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CARTAGENA PROTOCOL ON BIOSAFETY
Articles 15 and 16: Risk Assessment and Risk Management

The Global Industry Coalition (GIC)[1] continues to have significant concerns with the Guidance on Risk Assessment of Living Modified Organisms (Guidance), and development of further guidance on specific topics of risk assessment, under development by the Parties to the Cartagena Protocol on Biosafety (Protocol) for over seven years. We strongly oppose both endorsement of the Guidance in its current form, as well as establishment of a process for developing further guidance by the Parties at the eighth meeting of the Parties to the Protocol (COP/MOP-8) until fundamental concerns with process and output are adequately addressed. Notably, many Parties have suggested improvements to the Guidance that have not been fully vetted and incorporated, and this must be completed before it can be endorsed. In addition, significantly diverging views on the need for, and approach to, developing additional guidance remain, especially in regards to the need to address synthetic biology. Until there is clear agreement among the Parties that development of additional guidance is both necessary and warranted, the GIC believes that no further work by the AHTEG should be undertaken.

Background: Articles 15 and 16[2] of the Protocol outline requirements that relate to risk assessment and risk management of LMOs. Article 15 requires Parties to make decisions on the import of LMOs for intentional introduction into the environment in accordance with scientifically sound and evidence-based risk assessments. The general principles, methodological steps, and points to consider in the conduct of such risk assessments are set out in Annex III of the Protocol. Article 16[3] of the Protocol requires Parties to adopt measures and strategies for managing and controlling any risks identified by the risk assessment, and for preventing unintentional transboundary movements of LMOs with the objective to prevent adverse effects of the living modified organisms on the conservation and sustainable use of biological diversity.

The Parties have been discussing the topic of existing support/guidance for risk assessment and the potential need for additional guidance since their second meeting in 2004. Despite the outcome of the first AHTEG in 2005, which concluded that there was limited need for work on this topic, protracted efforts to realize basic guidance on risk assessment as well as guidance on specific topics and training materials have been in process for over seven years without demonstrated success.

At their sixth meeting in 2012, Parties requested testing of the Guidance which produced numerous comments for consideration. At their seventh meeting in 2014, the Parties again established a mechanism for revising and improving the Guidance on the basis of the feedback provided through the testing process undertaken prior to the meeting, with a view to having an improved version of the Guidance by COP/MOP-8. They also extended the work of an open-ended online forum on risk assessment and risk management (Online Forum) and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management to serve until COP/MOP-8. Lastly, taking into account the possibility that the provisions of the Protocol could also apply to living organisms resulting from synthetic biology applications (subject to the acceptance by the parties of an operational definition of synthetic biology), the Parties also recommended a coordinated approach with the Convention on Biological Diversity (Convention) on this issue.

[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] http://bch.cbd.int/protocol/text

Parties will consider the outcomes of the intersessional work on risk assessment and risk management at COP/MOP-8. The GIC's views on the proposed draft decision on these issues are outlined below.

A. GIC Views on the Elements for a Draft Decision on Articles 15 and 16 at COP/MOP-8

Regarding the "Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment"

- ***The GIC strongly opposes the proposal that the Guidance be endorsed and used in its current version in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment. The GIC contends that the results of the testing have not been thoroughly considered and incorporated, and in many cases, input from Parties has been ignored altogether, resulting in a version of the Guidance that lacks focus and clarity, is difficult to apply, and is of limited relevance.***
- Despite feedback from testing of the Guidance and efforts to "improve" it, the current version is even more lengthy, complex and difficult to follow than the version considered by the Parties at COP/MOP-7. In particular, the current version includes additional "boxes" containing special considerations for some topics (such as considerations for human health and centers of origin) which only further distract from the flow of the Guidance. In most cases, these "boxes" do not offer useful information, or include information that is outside of the scope of LMO risk assessment.[4] Furthermore, there is no consensus among Parties on whether these special considerations for risk assessment are even required.
- Specific and highly-relevant comments made by Parties during the testing process have not been taken into consideration, for example:
  - Many comments suggested the addition of a problem formulation step and the use of the problem formulation approach throughout the Guidance to help connect the five risk assessment steps. A definition and description of problem formulation have been added in the current version; however, there is no explanation of how to use problem formulation to move through the steps of the risk assessment in a logical and practical way. Thus, the current version of the Guidance is unlikely to be of help to inexperienced risk assessors, and would be of no value to experienced risk assessors that utilise alternative, more coherent sources of guidance.
  - Despite the input of many countries that the Guidance should not include monitoring, monitoring is still included and the title of the Guidance has even been modified in the current version to include "monitoring in the context of risk assessment".
  - Many countries have also commented about the disproportionate emphasis on uncertainty in the Guidance, most evident in the "identification and consideration of uncertainty" section, throughout the years of its development. The current version retains most of the original text in this section, and is even more complex and confusing and difficult to apply in practice.
  - Many countries also criticized the elaboration of the lists of "elements for consideration" found throughout the Guidance. The lists do not provide any context nor explanation of when they should be considered or to what environmental harm they are linked. In particular, elements such as combinatorial and cumulative effects were considered confusing and unclear by many, yet these remain in the Guidance.
- An attempt has been made in a new Annex to Part I of the Guidance, which was not subject to testing, to provide an example of the "most relevant" elements to consider in the different steps. However, the example is inaccurate and does not provide correct examples of assessment and measurement endpoints, nor an explanation of the relevance of the listed elements to consider.

