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Key Issues for COP-MOP6

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The sixth meeting of the Conference of Parties serving as the Meeting of Parties (COP-MOP6) to the Cartagena Protocol on Biosafety will be held from 1-5 October 2012 in Hyderabad, India. This briefing provides an overview of some of the key issues on the agenda for COP-MOP6 and what steps need to be taken to ensure effective implementation of the Protocol.

1. Handling, transport, packaging and identification (Article 18)

COP-MOP6 will be discussing two main issues under Article 18:

- (i) handling, transport, packaging and identification requirements for living modified organisms (LMOs) destined for contained use, and intended for intentional introduction into the environment and any other LMOs within the scope of the Protocol (paragraphs 2(b) and (c) of Article 18, respectively); and
- (ii) standards relevant to the identification, handling, packaging and transport practices of LMOs (paragraph 3 of Article 18).

While the available information indicates that many Parties still need to develop measures to implement the documentation requirements of paragraphs 2(b) and (c) of Article 18, the following are important considerations for a decision at COP-MOP6:

- The documentation accompanying shipments of LMOs destined for contained use, or intended for intentional introduction into the environment and any other LMOs within the scope of the Protocol, must contain specific information as spelt out in paragraphs 2(b) and (c) of Article 18, and must reach the biosafety competent authorities. The information includes clear identification as LMOs, requirements for safe handling, storage, transport and use, contact point for further information, etc. It could also include the LMO's unique identifier.
- The use of a commercial invoice as the documentation accompanying shipments of LMOs is not sufficient to fulfill biosafety requirements, as the commercial invoice may inadvertently bypass the biosafety authorities. A commercial invoice is also likely to contain additional information (such as prices) and the question of what needs to be shared with the biosafety authorities might lead to confusion and delays. What is needed instead is a separate, 'stand-alone' document which would allow the competent authorities to easily and clearly identify and regulate the LMO shipments that are coming into a country.
- The stand-alone document should contain a reference to the Biosafety Clearing House (BCH) as the BCH is now the global database containing the most updated information on LMOs, and is used also by countries that are not (yet) Parties to the Protocol. This could be done by incorporating the 'LMO Quick-links' in the stand-alone document. The LMO Quick-links developed under the BCH (<http://bch.cbd.int/resources/quicklinks.shtml>) are bar codes for each BCH entry. They are small image files, which can be easily copied and pasted, that identify an LMO through its unique identifier, trade name and a link to the BCH where information on the LMO is available (e.g. LMO characteristics, countries' decisions, risk assessments, etc.). Through the LMO Quick-links, the relevant BCH page - in at least all UN languages - can be easily accessed by either scanning the barcode or by typing the URL in a web browser. This means that full information about a particular LMO would be available to any customs or biosafety officer with a bar code scanner or a mobile phone. Because the Quick-links are easy recognizable, they would even work if the documents are in different languages. Their use would also greatly reduce duplication of work for both exporting and importing companies as well as for the biosafety authorities.

Paragraph 3 of Article 18 requires the consideration of the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices. At issue is the need to ensure that the current fragmentation of the relevant international regulations and gaps therein with respect to biosafety needs are adequately addressed. Calls to design, under the umbrella of the Cartagena Protocol, a new international standard unifying the best and most complete international norms to achieve biosafety objectives have regrettably not been acted upon.

The study commissioned by the Executive Secretary therefore provides detailed recommendations for action, a combination of which would help ensure the avoidance of adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Of particular note is that Parties should support the recognition of the Cartagena Protocol standards in the list of international standards, guidelines or recommendations applied by Members of the WTO under the Agreement on the application of Sanitary and Phytosanitary Measures (SPS Agreement). This is important, as SPS measures that conform to international standards, guidelines or recommendations are presumed to be consistent with the relevant provisions of the SPS Agreement and of GATT 1994.

2. Unintentional transboundary movements and emergency measures (Article 17)

Article 17 requires Parties to take appropriate measures to notify affected and potentially affected States, the BCH and other relevant bodies when it knows of an occurrence under its jurisdiction that leads, or may lead to an unintentional transboundary movement of a LMO. Notifications must be provided as soon as the Party knows of such situations, and relevant information must be communicated to the affected or potentially affected States. Consultations with affected States are also necessary to enable them to determine appropriate responses and initiate necessary action, including emergency measures.

