



Convention on Biological Diversity

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**Subsidiary Body on Scientific,
Technical and Technological Advice**
Twenty-sixth meeting
Nairobi, 13–18 May 2024
Item 6 of the provisional agenda*
Risk assessment and risk management

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Note by the Secretariat

I. Background

1. At its tenth meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety agreed to develop additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms containing engineered gene drives and established the Ad Hoc Technical Expert Group on Risk Assessment to carry out that task. It also specified in the terms of reference of the Expert Group that the materials should have a specific focus on engineered gene drive mosquitoes, taking into account the current experience with the organism, the type of gene drive and specific issues of risk assessment identified in annex I to decision CP-9/13, including existing reports, general considerations of living modified organisms containing engineered gene drives, and existing national and regional risk assessment experiences (decision CP-10/10).
2. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Protocol made a series of requests to the Executive Secretary to facilitate the work of the Expert Group, as detailed in section II of the present note.
3. Also in decision CP-10/10, the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to consider at its eleventh meeting further guidance on living modified fish, as well as additional issues on which guidance materials on risk assessment might be needed. In this respect, Parties were invited to submit 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.
4. In the same decision, the Subsidiary Body on Scientific, Technical and Technological Advice was requested to consider the outcomes of the Expert Group at its twenty-sixth meeting and to make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its eleventh meeting.
5. Section II of the present document contains a description of the activities undertaken with respect to the development of additional voluntary guidance materials to support case-by-case risk

* CBD/SBSTTA/26/1.

assessment of living modified organisms containing engineered gene drives, while the guidance materials so developed are provided in document CBD/SBSTTA/26/5/Add.1. Section III contains information on the needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and draft possible elements of decisions are provided in section IV.

II. Overview of the process carried out further to decision CP-10/10

6. Further to the provisions of decision CP-10/10 summarized in paragraphs 1 and 2 above, the Executive Secretary invited the submission of information on risk assessment; convened moderated discussions of the online forum; commissioned a detailed outline, with financial support from the Government of Finland and the European Union; collected and synthesized relevant information to facilitate the work of the Open-ended Online Forum on Risk Assessment and Risk Management and the Expert Group; and convened two meetings of the Group, with financial support from the European Union.

A. Commissioning of the detailed outline for the additional voluntary guidance materials

7. To support the development of the additional voluntary guidance materials, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary to commission the preparation of a detailed outline of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives, to be reviewed by the Open-ended Online Forum on Risk Assessment and Risk Management and to serve as a base for the work of the Expert Group. The Secretariat commissioned the International Centre for Genetic Engineering and Biotechnology to draft the detailed outline, with financial support from the Government of Finland and the European Union.

8. A draft outline was made available for discussion in the Open-ended Online Forum on Risk Assessment and Risk Management from 21 to 30 August 2023 (see sect. B), and the final draft detailed outline of the guidance materials was made available for the first meeting of the Expert Group, held from 1 to 3 November 2023.

B. Submissions of information on risk assessment and Open-ended Online Forum on Risk Assessment and Risk Management

9. With notification [No. 2023-007](#), dated 6 February 2023, the Executive Secretary invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit relevant information to support the work of the Expert Group.

10. In total, 14 submissions were received: five from Parties to the Protocol (Belarus, Belgium, Brazil, Colombia and Germany), one from a non-Party (Australia) and eight from relevant organizations (African Centre for Biodiversity, Crop-Life International/Global Industry Coalition, Foundation for Future Farming/Save Our Seeds, Foundation for the National Institutes of Health, Imperial College London, Outreach Network for Gene Drive Research, Testbiotech and Third World Network). A synthesis of the submissions was made available as information document CBD/CP/RA/AHTEG/2023/1/INF/2.

11. In the same notification, the Executive Secretary invited Parties to submit 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. A synthesis of the submissions received was made available in document CBD/CP/RA/AHTEG/2024/1/2.

12. The Secretariat convened a first session of the Open-Ended Online Forum on Risk Assessment and Risk Management from 10 to 25 April 2023, to collect views on elements to be included in the draft outline for the additional voluntary guidance materials, and a second session from 21 to 30 August 2023, to consider the draft outline. During the first round, 130 interventions were made from 17 Parties, 2 other Governments, 16 organizations and 1 representative from indigenous peoples and

local communities. During the second round, 94 interventions were made from 14 Parties, 1 other Government and 15 organizations. The inputs received were considered and incorporated during the finalization of the detailed outline, which formed the basis of the work of the Expert Group at its first meeting.

