regularly updated, building on experience gained and the scientific developments.

² Guidance documents are available on the EFSA website at: <http://www.efsa.europa.eu/en/gmo/gmoguidance.htm>.

Building on European-wide expertise

The EFSA develops its guidance in open consultation with stakeholders and interested parties, always performing a public consultation of a draft version of the document being prepared. EFSA also works closely with EU Member States during the GMO assessment process. This is done through a network of over 100 organisations and authorities across the EU including over 250 experts. EU Member States also give valuable input to EFSA on GMO applications during a commenting period. For transparency EFSA provides a summary of how input from Member States was addressed in each scientific opinion. Furthermore, during the evaluation of GM plant applications for cultivation, EFSA usually has a fruitful collaboration with EU Member States who volunteer to perform an initial environmental risk assessment, which is then considered by the GMO Panel in its final opinion.

Working Groups of the EFSA GMO Panel

Several working groups provide scientific support to the GMO Panel either as a standing working group or for specific time limited mandates³. Each working group is composed of GMO Panel experts and additional experts with complementing expertise. In light of the complexity of evaluation of GMO applications for market access, the GMO Panel is supported by three standing working groups, each focusing on specific areas of GM-plant risk assessment: (1) molecular characterization; (2) food and feed safety assessment; and (3) environmental risk assessment. The GMO Panel is supported by two additional standing working groups, one addressing molecular characterization and environmental risk assessment of GMMs and another providing support for the evaluation of post-market environmental monitoring reports.

Conclusion

In the EU, each GMO needs authorization prior to entry into the market. The applicant must submit a dossier with all relevant information needed to enable EFSA to conclude a risk assessment in accordance with the EU legislation and issue guidance. In conducting the risk assessment EFSA also considers any relevant scientific literature, ERA reports, scientific comments and information received from EU Member States through a European-wide network of GMO risk assessors. The risk assessment process is based on published guidance documents. EFSA holds open consultations on all draft guidance documents with input from EU Member States, scientists, the public and other stakeholders, thus helping to build a shared understanding of GMO risk assessment.

³ Further information about working groups of the Panel on Genetically Modified Organisms is available at: <http://www.efsa.europa.eu/en/gmo/gmowgs.htm>.



Administrative Systems for Handling Biosafety Issues in Kenya



EMERGING EXPERIENCES AND LESSONS LEARNED

by Roy B. Mugiira ● Mr. Roy B. Mugiira is the Ag. Chief Executive Officer of the National Biosafety Authority, Kenya. He can be contacted at: roybmugiira@gmail.com

Introduction

The biosafety regulatory framework in Kenya is comprised of a National Biotechnology Development Policy (published in 2006), a biosafety law (the Biosafety Act of 2009) and a set of draft biosafety regulations. The National Biotechnology Development Policy was approved in September 2006 to guide the research, development and application of biotechnology in various fields such as agriculture, environment, human and animal health and trade and industry. The Biosafety Act lays down legal and institutional frameworks for governing modern biotechnology in the country. It established the National Biosafety Authority (NBA) as the administrative mechanism for enforcing the biosafety law and its implementing regulations. The draft biosafety regulations are being scrutinized by the Attorney General's Chambers in readiness for their publication. The regulations currently under review address: (i) contained use, (ii) environmental release and (iii) import, export and transit of genetically modified organisms (GMOs).

Administrative Systems

The NBA is the competent authority of the government of Kenya on all matters related to biosafety. It is also the National Focal Point for the Cartagena Protocol and for the Biosafety Clearing House (BCH). The Biosafety Act established the NBA as a State Corporation. Its operations are managed by a Chief Executive Officer and overseen by a board of management (the NBA board).

