Workshop: Strengthening Asia's Participation in MOP8
24 – 26 October 2016, Kuala Lumpur, Malaysia

Chair's Notes

The workshop: "Strengthening Asia's Participation in MOP8" was held from 24 – 26 October 2016 in the Malaysian Agriculture Research and Development Institute (MARDI) in Serdang, Malaysia.

Aim of the workshop was to facilitate the participation of Asian scientists and other stakeholders in the upcoming 8th Meeting of the Parties to the Cartagena Protocol on Biosafety (MOP 8), which will be held from 4 to 16 December, in Cancun, Mexico.

The workshop was organized by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), in partnership with the Public Research and Regulation Initiative (PRRI), Malaysian Agricultural Research & Development Institute (MARDI), the Malaysian Biotechnology information Centre (MABIC) and Agricultural Biotechnology Institute of Malaysia (ABI).

The over 55 participants from 12 countries in the region included government officials, public sector scientists and other stakeholders with an interest in the implementation of national and international biosafety frameworks. Resource persons from India, Japan, MABIC, PRRI, USDA, and the private sector also participated in the meeting.

The participants were welcomed by Dr. Umi Kalsom Abu Bakar, DDG MARDI, who underlined the importance of agricultural research as countries wish to rely less on importation and produce more themselves. She referred to the promising next generation of young scientists and the need to train them in overcoming regulatory hurdles. In joining the welcome of the participants, Dr. Norihan Mohd Saleh, Director ABI, illustrated that modern biotechnology can contribute to the conservation of biological diversity and that the ABI was established under Malaysia's biotechnology policy. She mentioned that much work is still in the lab and greenhouse phase, and that overcoming regulatory hurdles is essential.

The Chairman of the workshop, Dr. Randy Hautea of ISAAA, briefly introduced the topics of the workshop:

- The role of modern biotechnology in the conservation and sustainable use of biodiversity
- The Convention on Biological Diversity (CBD)
- The Cartagena Protocol on Biosafety (CPB) and Meetings of the Parties to the CPB (MOPs)
- Main characteristics of functional national biosafety systems
- Key items on the agenda of MOP8:
- Related topics 'beyond the CPB'
- Regional collaboration.

Below are the Chair's notes on the main topics of the workshop. These notes are written in accordance with the 'Chatham House Rule, i.e. they reflect what has been said, but no who said what. These notes

are produced with the intention of giving a flavour of the presentations and the discussions, but are not intended to suggest consensus among participants.

Role of modern biotechnology in the conservation and sustainable use of biodiversity

With reference to Chapter 16 of Agenda 21 (1992), an introduction was given on modern biotechnology and how it relates to traditional breeding techniques. Modern techniques rely on knowledge gained since 1950s, e.g. DNA role in heredity, tissue culture, enzymes for DNA replication, repair, etc. several techniques were discussed, such as recombinant DNA techniques (cutting and splicing) and the newer techniques such as gene editing that allow even further precision.

Both conventional and modern techniques aim at addressing certain needs, e.g.: Farmer-oriented traits (e.g. Resistance to pests or drought, performance), processing traits (e.g.: altered composition), and consumer-oriented traits (e.g. flavour, nutrition).

The results of the use of conventional breeding and modern techniques can be categorized as:
- Mixing genes between sexually compatible organisms: e.g.: cross breeding, hybrids, MAS.
- Mixing genes between related species that do not cross breed naturally: e.g.: embryo-rescue.
- Introducing traits from an unrelated organism: e.g.: genetic modification/genetic engineering.
- Generating additional variation within existing genomes: e.g.: mutation breeding, genome editing.

The discussion in the workshop focused on examples various applications and lines of research conducted by participants that can contribute to the conservation and sustainable use of biodiversity.

Topic: The Convention on Biological Diversity (CBD).

The objectives of the CBD are:

- the conservation of biological diversity,
- the sustainable use of its components and
- the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.

As regards biotechnology, the CBD states in article 16 that access to and transfer of technology, including biotechnology, are essential for attaining the objectives of the CBD. Article 19 (*"Handling of Biotechnology and Distribution of its Benefits"*) specifies the obligations to engage in such technology transfer.

