



## Convention on Biological Diversity

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### Ad Hoc Technical Expert Group on Risk Assessment Second meeting

Montreal, Canada, 27 February–1 March 2024  
Items 3 and 4 of the provisional agenda\*

#### **Prioritized topics for which further guidance materials on risk assessment may be needed**

**Consideration of the draft additional voluntary guidance  
materials to support the case-by-case risk assessment of living  
modified organisms containing engineered gene drives**

### **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 requested the Executive Secretary, inter alia:

(a) To commission the preparation of detailed outline of additional guidance materials on risk assessment of living modified organisms containing engineered gene drives to be reviewed by the online forum as a base for the work of the Ad Hoc Technical Expert Group on Risk Assessment;

(b) To convene discussions of the Online Forum on Risk Assessment and Risk Management to review an outline of the additional voluntary guidance materials and to support the work of the Expert Group;

(c) To collect and synthesize relevant information to facilitate the work of the Online Forum and the Expert Group;

(d) To synthesize the views referred to in paragraphs 7 and 8 of the decision and the discussions of the Online Forum and make them available to the Expert Group.

2. The present document has been prepared to assist the Expert Group in its deliberations under agenda items 3 and 4 of the present meeting by providing an overview of the process undertaken in response to the requests made by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity in subparagraphs 10 (a) to 10 (d) of decision [CP-10/10](#).

3. In line with its terms of reference, the Expert Group will prepare a report containing the additional voluntary guidance materials to support the case-by-case risk assessment of living

\* CBD/CP/RA/AHTEG/2024/1/1.

modified organisms containing engineered gene drives and a list of prioritized topics of risk assessment on which further guidance materials on risk assessment may be needed, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-sixth meeting.

## II. Prioritized topics for which further guidance materials on risk assessment may be needed

4. In advance of the first meeting of the Expert Group, the Secretariat issued notification [No. 2023-007](#) to invite Parties to submit information on their needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms, in compliance with the request in paragraph 8 of decision CP-10/10. Three submissions, from Belarus, Brazil and Colombia, were received and made available on the [Biosafety Clearing-House](#).

5. At its first meeting, the Expert Group requested the Secretariat to renew the request for submissions,<sup>1</sup> and two additional submissions, from Malaysia and South Africa, were received and made available on the [Biosafety Clearing-House](#).

6. Submitting Parties suggested that four topics might require further guidance materials on risk assessment, namely:

- (a) Living modified aquatic organisms, including algae, crustaceans and fish;
- (b) Living modified organisms containing engineered gene drives;
- (c) Genome-edited plants and animals;
- (d) Operationalizing protection goals into useful assessment and management end points.

7. In addition, one Party indicated that, in its view, there was no area related to the risk assessment of living modified organisms that required consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol.

8. Information on the four topics suggested by Parties are detailed in the annex.

9. The members of the Expert Group are invited to prepare a recommendation for consideration by the Subsidiary Body on the need for further guidance on the risk assessment of living modified organisms. It should be noted that, at its eleventh meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol will consider the need to develop further guidance on living modified fish, subject to the provisions of annex I to decision [CP-9/13](#).

## III. Consideration of the draft additional voluntary guidance materials to support the case-by-case risk assessment of living modified organisms containing engineered gene drives

10. At its first meeting, the Expert Group organized its work for developing the additional voluntary guidance materials during the intersessional period until its second meeting. The Group members agreed to work on the basis of the detailed outline that had been prepared by the International Centre for Genetic Engineering and Biotechnology in accordance with decision [CP-10/10](#). They also agreed to structure the additional guidance materials using the problem formulation approach in a consistent manner aligned with annex III to the Protocol on Biosafety. In this regard, a revised draft outline for the additional voluntary guidance materials on risk assessment of living modified organisms containing engineered gene drives was developed and included in the report of the first meeting.<sup>2</sup>

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<sup>1</sup> Subsequently done through notification [No. 2023-129](#).

<sup>2</sup> CBD/CP/RA/AHTEG/2023/1/4, annex II.

11. The Group members were divided into five regionally balanced drafting groups to work on separate components of the additional voluntary guidance between the first and second meetings. The outcomes of the drafting groups were shared among members for review and consideration in preparation for the present meeting.

12. The draft 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 are provided in document CBD/CP/RA/AHTEG/2024/1/2/Add.1. The Expert Group will need to further advance those materials with a view to completing a draft for consideration by the Subsidiary Body at its twenty-sixth meeting.

## Annex

### **Information on the four topics suggested by Parties in relation to needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms**

1. In submissions received in response to notifications Nos. 2023-007 and 2023-129, Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity identified four issues or priorities areas of risk assessment of living modified organisms: (a) living modified aquatic organisms, including algae, crustaceans and fish; (b) living modified organisms containing engineered gene drives; (c) genome-edited plants and animals; and (d) operationalizing protection goals into useful assessment and management end points. The issues or priorities areas are described below. Bibliographic references provided through the submissions process are the same as those contained in document CBD/CP/RA/AHTEG/2023/1/INF/2, as no new bibliographic references were shared in the second round of submissions.

2. In one submission, a Party indicated that there was no area related to the risk assessment of living modified organisms that would require consideration or further guidance by the Conference of the Parties serving as the meeting of the Parties to the Protocol. The Party also indicated that it did not find any specific challenges to risk assessment frameworks and noted that guidance materials already existed. Furthermore, it believed that efforts should be directed towards the update of the national biodiversity strategies and action plans and the implementation of the indicators to monitor progress.