C. Meetings of the Ad Hoc Technical Expert Group on Risk Assessment

13. The Expert Group met twice, from 1 to 3 November 2023 and from 27 February to 1 March 2024, with financial support from the European Union. The Expert Group also used virtual engagements to carry out its work and met online. At its first meeting, the Expert Group agreed to follow a problem formulation approach and also agreed on the structure of the document. At its second meeting, it finalized the work on the guidance materials and the analysis of the new topics of risk assessment of living modified organisms.

14. The guidance materials were developed by regionally balanced drafting groups in the intersessional period between the two meetings of the Expert Group. In accordance with its terms of reference, the Expert Group developed additional voluntary guidance materials for conducting case-by-case risk assessments of living modified organisms containing engineered gene drives in accordance with annex III to the Protocol, and a specific focus of the material was engineered gene drive mosquitoes.

15. The report of the first meeting of the Expert Group was issued as document CBD/CP/RA/AHTEG/2023/1/4, and the report of the second meeting will be issued as document CBD/CP/RA/AHTEG/2024/1/3.

D. Overview of the additional voluntary guidance materials

16. The guidance materials are aimed at supporting the implementation of annex III to the Protocol by providing additional structure and greater focus to the steps outlined in subparagraphs 8 (a) and (b), using a problem formulation approach, while increasing the transparency of the risk assessment process. The problem formulation approach can be made operational through the following five steps: (a) identification of protection goals and definition of assessment end points; (b) identification of potential adverse effects on the assessment end points; (c) derivation of plausible pathways to harm; (d) formulation of risk hypotheses; and (e) engagement with stakeholders.

17. Following the problem formulation approach to risk assessment, the guidance materials describe how to assess harm to assessment end points, how to characterize the overall risk, how to provide recommendations on the acceptability and manageability of the risks, how to identify risk management strategies and how to implement monitoring, which correspond to the steps outlined in subparagraphs 8 (c) to (f) of annex III to the Protocol. In addition, related issues relevant to the overall decision-making process have been included in the final section of the guidance materials.

18. Annexes have also been appended to provide greater detail on issues related to modelling, uncertainty, the World Health Organization *Guidance Framework for Testing Genetically Modified Mosquitoes*, the taxonomic classification of Culicidae, mosquito vectors of disease, the landscape of development of engineered gene drive systems in mosquitoes and the molecular mechanisms of engineered gene drive systems.

19. Furthermore, mosquito-specific elements have been incorporated into the guidance materials, in text boxes, to provide the specific focus on mosquitoes requested in decision CP-10/10.

20. In line with decision CP-10/10, the guidance materials thus take existing reports, general considerations of living modified organisms containing engineered gene drives and existing national and regional risk assessment experience into consideration. The materials are provided in document CBD/SBSTTA/26/5/Add.1.

III. Needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms

21. In its decision [CP-9/13](#), the Conference of the Parties serving as the meeting of the Parties to the Protocol established a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms, for its consideration, with a view to developing further guidance on risk assessment on the specific issues identified. In annex I to the decision, it set out criteria for issues that might warrant such consideration.

22. In its decision [CP-10/10](#), in addition to deciding to develop additional voluntary guidance materials to support case-by-case risk assessments of living modified organisms containing engineered gene drives (as described in section II above), the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to consider at its eleventh meeting further guidance on living modified fish and additional issues on which guidance materials on risk assessment might be needed, further to the process established in decision CP-9/13, taking into account priorities identified by Parties and the report of the Expert Group.

23. In submissions received in response to notification No. [2023-007](#) and follow-up notification No. [2023-129](#), Parties to the Protocol identified four issues or priority areas of risk assessment of living modified organisms that might warrant the development of additional voluntary guidance materials, namely, living modified aquatic organisms, including algae, crustaceans and fish; living modified organisms containing engineered gene drives; genome-edited plants and animals; and operationalizing protection goals into useful assessment and management end points.¹

24. In line with its mandate, the Expert Group assessed the four topics proposed by Parties against the criteria outlined in annex I to decision CP-9/13. The Group noted that, in line with decision CP-10/10, the Conference of the Parties serving as the meeting of the Parties to the Protocol was expected to consider the development of additional voluntary guidance materials on risk assessment regarding living modified fish at its eleventh meeting. In this regard, there were a range of perspectives as to whether the topic of living modified aquatic organisms, including algae, crustaceans and fish identified by Parties for additional guidance materials could be considered within the context of those discussions. The Group concluded that no additional topics should be prioritized for the development of additional guidance at that point in time.

