

[Agenda item 11]
[Risk assessment and risk management]
Working Group II

Risk assessment and risk management

Non-paper

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,³ 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,⁴

1. *[Takes note of][Welcomes with appreciation]* the outcomes of the meetings of the Ad Hoc Technical Expert Group on Risk Assessment;⁵

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;⁶

[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;

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

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

³ See CBD/SYNBIO/AHTEG/2024/1/3.

⁴ See CBD/CP/RA/AHTEG/2024/1/3.

⁵ See CBD/CP/RA/AHTEG/2023/1/4 and CBD/CP/RA/AHTEG/2024/1/3.

⁶ CBD/CP/MOP/11/9.

[6. *Also calls* for the consideration of the related issues set out in the additional voluntary guidance materials,⁷ 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 evaluation of the needs and priorities identified by Parties through the submission of information in paragraph 8 below;

8. *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 Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment to consider self-limiting insects as a potential topic];

9. *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 set out in annex I to decision CP-9/13;

10. *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 pertaining to 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 8 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];

11. [*Further decides* that the process outlined in annex I to decision CP-9/13 will be applied to any trends or issues identified through the process of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology that are considered to be living modified organisms and may require further guidance on risk assessment;]

12. *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;

(a bis) Convene the Open-ended Online Forum on Risk Assessment and Risk;

(a ter) Prepare a synthesis of information submitted in response to paragraphs 8 and 9 above to support the work of the Ad Hoc Technical Expert Group on Risk Assessment;

(a quarter) Convene one meeting of the Ad Hoc Technical Expert Group on Risk Assessment;

(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) 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:

⁷ Ibid., sect. 7.

(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,⁸ with specific scientific and technical expertise relevant to the mandate of the Expert Group, and include experts from relevant international organizations and from indigenous 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 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,⁹;

(c) Analyse the information submitted by Parties further to paragraph 8 of decision CP-11/-- and the discussions of the Open-ended Online Forum on Risk Assessment and Risk Management, 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;

(d) Prepare a report for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice with a view to enabling the Subsidiary Body to prepare a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its twelfth meeting.

2. In undertaking its work, the Ad Hoc Technical Expert Group on Risk Assessment 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.

⁸ Decision VIII/10, annex III.

⁹ United Nations, *Treaty Series*, vol. 2226, No. 30619.