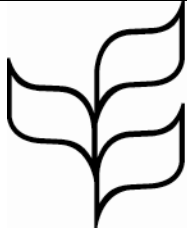




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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

Eighth meeting

Cancun, Mexico, 4-17 December 2016

Item 11 of the provisional agenda*

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLES 15 AND 16)

Note by the Executive Secretary

I. INTRODUCTION

1. In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety welcomed the results of the testing of the Guidance on Risk Assessment of Living Modified Organisms, and invited Parties, other Governments and relevant organizations to test or use the Guidance, as appropriate, in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment.

2. Furthermore, the Parties established a mechanism for revising and improving the Guidance on the basis of the feedback provided through the testing process established in decision BS-VI/12 with a view to having an improved version of the Guidance by its eighth meeting.

3. In the same decision, the Conference of the Parties serving as the meeting of the Parties to the Protocol:

(a) Extended the mandate of the Open-ended Online Expert Forum on Risk Assessment and Risk Management (Online Forum) and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management with revised terms of reference;

(b) Expanded the composition of the AHTEG to include one new member from each region;

(c) Invited Parties, other Governments and relevant organizations to confirm the nominations of their experts who were currently participating in the Online Forum on risk assessment and risk management;

(d) Requested the Executive Secretary to remove the records of experts whose nominations had not been confirmed;

(e) Further invited Parties, other Governments and relevant organizations to nominate additional experts to join the Online Forum using the format for the nomination of experts to the roster of experts.

* UNEP/CBD/BS/COP-MOP/8/1.

4. The Conference of the Parties serving as the meeting of the Parties, taking into account the possibility that the provisions of the Protocol could also apply to living organisms resulting from synthetic biology, also recommended to the Conference of the Parties to the Convention on Biological Diversity a coordinated approach on the issue of synthetic biology.

5. The present note is meant to assist the Conference of the Parties serving as the meeting of the Parties in its consideration of the agenda item on risk assessment and risk management at its eighth meeting. Section II provides an overview of the status of implementation of the Protocol's provisions on risk assessment and risk management. Section III presents information on the process for the expansion of the membership of the AHTEG to include one new member from each region. Section IV provides an overview of the process undertaken to improve the Guidance based on the results of the testing process, and changes to the mechanism for indexing background documents to the Guidance. Section V presents a synthesis of the outputs of the AHTEG, with input from the Online Forum, with regard to the topics prioritized for the development of additional guidance, as well as the views submitted by Parties on (a) needs and priorities for further guidance and (b) existing guidance on specific topics of risk assessment of living modified organisms (LMOs). Section VI presents some considerations on capacity-building on risk assessment. Section VII outlines possible elements for a draft decision for consideration by the Parties at their eighth meeting.

6. The following have been issued as addenda to the present note: (a) "Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment" (UNEP/CBD/COP-MOP/8/8/Add.1); (b) "Outline of guidance on risk assessment of living modified fish" (UNEP/CBD/COP-MOP/8/8/Add.2); and (c) "Outline of guidance on risk assessment of living modified organisms developed through synthetic biology" (UNEP/CBD/COP-MOP/8/8/Add.3).

7. The reports of the Online Forum and of the two meetings of the AHTEG are available as information documents UNEP/CBD/BS/COP-MOP/8/INF/2, 3 and 12.

II. TRENDS REGARDING THE IMPLEMENTATION OF RISK ASSESSMENT PROVISIONS TOWARDS OPERATIONAL OBJECTIVES 1.3 AND 1.4 OF THE STRATEGIC PLAN

8. Further to the information gathered, analysed and presented for the third assessment and review of the effectiveness of the Protocol and mid-term evaluation of its Strategic Plan (see UNEP/CBD/COP-MOP/8/12/Add.1), below is an overview of emerging trends, regarding the implementation of the Protocol's provisions on risk assessment and risk management as well as operational objectives 1.3 and 1.4 of the Strategic Plan since the second assessment and review of the Protocol.

9. A total of 57 per cent of Parties reported that they had already conducted a risk assessment for a living modified organism. This represents an increase of 9 per cent in the number of Parties that had already conducted risk assessments in relation to the baseline set during the second assessment and review process.

10. Among those Parties that had conducted risk assessments:

(a) 50 per cent reported that they had conducted more than 10 risk assessments in the preceding five years;

(b) 23 per cent were using the Guidance when conducting risk assessments or evaluating risk assessment reports submitted by notifiers;

(c) 8 per cent reported that they had not adopted or used any guidance documents for the purpose of conducting risk assessments;

(d) 15 per cent reported that they had either not at all or only in some cases conducted risk assessments of living modified organisms for intentional introduction into the environment or on domestic use of LMOs intended for direct use as food, feed, or for processing.