[4] E.g., "LM crops and the use of herbicides" and "Characterisation of LMOs developed through RNAi-based methods".

- ***As evidenced above, there continues to be a high degree of disagreement among members of AHTEG and on-line forum on technical and scientific issues relevant for the development of a usable and relevant Guidance that will actually assist inexperienced regulators with implementation of Articles 15 and 16 of the Protocol.*** After more than seven years of online discussions and face-to-face meetings, the record clearly establishes that a consensus on the content of the Guidance as drafted continues to be impossible to achieve. Efforts to improve it have only resulted in an increasing divergence of views, and this is reflected by the lack of clarity and focus in the content of the current version.
- The GIC recognizes the need that some Parties have for capacity-building in risk assessment, but considers that other established sources of guidance are more useful to assist Parties in implementing the Protocol. Examples include: the work in Latin America to develop environmental risk assessment guidance specific to that region, the work undertaken by the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology, and the information produced by the International Life Sciences Institute Center for Environmental Risk Assessment. Parties could benefit most from the experience of those Parties and other Governments with direct experience in undertaking environmental risk assessments for LMOs. This significant body of expertise accumulated over more than twenty years is not reflected in the Guidance as drafted.
- ***In addition, it is inappropriate for the Parties to request the Global Environment Facility to provide funding for a global capacity-building project on risk assessment and risk management based on the Guidance as such a project would emphasize the use of impracticable Guidance over these proven options and tools.*** This again demonstrates that it is premature to endorse the Guidance as currently written.
- ***Furthermore, the GIC recommends that Parties consider recognizing the importance and direct relevance of sharing experiences in conducting risk assessments that have formed the basis for decision-making.*** The Guidance– after incorporation of all relevant comments from the testing and actual examples - may be recognized as *one potential tool* in the area of risk assessment and risk management, while also recognizing that various other guidance materials with proven and tested utility already exist.

<u>Regarding the Development of Further Guidance on Specific Aspects of Risk Assessment</u>

- ***The GIC strongly disagrees with the element of the draft decision at COP/MOP-8 that proposes establishment of a process to develop guidance on risk assessment of LMOs developed in synthetic biology applications.*** It is premature to develop guidance for risk assessment of LMOs created through synthetic biology applications in the absence of consensus on the scope and definition of synthetic biology. The Parties to the Convention have been unable to reach consensus on a meaningful definition of synthetic biology, reflecting the divergence of views as to whether one is actually needed given the adequacy of the definitions of "biotechnology" in the Convention, and "modern biotechnology" and "living modified organism" in the Protocol.
- In addition, and very importantly, current methodologies of risk assessment are adequate to address risks of LMOs developed through current and foreseeable applications of synthetic biology. In the online forum discussion on this issue, no examples of LMOs could be identified by experts and experienced regulators that could not be handled by existing risk assessment principles and methodologies according to existing regulatory frameworks. This was also the case in the discussions of the open-ended online forum on synthetic biology, and the work of the AHTEG on Synthetic Biology.
- We also emphasize that the Guidance is intended to apply to any LMO that falls under the scope of the Protocol, and all topics proposed in the synthetic biology guidance outline are already addressed by either Annex III of the Protocol and/or the Guidance, making additional guidance in this area duplicative. The GIC supports the views of AHTEG

members that monitoring advances in synthetic biology would be a more appropriate way forward than developing risk assessment guidance on LMOs developed through synthetic biology.[5]