In other words, Article 17 spells out what Parties must do when LMO contamination happens. LMO contamination incidents worldwide have occurred with alarming frequency. According to the GM Contamination Register, a total of 366 known contamination cases and illegal releases have occurred since 2005, when the database was first set up (www.gmcontaminationregister.org). The GM Contamination Register is compiled from public reports and is managed by Greenpeace and GeneWatch UK. In 2012 alone, 24 individual cases have been recorded in countries in Asia, Africa and Europe, many involving unapproved LMOs.

However, from the analysis carried out by the Secretariat, very few Parties (only nine) have reported receiving information of unintentional transboundary movements arising from their jurisdiction, while the majority (133 Parties) reported that they have never received any such information, during the reporting period of the second national report. Moreover, four Parties reported unintentional introduction of LMOs into their jurisdiction in the form of imports of food or seeds, while two other Parties reported potential or unverified transboundary transfer of LMOs into their territories.

It is clear that there is a disjuncture between the known cases of unintentional transboundary movement and what is notified to Parties. This could be because the source of some contamination incidents may be from non-Parties to the Protocol. When contamination originates from Parties to the Protocol, regrettably not all have fulfilled their notification and consultation obligations.

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It would be therefore important for COP-MOP6 to take a decision that includes the development of tools and guidance that facilitate implementation and assist Parties to detect and take measures to respond to unintentional releases of LMOs. This must happen even if notification is not given directly to the affected States, but information is available from other sources, e.g. media reports, non-government organizations, etc. Furthermore, the decision should call on Parties that have not yet done so, to quickly establish and maintain measures to prevent unintentional transboundary movements, as well as mechanisms for addressing and implementing response actions and emergency measures.

Apart from the obligations of Parties that are spelt out in Article 17, the following have been identified as constituting important information and considerations that could help Parties deal with contamination incidents. These should be elements of a decision on the development of guidance to facilitate detection and response actions:

- Decisions and discussions under Article 18 (handling, transport, packaging and identification), in particular in the context of paragraph 2(a) relating to bulk shipments of LMOs intended for direct use as food, feed, or for processing (FFP). Furthermore, the decisions and discussions in relation to sampling and detection, including the establishment, through the BCH, of electronic networks of laboratories to facilitate identification, are especially pertinent.
- Risk assessment and risk management, in particular in relation to the Guidance on Risk Assessment of LMOs developed by the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, which already incorporates some elements relating to unintentional transboundary movements in relation to LM trees and mosquitoes.
- Liability and redress, in particular the taking of response measures under the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, in response to damage or sufficient likelihood of damage including what arises from unintentional transboundary movements.
- Capacity building, in particular in relation to determination of appropriate responses and initiation of necessary actions, including emergency measures, as well as for sampling and detection techniques.

The AHTEG on Risk Assessment and Risk Management could also be tasked with developing the guidance on measures in response to unintentional transboundary movement of LMOs.

3. Risk assessment and risk management (Articles 15 and 16)

In relation to risk assessment and risk management, several issues are to be discussed at COP-MOP6, including:

- (i) The main outcomes of the process of developing guidance on specific aspects of risk assessment and risk management, as carried out by the open-ended online forum and AHTEG on Risk Assessment and Risk Management, in particular the revised Guidance on Risk Assessment of Living Modified Organisms.
- (ii) LMOs that may have or that are not likely to have adverse effects on the conservation and sustainable use of biological diversity.

The Guidance on Risk Assessment of Living Modified Organisms developed since 2009 includes the extensively 'road tested' and revised 'Roadmap' on the necessary steps to conduct a risk assessment in accordance with Annex III of the Protocol, along with the tested

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and revised guidance on LM abiotic stress-tolerant plants, stacked plants and LM mosquitoes. These documents were welcomed by Parties to the Protocol at COP-MOP5 and have benefited from numerous rounds of feedback and peer review. Incorporating the feedback from the first generation of documents, the AHTEG then developed new guidance on LM trees and monitoring, themselves subject to several rounds of review. Together, this package constitutes guidance in three parts that is very useful for the Parties to the Cartagena Protocol in implementing their risk assessment and risk management obligations under the Protocol and national legislation.

