# BIOSAFETY PROTOCOL NEWS

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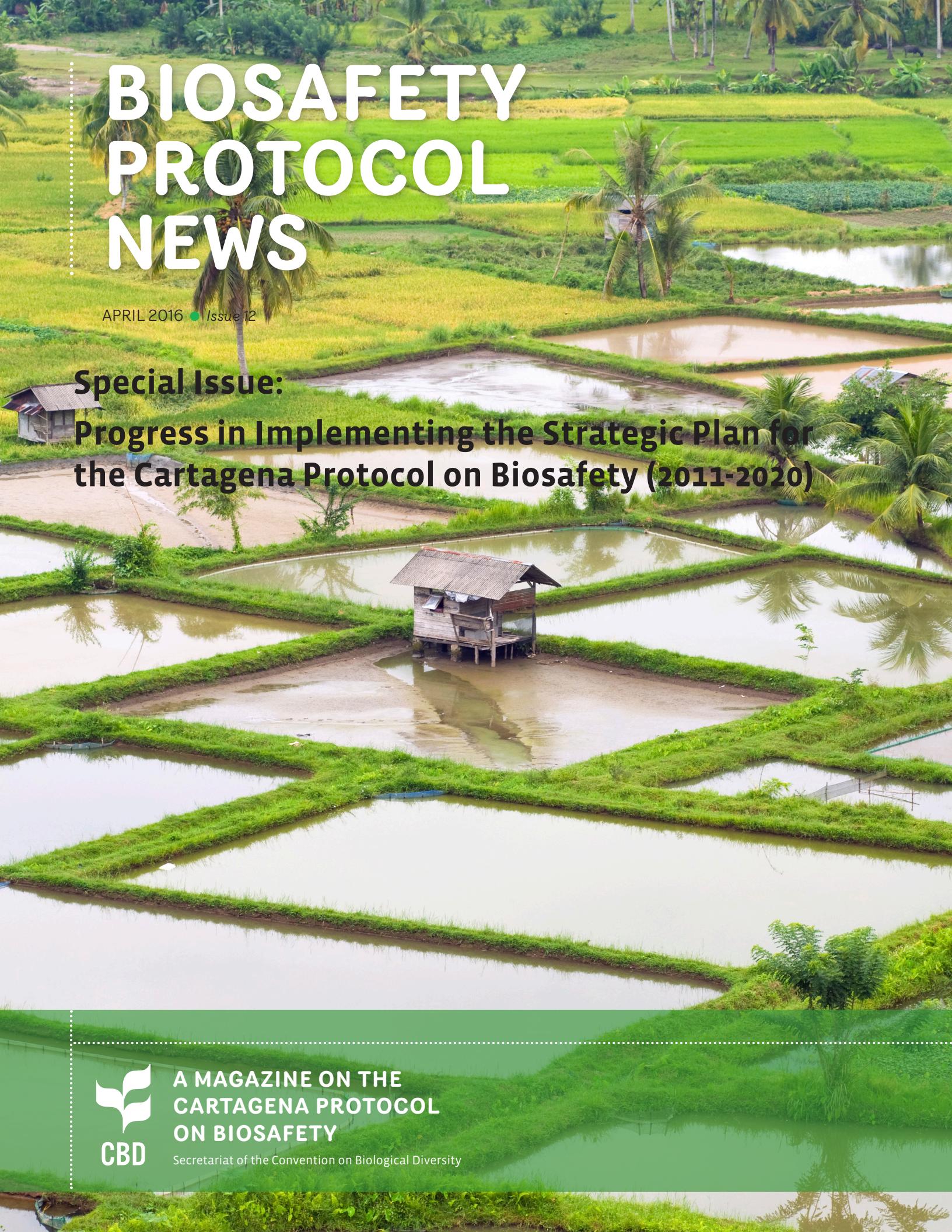
## Special Issue:
## Progress in Implementing the Strategic Plan for the Cartagena Protocol on Biosafety (2011-2020)



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CBD
Secretariat of the Convention on Biological Diversity

# BIOSAFETY PROTOCOL NEWS

APRIL 2016 ● *Issue 12*

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# Introduction

by **Braulio Ferreira de Souza Dias**

Executive Secretary, Convention on Biological Diversity

This special issue of the ***Biosafety Protocol News*** coincides with the preparations for the midterm evaluation of the Strategic Plan for the Cartagena Protocol on Biosafety, in conjunction with the third assessment and review of the Protocol, scheduled to be conducted at the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 8)[1]. Accordingly, the title of the issue is "Progress in Implementing the Strategic Plan for the Cartagena Protocol (2011-2020)".

The newsletter contains articles from all of the geographical regions of the United Nations and two organizations. Topics cover various aspects of implementation of the Protocol, in particular with respect to the operational objectives of the Strategic Plan. These issues include: National Biosafety Frameworks, risk assessment and risk management, handling, transport, packaging and identification, liability and redress, socio-economic considerations, unintentional transboundary movements, information sharing and the Biosafety Clearing-House (BCH), communication and outreach, including public awareness, education and participation and compliance with the Protocol.

This issue of the newsletter provides an in-depth review of the progress made and challenges encountered. Since the adoption of the Protocol in January 2000, many Parties have taken the necessary steps towards establishing legal, administrative, and other measures to implement their obligations under the Protocol. A comparative analysis of the second and third national reports on the implementation of the Protocol has indicated gradual progress. Further to the information provided in the national reports, the authors of the various articles elaborate more on their experiences and lessons learned. They also provide key recommendations that can assist stakeholders in their preparations leading up to COP-MOP 8.

Most contributors indicate that the development and implementation of legal frameworks is key to implementation of the Protocol. They also note the positive results that capacity-building projects make to biosafety systems (e.g. training materials, case studies, etc.)

Articles from Eastern Europe, Asia, and Africa provide valuable lessons on developing systems for communication, public awareness, education and participation, including access to information. The articles from Asia and the Global Industry Coalition (GIC) also provide experiences on the development and management of valuable national biosafety registries/clearing-houses as well as the Central Portal of the BCH.

Articles from Latin America and Eastern Europe also discuss experiences regarding the implementation of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress under the Protocol. These include the development of national administrative and legal instruments in order to have in place necessary response measures for potential damage to biodiversity caused by living modified organisms (LMOs).

An article from Western Europe highlights the importance of developing conceptual clarity on socio-economic considerations and to promote a better understanding of socio-economic considerations.

Three articles from West Asia, Africa and Easter Europe report on progress regarding handling, transport, packaging, and identification of LMOs, including the unintentional transboundary movement.

Articles from Asia, Africa and the GIC highlight work on risk assessment of LMOs under the Protocol, including training, consensus-building, developing guidance, and information sharing.

All contributors outline challenges regarding the slow implementation of biosafety systems. Lack of financial, technical, and institutional capacities are also highlighted. In addressing these challenges, there is recognition of the need to integrate biosafety into existing national, regional, and international environmental and sustainable development initiatives. In essence, biosafety needs to be better promoted as an environmental and sustainable development issue.

I would like to take this opportunity to thank all of the contributors to this issue of the newsletter. We need to enhance the implementation of the Protocol by minimizing the challenges that impede our activities. I urge Parties that have not submitted the third national report to do so as soon as possible. I also urge all Parties that have not yet done so to ratify the Supplementary Protocol prior to COP-MOP 8 to ensure its coming into force.

1 The Strategic Plan is available at: http://bch.cbd.int/protocol/issues/cpb_stplan_txt.shtml

# Socio-Economic Considerations under the Protocol: Experiences and Lessons Learned from Western Europe

NORWAY

by **Vidar Helgesen** ● **Minister of the Ministry of Climate and Environment.**
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In Norway, prior to the deliberate release of living modified organisms (LMOs), thorough scientific assessments of health and environmental effects must be carried out. In addition, the Norwegian authorities also assess socio-economic impacts, ethics, and whether the production and use of a given LMO may contribute to sustainable development. By establishing such a broad assessment approach, our aim is to contribute to the conservation and sustainable use of biodiversity. At the same time, our goal is to arrive at decisions that serve the common good and meet our societal needs.

In 2001, Norway was the third country to ratify the Cartagena Protocol on Biosafety. Under Article 26, Parties to the Protocol may consider socio-economic considerations when reaching national decisions regarding the authorization of LMOs. For Norway, through the Norwegian Gene Technology Act , the socio-economic dimension was already an integral part of LMO assessments in 1993.