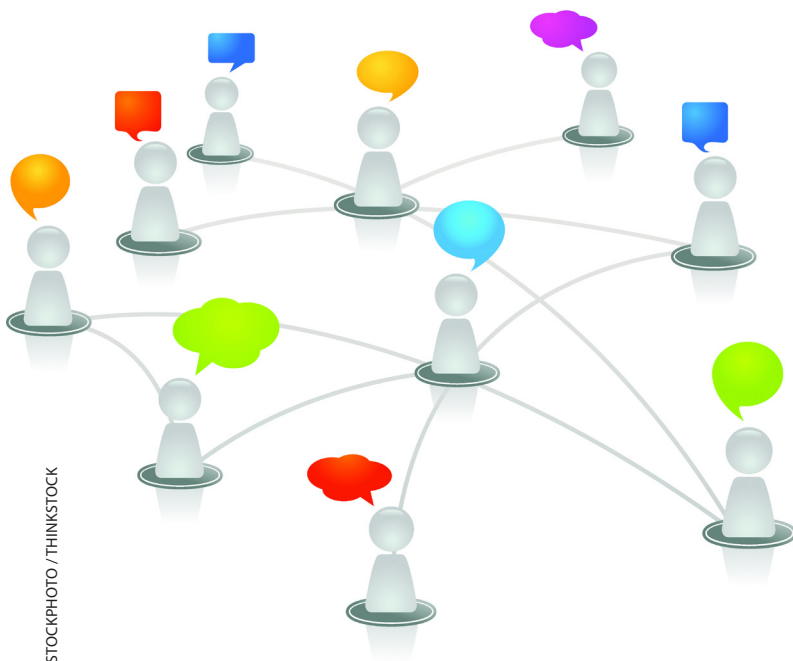
The NBA board was appointed in April 2010 and inaugurated in May 2010. It is comprised of seven appointed members, including: (i) a Chairperson (a prominent scientist), (ii) three experts in the fields of biological, environmental and social sciences and (iii) three representatives from the biotechnology industry, consumers and farmers. Other members of the NBA board are appointed to the board by virtue of their offices which include regulatory agencies and relevant government ministries or departments specified by the Biosafety Act.

These are:

1. The Kenya Plant Health Inspectorate Service (KEPHIS);
2. The National Environmental Management Authority (NEMA);
3. The Kenya Bureau of Standards (KEBS);
4. The Directorate of Veterinary Services (DVS);
5. The Directorate of Public Health (DPH);
6. The National Council for Science and Technology (NCST);
7. The Ministry of Agriculture;
8. The Ministry of Higher Education, Science and Technology; and
9. The Ministry of Finance.

To facilitate its work, the NBA board has constituted a technical committee comprising of the regulatory agencies and the ministry of agriculture, and chaired by the environmental expert member of the board. The technical committee is responsible for reviewing the applications and making recommendations to the board for approval.

Being a newly established institution, the NBA is currently developing its institutional capacity while handling applications for research work involving GMOs. A small team of officers from the Ministry of Higher Education Science and Technology is serving as the secretariat. In addition, the NBA is in the process of upgrading its website¹ and posting/updating information in the BCH. Further, the NBA is planning to conduct stakeholder workshops to prepare the second national report before the September 2011 deadline, with funding from the Global Environment Facility (GEF).



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¹ The NBA website is: <http://www.biosafetykenya.co.ke/frontpage.php>

Process for handling applications

The review and approval process starts with the receipt, and screening for administrative and technical completeness, of an application by the NBA secretariat. Once found to be complete the NBA acknowledges receipt of the application and sends it to members of the technical committee and two technical reviewers. The technical committee then meets to discuss the report of the reviewers and the feedback/ observations by the committee members and makes a recommendation for approval to the NBA board. If the application is approved, the decision is communicated to the applicant by the NBA secretariat.

In the communication of the decision, the applicant is directed to liaise with the appropriate regulatory agency to obtain the relevant permits as well as further information on the monitoring of the activity. For example, for an approval to conduct a confined field trial of a crop, the applicant is directed to liaise with KEPHIS to obtain import permits for the materials to be used and the guidelines for monitoring of the trial. If the application is for work involving genetically modified animals, the applicant is directed to liaise with the directorate of veterinary services.

Experiences and Lessons learned

In domesticating the Cartagena Protocol on Biosafety, Kenya chose to develop legislation specifically dedicated to biosafety, i.e. the Biosafety Act, 2009. The process leading up to enactment of the Act was lengthy and expensive. However, it was well facilitated by the Global Environmental Fund (GEF) and the Programme for Biosafety Systems (PBS) of the International Food Policy Research Institute (IFPRI).