That article 19 of the CBD is also the legal basis for the Cartagena Protocol on Biosafety (CPB), which states in its preamble that "*modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health*".

Topic: Characteristics of national regulatory frameworks for biosafety.

National biosafety regulations typically have the following structure:

- *General provisions*, e.g.: Objective, scope, definitions, general obligations
- *Operational provisions* for different categories of activities, e.g.: contained use, release into the environment, placing on the market, import, export. Different procedures may apply to different categories: e.g. standard requirements for handling (e.g. laboratory work), notification requirements (with or without waiting period), and authorisation requirements.
- *Other/Final Clauses*: e.g.: public information/participation, confidential information, inspections and enforcement, review and assessment of the regulatory framework, coming into force, etc.

Topic: The Cartagena Protocol on Biosafety (CPB) and Meetings of the Parties to the CPB (MOPs)

The CPB offers Parties that do not yet have domestic regulatory frameworks for biosafety in place, mechanisms for making informed decisions on transboundary movement of Living modified Organisms (LMOs), as well as international agreement on key aspects such as risk assessment and information sharing through the Biosafety Clearing House (BCH).

The approach of the CPB is similar to that of many national and regional biosafety systems: i.e. there is a general obligation for operators to conduct a risk assessment for activities covered by the regulation, and to apply any risk management measures indicated by the risk assessment.

The default CPB procedure for transboundary movement (TM) of LMOs for intentional introduction into the environment, is a stringent authorisation procedure, called the Advanced Informed Agreement procedure (AIA). Yet, the CPB also offers possibilities for establishing simplified procedures (such as notification procedures) and exemptions. The CPB does not require that the AIA procedure is taken as the default procedure for domestic regulations.

The CPB is structured as many national biosafety regulations with different types of provisions:

- **General provisions**, e.g.: Objective, scope, definitions, general obligations.
- **Operational provisions** *for specific cases of transboundary movement* as well as some *general rules pertaining to the operational rules.*
- **Other/Final Clauses** pertaining to the overall functioning of the CPB and MOPs.

Since the Protocol entered into force in 2003, seven Meetings of the Parties to the Protocol (MOPs) have been held. The next meeting, MOP8, will be held in Cancun, Mexico from December 4–17, 2016, in parallel with the 13th Conference of the Parties (COP13) to the CBD and the 2nd Meeting of the Parties (MOP2) to the Nagoya Protocol on Access and Benefit Sharing.

MOP8 agenda item 11: Risk Assessment and Risk Management (article 10 and 15 and Annex III CPB)

The discussion in the workshop focused on the draft guidance and on the draft MOP decisions to endorse the draft Guidance on risk assessment, to recommend its use, and to produce further guidance on LM Fish and SynBio.

The Draft Guidance: observations were made that the draft Guidance is very long, detailed and not easy to read, particularly for novice risk assessors. In addition, some participants noted that quite a number of the comments raised in the testing phase were not yet addressed. Several examples were given, e.g.: under the section "protection goals" it is stated: *"At the beginning of a risk assessment, components of the environment – species, habitats, services, etc. – that are valued by civil society and/or protected by relevant laws or policies are identified.*" The observation was made that this is not how risk assessment typically starts and that there is in fact little point in listing all the valued and protected components of the environment if there is no scientifically plausible scenario for interaction with the GM crop. Another comment was that the section on uncertainty gives the incorrect impression that we 'know nothing of nothing', rather than recognition that addressing uncertainty is a standard part of any scientific report, whether it is about LMOs or otherwise. A further observation was that the sections explaining the steps in the risk assessment just list points to consider without giving any guidance in which types of cases which points will be relevant, to be able to focus on 'need to know' rather than 'nice to know'. Several participants said that they would use their own national guidance instead. Another comment was made that in line with what the draft document itself says, it should not be called 'guidance' but rather 'reference document'.

It was recommended that people carefully read the entire guidance and discuss with colleagues at home.

