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## AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT

Montreal, Canada, 30 March-3 April 2020  
Item 7 of the provisional agenda\*

### REPORT OF THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT

#### INTRODUCTION

##### A. Background

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 Cartagena Protocol on Biosafety with a view to developing further guidance on risk assessment on the specific issues identified, taking into account annex I to the decision.
2. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety also decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment were needed for (a) LMOs containing engineered gene drives and (b) living modified fish. It established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment with the terms of reference set out in annex II to the decision. The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol further decided to extend the Online Forum on Risk Assessment and Risk Management to assist the AHTEG and invited submissions of information relevant to the work of the online forum and the AHTEG from Parties, other Governments, and indigenous peoples and local communities. The AHTEG is to submit the outcomes of its work for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice at its twenty-fourth meeting, prior to the tenth meeting of the Parties to the Protocol.
3. A face-to-face meeting of the AHTEG was scheduled to be held in Montreal at the offices of the Secretariat of the Convention on Biological Diversity. However, due to difficulties related to the global pandemic of COVID-19, the decision was made to hold the meeting virtually. The decision to change the format of the meeting was made in consultation with the Bureau of the Conference of the Parties.
4. The meeting was held virtually through a combination of live sessions and discussions through an online forum from 30 March to 3 April 2020.

##### B. Attendance

5. By notification 2019-095 of 24 October 2019, Parties, other Governments, indigenous peoples and local communities, relevant organizations and stakeholders were invited to nominate experts to the AHTEG.
6. The Secretariat received a total of 76 nominations from Parties to the Protocol and 23 nominations from observers, of which 3 were from non-Parties, 1 was from indigenous peoples and local communities,

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\* CBD/CP/RA/AHTEG/2020/1/1.

and 19 were from relevant organizations. The experts were selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice (see decision VIII/10, annex III), and through the application of [decision 14/33](#) on the procedure for avoiding or managing conflicts of interest in expert groups. The selection also took into account the expertise and experience of the nominees and the need to ensure equitable geographical distribution and gender balance.

7. Following consultation with the Bureau of the Subsidiary Body on Scientific, Technical and Technological Advice, the composition of the AHTEG was announced in notification 2019-119 of 23 December 2019.

8. Experts nominated by Brazil, Bulgaria, Croatia, Cuba, Finland, France, Jamaica, Japan, Nigeria, Norway, the Republic of Moldova, South Africa, the United Republic of Tanzania, Thailand and Turkmenistan attended the meeting. An expert from Australia (a non-Party to the Protocol) also attended the meeting.

9. One expert nominated by the Society for Wetland Biodiversity Conservation Nepal representing indigenous peoples and local communities participated in the meeting.

10. Experts nominated by the following organizations also participated in the meeting: The Centre for Integrated Research in Biosafety, Foundation for the National Institutes of Health, North Carolina State University, European Network of Scientists for Social and Environmental Responsibility, CSIRO Data 61, and Third World Network.

11. The list of participants is provided in annex II.

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

12. The meeting was opened at 8 a.m. on Monday, 30 March 2020, by the Acting Executive Secretary of the Convention on Biological Diversity, Ms. Elizabeth Maruma Mrema. She welcomed the experts and highlighted the importance of the task that the AHTEG had ahead. She encouraged the AHTEG members to share their technical expertise and to learn from one another in order to achieve better understanding of the issues that were central to their work during the meeting. A special mention was made of the exceptional circumstances under which the meeting was being held. She expressed her gratitude to the participants for their commitment and efforts made to take part in the meeting.

13. Following her opening remarks, the Deputy Executive Secretary, Mr. David Cooper, highlighted the very busy schedule of meetings in 2020 for the Convention and the Cartagena Protocol and explained that it was not possible to delay all the meetings in the calendar until normal operations could resume as that would jeopardize a number of processes. He explained that it was in that light that the Secretariat, in consultation with the Bureau, had decided to conduct a number of smaller, technical meetings through virtual means.

