Global Industry Coalition
Views on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety

Preparations for Online Forum on Risk Assessment and Risk Management
29 January – 12 February 2018

A. Background

During their 8th meeting in December 2016 (COP/MOP-8), Parties to the Cartagena Protocol on Biosafety (BSP) agreed to decision VIII/12 inviting Parties to submit to the Executive Secretary:

(a) Information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (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.

In addition, Parties agreed to extend the Online Forum on Risk Assessment and Risk Management to exchange experiences on risk assessment, provide information and views on, and perceived gaps in existing guidance materials, and proposals to address any gaps identified. The results of the submissions and the online forum discussions will be considered by the Subsidiary Body on Scientific, Technical and Technological Issues (SBSTTA) to recommend a way forward to address the needs, priorities and gaps identified in this submission for consideration at the Parties' 9th meeting in November 2018. This paper provides the GIC's views in relation to the upcoming Online Forum discussion which has been scheduled for 29 January to 12 February 2018.[1] The Online Forum will discuss the following two topics:

(a) Information and views on existing guidance materials on risk assessment and risk management; and

(b) Perceived gaps in existing guidance materials on risk assessment and risk management, and proposals to address any gaps identified.

B. GIC Views on Specific Online Forum Topics

i. Information and views on existing guidance materials on risk assessment and risk management

The GIC's overarching view on existing guidance materials on risk assessment and risk management is that significant and substantial guidance materials exist to ensure that robust and appropriately protective risk assessment. Such guidance materials are in line with the principles and methods of risk assessment and risk management in Annex III, and are appropriate for current and realistically foreseeable LMOs globally. Furthermore, there are no gaps in existing guidance on risk assessment and risk management (Section ii below). LMOs have been successfully developed, tested, and commercialized with no credible report of increased risk to the environment or human health for over 30 years. The environmental risk assessment of LMOs is founded on scientifically sound principles, which are also integrated into Annex III of the BSP. While experimental details and methodologies have advanced based on case-by-case

[1] The calendar of events is available at https://bch.cbd.int/onlineconferences/calendar_ra.shtml and the online forum itself can be accessed via the main forum page at http://bch.cbd.int/onlineconferences/forum_ra.shtml.

needs and new scientific knowledge, the fundamental principles imbedded in Annex III and other consensus documents have not changed and remain appropriate for all types of LMOs and their proposed releases.

In addition, existing guidance documents and well-established methodologies on risk assessments for LMOs that are consistent with the principles of Annex III of the BSP are readily available through the BCH and other websites. These are equally applicable to every current and realistically foreseeable LMOs. The accumulated practical experience of conducting risk assessments at national levels, the existing guidance materials, and the established risk management practices from countries with experience with LMOs and environmental releases can be used to guide and assist Parties that request guidance in conducting LMO risk assessments.

Furthermore, we note that the issue of "guidance" has been repeatedly and exhaustively addressed in multiple on-line fora, meetings within the risk assessment AHTEG, and meetings of the Parties to the BSP for over twelve years. Despite repeated requests for submissions on this topic and discussions on how best to proceed, near consensus has been reached that there is no need for additional guidance. The majority of Parties, non-Parties, and relevant stakeholders have consistently agreed that, in fact, a great deal of guidance exists, which combined with Annex III principles is suitable for its purpose under the BSP. The GIC continues to contend that a more appropriate path forward is for experienced Parties to share their best practices, existing guidance, and practical and real-life experience in undertaking risk assessments of various LMOs.

ii. Perceived gaps in existing guidance materials on risk assessment and risk management, and proposals to address any gaps identified.

As stated above, the GIC strongly believes that there are no gaps in existing guidance on risk assessment and risk management or foreseeable gaps in the future. As such, there is no need for work on developing further guidance on specific topics. Rather, Parties should be supported in making a concerted effort to collect and review the extensive guidance that currently exists, share it on the Biosafety Clearing-house (BCH), operationalize this material in the context of their national biosafety regulations and policies, and work bilaterally with countries experienced in risk assessment of LMOs. In addition, Parties should be devoting their limited resources to areas of BSP implementation where there is evidence of identified needs.

Also as noted above, the GIC recalls that the topic of guidance has been discussed for over twelve years. We are concerned that another on-line discussion on undefined issues like "gaps" will lead to the same outcome – lack of consensus, and no realistic path forward that will provide assistance to the Parties. Unless criteria are established to define "gaps" and the means to address these, as requested in decision VIII/12, the results of this on-line forum will be of limited usefulness. The GIC is prepared to comment on appropriate criteria and justifications in the online forum.

