

**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

Fourth meeting

Montreal, 4 - 8 June 2012

Item 2 of the provisional agenda*

ORGANIZATION OF WORK*Annotations to the provisional agenda***INTRODUCTION**

1. At their fourth meeting, the Parties to the Protocol in their decision BS-IV/11 established: (i) an open-ended online forum (hereafter “Open-ended Online Forum”) on specific aspects on risk assessment through the Biosafety Clearing-House; and (ii) an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management with the objective to develop further guidance on specific aspects of risk assessment and risk management.

2. At its fifth meeting, in decision BS-V/12, the Parties welcomed the document “Guidance on Risk Assessment of Living Modified Organisms” (hereafter “Guidance”) produced through the joint efforts of the two groups and mandated both the AHTEG and the Open-ended Online Forum to work, primarily online 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; and
- (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.

3. The Parties to the Protocol, in decision BS-V/12, also requested the Executive Secretary to convene, prior to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP): (i) ad hoc discussion groups and real-time online conferences under the Open-ended Online Forum, and (ii) two meetings of the AHTEG, as well as to compile the views and recommendations submitted by participants in the Open-ended Online Forum for consideration by the Parties.

* UNEP/CBD/BS/AHTEG-RA&RM/4/1.

4. A summary of the activities held to date during the intersessional period under the Open-ended Online Forum and AHTEG towards achieving the outcomes listed in decision BS-V/12 and paragraph 1 above is attached hereto as annex 1.

5. In finalizing the process of achieving the outcomes as contained in decision BS-V/12, the AHTEG will hold its fourth face-to-face meeting in Montreal, Canada from 4 to 8 June 2012. As mandated in the decision, the Group may also wish, at this final meeting to make recommendations to the Parties at its sixth meeting.

6. The revised “Guidance on Risk Assessment of Living Modified Organisms” and the latest versions of the guidance documents on “Monitoring of Living Modified Organisms Released into the Environment” and “Risk Assessment of Living Modified Trees” will be made available to the AHTEG for its consideration as documents UNEP/CBD/BS/AHTEG-RA&RM/4/2 – 4. A synthesis of the outputs of the Open-ended Online Forum from March 2011 to April 2012, prepared by the Secretariat, will also be made available to the AHTEG for its considerations as document UNEP/CBD/BS/AHTEG-RA&RM/4/5.

ITEM 1. OPENING OF THE MEETING

7. The meeting will be opened by Mr. Helmut Gaugitsch, Chair of the AHTEG, at 9 a.m. on 4 June 2012. The opening of the meeting will be followed by welcoming remarks from the Executive Secretary of the Convention on Biological Diversity.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Adoption of the agenda

8. 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/4/1).

2.2. Organization of work

9. The Group will be invited to consider the proposed organization of work as contained in annex II below. It is proposed that the meeting will be conducted in plenary session.

ITEM 3. SUBSTANTIVE ISSUES

10. 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-V/12 and reproduced in paragraph 2 above.

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

11. Under agenda item 3.1, the Group will be invited to finalize the revised “Guidance on Risk Assessment of Living Modified Organisms” (document UNEP/CBD/BS/AHTEG-RA&RM/4/2) for submission to the Parties at their sixth meeting, taking into account the outputs of the online discussions under the Open-ended Online Forum and the scientific editing by a consultant to improve the readability of the text and user friendliness.

3.2. Mechanism for future updates of the lists of background materials

12. At its third meeting, in discussing possible mechanisms for future updates of the lists of background materials on the basis of input from the online discussion, the Group agreed that the Chair, in consultation with the Bureau and Secretariat, would remain responsible for updating the list of background materials linked to the Guidance for the duration of its mandate. With reference to future updates of the background materials linked to the Guidance after completion of its mandate, the Group recommended that a regionally balanced group of experts (e.g., ten experts, two experts per region), appointed periodically by the Parties (e.g. every four years), would work online to update, rearrange or remove background materials linked to the Guidance.

