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10 Years of Promoting Safety in the Use of Biotechnology

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Introduction

by Braulio Ferreira de Souza Dias
Secretariat of the Convention on Biological Diversity

This special issue of the *Biosafety Protocol News* is being published to coincide with the tenth anniversary of the coming into force of the Cartagena Protocol on Biosafety. In line with the theme of the tenth anniversary: 10 Years of Promoting Safety in the Use of Biotechnology, the issue focuses on experiences and lessons learned over the past decade in the establishment and implementation of national biosafety systems.

The Protocol, a supplementary international agreement to the Convention on Biological Diversity, entered into force on 11 September 2003. It aims to ensure the safe handling, transfer and use of living modified organisms (LMOs) resulting from modern biotechnology.

Over the years, many Parties have taken the necessary steps to establish legal, administrative and other measures to implement their obligations under the Protocol. From the analysis of the second National Reports on the Implementation of the Protocol, 52 Parties reported that they have a domestic regulatory framework fully in place (another 56 Parties reported that it is partially in place). Furthermore, the national reports indicate that 75 Parties have one or more national biosafety laws, 69 Parties have one or more national biosafety regulations and 48 Parties have one or more sets of biosafety guidelines. Almost all Parties have designated a Competent National Authority that is responsible for performing the administrative functions required by the Protocol. In this issue, Moldova, Peru, Iran, Egypt, Thailand and Iran provide details on the status of their national biosafety regulatory regimes.

The United Nations Environment Programme (UNEP), as an implementing agency of the Global Environment Facility involved in biosafety capacity building, identifies some of the challenges encountered by Parties and offers some options to improve capacity-building delivery.

The Global Industry Coalition (GIC) highlights its work regarding the development and implementation of detailed guidance on shipping documentation for seeds and research materials and facilitation of access to GIC detection methods for commercialized biotechnology-derived products through a publicly available website. It also describes its work regarding the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, including an Implementation Guide and a binding contract among major technology providers.

The contribution from Third World Network (TWN) underlines the need for civil society to gain access to relevant information in order to raise public awareness and promote public participation in decision-making processes regarding LMOs.

While progress has been made in establishing biosafety systems, significant challenges still remain in making them fully functional to support effective implementation of the Protocol.

There is a need to commit more resources to biosafety capacity-building at all levels - national, regional and international - for the effective implementation of the Protocol.

I urge all Parties and other relevant biosafety stakeholders to redouble their commitments to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms.

I wish to thank the authors who contributed articles to this special edition of the *Biosafety Protocol News*.

A decade of building legal and institutional biosafety capacities in Egypt

BUILDING INSTITUTIONAL CAPACITIES TO ENSURE THE SAFETY OF GMOS IN A DEVELOPING COUNTRY

by Ossama El-Tayeb ● Professor Emeritus at Cairo University and National Focal Point for the Cartagena Protocol on Biosafety (omtayeb@link.net)

African countries need to consider several national factors to establish a legal biosafety system in order to implement the Cartagena Protocol on Biosafety.

As early as 1992, Egypt, through a series of ministerial decrees issued by the Minister of Agriculture, established an institutional mechanism for regulating biotechnology in the form of an "institutional" biosafety committee and a "national" biosafety committee (NBC).[1] These committees focused on research activities, in particular on "biosecurity", rather than issues under the Protocol. Establishing the committees was a requirement for receiving research funding from international entries. However, other government or non-governmental bodies did not have to abide by the decisions from the committees. There was no penalty for not abiding by the decrees of the Ministry of Agriculture. [2]

In addition, the decrees did not outline requirements on holding regular meetings of the committees or maintain records of meetings of the committees. [3] As there was no budget assigned specifically for the implementation of the decrees, they were limited to "research and isolated trials" of LMOs and excluded the commercialization and placing on the market of LMOs. The Ministry of Health issued a decree in 1997 requiring that any product derived from LMOs be released only after being certified "safe". It did not define, however, the nature of the product or establish a procedure to carry out such certification.

Major Accomplishments

A major accomplishment was Egypt's participation in the United Nations Environment Programme – the Global Environment Facility (UNEP-GEF) Pilot Biosafety Enabling Activity Project to draft a national biosafety framework (NBF). Based on the Egyptian Constitution, the Egyptian Environmental Affairs Agency (EEAA) was responsible for the national development of the NBF as an entity already responsible for the implementation of the Convention of Biological Diversity and negotiating the Cartagena Protocol on Biosafety. A major success resulting from the project was the development of an NBF in 1998, including a draft national biosafety law.

Another major accomplishment was the coordination between the NBC and the EEAA, currently under the Ministry of State for Environmental Affairs (MSE). The NBC requested the MSE to negotiate the Protocol and to draft a national biosafety law. With this significant involvement by Egypt, the Protocol was adopted in January 2000. In September 2000, Egypt signed the Protocol and ratified it in March 2003.

Egypt also participated in the UNEP-GEF NBF implementation project. For this purpose an Inter-ministerial Drafting Committee was established and instructed to develop efficient institutional mechanisms to address issues regarding LMOs. The Committee comprised of 14 officials, representing their respective government bodies. It prepared 11 technical reports and held four workshops. The workshops addressed the following:

- Existing biotechnology and the status of safety in biotechnology applications, including reviewing and assessing biosafety-related issues
- Existing national, bilateral and multilateral cooperative programs in research and development and the application of biotechnology;
- Existing mechanisms for harmonization of risk assessment and risk management, mutual acceptance of data and data validation;
- The extent and impact of the release and commercialization of LMOs.

With regards to the national biosafety law, when the ratification of the Protocol was reviewed by the People's Assembly, the MSE was instructed "to present a national biosafety law in

1 The biosafety committee was established to facilitate an agricultural biotechnology research institute.
2 The Minister of Agriculture, who chaired the committee, appointed the members of the NBC. The NBC were mostly officials from the Ministry of Agriculture. Other members of the NBC were from other entities participating in their personal capacity.
3 At times, the meetings of the committees were held only every three years.

MARTYM/PHOTOGUIDE.CZ, ASWAN NILE AREA, EGYPT

accordance with Article 2 of the Protocol during the same session". [4] Within days, the MSE constituted the drafting committee with representatives from 14 governmental and non-governmental bodies. The committee held a series of meetings and workshops featuring representatives from scientific expert bodies and other stakeholders. In total, 12 meetings and two consultative workshops were held from 2003 to 2004. Stakeholders were invited to consider the draft biosafety law with regards to possible implications to biosafety-related activities, express their observations in writing, and, appoint a liaison officer authorized by the organization to present views to the committee.

The committee also reviewed all relevant legislation which could possibly impact, or be impacted by the biosafety legislation. It reviewed and settled contentious issues regarding the draft biosafety law. As a result, in March 2004, an agreed draft biosafety law was presented to the MSE.

Lessons Learned

Following these initiatives, until the 25 January 2011 revolution, there have been few significant experiences and lessons learned. Progress has been slow, due largely to interventions and interference by international entities that viewed the draft national biosafety law as restrictive to their trade interests.

In all, Egypt is the largest importer of wheat and a major importer of corn, edible oils, feed additives and vegetable seeds. Although the country has changed significantly since the revolution, Egypt has limited democratic governance, transparency and ability to combat corruption. The country was politically tied to importing more than half of its demand for wheat. However, it is currently more than 80% self-sufficient in wheat production.

In addition, a draft biosafety law was approved; however, its adoption is based on developing an institutional structure. [5]

In the meantime, Egypt is participating in the UNEP-GEF NBF implementation project to establish institutional structures for implementing the draft biosafety law. This has significantly catalyzed national efforts. However, progress is slow due to the delay in promulgating the law. In the Egyptian legal system, any international agreement to which Egypt is a party takes precedence over any conflicting national law. As such, Egypt is bound to implement the Protocol by establishing a national biosafety law. However, in the absence of the national law, the country lacks clear implementation mechanisms. For example, a month before the revolution, a 70-ton consignment of LMO corn for planting arrived, which did not conform to the provisions of the Protocol. The MSE regarded it as an illegal shipment as it was approved for importation by using questionable documents. It caused a public outcry and national media coverage, including accusations of corruption. In January 2012, another shipment of 40 tons was imported and caused such anger among the public that the Ministry of Agriculture confiscated the shipment and destroyed it.

4 This coincided with the early steps in implementing the UNEP-GEF implementation project.

5 A draft biosafety law was first approved by the Ministry of Justice. The Cabinet of Ministers then instructed the MSE to present the law to the newly elected People's Assembly before it was dissolved by the Constitutional Court. It was then again approved by the legislative committee of the new Cabinet of Ministers and the Cabinet. Today, further progress is based on the new House of Representative to be elected.

In general, over the years, the major lessons learned include:

- Local trade interests are not as significant as international trade entities

- Corruption is a major challenge that has to be reckoned with by developing countries as they are vulnerable to pressure by multinational companies

- Even though public awareness of environmental issues may be low in poor countries, the media should be engaged and motivated to raise awareness, particulary if human health is at risk and corruption exists

- A sector-specific law, rather than a comprehensive one, should never be a legal barrier, for example, in the absence of significant commercial agriculture, an unclear distinction between seed and grain or a predominance of tiny plots of land owned by illiterate farmers who can avoid influences by large biotech businesses

- For a country with size and influence, such as Egypt, the biotech industry may be willing to mobilize unlimited resources and local "friends". However, there may still be a predominant scientific community who could be mobilized on the grounds of "collective national conscience". After all, scientists who collaborate with a corrupt system will always be a small minority. Egypt is aware of several independent scientific papers that report on the detection of LMO material in the Egyptian market and support efforts to regulate LMOs

- Political intergovernmental conflict is often a major challenge to effective inter-governmental coordination;

- The Biosafety Clearing-House (BCH) is an effective mechanism to facilitate the exchange of information on LMOs.