## The Norwegian Gene Technology Act

In line with other international and national LMO regulations, issues related to environmental or health risks are of paramount importance within the Norwegian regulatory framework for LMOs. In addition to health and environmental safety, the Norwegian Gene Technology Act has provisions regarding sustainability, benefits to society, and ethics in the spirit of the Brundtland Commission's report: Our common future (1987) . Sustainability is a complex term that, in the Norwegian legislation, has been ascribed quite a broad meaning. Assessments of sustainability should be global and ideally cover longer periods, even generations. Along with social consequences and economic issues, the impacts on biodiversity is an important element of sustainability. In the Norwegian Act, "Benefit to society" is primarily linked to the societal benefits and disadvantages within our national borders. With its LMO regulation, Norway's aim is to encourage responsible innovation, reflect on global and long-term effects, and to contribute to sustainable development.

The provisions on the socio-economic criteria in the Gene Technology Act are present in the preamble, in Article 10 relating to approval, and in appendix four of the Regulations relating to impact assessment pursuant to the Gene Technology Act . This appendix contains, for example, checklists with socio-economic (and ethics/sustainability related) considerations that can be asked when assessing a given LMO. The Norwegian Parliament has recognized that applications on biotechnology may have profound effects on society. That is why the Act sets out that socio-economic considerations must be assessed prior to an approval. At the same time, neither the Act itself, nor its legislative history, provides any clear guidance as to how the socio-economic dimension is to be understood. However, it is clear that the assessment does not focus on the benefits to the manufacturer or applicant. Moreover, it goes beyond the consumers or direct users. It is also a matter of third-party considerations and whether people become affected on a broader scale, for instance by changes in employment opportunities.

## The Norwegian Biotechnology Advisory Board

The Norwegian Biotechnology Advisory Board is a key player in Norway for socio-economic considerations in the context of LMOs. The Board is an independent body consisting of 15 members appointed by the Norwegian government. The composition of the board reflects that complex social issues preferably are not only discussed by experts. This is why various stakeholders and non-professionals are also board members who bring diverse and valuable perspectives to the table.

The Board has a mandate to evaluate the social and ethical consequences of modern biotechnology and to discuss usage that promotes sustainable development. The Board is mentioned in the Gene Technology Act and has contributed substantially to the national operationalization of the Act . When assessing an LMO, the Board has developed an approach which asks relevant questions. Through this exercise, favourable or unfavourable social consequences may be disclosed.

Part of the checklist structure for socio-economic impacts is as follows:

1. Characteristics of the product
Is it reasonable to say that there is a demand or a need for the product?
Is it reasonable to say that the product will solve or help to solve a social problem?
Is it reasonable to say that the product is significantly better than similar products that are already on the market?
Is it reasonable to say that there are alternatives that are more suitable than this product for solving or helping to solve the social problem in question?

2. Production and use of the product
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities?
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in rural areas in particular?
Will the product have a positive effect on industrial development and wealth creation, including new employment opportunities, in other countries?
Will the product tend to create problems for existing production that should be maintained?
Will the product tend to create problems for existing production in other countries?

An evaluation of the socio-economic impacts of an LMO, and whether it is of benefit to society, is based on a discussion of the answers to the relevant questions asked. Note that the above-mentioned list is not exhaustive. On the other hand, some questions may be irrelevant for a particular case.

## National decisions

To date, socio-economic considerations have not been given decisive weight in Norwegian decisions regarding LMOs for the market. Norway has decided to prohibit the deliberate release of several LMOs based on a combination of arguments, being both linked to health and environmental issues and related to sustainability and socio-economic considerations. A "mixed bag of arguments" was also the case for the assessment which lead to approvals of genetically modified carnations. For such LMOs, sustainability effects and socio-economic considerations did not outweigh the fact that the environmental risk was negligible and that health risk was absent.

## Challenges

The lack of relevant data is a challenge for Norway when assessing LMOs and socio-economic impacts . That is why Norwegian authorities regularly request additional information from applicants. Furthermore, data may be non-conclusive or merely indicative of a possible effect. The Norwegian Environment Agency is currently cooperating with

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the Norwegian Biotechnology Advisory Board in order to develop more trait-specific guidelines for assessment of sustainability and benefit to society. This work may lead to a clearer and more focused approach in the Norwegian assessment of socio-economic impacts of LMOs.

Two recent reports from the Norwegian Biotechnology Advisory Board may also serve as a basis for further development of the framework. One report is on herbicide resistant genetically modified plants and sustainability and the other is on insect resistant genetically modified plants and sustainability . These reports include more comprehensive lists of parameters that may be relevant to a deeper assessment of sustainability issues. Also, GenØk, the centre for biosafety in Norway, has published reports on the operationalization of the criteria for sustainability, social utility, and ethics. For example, there is an examination of the social and ethical issues raised by possible cultivation of genetically modified potato with late blight resistance in Norway .

**The Biotechnology Advisory Board evaluates the social impacts of modern biotechnology and LMOs contribution to sustainable development**

## Further work under the Protocol

With reference to the Strategic Plan of the Cartagena Protocol, Norway and other Parties are committed, by the year 2020, to develop guidelines regarding socio-economic considerations. Once available, guidance should be applied by Parties, as appropriate. This work is highly welcomed by the Norwegian government. It is in line with our national Gene Technology Act and may guide us to a better operationalization of our own national Act. This is also why Norway supported and co-chaired a workshop on socio-economic considerations in India in 2011 and is contributing financially to the current Ad Hoc Technical Expert Group (AHTEG) on Socio-Economic Considerations.

## Recommendations

Today's knowledge base is uneven with major differences across countries and regions. There is also significant variation in the capacity to use data, information, and knowledge in policy development and decision-making. Together, we must try to fill these gaps. Let us ensure that modern biotechnology is utilized for the common good and is a useful tool for the conservation and sustainable use of biological diversity!

# Compliance and Review under the Protocol: Experiences and Lessons Learned from Central and Eastern Europe

THE CZECH REPUBLIC

by **Milena Roudna** ● **Advisor at the Ministry of Environment.**
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## National Legislation, its Implementation and Enforcement

Legislation is a basis for the successful implementation of international obligations. The safe use of genetically modified organisms (GMOs) in the Czech Republic is regulated by Act 78/2004 on the Use of Genetically Modified Organisms and Genetic Products. The Act covers LMOs for contained use, deliberate release into the environment and placing on the market. Since its entry into force in February 2004, it has been amended several times and in line with developments at the global (the Cartagena Protocol on Biosafety) and regional (the European Union) level. The last amendment was adopted by the Czech Government in December 2015 and the process of approval in Parliament is ongoing. This amendment transposes the EU Directive 2015/412 enabling member countries to restrict or impose a ban on planting of GMOs on their territory. As a member country, some EU Regulations are directly applicable in the Czech Republic (especially those related to food and feed, including labelling). To Act 78/2004 there is a corresponding Decree 209/2004, on Detailed Conditions for the Use of GMOs and Genetic Products, which is amended on an ongoing basis to be in line with the Act. Due to the diverse use of GMOs, relevant national legislation, including that of other sectors, needs to be respected and kept in line with developments in biosafety requirements.

The Ministry of Environment is the Competent National Authority and plays a crucial role in the implementation of legislation by handling notifications and regulating the use of GMOs. It does so in close cooperation with the Ministry of Agriculture (e.g. rules of coexistence, GM food and feed) and the Ministry of Health (e.g. risks to human health). The Czech Commission for the Use of GMOs and Genetic Products was established on the basis of the Act as an expert advisory body of the Ministry of Environment. It consists of scientists, representatives of administrative authorities and specialized organizations, including non-governmental organizations (NGOs). The Commission assists in the assessment of notifications, consultation on draft policy and legislative documents, consultations on non-compliance or remedial measures, in methodology of sampling and detection, and provides information on new scientific developments and emerging issues.

With regards to enforcement, the Czech Environmental Inspectorate represents the main authority and closely cooperates with several other authorized supervisory bodies.

## Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

The Czech Republic ratified the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Protocol in February 2012. The ratification was based on existing national legislation – namely, (1) Act 167/2008 on Prevention of Ecological Damage and its Remedies, (2) Regulation of the Government 295/2011 on the Way of Risk Assessment of Environmental Damage and Detailed Conditions of Financial Security, and (3) the basic Act 89/2012 – Civil Code. At the European level, Directive 2004/35/EC, on Environmental Liability with Regards to the Prevention and Remedying of Environmental Damage, is applicable.

## Information sharing and submission of data to BCH

The legislation of the Czech Republic covers the right of its citizens to information through the Act on Free Access to Information and the special Act on the Right to Environmental Information. Specifically, in the field of genetic modification, the Act on the Use of Genetically Modified Organisms and Genetic Products applies. The list of authorized users, decisions, relevant legislation and other important information regarding the use of GMOs is made available to the public and updated on the website of the Ministry of the Environment (www.mzp.cz) in Czech. Through the Ministry website and official bullitin boards of relevant regional authorities, the public is consulted during the authorisation process of field trials. Information regarding coexistence, food and feed is available at the Ministry of Agriculture website (www.eagri.cz). All relevant information is also submitted in the national BCH Portal (http://www.mzp.cz/biosafety) in English alongside both mandatory information required under Article 20 of the Cartagena Protocol and other optional information which is important at the national level (e.g. national guidelines, reference materials or publications). Certain information is available in the EU BCH to which the Czech national BCH provides a link.

