

Modest progress in international regime on GMOs

A report on the outcome of the meeting of Parties to the Cartagena Protocol on Biosafety (29 September to 3 October 2014)

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After a week of sometimes rather contentious negotiations, countries finally agreed on continued work on the international regulation of genetically modified organisms (GMOs).

Clashes between countries that consider that GMOs require careful regulation, and those that continue to espouse the benefits of GMOs and hence minimal regulation, resulted in modest progress for the international biosafety regime.

The 7th Conference of the Parties to the Convention on Biological Diversity (CBD) serving as the Meeting of the Parties (COP-MOP7) to the United Nations Cartagena Protocol on Biosafety was held in Pyeongchang, Republic of Korea, on 29 September to 3 October. These meetings are held every two years.

The Cartagena Protocol enjoys nearly universal membership, with 168 Parties. Many of the countries that are not Parties to the Protocol are large GMO producing and exporting countries, such as the United States, Canada and Argentina. A number of developing country Parties such as Brazil and Paraguay are increasingly becoming significant producers and exporters of genetically modified soya beans. In addition, some Parties or their representatives are politically or ideologically aligned with the US and its biotechnology industry.

At this meeting, the polarized positions of countries resulted in protracted squabbling during the discussions on the two issues central to decision making on GMOs - risk assessment and risk management, and socio-economic considerations.

Under the Protocol, countries are required to conduct a risk assessment in order to take decisions on whether or not to import living modified organisms (LMOs), the term used in the Protocol. Furthermore, socio-economic considerations may be taken into account when taking decisions on LMOs. Most developing countries in particular, place great emphasis on socio-economic considerations, alongside the scientific and technical risk issues, when making decisions on LMOs.

Risk assessment and risk management

In risk assessment (Article 15) and risk management (Article 16), Parties considered a report from the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, including its work on guidance and a training manual on risk assessment of LMOs. They discussed capacity building based on an aligned package of the guidance and training manual, and whether or not there was need for development of further guidance on specific aspects of risk assessment. Additionally, Parties considered briefly the issue of synthetic biology and the role of the Protocol in addressing risks associated with it.

A previous AHTEG had developed a guidance document – “Guidance on Risk Assessment of Living Modified Organisms” – which was presented to COP-MOP6 in 2012 in Hyderabad, India. At that time, Parties could not agree to adopt the document. They instead “took note” of the AHTEG’s conclusions, commended the progress made on the development of the guidance, and decided to test the guidance at national and regional levels. Parties also agreed at that time that the guidance was not prescriptive, nor did it impose any obligations on Parties. A new AHTEG was constituted to continue the work of improving the guidance, along with an open-ended online forum.

The new AHTEG and online forum worked together intersessionally on three tasks identified by COP-MOP6: providing input to the Executive Secretary of the CBD (and the Cartagena Protocol on Biosafety) on testing of the guidance and analysis of the results; coordinating with the CBD Secretariat in the development of a package aligning the guidance with a training manual previously developed by the Secretariat; and considering the development of guidance on new topics of risk assessment and risk management, and recommending how to proceed with it.

In the conclusions of its meeting, the AHTEG recommended endorsement of the guidance, as well as the training package that aligns the guidance and the training manual. It recommended a mechanism for updating the guidance, taking into account the notion that the guidance is intended to be a “living document.” The AHTEG also recommended extending the mandate of both the AHTEG and the online expert forum, to continue the work of updating the guidance, as well as to develop further guidance on risk assessment of LMOs introduced in centres of origin and genetic diversity; living modified microorganisms and viruses; and living modified fish.

Several Parties at COP-MOP7 maintained a strong opposition to endorsing the guidance, and sought to prevent its use. Other Parties were opposed to endorsement of the guidance but accepted a process to allow the use of the guidance, along with further testing, during a process of improvement. Still others wanted the guidance endorsed or adopted.

In the final decision, the AHTEG and online forum were both extended, with a mandate to “revise and improve” the guidance (and the package that aligns the guidance and the training manual) on the basis of feedback provided through testing, with a view to having an “improved” version of the guidance by COP-MOP8 in 2016.

Because several countries were uncomfortable with the current composition of the AHTEG or wanted to be included in it, the decision “expands the composition of the AHTEG to add one new member from each region.” Mexico and Brazil both offered to host a meeting of the AHTEG in the intersessional period (between the 2 COP-MOP meetings in 2014 and 2016).

The final decision did not move forward on the development of further specific guidance. Instead, Parties were invited to submit information on “their needs and priorities for further guidance on specific topics of risk assessment of LMOs,” despite the fact that Parties have already been invited to do so, and the AHTEG has already made its recommendation for topics for further guidance. Parties were also invited to submit “existing guidance on specific topics of risk assessment of LMOs.”

COP-MOP8 will then only consider the “need for” the development of further guidance, in the context of operational objectives 1.3 (further development and support for

implementation of scientific tools on common approaches to risk assessment and risk management) and 1.4 (development of modalities for cooperation and guidance in identifying LMOs or specific traits that may have adverse effects on conservation and sustainable use of biological diversity) of the Protocol's Strategic Plan for the period 2011-2020.

