



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

Third meeting

Mexico City, 30 May - 3 June 2011

Item 2 of the provisional agenda*

ORGANIZATION OF WORK

Annotations to the provisional agenda

INTRODUCTION

1. At their fourth meeting, the Parties to the Cartagena Protocol on Biosafety, in their decision BS-IV/11, established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management and an open-ended online forum on specific aspects on risk assessment (hereinafter, “the Open-ended Online Forum”)¹ through the Biosafety Clearing-House (BCH) in accordance with the terms of reference annexed to that decision.

2. The Secretariat, with the approval of the Bureau of the fourth Conference of the Parties serving as the meeting of the Parties to the Protocol, established a continuous process, comprising three types of activities: (i) ad hoc online discussion groups; (ii) regional real-time online conferences; and (iii) face-to-face meetings of the AHTEG, to realize the outcomes as established in decision BS-IV/11.

3. A total of eighteen ad hoc online discussion groups and eight regional real-time online conferences under the Open-ended Online Forum and two face-to-face meetings of the AHTEG were held between November 2008 and April 2010. The outcomes of this process are summarized in the note by the Executive Secretary on the subject prepared for the fifth meeting of the Parties (UNEP/CBD/BS/COP-MOP/5/12)² which includes the “Guidance on Risk Assessment of Living Modified Organisms” (hereinafter, “the Guidance”).

* UNEP/CBD/BS/AHTEG-RA&RM/3/1.

¹ Available at http://bch.cbd.int/onlineconferences/forum_RA.shtml.

² Available at <http://www.cbd.int/doc/?meeting=MOP-05>.

4. At their fifth meeting, in decision BS-V/12, the Parties welcomed the Guidance and noted that its first version requires further scientific review and testing to establish its overall utility and applicability to living modified organisms of different taxa introduced into different environments. In this context, the Parties requested the Executive Secretary to: (i) translate the first version of the Guidance into all United Nations languages with a view to enabling a large number of experts to take part in the review process; (ii) coordinate with Parties and other Governments, through their technical and scientific experts, and relevant organizations, a review process of the first version of the Guidance; and (iii) make the comments of the review process available through the Biosafety-Clearing House.

5. The Guidance was translated into all the six official United Nations languages, and a scientific review was carried out by Parties, other Governments and relevant organizations between 4 February and 15 March 2011. A total of 33 submissions were received, of which 18 were from Parties, two from other Governments and 12 from organizations. All submissions received through the scientific review are available in the BCH at http://bch.cbd.int/onlineconferences/guidance_ra/review.shtml.

6. Furthermore, in its decision BS-V/12, the Parties decided to extend the current Open-ended Online Forum and the AHTEG. In the terms of reference annexed to the decision BS-V/12 and reproduced in annex I below, the Open-ended Online Forum and the AHTEG are to work primarily online and the AHTEG is to meet twice face-to-face prior to the sixth meeting of the COP-MOP with the view to achieving the following expected outcomes:

- (a) A revised version of the Guidance;
- (b) A mechanism, including criteria, for future updates of the lists of background materials;
- (c) Further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs by the Parties and taking into account the topics identified in the previous intersessional period.

7. The Parties further requested the Executive Secretary to convene, prior to their sixth meeting: (i) ad hoc discussion groups and real-time online conferences under the Open-ended Online Forum; and (ii) two meetings of the AHTEG. The Executive Secretary was also requested to compile the views and recommendations submitted by participants in the Online Forum for consideration by the Parties.

8. In implementing this request, the Secretariat convened a round of online discussion groups under the Open-ended Online Forum from 28 March 2011 to 18 April 2011 on topics derived from the expected outcomes listed in paragraph 6 above. A total of 160 interventions were posted on the three topics of discussion. All contributions received in these discussion groups are available through the BCH at http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml. A summary of the main outputs of the online discussions is available for consideration by the AHTEG in document UNEP/CBD/BS/AHTEG-RA&RM/3/2.

9. As a continuation of the process to achieving the requests contained in decision BS-V/12, the AHTEG will hold its third face-to-face meeting in Mexico City from 30 May to 3 June 2011.