To date, all GMO activities approved by the NBA (and its predecessor, the National Biosafety Committee) have been for contained use and not for release into the environment or commercial production.² However, it is anticipated that the publication of the biosafety implementing regulations will pave the way for commercial release of GM crops that have been undergoing confined field trials. There is an urgent need for the NBA to develop new guidelines for the commercial release of GMOs and to review existing guidelines for contained use of GMOs. Development of a large number of procedures and processes is still outstanding.

One of the major challenges encountered by the NBA has been the harmonization of the Biosafety Act with other related legislation. However, a coordination structure for biosafety regulatory agencies has been developed and is undergoing further review with a view to harmonizing the decision-making process and delineating the roles and responsibilities of various regulatory agencies with regard to GMOs.



In establishing the NBA, another major challenge encountered has been accurately determining the number of staff and the combination of technical skills required for the NBA to effectively implement its mandate. As well, the NBA has encountered other challenges, including politics and special or vested interests that often come into play when in setting up a new institution.

Conclusion

Institutional structures for implementing Kenya's biosafety regulatory framework are being put in place. However, sufficient procedures have not been fully established to handle applications for GMO activities at all the stages of product development. In general, the biosafety agenda, and the NBA in particular, has received good support from top policy makers in government. The NBA has received a favorable budget allocation from the Treasury and is adequately prepared to implement its legal and regulatory mandate regarding biosafety.

² Prior to the establishment of the NBA, activities involving GMOs were approved by the National Biosafety Committee (NBC) established under the National Council of Science and Technology (NCST).

Administrative Systems for Handling Biosafety Issues in Malaysia



EMERGING EXPERIENCES AND LESSONS LEARNED

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Introduction

Malaysia ratified the Cartagena Protocol on Biosafety in September 2003. However an administrative regulatory framework for biosafety was already in place since 1996. As Malaysia actively embarked on biotechnology with the launch of the National Biotechnology Policy in 2005, biosafety became increasingly important. In 2007 a Biosafety Act (the Act) was approved to regulate the release, importation and contained use of living modified organisms (LMOs) and the products of such organisms. After a series of negotiations with stakeholders, the Act entered into force in December 2009. This was later followed by the entry into force of the Biosafety (Approval and Notifications) Regulations in November 2010. As of 1 June 2011, six applications for release of LMOs into the environment and three applications for contained use have been approved/ endorsed under the Biosafety Act.

The operationalization of institutional bodies handling biosafety

The main institutional bodies responsible for handling biosafety in Malaysia are: the Ministry of Natural Resources and Environment (NRE), the National Biosafety Board (NBB) and the Genetic Modification Advisory Committee (GMAC).

The Ministry of Natural Resources and Environment (NRE) is the National Focal Point for the Cartagena Protocol on Biosafety (CPB-NFP), responsible for liaison with the Secretariat of the Convention on Biological Diversity on behalf of the Government.

The NBB was created in March 2010 shortly after the Biosafety Act entered into force in December 2009. Its main function is to make decisions pertaining to the release, importation, exportation and contained use of LMOs and products of LMOs. Other functions of the NBB include: (i) monitoring modern biotechnology activities in the country; (ii) promoting research, development, educational and training activities related to biosafety; and (iii) establishing mechanisms to facilitate the collection, storage and dissemination of data relating to modern biotechnology activities. The Chairman of the NBB is the Secretary General of the NRE and its members include representatives from six other relevant ministries and four other persons with knowledge and experience in disciplines or matters relevant to the Act.

The Genetic Modification Advisory Committee (GMAC) was established in May 2010 to provide scientific, technical and other relevant advice to the NBB. Members of GMAC consist of government experts from various science-based disciplines and other relevant disciplines, who are working mainly with Government agencies, research and academic institutes. The Committee also has one scientist who represents the private sector and another who represents

non-governmental organizations (NGOs). The Act provides for the NBB to establish other committees and for the GMAC to establish subcommittees, as needed, to assist them in fulfilling their mandates.