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

14. The AHTEG elected Ms. Wadzi Mandivenyi (South Africa) chair of the meeting.

15. The Group adopted the following agenda on the basis of the provisional agenda (CBD/CP/RA/AHTEG/2020/1/1) prepared by the Secretariat:

1. Opening of the meeting.
2. Organizational matters:
  - 2.1. Election of officers;
  - 2.2. Adoption of the agenda;
  - 2.3. Organization of work.
3. Risk assessment studies on living modified fish and living modified organisms containing engineered gene drives and recommendation on the need for guidance.
  - 3.1. Living modified fish;

- 3.2. Living modified organisms containing engineered gene drives.
  4. Adjustments to annex I of decision CP-9/13.
  5. Analysis on needs and priorities for further guidance identified by Parties in response to decision CP-VIII/12.
  6. Other matters.
  7. Adoption of the report.
  8. Closure of the meeting.
16. The Group agreed on the organization of its work as outlined in annex I to the revised annotated provisional agenda (CBD/CP/RA/AHTEG/2020/1/1/Add.1/Rev.1). It was noted that the revised organization of work included a combination of live virtual meeting sessions and online forum discussions hosted on the Biosafety Clearing-House and accessible only to members of the AHTEG and to Secretariat staff. The schedule of the meeting had been adjusted in an attempt to facilitate the participation of experts in different time zones.
17. A representative of the Secretariat made a brief introduction of the meeting documents, which were made available through the following website: <https://www.cbd.int/meetings/CP-RARM-AHTEG-2020-0>. In particular, she drew the attention of the experts to document CBD/CP/RA/AHTEG/2020/1/2 which included information relevant to the AHTEG's deliberations under the different agenda items of the meeting.

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

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

18. In decision CP-9/13, the Parties to the Protocol requested the Executive Secretary to commission a study informing the application of annex I of the decision to living modified fish. With the financial support of the Government of the Netherlands, the Executive Secretary commissioned JT Environmental Consultants to undertake the study, "Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish", which was issued as CBD/CP/RA/AHTEG/2020/1/3.
19. Mr. Jeremy Sweet of JT Environmental Consultants made a presentation on the study. He provided a brief overview of the status of genetic modification of fish. He noted that two categories of living modified fish had been commercialized to date: ornamental fish and fish for food consumption. He described the methods used to gather information for the study's analysis of the issue of living modified fish against decision CP-9/13, annex I. He then summarized the results of that analysis, according to the criteria in annex I, as well as the stock-taking exercise of resources on similar issues. Following the presentation, the experts had the opportunity to ask questions on the study.
20. As requested in paragraph (a) of its terms of reference, the AHTEG reviewed the study informing the application of decision CP-9/13, annex I, to living modified fish and performed an analysis according to annex I, supported by the data in the study. The review was conducted through online discussions on the Biosafety Clearing-House (BCH) that were then summarized by the Chair during the subsequent live session of the meeting in order to inform the AHTEG's analysis. In line with its mandate, the AHTEG did not revise the study. Further, according to paragraph (c) of its terms of reference, the AHTEG deliberated on the need for guidance to be developed on risk assessment of living modified fish. In those discussions, the AHTEG also considered the information in CBD/CP/RA/AHTEG/2020/1/2, section II A.
21. The outcomes of the deliberations are presented in annex I below.

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

22. Decision CP-9/13 requested the Executive Secretary to commission a study informing the application of annex I of the decision to living modified organisms containing engineered gene drives.

With the financial support of the Government of Germany, the Executive Secretary commissioned Perseus to undertake the study, “Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives”, which was issued as CBD/CP/RA/AHTEG/2020/1/4.

23. Mr. Patrick Rüdelsheim of Perseus made a presentation on the study. He gave a brief description of engineered gene drives as considered in the study, including different categories (suppression drives, replacement drives) and applications to date. He highlighted some considerations for risk assessment of living modified organisms containing engineered gene drives and summarized the study’s analysis against the criteria in annex I as well as the stock-taking exercise. Following the presentation, the experts had the opportunity to ask questions on the study.

24. Pursuant to paragraph (a) of its terms of reference, the AHTEG reviewed the study informing the application of decision CP-9/13, annex I, to living modified organisms containing engineered gene drives and performed an analysis according to annex I, supported by the data in the study. The review was conducted through online discussions on the BCH that were then summarized by the chair during the subsequent live session of the meeting in order to inform the analysis by the AHTEG. In line with its mandate, the AHTEG did not revise the study. Further, according to paragraph (c) of its terms of reference, the AHTEG deliberated on the need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives. In those discussions, the AHTEG also considered the information in CBD/CP/RA/AHTEG/2020/1/2, section II B.