Current Initiatives and recommendations

Today, the UNEP-GEF NBF implementation project is still ongoing. key outcomes include:

- The draft biosafety law agreed to by all stakeholders involved

- A draft risk assessment mechanism issued

- Two reference detection laboratories presently being established, with a third in the process of being approved.

Setting in place a national legal biosafety system to implement the Protocol may be a challenge in many developing countries. To overcome these challenges in Africa, key recommendations would be to build institutional capacities, including the establishment of an efficient institutional mechanism to undertake measures necessary for ensuring biosafety. Such an institutional mechanism should be able to effectively address conflicting trade interests, minimize corruption and promote public participation in the decision-making process regarding LMOs.

In Egypt an Inter-ministerial drafting committee is assigned to develop efficient biosafety institutional mechanisms

10th Anniversary: Biosafety regulatory regimes and administrative systems in Moldova

OVER THE PAST DECADE MOLDOVA HAS GAINED EXPERIENCE IN PROMOTING GOOD PRACTICES ON BIOSAFETY-RELATED ISSUES AND CONSIDERS BIOSAFETY A NATIONAL PRIORITY, AND MOST OF THE REGION AS A WHOLE HAS, AMONG OTHER THINGS, ADOPTED NATIONAL BIOSAFETY REGULATIONS

by Angela Lozan and Lazar Chirica ● Angela Lozan is the national Biosafety Clearing-House Focal Point of the Republic of Moldova (lozan@mediu.gov.md), and Lazar Chirica is a Deputy Minister of Environment, Republic of Moldova (chirica@mediu.gov.md)

Of the 166 countries are Parties to the Protocol, 21 are from the Central and Eastern European (CEE) region. The CEE region has, from the beginning, made efforts to meet the obligations under the Protocol and to achieve important progress in the development of national regulatory systems to minimize possible adverse effects to the environment and biodiversity from living modified organisms (LMOs).

The countries in the region, while they vary considerably in their historical, economic and political development., share many similarities, for example, with regards to traditional agricultural practices and historical bilateral trade relations. As reported in the Second National Reports, almost all of the region's countries have adopted national biosafety regulations, nominated Competent National Authorities (CNAs), developed notification procedures and established National Biosafety Clearing-Houses (NBCHs) to ensure public awareness and public participation. In addition, 12 countries reported that domestic regulations were fully in place, six countries reported they were partially in place and two countries had drafted it. Furthermore, member countries of the European Union (EU) have established efficient domestic biosafety frameworks in line with the Protocol and in accordance with EU biotechnology directives. Countries with economies in transition also made considerable progress towards the implementation of the Protocol and to promote good practices and gain experience at the national level.

Introduction

The first step to meeting obligations under the Protocol is to have a National Biosafety Framework (NBF) in place. Several CEE countries have benefited from the financial and technical support offered by the United Nations Environment Programme (UNEP) and the Global Environment Facility (GEF) on building national capacities for the development and implementation of NBFs. In addition, the opportunity to participate in the Biosafety Clearing-House Projects (BCH I and BCH II) has been highly advantageous. The projects have contributed to familiarization with scientific-based information and good international practices, especially with regards to decision-makers, the local public, civil society and other stakeholders. Moldova highly appreciates the productive collaboration and useful consultative advice from staff members of the Biosafety Division of the Secretariat of the Convention on Biological Diversity (SCBD) and the regional BCH advisers.

In addition, several interesting and useful regional training projects and workshops were organized by the Secretariat to provide CEE experts, decision-makers and academia the opportunity to participate in discussions and training exercises on specific biosafety topics. These include: the CEE Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of LMOs in Chisinau in 2007; the training on liability and redress and on socio-economic considerations in Ljubljana in 2012; and the 2012 workshop on liability and redress in Riga .

Moldova has also hosted the fourth session of the Meeting of the Parties to the Aarhus Convention in Chisinau, in 2011. During a side event on LMOs, participants at that meeting agreed to a commitment for further developments under Article 6 and Article 6 bis under the Aarhus Convention's GMO Amendment.

Over the past decade, following new developments initiated under the Protocol, CEE countries have been considering new initiatives and steps to address challenges. These include: conduct efficient risk assessments in line with the Roadmap for Risk Assessment of LMOs; establish liability and redress instruments; consider socio-economic considerations in decision-making process on LMOs; improve identification and detection of LMO facilities; update the BCH; and continue with public awareness activities on LMOs.

LESLIS_KS: /FLICKR / THE RAPE IS IN BLOSSOM, MOLDOVA

Major Accomplishments

Since the ratification of the Protocol, Moldova considers biosafety a national priority. Being a country with a long agricultural tradition, it is interested in promoting modern agriculture and improving its trade relations. Over the past decade, the country has also gained experience in promoting good practices on biosafety-related issues. The national biosafety law (2001) serves as the main legal instrument that regulates all types of uses of LMOs. In addition, the Ministry of Environment is nominated as the National Biosafety Authority and a National Biosafety Commission is in place to assist in providing scientific advice during the notification and decision-making processes of LMOs.

Moldova has also undertaken several measures to facilitate biosafety activities. For example, a national action plan on biosafety was established to comply with the provisions of the Protocol. In this regard, biosafety issues have been mainstreamed in a number of sectorial policies (e.g. agriculture, phyto-sanitary issues, seed production, intellectual property rights and health care). Regulations have also been developed, including to: enforce the national biosafety law; prevent illegal transboundary movement of LMOs; guide risk assessment and risk management procedures; and, assist with monitoring activities on LMOs.

In addition, with the support of the UNEP-GEF NBF development project, the NBF implementation project as well as BCHI and II projects, considerable advice and technical assistance was offered to Moldova. As a result, a national laboratory for seed certification was established with a real-time PCR machine, polymerase chain reaction machine, to provide the testing and identification of LMOs.[1]

There are also good practices in promoting awareness and training of national regulators and other professionals. A useful activity include a five-day training workshop on risk assessment and risk management held, in Chisinau in 2011, featuring a visiting expert from Russia,Dr. D. Dorohov. As a result of the workshop, domestic regulators, academia, members of the biosafety committee, students and other stakeholders gained valuable international experience and learned about procedures and rules on how to evaluate environmental and health risks associated with LMOs.

Another positive activity was the training of specialists, decision-makers on LMOs and decision-makers regarding the use of the BCH Central Portal and the creation of National BCH websites. This training was done under UNEP-GEF's BCH I and II projects. A number of training sessions, organized in Chisinau, were conducted by invited regional BCH advisers, including Dr. Aleksej Tarasjev (Serbia) and Ms. Vida Marlot (Slovenia). Moldova's BCH website contains important information and serves to include the public in the decision-making process on LMOs. [2]

Moldova has presently developed and set in place a mechanism for public awareness and public participation in the decision-making process on LMOs. The national biosafety law specifies, in Article 39, the requirements necessary to ensure transparent decision-making and public participation. In this regard, various methods and tools have been developed and implemented, including the national BCH website, biosafety records and public hearings.

In accordance with obligations under the Protocol to ensure monitoring of LMOs, the Biosafety Office of the Ministry of Environment recently implemented a research project on the testing of corn and soybean samples collected from Moldova's primary agricultural producers. The first results showed that currently there are no LMOs being cultivated in the country.

1 The laboratory is accredited to the ISO 17025 standard.

2 Moldova's BCH website is available at www.biosafety.md

To further address national needs to develop human resources and promote qualified personnel, biosafety courses were included in the educational curricula for undergraduate and Master's Degree students at the State University of Moldova and the State Agrarian University. In addition, the BCH training materials and interactive modules are used to train students.

As biosafety is considered a key issue at the global and regional level, Moldova hosted a number of events. Including:

- The CEE Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of LMOs (Chisinau, 2007, organized by SCBD)
- The UNEP meeting for National Project Coordinators (NPCs) on the Implementation of NBFs (Chisinau, 2009)
- The Seventh Coordination Meeting for Governments and Organizations Implementing and/or Funding Biosafety Capacity-building Activities (Chisinau, 2011, organized by SCBD)
- The Eighth meeting of the Liaison Group on Capacity-building for Biosafety, in Chisinau, 2011, organized by SCBD
- The fourth session of the Meeting of the Parties of Aarhus Convention COP - 4, (Chisinau, 2011). Moldova has also published and disseminated 21 books in its national language, including manuals, guidelines and brochures, to libraries and other public places.

Current perspectives and initiatives

Based on experiences of CEE countries, a number of activities need to be developed. For countries experiencing difficulties in developing human capacities for risk assessment and risk management there is a need for continued training of regulators and academia. The Roadmap on risk assessment and risk management and specific risk assessment guidelines elaborated by the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG) would be very useful in this regard. In addition, a regional approach to training would be efficient and helpful, taking into consideration the similarity of social and economic development, the current status of biosafety, human capacities of regulators and academia, as well as needs to develop common actions and harmonized methodologies for risk assessment and risk management in the CEE region. Furthermore, using regional languages may be very helpful during the trainings, as well while preparing the training materials and guidance for easier understanding by the national professionals and the public. It is important to establish good communication, exchange of knowledge and scientific information, long-term collaboration via face-to-face meetings, online forums and a national BCH website. The CEE should use the BCH training materials and modules available in regional languages.

