1 October 2018

CARTAGENA PROTOCOL ON BIOSAFETY (Protocol)
9th Meeting of the Conference of the Parties Serving as the Meeting of the Parties (COP/MOP-9)
Articles 15 and 16: Risk Assessment and Risk Management of Living Modified Organisms (LMOs)

The Global Industry Coalition (GIC)[1] is concerned with the proposed work plan reflected in COP/MOP-9 draft decision on risk assessment (RA) and risk management (RM). Lack of shared understanding about basic concepts in RA and RM has hindered successful development of guidance materials in the past. Therefore, before a new AHTEG is established to develop additional guidance on specific issues, clarity should be reached amongst Parties about processes that will enable successful work in this area in the future. The GIC strongly recommends Parties focus efforts on refining the process (Annex I of the COP/MOP-9 draft decision on RA and RM) for a structured analysis for the identification and prioritization of specific RA issues regarding LMOs. Parties must also clarify and agree upon how such process should be applied in practice. Developing this process is critically important and should follow a deliberate, step-wise approach of: (a) gathering ideas through an on-line process; (b) structuring these ideas in report that can be reviewed by the Parties; (c) drafting the process; and, (d) testing the process with select, real life examples of LMOs.

A. Background

Articles 15 and 16[2] of the Protocol outline requirements that relate to risk assessment (RA) and risk management (RM) of LMOs and require Parties to make decisions on the import of LMOs for intentional introduction into the environment in accordance with scientifically-sound and evidence-based principles. At their eighth meeting in 2016, the COP-MOP invited Parties to submit[3] to the Executive Secretary: (*a) information on their needs and priorities for further guidance on specific topics of RA of LMOs; (b) proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance; and (c) views on perceived gaps in existing guidance materials.* At the same meeting, Parties extended the Online Forum on RA and RM to exchange experiences on RA, provide information and views on, and perceived gaps in existing guidance materials, and proposals to address any gaps identified. Based on the outcomes of this work, the 22nd meeting of the Subsidiary Body on Technical and Technological Advice (SBSTTA) recommended a draft decision for consideration by the Parties at COP/MOP-9 on this issue.[4]
What follows are GIC views on the elements of the draft decision on RA and RM that Parties will consider at COP/MOP-9.

B. GIC Views on Elements of the Draft Decision RA and RM of LMOs

1. Establishment of a process for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration

The GIC strongly supports the establishment of a structured process for identification and prioritization of specific RA issues that may warrant additional guidance. This proposal recognizes the "*divergence of views*

[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.
[2] http://bch.cbd.int/protocol/text/.
[3] Nineteen Parties and 3 other governments submitted information to the Secretariat's notification SCBD/SPS/DC/MPM/MW/86376. Seven out of 19 Parties stated that they do not need any new guidance and that there are no gaps in existing guidance on RA; 8 out of 19 Parties identified need for guidance on LM fish; 8 out of 19 indicated need for guidance on synthetic biology, with 3 Parties (3/19) specifically identifying gene drives; 1 out of 19 Parties identified genome editing as a particular need. SBSTTA-22 singled out three topics for further consideration: [(i) living modified organisms produced through genome editing,] (ii) living modified organisms containing engineered gene drives and (iii) living modified fish (CBD/SBSTTA/REC/22/2).
[4] CBD/SBSTTA/REC/22/2.

among Parties on whether or not additional guidance on specific topics of risk assessment is needed"[5] and will be helpful in resolving such divergence. However, there must also be an aligned understanding amongst Parties on how this process is to be developed and implemented in practice. Developing this process is critically important and should follow a deliberate, step-wise approach of: (a) gathering ideas through an on-line process; (b) structuring these ideas in report that can be reviewed by the Parties; (c) drafting the process; and, only then, (d) testing the process with select, real life examples of LMOs. The GIC's view is that the criteria listed in Annex I should be developed, refined, further discussed and agreed upon, before being tested for the identification and prioritization of specific issues.

To that end, GIC recommends the following **edits to Paragraph 6 and Annex I** to underline the need and importance of evidence in the decision-making process, and streamline and clarify the process proposed in Annex I. We note that **Paragraph (e), subparagraph (i) of Annex I should be deleted in its entirety** as such determination can only be done after the completion of a LMO risk assessment process, while in the absence of such, it is only speculative information. Importantly, the criteria should be applied and met in full. Failing to do so will lead to a repetition of the protracted and unproductive discussions witnessed during the work of the former AHTEG on RA and RM (2008-2016).