11. Among Parties that had not yet conducted any risk assessments of LMOs, 37 per cent reported that they had been using the Guidance for training purposes.

12. Furthermore, the results of a separate analysis of the answers provided in the third national reports against the results of the testing of the Guidance show that, among the Parties that have conducted actual risk assessments, 60 per cent consider the Guidance useful.

III. COMPOSITION OF THE ONLINE FORUM AND THE AHTEG

13. In response to the requests in decision BS-VII/12, the Secretariat issued a notification¹ inviting Parties, other Governments and relevant organizations to (a) confirm the nominations of experts who were participating in the Online Forum, and (b) to nominate additional experts who were actively involved in risk assessment and risk management to participate in the Online Forum.

14. To expand the composition of the AHTEG, the Secretariat, in consultation with the Bureau of the Conference of the Parties serving as the meeting of the Parties, selected one new member from each of the five geographical regions from among those experts nominated to the Online Forum by Parties, taking into account their expertise and gender balance in accordance with the consolidated modus operandi of the Subsidiary Body on Scientific, Technical and Technological Advice of the Convention on Biological Diversity.²

15. The lists of members in the Online Forum and the expanded AHTEG are available through the Biosafety Clearing-House.³

IV. GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS AND MONITORING IN THE CONTEXT OF RISK ASSESSMENT

A. Improvements to the Guidance

16. In the terms of reference for the Online Forum and the AHTEG annexed to decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties established the following mechanism for revising and improving the Guidance on the basis of the feedback provided through the testing process established earlier in decision BS-VI/12:

(a) The Secretariat was requested to group the original comments provided through the testing of the Guidance in the form of a matrix based on the following categories: (i) statements that do not trigger changes; (ii) editorial and translational changes; (iii) suggestions for changes without a specified location in the Guidance; and (iv) suggestions for changes to specific sections of the Guidance (sorted by line numbers);

(b) The AHTEG was then requested to review the grouping of comments arranged by the Secretariat and deliberate on the suggestions for changes;

(c) The AHTEG was then to streamline the comments by identifying which suggestions were to be taken on board and providing justification for those suggestions that were not taken on board. The AHTEG was also requested to provide concrete text proposals for the suggestions to be taken on board with a justification where the original suggestion was modified;

(d) The Open-ended Online Forum and the AHTEG were subsequently requested to review all comments and suggestions with a view to having an improved version of the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties at its eighth meeting.

¹ Notification SCBD/BS/MPM/DA/83988 <https://www.cbd.int/doc/notifications/2014/ntf-2014-125-bs-en.pdf>

² Available at <http://www.cbd.int/doc/publications/bs-rules-en.pdf>

³ At http://bch.cbd.int/onlineconferences/participants_ra.shtml and https://bch.cbd.int/onlineconferences/RA_ahteg_participants, respectively.

17. In implementing the mechanism set out by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety for revising and improving the Guidance, the Secretariat grouped the comments provided through the testing of the Guidance into the specified categories. Subsequently, the AHTEG provided their feedback, through an online discussion,⁴ on the grouping of the comments and made suggestions on their improvement.

18. With a view to moving forward with the mandate, and taking into account the suggestions made by the AHTEG, a subgroup of AHTEG members held several rounds of online discussions and teleconferences whereby the members streamlined the grouped comments, identified and recommended which comments were to be taken on board with the view to improving the Guidance, while providing justification for those comments that were not taken on board.

19. Through online discussions held between April and July 2015,⁵ the Online Forum and/or AHTEG provided feedback on the work carried out by the AHTEG subgroup, took stock of the progress and challenges encountered and made further suggestions regarding the improvements to the Guidance.

20. After the first cycle of online activities, following the generous offers of the Government of Brazil to host a meeting of the AHTEG and of the European Union to provide financial support, the AHTEG held a face-to-face meeting in Brasilia from 16 to 20 November 2015. At the meeting, the AHTEG reviewed all the suggestions for improvements to the Guidance made by the subgroup on the basis of the comments provided through the testing of the Guidance and agreed on a plan of work to conclude its task.

21. Thereafter, the AHTEG subgroup continued working on the outstanding comments provided through the testing of the Guidance and addressed the various comments that called for concrete examples to be added to the Guidance.

22. The Online Forum and AHTEG provided feedback on the work of the AHTEG subgroup via online discussions. It is noted that, in providing feedback on the proposed revisions to the Guidance, the views shared among participants of the Online Forum diverged significantly on how to best improve the Guidance.