Developing capacities for the identification and detection of LMOs to ensure improved risk assessment procedures, monitoring, and customs control needs to be improved in many countries. A system of reference laboratories and validation of detection methods at the regional level would be helpful. The relatively high costs of LMO detection equipment usually provide some limitations to the countries in having a full operational national reference laboratory that meeting international requirements and standards. It would also be important to establish a regional center of excellency with selected laboratories for LMO identification and detection as a service for countries in the CEE region.

There is also a need to further consider socio-economic issues in decision-making on LMOs and risk assessment in accordance with the Article 26 of the Protocol, as many countries expressed their needs to consider socio-economic consideration and risks to biodiversity and to society at large. Special tools and guidance should be available to increase national capacities for countries with limited experience in this special field. These complex measures will permit countries to take informed decisions with regards to long-term sustainable development.

A liability and redress instruments and procedures should be established and implemented for response measures in the event of damage resulting from LMOs. The countries are invited to develop a system of administrative liability measures based on their domestic regulation to make biosafety efficient and develop their own capacities for taking measure to redress and potential damage to protect biodiversity and restore ecosystems.

> The key system in place is administrative systems to support the Biosafety Clearing-House, public awareness and participation and risk assessment

Conclusion

Overall most CEE countries have developed and implementated NBFs. They have also set in place a regulatory system and other systems that support the implementation of the Protocol. The key system in place is administrative systems to support the BCH, public awareness and participation and risk assessment. However, to enhance implementation of the Protocol a number of specefic measures have to be taken to set in place a system for:

- Enhancing capacity-building efforts, including training activites on a regional level.
- Enhancing implementation of key issues under the protocol, including the handling, transport, packaging and identification of LMOs, risk assessment of LMOs and socio-economic considerations uder the protocol
- Becoming a party to the Nagoya-Kuala Lumpur Supplementary Protocol on liability and Redress to the Protocol and establish a system to implement national rules and procedures on lirability and redress.

10 Years: Peru's national biosafety law born out of consensus

PERU HAS ESTABLISHED A SIGNIFICANT BIOSAFETY LAW THAT CONSOLIDATES A RANGE OF PARLIAMENTARY INITIATIVES TO REGULATE LMOS TO MEET ITS OBLIGATIONS OF THE CARTAGENA PROTOCOL ON BIOSAFETY

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In 1999, before the adoption of the catagena Protocolv on biosafety, Peru promulgated its national biosafety law (Law No. 27104) related to the prevention of risks derived from the use of biotechnology. The law covers eleven issues related to living modified organisms (LMOs) for the safe handling, transfer and use of LMOs.

During that period, there was not a solid environmental administrative system in place. National decisions regarding LMOs were entrusted to competent national authority (CNA) bodies in different ministries, for example, a political entity at the Fishing Sector; a public, promoter and developer of modern biotechnology, at the Agricultural Sector, and a regulator body at the Health Sector.

The greatest weakness of the biosafety law (Law No. 27104), despite the eleven issues related to handling LMOs, is that regulations focused only on the import of LMOs. It also rejects ("de pleno derecho") any LMO that has been observed or rejected, or has not been previously approved in another country.

The national biosafety law was developed in Peru when the country was just beginning to recover from a long period of social struggle and violence. The country had an influential central power but limited capacity to conduct international negotiations. During that time, the country's demand for introducing, developing and releasing LMOs (e.g. for cultivation or breeding in agriculture and fishery) was not significant. This still applies today. Peru's agricultural production consists mostly of fruits and vegetables for export and food crops for the domestic market, while the fisheries sector is fundamentally extractive, based on fishing and gathering. Aquaculture is still in its infancy, devoted mainly to raising trout, prawns and other aquatic species.

In late 2010, the implementation of biosafety law (Law No. 27104), and therefore the use of LMOs (e.g. cultivation or rearing) appeared to be imminent, given the approval of specific biosafety regulations by the agriculture sector. However, that approval sharpened the debate about its significance as an adequate instrument for the protection, conservation and use of biodiversity, as well as the protection of human health, with serious deficiencies identified in the country's capability to perform adequate risk analysis. This was mainly due to: absence of baselines on the potential effect of LMOs on biodiversity; weak institutional framework; and, inadequate quality infrastructure for regulatory purposes, including human resources, laboratories and specialized equipment.

Current status and initiatives

Over the years, the national economy has improved and the country has undergone a process of political decentralizatio throughout the different regions of the country. This is still evident today as the regions around the country currently handle most of the national public budget. As a result, between 2007 and 2011 as the proposal of a new biosafety law (N° 29811), known as the Moratorium law, was being discussed, 12 out of 24 regions issued their own local norms declaring their region "LMO-free".

The new biosafety law consolidates several parliamentary initiatives. This is the first time that a law as this one has support from all political parties and the sectors that make up the Executive Power of Peru.

One challenge was, however, was that while the Moratorium Law was adopted in December 2011[1], its provisions were not made public until a year later (Supreme Decree N°008-2012-MINAM). Still, the adoption of the law was one of the few cases in Peru were so much discussion and controversy lead to a major consensus [2] .

Apart from the challenge that the Moratorium comes whith 10-year time limit, it does not include all the obligations under the Cartagena Protocol. Specifically, it excludes LMOs used for confined use and LMOs for food, feed and processing.

A further challenge is that it focuses mainly on environmental issues regarding strengthening national capacities, developing infrastructure through the implementation and strengthening of a network of accredited laboratories for the detection

1 The Moratorium law covers the importation and production of LMOs in Peru for a period of 10 Years.
2 Regulations of the Moratorium Law were endorsed by the Ministry of Agriculture, Ministry of Production, Ministry of Economy and Ministry of Environment. It was also approved by the Council of Ministers

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It is essential that countries establish a national legal biosafety system and build administrative and technical capacities to implement the Protocol

of LMO, and setting baselines for the native biodiversity that could potentially be at risk from LMOs introduced into the environment, as well as those associated with production systems of important value for the Peruvian economy. In this regard, both the Ministry of Environment of Peru and various ministries, depending on the specific type of LMOs , have to coordinate tasks and appropriate assessments on the impact of the activities related to LMOs introduced into the environment.
This precautionary measure does not affect the extensive trade of grain and other products (e.g. pharmaceuticals and veterinary products) that the country needs. In fact, during the nearly two-year period of the Moratorium, it has not affected the supply of grains for animal production, food industry and veterinary products.

However, in general, the Moratorium is consistent with the Protocol, it recognizes "the crucial importance of centres of origin and centres of genetic diversity for humankind" and states that "Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol ".

Recommendations

The implementation of the moratorium has as its main reference the Regulation of Law No. 29811, through the Supreme Decree N°08-2012-MINAM. As a result an Action Plan was developed to handle LMO-related issues. The plan comprises:

- A program on Knowledge and Conservation of Native Genetic Resources for Biosafety (baseline), coordinated by the Ministry of Environment
- A program on Biotechnology and Competitive Development, which is promoting the use of genetic resources based on various biotechnologies, coordinated by National Agricultural Innovation Institute
- Special project for Capacity Building for the Modern Biotechnology Related to Biosafety (e.g. infrastructure and human resources), coordinated by National Council for Science, Technology and Technological Innovation
- A National Network of Accredited Laboratories for Monitoring of LMO detection, headed by National Authority for Accreditation and Intellectual Property Right
- An Advisory Multisectoral Commission, chaired by the Ministry of Environment.

These facilitate an administrative system and identifies the responsible body, and a legal framework, required to use resources (e.g., public budget and technical cooperation) to implement the Protocol.

Peru is also progressing in building its technical and scientific capacities to enable the country to use modern biotechnology in a responsible and safe manner for human well-being. Above all, Peru will keep its main priorities regarding the protection, conservation and use of biodiversity, and, consequently, its environment as a whole.

Peru is a country of both of opportunities and obligations. It comprises genetic diversity and domesticated animals and plants of actual and potential significance for both its sustainable development and that of mankind.

Conclusion

Peru has established a significant Moratorium Law to regulate LMOs to meet the obligations of the Cartagena Protocol on Biosafety. It is essential that countries establish a national legal biosafety system and build administrative and technical capacities to implement the Protocol. All countries in Latin America and the Caribbean should take similar steps to ensure the safety of modern biotechnology to directly contribute to conserving our biodiversity and promoting sustainable development.

First 10 Years: Establishing biosafety laws and policies in Thailand

FOR THE ASIA-PACIFIC REGION AS A WHOLE, BETTER INTER-LINKAGES AND SYNERGIES WITH EXISTING LAWS AND POLICIES NEED TO BE DEVELOPED AT THE NATIONAL LEVEL; WHILE AT THE REGIONAL LEVEL THERE IS A NEED TO DEVELOP AND HARMONIZE BIOSAFETY REGULATIONS, IMPROVE TECHNICAL LINKAGES AND ESTABLISH NETWORKSBIOSAFETY

by Banpot Napompeth ● The Founder and Advisor of the National Biological Control Research Center (NBCRC) at Kasetsart University, Bangkok (agrban@ku.ac.th)

Since 11 September 2003 when the Cartagena Protocol on Biosafety entered into force, issues regarding the safety of modern biotechnology, or biosafety, have remained a major concern at the national, regional and international level. At each level there exist controversies among proponents and opponents, including anti-living modified organisme (LMO) groups comprised of civic groups. These controversies concern whether or not there is a need to ensure the safe transfer, handling and use of LMOs in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.