In order to operationalize and implement the Act, a Biosafety Core Team was established in April 2008 shortly after the Act was enacted. In May 2011, the Biosafety Core Team was transformed into the Department of Biosafety which is headed by the Director General (DG) of Biosafety. The DG of Biosafety is the Secretary of the NBB and is responsible for carrying out all necessary duties in order for the NBB to fulfill its role as a regulatory body under the Act. The Department of Biosafety also serves as a "one stop" centre for all activities relating to biosafety in Malaysia.

For the purpose of institutional monitoring, any organization that undertakes modern biotechnology research and development (R&D) activities is required to establish an institutional biosafety committee (IBC) in order to ensure that those activities comply with the Biosafety Act 2007, the Biosafety (Approval and Notification) Regulations 2010 and any other related regulations and laws. IBCs are registered with the NBB and are obligated to report to the NBB. At the end of May 2011, 14 institutes have been established and registered their IBCs.

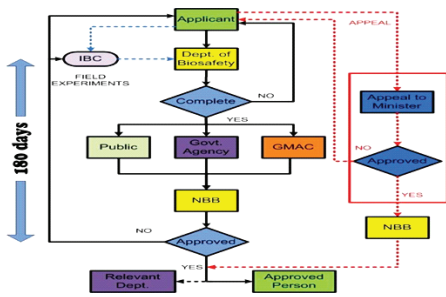
Procedures for handling applications and notifications

Activities involving LMOs and LMO products covered under the Biosafety Act are (i) release into the environment and importation of LMOs (Part III of the Act) and (ii) contained use and exportation of LMOs (Part IV of the Act).

In the case of approval for any release and importation of LMOs and their products, applications must be submitted to the DG of Biosafety together with the prescribed fees. The application must be accompanied with a risk assessment and a risk management report, an emergency response plan and other information specified by the NBB. If the application is for a field experiment, it must be assessed by the applicant's IBC prior to submission. Upon receipt, the DG of Biosafety refers the application to the GMAC for assessment and to other relevant Government agencies for comments. The GMAC meets as often as necessary in order to conduct the scientific assessment. In parallel, public participation is initiated for purposes of public disclosure of the application. In this regard, a public announcement is carried out twice in English and Malay language newspapers with nationwide coverage.

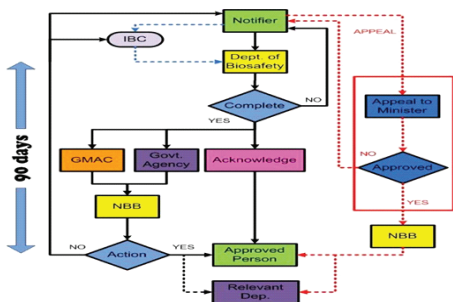
Consequently, the NBB considers the recommendations of GMAC, the comments from relevant Government agencies and the public views. The NBB then makes a decision on whether or not to grant an approval of the application. If the application is approved, a certificate of approval with terms and conditions, if any, is issued by the NBB to the approved person. As illustrated in Figure 1, the approval process takes a maximum of 180 days to be completed.

Figure 1: Application Process for LMO Releases



For contained use activities involving LMOs, applicants should inform the NBB of their intentions by means of a notification. The notifications must be submitted to the DG of Biosafety and should be accompanied by an emergency response plan, specific measures for the contained use activity and any other information specified by the NBB. If it is an R&D activity, it should be assessed by the applicant's IBC before submission to the DG of Biosafety. The applicant may carry out contained use activities upon receiving acknowledgment from the DG of Biosafety. Subsequently, the notification is referred to the GMAC and other relevant Government agencies for assessment. No public notification is required for contained use activities. After its assessment, the GMAC then makes a recommendation to the NBB whether the activity should be continued or if additional terms and conditions should be imposed. As illustrated in Figure 2, the NBB takes a maximum of 90 days to complete the assessment on the Notification. Notifications for exportation are exempted from the assessment process.

Figure 2: Notification Process for LMO Contained Use



For both the application of approval of LMO releases and the notification of LMO contained use, the applicant may claim confidentiality for any information submitted as long as it meets the established confidentiality criteria. The handling of the confidential information and documents is subject to both the Malaysian Official Secrets Act 1972 and the Biosafety Act 2007.

