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Item 5 of the provisional agenda*

RISK ASSESSMENT AND RISK MANAGEMENT

Note by the Executive Secretary

I. BACKGROUND

1. At its ninth meeting, 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) with a view to developing further guidance on risk assessment on the specific issues identified, taking into account annex I of decision CP-9/13.

2. The Conference of the Parties serving as the meeting of the Parties to the Protocol also decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish. It established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment to undertake a number of tasks in accordance with the terms of reference contained in annex II of decision CP-9/13. In addition, it decided to extend the Open-ended Online Forum on Risk Assessment and Risk Management in order to assist the AHTEG, and invited Parties, other Governments, indigenous peoples and local communities, and relevant organizations to submit to the Executive Secretary information relevant to the work of the online forum and the AHTEG.

3. Based on the above, the Conference of the Parties serving as the meeting of the Parties to the Protocol requested the Executive Secretary, subject to the availability of resources:

(a) To commission a study informing the application of annex I of the decision to (i) living modified organisms containing engineered gene drives and (ii) living modified fish, to facilitate the process of identification and prioritization, and present it to the Open-ended Online Forum and the AHTEG on Risk Assessment;

(b) To collect and synthesize relevant information to facilitate the work of the Online Forum and the AHTEG;

(c) To assist the lead moderator of the Online Forum in convening discussions and reporting on the results of the discussions;

(d) To convene a face-to-face meeting of the AHTEG.

4. Finally, the Subsidiary Body on Scientific, Technical and Technological Advice was requested to make a recommendation as to whether additional guidance materials on risk assessment are needed for (a)

* CBD/SBSTTA/24/1.

living modified organisms containing engineered gene drives, and (b) living modified fish for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its tenth meeting.

5. Section II below provides an overview of the 2019-2020 activities carried out in response to decision CP-9/13. Section III provides a draft recommendation for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.

II. OVERVIEW OF PROCESSES CARRIED OUT AS PER DECISION CP-9/13

6. Further to the elements of decision CP-9/13 as summarized in paragraphs 2 and 3 above, the Executive Secretary: (a) invited the submission of information on risk assessment; (b) convened moderated discussions of the online forum; (c) collected and synthesized relevant information to facilitate the work of the Online Forum and the AHTEG, and (d) convened a meeting of the AHTEG. More information on these activities is provided in the following subsections.

A. Submissions of information on risk assessment

7. The Executive Secretary issued notification 2019-009 (dated 1 February 2019), inviting Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information related to:

(a) Experience in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish (detailing how and for which cases); or else, lack of experience in doing so;

(b) Challenges experienced or foreseen in undertaking risk assessment of living modified organisms containing engineered gene drives and living modified fish;

(c) Specific needs (if any) to properly undertake risk assessment of living modified organisms containing engineered gene drives.

8. A total of 29 submissions were received by the Secretariat, of which 22 were from Parties, 2 from non-Parties, and 5 from organizations. A synthesis of the submissions has been issued as CBD/CP/RA/AHTEG/2020/1/INF/1 and the original submissions are available through the Biosafety Clearing-House at https://bch.cbd.int/onlineconferences/submissions.shtml. Relevant information from the submissions was included in the working document for the AHTEG.[1]

B. Commissioning of studies and Open-ended Online Forum on Risk Assessment and Risk Management

9. With the financial support of the Governments of Germany and the Netherlands, the Executive Secretary commissioned two studies to inform the application of annex I of decision CP-9/13 to (a) living modified organisms containing engineered gene drives, and (b) living modified fish.

10. Drafts of the studies were made available for discussion in the Online Forum convened through the Biosafety Clearing-House.[2] The discussions were held from 20 January to 1 February 2020 and were moderated by Ms. Marja Ruohonen-Lehto from Finland.

11. By notification 2019-095 (24 October 2019), Parties, other Governments, indigenous peoples and local communities and relevant organizations were invited to nominate experts to participate in the forum.

12. The total number of participants registered for the forum was 199. Of this total, 149 were from Parties, 4 were from non-Parties, 45 were from organizations and 1 represented indigenous peoples and local communities. A total of 59 participants were active, and 96 interventions were made. Out of this total,

[1] CBD/CP/RA/AHTEG/2020/1/2.

[2] http://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml

56 interventions were made by Parties, 4 by non-Parties, and 36 by organizations. There were no interventions made by representatives of indigenous peoples and local communities.

