



Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/RARM/AHTEG/2015/1/2
6 November 2015

ORIGINAL: ENGLISH

AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Brasilia, 16-20 November 2015

Item 3.2 of the provisional agenda*

OVERVIEW OF THE WORK DONE IN RESPONSE TO DECISION BS-VII/12

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 (COP-MOP) 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, as appropriate, the Guidance in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment.

2. In paragraph 4 of the same decision, COP-MOP extended the Open-ended Online Expert Forum on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (AHTEG), and expanded the composition of the AHTEG to add one new member from each region. Furthermore, in paragraph 8, COP-MOP invited Parties, other Governments and relevant organizations to confirm the nominations of their experts who are currently participating in the Online Forum, and requested the Executive Secretary to remove the records of experts whose nominations are not confirmed. COP-MOP further invited Parties, other Governments and relevant organizations to nominate additional experts to join the Online Forum.

3. COP-MOP also established the mechanism described below for revising and improving the Guidance on the basis of the feedback provided through the testing process with a view to having an improved version of the Guidance by its eighth meeting:

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

(b) The AHTEG shall review the grouping of comments done by the Secretariat and work on the suggestions for changes;

(c) The AHTEG shall streamline the comments by identifying which suggestions may be taken on board and by providing justification for those suggestions that may not be taken on board. The

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AHTEG will also provide concrete text proposals for the suggestions to be taken on board with a justification where the original suggestion was modified;

(d) The Online Forum and the AHTEG shall subsequently review all comments and suggestions with a view to having an improved version of the Guidance for consideration by COP-MOP at its eighth meeting;

4. In accordance with the terms of reference of the Online Forum and the AHTEG, while revising and improving the Guidance, an attempt should be made 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.

5. Furthermore, the AHTEG shall continue to operate the mechanism for regularly updating the list of background documents to the Guidance as established in decision BS-VI/12, paragraph 6, and improved as per paragraph 10 of decision BS-VII/12.

II. SUMMARY OF ACTIVITIES IN RESPONSE TO DECISION BS-VII/12

A. Expansion of the composition of the AHTEG

6. In response to the requests in paragraphs 4 and 8 of decision BS-VII/12, the Secretariat issued a notification¹ inviting Parties, other Governments and relevant organizations to (a) confirm the nominations of experts who are currently participating in the Online Forum, and (b) to nominate additional experts who are actively involved in risk assessment and risk management to participate in the Online Forum.

7. Furthermore, to expand the composition of the AHTEG, the Secretariat, in consultation with the COP-MOP Bureau, 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

B. Overview of the activities of the Online Forum and AHTEG

8. In implementing the mechanism set out by COP-MOP in decision BS-VII/12 to revise and improve the Guidance, the Secretariat grouped the original comments provided through the testing of the Guidance into five categories: (a) comments that do not trigger changes (i.e. comments related to the testing process as such); (b) overall evaluation of the Guidance; (c) suggestions for editorial and translational changes; (d) suggestions for substantive changes without a specified location in the Guidance; and (e) suggestions for substantive changes to specific sections of the Guidance.

9. Following the grouping exercise, the AHTEG was invited to provide feedback, through an online discussion,³ on the grouping of the comments done by the Secretariat and to propose practical ways forward on how to take the comments on board.

10. There was general acceptance among the members of the AHTEG with regard to the suggested grouping by the Secretariat of the comments provided by Parties and other stakeholders during the testing of the Guidance. The AHTEG emphasized that all comments needed to be considered during the revision of the Guidance. The AHTEG noted that comments submitted without a specific location in the Guidance (i.e. comments grouped under categories B and D) could be further grouped into subcategories based on

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 Online discussions held from 16 February to 2 March 2015 (see http://bch.cbd.int/onlineconferences/ahteg_ra.shtml)

similarities and subject matter, first focusing on the road map, followed by the other sections of the Guidance.

11. In moving forward with the suggestions proposed by the AHTEG in its online discussion, the Chair invited the AHTEG Subgroup⁴ to focus on the tasks of (a) further streamlining the comments by identifying which suggestions could be taken on board, and provide a justification for those suggestions that should not be taken on board, and (b) provide concrete text proposals for the suggestions to be taken on board with a justification where the original suggestion was modified.

12. The members of the Subgroup participated in two online discussions to: (a) review the grouping of comments done by the Secretariat and revising it as needed;⁵ (b) identify which general issues highlighted in the testing of the Guidance may be incorporated or improved upon; and (c) identify whether or not any of the topics for additional guidance, prioritized by the previous AHTEG, could also be incorporated during the revision process.⁶

13. In reviewing the grouping of comments, the members of the Subgroup reflected positively on the work done by the Secretariat and made proposals for revisions of the categories under which some of the comments were grouped.