SUCHÉ SKÁLY KOBEROVY/ UNSPLASH/CZECH REPUBLIC

MILENA ROUNDNA/REGIONAL TRAINING WORKSHOP ON BIOSAFETY ISSUES FOR THE COUNTRIES OF EASTERN EUROPE AND CENTAL ASIA ORGANIZED IN COOPERATION WITH FAO, CZECH REPUBLIC

### Communication, Education and Public Awareness

Communication is a prerequisite for the successful implementation of adopted legislation and regulatory measures. Communication needs to be developed at different levels, including among authorities, among decision-makers and experts, and with the public. Each of these levels require corresponding forms which respect national conditions.

In the Czech Republic, the Commission for the Use of GMOs and Genetic Products plays an important role in this respect. It enables discussion among representatives of authorities and institutions which are concerned with the use of GMOs. With regards to the public, an annual meeting is open to the public and is focused on key issues under the Protocol.

Education on biotechnology and biosafety is reflected in the curricula of Czech universities and special educational programmes. Elementary and secondary schools teaches these issues only in a broader context. Through their programmes, certain centres of environmental education contribute to the knowledge of teachers and children.

**The meetings of the Commission for the Use of GMOs and Genetic Products are open to the public once a year**

Public awareness can be enhanced in various ways, such as through media, publications and leaflets, meetings and workshops. From the Czech experience, cooperation proved to be very useful. The Czech Republic cooperates with the following:

- Professionals and civil society, NGOs, Local governments
- Nature conservation organizations and institutions
- Centres for environmental education Museums and similar institutions

### Support to Other Countries in Capacity Building

The Czech Republic has offered assistance on biosafety issues to other countries in the Balkans, Eastern Europe, and Central Asia. This bilateral assistance was offered on the basis of the requirements of other countries (e.g. in Macedonia). It was regional in the form of training workshops held in cooperation with the Food and Agriculture Organization and within national coordination between the Ministry of Agriculture and the Ministry of the Environment. Both forms were positively evaluated and the continuation of regional training workshops was recommended.

### Conclusion and Recommendations

The mission of the Strategic Plan for the Cartagena Protocol can only be achieved if appropriate measures are taken at the national level. Corresponding legislation is a basic step for further activities which should be followed up by implementation and enforcement measures.

Communication and cooperation among responsible authorities and implementing institutions is a prerequisite to a functioning biosafety system and successful implementation. Access to information and the sharing of information, as well as public awareness and education, play an important role of the Cartagena Protocol. Education in the field of biotechnology and biosafety can be incorporated into broader environmental education which can lead to greater support. Cooperation with universities, schools, centres of environmental education, civil societies and NGOs will attract broader audiences. Workshops, public events, and publications made available in the language of target groups are recommended ways of knowledge sharing.

Asistance to less advanced countries will enhance the implementation of the Strategic Plan at the regional and global level.

# The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Protocol: Experiences from Latin America

MEXICO

by **Claudia Colmenarez Ortiz** ● **Ph.D. candidate at the Department of European, Public and International Law, Faculty of Law at Gent University in Belgium and Independent Researcher for the Inter-ministerial Commission for Biosafety of GMOs. She can be reached at: Claudia.ColmenarezOrtiz@UGent.be**

## Overview

Mexico, like many other Parties to the Cartagena Protocol on Biosafety, has fully implemented domestic biosafety regulations but has made no significant progress on the issue of liability and redress under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol. For example, the implementation of domestic legislation, in compliance with the Cartagena Protocol, is operational while, on the other hand, the liability regulations are limited to comply with the minimum regulatory standards and response measures to address any 'environmental' or 'biodiversity' damage resulting from the use of LMOs.

Moreover, the ratification of the Supplementary Protocol faces some challenges: whether a Party or not, there is no international consensus on an ad-hoc definition of adverse effects on the conservation and sustainable use of biological diversity in this context (and these possible effects have not materialized yet). Therefore, in some other countries, where the full implementation of the Cartagena Protocol is a priority, the liability and redress issue is not considered with similar urgency.

| | | | |
|---|---|---|---|
| Focal area 1:<br><br>Facilitating the establishment and further development of effective biosafety systems for the implementation of the Protocol | Operational objective on Liability and Redress:<br><br>**To adopt and implement the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.** | **Indicator 1.5.2**<br>Percentage of Parties having in place national administrative and legal frameworks incorporating rules and procedures on liability and redress for damage caused by LMos. | Mexico has administrative and legal instruments that provide for response measures for damage to biodiversity resulting from LMOs. |
| Focal area 2:<br><br>Capacity building: To further develop and strengthen the capacity of Parties to implement the Protocol | Operational objective on Liability and Redress:<br><br>**To assist Parties to the Protocol in their efforts to establish and apply the rules and procedures on liability and redress for damage resulting from the transboundary movements of LMOs.** | **Indicators: 2.4.1** Number of eligible Parties that received capacity-building support in the area of liability and redress involving LMOs.<br>**2.4.2** Number of domestic administrative or legal instruments identified, amended or newly enacted that fulfill the objective of the international rules and procedures in the field of liability and redress. | Mexico has not received any financial and/or technical assistance for capacity- building in the area of liability and redress relating to LMOs.<br><br>Since the adoption of the Supplementary Protocol, domestic administrative and legal instruments have been identified as well as a newly enacted Law on Environmental Liability. |

## Context

The Strategic Plan for the Cartagena Protocol includes topics, which the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol (COP-MOP) may consider at its eight meeting, such as "To review the need for any guidance or assistance to Parties in their efforts to establish and apply the Supplementary Protocol and/or and national rules and procedures on liability and redress related to living modified organisms (LMOs)"[1].

Moreover, at COP-MOP7, one of the topics on the agenda was to raise awareness about the aims of the Supplementary Protocol in order to expedite its entry into force and encourage organizations to work towards the development of an explanatory guide on the Supplementary Protocol[2]. The latter reflects the fact that Parties are in need of guidance and capacity-building on liability and redress for biodiversity damage caused by LMOs.

Mexico signed the Supplementary Protocol on March 12, 2012 and ratified it on September 26, 2012[3]. Moreover, in its Third National Report on the Implementation of the Cartagena Protocol , Mexico provides the details and activities it has undertaken to implement the Supplementary Protocol. The following table reflects this information:

1 Decision BS-V/16 Strategic plan for the Cartagena Protocol on Biosafety for the period 2011-2020 Annex II Programme of Work of The Conference of The Parties Serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety For The Period 2012 2016, 2.3 (d)

2 Decision Adopted by the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on

Biosafety, BS-VII/11. Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress, Seventh meeting Pyeongchang, Republic of Korea, 29 September - 3 October 2014 UNEP/CBD/BS/COP-MOP/DEC/VII/11, para. 6,4, October, 2014

3 Third National Report on the implementation of the Cartagena Protocol on Biosafety, Record ID 109148, México

2015-11-02.

Mexico addresses damage to biodiversity in the Law on Biosafety of Genetically Modified Organisms (LBOGM) which specifically addresses, in Article 121 para. 1, civil liability for damage against persons and goods for GMO-related activities under the terms of federal civil legislation. In addition, under the same article, the LBOGM deals with environmental damage by providing that there is an assumption the misuse or mishandling of GMOs causes damage to the environment or biological diversity.

Moreover, the provisions laid down in Article 203 of the General Law for the Ecological Equilibrium and the Protection of the Environment establish the obligation to compensate in conformity with applicable civil legislation.

Finally, administrative sanctions will be implemented corresponding to acts or omissions which constitute infractions of this law in cases when these infractions constitute environmental crimes in accordance with the applicable provision in the Federal Penal Code[1].

Even though damage to biodiversity is addressed in Mexican legislation, capacity building measures should be implemented in order to properly define and evaluate damage. In particular, the Parties require, within the international approach, more guidance on implementing domestic law.

## Mexico has administrative and legal instruments that provide for response measures for damage to biodiversity resulting from LMOs

As explained above, capacity-building needs and priorities in the context of liability and redress have been partially addressed. The Supplementary Protocol also provides the basic elements to support the Parties in the implementation process. However, more assistance is needed in order to establish rules and procedures that address damage.

### Recommendations

In particular, the concept of damage and the definitions in the Supplementary Protocol should be discussed in further detail in compliance with the objectives of the Convention and the Cartagena Protocol. This should be done prior to addressing the operational provisions of the Supplementary Protocol.