13. At this meeting, the Secretariat will report to the Group on how the common format for submission of records to the Biosafety Information Resource Centre of the Biosafety-Clearing House (BIRC-BCH) was updated to enable background materials to be linked to specific sections of the Guidance and provide an overview of the responses to a notification inviting Parties, other Governments, relevant organizations and users of the BCH to submit background materials that are relevant to the Guidance.¹

14. The Group will be invited to consider whether there is a need to revise its recommendations to the Parties with regard to future updates of background materials relevant to the Guidance.

3.3. Further guidance on specific topics:

“Monitoring of Living Modified Organisms” and “Risk Assessment of Living Modified Trees”

15. Under this agenda item, members of the Group will be invited to finalize the two new guidance documents (i.e. UNEP/CBD/BS/AHTEG-RA&RM/4/3 and 4) for submission to the Parties at their sixth meeting, taking into account the outputs of the online discussions under the Open-ended Online Forum.

16. The Group will also be invited to consider how these documents could be formatted vis-à-vis the revised “Guidance on Risk Assessment of Living Modified Organisms” for consideration by the Parties at their sixth meeting.

ITEM 4. RECOMMENDATIONS TO THE CONFERENCE OF PARTIES SERVING AS THE MEETING OF PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

17. The Group will be invited to formulate its recommendations including future actions on risk assessment and risk management to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its sixth meeting for its consideration.

18. In its deliberations under this agenda item, the Group may also wish to consider, inter alia, the need for (i) development of additional guidance on specific aspects of risk assessment and risk management of living modified organisms and, possible mechanisms that could be considered for developing any additional guidance; and (ii) future activities related to the “Guidance on Risk Assessment of Living Modified Organisms” such as activities to further develop the capacity of Parties to conduct and review risk assessments.

ITEM 5. OTHER MATTERS

19. Under this item, participants may wish to raise and discuss any other matters relevant to the subject matter of the meeting.

¹ Notification SCBD/BS/CG/MPM/jh/78075 available at <http://www.cbd.int/doc/notifications/2011/ntf-2011-208-birc-en.pdf>.

ITEM 6. ADOPTION OF THE MEETING REPORT

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

ITEM 7. CLOSURE OF THE MEETING

21. The meeting is expected to close on the evening of Friday, 8 June 2012.

Annex I

SUMMARY OF ACTIVITIES HELD UNDER THE OPEN-ENDED ONLINE FORUM AND AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT

1. In order to achieve the outcomes mandated by the Parties in paragraph 3 of the annex to decision BS-V/12, the following activities were carried out:

Outcome (a): A revised version of the “Guidance on Risk Assessment of Living Modified Organisms”

2. In order to assist the work of the Open-ended Online Forum and AHTEG in achieving this outcome, the Executive Secretary was requested, prior to the third meeting of the AHTEG, 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 reviewing 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; (iii) make the comments of the review process available through the Biosafety-Clearing House.

3. In response to these requests, the Guidance was translated into all official United Nations languages and made available to the Parties, other Governments and relevant organizations for their scientific review between 4 February and 15 March 2011. A total of 33 scientific reviews were submitted (18 from Parties, 2 from other Governments and 12 from organizations). The majority of respondent Parties assessed the overall quality of the Guidance between good and very good. The majority of respondent Parties also indicated that the Guidance is consistent with the Cartagena Protocol and a useful tool to assist countries in conducting and reviewing risk assessments in a scientifically sound and case-by-case manner, and of living modified organisms introduced into various receiving environments.²

4. As a follow-up in the process, the Secretariat convened a round of ad hoc online discussion groups between 28 March and 11 April 2011 on the revision of the Guidance. A total of 121 interventions were posted under this topic of discussion.

5. On the basis of the scientific review and the online discussions, the AHTEG Chair, in consultation with the Bureau and the Secretariat, prepared a draft text. The Chair’s draft was sent to all AHTEG members in preparation for their third meeting, which took place in Mexico City from 30 May to 3 June 2011.³

6. At its third meeting, the AHTEG discussed the Chair’s draft, and developed a draft revised Guidance that would form the basis for further work in collaboration with the Open-ended Online Forum. The AHTEG also developed an action plan of activities to be carried out prior to the fourth meeting of the AHTEG. With regard to the revision of the Guidance, the action plan contained (i) testing of the draft revised Guidance, (ii) scientific editing by an external consultant, and (iii) online discussion groups and regional real-time conferences with participation of the Open-ended Online Forum and AHTEG.

