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

CONSIDERATIONS ON RISK ASSESSMENT AS PER DECISION CP-9/13

Note by the Executive Secretary

I. 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 its consideration 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 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 Conference of the Parties serving as the meeting of the Parties to the Protocol 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, indigenous peoples and local communities, and relevant organizations.

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 of 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 (SBSTTA) with a view to enabling the Subsidiary Body to prepare a recommendation for consideration by the Parties to the Protocol.

* Reissued for technical reasons on 19 March 2020.

4. The present document has been prepared to assist the AHTEG in its deliberations under the different agenda items of the provisional agenda for the meeting. Annex I to decision CP-9/13 is reproduced as an annex to the present document for ease of reference.

5. In addition, the AHTEG should bear in mind the following:

(a) The need for a coordinated approach on issues related to synthetic biology under the Convention and the Protocol (see, for example, decisions BS-VII/12, XII/24, CP-9/13 and 14/19). AHTEG members may wish to consult the report of the Ad Hoc Technical Expert Group on Synthetic Biology, as appropriate;[1]

(b) The objective of risk assessment under the Protocol is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

II. RISK ASSESSMENT STUDIES ON LIVING MODIFIED FISH AND LIVING MODIFIED ORGANISMS CONTAINING ENGINEERED GENE DRIVES AND RECOMMENDATION ON THE NEED FOR GUIDANCE

6. The information in this section is intended to address subparagraphs (a) and (c) (i) of the AHTEG's terms of reference, and to assist the AHTEG in its deliberations under item 3 of the provisional agenda for its meeting.

7. As requested in decision CP-9/13, the Executive Secretary invited Parties, other Governments, relevant organizations and indigenous peoples and local communities to submit information relevant to the work of the Online Forum on Risk Assessment and Risk Management and the AHTEG. More specifically, through notification 2019-009, submissions were invited on experience, challenges and needs in relation to risk assessment of living modified organisms containing engineered gene drives and living modified fish. A total of 29 submissions were received in response: 22 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.

8. 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 fish, and (b) living modified organisms containing engineered gene drives. Drafts of the studies were presented to the Online Forum, which was convened through the Biosafety Clearing-House from 20 January to 1 February 2020.[2]

9. Participants in the Online Forum were invited by the moderator to share information that:

(a) Could complement the studies, which might include further development of concepts, explanatory comments, relevant resources, and bibliographic references;

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

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

10. A report on the discussions in the Online Forum has been issued as CBD/CP/RA/AHTEG/2020/1/INF/2, and the comments received through the Online Forum were considered in producing the final versions of the studies.

11. In addition, the Secretariat compiled a list of bibliographic references provided through the submissions of information on risk assessment and risk management and the Online Forum, and additional references on the topics of engineered gene drives and living modified fish (see CBD/CP/RA/AHTEG/2020/1/INF/3).

[1] For the report, see CBD/SYNBIO/AHTEG/2019/1/3.

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

A. Living modified fish

12. According to paragraph (a) of its terms of reference, the AHTEG should review the study informing the application of annex I to decision CP-9/13 to living modified fish, and perform an analysis according to annex I, supported by the data in the study. Furthermore, according to paragraph (c) of its terms of reference, the AHTEG is to make recommendations on the need for guidance to be developed on risk assessment of living modified fish.

13. The study informing the application of annex I to decision CP-9/13 to living modified fish has been issued as CBD/CP/RA/AHTEG/2020/1/3. The study includes information on different transgenic traits that have been introduced into fish as well as information on experience with the commercialization, regulation, and risk assessment and risk management of living modified fish.

14. The AHTEG may wish to discuss and review the study, for which the executive summary could prove useful. In doing so, the AHTEG should bear in mind that the purpose of the study was to inform the application of annex I to the decision to living modified fish. The study was not aimed at either collecting data to inform the risk assessment process or performing a risk assessment on the topic of living modified fish.

15. In undertaking its analysis on living modified fish according to annex I to decision CP-9/13, the AHTEG may wish to consider the information provided in section 8 of the study, including both the structured analysis against the criteria in annex I of decision CP-9/13 and the stock-taking exercise.