Of the five major regions (Africa, Asia and the Pacific, Central and Eastern Europe, Latin America and the Caribbean, and Western Europe and Other Groups), the Asia and the Pacific region is the most diverse. Of the 166 Parties to the Protocol, 44 are from the Asia and the Pacific region. In terms of population and land area, they range from 1.4 billion people in China to only 1,398 people in Niue, and from 9.7 million square kilometers (km2) in China to 21 km2 in Nauru. In terms of economic development, the region is even more diversified from the most highly developed countries to the least developed countries.

These diversities are reflected in the status of implementation of the Protocol and in the development of both genetically modified (GM) and non-GM technology. Therefore it is encouraging to note that of the 121 countries that completed their National Biosafety Frameworks (NBFs) under the United Nations Environment Programme-Global Environment Facility (UNEP-GEF) Project, 36 were from the developing countries in Asia and the Pacific.

This article covers only some experiences and lessons learned, and it should not be assumed that these are typical of the whole region.

Major accomplishments

In Thailand, the National Science and Technology Development Agency (NSTDA) and the Ministry of Science, Technology and Environment established the biosafety guidelines drafting committee in 1990.[1] The guidelines were submitted in 1991 and approved in June 1992 with the appointment of the National Biosafety Committee (NBC). With no prior existing legal instrument in the country to regulate LMOs, the NBC served as an interim national regulatory authority until it ceased to operate in November 2005. It was in 1993 that the very first field trial of a GM crop (FLVR-SAVR tomato) was carried out in adherence to the biosafety guidelines and supervised by the NBC.

When the Convention on Biological Diversity entered into force on 29 December 1993, Thailand, as a signatory to the Convention, issued a ministerial announcement in June 1994, prohibiting imports of 40 GM plant species. This does not include imports for research, although an import permit is required by the Department of Agriculture. Furthermore, imports of food products derived from all prohibited GM crops, GM corn and GM soybean as raw materials intended for direct use as food or feed, or processing (LMOs-FFP) are allowed. Labeling requirements for these products were established in 2002 by the Ministry of Public Health.

By 1994, four GM crops with 16 traits were approved for confined research, small- and large- scale field trials and possible deregulation. However, on 3 April 2001, due to pressure from non-governmental organizations against LMOs, the cabinet declared a total ban on GM crop field trials pending the enactment of the national biosafety law. On 25 December 2007, the ban was partially lifted to allow GM crop field trials on government premises. As a result, public hearings are conducted on site and approvals granted on a case-by-case basis.

1 In 2004, the Ministry of Science, Technology and Environment (MOSTE) was split and became the Ministry of Science and Technology (MOST) and the Ministry of Natural Resources and Environment (MONRE). All biosafety-related matters were then transferred to the MONRE.

AARON GEDDES /FLICKR. THAILAND, KOH PHI PHI KRABI

Progress has been made with regards to biosafety policy and regulations but major challenges remains

[2] Progress has been made with regards to biosafety policy and regulations but major challenges remain. Thailand finalized its NBF in December 2007. It was approved by the cabinet, which then also approved Thailand's national biosafety law in January 2008. The law is presently in the process of being enacted.

Experiences and lessons learned in Thailand

According to the International Service for the Acquisition of Agri-Biotech Applications , China, India, Pakistan, Philippines and Myanmar are the major biotech crop countries, each growing 50,000 hectares or more of biotech or GM crops.

Most of these countries, if not all, face widespread opposition to GM technology as a result of organized anti-GMO NGOs. To overcome this obstacle, appropriate and effective public awareness and public participation may be useful, Effective public awareness and participations is, for example, recommended in the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, or the Aarhus Convention[3]

Current perspectives

The Asia-Pacific countries are highly diversified in terms of a number of issues, such as research and development, human resources, basic infrastructure and facilities and capacity-building mechanisms. They are aware of, and technically concerned with, the development and advancement of modern biotechnology at the global and regional level. The countries however face major constraints with regards to the implementation of the Protocol. Key issues include:

- Appropriate and effective regulatory systems are needed for developing countries in Asia-Pacific, regional cooperation on biosafety-related issues should be encouraged;

- The countries are at different stages of developing biotechnology, taking into account both GM and non GM technologies

- Closer cooperation and liaison is needed between different Competent National Authorities (CNAs) with regards to implementing biosafety laws and policies

- At the regional level, in addition to technical assistance and cooperation there is a need to harmonize technical requirements, regulatory procedures and legislation.

In conclusion, at the national level, there is a need to create better inter-linkages and synergies with existing laws and policies handled by different CNAs. At the regional level, there is also a need to develop and harmonize biosafety regulations, improve technical linkages, and to establish networks.

2 A field survey revealed that over 70 per cent of cotton crops being cultivated were GM cotton with possible transboundary movements to neighboring countries.

3 UNECE is the United Nations Economic Commission for Europe.

UNEP's capacity-building projects emphasize knowledge-sharing

UNEP'S CAPACITY-BUILDING PROJECTS, GUIDED BY THE GEF BIOSAFETY STRATEGY, EMPHASIZE KNOWLEDGE-SHARING THROUGH CAPACITY-BUILDING ACTIVITIES, NETWORKS AND ALLOW FOR DYNAMIC, TAILOR-MADE ADAPTATIONS TO MEET IDENTIFIED NEEDS

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The United Nations Environment Programme (UNEP) supports, with funding from the Global Environment Facility (GEF), the implementation of the Cartagena Protocol on Biosafety. As a result, UNEP assists Parties with meeting their obligations under the provisions of the Protocol.

Presently UNEP is implementing a portfolio comprising four types of initiatives:

- UNEP-GEF National Biosafety Framework (NBF) Development Project, which is undergoing a "terminal closure" based on the completion of the Project in 123 countries
- UNEP-GEF NBF Implementation Project which provides assistance to eligible Parties to the Protocol
- UNEP-GEF Biosafety Clearing-House (BCH) Project, which assisted 139 eligible countries to access and benefit the BCH Phase I Project. The project was followed-up on with the support from GEF 4 for 50 countries and recently renewed based on Parties requesting a new project that is currently being developed to support an additional number of Parties in GEF 5
- Support to the Second National Report on the Implementation of the Protocol on Biosafety in accordance with Article 33 of the Protocol.[1]

UNEP's capacity-building projects for biosafety initiatives are guided by the GEF Biosafety Strategy. The focus is on ensuring that there are clear and transparent national biosafety decision-making systems through which "*Potential risks of living modified organisms to biodiversity are identified and evaluated in a scientifically sound and transparent manner*". It is also guided by the Strategic Plan for the Protocol (2011-2020) [2]. UNEP continues to collaborate with the Secretariat of the Convention on Biological Diversity, GEF, Parties and partners to shape an integrated approach in supporting the implementation of the Protocol.

This approach was to develop a NBF whereby a Party could implement specific and unique national initiatives guided by the national policy, development and regulatory practices. Recently, the trend has been to move towards tailored, specific initiatives which strengthen decision making in national biosafety systems that are built on existing national capacities. Taking this approach requires additional global technical support to assist Parties to meet set objectives and to ensure implementation and enforcement of the NBFs.

Challenges

Major challenges facing Parties in developing and implementing NBFs or regional biosafety frameworks include:

- Access to the financial mechanism of the Protocol, the GEF, due to competing demands on the resource allocation referred to as the "biodiversity versus biosafety allocation challenge"

- Lack of taking national ownership and responsibility for developing and implementing policy and establishing opportunities for national measures on biotechnology and biosafety

- Lack of coordination when initiating a project

- Focusing capacity building on the needs of Parties, particularly in areas on technical and institutional frameworks, guided by national interests.

Best Practices and Lessons Learned

Best practices and lessons learned from the UNEP-GEF NBF Implementation Projects cover several areas, including: availability or development of regulatory frameworks as a critical and primary enabling activity to facilitate an operational national biosafety system; stakeholder and national institution-driven capacity building; mentoring, partnerships, cooperation and networking; capacity-building and knowledge-sharing; and , the role of good project management tools and databases to facilitate delivery of projected objectives.

