

CARTAGENA PROTOCOL ON BIOSAFETY Risk Assessment and Risk Management

The Global Industry Coalition (GIC)¹ is concerned that the “Guidance on Risk Assessment of Living Modified Organisms” developed in the AHTEG process does not reflect a consensus view of all AHTEG members, and therefore does not support publication in its current state. Rather, the GIC supports a work program on risk assessment and risk management of living modified organisms (LMOs) under the Biosafety Protocol that focuses efforts on the effective use of existing guidance materials on risk assessment currently available in accordance with the general principles, methodology and points to consider in Annex III of the Protocol. The GIC believes that taking on new work related to the “Guidance on Risk Assessment of Living Modified Organisms” will detract from this goal.

A. Background and Experience to Date

At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (MOP-4), in decision BS-IV/11, established an open-ended online forum on specific aspects on risk assessment through the Biosafety Clearing-House (BCH) and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management. Key elements of this decision were “the need for further guidance on specific aspects of risk assessment and risk management, and appropriate modalities for development of any such guidance”. To implement the elements of this decision, the Secretariat established a continuous process comprising: (i) an open-ended online forum; (ii) discussion groups on specific topics; (iii) two series of regional real-time online conferences (one prior to each AHTEG meeting); and (iv) two meetings of the AHTEG.

The major work product developed through this process that will be considered by the Parties at their fifth meeting (MOP-5) is a document entitled “Guidance on Risk Assessment of Living Modified Organisms” (Guidance Document) intended to provide further guidance on risk assessment including specific aspects of risk assessment and risk management. The AHTEG provided a number of recommendations related to the Guidance Document to the Parties that will serve as the basis for their deliberations on this issue at MOP-5.

B. GIC Views on the Elements of the MOP-5 Draft Decision

- The GIC is of the view that the Guidance Document does not reflect a work product that is a consensus of qualified expert views offered by all members of the AHTEG. As such, the GIC does not support publication in its current state, and is of the view that it should be reconsidered by the AHTEG using a more inclusive expert-input process before it is published as the basis for any capacity building or training activities.
- Accepting that the AHTEG itself sees the need for further testing and refinement of the Guidance Document (Annex IV (b)), the GIC does not support a work plan to further

¹ 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.

develop guidance materials on risk assessment on specific types of LMOs or traits based on the Guidance Document. Instead, Parties should focus their efforts on the effective use of existing guidance materials on risk assessment currently available in accordance with the general principles, methodology and points to consider in Annex III of the Protocol.

- The GIC notes that the Secretariat is committed to using various on-line fora as a mechanism for obtaining information to develop further guidance (i and iii above). However, in our experience, this mechanism needs much more work to increase its value and utility. Specific emphasis must be given to improving the transparency of decision making with regard to inclusion of input provided by participants in documents coming out of the process.
- In the event that the Parties decide at MOP-5 to go have the AHTEG continue its work related to risk assessment and risk management of LMOs, the GIC respectfully requests that the AHTEG:
 - Prioritizes the organization of risk assessment information available on the BCH in accordance with paragraph 2 of Decision BS-III/11;
 - Includes only credentialed scientific experts from Parties; and
 - Include qualified scientific experts as observers from other governments, particularly those with experience in environmental risk assessment, and from the private sector, academia and the public sector.