- It is also important to note that the inclusion of synthetic biology as a prioritized topic for the development of further guidance did not occur "on the basis of the priorities and needs indicated by the Parties" as required in the terms of reference for the Open-ended Online Forum and AHTEG in decision UNEP/CBD/BS/COP/MOP/VI/12. The AHTEG included synthetic biology as a topic for further guidance based on suggestions made by individuals acting in their personal capacity in the online forum, and not via any input from the Parties themselves. The very fact that synthetic biology is being pursued as a topic for further guidance demonstrates that the AHTEG did not follow its mandate on how to prioritize topics and indeed, disrespects the rules of procedures of the Convention and the Protocol.
- ***The GIC also strongly discourages Parties from extending the mandate of the Open-ended Online Expert Forum and the AHTEG beyond COP/MOP-8 with the objective of developing guidance on additional topics of risk assessment and risk management for which there is no justified current need***. Developing additional guidance on risk assessment and risk management for new topics is premature as it would take away the focus and attention required to achieve consensus the fundamental elements of risk assessment for scientifically-sound decision-making in relation to LMOs. If additional guidance is ultimately deemed necessary, the comments received during the testing of the Guidance should first be fully analyzed and taken into consideration when developing further guidance. **Moreover, the GIC continues to stress that a well-developed Guidance should apply to all potential types of LMOs under the Protocol.**
- It is also important to note that the rules of procedure governing the work of the Parties under the Protocol require AHTEGs to be convened "for a limited duration".[6] It is therefore appropriate for AHTEG to be discontinued after over seven years of existence and no clear and necessary mandate for ongoing work that cannot be completed by other means (e.g., through Parties and other Governments sharing experiences in conducting risk assessments via the Biosafety Clearing-House).
- **The GIC suggests that Parties follow a rational, stepwise approach in their work on risk assessment and risk management – an approach favored by many of the AHTEG members themselves.** The GIC considers it more productive to first focus on ensuring the current Guidance is of a quality and utility acceptable to the majority of Parties, Governments and expert observers, and that it accurately reflects how risk assessment has been used in more than 20 years of LMO risk assessment and decision-making. Only after completing the Guidance, and finalizing associated capacity building tools, would it be appropriate to consider the need to develop additional guidance documents on new topics. The Parties themselves can establish a process and mechanism to develop additional guidance documents if and when the need is identified.

For more information on this and other Protocol implementation issues, please visit http://croplife.org/plant-biotechnology/cartagena-protocol-on-biosafety/.

[5] See Annex I for more detailed GIC positions on the proposed Outline of Guidance on Risk Assessment of Living Modified Organisms Developed through Synthetic Biology (UNEP/CBD/BS/COP-MOP/8/8/ADD3).

[6] See Section 6.H.18 on page 26 of *the Rules, Procedures and Mechanisms Applicable to Processes under the Cartagena Protocol on Biosafety* locate at: https://www.cbd.int/doc/publications/bs-rules-en.pdf.

Annex I
GIC Positions on the Proposed Outline of Guidance on
Risk Assessment of LMOs Developed through Synthetic Biology
(UNEP/CBD/BS/COP-MOP/8/8/ADD3)

Background: In November 2015, the Risk Assessment Ad Hoc Technical Expert Group (AHTEG) under the Cartagena Protocol on Biosafety (Protocol) proposed to develop guidance for risk assessment of synthetic biology products, pending the outcomes of the synthetic biology deliberations at SBSTTA-20 (April 2016). Following SBSTTA-20, the Convention on Biological Diversity (Convention) Secretariat interpreted permissive language from the final report that suggested risk assessment methodologies may need to be updated for synthetic biology[7] as a "green light" for the AHTEG to begin developing such guidance. In May and June 2016, the risk assessment online forum considered the need to develop additional guidance for synthetic biology, having been informed of this "green light" to proceed. The majority of participants in these online discussions, many of whom represented Parties, considered it premature to develop guidance for synthetic biology since no example of LMOs could be identified that could not be handled by existing risk assessment principles and methodologies. Despite this, the Risk Assessment AHTEG proceeded with developing an "Outline of Guidance on Risk Assessment of Living Modified Organisms Developed through Synthetic Biology" for consideration by the Parties at COP13.