7. Parties, other Governments and relevant organizations were invited to submit the Guidance to their experts involved in risk assessment of living modified organisms for testing it for its overall utility and applicability. Similarly, the Secretariat also invited experts in the Open-ended Forum and participants to training courses in risk assessment to carry out the testing of the Guidance. A total of 24 Parties, one other Government and three organizations took part in the testing. Thirty-seven participants of capacity-

² The original submissions of the scientific review of the Guidance and an analysis can be found at http://bch.cbd.int/onlineconferences/ra_guidance/review.shtml.

³ The report of the meeting is available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736>.

building activities organized by the Secretariat also took part in the testing. The results of the testing indicate that the great majority of Parties consider the Guidance consistent with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III. The great majority of Parties also consider the Guidance a useful tool to assist countries in conducting and reviewing risk assessments of living modified organisms introduced into various receiving environments, in a scientifically sound and case-by-case manner.⁴

8. Three rounds of online discussions were held for the continued revision of the Guidance between July 2011 and January 2012 (i.e. prior, during and following the testing of the Guidance).

9. Following each activity listed in paragraphs 7 and 8 above, the AHTEG Chair, in consultation with the AHTEG Bureau and Secretariat, considered the views and comments provided for the progressive improvement of the revised Guidance.

10. In continuing this process, the Guidance was submitted to an external consultant for editorial improvements. On the basis of the suggestions by the consultant, the AHTEG Chair, in consultation with the AHTEG Bureau and Secretariat, is preparing a new version of the revised Guidance which will be made available for consideration during the Third Series of Regional Real-time Online Conferences and fourth meeting of the AHTEG.

11. The usefulness of the Guidance as a tool to assist countries in performing or reviewing LMO risk assessments, as well as its completeness were discussed during the Third Series of Regional Real-time Online Conferences comprising four regional conferences (Africa; Asia and the Pacific; Latin America and the Caribbean – GRULAC; Western Europe and Others Group and Central and Eastern Europe – WEOG and CEE), held from 11 to 19 April 2012. A total of 29 experts representing 18 Parties to the Protocol took part in the four regional real-time online conferences.⁵

Outcome (b): A mechanism, including criteria, for future updates of the lists of background materials

12. A round of online discussion on this outcome was held under the Open-ended Forum from 11 to 18 April 2011. A total of 19 interventions posted under this topic recommended several possible mechanisms and criteria for future updates of the list of background materials.

13. In discussing this outcome at its third meeting on the basis of input from the online discussion, the AHTEG agreed that the AHTEG Chair in consultation with the AHTEG Bureau and Secretariat would remain responsible for updating the list of background materials linked to the Guidance for the duration of AHTEG mandate.

14. Further, the AHTEG also agreed that the Secretariat would invite all Parties, non-Parties, relevant organizations and users of the BCH to submit background materials that are relevant to the Guidance for the consideration of the AHTEG.

15. Following the update of the BIRC common format to enable background materials to be linked to specific sections of the Guidance, the Secretariat invited Parties, other Governments and relevant organisations to submit, through their technical and scientific experts, as well as registered BCH users to submit to the Secretariat, background materials that are relevant to the Guidance.

⁴ The results of the testing of the Guidance are available through the BCH at http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml.

⁵ The full transcripts of the real-time online conferences are available at http://bch.cbd.int/onlineconferences/realtime_ra.shtml.

16. The online submission of background materials is ongoing through the BCH.⁶

17. With reference to future updates of the background materials linked to the Guidance after completion of its mandate, the AHTEG recommended that a regionally balanced group of experts (e.g., ten experts, two experts per region), appointed periodically by the Parties (e.g. every four years), would work online to update, rearrange or remove background materials linked to the Guidance.

Outcome (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 inter-sessional period

18. An online discussion related to this outcome was carried from 11 to 18 April 2011 under the Open-ended Forum. Participants were invited to indicate, taking into account the needs from Parties, which were the most important topics in order of priority for the development of additional guidance on specific aspects of risk assessment and risk management. The results of the priority setting exercise were published as document UNEP/CBD/BS/AHTEG-RA&RM/3/2.⁷

19. In discussing this outcome, the AHTEG agreed to develop guidance on the first two topics of a list resulting from the priority-setting exercise conducted in the Open-ended Online Forum, namely:

- (a) Monitoring of living modified organisms released into the environment; and
- (b) Risk assessment of living modified trees.