Endorsement: There was quite some discussion in the workshop on what 'endorsement' means. It was noted that while endorsement may not mean legally binding, it may have practical consequences, as governments may not feel comfortable not using guidance that has been internationally endorsed. A suggestion was made that those countries who see value in parts or all of the guidance are free to take that over in their own guidance without asking other countries to endorse the entire guidance.

Additional guidance on LM Fish and SynBio: observations were made that it would be better to improve the current guidance before embarking on new guidance. In addition the comment was made that for SynBio it is best to wait until it has been established whether the current guidance does not suffice for actual cases.

MOP8 Agenda item 11 – COP13 Agenda item 17: – Synthetic Biology.

Introduction: The discussion on Synthetic Biology under the CBD-COP had started under the heading of 'new and emerging issues', and were followed by an increasing work program under the CBD since 2011, including the establishment of an online forum and an AHTEG in 2015. The CPB-MOP AHTEG on risk assessment is currently also addressing the topic of Synthetic Biology as a possible additional topic for guidance.

Key point of discussion in the workshop was the definition of Synthetic Biology, whereby the point was made it is an 'umbrella' term representing the continuum of biotechnological development, encompassing all types of "new" and "old" biotechnological applications.

A key issue for Parties to the CBD is to decide whether SynBio is a 'new and emerging issue' under the CBD. The comment was made that no Party has proposed this and that there has been no assessment by SBSTTA in accordance with the COP-defined process for new and emerging issues.

Another major point of discussion in this context is whether synthetic biology is adequately covered by existing regulatory frameworks for LMOs (e.g. Cartagena Protocol), non-living products (e.g. regulatory frameworks for chemicals and pharmaceuticals) and components used in synthetic biology applications.

Other major synthetic biology issues overlap with the Cartagena Protocol, e.g. risk assessment, as well as with the Nagoya Protocol, e.g. application of access and benefit sharing obligations to digital/electronic DNA sequence information. It was emphasised that in the CDB discussions, there is a need to remember the scope of the CBD, i.e. its three objectives, and current and realistically foreseeable applications of synthetic biology. Notably, most of these applications involve contained uses of LM microorganisms.

In the discussion there were concerns raised that a potential outcome of the current CBD synthetic biology discussions could be additional or duplicating regulatory provisions specifically for synthetic biology without scientific justification, which would stifle an important field of research.

MOP8 agenda item 12: Socio economic Considerations in Decision making (article 26 CPB)

An introduction was given to Article 26 and the work of the AHTEG and the online forum aimed at producing conceptual clarity on what SECs mean in the context of article 26 of the CPB.

In the discussion, it was underlined that article 26 deals with the decision making process, and not with the risk assessment itself, and that the article does not entail an obligation, but rather discretion in decision making. The trigger for this article is a certain impact (positive or negative) of LMOs organisms on the conservation and sustainable use of biological diversity. Discussion focused on the results of the online discussion and the work of AHTEG. The observation was made that it is important that the work of the AHTEG and the online discussion stays within the scope of article 26.

MOP8 agenda item 13: Contained use and transit, Unintentional transboundary movements

Introduction: the AIA procedure does not apply to transboundary movement of LMOs destined for contained use or for LMOs contained in transit through a country.
In the discussion, the question was about the appropriateness of the synthesis of the submissions relating to contained use, since this is sovereign matter for a country's internal procedures rather than a mandate of the Protocol.

Introduction: Article17 of the CPB stipulates that it applies to unintentional transboundary movement of LMOs *that are likely to have significant adverse effects*.
In the discussion, the observation was made that to date, no such LMOs have been identified. It was noted that the work of the Network of Laboratories on a manual for the detection of LMOs needs to keep sight of the scope of Article 17, as well as the fact that one can only detect LMOs for which verified methods have already been developed.

MOP8 agenda item 16: Nagoya – Kuala Lumpur supplementary protocol on liability and redress

In the introduction the text of article 27 was presented as well some important distinctions: Liability vs Sanctions, Traditional damage vs damage to common goods (e.g. the environment'), and Civil liability vs administrative systems. A brief introduction was given to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and redress, and the Elements for a draft decision by MOP8. A brief introduction was also given on the complementary tool "the Compact', developed by some private sector companies. The discussion focused on the appropriateness of the administrative system in the field of possible damage to the environment. It was noted that the private sector widely supports the ratification of the Supplementary Protocol.