14. In identifying the general issues highlighted in the comments provided during the testing of the Guidance and taking into consideration the suggestions made during the discussions of the AHTEG, the Subgroup identified the general issues emerging from the comments of the testing of the road map and other sections of the Guidance, and subcategorized the comments under sections B and D while indicating which of the issues could be prioritized during the revision of the Guidance. These issues included:

- (a) Defining the audience;
- (b) Defining the scope of application (i.e. for field trial and/or full release of LMO);
- (c) Clarifying when the “points to be considered” are relevant and why;
- (d) Linking the five risk assessment steps;
- (e) Clarifying that risk assessors can draw on knowledge and experience gained from non-LMO risk assessments;
- (f) Improving the language of the Guidance;
- (g) Describing the role of the different actors in a risk assessment and mechanisms of communication;
- (h) Clarifying consistency with the Protocol if needed;
- (i) Providing “real-life” examples of LMO risk assessment and/or effects;
- (j) Elaborating on issues related to human health during environmental risk assessments.

15. Finally, the Subgroup identified the following topics, which had earlier been prioritized by the previous AHTEG, as potential candidates for integration into the road map as additional guidance:

- (a) Living modified fish;

⁴ Meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management, 2-6 June 2012, Bonn, <https://www.cbd.int/doc/meetings/bs/bsrarm-05/official/bsrarm-05-06-en.pdf>

⁵ Online discussions held from 9 to 23 March 2015, http://bch.cbd.int/onlineconferences/RA_ahteg_subgroup/

⁶ Online discussions held from 30 March to 13 April 2015, http://bch.cbd.int/onlineconferences/RA_ahteg_subgroup/

- (b) LMOs that produce pharmaceutical and industrial products;
- (c) Nutritionally altered living modified plants;
- (d) LMOs introduced in centres of origin and genetic diversity;
- (e) LMOs intended for introduction into unmanaged ecosystems;
- (f) LMOs created through use of dsRNA techniques, engineered to produce dsRNA or exposed to dsRNA;
- (g) LMOs containing RNAi;
- (h) LMOs produced through cisgenetics;
- (i) LMOs produced through synthetic biology;
- (j) Integrating human health into the environmental risk assessment;
- (k) Synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs.

16. Subsequently, the outcomes of the work of the subgroup were presented to the participants of the Online Forum to provide feedback on the general issues identified by the Subgroup that may be incorporated or improved in the Guidance.⁷

17. The participants in the Online Forum noted that the general issues identified by the Subgroup reflect the general issues raised through the testing of the Guidance. Some participants also provided more detailed feedback on these general issues for consideration by the subgroup in their future work.

18. In moving forward with its task and taking into account the suggestions made by the Online Forum, the Subgroup undertook a second round of online discussions to streamline the suggestions for changes provided through the testing of the Guidance.⁸

19. In completing its task, the Subgroup reviewed the comments under category D, “Suggestions for substantive changes without a specified location in the Guidance”, to streamline them by identifying the shared features between comments that fell within the same subcategories, as identified under paragraph 14 above, and recommended possible ways forward to address the challenges identified in the testing of the Guidance, as appropriate.

20. Furthermore, the Subgroup reviewed the comments under category E, “Suggestions for substantive changes to specific sections of the Guidance”, to identify which comments which were to be taken on board in moving forward with the review and improvement of the Guidance, while providing justification for those comments that were not taken on board.

21. Following those discussions, the entire AHTEG was invited to take stock of the progress and challenges encountered by the Subgroup.⁹

22. The members of the AHTEG were in agreement with the approach taken by the Subgroup in addressing the comments from the testing of the Guidance, and expressed support for the continuation of the process put in place in response to decision BS-VII/12. Some suggestions were made with a view to facilitating the work of the Subgroup.

⁷ Online discussion held from 27 April to 11 May 2015, http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml

⁸ Online discussion held from 25 May to 22 June 2015, http://bch.cbd.int/onlineconferences/RA_ahteg_subgroup/

⁹ Online discussion held from 11 to 18 July 2015, http://bch.cbd.int/onlineconferences/ahteg_ra.shtml

23. In moving forward with its task and taking into account the suggestions made by the AHTEG, the Subgroup took part in a third round of online discussions with a view to drafting concrete text proposals to address substantive revisions to the Guidance.¹⁰

24. In that discussion, guided by general issues to be prioritized during the revision of the Guidance, members of the Subgroup drafted concrete text proposals on the basis of the comments provided through the testing of the Guidance which were grouped under category E.

25. Following the completion of the draft revisions by the Subgroup, the Secretariat included in the draft document proposals for changes for comments under category C, “Suggestions for editorial and translational changes”.

26. The resulting document containing all the proposed revisions to the Guidance was reviewed by the Subgroup and has been issued as working document “Draft revised Guidance on Risk Assessment for Living Modified Organisms” (UNEP/CBD/BS/RARM/AHTEG/2015/1/3).¹¹ In addition, a document outlining the action taken towards each comment provided through the testing of the Guidance has been issued as information document “Detailed account on actions taken on individual suggestions from the testing of the Guidance” (UNEP/CBD/BS/RARM/AHTEG/2015/1/INF/1).¹²

¹⁰ Online discussion held in August and September 2015, http://bch.cbd.int/onlineconferences/RA_ahteg_subgroup/

¹¹ <http://www.cbd.int/doc/meetings/bs/bsrarm-ahteg-2015-01/official/bsrarm-ahteg-2015-01-03-en.pdf>

¹² <https://www.cbd.int/doc/meetings/bs/bsrarm-ahteg-2015-01/information/bsrarm-ahteg-2015-01-inf-01-en.xls>