16. In addition, information from the synthesis of submissions (CBD/CP/RA/AHTEG/2020/1/INF/1) could also complement the data in the study. In this respect, according to table 1 of the synthesis, 6 Parties and 2 non-Parties reported having experience in undertaking risk assessment of living modified fish, while 12 Parties reported having no experience in doing so. Furthermore, paragraph 11 of the same document presents some of the challenges identified through the submissions, such as understanding/predicting the adaptability of the living modified fish to the general aquatic ecosystem, insufficient information on fish behaviour and biological traits. Some of these challenges are related to issues captured in the study and by the online forum discussions.

17. Following its review of the study and analysis of the issue, the AHTEG may wish to make a recommendation on the need for guidance to be developed on risk assessment of living modified fish.

B. Living modified organisms containing engineered gene drives

18. According to paragraph (a) of its terms of reference, the AHTEG should review the study informing the application of annex I to decision CP-9/13 to living modified organisms containing engineered gene drives, and perform an analysis according to annex I, supported by the data in the study. Furthermore, according to paragraph (c) of its terms of reference, the AHTEG is to make recommendations on the need for guidance to be developed on risk assessment of living modified organisms containing engineered gene drives.

19. The study informing the application of annex I of decision CP-9/13 to LMOs containing engineered gene drives has been issued as CBD/CP/RA/AHTEG/2020/1/4. The study provides information on different types of engineered gene drives and the status of applications as well as considerations for risk assessment.

20. The AHTEG may wish to discuss and review the study, for which the executive summary could prove useful. In doing so, the AHTEG should bear in mind that the purpose of the study was to inform the application of annex I to the decision to LMOs containing engineered gene drives. The study was not aimed at either collecting data to inform the risk assessment process or performing a risk assessment on the topic of LMOs containing engineered gene drives.

21. In undertaking its analysis on LMOs containing engineered gene drives according to annex I of decision CP-9/13, the AHTEG may wish to consider the information provided in section 5 of the study, including both the structured analysis against the criteria in annex I of decision CP-9/13 and the stock-taking exercise. In addition, information from the synthesis of submissions

(CBD/CP/RA/AHTEG/2020/1/INF/1) could complement the data on the study for this purpose. According to table 1 of the synthesis, 1 Party reported having experience in undertaking risk assessment of LMOs containing engineered gene drives, and 16 Parties and 1 organization reported having no experience in undertaking risk assessment of living modified organisms containing engineered gene drives, while 1 Party stated that it had limited to no experience with risk assessment of such LMOs. In addition, paragraph 10 of the same document presents the challenges identified through the submissions, such as: difficulty in predicting the behaviour of organisms containing engineered gene drives prior to their release into the environment, high levels of uncertainty in the assessment of the likelihood of occurrence of adverse effects, lack of baseline data, insufficient data and knowledge, among others. Some of these challenges are related to issues captured in the study and by the online forum discussions.

22. Following its review of the study and analysis of the issue, the AHTEG may wish to make a recommendation on the need for guidance to be developed on risk assessment of LMOs containing engineered gene drives.

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

23. The information in this section is intended to address subparagraphs (c)(ii) of the AHTEG's terms of reference, and to assist the AHTEG in its deliberations under item 4 of the provisional agenda for its meeting.

24. In paragraph (c) of its terms of reference, the AHTEG is mandated to make recommendations on any adjustments to annex I of the decision. (Annex I of the decision is reproduced as an annex to the present document.)

25. The studies that have been commissioned are the first experience with the application of annex I to decision CP-9/13. From the research conducted to carry out the studies, it would appear that there are different interpretations of some of the criteria. For example, for the questionnaire undertaken as part of the study on living modified fish, different respondents may have had different understandings of criterion (e)(iii) – the specific issues concerning LMOs that have the potential to disseminate across national borders (see section 8.1(e) and annex 6 of the study on living modified fish).

