



Convention on Biological Diversity

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AD HOC TECHNICAL EXPERT GROUP ON RISK
ASSESSMENT AND RISK MANAGEMENT UNDER
THE CARTAGENA PROTOCOL ON BIOSAFETY
Brasilia, 16-20 November 2015
Item 2 of the provisional agenda*

ORGANIZATION OF WORK

Annotations to the provisional agenda

INTRODUCTION

1. In its decision BS-VII/12, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) welcomed the results of the testing¹ of the Guidance on Risk Assessment of Living Modified Organisms (hereafter “Guidance”), 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 the same decision, COP-MOP extended the Open-ended Online Expert Forum (Online Forum) on Risk Assessment and Risk Management and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, and expanded the composition of the AHTEG to add one new member from each region.

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: (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 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

* UNEP/CBD/BS/RARM/AHTEG/2015/1.

¹ For details about the process for testing the Guidance, see item 3.2 below.

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 Open-ended 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;

(e) 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.

4. Further, in accordance with the terms of reference of the Online Forum and 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. In advancing the process of achieving the outcomes as contained in decision BS-VII/12, AHTEG will hold its first face-to-face meeting during this intersessional period in Brasilia, from 16 to 20 November 2015.

ITEM 1. OPENING OF THE MEETING

6. The meeting will be opened by Mr. Helmut Gaugitsch, Chair of the AHTEG, at 9 a.m. on 16 November 2015.

7. The opening of the meeting will be followed by welcoming remarks by Mr. Charles Gbedemah, on behalf of Mr. Braulio Dias, Executive Secretary of the Convention on Biological Diversity, and by a representative of the Government of Brazil.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of a Rapporteur

8. Participants will be invited to elect a Rapporteur for the Group.

2.2. Adoption of the agenda

9. Participants will be invited to consider and adopt the provisional agenda for the meeting, as prepared by the Executive Secretary, in consultation with the Chair (UNEP/CBD/BS/RARM/AHTEG/2015/1/1).

2.3. Organization of work

10. The Group will be invited to consider the proposed organization of work as contained in annex I below. It is proposed that the meeting be conducted in plenary, breaking into smaller groups only if needed.

ITEM 3. SUBSTANTIVE ISSUES

11. Under item 3, the Group will have before it the documents made available by the Secretariat prior to the meeting with the view to achieving the expected outcomes outlined in decision BS-VII/12.

12. A list of documents is contained in annex II to assist the Group in its deliberations on substantive items.

3.1. Recapping the results of the testing of the “Guidance on Risk Assessment of Living Modified Organisms”

13. In response to a process set out by COP-MOP in decision BS-VI/12, Parties, other Governments and relevant organizations were invited in June 2013 to test the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House. The testing took place over a period of nine months and ended in March 2014.

14. A total of 56 submissions were made on the results of the testing of the Guidance from 43 Parties, 3 other Governments and 10 organizations. All submissions are available online at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

15. Under this agenda item, the Secretariat will briefly summarize the main trends and outcomes that emerged from the testing of the Guidance.

16. Documents from a previous face-to-face meeting of the AHTEG containing an analysis of the results of the testing (UNEP/CBD/BS/AHTEG-RA&RM/5/2) and suggestions for possible improvements to the Guidance (UNEP/CBD/BS/AHTEG-RA&RM/5/3) will be made available for this meeting as information documents.

3.2. Taking stock of the work done in response to decision BS-VII/12

17. Under this agenda item, the Chair of the AHTEG will provide an overview of the activities and results achieved to date in response to decision BS-VII/12.

18. Following the Chair’s presentation, a member of the AHTEG Subgroup will be invited to summarize the work carried out by the Subgroup during the intersessional period and how the Subgroup arrived at the proposed revisions of the Guidance.

19. In considering this item, the Group will have before it a note prepared by the Secretariat (UNEP/CBD/BS/RARM/AHTEG/2015/1/2) detailing the work done in response to decision BS-VII/12 that is relevant to the mandate of the Group, including its expansion and an overview of the activities carried out remotely through online tools.

3.3. Improving the Guidance on the basis of the comments and suggestions provided through its testing

20. Under this agenda item, the Group will review the draft substantive and editorial changes to the original text of the Guidance, as proposed by the Subgroup and the Secretariat, respectively, vis-à-vis the suggestions provided through the testing of the Guidance and input from the Online Forum.

21. The Group will also consider how to address the comments provided through the testing of the Guidance that are of general nature and overarching, in particular comments that were not yet addressed by the Subgroup, such as possible changes to the structure of the Guidance and the addition of practical examples.