13. In making their interventions, participants were encouraged to focus their comments on the substance of the studies rather than on editorial suggestions, and to share information that:

(a) Could complement the studies, e.g. further development of concepts, explanatory comments, relevant resources, bibliographic references, among others;

(b) Could identify any information gaps or factual errors;

(c) Was relevant to one or more of the aspects of annex I to decision CP-9/13.

14. Document CBD/CP/RA/AHTEG/2020/1/INF/2 provides a synthesis of the views shared through the Online Forum. For a full account of all views, it is recommended to refer to the original online interventions through the Biosafety Clearing-House (https://bch.cbd.int/onlineconferences/forum_ra/discussion.shtml).

15. Following the discussions in the Online Forum, the consultants revised and finalized the studies taking into account the comments made. The final versions of the studies were made available on the BCH[3] and to the AHTEG for its meeting. The studies have also been made available as information documents for the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (see documents CBD/CP/RA/AHTEG/2020/1/3 and CBD/CP/RA/AHTEG/2020/1/4).

C. Collection and synthesis of relevant information to facilitate the work of the Online Forum and the AHTEG

16. On the basis of decision CP-9/13, paragraph 11, in which the Executive Secretary was requested to collect and synthesize relevant information to facilitate the work of the Online Forum and the AHTEG, the information that appears below has been gathered by the Secretariat.

1. *Information on needs for guidance identified by Parties in their fourth national reports on the implementation of the Protocol*

17. Fourth national reports on the implementation of the Cartagena Protocol were due on 1 October 2019. Question 69 of the reporting format asked, "Does your country have specific needs for further guidance on specific topics of risk assessment of LMOs?". Some Parties also provided information on needs for further guidance on risk assessment of LMOs in the free text field under question 84.

18. Based on the above, the Secretariat summarized the information from the fourth national reports and included it in document CBD/CP/RA/AHTEG/2020/1/2, section IV. An updated version of this information is also presented in information document CBD/SBSTTA/24/INF/13.

2. *List of bibliographic references on engineered gene drives and living modified fish*

19. The Secretariat prepared a document compiling a list of references on engineered gene drives and living modified fish from various sources with the aim of supporting the deliberations of the AHTEG by providing background information that could be relevant for discussion on the various agenda items.[4] Additional bibliographic references were provided by some of the AHTEG members during the meeting. The list of references was updated accordingly and has been made available as information document CBD/SBSTTA/24/INF/7.

[3] https://bch.cbd.int/onlineconferences/studies.shtml

[4] CBD/CP/RA/AHTEG/2020/1/INF/3.

D. Meeting of the Ad Hoc Technical Expert Group on Risk Assessment

20. In decision CP-9/13, the Conference of the Parties serving as the meeting of the Parties to the Protocol decided to establish an Ad Hoc Technical Expert Group on Risk Assessment (AHTEG). The terms of reference for the AHTEG, set out in annex II to the decision, provide that the AHTEG, taking into account the work undertaken by the Ad Hoc Technical Expert Group on Synthetic Biology, shall:

(a) Review the studies informing the application of annex I of the decision to (i) living modified organisms containing engineered gene drives and (ii) living modified fish, and perform an analysis of these two groups of LMOs according to annex I of the decision, 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 decision CP-9/13;

(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.

21. 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.

22. 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, 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 for equitable geographical distribution and gender balance.

23. Following consultation with the Bureau of the Subsidiary Body, the composition of the AHTEG was announced in notification 2019-119 of 23 December 2019.

24. A face-to-face meeting of the AHTEG was scheduled to be held in Montreal. However, due to difficulties related to the global pandemic of COVID-19, the meeting was changed to a virtual meeting. The decision to change the format of the meeting was made in consultation with the Bureau of the Conference of the Parties.

25. Accordingly, the meeting was held virtually from 30 March to 3 April 2020 through a combination of live sessions and discussions through an online forum on the Biosafety Clearing-House and was chaired by Ms. Wadzi Mandivenyi from South Africa. The outcomes of the deliberations of the AHTEG are reproduced in the annex below.

26. Section I of the annex addresses the consideration by the AHTEG of the topic of living modified fish, including its review of the study, analysis according to the criteria in annex I of decision CP-9/13, stocking of resources on similar issues and consideration of the need for guidance to be developed on risk assessment of living modified fish. Section II contains the conclusions of the AHTEG on the topic of LMOs containing engineered gene drives, including its review of the study, analysis according to the criteria in annex I of decision CP-9/13, stocking of resources on similar issues and a recommendation on the need for guidance to be developed on risk assessment of LMOs containing engineered gene drives. Section III presents the outcomes of the discussions on possible adjustments to annex I of decision CP-

9/13, while section IV contains the outcomes of the discussions on needs and priorities for further guidance and gaps in existing guidance identified by Parties in response to decision CP-VIII/12.