This issue of whether additional guidance for LMOs developed through synthetic biology will first be considered by the Parties to the Convention when they address the overall draft decision on synthetic biology. The outcomes will then be forwarded to the Parties to the Protocol when they consider the draft decision on risk assessment. As such, the information below provides industry views on this issue for the discussions in both forums.

GIC Views on the Development of Additional Risk Assessment Guidance for LMOs Developed Through Synthetic Biology

1. **Additional Guidance specific to risk assessment of LMOs produced through synthetic biology is unnecessary for the following reasons:**
   a. Synthetic biology is within the scope of "biotechnology" as defined by the Convention, and "modern biotechnology" as defined by the Protocol. A well-developed guidance should apply to all potential types of LMOs within this scope.
   b. Experts and experienced regulators in all Convention and Protocol synthetic biology processes (open-ended online fora and AHTEGs) have been unable to identify specific examples of LMOs created by current and realistically foreseeable synthetic biology applications that would present novel challenges that could not be managed using existing risk assessment approaches.
2. **The "Outline" contains "specific considerations" that do not reflect the views of experts and experienced regulators in the online discussions held specifically on this topic, as these are not derived from these discussions. Rather, the specific considerations appear to have been drawn from all Convention and Protocol processes connected to synthetic biology. These "Specific Considerations" include:**
   a. Choice of comparators: The Guidance as drafted already contains a substantial section on comparators ("The choice of comparators") that, consistent with the principles of Annex III, recognizes that the choice of appropriate comparator(s) needs to be determined on a

[7] See UNEP/CBD/SBSTTA/REC/XX/8, preambular pargraph (e), which states: "The general principles and methodology for risk assessment under the Cartagena Protocol and existing biosafety frameworks provide a good basis for risk assessment regarding living organisms developed through current and near future applications of synthetic biology, but such methodologies may need to be updated and adapted for current and future developments and applications of synthetic biology."

case by case basis, and that alternatives to comparator-based risk assessment may be more appropriate in some circumstances. These principles remain entirely applicable to LMOs created by synthetic biology. Any expansion of this guidance on comparators specifically for LMOs created by synthetic biology must be based on current and realistically foreseeable applications that present novel challenges that cannot be managed by existing approaches to comparator choice, and none have been identified at the present time.

b. LMOs being developed faster and with an increased number of modified traits: The content of this section of the outline is based on speculative assumptions that are not consistent with the inability of experts and experienced regulators to identify examples of current and realistically foreseeable synthetic biology applications that present novel challenges for risk assessment. In reality, many examples exist of LMOs with multiple traits for which existing risk assessment methodologies and approaches were adequate. Further, it is the characteristics of the traits that are important in risk assessment, not the number of traits, and these are assessed on a case-by-case basis consistent with the principles of Annex III. We emphasise that for any additional guidance on synthetic biology to be meaningful, it must have a basis in current and realistically foreseeable applications where novel and specific challenges to risk assessment can be identified.
c. Potential to alter wild populations, species and ecosystems: This section is focused on gene drives, which in our view are not synthetic biology. Gene drives are merely enabling tools for achieving biased inheritance of a particular gene/allele in a population. The identification of novel challenges for conducting risk assessments with LMOs containing gene drives is currently a developing area of research requiring the participation of a broader range of stakeholders and expertise than the AHTEG.
d. LM microorganisms resulting from synthetic biology: A well-developed Guidance should apply to all potential types of LMOs under the Protocol, including microorganisms. Any deficiencies in the Guidance in regard to LMOs (particularly LMOs that are not plants) should be addressed in the Guidance itself, not with additional guidance for synthetic biology. Further, no examples of current and realistically foreseeable synthetic biology applications involving "complex LM microorganisms" have been identified by experts and experienced regulators for which existing risk assessment approaches were insufficient.
e. Increased accessibility to techniques of synthetic biology: The activities of citizen scientists, where regulated, will be subject to the same risk assessment methodologies as other (institutional) scientists. The issue here is not risk assessment methodology but biosafety awareness and information sharing within that community. It is not clear how additional guidance on risk assessment for synthetic biology is useful to this community or even within the scope of the Convention or the Protocol.
f. Detection of LMOs developed through synthetic biology using genome editing: This section is focused on genome editing, which in our view is not synthetic biology. Genome editing is merely an enabling technology that may be used in synthetic biology applications, as well as other applications. Any consideration of detection methods would be better addressed by the Network of Laboratories for the Detection and Identification of LMOs.