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1 LBOGM Article 121 para. 7, Federal Penal Code Artícle 420 Ter.

# Unintentional Transboundary Movements of LMOs: Experiences from Central and Eastern Europe

SLOVAKIA

by **Miroslava Feketova, Tatiana Horecka and Natalia Mogelska**

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Nature has no borders so life, including living modified organisms (LMOs) may spread across national boundaries. It forces the proponents of LMOs to have appropriate guidelines that extensively address the issue of the transboundary movement of LMOs. Cooperation with neighbouring countries on environmental issues is correspondingly important.

The Slovak Republic is a small, land-locked country in the heart of Europe. There are several strong reasons for it to play an active role in cooperation on environmental issues, particularly with neighbouring countries: Slovakia is at the intersection of important ecosystems and therefore a host to rich biodiversity. Two Slovak sites, registered on the United Nations Educational, Scientific and Cultural Organization (UNESCO) list of world cultural and natural heritage sites, are transboundary nature sites. The deliberate release of LMOs or an accidental release (e.g. from a facility handling LMOs for contained use) may, in certain circumstances, give rise to an unintentional transboundary movement of LMOs. Accordingly, the Slovak legal system stipulates detailed rules on how to prevent or minimize the risks associated with such movements.

Only genetically modified organisms (GMOs) or genetic products authorised for placing on the market in the European Union (EU) may be imported or exported to and from the Slovak Republic. Furthermore, the entity responsible for LMOs for contained use may import or export GMOs if they are covered by the authorisation provided that they are exclusively intended for contained use. On the other hand, the entitiy authorised to import or export GMOs for other purposes than placing on the market is obliged to have the consent of the Ministry of Environment. Transboundary movements within the EU are considered neither as exports nor imports. However, such transport must be described in the notification for LMOs for contained use or deliberate releases of LMOs for other purposes than placing on the market, as appropriate (e.g. packaging, means of transport, emergency measures, etc.)

The authorisation recipient is obliged to ensure that no genetically modified material derived from field trials is placed on the market or causes an unintentional transboundary movement.

The isolation distance from the nearest field is not prescribed in the legislation. This is because it is crop-specific and therefore the distance is set on a case-by-case basis of individual authorisations. Genetically modified plants are usually destroyed at the trial site with the exception of samples that are taken for further analyses and are then destroyed afterwards. Handling of genetically modified material and waste management, as well as storage and means of transport, must be described in detail in the notification dossier.

Every entity that handles genetically modified seeds, cultivates plants or analyses them after harvesting must be authorised. From 2007–2013, the only experimentally grown genetically modified plant was maize with the exception of one sugar beet.

After its commercial release, a genetically modified plants may be grown on very large areas. However, the coexistence control and legal and precautionary measures concerning GM and non-GM agricultural crops in Slovakia are in force to avoid the unintended presence of GMOs in conventional and organic crops. The only transgenic crop currently authorized for commercial cultivation and grown in Slovakia is MON810 corn.

Since the first year of genetically modified crop cultivation in 2007, the coexistence concept in the Slovak Republic is obligatory for every farmer growing genetically modified crops. Nevertheless, from 2006–2011, small GM admixtures (the mean contamination level 0,07%) in harvested crops from neighbouring non-GM maize fields were observed. The contamination was caused due to a combination of factors such as contamination by sowing machines, harvesting machines, transport and storage. The appropriate corrective measures were applied[1].

1 Horváth, L. Horecká, T., Feketová, M. (2012) Cultivation of Biotech Crops, Control

JOHAN FOXX/THINKSTOCK

The inspection of GM fields and neighbouring conventional maize fields (including field characteristics such as distances, areas, flowering synchronicity and prevailing winds) and the sampling of harvested crops are conducted by the inspectors of the Central Control and Testing Institute of Agriculture (CCTIA). The Department of Molecular Biology (DMB) of the CCTIA is a reference laboratory for the control of coexistence. It is responsible for the detection, identification, quantification, and evaluation of LMO admixtures in harvested crops in non-GM fields. The DMB is a member of the Biosafety Clearing House Network of Laboratories for the Detection and Identification of LMOs. It is also is a member of the European Network of GMO laboratories (ENGL).

The main executive body on environmental policy is the Slovak Environmental Inspectorate (SEI) with countrywide responsibility for environmental compliance assurances, including enforcement of the Cartagena Protocol. Its responsibilities also concern trade in endangered species (under the Convention on International Trade in Endangered Species (CITES)) and access to genetic resources (under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS)). In this respect, cooperation between inspectors is an asset and, in a broader sense, information sharing is considered an integral part of the regulation. In cooperation with customs authorities, the SEI performs controls on transboundary movements of waste, dangerous chemicals and pesticides, endangered species, and LMOs.

The few events of illegal use of LMOs (e.g. zebra danios, rat, flax, soybean, and maize) occurred because the user had not recognized that the organisms were genetically modified. The sources of the illegal LMOs were discovered within the EU and therefore the cases have been dealt with in conformity with EU regulations. These measures taken were intended to stop the use the LMOs. Note, however, that this was done because the LMOs were illegal at the time and not because of the identification of any adverse effects.

of Co-existence and Environmental Monitoring of GM Plants in Slovakia, Plant Protect. Sci. Vol. 48.

The year 2016 marks the 15th year of Slovak biosafety regulation at the national level. The data gathered through inspections verified the effectiveness of isolation distances, technical rules, and production practices and support the conclusion that the state authorities are not aware of any serious illegal use of LMOs in the Slovak Republic, including unintentional transboundary movement.

**Coexistence controls as well as legal and precautionary measures concerning GM and non-GM agricultural crops are in force to avoid the unintended presence of GMOs in conventional and organic crops**

## Recommendations

The cooperation of inspectors from various institutions handling LMOs is an asset and the information sharing must be considered as an integral part of regulation in a broader sense. Communication at a personal level as well as the opportunity to compare and verify the experiences of control activities in international workshops is very valuable and in Europe possible due to the network for GMO inspectors and inspectorates – the European Enforcement Project on Contained Use and Deliberate Release of GMOs (EEP). We consider regional networks with the aim to exchange experiences on methodologies for inspection and enforcement very useful.

There is also one recommendation for the users of LMOs. They should not be afraid to contact the authorities for clarification in case of doubt as this feedback helps to improve the activity of authorities in the field of public awareness.

# Compliance and Review under the Protocol: Experiences and Lessons Learned from Northern Africa

TUNISIA

by **Kaouthar Tlichealou** ● **Executive Manager of the Agency of Protection and Land use Coastal Areas.**
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The Cartagena Protocol on Biosafety, ratified by Tunisia in 2002 , is an important instrument that ensures the safe transfer, handling and use of living modified organisms, commonly known as genetically modified organisms (GMOs)[1].

Being aware of the impact of rapidly expanding modern biotechnology on the economy and the environment, Tunisia was engaged in the process of developing a national biosafety framework (NBF). As a result, a number of initiatives took place as follows:

- The establishment of any institutes, schools, research centres and laboratories specializing in biotechnology;

- The agriculture, health, environment and industry sectors developed biotechnological approaches;

- The establishment of a National Gene Bank;

- The establishment of a permanent commission on GMOs; and

- Biosafety reflected in national interests

From 2007 to 2015, Tunisia took part in the United Nations Environment Programme – Global Environment Facility (UNEP-GEF) Project to support implementation of the NBF in Tunisia. The main objectives of the project were as follows:

- Integration of biosafety in the a national development strategy;
- Establishment and consolidation of a fully functional and responsive regulatory regime in line with other international obligations;
- Preparation of specific training guides and manuals on risk assessment of LMOs;
- Enhancement of the existing institutional facilities and infrastructures to undertake GMO detection and monitoring activities;
- Establishment of a mechanism for enforcement monitoring; and
- The promotion of public awareness and participation under the Protocol.

With regards to the national biosafety strategy, national consultative meetings were held to identify elements for strategic biosafety activities and to prepare and review the implementation of the Protocol.

## The National Legal Framework on Biosafety

The first legal framework was drafted in 2001. It contains two draft laws on as follows:

- The use, import, transit, and deliberate release of GMOs; and

- The direct use of GMOs for food or feed.

In 2005, the Ministry of Environment opted for one draft law for GMOs for contained use, GMOs for direct use for food or feed, transit of GMOs, and the deliberate release of GMOs.

However, up until 2009, no national consensus was reached between national departments in the Tunisian government. After meetings of the National Biosafety Committee (NBC), a draft law on GMO and GMO products was reviewed and adopted in Tunisia.

In 2011, after the Tunisian revolution, a new context emerged. By 2014, there was a better understanding of biosafety and biotechnology issues and the national technical biosafety commission drafted a new version of the law on biosafety that integrates the issues of pathogens and invasive alien species.