The package of guidance documents is both credible and consensus-building. Developed by a group of experts from industry, academia, government and civil society, it has achieved an effective compromise that adequately promotes safety without unduly burdening industry or inhibiting research, while bringing clarity and transparency to regulation.

The AHTEG has thus more than adeptly fulfilled the Parties' request for it to develop further guidance on risk assessment and risk management. It has also proved its utility in being able to respond to Parties' needs in addressing specific topics of risk assessment and risk management.

Therefore, at COP-MOP6, Parties should decide to:

- Endorse the Guidance and ensure its wide accessibility, dissemination and usage.
- Integrate the Guidance into capacity-building activities on risk assessment, including into the training manual on risk assessment that has been developed by the Secretariat and used in training courses on risk assessment.
- Integrate the Guidance within the draft Results-Oriented Capacity-Building Action Plan (2012-2020), in its Focal Area 2 on Risk Assessment and Risk Management.
- Extend the mandate of the AHTEG, with the objective of developing guidance on new topics of risk assessment and risk management, including in relation to unintentional transboundary movement of LMOs.

On the issue of identification of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, it is important to note that discussion on this issue is within the context of Article 7, paragraph 4 and is thus only relevant to the application of the advance informed agreement procedure. It cannot be used to make any extrapolations on the 'safety' of a particular LMO.

It is actually not scientifically possible to identify any LMOs that can be classified as not likely to have adverse effects. The risk assessment process set out in the provisions and Annex III of the Cartagena Protocol on Biosafety should be carried out on a case-by-case basis; the specific LMO concerned, its intended use and the likely potential receiving environment are all important considerations. The latter criteria mean that the potential adverse effects of a LMO are dependent on its specific characteristics, how it is used and where it is released. These will vary in different ways and would be influenced also by environmental, health and socio-economic factors.

Therefore, case-by-case risk assessments cannot be transferable to all potential receiving environments. It follows that any generic identification of LMOs that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, is not possible. In fact, such a priori assumptions regarding the safety of an LMO would seriously undermine the case-by-case principle of risk assessment that is enshrined in the Cartagena Protocol. Moreover, if there is damage caused by a LMO, liability and redress applies regardless of whether that LMO has been identified as

being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Parties should therefore reconsider the relevance of Article 7, paragraph 4 in light of the objectives of the Cartagena Protocol and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress.

4. Socio-economic considerations (Article 26)

It is clear that the socio-economic dimension needs to be an integral part of sound and comprehensive assessments of LMOs. Many Parties have incorporated socio-economic, and even cultural and ethical considerations into their national biosafety frameworks and national laws that regulate LMOs. Nonetheless, Parties have expressed the need for further guidance to implement their policy choice to include socio-economic considerations in their decision-making on LMOs.

At COP-MOP5, the Parties considered the recommendation of the sixth Coordination Meeting for Governments and Organizations Implementing or Funding Biosafety Capacity-Building Activities to establish an ad hoc expert group on socio-economic considerations. Some Parties at the time felt that the issue was not mature enough for consideration by an ad hoc expert group yet, thus COP-MOP5 asked for regional online conferences and a regionally-balanced workshop to be convened first.

Together with a series of online discussion groups on socio-economic considerations, these activities were carried out successfully in 2011. The time is therefore ripe for the establishment of an ad hoc technical experts group to further progress the work on socio-economic considerations under the Protocol, to meet the needs of Parties to the Protocol. Parties should decide to do so at COP-MOP6, and the following tasks were identified by the workshop in 2011 for the ad hoc technical expert group to undertake:

- Develop conceptual clarity on socio-economic considerations;
- Compile and review information on the socio-economic impacts of LMOs, including information available on specific cases; and
- Develop guidelines on socio-economic considerations that would, among other things, identify key questions to be answered and provide minimum common elements that could be used in considering the socio-economic impacts of LMOs.