



Convention on Biological Diversity

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Yerevan, 19–30 October 2026

Agenda item 13

Risk assessment and risk management of living modified organisms

Working Group II

Risk assessment and risk management of living modified organisms

Draft decision submitted by the Chair of Working Group II

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

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

1. *Expresses appreciation* for the work of the Ad Hoc Technical Expert Group on Risk Assessment¹ and its application of the criteria set out in annex I to decision [CP-9/13](#) to the topics 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 one additional voluntary guidance material³ in accordance with annex III to the Cartagena Protocol on Biosafety⁴ and the methodology set out in *Biosafety Technical Series 07*⁵, which it had welcomed in its decision [CP-11/7](#), and other methodologies, using the information provided through submissions and through the Open-ended Online Forum on Risk Assessment and Risk Management, as well as using other tools for improving efficiency, to support Parties in the implementation of the methodology to living modified fish;

3. *Also decides* to expand capacity-building efforts on the risk assessment and risk management of living modified organisms, making use of existing information, guidance materials and approaches to risk assessment of living modified organisms in particular those described in *Biosafety Technical Series 07*;

[4. *Further decides* 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, women, youth, academia and relevant organizations to submit relevant information, such as national and regional risk assessment experiences and existing resources for risk assessment for the selected topics, to support the work of the Ad Hoc Technical Expert Group on Risk Assessment;]

¹ See [CBD/CP/RA/AHTEG/2025/1/3](#).

² See [CBD/SBSTA/27/6](#), annex.

³ The guidance shall remain non-prescriptive and should not create additional obligations for the Parties.

⁴ United Nations, *Treaty Series*, vol. 2226, No. 30619.

⁵ Available at <https://bch.cbd.int/en/database/VLR/BCH-VLR-SCBD-280754>.

[5 Alt. *Invites* Parties, other Governments, indigenous peoples and local communities, women, youth, academia and relevant organizations that have used *Biosafety Technical Series 07* to submit information on their experiences and assessment of its applicability and usefulness to the Executive Secretary;]

6. *Invites* Parties, including those that submitted priorities for guidance on risk assessment through their fifth national reports, 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](#);

[7. *Invites* Parties, other Governments, indigenous peoples and local communities, women, youth, academia and relevant organizations to submit relevant information to improve the efficiency of the process set out in annex I to decision [CP-9/13](#), including through the use of innovative tools, such as artificial intelligence, to support the work of the Ad Hoc Technical Expert Group on Risk Assessment;]

[8. *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 and the peer review of the topics proposed by Parties in line with annex I to decision [CP-9/13](#);

9. *Also decides* to consider at its thirteenth meeting additional issues on which guidance materials on risk assessment may be needed, in accordance with the process established in decision [CP-9/13](#), 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;⁶]

[10. *Invites* Parties and other Governments to submit voluntarily information on experiences with the implementation of the simplified procedure provided in Article [13](#) of the Cartagena Protocol and the bilateral, regional and multilateral agreements and arrangements provided in its Article [14](#) in relation to the risk assessment and risk management of living modified organisms;]

[11. *Decides* to consider at its thirteenth meeting the information submitted in response to paragraph 10 above;]

12. *Urges* Parties, and invites other Governments, indigenous peoples and local communities, and women, youth and relevant organizations, to engage in broad international cooperation to share information and experiences related to risk assessment, in particular through the Biosafety Clearing-House, and promote capacity-building and development activities identified by Parties;

13. *Invites* the regional and subregional technical and scientific cooperation support centres⁷ to assist Parties in addressing their needs and priorities on risk assessment and risk management;

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

[(a) To 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;]

[(b) To 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, women and youth organizations, academia and other relevant organizations;]

⁶ [Living modified algae,] [living modified fish,] [living modified microorganisms,] [living modified organisms expressing genome editing machinery for pest or pathogen control,] [long-term and cumulative effects of genetic constructs and living modified organisms,] [operationalizing protection goals into relevant assessment and measurement end points,] [the use of living modified organisms in centres of origin and in traditional agricultural systems].

⁷ See www.cbd.int/tsc/tscm/subregionalcentres.

(c) To synthesize information collected in response to paragraphs [5] [, 7] and [10] of the present decision[and through the Open-ended Online Forum on Risk Assessment and Risk Management], as well as the information related to specific needs for further guidance on specific topics of risk assessment and risk management in national reports;⁸

(d) To compile and synthesize the information submitted by Parties pursuant to paragraph 6 above against the criteria contained in annex I to decision [CP-9/13](#) for submission to the Open-ended Online Forum on Risk Assessment and Risk Management for peer review;

(e) To synthesize the outcomes of the peer review referred to in paragraph 8 above and submit the synthesis to the Subsidiary Body on Scientific, Technical and Technological Advice for consideration 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;

(f) To continue to undertake capacity-building and development activities on existing guidance materials through regional workshops in order to support the risk assessment of living modified organisms, in collaboration with relevant initiatives and partnerships, as appropriate, ensuring equitable representation of all developing country Parties;

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

[15. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the meetings of the Ad Hoc Technical Expert Group on Risk Assessment and the list of peer-reviewed topics proposed by Parties 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 a recommendation to the Conference of the Parties serving as the meeting of the Parties to the Protocol for consideration at its thirteenth meeting.]

[

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,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, women and youth, 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;

⁸ As provided in response to question 68 of the fifth national report under the Cartagena Protocol.

⁹ See [CBD/CP/MOP/11/9](#).

¹⁰ Decision [VIII/10](#), annex III.

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

(c) [Develop draft additional voluntary guidance materials for [one topic][two topics], in accordance with annex III to the Cartagena Protocol, that are supplementary, concise, focused and non-duplicative to relevant materials on the risk assessment of living modified organisms;]

(d) Consider the information submitted further to paragraph 7 of the present decision and, on that basis, to draft recommendations for improving the efficiency of the process set out in annex I to decision [CP-9/13](#) of 28 November 2018, including through the use of innovative tools, such as artificial intelligence;

(e) [On the basis of the draft recommendations drafted pursuant to subparagraph (d) above, develop a plan for the execution of a test run of the potential new methodology and then, on the basis of the test run, provide options for potential refinements, if any, with a view to making that process the standard process for the development of future guidance;]

(f) Prepare a report containing the draft additional voluntary guidance materials and recommendations for improving the efficiency of the process established in decision [CP-9/13](#), for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice 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 conducting its work, the Expert Group shall consider the information submitted pursuant to paragraphs 5 and 7 of the present decision, the discussions held in the Open-ended Online Forum on Risk Assessment and Risk Management and the synthesis of information prepared by the Secretariat pursuant to subparagraph 14 (c) of the present decision.

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.

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