25. In addition, the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology to Support the Process for Broad and Regular Horizon Scanning, Monitoring and Assessment recognized self-limiting insects as a potential topic for the further development of guidance on risk assessment in line with annex I to decision CP-9/13. However, that topic would need to be considered within the context of the criteria outlined in the decision, and more information would be needed from Parties to inform future deliberations.

¹ Explanation of concepts of protection goals, assessment end points and measurement end points can be found in section 1.3.1 of the annex to document UNEP/CBD/BS/COP-MOP/8/8/Add.1.

IV. Recommendations

26. Further to the request in decision CP-10/10 to develop additional voluntary guidance materials to support case-by-case risk assessments of living modified organisms containing engineered gene drives, the Subsidiary Body may wish to recommend that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopt elements of 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 decision CP-10/10 of 10 December 2022,

1. *Welcomes* the outcomes of the meetings of the Ad Hoc Technical Expert Group on Risk Assessment;²
2. *Endorses* the additional voluntary guidance materials on the risk assessment of living modified organisms containing engineered gene drives;
3. *Encourages* Parties, other Governments and relevant organizations and stakeholders to make use of the additional voluntary guidance materials;
4. *Calls* for broad international cooperation, knowledge-sharing, capacity-building and resource mobilization to support, inter alia, the application of the additional voluntary guidance materials.

27. Further to the requests in decision CP-10/10 to consider further guidance on living modified fish and additional issues on which guidance materials on risk assessment might be needed, the Subsidiary Body may wish to recommend that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopt the following additional elements of a draft decision, noting that the elements are set out below without prejudice to its decision to proceed or not with the development of such guidance.

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

Recalling decision CP-10/10 of 10 December 2022,

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,

1. *Decides* to establish an ad hoc technical expert group with terms of reference as contained in the annex to the present decision for the development of guidance materials to support the risk assessment of living modified fish;
2. *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;
3. *Decides* to extend the Open-ended Online Forum on Risk Assessment and Risk Management to contribute to the development of guidance materials in support of the risk assessment of living modified fish;
4. *Requests* the Secretariat:
 - (a) To commission, subject to the availability of resources, and in compliance with decision 14/33 of the Conference of the Parties to the Convention on Biological Diversity³ of

² CBD/CP/RA/AHTEG/2023/1/4 and CBD/CP/RA/AHTEG/2024/1/3.

³ United Nations, *Treaty Series*, vol. 1760, No. 30619.

29 November 2018 on the procedure for avoiding or managing conflicts of interest in expert groups, a detailed outline of additional guidance materials on risk assessment of living modified fish;

(b) To synthesize the information submitted by Parties, other Governments and relevant organizations to facilitate the work of the Ad Hoc Technical Expert Group on Risk Assessment;

(c) To 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.

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, 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 peoples and local communities, in compliance 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 a meeting before the twelfth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, and perform its work by online means of communication and engagement, as appropriate;

(c) Develop additional voluntary guidance materials for conducting case-by-case risk assessments 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 9 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 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;⁴ 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 Cartagena Protocol on Biosafety.

⁴ CBD/CP/RA/AHTEG/2020/1/3.

28. Further to the regular process established in decision CP-9/13 for the identification and prioritization of specific issues regarding risk assessments of living modified organisms for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol with a view to developing further guidance on risk assessment on the specific issues identified, the Subsidiary Body may wish to recommend that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol adopt elements of 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 decision [CP-9/13](#) of 28 November 2018, by which it established the process for the identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration,

Recalling also paragraph 17 of decision [BS-VII/12](#) of 3 October 2014, in which it recommended a coordinated approach on the issue of synthetic biology, 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 annex I to decision CP-9/13,

1. *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 and, in doing so, to consider self-limiting insects as a potential topic;

2. *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;

3. *Requests* the Secretariat:

(a) To synthesize the information submitted by Parties, other Governments and relevant organizations in response to the invitation in paragraph 1 above;

(b) To convene discussions of the Open-ended Online Forum on Risk Assessment and Risk Management;

(c) To collect and synthesize relevant information to support the risk assessment of self-limiting insects and to make it available on the Biosafety Clearing-House;

(d) To convene, subject to the availability of resources, capacity-building activities in support of risk assessment with a particular focus on risk assessments of living modified organisms containing engineered gene drives.
