



Convention on Biological Diversity

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Ad Hoc Technical Expert Group on Risk Assessment First meeting

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Items 3, 4 and 5 of the provisional agenda*

**Comments on the detailed outline of additional voluntary
guidance materials to support the case-by-case risk assessment
of living modified organisms containing engineered gene drives**

**Working modalities for the development of additional
voluntary guidance materials**

Review of the detailed outline

Considerations on risk assessment

Note by the Secretariat

I. Introduction

1. In its decision [CP-10/10](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity agreed to develop 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..
2. In accordance with its terms of reference, contained in the annex to decision CP-10/10, the Ad Hoc Technical Expert Group on Risk Assessment established under the decision must:
 - (a) Meet twice, subject to the availability of funds and prior to the eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol, with at least one of the meetings being in person, and perform necessary tasks between its two meetings supported by online means of communication and engagement;
 - (b) Develop 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. A specific focus of the materials should be 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;
 - (c) Analyse the information submitted by Parties in accordance with paragraph 8 of decision CP-10/10 and, on that basis, prepare a list of prioritized topics on which further guidance

* CBD/CP/RA/AHTEG/2023/1/1.

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, including draft additional voluntary guidance materials on living modified organisms containing engineered gene drives and a list of prioritized topics on which further guidance materials on risk assessment may be needed, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice;

(e) Consider the synthesis of views from the submissions and discussions in the Open-ended Online Forum on Risk Assessment prepared by the Executive Secretary, 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 organisms containing engineered gene drives,¹ guidance materials already available, relevant decisions on risk assessment and risk management adopted under the Protocol and any other relevant information collected by the Executive Secretary further to paragraph 10 (c) of decision CP-10/10.

3. In addition, the Expert Group should bear in mind the following:

(a) There is a need for a coordinated approach on issues related to synthetic biology under the Convention and the Protocol (see, for example, decisions [BS-VII/12](#), [XII/24](#), [CP-9/13](#) and [14/19](#));

(b) The objective of risk assessment under the Protocol is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the potential receiving environment, as well as risks to human health, with a particular focus on transboundary movements.

II. Overview of the process

4. The information in the present section is intended to provide the Expert Group with an overview of the process undertaken in response to the requests laid out in subparagraphs 10 (a) to (d) of decision CP-10/10 and to assist the Expert Group in its deliberations under agenda item 4.

5. To support the development of the additional voluntary guidance materials on risk assessment of living modified organisms containing engineered gene drives, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol requested the Executive Secretary to commission the preparation of a detailed outline of such materials, to be reviewed in the Online Forum and serve as a base for the work of the Expert Group. Through notification No. [2023-007](#), the Executive Secretary invited Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information relevant to the work of the Expert Group. It also invited Parties to submit information related to their needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms.

6. A total of 14 submissions of information related to the development of additional voluntary guidance materials were received: five from Parties, one from another Government and eight from relevant organizations. In addition, three submissions related to the needs and priorities of Parties were received. A synthesis of the submissions has been issued as document CBD/CP/RA/AHTEG/2023/1/INF/2, while the original submissions are available through the Biosafety Clearing-House.²

7. The Secretariat held the first session of the Online Forum from 10 to 25 April 2023³ to collect views on elements to be included in the outline for the additional voluntary guidance materials.

¹ CBD/CP/RA/AHTEG/2020/1/4.

² See <https://bch.cbd.int/en/submissions-to-notifications?schema=submission¤tPage=1¬ification=2023-007>.

³ See <https://bch.cbd.int/en/portals/risk-assessment/forum/first-session>.

8. With financial support from the Government of Finland and the European Union, the Executive Secretary commissioned the International Centre for Genetic Engineering and Biotechnology to draft a detailed outline consistent with paragraph 10 (a) of decision CP-10/10. The draft outline was submitted to the Online Forum at its second session, which was held through the Biosafety Clearing-House from 21 to 30 August 2023.⁴

9. A report on the discussions held in the two sessions has been issued as document CBD/CP/RA/AHTEG/2023/1/INF/1. The comments received through the online discussions were considered by the International Centre for Genetic Engineering and Biotechnology in producing the detailed outline of the additional voluntary guidance materials to be considered by the Expert Group.⁵

10. Following its review of the outline and analysis of the issues identified, the Expert Group may wish to create subgroups to work on the refinement of the specific elements and make changes to the detailed outline of the additional voluntary guidance materials.

III. Detailed outline of additional voluntary guidance materials for conducting case-by-case risk assessments of living modified organisms containing engineered gene drives

11. The information in the present section is intended to provide the Expert Group with the base elements to support the work outlined in paragraph 1 (c) of its terms of reference. Accordingly, the Expert Group will be invited to consider the draft outline and the elements to be incorporated into the 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.

12. In the detailed outline produced by the International Centre for Genetic Engineering and Biotechnology, the additional voluntary guidance materials have been divided into two sections, namely, part A, which deals with general considerations of living modified organisms containing engineered gene drives, and part B, which is related to the special focus of the materials on engineered gene drive mosquitoes. Considerations related to both parts are detailed below.

13. In its deliberations under agenda item 5, the Group may wish to review the synthesis of submissions on risk assessment,⁶ the summary of discussions of the Online Forum⁷ and how the International Centre for Genetic Engineering and Biotechnology has addressed individual interventions from the online discussions.⁸ In so doing, the Expert Group may also wish to deliberate on the key elements that have been identified as requiring further analysis for the development of the additional voluntary guidance materials.