22. In considering this item, the Group will be invited to work on the basis of the background document (UNEP/CBD/BS/RARM/AHTEG/2015/1/3) containing draft revisions to the Guidance as a work in progress. Furthermore, the Group will also have before it an information document

(UNEP/CBD/BS/RARM/AHTEG/2015/1/INF/1) identifying which suggestions from the testing were taken on board in the draft revised Guidance and providing justification for those suggestions that were not taken on board.

3.4. Considering whether and how the topics prioritized by the AHTEG for the development of additional guidance could be incorporated and/or further developed during the revision of the Guidance

23. In its decision BS-VI/12, COP-MOP mandated the AHTEG to consider and recommend to COP-MOP 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 a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes.

24. In response to that decision and in its face-to-face meeting held in 2014, the AHTEG agreed that further development of guidance on additional specific topics of risk assessment was still needed, and, therefore, it recommended that the mandates of the Online Forum and the AHTEG should be extended with revised terms of reference to include the development of further guidance on specific topics of risk assessment. The AHTEG also recommended the development of further guidance on topics identified 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 as shown in annex III below.

25. In accordance with its current terms of reference, which are annexed to decision BS-VII/12, the Online Forum and AHTEG, while revising and improving the Guidance, should attempt 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.

26. In considering this item, the Group will be invited to refer to annex III and to consider whether and how the topics prioritized by the AHTEG can be taken into account during the revision of the Guidance.

27. Furthermore, the Group will have before it an information document containing an overview of the status of the implementation of operational objectives 1.3, 1.4 and 2.2 of the Strategic Plan for the Protocol (UNEP/CBD/BS/AHTEG-RA&RM/5/5), including questions on whether the available training materials and technical guidance on risk assessment and risk management concerning LMOs are sufficient and effective.

3.5. Updating the list of background documents to the Guidance

28. In its decision BS-VI/12, COP-MOP established a mechanism whereby the AHTEG is responsible for regularly updating the list of background documents to the Guidance in a transparent manner. According to this mechanism, the background documents on the list will be revalidated by the Group every five years or as appropriate. Documents not revalidated after this time period will initially be flagged for one year as “possibly outdated” and will be deleted from the list of background materials after an additional year. Furthermore, the Group will submit a report on its activities to the Conference of the Parties serving as the meeting of the Parties to the Protocol at each of its meetings.

29. In its decision BS-VII/12, COP-MOP further elaborated on the mechanism for updating the list of background documents by requesting the Executive Secretary, among other things, to index the background documents for author affiliation, for example, government, academic institutions, non-governmental organizations and business.

30. Under this agenda item, the Chair will provide a brief overview of the work done on the list of background documents linked to the Guidance. The Chair will also propose a way forward for a process to revalidate the background documents, review the indexation for author affiliation and improve the way in which documents are linked to the Guidance.

31. The Group will be invited to consider the Chair's proposal with a view to improving the list of background documents linked to the Guidance and to prepare a report on the revalidation of documents and improvements to the list of background documents for the consideration of COP-MOP at its eighth meeting.

3.6. Developing a plan of work for further improving the Guidance prior to the next meeting of the Group

32. To facilitate the implementation and coordination of its work with a view to improving the Guidance, as per its mandate in decision BS-VII/12 and in collaboration with the Online Forum, the Group will be invited to develop a work plan on the basis of its deliberations on previous substantive issues.

33. The work plan will detail the upcoming activities of the Group and the Online Forum until the next face-to-face meeting of the Group and will include a timeframe and expected outputs. On the basis of the agreed plan of work, the Secretariat will post a tentative calendar of activities in the Online Forum.

ITEM 4. OTHER MATTERS

34. Under this item, the Group may wish to raise and discuss any other matters relevant to its mandate.

ITEM 5. ADOPTION OF THE REPORT OF THE MEETING

35. The Group will be invited to consider and adopt the draft report of its meeting on the basis of a draft to be prepared and submitted by the Rapporteur.

