

## CARTAGENA PROTOCOL ON BIOSAFETY Risk Assessment and Risk Management

- Existing guidance materials and models provide a solid foundation for the Cartagena Protocol on Biosafety (Protocol) risk assessment process to facilitate decision-making on living modified organisms (LMOs), including newer applications of modern biotechnology such as trees, fish, and specific plant varieties. Parties must now focus on completing the work described in decisions from earlier meetings of the Parties as it relates to organizing this existing information on risk assessment.
- Parties should focus their limited resources on information-sharing and collaboration with other international organizations working in this area. Establishing new systems, standards or guidance under the Protocol must be done using the existing information as the foundation, following a science-based approach, or it will impede Parties from the objective of implementing the Protocol requirements and meeting its goals and objectives.
- Any *ad hoc* Technical Experts working group on risk assessment must include only credentialed scientists, including qualified scientists from the private sector, academia and the public sector.

### A. Existing guidance and information to support risk assessment and risk management

- An adequate number of risk assessment models and guidance exist that are compatible with the Protocol that could be used today to support decision-making for LMOs under the Protocol. At the third meeting of the Parties to the Protocol, Parties requested that the Executive Secretary compile and organize this body of information within the Biosafety Clearing-House (BCH) in a manner consistent with Article 20.<sup>1</sup> To this end, the private sector supports continued information-sharing on this guidance material on the BCH and encourages the Secretariat to focus resources on completing this work.

### B. Further guidance on specific aspects of risk assessment and risk management

- With respect to the possible development of further guidance on specific aspects of risk assessment and risk management for emerging applications of modern biotechnology, including transgenic trees, fish and specific plant species, Parties should be reminded of and encouraged to use the existing guidance on risk assessment currently available in accordance with the general principles, methodology and points to consider in Annex III of the Protocol.
- In fact, participants at an Expert Workshop on Risk Assessment for Future Applications of Modern Biotechnology sponsored by Canada and Norway to advise the Parties on this issue:
  - Confirmed that risk assessments should be conducted on a case-by-case basis as reflected in the Protocol;
  - Agreed that the general principles and methodologies for risk assessment contained in Annex III to the Protocol also apply to transgenic fish, trees, viruses and pharmaplants; and
  - Recommended that existing information on risk assessments of LMOs should be made readily available through the BCH.
- Parties must now address the issue of whether to develop new guidance materials on specific aspects of risk assessment and risk management for these emerging applications of modern

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<sup>1</sup> COP-MOP 3 Decision BS-III/11.

The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety 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.

biotechnology.<sup>2</sup> The private sector believes any new guidance that is developed must be done using the existing information as the foundation, following a science-based approach and without prejudice or bias based on purely theoretical perceptions of risk or potential adverse effects to the conservation and sustainable use of biodiversity. We further suggest that Parties take advantage of this existing expertise, as well as the numerous other international fora in which such guidance is being developed, such as the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology and the International Plant Protection Convention. The private sector supports the work of the Secretariat of the Convention on Biological Diversity to make this information available on the Biosafety Clearing-House.

- The private sector believes that it is premature to convene an *ad hoc* technical expert group on risk assessment to consider the need for further guidance on specific aspects of risk assessment and risk management until the Secretariat completes its work to organize available guidance on the BCH in accordance with paragraph 2 of Decision BS III/11. Convening a technical expert group on risk assessment to help the Secretariat complete this important work should be higher priority than beginning new work on risk assessment and risk management. However, should Parties decide that such an experts group is necessary, it must include only credentialed scientists, including qualified scientists from the private sector, academia and the public sector.