The law provides for an appeal process to the Minister of Natural Resources and Environment for rejected applications.

Information and decisions pertaining to the applications for release and notifications are available in the Malaysian biosafety website.¹

Challenges encountered, good practices and lessons learned

The most important aspect in implementing the Act has been its acceptance by all stakeholders. Many consultations were held, in particular with industry and NGOs, to ensure clear understanding of the purpose of the Act. The goal was to create an enabling piece of legislation for the development of modern biotechnology balanced with protection of the environment and human health. As a result of this consultation process, stakeholders have been very cooperative in the implementation of the Act.

The GMAC plays a crucial role in the assessment process. Therefore its membership pool must have a wide range of expertise and experience. In light of the experience gained, additional GMAC members may be elected. In order to ensure inclusiveness in the decision-making process, it is also important to have science experts representing the interests of the private sector and NGOs. Furthermore, in order to ensure the credibility of decisions, conflicts of interest must always be disclosed.

To date, the greatest challenge has been in the area of capacity-building across all sectors. Fortunately, with funding from the NRE-GEF-UNDP Project, a series of seminars, training workshops and consultations have been carried out for important stakeholders, including decision-makers from various agencies, researchers, business, consumers and civil society. Furthermore, a number of publications, including various manual and guidelines, for example Guidelines for Institutional Biosafety Committees (IBC) have been published. In addition, technical sessions have been carried out to empower research institutions, including on how to set up and run an IBC and how to complete application forms.

Public consultation is a critical component of the biosafety regulatory system and must be carried out in an effective and transparent manner. Enough time must be provided for public input and all questions must be given due consideration. In this regard, proper risk communication and press briefings are crucial.

Conclusion

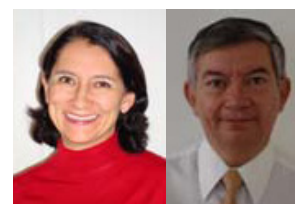
It was a difficult journey for the Biosafety Act in Malaysia to become a reality. However, it is a positive and promising beginning for Malaysia not only to take a proactive approach towards protecting human health and the environment from the possible adverse effects of the products of modern biotechnology but also to facilitate the application of modern biotechnology, while fulfilling the obligations under the Cartagena Protocol on Biosafety. A lot of work still needs to be done to build critical capacities required to implement an effective biosafety regulatory system. Public consultations will be a continuing activity and the wider public will need to be educated. The media and political figures will also have to be engaged to gain understanding of the biosafety issues.



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¹ <http://www.biosafety.nre.gov.my/>

Administrative Systems for Handling Biosafety Issues in Mexico



EMERGING EXPERIENCES AND LESSONS LEARNED

by Sol Ortiz García and Reynaldo Ariel Álvarez Morales ● Ms. Sol Ortiz García is the Technical Director for Information and Research Support at CIBIOGEM. She can be contacted at: sortiz@conacyt.mx. Mr. Reynaldo Ariel Álvarez Morales is the Executive Secretary of the Inter-Secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM), Mexico. He can be contacted at: ralvarez@conacyt.mx.

Introduction

Mexico received the first application to carry out a field trial with a genetically modified (GM) crop in 1988. At that time there was no specific legislation to regulate such an activity. Since then, several developments have taken place. Mexico signed and ratified the Cartagena Protocol on Biosafety in 2003 and enacted the National Biosafety Law for Genetically Modified Organisms (LBOGM), which came into force in 2005. The LBOGM and along with other legal instruments puts into practice the fundamental concepts of the Cartagena Protocol at the national level to ensure the safe use of modern biotechnology.

The LBOGM identifies the following three Competent National Authorities (CNAs) which are responsible for regulating activities involving genetically modified organisms (GMOs) or living modified organisms (LMOs) as referred to in the Protocol: (i) Ministry of Health, (ii) the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), and (iii) the Ministry of Environment and Natural Resources (SEMARNAT).

The Ministry of Health primarily handles applications for LMOs intended for direct use as for food or feed, or for processing (LMOs-FFP) as well as LMOs for bioremediation and public health. Within the Ministry, the Federal Commission for the Protection against Sanitary Risk (COFEPRIS), through its Evidence and Risk Management Commission, carries out a risk/safety assessment for each LMO.