23. Subsequently, following a generous financial contribution from the Government of Mexico, the AHTEG met for a second time during the intersessional period in Mexico City from 25 to 29 July 2016. At the meeting, the AHTEG concluded the work of revising and improving the Guidance taking into account the results of the testing process, as established in decision BS-VI/12, and the input provided through the Online Forum. The AHTEG endeavoured to reconcile the different views coming from the Online Forum by following an inclusive approach to explore all possibilities to reach a middle ground on the outstanding issues.

24. The improved version of the Guidance, the title of which was changed to read “Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment”, has been issued for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its eighth meeting (see UNEP/CBD/BS/COP-MOP/8/8/Add.1).

25. The reports of the Online Forum and the two meetings of the AHTEG, as well as a detailed account of the actions taken regarding individual comments from the testing of the Guidance, are available as information documents UNEP/CBD/BS/COP-MOP/8/INF/2, 12, 3, and 4, respectively. The calendar of activities and online discussions held by the Online Forum and AHTEG during the intersessional period are available at http://bch.cbd.int/onlineconferences/forum_ra.shtml.

⁴ The online discussions of the AHTEG are available at http://bch.cbd.int/onlineconferences/ahteg_ra.shtml.

⁵ The online discussions held jointly by the Online Forum and the AHTEG are available at http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml.

B. Improvements to the mechanism for updating the background documents to the Guidance

26. In its decision BS-VI/12, the Conference of the Parties serving as the meeting of the Parties established a mechanism for the regular update of the list of background documents linked to the Guidance in a transparent manner, and mandated AHTEG to operate the mechanism and report to it at its seventh meeting.

27. In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties requested the Executive Secretary to improve the mechanism for updating background documents to the Guidance as follows:

(a) Extend the period for commenting on the background documents to three weeks and send an automatic reminder after two weeks to the group operating the mechanism;

(b) Raise awareness of the background documents linked to the Guidance by, for example, adding information and links in the Biosafety Clearing-House and inviting experts in the specific topics of the Guidance to submit background documents;

(c) Index the background documents for author affiliation, for example, government, academic institutions, non-governmental organizations and business;

28. At its second meeting, in Mexico City, the AHTEG considered more specific locations in the Guidance where the background documents could be linked and invited the Secretariat to continue its work in updating and validating the background documents.

29. The AHTEG also noted possible challenges in the process of indexing the background documents on the basis of author affiliation, particularly in cases where there are multiple authors or where the author is unknown. In establishing a way forward on this matter, the AHTEG agreed that documents should be indexed on the basis of the affiliation of the corresponding author and/or the institution taking responsibility for the documents, as appropriate.

30. The Secretariat, in responding to decision BS-VII/12 and taking into account the views of the AHTEG, introduced the improvements to the mechanism for updating background documents as outlined in paragraph 27 above.

V. DEVELOPMENT OF FURTHER GUIDANCE ON TOPICS PRIORITIZED ON THE BASIS OF THE NEEDS INDICATED BY THE PARTIES WITH A VIEW TO MOVING TOWARDS OPERATIONAL OBJECTIVES 1.3 AND 1.4 OF THE STRATEGIC PLAN AND ITS OUTCOMES

31. At its sixth meeting, in the annex to decision BS-VI/12, the Conference of the Parties serving as the meeting of the Parties mandated the Online Forum and the AHTEG to provide recommendation to its seventh meeting on how to proceed with respect to the development of further guidance on specific topics of risk assessment, selected on the basis of the priorities and needs indicated by the Parties with the view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan for the Cartagena Protocol and its outcomes.⁶ In response to this request, the AHTEG provided the Conference of the Parties serving as the meeting of the Parties at its seventh meeting with a list of 16 topics prioritized for the development of further guidance.⁷

32. At its seventh meeting, in the annex to decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties mandated the AHTEG, while revising and improving the Guidance, to take into account the topics prioritized by the AHTEG, on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes, for the development of further guidance.

⁶ See decision BS-VI/12, annex, para. 3(c).

⁷ See UNEP/CBD/BS/COP-MOP/7/10/Add.2, paras. 37-38.

33. Furthermore, in its decision BS-VII/12, paragraphs 5 to 7, the Conference of the Parties serving as the meeting of the Parties:

(a) Invited Parties to submit (i) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and (ii) existing guidance on specific topics of risk assessment of living modified organisms;

(b) Requested the Executive Secretary to synthesize the views submitted through subparagraph (a) above for consideration of the eighth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(c) Agreed to consider, at its eighth meeting, the need for the development of further guidance on topics prioritized on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes.