### **C. Collaborating in identifying LMOs or specific traits that may have an adverse effect on the conservation and sustainable use of biodiversity**

- All of the companies which develop and offer agricultural biotechnology traits and products are confident in the safety of these products and in the rigor of their risk assessment processes, including the regulatory reviews. That confidence has been affirmed by the hundreds of independent national risk assessments, approvals and authorizations for release into the environment for field trials, production and for import as LMO-FFPs in many countries that are Parties to the Protocol.
- It is because these LMOs have been thoroughly assessed prior to release that the Secretariat can *correctly* conclude in paragraphs 28 and 38, respectively, of the background document on risk assessment for consideration by the Parties at their fourth meeting that “[i]nformation from relevant scientific bodies on the potential adverse impacts of specific novel traits has been difficult to find”, and “there are few findings issued by relevant scientific bodies about the potential of specific living modified organisms and novel traits that may cause adverse effects on the conservation and sustainable use of biological diversity.”
- Given this history of safe use and the weight of evidence to date, the private sector strongly objects to a subsequent statement and to the general conclusions drawn with respect to this item for discussion at MOP-4 that a possible reason for this lack of information could be due to, “scarcity of reliable scientific data and publicly available information on these issues.” Were the Secretariat to request reliable, scientific publicly available data on this issue, they would receive thousands of publications, many of which are peer-reviewed. Again, the private sector strongly contends that the true reason for the scarcity of science-based information pointing to the potential for LMOs to cause adverse effects on the conservation and sustainable use of biodiversity is in fact due to the proven safety of LMOs and ability to conduct field trials safely.
- The private sector also strongly cautions Parties that the information presented in paragraphs 29 and 30 to 36 is incomplete, and fails to provide “reliable scientific data” on the potential adverse effects of LMOs to the conservation and sustainable use of biodiversity. For example, the background document misrepresents the result of the Farm Scale Trials in the UK where the

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<sup>2</sup> Ibid.

effect observed was related to weed management and *not* the LMO. Furthermore, we feel that this information in these paragraphs reflects a bias toward an unproven belief that LMOs are intrinsically “risky”. The private sector strongly rejects the analysis provided in Section V and the Conclusion of the background document. As such, we will support only decisions in Section C that are scientifically-sound and based in the principle of case-by-case assessment.

- Finally, accepting the intent of Article 21 of the Protocol, the private sector cautions against the potential misinterpretation in Paragraph 43(a) of the draft decision for consideration at MOP-4 that withdrawal of an application is equivalent to having identified a potential adverse effect on the conservation and sustainable use of biodiversity.

#### **D. Capacity building relevant to risk assessment**

- Capacity building on risk assessment and risk management under the Protocol should focus on assisting countries in understanding how they can use existing risk assessment models and guidance as well as experience from the private sector to fulfill their Protocol obligations, and should not focus on the development of a new risk assessment system or standards. *Ad hoc* technical expert groups including qualified scientists from the private sector, academia and the public sector could be used on an as-needed basis should there be a need to respond to specific scientific or technical issues. We also support greater transparency and science-based criteria by which issues get referred to *ad hoc* technical experts groups.

#### **Background:**

The Protocol requires Parties to make decisions on import of LMOs for intentional introduction into the environment in accordance with scientifically sound risk assessments (Article 15). It sets out, in Annex III, general principles, methodological steps, and points to consider in the conduct of risk assessment. The general principles include, among others:

- Risk assessment should be carried out in a scientifically sound and transparent manner;
- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;
- Risks should be considered in the context of risks posed by the non-modified recipients or parental organisms; and
- Risks should be assessed on a case-by-base basis.

The methodology described in Annex III of the Protocol follows the proven, well-accepted risk assessment paradigm, including identification of potential harmful characteristics of an LMO that may have an adverse effect on biodiversity (e.g., toxicity). Risks are then evaluated based on a combined analysis of the likelihood of the identified risks materializing and the consequences were they to do so.

At the third Meeting of the Parties (13-17 March 2006), the Parties agreed that there currently exists sufficient general guidance materials and information to support environmental risk assessment of LMOs under the Protocol. They also decided that there was a potential need for additional guidance on specific aspects of risk assessment and risk management such as guidance focused on particular types of LMOs, intended uses, types of risks and receiving environments. As such, at their fourth meeting in Bonn, Germany from 12-16 May 2008, Parties will consider the need for such further guidance and the appropriate modalities for development of any such guidance. In addition, the background document for MOP-4 invites Parties to consider LMOs or specific traits that may have adverse effects on the conservation and sustainable use of biodiversity.