25. The outcomes of these deliberations are presented in annex I below.

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

26. Paragraph (c)(ii) of its terms of reference mandated the AHTEG to make recommendations on any adjustments to annex I of decision CP-9/13.

27. The AHTEG discussed this item on the basis of the information in section III of document CBD/CP/RA/AHTEG/2020/1/2, and on the basis of its own experience acquired through its work in analysing the issues of living modified fish and LMOs containing engineered gene drives according to the criteria in annex I, under agenda item 3.

28. The outcomes of the AHTEG’s deliberations on this matter are presented in annex I below.

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

29. Paragraph (b) of its terms of reference requested the AHTEG to 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 to prepare an analysis.

30. The AHTEG discussed this item on the basis of the information in CBD/CP/RA/AHTEG/2020/1/2, section IV.

31. The outcomes of the AHTEG’s deliberations on the matter are presented in annex I below.

#### **ITEM 6. OTHER MATTERS**

32. The AHTEG paid tribute to Mr. Martin Khor, Chair and former Director of the Third World Network, who had died on 1 April 2020.

#### **ITEM 7. ADOPTION OF THE REPORT**

33. The chair introduced the draft report of the meeting, which was adopted as orally amended.

#### **ITEM 8. CLOSURE OF THE MEETING**

34. Following the customary exchange of courtesies, the meeting was closed at 11.20 p.m. on Friday, 3 April 2020.

*Annex I***OUTCOMES OF THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP  
ON RISK ASSESSMENT****I. LIVING MODIFIED FISH****A. Review of the study and analysis according to annex I of decision CP-9/13**

1. The AHTEG agreed that the “Study on risk assessment: application of annex I of decision CP-9/13 to living modified fish” was a good basis from which to work in order to conduct its analysis. The AHTEG also identified that more information on the potential impacts of living modified fish on biodiversity would be useful to complement the research presented in the study. As part of the review of the study by the AHTEG, some specific points were raised concerning risk assessment of living modified fish and these points are included as part of the analysis below.

**(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in transition.**

2. The AHTEG recognized that the issue of living modified fish has been identified by some Parties as a priority through various sources, including the submissions of information pursuant to decision CP-VIII/12, the online forum in 2018, the survey conducted as part of the study, and the fourth national reports on the implementation of the Cartagena Protocol on Biosafety.

3. The AHTEG acknowledged that different Parties may have different challenges for risk assessment of living modified fish and that these challenges may result in some Parties placing a higher priority on this topic. Further information on some of the challenges related to risk assessment of living modified fish are included in the analysis by the AHTEG under criterion (c) below.

**(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.**

4. The AHTEG considered that living modified fish fall within the scope and objective of the Cartagena Protocol on Biosafety.

**(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.**

5. The AHTEG recognized that existing risk assessment methodologies would apply for living modified fish but noted that there are specific technical or methodological challenges that require further attention. These challenges may be due to:

- (a) A lack of data or methods to collect data to inform the risk assessment process;
- (b) Limited applicability of some risk assessment methodologies to living modified fish;
- (c) Lack of tools to estimate consequences, likelihoods and uncertainty;
- (d) Difficulties in establishing comparator baselines;
- (e) Difficulties in relation to monitoring;
- (f) Lack of experience or capacity;
- (g) The specific nature of the biology of fish;
- (h) The specific nature of the possible genetic modifications.

6. Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified fish, as further detailed under criterion (d) below.