1 The Cartagena Protocol on Biosafety is an additional agreeement to the United Nations Convention on Biological Diversity. It was adopted in Montreal, 29 January 2000 and entered into force on 11 September 2003. It entered into force for Tunisia 11 September 2003.

In 2015, the government dedicated time to examine the drafts on invasive alien species and the related issue regarding liability and redress under the Protocol. Also, in 2014, a decree to create a National Authority on Biosafety was drafted. The objective of the National Authority on biosafety include:

- Coordinating of the National Network Laboratories for GMO detection and quantification;
- Maintaining the National Register of GMOs and their products approved at the national level;
- Amending the list of modern biotechnology techniques and methods for genetic modification and updating it on a regular basis;
- Preparing and updating the list of national experts in the field of biosafety in accordance with the requirements of the Protocol; and
- Facilitating the exchange of scientific, technical, environmental, and legal expertise in the field of biosafety.

### Monitoring and Enforcement

The competent national authorities in the Ministry of Environment in Tunisia (DGEQV) prepared methodologies and procedures for monitoring, inspection, and enforcement as follows:

- In 2012, three agreements were signed regarding capacity building that concerned a network of national laboratories for GMO detection and quantification, a central laboratory for analysis, a technical center of food analysis, and a laboratory of seeds at the Ministry of Agriculture.
- Stakeholders benefitted from overseas training which improved their expertise in investigating GMOs.
- Most of the equipment and laboratory items, e.g. biology molecular items (e.g. a GMO detection and quantification kit), was purchased for the national laboratories network for GMOs after having signed the conventions (the gene bank, the central laboratory for analysis, the technical center for food analysis, and the laboratory of seeds at the Ministry of Agriculture).

## A commission on biosafety communication and public awareness prepared an action plan

### Training

Over the last years, there was also a number of capacity-building training initiatives as follows:

- Series of training sessions and practical activities on sampling, detection and identification of GMO's organised in 2014 .
- The signing of the Network Laboratories Commission: an agreement for the implementation of the national Laboratories Network (GMO detection and quantification) in 2015 . This includes a biotechnology research center (e.g. Centre de Biotechnologie de Sfax (CBS)) for members of the network to contribute to scientific monitoring of GMOs.

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### Public awareness, education and participation

Regarding public awareness, education and participation under the Protocol, a number of activities took place over the recent years. From 2014 to2015, several meetings on public awareness were organized with the participation of nongovernmental organizations and other stakeholders, including the media . There was also an interactive CD-ROM on GMO's disseminated at different national events with a translated designed publication of technical guides.

Over the years, a strategy and action plan on biosafety was also developed. n 2014, a commission on communication and public awareness was established. One of the tasks is the preparation of an action plan regarding communication on biosafety soon to be adopted.

### Recommendations

To implement the biosafety legal framework and strategy, the main lessons learned experience is that Tunisian authorities should:

- Integrate biotechnology development and biosafety processes in the general national plan of development;
- Review national policies, laws, and regulations in the related sectors for subsequent implementation of the biosafety framework, particularly on control procedures and risk assessment;
- Develop a consultative approach to familiarize different stakeholders with the contents of the biosafety framework;
- Develop the national Biosafety Clearing-House;
- Ensure technical training on important issues under the Protocol, particularly on risk assessment and GMO detection;
- Facilitate the accessibility of biosafety information and elaborate on a national strategy for public awareness, education and participation under the Protocol;
- Encourage studies and research on biotechnology and biosafety; and
- Enhance coordination between the public and private institutions and other stakeholders on biosafety processes.

# Outreach and Information Sharing under the Protocol: Experiences and Lessons Learned from Asia

VIETNAM

by **Hoang thi Thanh Nhan** ● **Biosafety Clearing-House Focal Point and Emergency Measures Contact Point. She can be reached at: hoangnhan.bca1@gmail.com**

Vietnam became a party to the Cartagena Protocol on Biosafety in 2004. Since then, Vietnam has been obliged to comply with and implement all of the provisions of the Protocol.

To implement the Protocol, as well as to promote development and safe use of biotechnology in our country, the Government of Vietnam has issued a set of policies and regulations on biosafety. Up until now, a biosafety framework has been put in place. The Ministry of Natural Resources and Environment (MONRE) and the National Focal Point for the Cartagena Protocol on Biosafety have actively participated in the Central Portal of the Biosafety Clearing-House (BCH) which was established under Article 20 of the Protocol.

Thanks to the United Nations Environment Program (UNEP) and the Global Environment Facility (GEF), Vietnam took part in the first BCH project as well as add-on projects of the development and implementation of the national biosafety framework. Besides the establishment and operation of a national BCH, MONRE has formulated regulations to enable the operation of the national BCH and the participation of Viet Nam in the Central Portal of the BCH. It also raised awareness by carrying out a series of nation-wide training and outreach activities.

The creation of a legal environment to enable the operation of the national BCH and information-sharing mechanism on biosafety.

The information-sharing mechanism on biosafety and the public role in decision-making are key elements under the Protocol and detailed regulations are stipulated in the following legal documents:

- The Law on Biodiversity (2008) provides articles on publishing information on potential risks to biodiversity from genetically modified organisms (GMOs), genetic specimens of GMOs and corresponding management measures (Article 67).

- Decree No. 69/2010/ NĐ-CP, dated 21 June 2010, of the Government on biosafety management of GMOs, genetic specimens, and products of GMOs. It regulates: Labeling goods containing GMOs, GMO products; Security of information about GMOs; Disclosure of information about GMOs with respect to the environment, biodiversity, human and animal health; and Management of a database on GMOs. For example, with regards to disclosure of information, in the decision-making process for Certificates of Biosafety, in order for a Certificate must issued for a GMO to be used as food/animal feed, a risk assessment summary must be published on the website for public comments 30 days prior.

- Circular No. 09/2012/TT-BTNMT, dated 22 August 2012, from the Minister of Natural Resources and Environment on the provision and exchange of information and data on GMOs. This Circular provides specific provisions on figures, information and databases on GMOs, the development and management of a database on GMOs, and the posting, provision, exploitation and use of information.

These initatives give mandates to different organizations regarding the proper sharing of information on biosafety. Operating the National BCH and making use of the Central Portal of the BCH for sharing and using information

Since 2006, the MONRE has acted as the National Focal Point and has directed the development and operation of national BCH (www.antoansinhhoc.vn). The National BCH provides the following information:

- The system of biosafety management agencies;
- Procedures for granting licenses,certificates orconfirmation letters;
- Public comments on risk assessments of GMOs;
- A list of GMOs granted licenses of, for example, assays, certificates of biosafety,or confirmation of being qualified to be used as food and feed;
- Domestic and international news; and
- References for biosafety including, for example, a network of experts on biosafety, materials, publications, conferences, workshops.

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In accordance with the Protocol, the national focal point for the BCH also provides updated information on biosafety on the Central Portal of the BCH. Within the country, the MONRE has engaged competent national authorities in order to provide information. They have been trained on how to participate in the national BCH and the Central Portal. Vietnam's authorities also make use of information available in the Central Portal of the BCH, during the decision-making process on GMOs, such as information on risk assessments, decisions on the intentional release of GMOs into the environment or using them for food, feed and processing.

Vietnam has benefited from the information available in the Central Portal of the BCH regarding managing GMOs within the country

### Outreach and information sharing

Since 2006, the MONRE has been collaborating with other ministries and international organizations to conduct various workshops and training in order to enhance capacity and awareness for various stakeholders, including management of staff and researchers at the central and local levels.

Information on biosafety is also widely published through mass media.

Other outreach materials that are helping to improve biosafety awareness were also developed and distributed. They include, for example, frequently asked questions about GMOs and pocket books on fundamental knowledge about biosafety.

### Conclusion and recommendations

It has been more than ten years since Vietnam became a Party to the Cartagena Protocol and it has made significant efforts to fulfil its obligations as a Party. Vietnam has been prompt in providing updated information on biosafety in the Central Portal of the BCH. It has also conducted many other activities to share information and raise public awareness on biosafety. Furthermore, it has benefited from the information available in the Central Portal of the BCH for GMO management within the country. Current public awareness of biosafety issues has significantly increased.

So far, the Central Portal of the BCH has been operating efficiently and is a good tool for information sharing and learning among Parties and other stakeholders. This has been a good experience for other working thematic areas to draw upon, such as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.

In order to implement the protocol on biosafety effectively, we would recommend the Secretariat to continue facilitating the information-sharing mechanism on biosafety, using the current BCH to share best practices as a model for managing GMOs, providing outreach services of the Protocol to enhance relevant national and international stakeholders by making available on the BCH outreach materials on biosafety, providing training on outreach skills, as well as increasing understanding of the relationship between the Protocol and the Convention on Biological Diversity and other biosafety-related agreements.