1 More information is available at: http://bch.cbd.int/protocol/cpb_natreports.shtml
2 The Strategic Plan was adopted at the fifth Conference of the Parties serving as the meeting of the Parties (COP-MOP 5), in decision BS V/16 (http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=12329)

SEIYA KAWAMOTO / LIFESIZE / THINKSTOCKI

There are major challenges facing Parties in developing and implementing national biosafety frameworks, including access to the financial mechanisms of the Protocol – the Global Environment Facility

Key valuable lessons learned, captured in the portfolio-wide biosafety capacity initiatives, include:

- Delivery of peer-reviewed training tools and toolkits to assist in the development and implementation of the NBFs. These have become useful resources for countries and several capacity-building initiatives

- Emphasis on national ownership and tailored- specific initiatives

- A project focused on a range of NBF implementation-specific initiatives, based on the five components of the NBF and specific thematic initiatives or frameworks to support systems for national biosafety decisions as per the GEF Biosafety Strategy, the Strategic Plan for the Protocol (2011 – 2020) and

the guidance from the meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOPs)[3];

- The meetings of the project coordinators established a platform for the exchange of information and an avenue to include ongoing COP-MOP guidance for post-project implementation. This, and other interactive measures, are used to advocate and provide technical guidance for the Strategic Plan, the programme of work on public awareness, education and participation concerning the safe transfer, handling and use of Living Modified Organisms (2011-2015) and other emerging trends in biosafety and biotechnology

- The system of the BCH Regional Advisors for the UNEP-GEF BCH Project that lead to an improved acceptance of expertise at the regional level by encouraging cultural and language compatibility. As a result, there was an increase in the use resources, partnerships and networking beyond the project

- Measures to take national-ownership and other approaches to implementing the Protocol. These approaches are for implementing any multinational instrument or treaty as there is a direct obligation by Parties. For example, strong national ownership is extremely critical to the development of supportive mechanisms in reaching implementation goals set by Parties. A review of progress demonstrates that a clearly defined institutional mechanism, backed by approved regulatory frameworks, allows for a more realistic trend in meeting set targets. In other words, national biosafety activities that are mainstreamed into the institutional mandates with direct oversight of the institutional executive boards leads to a more focused and fast-tracked approach to the management support, provision and dedication of resources

3 The five components of the NBFs are to develop: a national biosafety policy, a regulatory regime, an administrative system, mechanisms for public awareness, education and participation and systems for follow up.

• Another tool developed for project management which is becoming a global resource for partners is ANUBIS (https://anubis.unep.org). A thorough "hands on training" on the

• Partnerships, cooperation and networking initiatives. Biosafety is a cross-cutting issue and extends to multi-sectoral areas based on the national development agenda, including the environment, agriculture, health, industry and others. UNEP's capacity-building projects, guided by its field experience, continue to focus on global partnerships, cooperation and networks using internal national resources and capacity. These networks are working towards South-South and North-South cooperation at the bilateral and regional level

• The capacity-building and knowledge sharing initiatives. UNEP's capacity-building projects have resulted in the development of knowledge-sharing materials and tools that are built into all the biosafety projects with a strong focus on risk assessment of LMOs, handling, transport, identification and packaging of LMOs and information sharing to assist Parties to meet their obligations under the Protocol at the national, regional and global levels. A notable example is the UNEP-GEF BCH Project which, through the Regional Advisors' network and the Virtual Learning Environment platform, has developed global resources. They include training materials, case studies, learning tools, presentations and webinar materials targeting specific audiences including Parties, the private sector, civil society and academia[1] .

• Another tool developed for project management which is becoming a global resource for partners is ANUBIS (https://anubis.unep.org). A thorough "hands on training" on the reporting tool addresses a lot of the supervisory difficulties with reporting. It tends to assist national partners in meeting their national obligations as it serves as a ready information resource for tools, guidelines and materials developed through the biosafety projects for all the countries involved in the biosafety projects. This helps to avoid a lot of duplication and promotes the efficient use of technical resources. The tool has also become a critical data backup for partners and reference tool for evaluations and audits as it serves as a one stop repository for all UNEP-GEF Biosafety Projects and recently also for data on NBSAPs and national biodiversity reports.

Conclusion

UNEP's capacity-building projects continue to emphasize knowledge sharing through their formal capacity-building activities and their networks. The developed tools are continuously updated and made available to the public. A clearly defined mechanism, supportive measures for interactivity and inputs by Parties and other relevant stakeholders allow for dynamic and tailor-made adaptations to meet identified needs.

An analysis of the portfolio highlights issues which can impact positively or negatively on the delivery of project objectives and implementation of the Protocol. It includes the following

• The need to build or have scientifically robust legal and technical frameworks with clearly defined institutional mechanisms. These should ensure the involvement of relevant stakeholders. They should be put in place to ensure partnerships and learning through the use of consultants selected from the pool of existing international and national consultants

• There should be clearly defined measures for sustainability guided by the obligations of Parties, changing trends in biosafety and national imperatives

• UNEP's initiatives should dedicate time and focus attention on a national biosafety system which allows for the review of issues and mechanisms as an ongoing process while considering new lessons learned, trends and developments from the COP-MOP processes, international and national development policy discourse, etc.

• The issue of resource allocation is critical at all levels and, in the case of the GEF Biosafety Portfolio, there is a need for a review of the biodiversity allocation guided by the history of periodic, notional and immediate consideration of GEF resources since the introduction of the new Resource Allocation Framework.

1 See Virtual Learning tools at http://moodle.bch2project.org/ and on the Central Portal at http://bch.cbd.int/help/training-materials.shtml. See also tools for national participation in the BCH – Hermes and Ajax Plug in http://bch.cbd.int/resources/solutions/

Civil society helps promote safety in the use of biotechnology: Third World Network

ACCESS TO INFORMATION IS CRITICAL AS EXPERIENCE SUGGESTS THAT IF THE PUBLIC HAS ACCESS TO CREDIBLE SCIENCE AND INFORMATION, IT CAN BE EASILY ENGAGED AND MAKE INFORMED DECISIONS ON LMOSNETWORKS AND ALLOW FOR DYNAMIC, TAILOR-MADE ADAPTATIONS TO MEET IDENTIFIED NEEDS

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From the early days of modern biotechnology, civil society has actively and consistently raised concerns about the environmental, health and socio-economic risks of genetic engineering and its products. Many non-governmental organizations, farmers' organizations and indigenous peoples' organizations have been active in raising public awareness. They have collaborated with scientists engaged in biosafety research by holding campaigns to increase public awareness, education and participation as well as informing policy makers.

The efforts of civil society have helped to shape international regulatory frameworks and policies regarding living modified organisms (LMOs), commonly known as genetically modified organisms (GMOs). Information from civil society and scientists helped to shape the discussions leading up to the adoption of the Cartagena Protocol on Biosafety, including the provision on public awareness and participation (Article 23). It also encouraged industry to actively participate in the discussions.

Notable civil society contributions include the existing international *de facto* moratorium on field testing or commercial use of genetic use restriction technology (GURTs). Because GURTs aim to restrict the use of genetic material and their related traits, they are seen as impinging upon the rights of farmers.[1]

In 1999, in response to an avalanche of public opposition, two of the world's largest seed and agrochemical corporations, Monsanto and AstraZeneca (currently Syngenta), publicly committed themselves to not commercialize "Terminator" seeds. Continued public pressure also led the former Director-General of the Food and Agriculture Organization of the United Nations (FAO) to publicly declare FAO's opposition to "Terminator Technology" as a threat to food security.[2] As a result, several countries, including India and Brazil, currently have legislation prohibiting the use of "Terminator Technology".

Today, the role of civil society is just as important in implementing the Protocol because governments need expertise from the public (e.g. indigenous people, farmers, scientists, social scientists, ecologists, health workers, lawyers) who may not be part of the formal decision-making process on LMOs. Civil society can help to ensure a public-peer review by designing and establishing biosafety systems, including procedures for risk assessment and risk management, collective decision-making on LMOs and vigilant monitoring (e.g. monitoring of unintended impacts of LMOs).

In addition, the Protocol's provision on public participation requires governments to consult the public in the decision-making process on LMOs. Apart from participating directly in consultation exercises, civil society can help to mobilize the public, particularly sections of the public that are more marginalized, to participate in the decision-making process on LMOs.

For example, in early 2010, India, in the national consultation on Bt brinjal, organized seven public meetings. By doing so it experienced unprecedented participation by a wide range of stakeholders, including almost 8,000 people from different sectors of society. Civil society played a crucial role in mobilizing participation, raising awareness and engaging independent scientists to highlight biosafety concerns. As a result, the Minister of Environment endorsed the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development. A moratorium on the release of Bt brinjal was set in place until independent scientific studies determine, to the satisfaction of both the public and other relevant stakeholders, that its use is safe in terms of long-term impacts on human health and the environment.

1 The de facto moratorium was adopted by the Convention's fifth governing body meeting in 2000. At the time, civil society played a big role with the ETC Group (formerly RAFI) first discovering patents on the technology in 1998 and then alerting the global community. It coined the term "Terminator Technology" to raise awareness and promote the need for a global ban on the technology.
2 A letter-writing campaign by the Global Response, a US-based non-profit organization, saw 4,000 of its members in forty countries writing to FAO on the issue.

MERIJN VAN DER VLIET /RICEFIELD WITH FARMER IN INDONESIA / ISTOCKPHOTO /

Civil society has collaborated with scientists by holding campaigns to increase public awareness, education and participation as well as informing policy makers.

Current Perspective

While civil society continues to contribute to promoting safety in the use of modern biotechnology, including in the adoption of precautionary measures, many challenges remain. First, civil society is often at a disadvantage in terms of resources and political influence compared to the proponents of genetic engineering that include some of the largest multinational corporations in the world. Despite these constraints, civil society continues to contribute positively to biosafety discussions at the national and international level.

Access to information is another critical aspect. Experience demonstrates that if the public has access to credible science and information, it can easily be engaged and make informed decisions regarding LMOs. However, civil society does not always have access to information including raw scientific data. Such information is often withheld on the grounds that it is confidential which impedes ensuring the safety of modern biotechnology. For example, scientific data on GM maize (MON 863) was initially kept confidential but Greenpeace brought the issue to court and Monsanto was ordered to divulge the information. Once the data was made available to civil society and independent scientists for scrutiny, a re-analysis of the data came to very different conclusions than that of the developer, Monsanto. For example, indications of hepatorenal toxicity led to a review of the data by several Competent National Authorities. While the findings and significance of the re-analysis have been debated, important independent scientific scrutiny was made possible through the efforts of civil society and concerned scientists.