**(d) The challenges in addressing the specific issue are clearly described.**

7. Regarding the specific challenges related to the risk assessment of living modified fish, the AHTEG discussed the following potential challenges:

- (a) Related to fish biology:
  - (i) Insufficient knowledge on fish biology, genetics and ecology;
  - (ii) Fish mobility (for example, ability to swim vast distances), and therefore to enter different ecosystems;
  - (iii) Fish have the potential to be invasive and to hybridize with wildtype populations;
  - (iv) Fish demonstrate diverse morphological, genetic, physiological, and behavioural adaptations to highly variable aquatic environments;
- (b) Related to genetic modification:
  - (i) Introduced genetic modification (for example, enhanced growth) may confer competitive advantages within the environment;
  - (ii) Uncertainties associated with next generation effects, including considerations of evolutionary dynamics;
  - (iii) Some transformations of fish can result in pleiotropic and secondary effects, which can have pronounced effects on the phenology and behaviour of fish.
- (c) Related to data collection and availability:
  - (i) Challenges in simulating natural environments under experimental conditions;
  - (ii) Data on environmental behaviour (for example, interactions with different species), environmental factors which influence living modified fish reproduction and monitoring is very limited;
  - (iii) Knowledge on aquatic environments and genotype-environment interactions;
  - (iv) Difficulty in determining whether survival, migration, spawning, hybridization and introgression of living modified fish would occur under natural conditions and in different environments.
- (d) Related to experience:
  - (i) Limited experience performing risk assessments of living modified fish;
  - (ii) The experience in undertaking risk assessment of living modified fish varies among countries;
  - (iii) Experience with risk assessment of living modified fish is limited to containment conditions.
- (e) Related to risk assessment methodologies:
  - (i) Difficulties in establishing baselines;
  - (ii) Need for additional tools to estimate consequences and likelihoods of risks and uncertainty because of the complexity of the species and the receiving environment.
- (f) Related to monitoring and risk management:
  - (i) Methods to monitor living modified fish in the environment.

8. Data on releases of non-modified, non-indigenous fish was noted as being available (for example, the United States Geological Survey's Non-Indigenous Aquatic Species Program). Similarly, it was suggested that data from non-modified fish species, such as invasive alien fish species, and lessons from

commercial fish farming may be a source of experience that can inform potential environmental effects of living modified fish, without assuming an equivalence.

9. It was noted that while some tools exist to predict the survival and dissemination of fish species in the environment (for example, the Fish Invasiveness Screening Kit), it was also suggested that an agreed standard model for estimating dispersal and population dynamics would be useful.

10. Further, some AHTEG members noted that obtaining reliable data for risk assessment can be a challenge, but it does not necessarily mean a challenge to the risk assessment methodology itself.

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

**(i) Have the potential to cause adverse effects on biodiversity, in particular those that are 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) May be introduced into the environment either deliberately or accidentally;**

**(iii) Have the potential to disseminate across national borders;**

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

11. The AHTEG noted that the study's analysis of criterion (e)(i) contained relatively little information on potential impacts of living modified fish on biodiversity and additional information would be useful, while also noting the potential relevance of information in section 6.4 of the study. Building on the information in the study, experts identified potential adverse effects of living modified fish on biodiversity, for example, the potential for faster growing living modified salmon to out-compete naturally occurring smaller salmon.

12. Experts shared perspectives on the importance of many wild fish species to indigenous peoples and local communities and highlighted the importance of the relationship between indigenous peoples and local communities and biodiversity. It was suggested that there is a need to consider sociocultural impacts related to adverse effects on native fish populations resulting from a release of living modified fish, ensuring the full and effective participation of indigenous peoples and local communities.

13. It was recalled that no living modified fish have been developed for release into the environment and those living modified fish that have been released unintentionally, for example, ornamental fish, were not likely to survive in the environment. It was also suggested, however, that the important consideration was that living modified fish had been released into the environment, and whether or not these fish would persist was not relevant for this criterion.

14. The AHTEG agreed that living modified fish have the potential to disseminate across national borders.

15. The AHTEG recognized that several species of living modified ornamental fish as well as living modified Atlantic salmon have been commercialized.

## **B. Stocktaking of resources on similar issues**

16. The AHTEG recognized that resources related to risk assessment of living modified fish do exist, including documents prepared by the European Food Safety Authority and the Organisation for Economic Co-operation and Development and in the context of the Cartagena Protocol on Biosafety as well as resources on risk assessment of living modified animals in general. For some experts, these documents were sufficient for risk assessment of living modified fish, noting that additional guidance would not be able to address challenges related to the lack of data. Other experts were of the view that specific considerations related, for example, to prolonged exposure or next generation effects, were missing from these documents and, so, more detailed guidance was needed. It was also suggested that most existing

resources are for animals in general and guidance focused on fish would be useful and better adapted to the specific challenges they posed.