A. Part A: risk assessment of living modified organisms containing engineered gene drives

14. During the online discussions, while there was support for the structure of the detailed outline, there were varying views regarding the approach of presenting the detailed outline in two parts, with part A addressing general aspects of environmental risk assessment of living modified organisms containing engineered gene drives and part B containing an example of the engineered gene drive *Anopheles* mosquitoes. There was, however, general agreement that the draft outline remained consistent with the language of the Protocol. In addition, the submitters also indicated a number of issues similar to those identified during the online discussions.

⁴ See <https://bch.cbd.int/en/portals/risk-assessment/forum/second-session>.

⁵ CBD/CP/RA/AHTEG/2023/1/1/3.

⁶ CBD/CP/RA/AHTEG/2023/1/INF/2.

⁷ CBD/CP/RA/AHTEG/2023/1/INF/1.

⁸ Available at http://bch.cbd.int/protocol/risk_assessment/comments_add_vol_guide_mat-egd-lmos.xls.

15. The Expert Group may wish to consider a number of issues for further discussion and elaboration in the draft outline. Specific elements for consideration include the following:

- (a) Structure and scope of the additional voluntary guidance materials in relation to the guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment;⁹
- (b) Structure of additional voluntary guidance materials (e.g. parts A and B, as in the present document, or a document focused on a single mosquito species);
- (c) Application of the road map for risk assessment of living modified organisms;¹⁰
- (d) Treatment of uncertainty;
- (e) Potential role and methodology of modelling;
- (f) Methodology for the environmental risk assessment of living modified organisms containing engineered gene drives (e.g. suitability, use of quantitative data);
- (g) Precautionary principle, protection goals, assessment end points and measurement end points;
- (h) Engineered gene drive terminology;
- (i) Following a phased development approach, as recommended by the World Health Organization in its *Guidance Framework for Testing of Genetically Modified Mosquitoes*, as opposed to the potential irreversible release of living modified organisms containing engineered gene drives;
- (j) Problem formulation;
- (k) Public engagement and inclusion of a broad range of expertise;
- (l) Incorporation of existing guidelines, guidance materials and resource materials from complementary processes.

B. Part B: risk assessment of engineered gene drive *Anopheles* mosquitoes for malaria control

16. It is indicated in decision CP-10/10 that a specific focus of the material should be engineered gene drive mosquitoes. The Expert Group may wish to discuss and review part B of the draft outline, which covers the risk assessment of engineered gene drive *Anopheles* mosquitoes for malaria control.

17. In undertaking its analysis and considering the interventions made in the Online Forum, as well as the submissions of information, the Expert Group may also wish to consider the following aspects highlighted in the Online Forum and submissions:

- (a) Overall approach and structure of part B (e.g. use of case study, use of realistic scenarios);
- (b) Choice of mosquito species for inclusion (e.g. single or multiple species, such as the *Anopheles* species complex (*A. gambiae*, *A. arabiensis*, *A. stephensi* and *A. funestus*) or *Anopheles* sp. and *Aedes aegypti*);
- (c) Consideration of a broad range of comparators (e.g. non-modified strains, non-engineered gene drive living modified insects and *Wolbachia*);
- (d) Socioeconomic considerations;
- (e) Risk analysis versus benefits analysis;
- (f) Public participation.

18. The challenges identified in the submissions also included the difficulty in predicting the behaviour of organisms containing engineered gene drives before their release into the environment,

⁹ UNEP/CBD/BS/COP-MOP/8/8/Add.1, annex.

¹⁰ Ibid., part I.

high levels of uncertainty in the assessment of the likelihood of occurrence of adverse effects, the lack of baseline data and insufficient data and knowledge.

19. The members of the Expert Group are invited to consider the information provided for their work in the development of the additional voluntary guidance materials. on the risk assessment of living modified organisms containing engineered gene drives with a specific focus on engineered gene drive mosquitoes. The detailed outline of the guidance materials is expected to serve as a basis for the development of the final guidance materials, which will be submitted to the Subsidiary Body on Scientific, Technical and Technological Advice. The members of the Expert Group may also wish to consider the study on risk assessment: application of annex I to decision CP-9/13 to living modified organisms containing engineered gene drives and the report of the Ad Hoc Technical Expert Group on Risk Assessment on its work contained in document [CBD/CP/RA/AHTEG/2020/1/5](#).

C. Information related to the needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms (para. 8 of decision CP-10/10)

20. The information in the present section is intended to provide the Expert Group with the base elements for supporting the work outlined in paragraph 1 (d) of its terms of reference. The members of the Expert Group are invited to refer to the information provided in the synthesis of submissions.

21. From the three submissions received, two topics suggested by Parties may require further guidance materials on risk assessment, namely:

- (a) Living modified aquatic organisms, including algae, crustaceans and fishes;
- (b) Living modified organisms containing engineered gene drives.

22. More specifically, for living modified organisms containing engineered gene drives, the ecological function of the target organism and the potential for transboundary movements were suggested as two particular challenges in terms of risk assessment.

23. Regarding the third submission, it was suggested that there was no need for the development of further guidance materials for the risk assessment of living modified organisms.

24. The members of the Expert Group are invited to prepare a recommendation for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice on the need for further guidance on the risk assessment of living modified organisms. The members may also wish to consider the elements related to the living modified organisms containing engineered gene drives in their development of additional voluntary guidance materials.