Depending on the results of the evaluation, the Sanitary Authorization Commission issues an authorization for the commercialization of the LMO, including importation for FFP. The Ministry of Health issued its first approval for an LMO in 1995 and has since then they have approved a total of 93 different LMOs.

SAGARPA and SEMARNAT are responsible for regulating LMOs destined for contained use and LMOs for intentional release into the environment. The type of LMO determines which of the two Ministries receives the application. SAGARPA receives all the applications for LMOs that are cultivated plants. It then sends the applications to SEMARNAT for a binding opinion based on environmental risk assessments.

At the highest level the Intersecretarial Commission for Biosafety of Genetically Modified organisms (CIBIOGEM) coordinates the policies and federal regulation of activities related to LMOs. In addition to the three CNAs, the CIBIOGEM is comprised of three other ministries (i.e. ministries of education, economy and treasury), as well as the National Council of Science and Technology (CONACYT). Its Executive Secretary is the National Focal Point for the Cartagena Protocol.

Handing of applications for intentional release into the environment

The LMOs destined for contained use require presentation of a notification while LMOs for intentional release into the environment require presentation of an application. If the decision is in the affirmative, the appropriate CNA issues a permit. The permit may include conditions and biosafety measures to be undertaken.

The intentional release of LMOs into the environment is regulated in three stages: (i) experimental release, (ii) pilot phase release and (iii) commercial release. Each stage has a different timeframe for resolution. The decision-making process is based on scientific and technical risk assessments carried out on a case-by-case and step-by-step basis. The context of risks posed by the non-modified organisms is also considered. There are several administrative units and scientific advisory committees involved in the risk assessment and the decision-making process. In addition, for each application, the CNA carries out a public consultation process whereby the general public is invited to submit comments in relation to the application under review.



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The administrative process for handing applications for intentional environmental release for a cultivated modified plant is as follows:

- Once SAGARPA receives an application, it acknowledges receipt of the application and verifies if the information submitted is complete (according to article 16 of the biosafety bylaw). In case of an experimental release, the dossier is sent to both SEMARNAT and the National Register for GMOs (RNOGMs).¹
- When SEMARNAT receives the application, through the General Direction of Impact and Environmental Risks (DGIRA), the information presented is verified and the application is sent to: (i) the National Institute of Ecology (INE), and (ii) the National Commission for the Use and Knowledge of Biodiversity (CONABIO). The two bodies evaluate the environmental risks associated with the release of the concerned LMO and present opinions to the DGIRA. CONABIO's review is mostly focused on geographic and distribution analyses to determine the possibility for gene flow. INE focuses on the environmental protection goals and evaluates environmental risks following a systematic protocol to identify possible adverse effects. It also estimates categorized levels of risks following a flowchart similar to a decision tree.
- SAGARPA publishes a copy of the application on its website for the public consultation process, conducts its own risk assessment and convenes its Scientific and Technical Advisory Committee for advice.

The decision-making process considers the inputs of all the stakeholders involved.

Challenges encountered

Modern biotechnology presents an important step forward towards the advancement of crop improvement. However, regulation of this technology has been based on unsubstantiated and exaggerated fears. This has led to a rather complicated regulatory system which national institutions of scientific and technology development, as well as local industry, have found difficult to understand and comply with. Therefore, along with the introduction of the biosafety legislation, Mexico is establishing programs aimed to foster and encourage research and development in order to ensure that the society reaps the benefits of biotechnology. Mexico is also offering proper orientation to academic and research institutions to enable them to effectively handle the regulatory issues.

Conclusion

New technologies are not always easily accepted by society. However, it is not with discourse or promises that acceptance can be achieved. The fine balance that must be struck by authorities enforcing biosafety legislation is to ensure the safety of the technology without hindering the national development and innovations. In this way, society would be given the opportunity to determine whether the technology offers them real benefits and accordingly make an informed decision to accept or reject it, completely or partially. In any event, the goal must be that society takes decisions based on knowledge and experience rather than on the basis of fear or inaccurate information.