17. The AHTEG also acknowledged the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3). It noted that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

**C. Need for guidance to be developed on risk assessment of living modified fish**

18. The AHTEG noted a range of perspectives on the need for the development of guidance on risk assessment of living modified fish.

19. Some experts were of the view that all the criteria in decision CP-9/13, annex I, had been met and that, accordingly, there was a clear need and rationale for guidance to be developed on this topic. It was suggested that there are specific issues and challenges related to risk assessment of living modified fish that would be well suited to guidance and also that the development of guidance would help to pool resources and experiences on risk assessment in this area.

20. Other experts recognized that there could be a need for guidance but were of the view that existing documents can help to address this need and accordingly, the development of guidance on risk assessment of living modified fish should not be prioritized at the moment.

21. Some experts were of the view that not all the criteria were met and there was no need for the development of guidance on risk assessment of living modified fish. They suggested that the focus should be on capacity-building, sharing of experience as well as sharing of existing guidance materials, including in different languages. Experts suggested that given that approvals are for confined use and there are no indications that commercial fish species are being developed for environmental release to date, the development of guidance on risk assessment of living modified fish was not a priority.

22. One expert considered that she had insufficient information to reach a decision on the need for the development of guidance on living modified fish.

23. There were also some questions concerning what was meant by “guidance” in decision CP-9/13 and what types of guidance should be considered.

**II. LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES**

**A. Review of the study and analysis according to annex I of decision CP-9/13**

24. The AHTEG agreed that the “Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives” was a good basis for its work, and it was noted that it provided a useful overview of the current status of engineered gene drive technologies and potential applications. The AHTEG noted that the scope of the study was engineered (or synthetic) gene drives of sexually reproducing organisms. It noted that some of the terms used in the study, such as “reversibility” and “population replacement drive”, were not necessarily used in line with the understanding of some of the experts of the AHTEG. It was also recognized that there was additional information not covered by the study that could support the AHTEG’s deliberations. Specific points relevant to annex I of decision CP-9/13 that were raised during the review are included as part of the analysis below.

25. The importance of benefit analysis in relation to potential applications of living modified organisms containing engineered gene drives was noted in the context of decision-making.

<p><b>(a) They are identified by Parties as priorities, taking into account the challenges to risk assessment, particularly for developing country Parties and countries with economies in</b></p>
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**transition.**

26. The AHTEG noted that the issue of living modified organisms containing engineered gene drives has been identified as a priority by Parties through various sources, including the submissions of information in response to decision CP-VIII/12, the “Study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineered gene drives”, and fourth national reports on the implementation of the Cartagena Protocol on Biosafety. The cross-cutting nature of the issue of organisms containing engineering gene drives with other areas or work under the Convention on Biological Diversity (for example, synthetic biology) was also noted. The AHTEG further noted that developing countries could be the first ones to be confronted with the need to perform a risk assessment for organisms containing engineered gene drives, for example living modified mosquitos containing engineered gene drives. The importance of proper assessment of potential risk from the release of organisms containing engineered gene drives for indigenous peoples and local communities was also noted to ensure free, prior informed consent and full and effective participation.

27. Further information regarding the challenges related to risk assessment of living modified organisms containing engineered gene drives are included in the analysis of the AHTEG under criteria (c) and (d) below.

**(b) They fall within the scope and objective of the Cartagena Protocol on Biosafety.**

28. The AHTEG considered that LMOs containing engineered gene drives fall within the scope and objective of the Cartagena Protocol on Biosafety.

**(c) They pose challenges to existing risk assessment frameworks, guidance and methodologies, for example, if the issue at hand has been assessed with existing risk assessment frameworks but poses specific technical or methodological challenges that require further attention.**

29. The AHTEG recognized that, while existing risk assessment methodology may still be applicable for LMOs containing engineered gene drives, there are specific technical or methodological challenges that require further attention. These include: a lack of data to inform the risk assessment process; the limited applicability of some aspects of risk assessment methodologies to living modified organisms containing engineered gene drives, such as challenges to the comparative risk assessment framework and monitoring methods, lack of guidance on how to assess uncertainty, lack of validated modelling tools; and lack of experience or capacity.

