



Convention on Biological Diversity

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**Subsidiary Body on Scientific,
Technical and Technological Advice**
Twenty-seventh meeting
Panama City, 20–24 October 2025
Agenda item 7
Risk assessment and risk management

Risk assessment and risk management of living modified organisms

Draft recommendation submitted by the Chair

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 Cartagena Protocol on Biosafety¹ 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. *Expresses appreciation* for the work of the Ad Hoc Technical Expert Group on Risk Assessment² 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;³

[2. *Decides* to develop a maximum of two additional voluntary guidance materials in accordance with annex III to the Cartagena Protocol on Biosafety,⁴ for the topics of [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], while avoiding duplication with and, where appropriate, supplementing existing guidance materials;]

[3. *Also decides* to expand capacity-building efforts on the risk assessment and risk management of living modified organisms, making use of existing information, approaches and guidance materials on the topic, including those produced under the Cartagena Protocol, such as *Biosafety Technical Series 07*;]

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

² See [CBD/CP/RA/AHTEG/2025/1/3](#).

³ See [CBD/SBSTTA/27/6](#), annex.

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

[3.alt *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 the approach to risk assessment of living modified organisms 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;]

[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]

[8. *Invites* Parties, other Governments, indigenous peoples and local communities, and women, youth and relevant organizations to submit information on experiences with the implementation of the simplified procedure provided in Article [13](#) of the Cartagena Protocol, bilateral, regional and multilateral agreements and arrangements provided in Article [14](#) of the Protocol, and on the transportability of data for risk assessment of living modified organisms[, recognizing that the acceptance of risk assessment data from other countries shall be subject to national evaluation and confirmation of ecological relevance and comparability];]

[9. *Decides* to consider at its thirteenth meeting the information submitted in response to paragraph 8 above;]

10. *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 with regard to the topics prioritized by the [Ad Hoc Technical Expert Group on Risk Assessment;⁶][Subsidiary Body on Scientific, Technical and Technological Advice;]

11. *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;

12. *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;]

⁵ [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].

⁶ See [CBD/CP/RA/AHTEG/2025/1/3](#).

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

[(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;]

(c) To synthesize information collected in response to paragraphs [5] and [8] 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 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;

(e) 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;

[13. *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 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 Protocol for consideration at its thirteenth meeting.]

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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;

(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 assessments of living modified organisms containing engineered gene drives¹² and avoiding duplication with existing guidance materials,

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.

¹² See [CBD/CP/MOP/11/9](#).

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 Protocol;

(d) [Develop draft technical notes¹³ 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],¹⁴[Develop concise supplementary guidance for voluntary use that provides specific, clear and focused information on [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]] in accordance with annex III to the Cartagena 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 Protocol. [The guidance may include procedural or practical elements or points to consider during risk assessment.]

2. In conducting 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 held in the Online Forum¹⁵ and the list of bibliographical references provided in the submissions from Parties and during the discussions held in the Online Forum.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.

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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 on the use of living modified organisms in centres of origin and in traditional agricultural systems should be consistent with the Akwé: Kon Voluntary Guidelines for the Conduct of Cultural, Environmental and Social Impact Assessments regarding Developments Proposed to Take Place on, or which are Likely to Impact On, Sacred Sites and On Lands and Waters Traditionally Occupied or Used by Indigenous and Local Communities.

¹⁵ [CBD/CP/RA/AHTEG/2025/1/INF/1.](#)

¹⁶ [CBD/CP/RA/AHTEG/2025/1/INF/2.](#)