



## Convention on Biological Diversity

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ENGLISH ONLY

AD HOC TECHNICAL EXPERT GROUP  
ON RISK ASSESSMENT  
Online, 30 March - 3 April 2020

### REVISED ANNOTATED PROVISIONAL AGENDA

#### INTRODUCTION

1. In [decision CP-9/13](#), the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety decided to establish a process for the identification and prioritization of specific issues regarding risk assessment of living modified organisms (LMOs) 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, taking into account annex I of the decision.
2. The Parties to the Protocol also decided to consider at its tenth meeting whether additional guidance materials on risk assessment are needed for (a) LMOs containing engineered gene drives and (b) living modified fish, and to establish an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment. In addition, the Parties decided to extend the online forum on risk assessment and risk management in order to assist the AHTEG and invited submissions from Parties, other Governments and indigenous peoples and local communities of information relevant to the work of the online forum and the AHTEG.
3. As set out in annex II to the decision, the AHTEG on Risk Assessment, taking into account the work undertaken by the AHTEG on Synthetic Biology, shall:
  - (a) Review the studies informing the application of annex I to the decision to (i) LMOs containing engineered gene drives and (ii) living modified fish and perform an analysis on these two categories of LMOs according to annex I, and supported by the data in the study;
  - (b) Consider the needs and priorities for further guidance and gaps in existing guidance identified by Parties in response to decision [CP-VIII/12](#) with regard to specific topics of risk assessment and prepare an analysis;
  - (c) Make recommendations on (i) the need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives and living modified fish, and (ii) any adjustments to annex I of the decision;
  - (d) Prepare a report for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice with a view to enabling the Subsidiary Body to prepare a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its tenth meeting.
4. Pursuant to this decision, the Secretariat:
  - (a) Issued a [notification](#) inviting the submission of information as outlined in paragraph 2 above;

(b) Commissioned two studies, informing the application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives and living modified fish, to facilitate the process referred to in paragraph 1 above;

(c) Convened a series of moderated online discussions of the Open-ended Online Forum on Risk Assessment and Risk Management in January 2020;<sup>1</sup>

(d) Compiled and synthesized the outputs of the activities referred to in subparagraphs (a) and (c) above to facilitate the deliberations of the AHTEG.

5. With financial support from the Governments of the Netherlands and Switzerland, a meeting of the Ad Hoc Technical Expert Group on Risk Assessment will be held online from 30 March to 3 April 2020. The meeting will be conducted in English.

6. The meeting will be held through a combination of live virtual sessions and online forum discussions on the website of the Biosafety Clearing-House (BCH), as outlined in annex I below.

7. The report of the AHTEG will be submitted for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-fourth meeting.

#### **ITEM 1. OPENING OF THE MEETING**

8. A representative of the Secretariat will open the meeting at 8 a.m. EDT on 30 March 2020.<sup>2</sup>

#### **ITEM 2. ORGANIZATIONAL MATTERS**

##### **2.1. Election of officers**

9. The AHTEG will be invited to elect a chair or chairs for the meeting.

##### **2.2. Adoption of the agenda**

10. The AHTEG will be invited to consider and adopt its agenda on the basis of the provisional agenda prepared by the Acting Executive Secretary ([CBD/CP/RA/AHTEG/2020/1/1](https://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml)).

##### **2.3. Organization of work**

11. The AHTEG will be invited to consider and adopt the proposed organization of its work as contained in annex I below.

12. The working documents and information documents prepared for the meeting are listed in annex II below.

#### **ITEM 3. RISK ASSESSMENT STUDIES ON LIVING MODIFIED FISH AND LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES AND RECOMMENDATION ON THE NEED FOR GUIDANCE**

13. Deliberations under this item will be supported by three working documents:

(a) A note by the Executive Secretary on “considerations on risk assessment as per decision CP-9/13” (CBD/CP/RA/AHTEG/2020/1/2), which will include relevant information from the work of the online forum and information submitted by Parties, other Governments, indigenous peoples and local communities, and relevant organizations as well as other information relevant to the terms of reference of the AHTEG;

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<sup>1</sup> [https://bch.cbd.int/onlineconferences/forum\\_ra/discussion.shtml](https://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml)

<sup>2</sup> EDT (Eastern Daylight Time) is the time in Montreal, which is equivalent to Greenwich Mean Time minus 4 hours (GMT-4)

(b) “Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish” (CBD/CP/RA/AHTEG/2020/1/3);

(c) “Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives” (CBD/CP/RA/AHTEG/2020/1/4).