¹ The RNOGMO is an information instrument which communicates to the public all of the activities related to the use of LMOs. It can be accessed through the website of the Intersecretarial Commission for Biosafety of Genetically Modified organisms (CIBIOGEM): <http://www.cibiogem.gob.mx/eng/Paginas/Home.aspx>



Useful information



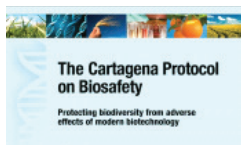
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NEW PUBLICATIONS AND FACT SHEETS



The COP-MOP 5 decisions booklet entitled:
 "Biosafety: Setting a New Agenda".
 The booklet is available at:
http://bch.cbd.int/protocol/cpb_publications.shtml

OTHER UPDATES



A video on the Cartagena Protocol
 is available at:
[http://bch.cbd.int/protocol/cpb_media_](http://bch.cbd.int/protocol/cpb_media_video1.shtml)
[video1.shtml](http://bch.cbd.int/protocol/cpb_media_video1.shtml)



Fact sheet on the Cartagena Protocol on Biosafety is available at:
<http://www.cbd.int/undb/media/factsheets/en/undb-factsheet-biosafety-en.pdf>

Fact sheet on the Nagoya - Kuala Lumpur
 Supplementary Protocol on Liability and Redress is available at:
<http://www.cbd.int/undb/media/factsheets/en/undb-factsheet-nkl-en.pdf>

Other fact sheets for the United Nations Decade on Biodiversity
 are available at: <http://www.cbd.int/2011-2020/media/>



The second regular national
 report is to be submitted to the
 Secretariat, no later than 30th
 September 2011
 For more information, please visit:
[http://bch.cbd.int/protocol/cpb_natreports.](http://bch.cbd.int/protocol/cpb_natreports.shtml#natrep2)
[shtml#natrep2](http://bch.cbd.int/protocol/cpb_natreports.shtml#natrep2)



Subscription to the Newsletter
 Please visit:
http://bch.cbd.int/protocol/cpb_newsletter.shtml

Recent and upcoming biosafety events

RECENT MEETINGS

Biosafety Clearing House (BCH)

From 31 January to 4 February 2011, the Secretariat hosted a UNEP-GEF Workshop entitled 'Regional Advisors Training on Renewed Operations and Content of the Biosafety Clearing-House (BCH)'. The training, organized within the framework of the recently approved UNEP - GEF global "Project for Continued Enhancement of Building Capacity for Effective Participation in the Biosafety Clearing-House" (also known as BCHII), was attended by 32 BCH Regional Advisors who, through this project, will be delivering training on the BCH to 50 participating countries.

The Secretariat hosted the sixth meeting of the Informal Advisory Committee on the Biosafety Clearing-House (BCH IAC 6) in Montreal from 30 March – 1 April 2011. Participants discussed, among other things, the Strategic plan for the Protocol and its relevance to the Biosafety Clearing-House and future challenges, latest developments in the Biosafety Clearing-House and on-going projects and collaboration with the UNEP-GEF BCH II Capacity-Building Project.

Liability and Redress

The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was opened for signature by Parties to the Cartagena Protocol on Biosafety on 7 March at the United Nations Headquarters. Colombia was the first country to sign the Supplementary Protocol, followed by Denmark, Sweden and The Netherlands. It will remain open for signature until 6 March 2012. As of 16 June 2011, 24 countries had signed the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

The Secretariat organised the first regional workshop on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety for Central and Eastern Europe in Ljubljana, Slovenia from 16 to 17 June 2011. The main purpose of the workshop was to promote awareness of the Supplementary Protocol and to identify needs and requirements by Parties with a view to expediting its early entry into force and implementation. The workshop also provided an opportunity for participants to consider issues related to the implementation of other decisions of the fifth meeting of Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in particular, decision BS-V/14 on preparation of second national reports, decision BS-V/15 on assessment and review and decision BS-V/16 on the strategic plan.

