

SUBSIDIARY BODY ON SCIENTIFIC,
TECHNICAL AND TECHNOLOGICAL ADVICE
Twenty-fourth meeting
Online, 3 May – 9 June 2021
Agenda item 5

RISK ASSESSMENT AND RISK MANAGEMENT

Draft recommendation submitted by the Chair

The Subsidiary Body on Scientific, Technical and Technological Advice *recommends* 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 of 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,

Also recalling decision BS-VII/12, paragraph 17, in which it recommended 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 the possibility that the provisions of the Protocol might 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
2. *Takes note* of the clarifications made by the Ad Hoc Technical Expert Group on 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
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, *decides* not to proceed, at this stage, with the development of additional voluntary guidance materials on risk assessment regarding living modified fish, and *encourages* Parties and *invites* other Governments and relevant organizations to promote international cooperation, information sharing and capacity-building on risk assessment of living modified fish, and to make use of existing guidance materials, [with a view to considering further guidance on living modified fish at its eleventh meeting;]
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

¹ CBD/CP/RA/AHTEG/2020/1/5.

² See CBD/CP/RA/AHTEG/2020/1/5, annex I, sect. III.

containing engineered gene drives should be developed, and *agrees* to develop such additional voluntary guidance materials as per annex I;

[6. *Requests* a panel of 3 to 6 experts selected in a way to warrant the required scientific expertise to develop a detailed outline and first draft of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives to ensure a fast and efficient drafting process;]

7. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment that will work according to the terms of reference annexed hereto;

8. *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;

9. *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] [following] the criteria set out in decision CP-9/13, annex I;

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

11. *Requests* the Executive Secretary:

[(a) To contract, subject to the availability of resources, a panel of three to six experts selected in a way to warrant the required scientific expertise to develop a detailed outline and first draft of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives;]

(b) To convene online discussions of the Online Forum on Risk Assessment and Risk Management to review an outline and a first draft of the additional voluntary guidance materials and to support the work of the Ad Hoc Technical Expert Group;

(c) To collect and synthesize relevant information to facilitate the work of the Online Forum and the Ad Hoc Technical Expert Group;

(d) To synthesize the views referred to in paragraphs 8 and 9 above and the discussions of the Online Forum and make them available to the Ad Hoc Technical Expert Group;

(e) 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;³

(f) To facilitate the process of identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration, as established in paragraph 6 of decision CP-9/13, by making information submitted by Parties on issues identified in accordance with 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;

(g) 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;

(h) To explore ways to facilitate and support capacity-building and knowledge-sharing and technology transfer regarding risk assessment and risk management of living modified organisms;

(i) To provide dedicated web pages in the Biosafety Clearing-House to facilitate easy access and raise awareness of available information that is relevant for risk assessment of living modified organisms, including living modified fish and organisms containing engineered gene drives;

³ Depending on restrictions due to the pandemic situation.

12. *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;

13. *Decides* 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 pursuant to paragraph 9 above and the report of the Ad Hoc Technical Expert Group as per paragraph 1(f) 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 experts selected in accordance with the section H of the consolidated *modus operandi* of the Subsidiary Body on Scientific, Technical and Technological Advice, ensuring specific [scientific] expertise on organisms containing engineered gene drives and their potential effects on biodiversity as well as on issues relevant to the mandate of the Group, and including experts from relevant international organizations,⁴ 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;

[(b Consider modalities of operation to ensure a fast and efficient drafting process, [including a small drafting group] based on a first draft reviewed by the Online Forum, as appropriate;]

(c) 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;

[(d) Develop additional voluntary 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. A specific focus of this material should be engineered gene drive mosquitos [taking into account general considerations of living modified organisms containing on gene drives,][challenges identified by the Ad Hoc Technical Expert Group on Risk Assessment⁵ and process identified in annex 1 of decision CP-9/13] and existing national and regional risk assessment experiences. [taking into account human health, environmental and socioeconomic impacts as well as traditional knowledge and the value of biodiversity to indigenous peoples and local communities]]

(e) Analyse the information submitted by Parties as per paragraph 9 and, on the basis of this, prepare a list of prioritized topics on which further guidance materials on risk assessment may be needed according to criteria in decision CP-9/13, annex I;

(f) Prepare a report, including draft additional voluntary guidance materials on living modified organisms containing engineered gene drives and a list of prioritized topics as per paragraph (e) above, on which further guidance materials on risk assessment may be needed, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

⁴ Such as the World Trade Organization, the International Union for Conservation of Nature, the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services and the Food and Agriculture Organization of the United Nations.

⁵ CBD/SBSTTA/24/5, annex, paras. 4-41.

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, including those 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”,⁶ guidance materials already available, 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 11 (c) of decision CP-10/--.

⁶ CBD/CP/RA/AHTEG/2020/1/4.