ITEM 1. OPENING OF THE MEETING

10. The meeting will be opened by Mr. Helmut Gaugitsch, Chair of the AHTEG, at 9 a.m. on 30 May 2011. The opening of the meeting will be followed by welcoming remarks from a representative of the Government of Mexico and remarks by a representative of the Secretariat.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Adoption of the agenda

11. 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/AHTEG-RA&RM/3/1).

2.2. Organization of work

12. The Group will be invited to consider the provisional programme of work as outlined in annex II below. The proposed organization of work provides for the meeting to be conducted in plenary session. However, the Group may consider setting up sub-working groups, as appropriate, to facilitate its work.

ITEM 3. SUBSTANTIVE ISSUES

13. Under item 3, the Group will be invited to revise the first version of the Guidance and assess its overall applicability and utility to living modified organisms across different taxa and receiving environments, with the view to achieving the expected outcomes outlined in decision BS-V/12 and reproduced in paragraph 6 above.

3.1. Revision of the “Guidance on Risk Assessment of Living Modified Organisms”

14. Under agenda item 3.1 and pursuant to paragraph 3 (a) of its terms of reference, the Group will be invited to revise and improve the text of the current version of the Guidance on the basis of the results of the scientific review and interventions made in the Open-ended Online Forum.

15. To assist in the revision process, the AHTEG Chair, in consultation with the AHTEG Bureau and the Secretariat, incorporated the views submitted during the scientific review and online discussions into a Chair’s draft for the revision of the Guidance on Risk Assessment of LMOs (UNEP/CBD/BS/AHTEG-RA&RM/3/3). The Group will be invited to work on the basis of the Chair’s draft.

3.2. Possible mechanisms, including criteria, for future updates of the lists of background materials

16. Under agenda item 3.2 and pursuant to paragraph 3 (b) of the terms of reference of the Group, the Secretariat will make a short presentation on how the common format for submission of records to the Biosafety Information Resources Centre could be updated in order to link its records on risk assessment to specific sections of the Guidance.

17. The Group will be invited to consider criteria for the selection of relevant background documents to be linked to the Guidance and to propose a way forward for the revision of the current list of background materials based on the agreed criteria.

18. The Group will also be invited to consider possible mechanisms for future update of the list of background materials for recommendation to the sixth meeting of the Parties. Possible elements of the mechanism may include “who” is to be responsible for updating and maintaining the list of background materials linked to the Guidance, taking into account the long-term sustainability of any proposed mechanism in order to add new relevant documents and/or exclude documents that are no longer relevant based on the criteria referred to in paragraph 17 above.

3.3. New specific topics of risk assessment for the development of further guidance

19. Under agenda item 3.3 and pursuant to paragraph 3 (c) of its terms of reference, the Group will be invited to select new specific topics of risk assessment and risk management for the development of further guidance on the basis of the topics prioritized by the Open-ended Online Forum and contained in annex IV below.

20. The Group will be invited to consider the way forward by the Group for the development of further guidance on the selected new specific topics.

3.4. Action plan for achieving the expected outcomes

21. With a view to achieving its expected outcomes prior to the sixth meeting of the Parties, under agenda item 3.4, the Group will be invited to develop an action plan detailing how the Group intends to carry out its work primarily online and together with the Open-ended Online Forum, according to decision BS-V/12, in order to:

(a) Finalize the revised version of the Guidance on the basis of the work initiated at the third meeting of the Group, and further testing associated with capacity-building activities and any testing initiated by the AHTEG and organized by the Executive Secretary;

(b) Prepare a recommendation on a mechanism, including criteria, for future updates of the lists of background materials; and

(c) Develop and finalize further guidance on new specific topics of risk assessment.

ITEM 4. OTHER MATTERS

22. Under this item, participants will be invited to raise other matters related to the subject matter of the meeting.

ITEM 5. ADOPTION OF THE MEETING REPORT

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

ITEM 6. CLOSURE OF THE MEETING

24. The meeting is expected to close at 5 p.m. on Friday, 3 June 2011.

*Annex I***TERMS OF REFERENCE FOR THE OPEN-ENDED ONLINE FORUM AND AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT***Methodology*

1. The open-ended online forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall work primarily online to (i) revise and test the first version of the Guidance on the basis of the results of the scientific review process, the testing associated with capacity-building activities and any testing initiated by the Ad Hoc Technical Expert Group and organized by the Executive Secretary, and (ii) assess the overall applicability and utility of the Guidance to living modified organisms across different taxa and receiving environments, with the view to achieving the expected outcomes outlined below;
2. The Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall meet twice face-to-face prior to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