#### **I. Living modified aquatic organisms, including algae, crustaceans and fish**

3. Two submitting Parties indicated that living modified aquatic organisms were a priority for the development of further guidance on risk assessment.

4. According to those Parties, the risk assessment and risk management of living modified aquatic organisms, including algae, crustaceans and fish, may require additional consideration. They said that the issue fell within the scope and objective of the Protocol and that research and development with regard to living modified fish were ongoing, with several types of living modified fish being developed, and that their use in commercial farming was expanding. They also indicated that there had been open-field trials and increased commercial development of living modified algae.

5. A submitting Party mentioned that large-scale releases into aquatic ecosystems (e.g. ponds, lakes, rivers and oceans) might create specific challenges and difficulties with:

- (a) Predicting and evaluating the rate of reproduction and distribution;
- (b) Predicting and evaluating the replacement rates of populations of wild relatives;
- (c) Evaluating the ecological niche that living modified organism would occupy;
- (d) Evaluating how the replacement or modification of wild populations influenced the ecological niche and the other organisms within it;
- (e) Monitoring living modified aquatic organisms in natural habitats;
- (f) Controlling aquatic organisms in their natural habitat;
- (g) Preventing dissemination across national borders and through waterways;
- (h) Monitoring of aquatic organisms in aquatic (marine) areas beyond national jurisdiction;
- (i) Neutralizing a particular species in the case that damage had occurred.

6. Furthermore, one Party indicated that, owing to the fragility of aquatic ecosystems, any potential adverse impacts caused by living modified aquatic organisms could be irreversible.

## **II. Living modified organisms containing engineered gene drives**

7. Submitting Parties indicated two particular challenges with regard to living modified organisms containing engineered gene drives that might require additional consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol: the ecological function of the target organism; and the potential for transboundary movements.

8. The submitting Parties noted that one challenge to risk assessment linked to the release of those modified organisms was the ecological function of the target organism. It noted that living modified organisms containing engineered drives could be designed to remove or eliminate a population from the environment. Such removal could introduce a new variable into the assessment, mitigation and communication of risk, as well as into the treatment of uncertainty.

9. In addition, the submitting Parties mentioned the greater potential for transboundary movements, which could also pose challenges to existing risk assessment frameworks. The engineered drive being designed to spread, the scale of the risk assessment would increase. There might thus be challenges to estimating all possible impacts over a large area.

## **III. Genome-edited plants and animals**

10. A submitting Party indicated that genome editing could be considered an in vitro nucleic acid technique and was included in the national regulatory scope of some countries and Parties to the Protocol. As such, plants and animals manipulated using genome editing could potentially be considered as modern biotechnology and therefore fall under the scope of the Protocol. The Party suggested that ensuring proper risk assessment and sufficient risk management would thus be in line with the objectives of the Protocol.

11. The submitting Party suggested that organisms produced through the use of genome editing did not have a history of safe use, which might cause a challenge, given that the technique was relatively new and that risk assessment mechanisms had yet to be established in some jurisdictions. Furthermore, experience with the release of such organisms was lacking. The Party therefore suggested that a guidance document with points to consider would be useful.

## **IV. Operationalizing protection goals into useful assessment and management end points**

12. A submitting Party indicated that operationalizing protection goals into useful assessment and management end points was related to Articles 15 (risk assessment) and 16 (risk management) of the Protocol. In its view, the topic had not been fully covered in existing guidance documents and technical resources, even though it was essential for conducting risk assessment in compliance with the Protocol.

13. The submitting Party noted that assessment end points had not been specifically defined for use in risk assessment and risk management of living modified organisms in several Parties. In addition, the lack of definition could have implications for the monitoring of living modified organisms.

14. The submitting Party suggested that the guidance could help to highlight the approaches that Parties had adopted and the alternative approaches available to them for defining specific end points, while taking into account their national circumstances. Furthermore, the use of case studies with headline indicators could illustrate different situations and testing criteria for the developed protection goals and assessment end points.

## Enclosure

### **Identification and prioritization of specific issues of risk assessment of living modified organism that may warrant consideration**

1. In annex I to decision [CP-9/13](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity established a process for recommending specific issues of risk assessment for its consideration. It indicated that the process should include a structured analysis to evaluate whether the specific issues fulfilled the following criteria:

(a) They were identified by Parties as priorities, taking into account the challenges to risk assessment, in particular for developing country Parties and countries with economies in transition;

(b) They fell within the scope and objective of the Protocol;

(c) They posed challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand had been assessed with existing risk assessment frameworks but posed specific technical or methodological challenges that required further attention;

(d) The challenges in addressing the specific issue were clearly described and considering, inter alia:

(e) The specific issues concerning living modified organisms that:

(i) Had the potential to cause adverse effects on biodiversity, in particular those that were serious or irreversible, taking into account the urgent need to protect specific aspects of biodiversity, such as an endemic/rare species or a unique habitat or ecosystem, taking into account risks to human health and the value of biological diversity to indigenous peoples and local communities;

(ii) Might be introduced into the environment either deliberately or accidentally;

(iii) Had the potential to disseminate across national borders;

(iv) were already, or were likely to be, commercialized or in use somewhere in the world.

2. In addition, the process should consider a stocktaking exercise to determine whether resources on similar issues had been developed by national, regional and international bodies and, if so, whether such resources might be revised or adapted to the objective of the Protocol, as appropriate.

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