MOP8 agenda item 17: Public Awareness, Information and Involvement.

Discussion focused on the need to address in public information **both** biotechnology and biosafety.

A key component in public information is two-way communication and involvement. It was discussed that governments can do (much) more in this respect. It was also pointed out that while the BCH is a

very important element of the CPB, it should be recognised that public engagement and participation cannot be solely achieved through BCH.

In the context of the BCH, the observation was made that countries should do much more to keep their part of the BCH up to date.

MOP8 agenda item 14: Review of implementation and effectiveness of the Protocol

Introduction: Review and assessment are standard elements of both national regulations and the CBP. Review looks at the legal text in the light of gained experience and new scientific developments, and assessment looks at the implementation of the national or international regulations. In particular, assessment looks at aspects as: **Effectiveness** (does the regulation achieve its objective), **Efficiency** (e.g. does implementation occur at the least possible costs for the government and for the regulated community), and **unintended impacts** (e.g.: impacts on public research).

It was discussed that in terms of effectiveness, the SBSTTA on Implementation focused on how many Parties have fully put in place legal, administrative and other measures, but an equally important question is how many countries that do not yet have a domestic framework for biosafety have in place actually made AIA decisions on import. From the BCH it appears that very few countries without a domestic framework for biosafety have actually made AIA decisions on import, which would suggest that one of the main functions of the CPB is not being used much.

'Beyond the CPB'.

Draft Cancun Declaration

The participants discussed the draft Cancun Declaration and noted the multiple references to the need for innovation and research. Some participants felt that the text could even be sharper and clearer, referring to article 16 and 19 of the CBD.

It was recommended that people carefully read the entire text and discuss with colleagues at home.

Mainstreaming of Biosafety into NBSAPS

An introduction was given on the current process of mainstreaming biosafety into National Biodiversity Action Plans, and the ongoing webinars on the matter. Participants were alerted to ongoing webinars on the matter.

In the discussions, the observation was made that – referring to article 16 and 19 - it would be good to also mainstream biotechnology and its potential applications in National Biodiversity Action Plans.

The Nagoya Protocol on Access and Benefit Sharing.

An introduction was given recalling the third objective of the CBD: "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources", article 15 of the CBD, the Bonn Guidelines, and the adoption of the binding Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation. The 'Nagoya Protocol' entered into force in 2014, MOP1 took place in 2014, Pyeong Chang, the Republic of Korea, and MOP2 will take place in 2016, Cancun, Mexico.

Key elements of the Nagoya Protocol are:

- Parties to take legislative, administrative and policy measures regarding access and compliance,
- Accession on Mutually Agreed Terms (MAT), and subject to consent / permit
- Provider should inform ABS-CH of permit

Details were presented and discussed on scope, definitions, access, benefit sharing, compliance and monitoring, Interaction with other International Instruments (e.g. ITPGR), implementation challenges and topics on the MOP2 agenda.

The WTO

An introduction was given on the WTO Agreements that were the outcome of the 1986-1994 Uruguay Round of negotiations held under GATT:

- SPS Agreement (1995)
- TBT Agreement (1995)

The SPS Agreement recognises WTO Members' rights to provide a level of health protection they deem appropriate, and their obligation to ensure that those rights are not misused and result in disguised barriers to trade. The SPS agreement also recognises that countries can set their own standards based on science/data, provided that they are applied only to the extent necessary to protect human, animal and plant health; and that they are not arbitrary or used to unjustifiably discriminate. See also article 2.2 WTO – SPS Agreement:

Regional collaboration.

Several examples of collaborative projects on biotechnology and biosafety were presented.

The discussion focused on the usefulness of bilateral collaboration within the region, and new possibilities of collaboration were explored.

The comment was made that useful collaboration also includes collaboration between farmers and scientists, and an example was given of a so called 'farmers-scientist' network that is active in Europe.