# From Capacity Building to Biosafety Systems under the Protocol : Experiences and Lessons Learned from West Asia

LEBANON

by **Elsa Sattout** ● **Consultant on the CBD, CPB and ABS Protocol.**
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The Cartagena Protocol on Biosafety (CPB) was adopted in January 2000 and came into force on 11 September 2003. Since then, Parties in the west Asian countries have been assessing their biosafety systems and capacities while paving the way for the application of the required biosafety procedures for the Protocol's implementation. Putting in place national or regional biosafety systems, and strengthening existing capacities, are at the heart of effective implementation. Biosafety systems include risk assessment and risk management (Articles 15 and 16), information sharing (Article 20), and handling administrative procedures regarding the transfer and use of genetically modified organisms (GMOs) (Articles 7, 11, and 18). Strengthening existing capacities includes scientific and technical training in biosafety management and the use of risk assessment and biosafety management. In Article 22 of the Protocol, Parties "shall cooperate in the development and/or strengthening of institutional and individual capacities on biosafety and biotechnology for the purpose of the effective implementation of the protocol."

To date, all west Asian countries (namely Bahrain, Iraq, Jordan, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, and Yemen) have signed the Protocol. Since their ratification in 2003, countries in the region have been active in mobilizing efforts to develop national policies and laws for the implementation of the Protocol. Especially in Jordan, Lebanon, Syria, and Yemen, this was assisted by participating in the first cluster of the United Nations Environment Programme – the Global Environment Facility (UNEP-GEF) projects on the development of National Biosafety Frameworks (NBFs) and the countries national Biosafety Clearing-House (nBCH). However, in those countries, laws are still lacking, which are guidelines and effective tools for the implementation of the Protocol. Gaps remain at the administrative level where there is a need to foster cooperation between the national authorities involved in biosafety management. After 2010, countries in the Persian Gulf have recorded further achievements in preparation for the implementation of the Protocol. For example, in 2014 the Sultanate of Oman developed its NBF and law, the United Arab Emirates (UAE) recently initiated a series of activities aimed at the development of its NBF with related implementation tools, and Saudi Arabia and Qatar adopted temporary measures while awaiting the development of biosafety laws and other national tools for the implementation of the Protocol.

The NBFs of the west Asian countries have sought sound national policies which focus on:

(1) Promotion of sound and orderly research and development in the field of modern biotechnology;
(2) Minimization of the risks likely to be caused by products of modern biotechnology to ensure the protection of human health, biodiversity and the environment; and
(3) Regulation of the transboundary movement of the products resulting from modern biotechnology by establishing relevant policies, governance structure, and regulatory systems .

Parties are anticipating capacity-building programmes and systems to operationalize the implementation of their biosafety laws and NBFs.

Biosafety systems have been advancing at a slow pace. Few Parties in the region have developed their nBCH. Although Jordan, Lebanon, and Syria launched their nBCH (under either the UNEP-GEF NBF project or Biosafety Clearing-House I project), national nodes are still in great need of information and records indicative of the degree of effective implementation of the Protocol in the region. At another level, advances in handling procedures in countries stemmed from reliance on existing regulatory measures and standards. Also, in Kuwait, Oman and UAE, there are accredited laboratories and food safety laws on the labeling and detection of GMOs which define the range of acceptance. In Lebanon, the UNEP-GEF NBF project mobilized efforts to define a nationally accredited laboratory for GMO detection. In this context, through a Master of Science thesis on GMO detection in imported Food and Feed for Processing (FFPs) an accredited laboratory at the American University of Technology and Science (AUST) was used to set up protocols for the detection of GMOs. Post-graduate research studies

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have contributed to strengthening technical capacity in applied biotechnology research. Additionally, a regional project, undertaken by the Food and Agriculture Organization (FAO) between 2011 and 2013, targeted the Northern Arabian Peninsula and upgraded existing systems on GMO detection and improved existing tools. This paved the way for Risk Assessment and Risk Management (RARM). However, there is still a lot to implement in the field of RARM throughout the region.

The first cluster of UNEP-GEF projects on NBF initiated a series of activities that raised awareness on the CPB and biosafety. Capacity-building needs have been assessed and plans for related programs have been integrated in the NBFs of Parties including in Lebanon, Syria, Jordan, and Oman. While mechanisms for RARM have been put in place in Jordan, training activities on RARM are few. Only one training activity was reported in each of these countries: Bahrain, Iraq, Lebanon, Oman, and UAE. Therefore, national strategies and detailed action plans are still needed in order for government agencies and academic/research institutions to strengthen their systemic, institutional, and technical capacities in the field.

Diversity of scientific communities in the region is at the heart of advancement in biotechnology. However, there is still a need for astrong foundation of an enabling environment to integrate biosafety practices in the existing regional networks (e.g. at www.plantgenetic.com) and to develop inclusive national and regional plans which combine practices in biotechnology with biosafety management. While countries have been striving to strengthen technical capacity in biotechnology and to execute research projects/studies, they are still lacking the long-term vision for a framed research agenda integrating RARM capacity building and better operationalization of the nBCH. Regional networks that have been established over the past few years remain having minor interactive information and lack the strong leadership required to fill in the existing gaps in regulatory measures related to biosafety. The perpetual evolution of the science of biotechnology and the slow pace of advancement in biosafety are keeping Parties in the region behind what is needed to move forward. At present, the Regional Plant Genetic Resources Knowledge and Innovation Network Platform for Near East and North Africa is comprised of nine countries. This virtual platform gathers professionals and practitioners working on plant genetic resources related to sustainable agriculture and food security. The existing network provides a space for information sharing between the institutions in the member countries and plays a leading role in boosting efforts for the effective implementation of the Protocol.

**The Regional Plant Genetic Resources Knowledge and Innovation Network Platform for Near East and North Africa is a platform for professionals of plant genetic resources. It facilitates information sharing between the institutions in the member countries and plays a leading role in boosting efforts for the effective implementation of the Protocol.**

## Recommendations

The challenges in implementing the Protocol still weigh on government officials in west Asian countries. On top of the overwhelming agenda, with few allocated officials, and instability in the region, the availability of funds dedicated to the implementation of the Protocol hinders advancement in some countries. On another general note, there is a sense that climate change has taken over the GEF budgeting agenda for countries. It is crucial that Parties maintain momentum with strong leadership to improve the governance aspect, communication, and technical implications of the implementation of the Protocol. It could be that only a spoonful of guidelines on how to boost the Protocol and its implementation is what is needed in the west Asian countries! These could stem from a regional initiative undertaken by existing centers and institutions. The existing regional institutions and networks, either those independent or affiliated to universities and governments, can play a major role in encouraging the adoption of a culture supportive of biosafety in labs and elsewhere.

# Risk Assessment under the Protocol: Experiences and Lessons Learned from Industry

## THE GLOBAL INDUSTRY COALITION

by **Thomas E. Nickson** ● **Chair of the Global Industry Coalition Risk Assessment Workgroup.**
**He can be reached at: thomas.nickson@monsanto.com**

The Biosafety Clearing-House (BCH) was established under Article 20 of the Cartagena Protocol on Biosafety (Biosafety Protocol) as a primary mechanism to facilitate the exchange of biosafety information related to living modified organisms (LMOs). At their second meeting, Parties to the Biosafety Protocol initiated a process aimed at compiling information, submissions, and expert inputs on experiences related to implementing Article 15 (risk assessment) and Article 16 (risk management) of the Biosafety Protocol in order to support national implementation efforts by Parties in these areas.

Since that time, the Global Industry Coalition (GIC) has compiled and submitted information on risk assessment and risk management, as well as on a number of other topics, through the BCH[1]. Additionally, the GIC has actively been engaged in multiple fora including online and face-to-face meetings of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEGs) and the discussion groups of the Open-ended Online Expert Forum on Risk Assessment and Risk Management (Online Forum). Our goal has been to share best practices and state-of-the-art, science-based information on risk assessment and risk management to support the work of the Secretariat in assisting Parties in the implementation of Article 15 and 16.

Below are brief reflections and recommendations on the ongoing process to develop guidance on risk assessment and risk management as mandated by Parties at every Conference of the Parties serving as the meeting of the Parties (COP-MOP) since its fourth meeting in 2008.

We are currently witnessing experts debating over widely divergent ideas on risk assessment of LMOs under the Biosafety Protocol. Experiences among the participating experts varies widely, from academic involvement and critical analysis to the real-world experiences of writing, submitting and conducting risk assessments for, and by, regulatory authorities. Over the years, numerous versions of the non-binding guidance ("the Guidance on Risk Assessment of LMOs") and training materials have been drafted and "tested" multiple times without achieving consensus (most recently by 43 Parties, 3 non-Parties, and 10 organizations (see: http://bch.cbd.int/protocol/testing_guidance_RA.shtml).