A. Outputs of the AHTEG, with input from the Online Forum, with regard to the topics prioritized for the development of additional guidance

34. In accordance with the task outlined in their terms of reference and in paragraph 32 above, the AHTEG, with input from the Online Forum, considered whether and how the topics previously prioritized for the development of additional guidance could be incorporated into the Guidance or be developed as separate guidance.

35. As a result, the AHTEG addressed the following topics by adding information boxes under the relevant sections of the Roadmap:

(a) “LMOs introduced in centres of origin and genetic diversity” and “LMOs intended for introduction into unmanaged ecosystems” (addressed together);

(b) “LMOs created through use of dsRNA techniques, engineered to produce dsRNA or dsRNA” and “LMOs containing RNAi”;

(c) “Integrating human health into the environmental risk assessment” taking into account the topics “Nutritionally altered living modified plants” and “LMOs that produce pharmaceutical products”, as appropriate;

(d) “Synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs”.

36. Furthermore, taking into account the needs indicated by Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and recommendations by the Subsidiary Body on Scientific, Technical and Technological Advice to the Convention on Biological Diversity at its twentieth meeting, the AHTEG decided to recommend to the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety the development of separate additional guidance on:

(a) Risk assessment of LM fish;

(b) Risk assessment of LMOs produced through synthetic biology.

37. The AHTEG prepared outlines on the two topics to facilitate consideration, by the Conference of the Parties serving as the meeting of the Parties at its eighth meeting, of the need to develop further guidance these two topics. The outlines developed by the AHTEG, with input from the Online Forum, are available as addenda 2 and 3 to the present note.

38. As a result of the work described in paragraphs 35 and 36 above, the list of topics prioritized by the AHTEG for the development of separate additional guidance was reduced to the following five topics, which remain to be addressed at a later stage, as appropriate:

(a) Risk assessment of living modified microorganisms and viruses;

- (b) Risk assessment of living modified animals;
- (c) Risk assessment of LM insects;
- (d) Risk assessment of living modified organisms produced through cisgenetics;
- (e) Co-existence between LMOs and non-LMOs in the context of small scale farming.

39. It is noted that the views shared among participants in the Online Forum diverged significantly on whether or not the topics prioritized by the AHTEG for the development of guidance need to be incorporated into the Roadmap or developed as further guidance. In particular, several participants in the Online Forum were of the view that: (a) the Roadmap needs to be general and robust enough to cover all topics; and (b) some of the topics prioritized by the previous AHTEG do not warrant specific consideration in the context of environmental risk assessment of living modified organisms and, therefore, the development of specific guidance on these topics was not considered necessary.

B. Synthesis of views on (a) needs and priorities for further guidance and (b) existing guidance on specific topics of risk assessment of living modified organisms

40. The Secretariat issued a notification⁸ inviting Parties to submit (a) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, and (b) existing guidance on specific topics of risk assessment of living modified organisms.

41. A total of 17 submissions were made by Austria, Belarus, Bosnia and Herzegovina, Bulgaria, Colombia, the European Union, Finland, the Islamic Republic of Iran, Japan, Mauritania, Mexico, Niger, Nigeria, Peru, Spain, Trinidad and Tobago, and the United Kingdom of Great Britain and Northern Ireland.

42. With regard to their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms, a total of 11 Parties identified at least one topic of risk assessment or risk management of living modified organisms that was considered a priority for the development of new guidance. Five Parties indicated no need for the development of further guidance on specific aspects of risk assessment or risk management of living modified organisms. One Party did not have any particular view on the issue.

43. The following topics were identified by Parties as priorities for the development of new guidance:⁹

- (a) Risk assessment of living modified organisms developed through synthetic biology;
- (b) Risk assessment of living modified fish;
- (c) Risk assessment of living modified animals;
- (d) Risk assessment and risk management strategies for living modified microorganisms intended for introduction into the environment, including living modified soil microbes;
- (e) Risk assessment of living modified birds;
- (f) Risk assessment of living modified algae;
- (g) Risk assessment of living modified organisms developed through paratransgenesis;
- (h) Environmental application of in vitro nucleic acid techniques that overcome natural physiological reproductive or recombination barriers, e.g., for use in pest management;
- (i) Risk assessment of combinatorial effects of living modified organisms;

⁸ The notification is available at <http://www.cbd.int/doc/notifications/2015/ntf-2015-138-bs-en.pdf>.

⁹ The list was compiled and is presented in descending order of priority. Priority was determined based on the number of Parties identifying a particular topic for the development of further guidance. Each of the topics under (a) to (d) was identified as priority by multiple Parties, while each of topics from (e) to (m) was identified by a single Party.