Finally, the risk assessment/risk management decision recommends to the CBD COP that there should be a coordinated approach between the COP and the COP-MOP on the issue of synthetic biology, "taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology."

The 12th Meeting of the CBD COP is meeting in Pyeongchang from 6 to 17 October 2014, where synthetic biology is on the agenda.

Socio-economic considerations

An AHTEG on socio-economic considerations was established after much debate at the previous COP-MOP6 in Hyderabad. Its tasks were to examine the outcomes of a stocktaking exercise and online forums on this issue, to develop conceptual clarity on socio-economic considerations. COP-MOP7 was to decide on possible next steps towards developing guidance on taking socio-economic considerations into account in national decision-making on imports of LMOs.

Because of the reluctance of some Parties to explicitly mention the development of guidance, the decision does not do so, but instead relates the next steps to operational objective 1.7 of the Strategic Plan and its "outcomes". Operational objective 1.7 is "to, on the basis of research and information exchange, provide relevant guidance on socio-economic considerations that may be taken into account in reaching decisions on the import of LMOs."

The issue of socio-economic considerations was one of the most controversial issues during the negotiations of the Protocol itself. Developing countries wanted to preserve their right to take socio-economic considerations into account when taking a decision on imports of LMOs, as they consider this issue highly important and significant within a developing country context. Some developed countries opposed this, as they consider the issue not relevant for LMO decision making, and a potential trade barrier, preferring that decisions are taken solely or primarily on the basis of scientific and technical risk assessment.

The compromise is contained in Article 26 of the Cartagena Protocol, which states that "Parties may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biological diversity to indigenous and local communities, in reaching a decision on import under the Protocol or under its domestic measures to implement the Protocol".

At COP-MOP7, the central issues were around whether or not the AHTEG should proceed to work on guidance on socio-economic considerations envisaged under the Strategic Plan, and whether or not conceptual clarity has been sufficiently addressed by the AHTEG, which had adopted a descriptive approach to reach conceptual clarity on socio-economic considerations as no one single definition could be agreed on by all Parties. There was also heated debate on a number of issues which had surfaced during the AHTEG discussions, with regard to socio-

economic considerations in relation to risk assessment, human health and other international obligations.

Parties agreed that the work of the AHTEG should continue, and cautiously moved towards the development of guidance by mandating the AHTEG to work “in a stepwise approach” on “developing an outline for guidance with a view to making progress towards achieving operational objective 1.7 of the Strategic Plan and its outcomes”. It is also to work on “the further development of conceptual clarity...taking into account and improving upon”, among others, ‘Elements of a Framework for Conceptual Clarity on Socio-Economic Considerations’ produced by the AHTEG. The AHTEG is to submit its report to the next COP-MOP in 2016.

Online discussion groups will be convened to facilitate the exchange of views, information and experiences including on international obligations that may be relevant to socio-economic considerations; socio-economic considerations and the value of biological diversity to indigenous and local communities; environment-related aspects of socio-economic considerations; and the relationship “if any” with risk assessment and human-health related issues. In particular, the interface between socio-economic considerations and risk assessment, and human-health related aspects of socio-economic considerations remain highly contentious.

The issue of commissioning a study on international agreements that may have relevance to socio-economic considerations as provided in Article 26 had the distinction of remaining the last unresolved issue of the COP-MOP. Many developing countries were supporting this study as “other international obligations” include agreements relating to trade, environment, human rights, and food and agriculture.

Since the Protocol itself was negotiated, increased understanding of the World Trade Organization (WTO) agreements as well as an understanding of other agreements in which socio-economic considerations are rooted and grounded in, have tipped the balance in viewing the qualifier in Article 26 as solely relating to the WTO agreements, and negative for biosafety implementation.

In fact, some studies on this issue have clearly pointed to the fact that most countries are Party to multiple agreements on human rights, environment, food and agriculture and that these obligations must be respected. In addition, the WTO agreements also provide for socio-economic considerations to be taken into account, and contain enough flexibilities for robust biosafety implementation.

Paraguay, which had not been able to agree to the study in the contact group discussions, finally agreed to the following text: “To commission, subject to the availability of funds, a study on international agreements that may have relevance to socio-economic considerations as provided for in Article 26 of the Cartagena Protocol on Biosafety and to make the report available on the Biosafety Clearing House.”

Unintentional transboundary movements and emergency measures

Article 17 of the Cartagena Protocol addresses unintentional transboundary movements and emergency measures to be taken in the case of such movements. The Protocol requires Parties to take appropriate measures to notify affected or potentially affected States when it knows of a release leading to an unintentional transboundary movement of an LMO that is

likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Many cases of unintentional movements have taken place since the introduction of genetically modified organisms into international commerce. The bulk of these unintentional movements come in the form of contamination of commodities, such as maize, soya, canola, or rice, for food or animal feed, or for processing.

During the negotiations at COP-MOP7, Parties considered the distinction between unintentional transboundary movements (Article 17) and illegal transboundary movements (Article 25). Parties decided to gather views on the matter and submit the question for consideration by the Compliance Committee at its subsequent meeting for clarification.

