



Convention on Biological Diversity

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**Subsidiary Body on Scientific,
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Twenty-sixth meeting
Nairobi, 13–18 May 2024
Agenda item 6
Risk assessment and risk management

Risk assessment and risk management

Draft recommendation submitted by the Chair

The Subsidiary Body on Scientific, Technical and Technological Advice

Recommends that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety 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 Article 1 of the Cartagena Protocol on Biosafety,¹

Recalling also decision [CP-10/10](#) of 10 December 2022,

Recalling further decision [CP-9/13](#) of 28 November 2018, by which it established a process for the identification and prioritization of specific issues regarding the risk assessment of living modified organisms that might warrant consideration,

Recalling paragraph 7 of decision 14/19 of 29 November 2018 of the Conference of the Parties to the Convention on Biological Diversity,² in which the Conference of the Parties emphasized the need for a coordinated, complementary and non-duplicative approach on issues related to synthetic biology under the Convention and its Protocols, [and noting the conclusions of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment, in particular its recommendation to consider self-limiting insects as a potential topic for the further development of guidance on risk assessment in line with the process set out in annex I to decision CP-9/13,]

Taking note of the assessment by the Ad Hoc Technical Expert Group on Risk Assessment of additional issues on which guidance materials on risk assessment may be needed,³

¹ United Nations, *Treaty Series*, vol. 2226, No. 30619.

² United Nations, *Treaty Series*, vol. 1760, No. 30619.

³ See CBD/CP/RA/AHTEG/2024/1/3.

1. [Takes note of][Welcomes with appreciation] the outcomes of the meetings of the Ad Hoc Technical Expert Group on Risk Assessment;⁴

2. [Also welcomes][Acknowledges][Endorses] the additional voluntary guidance materials to support the case-by-case risk assessment of living modified organisms containing engineered gene drives;⁵

[3. *Encourages* Parties, other Governments, indigenous peoples and local communities, women and youth organizations and relevant organizations and stakeholders to make use of the additional voluntary guidance materials in conducting relevant risk assessments and as a tool for capacity-building activities in risk assessment;]

4 *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders that have used the voluntary guidance materials to submit information on their experiences and assessment of the applicability and usefulness of the materials to the Executive Secretary;

5. *Calls* for broad international cooperation, knowledge-sharing, capacity-building and resource mobilization to support, inter alia, the application of the additional voluntary guidance materials;

[6. *Also calls* for the consideration of the related issues set out in the additional voluntary guidance materials,⁶ including traditional knowledge, innovation and practices of indigenous peoples and local communities, when using the voluntary guidance materials;]

[

7. *Decides* to establish an ad hoc technical expert group on risk assessment, with the terms of reference contained in the annex to the present decision, tasked with the development of additional voluntary guidance materials to support the case-by-case risk assessment of living modified fish;

8. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Secretariat information relevant to the work of the Ad Hoc Technical Expert Group on Risk Assessment;

9. *Decides* to extend the Open-ended Online Forum on Risk Assessment and Risk Management to contribute to the development of additional voluntary guidance materials in support of the case-by-case risk assessment of living modified fish;

10. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider at its twenty-eighth meeting the outcomes of the work of the Ad Hoc Technical Expert Group on Risk Assessment and to make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its twelfth meeting;

]

11. *Invites* Parties to submit detailed information on their needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms, including a rationale following the criteria set out in annex I to decision CP-9/13[, taking into account the recommendation of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to consider self-limiting insects as a potential topic];

⁴ CBD/CP/RA/AHTEG/2023/1/4 and CBD/CP/RA/AHTEG/2024/1/3.

⁵ CBD/SBSTTA/26/5/Add.1.

⁶ Ibid., sect. 7.

12. *Decides* to extend the Open-ended Online Forum on Risk Assessment and Risk Management to support the analysis of further topics of risk assessment in accordance with the criteria outlined in annex I to decision CP-9/13;

13. *Also decides* to consider at its twelfth 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 the risk assessment of living modified organisms established in decision CP-9/13, taking into account the needs and priorities identified by Parties pursuant to paragraph 11 above [and the report of the Ad Hoc Technical Expert Group on Risk Assessment submitted pursuant to paragraph 1 (e) of its terms of reference];

14. *Requests* that the Secretariat, subject to the availability of resources:

(a) Prepare a synthesis of the information submitted in response to paragraph 4 above for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its twelfth meeting;

(b) Convene capacity-building and development activities in support of risk assessment with a particular focus on the risk assessment of living modified organisms containing engineered gene drives;

[

(c) Develop a detailed outline of additional guidance materials on the risk assessment of living modified fish for peer review, in preparation for the work of the Ad Hoc Technical Expert Group on Risk Assessment;

(d) Convene online discussions of the Open-ended Online Forum on Risk Assessment and Risk Management to support the work of the Ad Hoc Technical Expert Group on Risk Assessment in drafting a detailed outline for the case-by-case risk assessment of living modified fish;

(e) Synthesize the information submitted by Parties, other Governments and relevant organizations in order to facilitate the work of the Ad Hoc Technical Expert Group on Risk Assessment;

(f) Convene, subject to the availability of resources, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment, at least one of which should be held in person;

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[(g) Collect relevant information to support the risk assessment of self-limiting insects and make it available on the Biosafety Clearing-House.]

[Annex

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

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

(a) Be composed of experts, selected in accordance with section H of the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice,⁷ with specific scientific and technical expertise on living modified fish and their potential effects on biodiversity and on issues relevant to the mandate of the Expert Group, and include experts from relevant international organizations and from indigenous

⁷ Decision VIII/10, annex III.

peoples and local communities, in line with decision 14/33 of 29 November 2018 on the procedure for avoiding or managing conflicts of interest in expert groups;

(b) Subject to the availability of funds, hold at least one in-person meeting before the twelfth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety,⁸ and perform its work by means of online communication and engagement, as appropriate;

(c) Develop additional voluntary guidance materials for conducting the case-by-case risk assessment of living modified fish in accordance with annex III to the Protocol, taking into account the current experience with the organisms and specific issues of risk assessment identified in annex I to decision CP-9/13 of 28 November 2018, including existing reports, general considerations of living modified fish and existing national and regional risk assessment experiences;

(d) Analyse the information submitted by Parties further to paragraph 11 of decision CP-11/--, and on that basis prepare a list of prioritized topics on which further guidance materials on risk assessment may be needed according to the criteria set out in annex I to decision CP-9/13;

(e) Prepare a report, including draft voluntary guidance materials on living modified fish and a list of prioritized topics further to subparagraph (d) above, on which further guidance materials on risk assessment may be needed, for consideration by the Subsidiary Body.

2. In undertaking its work, the Expert Group shall consider the synthesis of views from the submissions and discussions in the Open-ended Online Forum on Risk Assessment and Risk Management prepared by the Secretariat; existing resources, including those identified in the stocktaking exercise of the study on risk assessment: application of annex I to decision CP-9/13 to living modified fish;⁹ guidance materials already available; and relevant decisions on risk assessment and risk management adopted by the Conference of the Parties serving as the meeting of the Parties to the Protocol.]

⁸ United Nations, *Treaty Series*, vol. 2226, No. 30619.

⁹ CBD/CP/RA/AHTEG/2020/1/3, annex.