26. Both studies also noted the limited information available to analyse some criteria, in particular the aspect of criterion (e)(i) that addresses the value of biodiversity to indigenous peoples and local communities (see section 8.1(e) of the study on living modified fish and section 5.1.4 of the study on LMOs containing engineered gene drives).

27. During the online forum, it was pointed out that there might be challenges in interpreting how to apply the criteria to arrive at a decision, indicating that it is not clear, for instance, if all the criteria must be met.

28. In its discussions under this item, the AHTEG may wish to consider any challenges that arise as part of its analysis of the topics of living modified fish and organisms containing engineered gene drives under item 3 of the provisional agenda.

IV. INFORMATION RELATED TO NEEDS AND PRIORITIES FOR FURTHER GUIDANCE AND GAPS IN EXISTING GUIDANCE

29. The information in this section is intended to address subparagraph (b) of the AHTEG's terms of reference and to assist the AHTEG in its deliberations under item 5 of the provisional agenda for its meeting.

30. In decision CP-VIII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol invited Parties 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.

31. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Protocol also decided to extend the Online Forum on Risk Assessment and Risk Management to exchange

experiences on risk assessment, provide information and views on, and perceived gaps in existing guidance materials, and proposals to address any gaps identified.

32. Based on the above, the Secretariat prepared two information documents for the twenty-second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice during the previous intersessional period: synthesis of submissions by Parties in response to paragraph 6 of decision CP-VIII/12 (CBD/SBSTTA/22/INF/11), and report of the Open-ended Online Forum on Risk Assessment and Risk Management (CBD/SBSTTA/22/INF/12).

33. In paragraph (b) of its terms of reference, the AHTEG is requested 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 prepare an analysis.

34. Accordingly, the paragraphs below present a summary of the views on gaps and needs and priorities for further guidance expressed through the 2017 submissions received in response to decision CP-VIII/12 and the 2018 discussions of the Online Forum. 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, information on needs for guidance identified by Parties in their fourth national reports on the implementation of the Protocol is also included.

35. The AHTEG may wish to consider the different views and suggestions and prepare an analysis.

Gaps in existing guidance and needs and priorities for further guidance

36. Extensive information on perceived gaps in existing guidance and needs and priorities for further guidance has been provided through the 2017 submissions and the 2018 discussions of the Online Forum. In many instances, suggestions on gaps in existing guidance are linked to needs for the development of further guidance.

37. In addition, some information on specific needs for guidance on risk assessment has also been provided through the fourth national reports of the implementation of the Cartagena Protocol, which 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?" A total of 65% of Parties replied "yes".[3] In the free text field, some Parties identified specific needs for further guidance on risk assessment of LMOs. This information is included in the summary in paragraph 42 below.[4]

38. A number of general comments on perceived gaps in existing guidance documents and needs and priorities for further guidance have been made through the 2017 submissions and the 2018 discussions of the Online Forum. These include the following:

(a) Information is lacking on how to perform the assessment of certain LMOs when no appropriate comparators exist (e.g. pathogenic organisms, comparators which will not survive in the receiving environments);

(b) Specific "limits of concern" still need to be further elaborated for different areas of biosafety risks and measurement endpoints;

(c) There is a need for further harmonization of terminology and its use in the different guidelines as well as a need to update most of the existing guidelines;

(d) Information on how to manage the risks identified during the risk assessment process is lacking;

[3] Based on the information provided in the 99 fourth national reports published in BCH as of 6 March 2020, https://bch.cbddev.xyz/reports.

[4] This information replaces information document CBD/CP/RA/AHTEG/1/INF/4.

(e) Gaps in existing guidance include issues such as open-field transfer of nucleic acids (either RNA or DNA) to plants and animals, e.g., as biological pesticides; centres and origins of genetic diversity; and genotype x environment interactions;

(f) Human health is only marginally addressed in existing guidance on risk assessment of LMOs;

(g) There is a lack of information on how scientific knowledge accumulated through previous environmental risk assessments can be efficiently used to further improve the risk assessment process.