ITEM 6. CLOSURE OF THE MEETING

36. The meeting is expected to close in the evening of Friday, 20 November 2015.

Annex I

**PROVISIONAL PROGRAMME OF WORK FOR THE MEETING OF THE AD HOC
TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT**

Monday, 16 November 2015

9 a.m.	Opening of the meeting (agenda item 1)
Morning	Organizational matters (agenda item 2)
	Substantive issues (agenda item 3)
	Recapping of the results of the testing of the “Guidance on Risk Assessment of Living Modified Organisms” (agenda item 3.1)
	Taking stock of the work done in response to decision BS-VII/12 (agenda item 3.2)
Afternoon	Improving the Guidance on the basis of the comments and suggestions provided through its testing (agenda item 3.3)

Tuesday, 17 November 2015

Morning	Improving the Guidance on the basis of the comments and suggestions provided through its testing (agenda item 3.3) (<i>continued</i>)
Afternoon	<i>Visit to the Biosafety Programme at EMBRAPA (Brazilian Agricultural Research Corporation)</i>

Wednesday, 18 November 2015

Morning	Improving the Guidance on the basis of the comments and suggestions provided through its testing (agenda item 3.3) (<i>continued</i>)
Afternoon	Agenda item 3.3 (<i>continued</i>)

Thursday, 19 November 2015

Morning	Considering whether and how the topics prioritized by the AHTEG for the development of additional guidance could be incorporated and/or further developed during the revision of the Guidance (agenda item 3.4)
Afternoon	Updating the list of background documents to the Guidance (agenda item 3.5)
	Developing a plan of work for further improving the Guidance prior to the next meeting of the Group (agenda item 3.6)

Friday, 20 November 2015

Morning	Developing a plan of work for further improving the Guidance prior to the next meeting of the Group (agenda item 3.6) (<i>continued</i>)
	Other matters (agenda item 4)
Afternoon	Adoption of the report of the meeting (agenda item 5)
	Closure of the meeting (agenda item 6)

*Annex II***LIST OF DOCUMENTS FOR THE MEETING OF THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT****Official documents**

UNEP/CBD/BS/RARM/AHTEG/2015/1/1	Provisional agenda
UNEP/CBD/BS/RARM/AHTEG/2015/1/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/RARM/AHTEG/2015/1/2	Overview of the work done in response to decision BS-VII/12
UNEP/CBD/BS/RARM/AHTEG/2015/1/3	Draft revised Guidance on Risk Assessment of Living Modified Organisms – Work in Progress

Information documents

UNEP/CBD/BS/RARM/AHTEG/2015/1/INF/1	Detailed account on actions taken on individual suggestions from the testing of the Guidance
UNEP/CBD/BS/COP-MOP/6/13/Add.1	Guidance on Risk Assessment of Living Modified Organisms
UNEP/CBD/BS/AHTEG-RA&RM/5/2	Analysis of the results of the testing of the “Guidance on Risk Assessment of Living Modified Organisms”
UNEP/CBD/BS/AHTEG-RA&RM/5/3	Compilation of the suggestions for improvements to the “Guidance on Risk Assessment of Living Modified Organisms”
UNEP/CBD/BS/AHTEG-RA&RM/5/5	Overview of the status of the implementation of operational objectives 1.3, 1.4 and 2.2 of the Strategic Plan for the Protocol

Annex III

**LIST OF TOPICS FOR THE DEVELOPMENT OF FURTHER GUIDANCE ON
SPECIFIC TOPICS OF RISK ASSESSMENT**

1. In its report,¹ the AHTEG recommended the development of further guidance on the following 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:²

- (a) Risk assessment of living modified organisms introduced in centres of origin and genetic diversity;
- (b) Risk assessment of living modified microorganisms and viruses;
- (c) Risk assessment of living modified fish.

2. In addition to the three prioritized topics above, AHTEG also identified the following list of topics for future consideration, if and when appropriate:³

- (a) Risk assessment of living modified animals;
- (b) Risk assessment of LM insects;
- (c) Risk assessment of living modified organisms created through use of dsRNA techniques, engineered to produce dsRNA or exposed to dsRNA;
- (d) Risk assessment of living modified organisms containing RNAi;
- (e) Risk assessment of living modified organisms produced through cisgenetics;
- (f) Risk assessment of living modified organisms that produce pharmaceutical and industrial products;
- (g) Risk assessment of nutritionally altered living modified plant;
- (h) Risk assessment of living modified organisms produced through synthetic biology;
- (i) Risk assessment and management of LMOs intended for introduction into unmanaged ecosystems;
- (j) Co-existence between LMOs and non-LMOs in the context of small scale farming;
- (k) Guidance on integrating human health into the environmental risk assessment;
- (l) Guidance on health impacts of LMOs and herbicides that are part of the technology package that accompanies them;
- (m) Guidance on the synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs.

¹ UNEP/CBD/BS/AHTEG-RA&RM/5/5.

² The topics listed are not ranked in any particular order.

³ The topics listed are not ranked in any particular order and include topics that were originally in documents UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1 and UNEP/CBD/BS/AHTEG-RA&RM/5/5, noting that some topics were removed from the original lists as they are already being addressed in other forums under the Protocol.