Access to information is also necessary for meaningful public participation. To participate fully in the decision-making processes on LMOs, there needs to be proper channels and possibilities for participation. A clear decision-making process regarding LMOs includes: what has (or has not) been taken into account and why; regular feedback to those who participate; and, open and respectful attitudes by all concerned. Finally, there is a need for a democratic, transparent and accountable decision-making process regarding LMOs. A committed and watchful civil society will ensure better decisions regarding biosafety issues and clearer ways forward for a sustainable planet.

Industry coalition's first-hand experiences provide support to Parties : Global Industry Coalition

THE GLOBAL INDUSTRY COALITION PROVIDES A ONE-STOP SOURCE FOR CONCRETE, RELIABLE AND ACCURATE INFORMATION FOR COUNTRIES INVOLVED IN THE GLOBAL TRADE OF LMOS AND HAS PARTICIPATED IN EVERY GOVERNING BODY MEETING OF THE PROTOCOL

by Sarah Lukie ● Executive Director, The Compact; Managing Director for International Regulator Affairs, Crop Life International & Executive Secretary, Global Industry Coalition. (sarah.lukie@croplife.org)

Over a decade ago, as countries were negotiating the text of the Cartagena Protocol on Biosafety, the plant science industry recognized the need to engage in these negotiations in a committed, sustained and coordinated manner. Accordingly, the Global Industry Coalition (GIC), a coalition of trade associations and companies involved in plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment, was established to provide a one-stop source for concrete, reliable and accurate information for countries involved in the global trade of living modified organisms (LMOs). Thus over the past decade GIC members have participated in every governing body meeting of the Protocol (COP-MOP) and the evolving discussions on implementation.

The GIC has continuously supported capacity-building efforts related to:

- Development and implementation of National Biosafety Frameworks (NBFs)
- Improvement of information registered in the Biosafety Clearing-House (BCH)
- Development and implementation of detailed guidance on shipping documentation for seeds and research materials
- Making available the GIC detection methods for commercialized biotechnology-derived products available on a publicly-available website
- Most recently, the liability and redress discussions which culminated in the adoption of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

As the work of the Protocol continued to evolve, the GIC's work shifted from simply coordinating resources for Parties to focusing on supporting Parties through the GIC's unique breadth of experience and knowledge of LMOs. For example, GIC members are the primary entities that are globally commercializing LMOs. In this regard, the GIC can contribute to providing valuable information through the BCH. The GIC has provided the following in the BCH: Links to the commercial status of all LMOs; and, resource materials to the Biosafety Resource Information Center (BIRC).The GIC has also worked directly with Parties to ensure that all products approved in countries are accurately listed. Today, the GIC's industries continue to share their expertise and resources to ensure that the BCH is a relevant and useful tool for Parties.

Introduction

For over 15 years, the GIC has also used its experience to contribute to negotiations surrounding the provisions on handling, transport, packaging and identification of LMOs (Article 18). At the first COP-MOP, the GIC actively participated in discussions with Parties on the implementation of paragraphs 2(b) and 2(c) of Article 18 of the Protocol relating to the shipping documentation requirements for contained use of LMOs and LMOs intended for intentional introduction into the environment. Prior to these discussions, the GIC had created its own implementation guidelines for these provisions which were put into use regarding shipping documentation for seeds and research materials. This effort was acknowledged by Parties at COP-MOP 2 and the guidance was subsequently supported by Parties at COP-MOP 4 and COP-MOP 6. Today, it is still used by GIC members. They view it as a significant contribution by technology providers which anticipated the need to ensure that adequate information was available to customs officers.

The GIC's industries have most recently been engaged in the successful liability and redress negotiations. The GIC participated in the discussions of the working groups at the COP-MOP which resulted in the development and adoption of the Supplementary Protocol. The GIC is very satisfied with the Supplementary Protocol and in particular its role

MATTHEW DIXON / ISTOCKPHOTO / THINKSTOCK

The Global Industry Coalition has developed an Implementation Guide to assist in developing mechanisms to address the possible event of damage to biodiversity

of continuing to support Parties in the Supplementary Protocol's implementation. For example, the GIC has developed an Implementation Guide, a "how-to manual", to assist in developing mechanisms to address the possible event of damage to biodiversity, while conforming to the language in the Supplementary Protocol. Currently, the Implementation Guide is the sole capacity-building tool to assist Parties in implementing the Supplementary Protocol. It has gained the support of the co-chairs of the Liability and Redress Working Group who facilitated the negotiations of the text of the new treaty.

Current Perspectives

Furthermore, while the GIC's development of the Implementation Guide was an important resource for the plant science industry and the Parties, GIC is proud of the creation and establishment of The Compact, the binding contract among the six major technology providers (BASF, Bayer CropScience, Dow AgroSciences, DuPont, Monsanto, and Syngenta) to compensate or remediate damage to biodiversity caused by their products. The Compact, created to complement domestic and international law, represents industry's commitment to corporate social responsibility and confidence in the environmental safety of its products. The development of The Compact was an important milestone for the plant science industry as it demonstrated industry's ability to align with the issue of liability and redress under the Protocol and collectively work to develop a timely and science-based framework for liability claims. It also facilitates working with stakeholders, on a global level, through its Advisory Council, in order to continue to improve The Compact, its guidelines and to increase its membership.

Over the past decade, during its involvement with the Protocol, the GIC certainly experienced frustration during late-night negotiations and when progress seemed impossible. However, there were also times when professional and industry milestones were being celebrated. During these moments GIC knew it was contributing to the development of the work of the Protocol and felt a sense of pride knowing that it had helped develop tools such as The Compact and Implementation Guide that should continue to be valuable resources to Parties for years to come. It has been a unique opportunity for the GIC to be able to support Parties and delegates through the sharing of first-hand experiences and to work with other partners, such as scientists and the international grain trade industry, to help shape the work of the Protocol as it evolves.

Despite the anticipated extreme growing conditions caused by climate change, as well as the limited supply of natural resources, plant biotechnology and its LMO products offer great potential for growers and consumers around the world for a safe and secure food supply. The GIC will continue contributing to the implementation of the Protocol and to the upcoming important negotiations at the meetings of its governing body. It looks forward to continuing to face the challenges ahead and to the privilege of representing the GIC and the plant science industry.

A major milestone 2013: A new law will help Iran promote safety in the use of biotechnology

OVER THE YEARS IRAN HAS UNDERTAKEN A RANGE OF KEY INITIATIVES IN DEVELOPING AND IMPLEMENTING SYSTEMS TO COMPLY WITH THE PROVISIONS OF THE PROTOCOL

by Nasrin Sadat Esmailzaeh ● Iran's National Focal Point for the Biosafety Clearing-House (BCH-NFP), Secretary of Ministry of Science, Research & Technology Biosafety Committee, National Institute of Genetic Engineering & Biotechnology (nasrin@nigeb.ac.ir).

Since the adoption of the Protocol, Parties have progressed steadily in developing and implementing systems to comply with the provisions of the Protocol. Many countries have developed and/or strengthened their capacities vis–à–vis biosafety. Iran, like many other countries, has carried out activities in this regard, with the most important highlighted here.

With a population of approximately 77 million and total land area of 1,648,195 square kilometers, Iran is situated in southwest Asia. The southern half of the country lies in the subtropical zone and the northern half of the country is in the temperate zone. There is also a desert zone in the middle of the country. Iran borders Iraq and Turkey to the west, Pakistan and Afghanistan in the east, Turkmenistan in the northeast, and Azerbaijan and Armenia in the northwest. The country also has coastlines in the north and in the south.

Introduction

Iran considers modern biotechnology important to its social and economic development. Today, issues relating to modern biotechnology are included in policies, plans and research activities.[1]

In this regard, the National Biotechnology Committee was established in 2000. As a result, the National Biotechnology Strategy, a ten-year plan, was developed and ratified by the Cabinet of the Ministers on 5 May 2004. The plan includes the development of biotechnology in the following areas: health and medicine, agriculture (e.g. plant, livestock and marine life), industry and mining, the environment, and, bioethics. Accordingly, based on the Strategy, the Biotechnology Development Council (BDC) was established in 2005 to: lead the biotechnology development, promote the private and the public sector, and, raise public awareness of biotechnology.

After almost two decades of undertaking these activities, Iran has improved its production of recombinant bio-pharmaceuticals, recombinant vaccines (e.g. human and animal vaccines), bio-fertilizers, animal cloning, stem cell technologies, and research on production of transgenic plants and animals.

Statistically, in 2011, Iran became the first in the region and fourteenth in the world to publish scientific articles on biotechnology. At this time, over 5000 post-graduate students were studying in various biotechnology-related fields; and 120 universities, 40 institutes and research centers and 200 companies were working on issues related to modern biotechnology.

Major accomplishements

The fundamental and strategic policies of the Islamic Republic of Iran, while emphasizing the development of modern biotechnology, cover protecting the environment from any harmful effect of this technology especially recombinant DNA technology and the development of living modified organisms (LMOs). The National Biotechnology Strategy emphasizes that "the development of biotechnology should be in accordance with the observation of biosafety regulations." Over the years, Iran has undertaken key initiatives, including: ratifying the Convention on Biological Diversity (6 August 1996); ratifying the Cartagena Protocol on Biosafety (18 February 2004); and setting in place administrative and legal systems to implement the Protocol.