Expected outcomes

3. The open-ended online forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall work together with the view to developing and achieving the following:
 - (a) A revised version of the “Guidance on Risk Assessment of Living Modified Organisms”;
 - (b) A mechanism, including criteria, for future updates of the lists of background materials;
 - (c) Further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs by the Parties and taking into account the topics identified in the previous intersessional period;

Reporting

4. The open-ended online forum and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management shall submit final reports detailing their activities, outcomes and recommendations for consideration by the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

Annex II

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

Monday, 30 May 2011

9 a.m.	Opening of the meeting (agenda item 1)
Morning	Organizational matters (agenda item 2) and Substantive issues (agenda item 3)
Afternoon	Revision of the “Guidance on Risk Assessment of Living Modified Organisms” (agenda item 3.1)

Tuesday, 31 May 2011

Morning	Revision of the “Guidance on Risk Assessment of Living Modified Organisms” (agenda item 3.1) (<i>continued</i>)
Afternoon	Revision of the “Guidance on Risk Assessment of Living Modified Organisms” (agenda item 3.1) (<i>continued</i>)

Wednesday, 1 June 2011

Morning	Possible mechanisms, including criteria, for future updates of the lists of background materials (agenda item 3.2)
Afternoon	Possible mechanisms, including criteria, for future updates of the lists of background materials (agenda item 3.2) (<i>continued</i>)

Thursday, 2 June 2011

Morning	New specific topics of risk assessment for the development of further guidance (agenda item 3.3)
Afternoon	New specific topics of risk assessment for the development of further guidance (agenda item 3.3) (<i>continued</i>)

Friday, 3 June 2011

Morning	Action plan for achieving the expected outcomes (agenda item 3.4)
Afternoon	Other matters (agenda item 4) and Adoption of the meeting report (agenda item 5)
5 p.m.	Closure of the meeting (agenda item 6)

*Annex III***LIST OF DOCUMENTS FOR THE SECOND MEETING OF THE AD HOC TECHNICAL
EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT***Working documents*

UNEP/CBD/BS/AHTEG-RA&RM/3/1	Provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/3/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/3/2	Analysis of the online discussions under the Open-ended Online Expert Forum on Risk Assessment and Risk Management (March-April 2011)
UNEP/CBD/BS/AHTEG-RA&RM/3/3	Chair's draft for a revision of the "Guidance on Risk Assessment of Living Modified Organisms"

Other background documents

UNEP/CBD/BS/AHTEG-RA&RM/1/3	Report of the first meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety
UNEP/CBD/BS/AHTEG-RA&RM/2/5	Final report of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety
UNEP/CBD/BS/COP-MOP/5/12	Risk assessment and risk management (Articles 15 and 16) (note by the Executive Secretary prepared for the fifth meeting of the Parties to the Protocol)

*Annex IV***RESULTS OF THE PRIORITY SETTING OF NEW SPECIFIC TOPICS FOR
THE DEVELOPMENT OF FURTHER GUIDANCE³**

Topic	Score
Post-release monitoring and long-term effects of LMOs released into the environment	32
Risk assessment of living modified trees	27
Risk assessment of living modified fish	23
Risk assessment of living modified microorganisms and viruses	21
Risk assessment and risk management in specific receiving environments	12
Risk assessment of living modified plants for biofuels	11
Environmental risk assessment and monitoring taking into account human health	8
“Co-existence” between LMOs and non-LMOs in the context of small-scale farming	7
Risk assessment living modified organisms for production of pharmaceutical and industrial products	6
Risk assessment of living modified pharmaplants	3
Unintentional transboundary movements	3
Risk assessment of living modified organisms produced through synthetic biology	2
Establishment of criteria for transparency and reproducibility of information	2
Uncertainty analysis	1
Risk assessment of living modified crops	0
Interface between risk assessment and risk management	0
Risk assessment and management of LMOs intended for introduction into unmanaged environments	0

³ Information on the process for setting the priority of new specific topics for the development of further guidance may be found in document UNEP/CBD/BS/AHTEG-RA&RM/3/2.