20. At that meeting, the AHTEG also agreed to establish two sub-working groups (SWGs) on the chosen topics and included, in its action plan, a detailed summary of the activities to be followed for the achievement of this outcome.

21. In accordance with its mandate and action plan, the AHTEG SWGs worked closely with the Open-ended Online Forum in order to draw on the additional scientific expertise available in the Forum. Six online discussions were carried out between July 2011 and January 2012 for continuous improvement of the guidance documents “Monitoring of Living Modified Organisms Released into the Environment” and “Risk Assessment of Living Modified Trees”.

22. A face-to-face meeting of the AHTEG SWGs was held in Bonn, Germany, from 13 to 15 February 2012 to advance the work on the two draft guidance documents. The outcomes of that meeting were advance draft versions of the guidance documents.

23. As a follow-up, participants of the Open-ended Online Forum were invited to recommend editorial improvements to these documents during a final round of online discussions held from 27 February to 11 March 2012.

24. On the basis of the suggestions for editorial improvements, the Chairs of the SWGs, in collaboration with the members of the respective SWGs, are preparing revised advance draft documents on the two topics for consideration during the Third Series of Regional Real-time Online Conferences and fourth meeting of the AHTEG.

25. The scientific soundness of the guidance documents “Monitoring of Living Modified Organisms Released into the Environment” and “Risk Assessment of Living Modified Trees” was discussed at the Third Series of Regional Real-time Online Conferences (see paragraph 11 of this annex).

⁶ At <http://bch.cbd.int/managementcentre/edit/resource.shtml>.

⁷ Available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736>.

Annex II

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

Monday, 4 June 2012

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

Tuesday, 5 June 2012

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| Morning | Revised “Guidance on Risk Assessment of Living Modified Organisms” (agenda item 3.1) (<i>continued</i>) |
| Afternoon | Mechanism for future updates of the lists of background materials (agenda item 3.2) |
| | Further guidance on specific topics: “Monitoring of Living Modified Organisms” and “Risk Assessment of Living Modified Trees” (agenda item 3.3) |

Wednesday, 6 June 2012

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| Morning | Further guidance on specific topics: “Monitoring of Living Modified Organisms” and “Risk Assessment of Living Modified Trees” (agenda item 3.3) (<i>continued</i>) |
| Afternoon | Further guidance on specific topics: “Monitoring of Living Modified Organisms” and “Risk Assessment of Living Modified Trees” (agenda item 3.3) (<i>continued</i>) |

Thursday, 7 June 2012

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| Morning | Further guidance on specific topics: “Monitoring of Living Modified Organisms” and “Risk Assessment of Living Modified Trees” (agenda item 3.3) (<i>continued</i>) |
| Afternoon | Recommendations to the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety (agenda item 3.4) |

Friday, 8 June 2012

- | | |
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| Morning | Recommendations to the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety (agenda item 3.4) (<i>continued</i>) |
| Afternoon | Other matters (agenda item 5) |
| | Adoption of the meeting report (agenda item 6) |
| Evening | Closure of the meeting (agenda item 7) |

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

UNEP/CBD/BS/AHTEG-RA&RM/4/1	Provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/4/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/4/2	Guidance on Risk Assessment of Living Modified Organisms (version of 2 April 2012)
UNEP/CBD/BS/AHTEG-RA&RM/4/3	Monitoring of Living Modified Organisms (version of 2 April 2012)
UNEP/CBD/BS/AHTEG-RA&RM/4/4	Risk Assessment of Living Modified Trees (version of 2 April 2012)
UNEP/CBD/BS/AHTEG-RA&RM/4/5	Analysis of the online discussions under the Open-ended Online Expert Forum on Risk Assessment and Risk Management (March 2011 – April 2012)

Other 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/AHTEG-RA&RM/3/4	Report of the third 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/SWG _s /1/2	Report of the Meeting of the Sub-working Groups 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)