In August 2000, the National Biosafety Committee (NBC) was established as part of the Ministry of Science, Research and Technology to discuss and make decisions on, among other things, the country becoming a Party to the Protocol. As a result of the committee's efforts, the Islamic Consultative Assembly of Iran, the Iranian Parliament, ratified the Protocol on 20 November 2003.

1 Some of these activities also include: The Iran vision 1404 and the National holistic map.

DARIUSH MOHAMMADI /FLICKR , IRAN

Subsequently, in a session held on 13 July 2005, the Ministers' cabinet formally approved the formation of the National Biosafety Council (NBC) that included: the Minister of Science, Research and Technology; the Minister of Health and Medical Education; the Minister of Agriculture; and the Head of the Environmental Protection Organization. The Environmental Protection Organization was designated as the secretariat of the NBC. In addition, the Ministerial Biosafety Committee was also established to implement biosafety regulations in the relevant executive bodies.

Iran participated in the United Nations Environment Programme – Global Environment Facility (UNEP-GEF) Project on development of the National Biosafety Framework (NBF) in September 2004. Following the development of the NBF in 2006, a draft national biosafety law was developed by a committee comprising experts from the Ministry of Science, the Ministry of Agriculture and the Environmental Protection Organization. This draft law was assessed during a series of meetings by the National Coordinating Committee of the NBC. After being approved by the Cabinet of Ministers, Iran's Parliament ratified the draft law on 29 July 2009. The biosafety Law then came into force on 27 August 2009. Today, all issues related to the production, application, release, transport and use of LMOs are addressed in accordance with the provisions of the national biosafety law.

Based on Article 4 of the Biosafety law, handling issues related to
modern biotechnology, with regards to regulating LMOs as referred to in the Protocol, fall under the responsibility of the competent national authorities bodies. These include:

- The Minister of Agriculture : issues related to production of LMOs in the agricultural sector and natural resources
- The Minister of Health and Medical Education: issues related to health and safety of food, cosmetics and medical materials
- The Environmental Protection Organization: issues related to wild life and evaluation of the environmental risk assessment based on scientific documents provided by an applicant.

To facilitate the implementation of the biosafety law, and clarify the relationship between the legislative duties and relationship between executive bodies, a draft of the executive regulations of the biosafety law was developed by a specialized committee of the NBC. The law specifies all of the details and processes related to field trials, production, release, import and export, transport, purchase and sale, distribution, consumption and use of LMOs and their products. It was approved by NBC on 7 April 2012 and came into force on 10 July 2013.

Iran's Biosafety Clearing-House

The National Institute of Genetic Engineering and Biotechnology (NIGEB), affiliated with the Ministry of Science, Research and Technology, has been responsible for Iran's BCH since 2004. NIGEB's activities to promote information sharing, public awareness and public education include:

- Registering and updating required information on the BCH website
- Providing a mailing list of relevant stakeholders and disseminating biosafety news
- Publishing biosafety bulletins

Due to the increasing development of modern biotechnology, it is crucial to become a Party to the Protocol and effectively implement

- Translating Protocol Articles into Farsi
- Compiling, publishing and translating a brochure on the introduction of the BCH
- Participating in various national and international biosafety seminars and workshops
- Participating in the UNEP-GEF Capacity-building Project on Building Capacity for Effective Participation in BCH in 2009 including:

  - Organizing three national workshops
  - Establishing national BCH website[1]
  - Publishing booklet "UNEP-GEF Project on Building

Capacity for Effective Participation in the BCH" in Farsi, in August 2009.

- Organizing biosafety workshops, including:

  - Biosafety Analysis of Transgenic Plants, 26 February 2005 - 2 March 2005
  - First International Congress of Bioethics, 26 - 28 March 2005
  - First International Workshop on: Biosafety and Risk assessment for the Environmental Release of GMOs, 12 - 16 November 2005
  - Second International Congress of Bioethics, 5 - 7 February 2011
  - First International Workshop of Bioethics and Ethical Aspects of Biosafety, 20 - 22 November 2011, with NIGEB, in collaboration with the International Centre for Genetic Engineering and Biotechnology (ICGEB)
  - Signed a memorandum of understanding with ICGEB in 2012 for the establishment of the regional center for bioethics and biosafety .

Recommendations

Due to outcomes and lessons learned from the above, it can be concluded that successful implementation of the Protocol, requires Parties to, among other things:

- Set in place national administrative systems for biosafety that includes several ministries handling biosafety issues
- Develop and implement national biosafety laws, policies and regulations
- Develop and strengthen technical, institutional and human capacities in biosafety
- Put in place an information management system through a national BCH website and share information through the BCH
- Promote public awareness, education and participation concerning a healthy environment and the safe application of LMOs.

Due to the increasing development of modern biotechnology, it is crucial to become a Party to the Protocol and effectively implement its provisions. [2]

1 The website is available at http://ir.biosafetyclearinghouse.net/

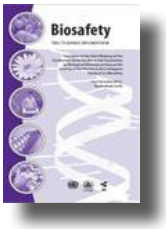
2 Acknowledgement: Many thanks to Professor Abbas Lotfi, the Director General of the NIGEB and the Head of the Ministerial Biosafety Committee, for making available valuable data on biotechnology and for his valuable comments on the article.

United Nations Photo/FLICKR.

Useful information


JULIEN MAASS/FLICKR.

New publications and information



Decision booklets
(http://bch.cbd.int/protocol/cpb_mopmeetings.shtml)

Testing of the Guidance on Risk Assessment of LMOs
http://bch.cbd.int/protocol/testing_guidance_RA.shtml

Regional Networks
(http://bch.cbd.int/onlineconferences/portal_art23/regnetworks.shtml)

The Africa Network
(http://bch.cbd.int/onlineconferences/portal_art23/regnet_africa.shtml)

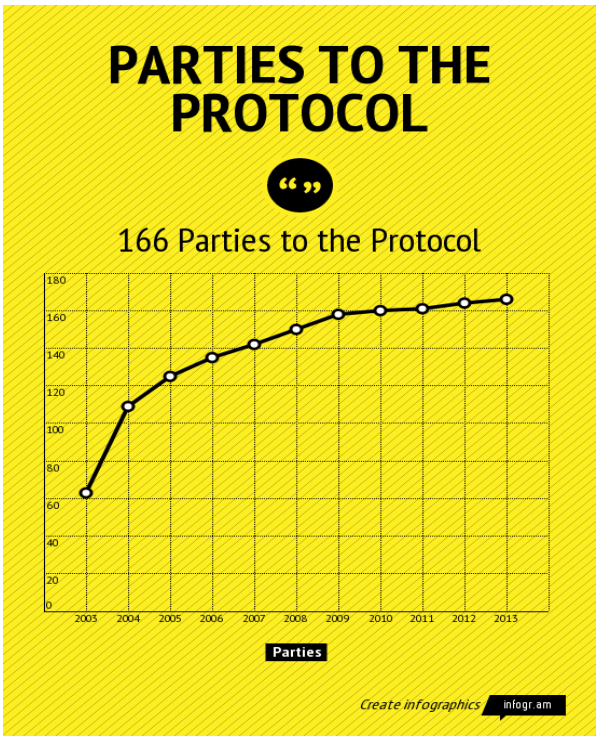
The African Regional Discussion Group
(http://bch.cbd.int/onlineconferences/portal_art23/regnet_africa.shtml)

Asia-Pacific Regional Discussion Forum
(http://bch.cbd.int/onlineconferences/portal_art23/regnet_asia.shtml)

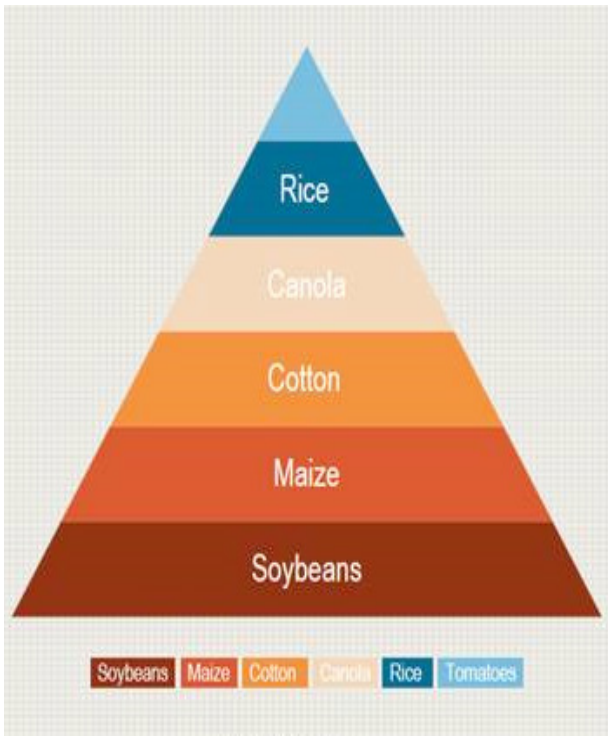
10th anniversary website
(http://bch.cbd.int/protocol/10thAnniversary.shtml)

