**NON-paper**

RISK ASSESSMENT

Further to the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-9/13, paragraph 12, and in the light of the outcomes of the discussions of the AHTEG, the Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, at its tenth meeting, adopt a decision along the following lines:

*The Conference of the Parties serving as the meeting to the Parties to the Cartagena Protocol on Biosafety,*

*Recalling* decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish;

***Further recalling* decision BS-VII/12, paragraph 17, in which it recommends to the Conference of the Parties to the Convention of Biological Diversity a coordinated approach with the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety on the issue of synthetic biology, taking into account that the provisions of the Protocol may also apply to living organisms resulting from synthetic biology;**

***Noting* the existing voluntary guidance on the assessment of socio-economic considerations in the context of article 26 of the Cartagena Protocol on Biosafety;**

1. *Welcomes* the outcomes of the discussions of the Ad Hoc Technical Expert Group on Risk Assessment;[[1]](#footnote-1)
2. *Takes note* of the clarifications made by the Ad Hoc Technical Expert Group to annex I of decision CP-9/13 regarding the process for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration;[[2]](#footnote-2)
3. ***Welcomes*** the analysis done by the Ad Hoc Technical Expert Group on the topics of (a) living modified organisms containing engineered gene drives and (b) living modified fish according to decision CP-9/13, annex I;
4. *Notes* the range of perspectives on the need for the development of guidance on risk assessment of living modified fish, and decides not to **prioritize**, at this stage, **the development of** additional **voluntary** guidance materials on risk assessment regarding living modified fish, **and *encourages* Parties, other Governments and relevant organizations to promote international cooperation, knowledge sharing and capacity-building on risk assessment of living modified fish, and to make use of existing guidance materials;**
5. *Endorses* the recommendation of the Ad Hoc Technical Expert Group that **additional voluntary** guidance **materials to support case-by-case** risk assessment of living modified organisms containing engineered gene drives should be developed**, and *agrees* to develop such guidelines as per annex 1**;
6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to **work** according to the terms of reference annexed hereto;
7. *Invites* Parties, other Governments, indigenous peoples and local communities and relevant organizations to submit to the Executive Secretary information relevant to the work of the Ad Hoc Technical Expert Group;

**(7 bis) *Invites* Parties to also submit information on their needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms including a rationale reflecting the criteria set out in annex I of decision CP-9/13;**

(**7ter) *Calls* upon Parties, other Governments and relevant organizations to continue to disseminate information and share experiences, especially through the Biosafety Clearing-House, useful for the risk assessments of living modified organisms, including living modified fish and organisms containing engineered gene drives;**

1. *Requests* the Executive Secretary:
   * 1. To convene online discussions of the Online Forum on Risk Assessment and Risk Management to **review an outline and a first draft of the technical guidance and to** support the work of the Ad Hoc Technical Expert Group**;**
     2. To collect and synthesize relevant information to facilitate the work of the Online Forum and the Ad Hoc Technical Expert Group;
     3. To synthesize the views referred to in paragraph 7 **and 7 bis** above and the discussions of the Online Forum and make them available for the Ad Hoc Technical Expert Group;
     4. To convene, subject to the availability of resources, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment **with at least one of the meetings as a face-to-face;**

**(e) To facilitate the process of Identification and Prioritization of Specific Issues of Risk Assessment of Living Modified Organisms that May Warrant Consideration established on paragraph 6 of decision CP-9/13, by making information submitted by Parties on issues identified according to annex I of the same decision, as well as information useful for the risk assessment of those topics, available through a dedicated web page within the Biosafety Clearing-House;**

**(f) To ensure the full and effective participation of indigenous peoples and local communities in the discussions and in the work on risk assessment under the Cartagena Protocol;**

**(g) To explore ways to facilitate and support capacity-building and knowledge-sharing regarding risk assessment of living modified organisms;**

1. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;
2. *Decide*s to consider, at its eleventh meeting, additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, taking into account priorities identified by Parties **in paragraph 7bis above and the report of the Ad Hoc Technical Expert Group as per paragraph (d) of its terms of reference.**

*Annex*

# Terms of reference for the Ad Hoc Technical Expert Group on Risk Assessment

1. The Ad Hoc Technical Expert Group (Group) on Risk Assessment shall:

(a)  Be composed of expertsselected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice, **ensuring expertise on engineered ge****ne drives as well as on issues relevant to the mandate of the Group, and including experts from relevant international organisations,** **as well as indigenous peoples and local communities,** **and applying** **decision 14/33 on the procedure for avoiding or managing conflicts of interest in expert groups;**

**(a bis) Consider modalities of operation to ensure a fast and efficient drafting process, including the use of a small drafting group, as appropriate;**

(b) Meet twice, subject to the availability of funds and prior to the eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, **with at least one of the meetings being face-to-face,** and perform necessary tasks between its two meetings **supported by online means of communication and engagement;**

(c) Develop **additional** **voluntary** **technical** guidance **materials** for conducting **case-by-case** risk assessments of living modified organisms containing engineered gene drives in accordance with annex III of the Protocol, **with a focus on engineered gene drives mosquitos, and based on a first draft reviewed by the Online Forum and;**

**(c bis) Analyse the information submitted by Parties as per paragraph 7bis and prepare a prioritized list of topics on which further guidance materials on risk assessment may be needed;**

(d) Prepare a report, including draft **additional** **voluntary** **technical** guidance **materials** **on living modified organisms containing engineered gene drives and a prioritized list of topics on which further guidance materials on risk assessment may be needed**, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.

2. In undertaking its work, the Group shall consider the synthesis of views from the submissions and discussions in the online forum prepared by the Executive Secretary; existing resources identified in the stock-taking exercise of the “study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives”;[[3]](#footnote-3) **relevant decisions on risk assessment and risk management** **taken under the Cartagena Protocol on Biosafety** and any other relevant information collected by the Executive Secretary further to paragraph **8c** of decision CP-10/--.

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1. CBD/CP/RA/AHTEG/2020/1/5. [↑](#footnote-ref-1)
2. See CBD/CP/RA/AHTEG/2020/1/5, annex I, sect. III. [↑](#footnote-ref-2)
3. CBD/CP/RA/AHTEG/2020/1/4. [↑](#footnote-ref-3)