30. The AHTEG also recognized that solutions to the challenges posed by LMOs with engineered gene drives will entail reconsideration of risk assessment and monitoring methods, as well as making more widely available the necessary expertise, training and resources required and the participation of indigenous peoples and local communities.

31. The AHTEG also noted that LMOs containing engineered gene drives have the potential to result in an irreversible impact on biodiversity at various scales up to the global level, and international cooperation may be required for risk assessment.

32. The AHTEG pointed out that no actual release of an LMO with engineered gene drives has been assessed to date.

33. Recognizing the linkages between criteria (c) and (d), the AHTEG further described the challenges related to living modified organisms containing engineering gene drives as detailed in criterion (d) below.

**(d) The challenges in addressing the specific issue are clearly described.**

34. Regarding the specific challenges related to the risk assessment of living modified organisms containing engineered gene drives, the AHTEG described the following challenges, recognizing that some of these challenges may relate to more than one of the categories below and may not relate to all types of drives:

- (a) Related to the engineered gene drive system:
  - (i) Super-Mendelian inheritance, genetic and phenotypic stability, and persistence and invasiveness;
  - (ii) Difficulty in predicting all relevant genomic effects that could emerge in the next and subsequent generations, and from interactions with the receiving environments;
  - (iii) Controllability of engineered gene drive systems after release;
  - (iv) Evaluation of off-target changes and their consequences over time in different genetic backgrounds and their potential accumulation in populations;
  - (v) The potential for the engineered gene drive to evolve after release, including through unexpected genetic drift;
- (b) Related to the target organism/species:
  - (i) Need for information on the potential genetic diversity of the target species;
  - (ii) Need for information on the functional role of the targeted species and potential interfertile species in the various ecosystems that may be encountered;
  - (iii) Consideration of the reproductive strategies, population dynamics and life cycle of the target organism;
  - (iv) Consideration of possible development of resistance in pathogens regarding vector control;
- (c) Related to the receiving environment:
  - (i) Limited information on the potential interactions with natural receiving environments;
  - (ii) Limited information on long-term evolutionary processes occurring in these ecosystems;
  - (iii) Need for information on potential for cross-hybridization with non-target species;
  - (iv) Diversity of potential receiving environments;
- (d) Related to risk assessment methodologies:
  - (i) Difficulties of applying the stepwise approach of environmental release;
  - (ii) Challenges to the comparative risk assessment framework;
  - (iii) Assessing and taking into consideration uncertainty;
  - (iv) Need to address the broader temporal and spatial scale;
  - (v) Higher dependency on model-based predictions (for example, to address the long temporal and wide spatial scale of some engineered gene drive applications and to anticipate the range of scenarios for the possible evolution of the engineered gene drive in the environment);
  - (vi) Difficulty to comprehensively assess risks prior to release;
  - (vii) Difficulties in assessing next generation effects of organisms containing engineered gene drives;
  - (viii) Potential adverse effects may differ depending on the type of gene drive mechanism (for example, population suppression drives versus modification drives);
  - (ix) The need to develop knowledge and procedures for assessing the engineered gene-drive's long-term effects on ecosystems;
- (e) Related to data collection and analysis:

- (i) Additional information needed on the molecular characterization of both the engineered gene drive mechanism and the engineered gene drive-bearing organism;
  - (ii) Information to predict off-target effects and potential consequences in the target organism;
  - (iii) Lack of environmental and ecological data;
  - (iv) Difficulties with obtaining data for relevant modelling;
  - (v) Difficulties with validation and calibration of modelling data before the occurrence of an environmental release;
- (f) Related to risk management and monitoring:
- (i) Post-release environmental monitoring is challenging;
  - (ii) Evaluation of impacts over long periods of time;
  - (iii) Need for monitoring plans at supranational level to follow the spread of the engineered gene drive;
  - (iv) Proven strategies for controlling the spread of an engineered gene drive, should monitoring data show that it has some negative impact on health or the environment;
  - (v) Unavailability of management plans for possible reversion.

