

Agenda item 7

Risk assessment and risk management

Risk assessment and risk management of living modified organisms

Non-paper

The Subsidiary Body on Scientific, Technical and Technological Advice

Recommends that, at its twelfth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopt a decision along the following lines:

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

Recalling decisions [CP-9/13](#) of 28 November 2018 and [CP-11/7](#) of 30 October 2024,

1. *Appreciates* the work of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment¹ and acknowledges the structured analysis of the topics of risk assessment proposed by Parties in relation to needs and priorities for further guidance on specific topics of risk assessment of living modified organisms;²

2. *Decides* to develop additional voluntary guidance materials for the topics of living modified fish and living modified microorganisms, while avoiding duplication with existing guidance materials in accordance with Annex III to the Cartagena Protocol;

3. *Also decides* to develop technical notes³ for voluntary use for the topics of operationalizing protection goals into relevant assessment and measurement end points and the use of living modified organisms in centres of origin and in traditional agricultural systems,⁴ while avoiding duplication with existing guidance materials in accordance with Annex III to the Cartagena Protocol;

4. *Decides further* to establish a new ad hoc technical expert group on risk assessment, with the terms of reference contained in the annex to the present decision;

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

6. *Decides* to extend 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;

7. *Also decides* to consider at its thirteenth meeting additional issues on which guidance materials on risk assessment may be needed, further to the process established in decision [CP-9/13](#) for the identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration, taking into account the priorities identified by Parties, including in their national reports, and the topics identified by the Ad Hoc Technical Expert Group on Risk Assessment;⁵

¹ See CBD/CP/RA/AHTEG/2025/1/3.

² CBD/SBSTTA/27/6, annex.

³ A technical note may be a concise document that provides practical information on a specific topic or issue. It supplements existing guidance materials and may include procedural elements or points to consider when addressing a specific topic or context.

⁴ The technical note for the topic of the use of living modified organisms in centres of origin and in traditional agricultural systems should be consistent with the Akwé: Kon Voluntary Guidelines.

⁵ Living modified algae, Living modified organisms expressing genome editing machinery for pest or pathogen control and Long-term and cumulative effects of genetic constructs and living modified organisms.

8. *Invites* Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit information on experiences related to the implementation of simplified procedures given in Articles 13 of the Cartagena Protocol, and bilateral, regional and multilateral agreements and arrangements provided in Article 14 of the Protocol, and on data transportability for risk assessment of living modified organisms;

9. *Decides* to consider at its thirteenth meeting the information submitted in response to paragraph 8 to this present decision;

10. *Urges* Parties and invites other Governments and relevant organizations to engage in broad international cooperation to share information and experiences related to risk assessment and promote capacity-building and development activities with regard to the topics prioritized by the Ad Hoc Technical Expert Group on Risk Assessment;⁶

11. *Invites* the subregional technical support cooperation centres to assist Parties in addressing their needs and priorities on risk assessment and risk management⁷;

12. *Requests* the Executive Secretary, subject to the availability of financial resources, to:

(a) Convene at least two meetings of the Ad Hoc Technical Expert Group on Risk Assessment, one of which will be in person, before the thirteenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety;⁸

(b) Convene discussions in the Open-ended Online Forum on Risk Assessment and Risk Management during the same intersessional period and encourage the active participation of indigenous peoples and local communities, academia and other relevant organizations;

(c) Synthesize information collected in response to paragraphs 5, 6, and 8 of the present decision, as well as in the information related to risk assessment and risk management in national reports;

(d) Continue to undertake capacity-building and development activities to support the risk assessment of living modified organisms in collaboration with relevant initiatives and partnerships, as appropriate;

(e) Continue to collect experiences and assessment of the applicability and usefulness of the additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms containing engineered gene drives⁹ and make them available through the Biosafety Clearing-House;

13. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the meeting of the Ad Hoc Technical Expert Group on Risk Assessment at a meeting held before the thirteenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol and to make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

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

⁶ See CBD/CP/RA/AHTEG/2025/1/3.

⁷ See <https://www.cbd.int/tsc/tscm/subregionalcentres>.

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

⁹ See CBD/CP/MOP/11/9.

Technological Advice,¹⁰ with specific scientific and technical expertise relevant to the present mandate, and include experts from academia, relevant international organizations and 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, as amended in decision [CP-11/6](#) of 1 November 2024;

(b) Subject to the availability of funds, hold at least two meetings, one of which will be in person, before the thirteenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety¹¹ and perform any necessary tasks between its two meetings by online means of communication and engagement;

(c) Develop draft additional voluntary guidance materials for living modified microorganisms and living modified fish, in accordance with Annex III to the Cartagena Protocol, taking into account approaches to risk assessment set out in the additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms containing engineered gene drives¹² and avoiding duplication with existing guidance materials and, for consideration by the Subsidiary Body at a meeting held before the thirteenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol;

(d) Develop draft technical notes¹³ for voluntary use for the operationalizing protection goals into relevant assessment and measurement end points and the use of living modified organisms in centres of origin and in traditional agricultural systems¹⁴, in accordance with Annex III to the Protocol and avoiding duplication with existing guidance materials, for consideration by the Subsidiary Body at a meeting held before the thirteenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol.

2. In undertaking its work, the Expert Group shall consider the information submitted pursuant to paragraph 5 of the present decision, the discussions held in the Open-ended Online Forum on Risk Assessment and Risk Management, the synthesis of information prepared by the Secretariat pursuant to paragraph 12(c) of the present decision, the synthesis of submissions of information on risk assessment and the discussions of the Open-Ended Online on Risk Assessment and Risk Management¹⁵ and the list of bibliographic references provided in the submissions from Parties and during the discussions of the Open-ended Online Forum on Risk Assessment and Risk Management.¹⁶

3. In conducting its work, the Expert Group shall also consider information produced by other international, regional and national bodies, to avoid the duplication of existing materials.

¹⁰ Decision [VIII/10](#), annex III.

¹¹ United Nations, *Treaty Series*, vol. 2226, No. 30619.

¹² See [CBD/CP/MOP/11/9](#).

¹³ A technical note may be a concise document that provides practical information on a specific topic or issue. It supplements existing guidance materials and may include procedural elements or points to consider when addressing a specific topic or context.

¹⁴ The technical note for the topic of the use of living modified organisms in centres of origin and in traditional agricultural systems should be consistent with the Akwé: Kon Voluntary Guidelines.

¹⁵ [CBD/CP/RA/AHTEG/2025/1/INF/1](#).

¹⁶ [CBD/CP/RA/AHTEG/2025/1/INF/2](#).