The issue of gaps has been discussed in earlier forums especially most recently in the online forum on synthetic biology. Anticipating that specific perceived gaps will be revisited in this forum, the GIC wishes to recall several specific examples of topics raised by Parties and non-Parties in previous forums that are perceived as "gaps" in existing risk assessment and risk management guidance and the conclusions reached and arguments made during these forums:

(a) Four online fora on synthetic biology were held between 3 July and 2 October 2017, which address, *inter alia*, technological developments, potential impacts and adverse effects, and risk assessment and risk management measures relative to the topic. Summaries from these forums are available on-line, and while the discussions were very broad with much disagreement, we would like to refer to quotes from moderator summaries from three of the four online forums:

1. "In light of the frameworks that are already in place in the context of the Cartagena Protocol there is probably no need for new or unique regulations or provisions, and that if new regulations are put in place they have to be evidence-based and proportionate to risk."
2. "There was a general agreement amongst participants that most, if not all, living organisms that are already developed or are currently under research and development through techniques of synthetic biology fall under the definition of living modified organisms under the Cartagena Protocol".
3. "There was general agreement amongst participants that current risk management measures and best practices, such as confinement strategies, restrictions in use, monitoring and reporting requirements as well as contingency plans, that are in use for "traditional" LMOs are also sufficient in the context of living organisms developed through current and near future applications of synthetic biology"

The GIC also highlights that the views expressed by the majority of experienced regulators have not identified specific examples of current or foreseeable synthetic biology applications in the various information gathering activities under the CBD and BSP that present novel regulatory challenges or biosafety risks that cannot be managed by the existing LMO/GMO regulatory frameworks.

Finally, in the above-mentioned forum, perceived "gaps" have been attributed to a myriad of realistic and hypothetical products derived from synthetic biology techniques. Many of the components and non-living products of synthetic biology are not in the scope of the BSP, however they are regulated (where appropriate) by a variety of international and national mechanisms, e.g. chemicals and pharmaceuticals are regulated, as appropriate, by long-established sectorial regulatory regimes governing their safe use and trade.

(b) In previous submissions, meetings and online forums, some participants have suggested that genome editing is an area where there is a gap in guidance on risk assessment and risk management. The GIC contends that genome editing is best understood and correctly described as one of many enabling tools that may be used in various biotechnological applications. As a tool of biotechnology, genome editing is within the scope of "biotechnology" as defined by the BSP and certain applications are also within the scope of "modern biotechnology" as defined by the BSP. For example, plants developed using genome editing may be comparable to transgenic/LM plant organisms developed using established recombinant technologies, or they may be comparable to plants developed using conventional breeding tools. For both, there exists extensive evidence for the lack of adverse environmental impacts, and neither presents a fundamental change in risk or in the approach to assessing risk. The inclusion or exclusion of certain applications of genome editing and their resulting organisms from the definitions of "modern biotechnology" or "LMO" do not represent "gaps" in regulatory oversight.

(c) Gene drive applications have also been suggested in a previous online forum and in submissions to the Secretariat as warranting the development of specific risk assessment guidance, or minimum standards for data and evaluation requirements under the CBD/BSP. However, the GIC contends that prior to agreeing to move forward in developing guidance under the BSP, there is a need to assess the feasibility of engineered gene drive applications, and identify the most appropriate forum for developing risk assessment guidance. For mosquitoes, the scientific community pointed out that this work is already underway in fora with the relevant expertise, e.g. the 2014 "Guidance Framework for Testing Genetically Modified Mosquitos" developed by WHO and the Foundation for the NIH (FNIH) is being updated to include gene drives. Mosquitoes are the only application of engineered gene drives where proof of concept was demonstrated. However, this research remains in the early stages with technical challenges reported, e.g. evolution of resistance in laboratory populations. All other applications of engineered gene drives are currently conceptual and releases into the environment are thus not currently foreseeable. The development of environmental risk assessment guidance for engineered gene drives needs to be based in experimentally derived scientific evidence that is yet to be accumulated. Thus, the GIC believes that it is still premature to begin development of guidance in the absence of sufficient information on the subject. The GIC notes that information of naturally occurring gene drives can serve as a good basis for defining relevant assessment criteria for engineered gene drives in the future.

C. Conclusions

The GIC recognizes that the issue of developing risk assessment guidance has been ongoing for many years without evidence of significant progress. The GIC agrees with the prevailing view among countries with experience in risk assessment of LMOs that there is currently no need to develop new, additional guidance on special topics related to current and foreseeable LM technological applications. Rather, better and more appropriate paths forward would be to leverage existing guidance and experience through bilateral mechanisms and efficient use of the BCH in accordance with Articles 14 and 20 of the BSP.

The GIC is concerned that this on-line forum with its two open questions will not provide additional clarity and is unlikely to serve the needs of Parties. We support the development of consensus-based criteria and a decision process that could be used at meetings of the Parties to determine when new, additional guidance is needed as requested in Decision VIII/12.

The GIC contends that efforts and resources would be more appropriately spent on efforts by the Parties and other Governments to collect and review the extensive guidance that currently exists in countries with experience in developing, testing, and commercializing LMOs, and to operationalize these materials in the context of their national biosafety regulations and policies. Parties should focus on sharing experiences and real case examples of risk assessment, taking into account practical and real-life experience of risk assessors.