Public Awareness:

The Secretariat implemented various activities to promote public awareness of the Protocol and to facilitate the implementation of the programme of work on public awareness, education and participation concerning the safe transfer, handling and use of LMOs (2011-2015). Some of the activities undertaken include:

- (a) A side event was co-organised with the Aarhus Convention Secretariat, on 30 June 2010 in Chisinau, Republic of Moldova, during the fourth session of the Meeting of the Parties to the Aarhus Convention. More than 40 participants attended. The participants discussed practical ways to maximize synergies in the implementation of the Cartagena Protocol on Biosafety and the Aarhus Convention;
- (b) Production of a video on the Cartagena Protocol on Biosafety available at: http://bch.cbd.int/protocol/cpb_media_video1.shtml; and

LEFT: The Central and Eastern European Regional Workshop on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress. RIGHT: Exhibition highlighting the UN Decade on Biodiversity and the Cartagena Protocol on Biosafety at the Redpath Museum.



(c) An exhibition highlighting the UN Decade on Biodiversity organised, in collaboration with the Redpath Museum, on 29 May at McGill University as part of the Montréal Museums Day. The event, which was attended by more than 4800 visitors, aimed to raise awareness of, among other things, the Cartagena Protocol on Biosafety. It also aimed to increase participation of academia in biodiversity and biosafety activities.

Capacity-building

The seventh Coordination Meeting for Governments and Organizations Implementing and/or Funding Biosafety Capacity-building Activities was held 4-6 April 2011 in Chisinau, Republic of Moldova. The meeting recommended a number of actions that may be taken to foster capacity-building for enforcement of national biosafety regulatory frameworks and for implementation of the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress.

The eighth meeting of the Liaison Group on Capacity-building for Biosafety was held 7-8 April 2011 in Chisinau, Republic of Moldova. The participants made a number of recommendations on the organization of the workshop on capacity-building for research and information exchange on socio-economic impacts of LMOs and the second comprehensive review of the Action Plan for Building Capacities for the Effective Implementation of the Protocol.

Handling, Transport, Packaging and Identification

The Secretariat organized and serviced the Central and Eastern European Regional Training of Trainers' Workshop on the Identification and Documentation of LMOs under the Cartagena Protocol on Biosafety from 11 to 15 April 2011 in Ljubljana, Slovenia. The workshop was aimed at introducing the participants to the requirements of the Protocol regarding the identification and documentation of LMOs and techniques and methodologies that may be used for the implementation of these requirements. The workshop had practical laboratory sessions on the detection of LMOs, which were conducted at the Agricultural Institute of Slovenia and the National Institute of Biology, and a field-study visit to a customs-control point where participants learned about the operations at the Slovenian port of Koper and its efforts in controlling the entry of LMOs to the country. An output of the workshop was that

participants agreed to form an online discussion group to continue exchanging information on challenges in the region for the identification and documentation of LMOs.

Risk Assessment and Risk Management

The Third Meeting of the Ad hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management took place from 30 May - 3 June 2011 in Mexico City, Mexico. The AHTEG made a number of revisions to the "Guidance on Risk Assessment of Living Modified Organisms" and agreed to a mechanism for future updates of the background materials for the Guidance. In addition, the Group agreed to develop guidance on the first two topics of the list resulting from the priority-setting exercise conducted in the Open-ended Online Forum, namely: (i) Post-release monitoring and long-term effects of LMOs released into the environment; and (ii) Risk assessment of living modified trees.

UPCOMING MEETINGS

21 - 22 July 2011, Addis Ababa, Ethiopia: African Regional Workshop on the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

October 2011: Online Forum on Strategic Approaches to Capacity-building in Biosafety

5 - 7 October 2011, Montreal, Canada: Eighth meeting of the Compliance Committee under the Cartagena Protocol on Biosafety

November 2011, India: Asia-Pacific Regional Training of Trainers' Workshop on the Identification and Documentation of Living Modified Organisms

14 - 16 November 2011, India: Workshop on Capacity-building for Research and Information Exchange on Socio-economic Impacts of Living Modified Organisms

1 - 5 October 2012: Hyderabad, India: Sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol on Biosafety

LEFT: Regional Advisors Workshop on the BCH. RIGHT: CEE Workshop on LMO Identification





The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking into account risks to human health.

The Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety is an international treaty which aims to contribute to the conservation and sustainable use of biodiversity by providing international rules and procedures for liability and redress in the event of damage resulting from LMOs.