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

- (i) Have the potential to cause adverse effects on biodiversity, in particular those that are 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) May be introduced into the environment either deliberately or accidentally;**
- (iii) Have the potential to disseminate across national borders;**
- (iv) Are already, or are likely to be, commercialized or in use somewhere in the world.**

35. The AHTEG recognized the need for information on potential impacts of living modified organisms containing engineered gene drives on biodiversity and noted that the study's analysis of criterion (e)(i) contained relatively little such information. For example, the AHTEG suggested that effects on biodiversity and ecosystems should not be limited to keystone species, valued species or ecosystem services as currently reflected in the study but, rather, examined in a more comprehensive manner. Notwithstanding this, the experts acknowledged the potential for living modified organisms containing engineered gene drives to cause adverse, and in some cases irreversible, effects on biodiversity. It was further suggested that the potentially global spread of living modified organisms containing engineered gene drives could then impact endemic/rare species or a unique habitat or ecosystems. It was also suggested that LMOs containing engineered gene drives could adversely affect disease transmission.

36. Experts noted the perspectives of indigenous peoples and local communities, and the particular importance of nature and biodiversity for them. It was recognized that more information was needed to better understand the potential implications of the release of organisms containing engineered gene drives for indigenous peoples and local communities. In particular, when the broad spread of an LMO with an engineered gene drive is likely, it would be challenging for instance, to obtain the free, prior and informed consent of indigenous peoples and local communities and their full and effective participation, although it was also noted that this was a necessary step.

37. Regarding criterion (e)(ii), the AHTEG noted that living modified organisms containing engineered gene drives could be introduced into the environment, either accidentally or deliberately.

38. Concerning criterion (e)(iii), the AHTEG agreed that living modified organisms containing engineered gene drives have the potential to disseminate across national borders.

39. Regarding criterion (e)(iv), the AHTEG noted that living modified organisms containing engineered gene drives were likely to be utilized and/or released in the near future.

#### **B. Stocktaking of resources on similar issues**

40. The AHTEG concluded that resources related to risk assessment of living modified organisms containing engineered gene drives do exist and could be useful for the purpose of undertaking risk assessments. However, it was acknowledged that the resources currently available are not applicable on a global level.

41. The AHTEG noted the compilation of bibliographic references that had been prepared by the Secretariat as an information document for the meeting (CBD/CP/RA/AHTEG/2020/1/INF/3) and that the compilation would be revised and updated with additional references, including those provided by AHTEG members, and made available for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

#### **C. Need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives**

42. Having undertaken the review of the study and performed an analysis of the topic of living modified organisms containing engineered gene drives against annex I of decision CP-9/13, the AHTEG recommended that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed, noting that all criteria have been fulfilled.

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

43. The AHTEG considered possible adjustments to annex I of decision CP-9/13, including taking into account its experience in applying it to the specific issues of living modified fish and living modified organisms containing engineered gene drives.

44. The AHTEG discussed the different elements in annex I. It noted that criteria (a) through (d) should be understood as mandatory criteria while criterion (e) was “for consideration”.

45. The AHTEG discussed the relationship between criteria (c) and (d) and noted that criterion (d) was meant to gather information and further details to substantiate the challenges identified under criterion (c).

46. The AHTEG noted that criterion (e)(iv) was not limited to those living modified organisms that are already or are likely to be commercialized, as the criterion also referred to those that are already or are likely to be “in use”.

47. It was recognized that the stock-taking exercise provided for in annex I would also include work undertaken by other international bodies.

48. The AHTEG did not recommend any adjustments to annex I.

### **IV. ANALYSIS ON NEEDS AND PRIORITIES FOR FURTHER GUIDANCE IDENTIFIED BY PARTIES IN RESPONSE TO DECISION CP-VIII/2**

49. The AHTEG considered the various topics suggested by Parties in their submissions made in response to decision CP-VIII/12, summarized in document CBD/CP/RA/AHTEG/2020/1/2 and further elaborated in the SBSTTA/22/INF/11 and SBSTTA/22/INF/12 documents. In doing so, it was noted that the mandate of the AHTEG for this task had not been elaborated very clearly.

50. There were different views on whether some of the topics that were identified by Parties as priorities in response to decision CP-VIII/12 should be considered under the process for identification and prioritization of specific issues on risk assessment of living modified organisms.

51. The AHTEG also took note of the horizon scanning process proposed by the AHTEG on Synthetic Biology and additionally suggested that there could be potential synergies between the two AHTEGs.

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