After the last meeting of the AHTEG in Brasilia, in November 2015, several difficult but significant issues remained unresolved and they have been sidelined for the time-being. However, time to resolve these issues is short since the results of these efforts will be considered at the next COP-MOP in December 2016 in Cancun, Mexico.

In the face of highly divergent views of the Guidance, the Secretariat and the Chair have worked very hard to find an agreement. As mentioned, efforts to improve the Guidance took the form of multiple rounds of "testing" by Parties and other stakeholders. In addition, smaller sub-working groups have been tasked to resolve or accommodate many challenging elements of the Guidance. If bringing the roadmap to some definitive endpoint was not challenging enough, recent mandates from Parties have been interpreted as calling for additional work. This includes the development of further guidance materials on special topics (listed below), prioritization of more topics for guidance (listed below), as well as a mechanism to annotate guidance documents with relevant references into documents and develop training materials based on the (as yet uncompleted) guidance:

Proposed Further Guidance: (a) risk assessment of living modified plants with stacked genes for traits; (b) risk assessment of living modified plants with tolerance to abiotic stress; (c) risk assessment of living modified trees; (d) post-release monitoring and long-term effects of LMOs released into the environment; and (e) risk assessment of living modified mosquitoes.

Proposed Topics for Guidance: (a) risk assessment of living modified trees; (b) risk assessment of living

1 The GIC receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.


ALEX AHOI/UNSLASH/SCHUPPEN 52, HAMBURG, DEUTSCHLAND

## GIC's engagement in implementation of the Protocol was through sharing years of experiences and information on risk assessment and risk management of LMOs

microorganisms and viruses; and (d) risk assessment and risk management in specific receiving environments.
The AHTEG continues to work through a combination of online and face-to-face exchanges to address the challenging issues that remain in the Guidance Document. After first achieving consensus, perhaps the second greatest challenge this AHTEG will face will be to complete the job of resolving and/or accommodating the numerous and disparate comments and suggestions received as a result of the testing. Efforts are again being made to create a process to manage this challenge.

Nevertheless, the question remains whether it is possible for all of the contradictory suggestions to be reconciled and if, in the end, guidance will be produced that is useful and grounded in real-world experiences.

The GIC will continue to support national implementation of the Biosafety Protocol, including Articles 15 and 16. Our engagement in implementation through discussions on risk assessment and risk management has focused on sharing our years of experiences in this area. We also draw upon information from others with relevant experiences. We have engaged in these fora with the intention of supporting outcomes and work products that provide maximum value to the largest number of Parties under the Biosafety Protocol.

### Recommendations

The GIC recommends that:

- Parties recognize the importance of sharing experiences in conducting risk assessments that formed the basis of their decision-making, particularly by those Parties and other government with extensive experience in this area. With this information, the AHTEG can ensure that any guidance developed accurately reflects these experiences. Furthermore, focus should be placed on developing foundational guidance that reflects a consensus among experts. If this can be achieved then the need for additional guidance can be better determined and subsequently developed.

- Guidance developed through the expert processes must accurately reflect and clearly communicate how risk assessment has been used in decision-making. In this way, a final guidance will serve the needs of Parties for information to implement, based on real-world experiences, Article 15 and 16.

The GIC looks forward to continuing the work on these important articles in the lead-up to the next COP-MOP in December 2016.

SEIYA KAWAMOTO;/THINKSTOCK

# Useful Information

LAURIN RINDER/THINKSTOCK

SCBD e-Learning Platform

## E-learning Modules

- Access to Information
- Public Participation

Soon available at the CBD website


## New Tools - Programme of Work on PAEP

Aarhus Convention/CBD Checklist and Tools Document

National Communication Plan Template

http://bch.cbd.int/onlineconferences/portal_art23/pa_main.shtml

## NBSAPs Forum on Biosafety

Mainstream Biosafety into National Biodiversity Strategies and Action Plans, please join us.

http://nbsapforum.net/#categories/340

## Annual Exhibition at the Redpath Museum, McGill University, Montreal

May 2015

Highlighting:

The UN Decade on Biodiversity and the International Day of Biodiversity

4000 visitors


## Fair at COP-MOP 7

Presentation:

The Republic of Korea

https://www.cbd.int/mop7/cepafair/default.shtml

## Online Discussions

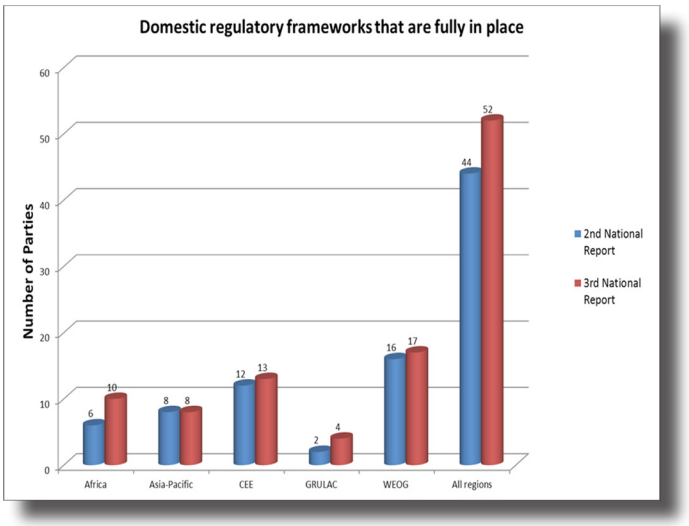
- Discussion groups on public participation regarding LMOs
- Online discussions on detection and identification, including unintentional transboundary movement and sampling, detection and identification of LMOs
- Open Ended Online Forum and AHTEG on Risk Assessment and Risk Management of LMOs
- Open-ended online forum on the issue of synthetic biology
- Online discussions for the FAO-CBD-OECD on databases

For more updates, please review the bi-annual reports at https://www.cbd.int/secretariat/qr/default.shtml

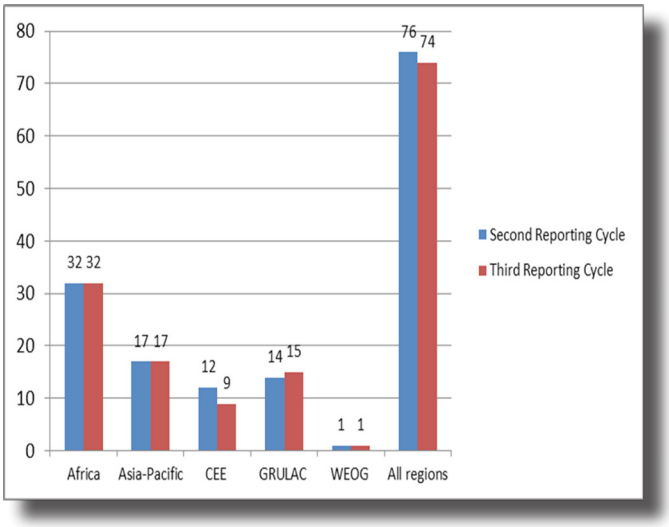
893 Likes, please join us at https://www.facebook.com/UN.Biosafety

# Statistics

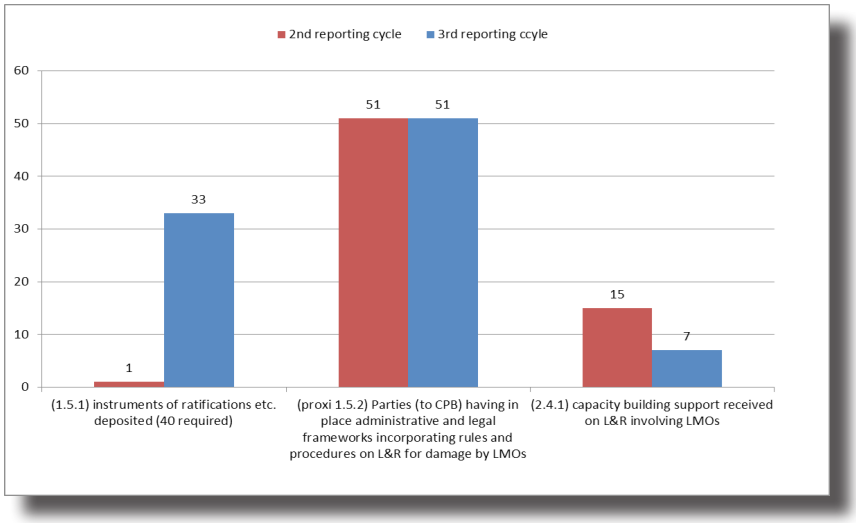
## Domestic regulatory frameworks




## Capacity-building needs




## Implementation of Liability and Redress (Operational objectives 1.5 and 2.4)




**Source: National reports at http://bch.cbd.int/database/reports/**

# Recent and Upcoming Biosafety Events

## Events related to the Strategic Plan for the Protocol

### COP-MOP 7

In its decision BS-VII/3, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) decided to undertake, at its 8th meeting, the third assessment and review of the effectiveness of the Protocol and the mid-term evaluation of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011-2020, drawing upon information from the 3rd national reports as a primary source, the BCH and, where appropriate, additional data collected through dedicated surveys.