14. These documents will be complemented by a number of information documents, including: (a) a synthesis of submissions of information on experiences, challenges and needs regarding risk assessment of living modified organisms containing engineered gene drives and living modified fish (CBD/CP/RA/AHTEG/2020/1/INF/1), (b) a synthesis of the interventions from the open-ended online forum (CBD/CP/RA/AHTEG/2020/1/INF/2), (c) list of bibliographic references (CBD/CP/RA/AHTEG/2020/1/INF/3), and (d) a compilation of information on risk assessment from the fourth national reports on the implementation of the Protocol (CBD/CP/RA/AHTEG/2020/1/INF/4).

15. The consultants commissioned to undertake the two studies will present an overview of their findings.

### **3.1. Living modified fish**

16. According to its terms of reference, the AHTEG is:

(a) To review the study informing the application of annex I of decision CP-9/13 to living modified fish;

(b) To perform an analysis on living modified fish in accordance with annex I of decision CP-9/13 and supported by the data in the studies;

(c) To make recommendations on the need for guidance to be developed on risk assessment of living modified fish.

15. In its deliberations, the AHTEG will be invited to consider the relevant parts of document CBD/CP/RA/AHTEG/2020/1/2 as well as the “study on risk assessment: application of annex I of decision CP-9/13 to living modified fish” (CBD/CP/RA/AHTEG/2020/1/3).

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

17. According to its terms of reference, the AHTEG is:

(a) To review the study informing the application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives;

(b) To perform an analysis on living modified organisms containing engineered gene drives, according to annex I of decision CP-9/13, and supported by the data in the study;

(c) To make recommendations on the need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives.

18. In its deliberations, the AHTEG will be invited to consider the relevant parts of document CBD/CP/RA/AHTEG/2020/1/2 as well as the “study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives” (CBD/CP/RA/AHTEG/2020/1/4).

### **ITEM 4. ADJUSTMENTS TO ANNEX I OF DECISION CP-9/13**

19. As per item (ii) of paragraph (c) of its terms of reference, the AHTEG is to make recommendations on any adjustments to annex I of decision CP-9/13.

20. The AHTEG will be invited to consider the relevant parts of document CBD/CP/RA/AHTEG/2020/1/2 for its deliberations. The AHTEG may also wish to consider any relevant points that emerged during its discussions under agenda item 3.

**ITEM 5. ANALYSIS ON NEEDS AND PRIORITIES FOR FURTHER GUIDANCE IDENTIFIED BY PARTIES IN RESPONSE TO DECISION CP-VIII/12**

21. As per paragraph (b) of its terms of reference, the AHTEG will consider the needs and priorities for further guidance and gaps in existing guidance identified by Parties pursuant to decision [CP-VIII/12](#)<sup>3</sup> with regard to specific topics of risk assessment and prepare an analysis.

22. The submissions received in response to paragraph 6 of decision CP-VIII/12 were synthesized in document CBD/SBSTTA/22/INF/11. In addition, the question of gaps in existing guidance materials on risk assessment and proposals to address any gaps was discussed through the Open-Ended Online Forum on Risk Assessment in 2018,<sup>4</sup> and these discussions were summarized in document CBD/SBSTTA/22/INF/12. Relevant information from these documents has been included in the working document for this meeting (CBD/CP/RA/AHTEG/2020/1/2), which the AHTEG will be invited to consider in order to prepare its analysis.

**ITEM 6. OTHER MATTERS**

23. Under this item, participants may raise other matters relevant to the subject matter of the meeting.

**ITEM 7. ADOPTION OF THE REPORT**

24. The AHTEG will be invited to consider and adopt the report on the meeting.

**ITEM 8. CLOSURE OF THE MEETING**

25. The meeting is expected to close at 1 p.m. EDT on Friday, 3 April 2020.

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<sup>3</sup> In decision CP-VIII/12, paragraph 6, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety invited Parties, among other things, to submit to the Executive Secretary information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and views on perceived gaps in existing guidance materials.