27. The full report of the meeting of the AHTEG is also available as information document CBD/CP/RA/AHTEG/2020/1/5.

III. SUGGESTED RECOMMENDATION

28. Further to the request of the Conference of the Parties serving as the meeting of the Parties to the Protocol in decision CP-9/13, paragraph 12, and in the light of the outcomes of the discussions of the AHTEG, the Subsidiary Body on Scientific, Technical and Technological Advice may wish to recommend that the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, at its tenth meeting, adopt a decision along the following lines:

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

Recalling of decision CP-9/13, paragraph 7, in which it decided to consider, at its tenth meeting, whether additional guidance materials on risk assessment are needed for (a) living modified organisms containing engineered gene drives, and (b) living modified fish,

1. *Welcomes* the outcomes of the discussions of the Ad Hoc Technical Expert Group on Risk Assessment;[5]

2. *Takes note* of the clarifications made by the Ad Hoc Technical Expert Group to annex I of decision CP-9/13 regarding the process for identification and prioritization of specific issues of risk assessment of living modified organisms that may warrant consideration;[6]

3. *Notes* the analysis done by the Ad Hoc Technical Expert Group on the topics of (a) living modified organisms containing engineering gene drives and (b) living modified fish according to decision CP-9/13, annex I;

4. *Notes* the range of perspectives on the need for the development of guidance on risk assessment of living modified fish, and *decides* not to develop, at this stage, additional guidance materials on risk assessment regarding living modified fish;

5. *Endorses* the recommendation of the Ad Hoc Technical Expert Group that guidance for the risk assessment on living modified organisms containing engineered gene drives should be developed;

6. *Decides* to establish an Ad Hoc Technical Expert Group on Risk Assessment to develop additional guidance materials on risk assessment for living modified organisms containing engineered gene drives according to the terms of reference annexed hereto;

7. *Invites* Parties, other Governments, indigenous peoples and local communities and relevant organizations to submit to the Executive Secretary information relevant to the work of the Ad Hoc Technical Expert Group, prior to its first meeting;

8. *Requests* the Executive Secretary:

(a) To convene online discussions of the Open-ended Online Forum on Risk Assessment and Risk Management to support the work of the Ad Hoc Technical Expert Group;

(b) To collect and synthesize relevant information to facilitate the work of the Online Forum and the Ad Hoc Technical Expert Group;

[5] CBD/CP/RA/AHTEG/2020/1/5.

[6] See CBD/CP/RA/AHTEG/2020/1/5, annex I, sect. III.

(c) To synthesize the views referred to in paragraph 5 above and the discussions in the Online Forum and make them available for the Ad Hoc Technical Expert Group;

(d) To convene, subject to the availability of resources, two meetings of the Ad Hoc Technical Expert Group on Risk Assessment;

9. *Requests* the Subsidiary Body on Scientific, Technical and Technological Advice to consider the outcomes of the Ad Hoc Technical Expert Group on Risk Assessment and make a recommendation for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol at its eleventh meeting;

10. *Decides* to consider, at its eleventh meeting, additional issues on which guidance materials on risk assessment may be needed, further to the process for the identification and prioritization of specific issues of risk assessment of living modified organisms established in decision CP-9/13, taking into account priorities identified by Parties, including through their national reports.[7]

Annex (to the draft decision)

TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT

1. The Ad Hoc Technical Expert Group (Group) on Risk Assessment shall:

(a) Be composed of experts selected in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice;

(b) 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 on Biosafety, and perform necessary tasks between its two meetings;

(c) Develop guidance for conducting risk assessments of living modified organisms containing engineered gene drives in accordance with annex III of the Protocol;

(d) Prepare a report, including draft guidance, for consideration by the Subsidiary Body on Scientific, Technical and Technological Advice.

2. In undertaking its work, the Group shall consider the synthesis of views from the submissions and discussions in the online forum prepared by the Executive Secretary; existing resources identified in the stock-taking exercise of the "study on risk assessment: application of annex I of decision CP-9/13 to living modified organisms containing engineering gene drives";[8] and any other relevant information collected by the Executive Secretary further to paragraph 6(b) of decision CP-10/--.

[7] A synthesis of relevant information provided in the fourth national reports is available as CBD/CP/--.

[8] CBD/CP/RA/AHTEG/2020/1/4.

Annex

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 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.

(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.

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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