Statistics

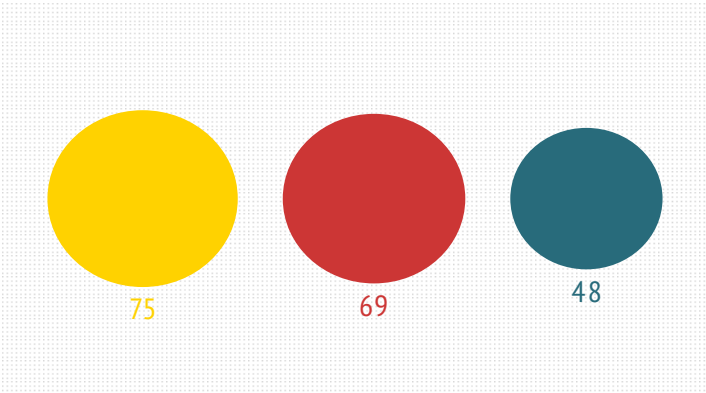
Total number of Parties to the Protocol



Total Number of Decisions on LMOs Submitted to the BCH



Total number of laws, regulations and guidelines indicated in the second national reports



Source: Infogr.am

Recent and upcoming biosafety events

RECENT KEY MEETINGS AND EVENTS

COP-MOP 6

The sixth meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP 6) took place in Hyderabad, India on 1-5 October 2012, with over 1300 participants in attendance. The meeting adopted 16 decisions on a number of standing issues, including: compliance committee; the Biosafety Clearing-House; the financial mechanism and resources; and cooperation with other organizations, conventions and initiatives. A number of substantive issues arising from previous decisions of COP-MOP were also discussed, which included: capacity-building activities and the use of the roster of biosafety experts; handling, transport, packaging and identification of LMOs; notification requirements; Liability and Redress; unintentional transboundary movements and emergency measures; risk assessment and risk management ; subsidiary bodies; socio-economic considerations; monitoring and reporting; and assessment and review. For more information, please find the press release at http://www.cbd.int/doc/press/2012/pr-2012-10-06-mop6-en.pdf?dowload and the COP-MOP 6 final report at http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4715.

Socio-economic considerations

The Secretariat organized, in line with decision VI/13 of the sixth meeting of the Parties to the Cartagena Protocol on Biosafety, online discussion groups and regional online real-time conferences to facilitate the exchange of views, information and experiences on socio-economic considerations among Parties, other Governments, relevant organizations and indigenous and local communities in the context of Article 26.

The Secretariat convened the online discussion groups from 11 March 2013 to 16 April 2013. A total of 113 people were registered for the discussions and 49 of them have made at least one intervention. A total of 297 messages were posted. 52 percent of these messages were posted from people located in developed countries and 48 percent from developing countries. The Secretariat has prepared a summary of the discussions.

The Secretariat also convened four Regional Real-time Online Conferences on Socio-economic Considerations for: (i) Western Europe and Others Group and Central and Eastern Europe, 13 June 2013; (ii) Asia and the Pacific, 17 June 2013; (iii) Africa, 20 June 2013; and (iv) Group of Latin America and the Caribbean, 27 June 2013. A total of 40 Parties, 4 non-Parties and 6 other observers participated in the conferences.

Compliance committee

The Compliance Committee held its tenth meeting in Montreal from 29 to 30 May 2013. The Committee considered the outcomes of the sixth meeting of the Parties to the Protocol with regard to items relevant to compliance and the follow up activities undertaken by the Secretariat. It reviewed compliance on the basis of the second national reports, with a focus on the priority issues identified by the sixth meeting of the Parties. It also reviewed general issues of compliance as regards: (i) introducing legal, administrative and other measures necessary for the implementation of the Protocol; (ii) making information available to the Biosafety Clearing-House as required under the various provisions of the Protocol; and (iii) promoting public awareness, education and participation, including using the programme of work adopted by the fifth meeting of the Parties to the Protocol. The Committee agreed to various measures and timelines to follow up with Parties that are still required to comply with their obligations with respect to national reporting and putting in place legal and administrative measures necessary to implement their obligations under the Protocol. For further details, see the report of the meeting in document . UNEP/CBD/BS/CC/10/5

Biosafety Clearing-House

The Secretariat, in collaboration with and support of the UNEP-GEF Biosafety Project, convened a training workshop for National Focal Points for the Biosafety Clearing-House (BCH-NFPs) from 28 to 29 September 2012, in Hyderabad, India. More than 40 participants received comprehensive training in the general navigation of the BCH and management of national records.

Photo: Tenth meeting of the Compliance Committee under the Cartagena Protocol on Biosafety (BSCC-10), 29 - 31 May 2013 Montreal, Canada.

The eighth meeting of the Informal Advisory Committee of the Biosafety Clearing-House (BCH-IAC) was convened. It consisted of discussions of issues through an online forum which began on 18 March 2013 and concluded with a real-time online teleconference on 17 April 2013. Participants discussed (i) Developments in the Biosafety Clearing-House and ongoing projects; (ii) Outcomes of the conclusions and recommendations of the sixth and seventh meetings of the Informal Advisory Committee on the Biosafety Clearing-House; (iii) Outcomes of the BCH-IAC Survey; (iv) Ongoing collaboration with the UNEP-GEF project for continued enhancement of building capacity for effective participation in the Biosafety Clearing-House (BCH II); and (v) Requests to the Executive Secretary from the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP).

Public awarenesse and participation

The Secretariat implemented various activities to promote public aware¬ness 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:

- During COP-MOP 6, a fair on national experiences with the implementation of the Protocol was held, including a number of presentations, posters and publications;
- Two training workshops took place on public awareness, education and participation concerning the safe transfer, handling and use of LMOs. The training workshop for Africa took place 5 - 9 November 2012, in Kampala, Uganda. More than 40 participants attended the workshop. The training workshop for Asia-Pacific took place 25 - 29 March 2013, in Hanoi, Viet Nam. The purpose of the workshop was to enhance the capacity of Parties and other Governments, to effectively implement the programme of work on public awareness, education and participation concerning the safe transfer, handling and use of LMOs and to share experiences and lessons learned. The workshop, among other things, provided an opportunity for participants to develop draft outreach strategies or communication plans and draft national action plans or national frameworks;

- An exhibition on 29 May 2013 at McGill University, in collaboration with the Redpath Museum, highlighting the UN Decade on Biodiversity. The event, which was attended by more than 3000 visitors, contributed to raising awareness on the Protocol as one of the tools in promoting the conservation and sustainable use of biodiversity;

- The launch of the Regional Networks on PAEP under the Portal Public Awareness, Education and Participation Concerning the Safe Transfer, Handling and Use of LMOs, including an African Network on PAEP. The African Network has two regional discussion groups (English and French) and two information boards (English and French).

- Development and dissemination of two publications: (i) The Decision booklets for the sixth Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 6) in all 6 official languages of the United Nations (Arabic, Chinese, English, French, Russian and Spanish) available at http://bch.cbd.int/protocol/cpb_publications.shtml; and (ii) The Youth Guide to Biodiversity (1st edition), including a biosafety and agriculture part. The guide is available at https://bch.cbd.int/database/record.shtml?documentid=104830; and

- Preparation of the 10th anniversary of the entry into force of the Protocol, a promotional video and a website available at : http://bch.cbd.int/protocol/10thAnniversary.shtml

LEFT: Africa Regional Capacity-building Workshop on Public Awareness, Education and Participation concerning the Safe Transfer, Handling and Use of Living Modified Organisms, 5 - 9 November 2012, Kampala, Uganda. RIGHT: Asia-Pacific regional training workshop on public awareness, education and participation concerning the safe transfer, handling and use of LMOs, 25 - 29 March 2013, Hanoi, Viet Nam

Risk Assessment and Risk Management

The Secretariat organized online discussions through the Open-ended Online Forum on Risk Assessment and Risk Management from 3 to 14 December 2012. The discussions were intended as a brainstorming exercise aimed towards the development of a package that aligns the Guidance on Risk Assessment of LMOs (e.g. the Roadmap) with the training manual "Risk Assessment of LMOs" in a coherent and complementary manner, for further consideration of the Parties.

Capacity Building

The Caribbean Sub-regional Workshop on Capacity-building for the effective implementation of the Cartagena Protocol on Biosafety took place from 4 to 8 March 2013, in Saint George's, Grenada. The workshop was attended by 25 participants. Participants discussed the Strategic Plan for the Protocol (2011-2020) and other recent developments under the Protocol, such as the Framework and Action Plan for Capacity-Building (decision BS-VI/3, annex I) and its potential role in facilitating national and regional level capacity-building efforts. They were also introduced to the following: the overview of the core requirements of the Nagoya — Kula Lumpur Supplementary Protocol on liability and Redress; measures required to implement the Supplementary Protocol at the national level; and the significance of ratifying or acceding to the Supplementary Protocol and procedures towards ratification and accession.

UPCOMING MEETINGS

28 October 2013 - 1 November 2013, Bolivia
TENTATIVE

Ad Hoc Technical Expert Group Meeting on Socio-Economic Considerations under Article 26 of the Cartagena Protocol on Biosafety

29 September 2014 - 3 October 2014, Pyeongchang, Republic of Korea
Seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP 7)

Photo: Sixth Meeting of the Conference of the Parties serving as meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 6), Hyderbad, India, 1-5 October 2012.

LEFT: COP-MOP6 Press Conference. RIGHT: CEPA fair during COP-MOP 6

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.