Parties also considered what information exporters might be required to share with affected States when notifying them of the first intentional movement of LMOs, in order to be able to distinguish between intentional and unintentional movement of LMOs. Many Parties had wanted more specific information to be provided, including the “sequences of vectors, modified genetic elements and their flanking regions.” A number of Parties had also argued that access to reference materials such as control samples was essential for accurate identification and detection.

In compromise language, it was decided that Parties should ensure that a “notifier”, those exporters responsible for LMOs that will be intentionally introduced into the environment of a Party of import (such as for field trials), provide “all the information necessary to detect and identify the LMO, including information allowing for its unique identification and where reference materials may be obtained.”

The Parties did not address in the decision what specific information should be provided in the case of unintentional transboundary movements of LMOs for food and feed, or for processing. Parties did, however, mandate the creation in the Biosafety Clearing-House of a system for easy identification of notifications relating to unintentional transboundary movements of LMOs. Parties were requested to submit their views on what type of information should be exchanged through the Biosafety Clearing-House on unintentional and illegal movements.

Finally, the Parties suggested the continued work of an online network of laboratories focusing on the detection and identification of LMOs, as well as additional online and face-to-face capacity-building activities, such as workshops on sampling, detection, and identification of LMOs.

Handling, transport, packaging and identification

On the issue of handling, transport, packaging and identification of LMOs, Parties decided to continue to use the controversial labeling “may contain” for LMOs intended for direct use as food or feed or for processing.

The content of shipping labels for LMOs had been under debate throughout the negotiation of the Protocol’s text, and was unresolved at the time of finalization of the Protocol. Article 18.2(a) of the Protocol specified that Parties “shall take a decision on the detailed

requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol.”

In 2006, at COP-MOP3 in Curitiba, Brazil, the Parties adopted provisional language requiring Parties to label shipments that “may contain” LMOs, without requiring precise identification of the LMOs contained inside, nor even precise determination of whether the shipment does or does not contain LMOs. Parties were to review and assess experience gained with the implementation of labeling requirements at their fifth meeting, and take a decision at their sixth meeting, which was subsequently delayed to COP-MOP7 in Pyeongchang. Parties were also to consider the need for a “stand-alone document”, that is, a unique customs form for LMO shipments.

At COP-MOP7, Parties decided to continue to use “may contain” to identify transboundary movements of LMOs as decided at COP-MOP3. Furthermore, the Parties decided that “a further review of the need for a stand-alone document is not required unless a subsequent meeting of the Parties so decides.”

Finally, the Parties are still not in agreement on the need for developing new standards with regard to identification, handling, packaging and transport practices (Article 18.3), requesting instead that the Executive Secretary of the CBD “continue to collaborate with relevant international standard-setting bodies and ... keep abreast of any new developments in relevant international regulations.”

Further work and new meeting arrangements

The next COP MOP (and CBD COP) will be held in Mexico in 2016. A very significant procedural decision was made at COP-MOP7 that future meetings of the CBD COP, Cartagena Protocol COP-MOP, and Nagoya Protocol on Access and Benefit Sharing COP-MOP will be held concurrently during a two-week period. This decision must be confirmed with a parallel decision by the COP that is currently meeting in Pyeongchang.

Currently, the Cartagena Protocol COP-MOP is held for one week prior to the CBD COP of two weeks. The Nagoya Protocol will enter into force on 12 October 2014 and its first COP-MOP will be held for a week during the second week of the CBD COP. The Protocol was also negotiated under the CBD to implement the access and benefit sharing provisions.

Concurrent meetings of the three bodies during a two-week period would be an organizational and logistical challenge that was viewed by the Parties as necessary to promote better integration and efficiency in the work of the COP and the Cartagena COP-MOP. However, for developing countries with small delegations, and often not fluent in English, this can be a significant impairment to their full and effective participation.

Multiple concurrent meetings require sufficient numbers in a country delegation to be able to participate in all the plenary, working group, contact group and friends of the chair meetings. In addition to this challenge, interpretation in all the six UN languages is usually restricted to two meeting rooms where larger meetings are held. Actual negotiations take place in contact groups or friends of the chair setting that do not have translation provided. As such, the availability of financial resources is critical in order to ensure that developing countries, especially least developed countries, small island states and countries with economies in transition are allowed a level playing field in the negotiations.

Additionally, COP-MOP7 decided that a Subsidiary Body on Implementation (SBI), if established by COP12, would also serve the Cartagena Protocol. This new body would assist in the implementation of the various treaties. The COP already has a Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) that meets intersessionally, and it is expected that the SBI would meet concurrently with the SBSTTA.

COP-MOP7 also took decisions on the Biosafety Clearing House; cooperation with other organizations, conventions and initiatives; compliance; the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (under the Cartagena Protocol and not yet in force); monitoring and reporting; assessment and review of the effectiveness of the Cartagena Protocol; matters related to the financial mechanism; contained use of LMOs; and on the administration of the Protocol.+