39. A number of comments in the submissions, online discussions and the fourth national reports suggested a need for guidance on risk assessment of organisms developed through synthetic biology, including organisms produced through genome editing and other new breeding techniques. Some of the views on why there is a need for guidance in this area included the following:

(a) The application of synthetic biology is evolving rapidly, and, while existing risk assessment methodologies for LMOs may be applicable, several developments pose new risk assessment challenges that may require different approaches from existing risk assessment methodologies. For example, the risk assessment of organisms that are substantially different from existing LMOs will be associated with high levels of uncertainty, and it may be difficult to find suitable comparators to conduct a comparative assessment;

(b) The complexity of LMOs that may result from genome editing and the need to further examine the detection and assessment of unintended off-target changes at the DNA level;

(c) Perceived issues with off-target effects and identification of assessment endpoints.

40. At the same time, however, others expressed the view that all LMOs developed to date, including organisms developed through recent advances in synthetic biology as well as organisms containing engineered gene drives, can be assessed based on available guidelines. Some of the specific reasons expressed as to why guidance is not needed in this area were the following:

(a) While there may be limited experience in assessing the risks of LMOs developed through applications of synthetic biology, and risk assessment of such LMOs may be more complex, what is needed is case-by-case risk assessment (including the thoughtful application of guidance and prior experience and potentially the collection of new information), which cannot be addressed or avoided through the creation of guidance;

(b) Practical challenges due to the time required to develop new guidance. The speed of scientific development will outpace the development of guidance thus, LMOs developed through new techniques should be assessed using existing guidance, and assistance can be provided on how to apply this guidance to specific cases.

41. Other specific proposals for topics for the development of guidance were as follows:

(a) Living modified animals/mammals: some living modified animals have been approved for environmental release, and it was suggested that guidance is needed in order to be able to assess the risks of such releases;

(b) Living modified birds due to the mobility of birds, their migratory, courting and nesting behaviours, and their important role as zoonosis carriers, all of which create challenges for risk assessment;

(c) Living modified arthropods, including insects due to their role in the food chain, including pollination, as well as their dual nature with some considered pests and others considered beneficial organisms;

(d) Living modified microorganisms and viruses: some living modified microorganisms and viruses have been approved for environmental release, and it was suggested that guidance is needed in order to be able to assess the risks of such releases;

(e) Living modified algae to facilitate risk assessment of release into the environment of such algae;

(f) Guidance on assessing the risks of LMOs on soil-dwelling organisms due to the possible impacts of LMOs (e.g. with modified root architecture, nutrition, root exudates) on soil biodiversity, soil fertility and plant health;

(g) LMOs produced through cisgenetics;

(h) LMOs involving paratransgenesis;

(i) LMOs created using RNAi techniques: it was suggested that guidance is needed on characterizing potential exposure pathways and hazards, including off-target gene silencing, target gene silencing in non-target organisms, environmental persistence of small RNAs;

(j) Cumulative and long-term effects of LMOs in the environment, including being able to better assess potential pleiotropic effects due to cross-talk mechanisms;

(k) Gene flow: it was suggested that potential effects of LMOs on gene flow and gene pools are inadequately addressed in existing guidance.

42. In contrast, a number of the 2017 submissions as well as comments in the 2018 discussions of the Online Forum expressed the view that existing guidance documents on specific topics of risk assessment of living modified organisms were sufficient; they perceived no gaps in guidance and recommended that no new guidance should be developed for the time being. It was suggested that availability and access to existing guidance should be facilitated through the BCH and that examples of experience with conducting risk assessments should be shared. It was also suggested that training and experience were required rather than additional guidance.

Annex

IDENTIFICATION AND PRIORITIZATION OF SPECIFIC ISSUES OF RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS THAT MAY WARRANT CONSIDERATION

(reproduced from annex I of decision CP-9/13)

The process for recommending specific issues of risk assessment for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety should include a structured analysis to evaluate whether the specific issues fulfil the following criteria:

(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;

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

(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;

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

and considering, inter alia:

(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;

and consider a stock-taking exercise to determine if resources on similar issues have been developed by national, regional and international bodies and, if so, whether such resources may be revised or adapted to the objective of the Cartagena Protocol, as appropriate.

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