In the same decision, COP-MOP requested the relevant subsidiary body (i.e. the Subsidiary Body on Implementation) entrusted with the task of reviewing the implementation of the Protocol, including contributions from the Liaison Group on Capacity-Building and input from the Compliance Committee.


### Capacity-building

In response to the above decision, the 11th meeting of the Liaison Group on Capacity-building for Biosafety was convened, in Montreal, from 14 to 16 March 2016, to review the analysis of the status and trends in the implementation of the Protocol prepared by the Secretary and considered general conclusions and recommendations to the Subsidiary Body on Implementation (when and where)

The Liaision group discussed the status and trends in implementing the Protocol and decided on some draft conclusions and suggestions on the possible way forward.

### Compliance Committee

The 12th Committee Committee meeting (where and when) discussed the COP-MOP 7 decision, BS-VII/3, and agreed on the scope of the input it would provide into the 3rd assessment and review of the Protocol and the mid-term evaluation of the Strategic Plan, taking into account the role of the Liaison group on capacity-building and the Subsidiary Body on Implementation. The Committee agreed on the focus of its input.

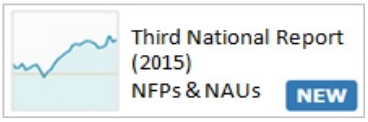
The 13th Compliance Committee meeting, 13-15 May 2015, in Montreal, evaluated the status of implementation of the Protocol in meeting its objectives.

To assist the Committee provided an analysis of information from third national reports and presented findings against the baseline established in the context of the second assessment and review completed by COP-MOP at its 6th meeting and through a survey on the Strategic Plan carried out after the 6th meeting to gather information corresponding to indicators in the Strategic Plan that could not be obtained from the second national reports or through other existing mechanisms.

The Compliance Committee is preparing a report, including recommendations, for submission to COP-MOP 8.

### The Biosafety Clearing-House

The Secretariat has developed an analyser tool which allows the responses provided by Parties in their third national reports to be compared with the responses provided by the same Parties in their second national reports and the survey. The analyser tool is available at http://bch.cbd.int/database/reports/




The 11th meeting of the Liaison Group on Capacity-building for Biosafety

The 12th Committee Committee meeting

## Mainstreaming Biosafety

The Secretariat has held six workshops on mainstreaming biosafety into National Biodiversity Strategies and Action Plans and Resource Mobilization since 2014. The overall objective of the workshops was to strengthen the capacity of Parties in the respective regions to integrate biosafety into NBSAPs and national development plans and mobilize resources for the implementation of the Protocol in line with the Strategic Plan for the Protocol and the relevant Aichi Biodiversity Targets. They also aimed to improve understanding of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

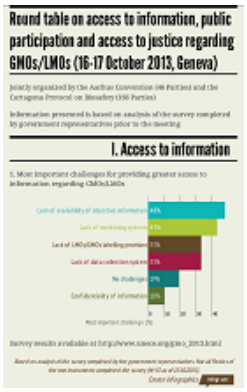
## Other Meetings

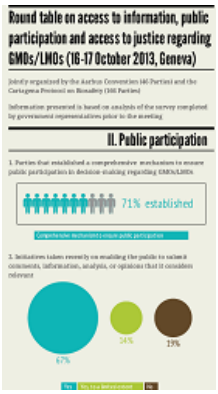
- Tenth meeting of the Informal Advisory Committee on the Biosafety Clearing-House, 11 - 12 April 2016, Ispra, Italy
- Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management, 16 - 20 November 2015, in Brasilia, Brazil and 2 - 6 June 2014, in Bonn, Germany
- Meeting of the Ad Hoc Technical Expert Group on Synthetic Biology, 21 - 25 September 2015, in Montreal, Canada
- Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms, 9 - 11 June 2015, in Ispra, Italy
- Ninth meeting of the Informal Advisory Committee on the Biosafety Clearing-House, 2 - 4 April 2014, in Ispra, Italy
- Ad Hoc Technical Expert Group Meeting on Socio-economic Considerations, 17 - 21 February 2014, in Seoul, Republic of Korea
- Round table on access to information, public participation and access to justice regarding LMOs/GMOs, 16 - 17 October 2013, in Geneva, Switzerland

Survey results from the Roundtable are available at:

http://www.unece.org/index.php?id=31702#/

Left standing: Chair: Mr. Joachim Kreysa of the tenth meeting of the Informal Advisory Committee on the Biosafety Clearing-House




Co-Chairs at the AHTEG meeting on Socio-economic Considerations

From right: SCBD: Kathryn Garforth and Co-Chairs: Mr. Andreas Heissenberger from Austria and Ms. Ranjini Warrier from India


Group meetings at the AHTEG meeting on Socio-economic Considerations

## Upcoming Meetings

- Tenth meeting of the Informal Advisory Committee on the Biosafety Clearing-House, 11 April 2016 - 12 April 2016, in Ispra, Italy
- Ad Hoc Technical Expert Group on Risk Assessment and Risk Management, 25 July 2016 - 29 July 2016, in Mexico City, Mexico
- First meeting of the Subsidiary Body on Implementation (SBI 1), 2 - 6 May 2016, in Montreal, Canada
- Second round table on access to information, public participation and access to justice regarding LMOs/GMOs, 15-17 November 2016, in Geneva, Switzerland
- Eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP8), 4 December 2016 - 17 December 2016, in Cancun, Mexico

## Other Upcoming Events

- COP-MOP 8 Fair in collaboration with the CEPA COP 13 Fair
- International Day for Biodiversity, 22 May 2016, on Mainstreaming Biodiversity; Sustaining People and their Livelihoods. Review information at https://www.cbd.int/idb/2016/ and submit any relevant biosafety messages by 1 May 2016 to ulrika.nilsson@cbd.int
- Annual exhibition at the Redpath Museum, McGill University, to promote biosafety and sustainable development, 29 May 2016

636 subscripers to the newsletter, please join at: https://bch.cbd.int/member/subscriptions.shtml

Campaing to Join the IBD celebration


## Other non-SCBD Meetings and Events

-The 11th Session of the Commission on Phytosanitary Measures (CPM - 11), 4 to 8 April 2016, in Rome, Italy

-OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 13-15 April, 2016, in Paris, France

-International Mother Earth Day, 22 April

-83rd General Session of the World Assembly of OIE Delegates, 24-29 May 2015, in Paris, France

-Second meeting of the UN Environment Assembly, 23 – 27 May 2016, in Nairobi, Kenya

-Symposium on EuroAsian Biodiversity, 23 – 27 May 2016, in Antalya-Turkiye

-8th Trondheim Conference on Biodiversity, 30 May-3 June 2016 , in Trondheim, Norway

-154th Session of FAO Council, 30 May-1 June 2016, in Rome, Italy

-World Environment Day, 5 June 2016

-2nd International Conference on Food Safety and Regulatory Measures, 6-8 June 2016, in London, UK

-50TH GEF Council, 6-9 June 2016, in Washington DC

-International Conference on Plant Physiology & Pathology, 9-10 June 2016, in Dallas, USA

-Committee on Sanitary and Phytosanitary Measures, 6- 7 July 2016, in Rome, Italy

-High Level Political Forum on Sustainable Development (under ECOSOC), 11-20 July, 2016, in New York, USA

-International Youth Day, 12 Auguest 2016

-7th International Crop Science Congress, 14-19 August 2016, in Beijing, China

-United Nations Day for South-South Cooperation, 12 September 2016

-4th Annual South Asia Biosafety Conference, 19-21 September 2016, in Hyderabad, India

-25th Session FAO Committee on Agriculture (COAG), 26-30 September 2016, in Rome, Italy

-R-Biopharm: Workshop on Detection of pathogens and genetically modified organisms; detection of animal species, 26-28 September 2016, real-time

-World Bank Annual Meeting, 7-9 October 2016, in Washington, D.C.

-International Day of Rural Women, 15 October 2016

-World Food Day, 16 October 2016

-43rd Session FAO Committee on World Food Security, 17-22 October, 2016, in Rome, Italy

-United Nations Day, 24 October 2016

-103rd Session FAO Committee on Constitutional and Legal Matters, 24-26 October 2016, in Rome, Italy

-51ST GEF Council, November 2016, in Washington D.C.

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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.