6. *Decides to establish a* ***structured*** *process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol with a view* ***to assess whether additional guidance is warranted*** ~~*developing further guidance on risk assessment*~~ *on the specific issues identified* ***by applying*** ~~*, taking into account*~~ ***the process and criteria outlined*** *in annex I;*

GIC recommends changes in parts of Annex I as follows:

The process for recommending specific issues of risk assessment for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety should include a structured analysis to evaluate whether the specific issues fulfil ***all of*** *the following* ***criteria****:*

(a) Are identified by Parties as priorities ***and are supported by evidence as to why they are considered a priority****, taking into account* ***also*** *the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition;*

(b) Fall within the scope of the Cartagena Protocol;

(c) Pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, the issue at hand has been assessed with existing risk assessment frameworks but ~~*pose*~~ *specific technical or methodological challenges* ***have been identified*** *that require further attention;*

(d) The challenges in addressing the specific issue are clearly described ***and supported by a sufficient body of evidence upon which to draft scientifically-sound guidance****;*

~~*and considering, inter alia*~~*:*

(e) The specific issues concern living modified organisms that:

~~*(i) Have the potential to cause [serious or irreversible] adverse effects on biodiversity, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;*~~

(iv) Are ~~*already, or*~~ *are likely to be commercialized* ***in the near future*** ~~*or in use somewhere in the world;*~~

and ***evaluate*** ~~*consider a stock-taking exercise to determine*~~ *if resources on similar issues have been developed by national, regional and international bodies and, if so, whether such resources may be revised or adapted to the objective of the Cartagena Protocol, as appropriate.*

[5] CBD/SBSTTA/REC/22/2, para 2

2. Establishment of an ad hoc technical expert group on risk assessment and request to the Executive Secretary to commission a study informing the application of Annex I criteria for identification and prioritization of issues

The GIC does not support the establishment of the AHTEG until clarity is given as to the purpose of additional guidance and how it should be developed. As such, an AHTEG for the development of additional guidance is not justified until the Annex I criteria are developed, refined and agreed upon. A clear agreement on the practical application of Annex I criteria is a prerequisite for the successful use of the process in the future.

The GIC recommends **deletion of paragraph 8 and Annex II**.

GIC also recommends the **deletion of paragraph 11(a),** which requests the Executive Secretary to commission a study informing the application of Annex I on a selection of potential issues. Annex I process and criteria must be further developed and agreed upon before it is used in practice, including by the Executive Secretary. Furthermore, the current draft decision 11 (a) constitutes duplicative activity to that of the proposed AHTEG and the on-line forum.

3. **Consideration by COP-MOP-10 whether additional guidance materials on risk assessment are needed for: [(i) living modified organisms produced through genome editing,] (ii) living modified organisms containing engineered gene drives and (iii) living modified fish**

As outlined above, the GIC is of the view that it is critical to first agree upon the process and criteria for identification and prioritization of issues (Annex I) and to reach a shared understanding how these will be applied in practice before any further work is conducted for prioritization of issues. Therefore, we **recommend the deletion of paragraph 7 and edits to paragraph 12** as follows.

12. *Requests the Subsidiary Body on Scientific, Technical and Technological Advice to make a recommendation* ***on the practical implementation of the process and criteria for identification and prioritization of issues that require*** ~~*for*~~ *additional guidance materials on risk assessment* ~~*are needed for*~~ ***as identified by the structured process described in Annex I*** ~~*[(i) living modified organisms produced through genome editing,] (ii) living modified organisms containing engineered gene drives, and (iii) living modified fish*~~ *for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its* ~~*tenth*~~ ***eleventh*** *meeting.*

If a list of topics is retained, the GIC strongly disagrees with retaining genome editing in this list (currently in square brackets) and recommends that it is deleted throughout the draft decision. The term "genome editing" represents a broad collection of techniques and potential outcomes, some of which will not be LMOs. Where gene editing results in LMOs, existing RA guidance and the methodology and principles for RA of Annex III of the Protocol are applicable. Furthermore, we note that the criteria of Annex I can only be applied successfully to concrete cases and not to broadly-defined categories such as LM fish or engineered gene drives.