<sup>4</sup> [http://bch.cbd.int/onlineconferences/2016\\_2018period.shtml](http://bch.cbd.int/onlineconferences/2016_2018period.shtml).

*Annex I***PROVISIONAL ORGANIZATION OF WORK**

<i>Date/time (GMT-4)</i>	<i>Agenda item</i>	<i>Virtual meeting (live)</i>	<i>Online forum discussions</i>
<b>Monday, 30 March 2020</b>			
8 - 10 a.m.	Item 1. Opening of the meeting. Item 2. Organizational matters. Item 3. Risk assessment studies on living modified fish and living modified organisms containing engineered gene drives and recommendation on the need for guidance.	Opening statements and introductions. Election of co-chairs, adoption of the agenda, proposed organization of work. Presentation of the two studies by the authors and questions and answers.	
10 a.m. – 10 p.m.	Item 3. Risk assessment studies on living modified fish and living modified organisms containing engineered gene drives and recommendation on the need for guidance.		Online discussions <sup>1</sup> - review of the studies
<b>Tuesday, 31 March 2020</b>			
8 a.m. - 12 noon	Item 3.1. Living modified fish.	<ul style="list-style-type: none"> <li>• Analysis on living modified fish according to annex I of decision CP-9/13.</li> <li>• Recommendation on the need for guidance to be developed on risk assessment of living modified fish.</li> </ul>	
<b>Wednesday, 1 April 2020</b>			
5 – 9 a.m.	Item 3.2. Living modified organisms containing engineered gene drives.	<ul style="list-style-type: none"> <li>• Analysis on LMOs containing engineered gene drives according to annex I of decision CP-9/13.</li> <li>• Recommendation on the need for guidance</li> </ul>	

<sup>1</sup> Participants can post their comments sharing their views at any time during the timeframe indicated for the online discussion of each topic. This is meant to provide flexibility for participants considering the differences in time zones.

<i>Date/time (GMT-4)</i>	<i>Agenda item</i>	<i>Virtual meeting (live)</i>	<i>Online forum discussions</i>
		to be developed on risk assessment of LMOs containing engineered gene drives.	
9 a.m. - 5 p.m.	Item 4. Adjustments to annex I of decision CP-9/13		Online discussions
9 a.m. - 5 p.m.	Item 5. Analysis on needs and priorities for further guidance identified by Parties in response to decision CP-VIII/12		Online discussions
<b>Thursday, 2 April 2020</b>			
8 a.m. - 12 noon	Item 4. Adjustments to annex I of decision CP-9/13. Item 5. Analysis on needs and priorities for further guidance identified by Parties in response to decision CP-VIII/12. Item 6. Other matters.	Discussions building on views shared through online forum discussions. Discussions building on views shared through online forum discussions.	
<b>Friday, 3 April 2020</b>			
6 a.m. – 1 p.m.	Item 7. Adoption of the report. Item 8. Closure of the meeting.	Adoption of the report and closing statements.	

*Annex II*

**LIST OF DOCUMENTS**

**Working documents**

CBD/CP/RA/AHTEG/2020/1/1	Provisional agenda
CBD/CP/RA/AHTEG/2020/1/1/Add.1/Rev.1	Revised annotated provisional agenda
CBD/CP/RA/AHTEG/2020/1/2	Considerations on risk assessment as per decision CP-9/13
CBD/CP/RA/AHTEG/2020/1/3	Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish
CBD/CP/RA/AHTEG/2020/1/4	Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives

**Information documents**

CBD/CP/RA/AHTEG/2020/1/INF/1	Synthesis of submissions on experiences, challenges and needs regarding risk assessment of living modified organisms containing engineered gene drives and living modified fish
CBD/CP/RA/AHTEG/2020/1/INF/2	Synthesis of the interventions from the Open-ended Online Forum
CBD/CP/RA/AHTEG/2020/1/INF/3	List of bibliographic references
CBD/CP/RA/AHTEG/2020/1/INF/4	Compilation of information on risk assessment from the fourth national reports on implementation of the Protocol
CBD/SYNBIO/AHTEG/2019/1/3	Report of the Ad Hoc Technical Expert Group on Synthetic Biology

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