- (j) Risk management and monitoring strategies for the introduction of LMOs in unmanaged ecosystems;
- (k) Identification of living modified organisms or specific traits that may have adverse effects to the conservation and sustainable use of biodiversity, taking into account risks to human health;
- (l) Risk assessment of indirect effects associated with living modified organisms;
- (m) Transportability of data from environmental risk assessment of LMOs grown under field trials to other receiving environments.

44. There were also topics identified by Parties in their submissions for the development of additional guidance that were not directly related to environmental risk assessment, such as food safety and socioeconomic considerations of living modified organisms.

45. Furthermore, some Parties suggested that the following may be taken into account when selecting new topics for the development of guidance:

- (a) The practical relevance of the topic to the objective of Cartagena Protocol, prioritizing topics that are currently relevant or that are going to be relevant in near future, and that are not yet adequately covered in the “Roadmap for Risk Assessment” (Part I of the existing Guidance);
- (b) The scope of the topics, avoiding those that are too broad or poorly defined;
- (c) The rate of scientific and technological development under a certain topic and whether a guidance on that topic would still be relevant at the time when it was ready to be used;
- (d) Most suitable ways to address the new topics, for example by adding additional text into the existing Roadmap or as an appendix to the Guidance, or by developing new separate guidance;
- (e) Whether similar guidance has been developed by national, regional and international bodies and, if so, their relevance to the objective of Cartagena Protocol and whether they can be revised or adapted to the objective of the Protocol, as appropriate.

46. With regard to existing guidance on specific topics of risk assessment of living modified organisms, several Parties identified existing guidance documents, guidelines and checklists that have been adopted and/or are being used. A few Parties indicated that they have neither adopted or are using any guidance on risk assessment.

47. Among the existing guidance documents on environmental risk assessment that were identified by Parties, most were focused on risk assessment of living modified plants. One exception is the “Guidance on the environmental risk assessment of genetically modified animals” which was developed by the European Food Safety Authority.¹⁰

48. There were also a number of identified guidance documents on topics other than environmental risk assessment of living modified organisms, including guidance on safety assessment of food and feed derived from living modified organisms.

49. Most of the guidance documents identified by Parties in their submissions were already available through the Biosafety Clearing-House, and those that were missing, were added.

VI. CAPACITY-BUILDING

50. In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties requested the Executive Secretary, subject to the availability of funds, to conduct capacity-building activities in risk assessment using the package aligning the Guidance and the Training Manual on Risk Assessment.

¹⁰ Available at <http://www.efsa.europa.eu/en/efsajournal/pub/3200>.

51. Given that the Guidance underwent substantial changes during the past intersessional period in response to decision BS-VII/12, the organisation of capacity building activities by the Secretariat was deferred to the next intersessional period, subject to the availability of funds, in order to update the aligned package to take into account the revisions and improvements to the Guidance.

VII. ELEMENTS FOR A DRAFT DECISION

52. Having concluded its work as mandated in its terms of reference in decision BS-VII/12 and recognizing the challenge in reconciling some of the diverging input from the Online Forum, the AHTEG made the following recommendations for consideration by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety at its eighth meeting:

Regarding the “Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment”

- (a) Endorsing the Guidance and inviting Parties, other Governments and relevant organizations to use the Guidance for conducting actual risk assessments and capacity-building activities;
- (b) Inviting Parties to share their experience in using the Guidance through their national reports with a view to monitoring and ensuring applicability of the Guidance in relation to scientific progress;
- (c) Requesting the Executive Secretary:
 - (i) To make available through the Biosafety Clearing-House a description of the process followed to revise and improve the Guidance and its outcomes, and to facilitate the sharing of experience in using the Guidance among its users;
 - (ii) To conduct capacity-building activities in risk assessment of LMOs using the Guidance, subject to the availability of funds;
- (d) Requesting the Global Environment Facility to provide funding for a global capacity-building project on risk assessment and risk management with an emphasis on the use of the Guidance.

Regarding the development of further guidance on specific topics of risk assessment

- (e) Establishing a process for the development of guidance on the following topics on the basis of the outlines developed by the AHTEG:
 - (i) “Risk assessment of living modified fish”;
 - (ii) “Risk Assessment of LMOs developed through synthetic biology”, in coordination with relevant processes under the Convention on Biological Diversity.
- (f) Extending the Open-ended Online Expert Forum and the AHTEG to develop guidance on the topics listed under paragraph (e) above, and to take into account additional topics, including those identified by Parties in their submissions and by the AHTEG.
