



## 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

First meeting  
Montreal, 20-24 April 2009

### ORGANIZATION OF WORK

#### *Annotations to the provisional agenda*

#### INTRODUCTION

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-IV/11, established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management under the Cartagena Protocol on Biosafety. The AHTEG was mandated to meet twice prior to the fifth meeting of the Parties, in October 2010, within an interval of not less than ten months, and perform the tasks outlined in the annex to decision BS-IV/11 in order to achieve the proposed outcomes. The terms of reference of the Group as decided upon by the Parties are reproduced in annex I below.
2. In the same decision, the Parties to the Protocol also established an Open-ended Online Expert Forum on Risk Assessment and Risk Management through the Biosafety Clearing-House (BCH) with the view to identifying major issues related to specific aspects of risk assessment and risk management specified in the terms of reference for the Ad Hoc Technical Expert Group. The Parties further requested the Executive Secretary to convene ad hoc online discussion groups and at least one real-time online conference per region prior to each of the two meetings of the Ad Hoc Technical Expert Group.
3. To implement the various elements of the decision in a systematic manner, the Secretariat, with the approval of the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol, has made the necessary arrangements for a continuous process comprising: (i) an open-ended online forum; (ii) discussion groups on specific topics; (iii) two series of regional real-time online conferences (one prior to each AHTEG meeting); and (iv) two meetings of the Ad Hoc Technical Expert Group.

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4. Participants in the open-ended online expert forum on risk assessment and risk management were nominated by Parties, other Governments and relevant organizations, on the basis of their expertise on risk assessment and risk management of living modified organisms (LMOs), using the criteria and common format adopted by the Parties to the Protocol for the nomination of biosafety experts to the roster of experts. To date, a total of 192 experts have been registered to the forum.

5. A total of eight ad hoc online discussion groups on specific topics of risk assessment and risk management <sup>1/</sup>, as well as four regional real-time online conferences (Europe, Latin America, Africa and Asia <sup>2/</sup>) have so far been organized with the objective of identifying major issues related to the specific aspects of risk assessment and risk management as defined in the terms of reference for the Ad Hoc Technical Expert Group.

6. An analysis of the main outputs of the open-ended online expert forum will be made available as document UNEP/CBD/BS/AHTEG-RA&RM/1/2.

7. Participants in the Ad Hoc Technical Expert Group were selected in accordance with the consolidated *modus operandi* of the Convention's Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) <sup>3/</sup>, taking into consideration geographical distribution and gender, on the basis of their active participation in the open-ended online expert forum, and with the approval of the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

8. The results of the work of the Ad Hoc Technical Expert Group, which will include the outputs from its two meetings and the related work between the two meetings, will be reported to fifth meeting of the Parties, to be held in October 2010. The results will also be made publicly available through the Biosafety Clearing House.

## **ITEM 1. OPENING OF THE MEETING**

9. The Executive Secretary of the Convention on Biological Diversity will open the meeting at 9:30 a.m. on Monday, 20 April 2009, followed by the introduction of the members of the Ad Hoc Technical Expert Group, as well as the observers present.

## **ITEM 2. ORGANIZATIONAL MATTERS**

### ***2.1. Election of officers***

10. Participants will be invited to elect a Chairperson and Rapporteur for the Group.

### ***2.2. 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 (UNEP/CBD/BS/AHTEG-RA&RM/1/1).

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<sup>1/</sup> The topics and contents of the online discussion groups are available at [http://bch.cbd.int/onlineconferences/discussiongroups\\_ra.shtml](http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml)

<sup>2/</sup> The full transcripts of the regional real-time online conferences are available at [http://bch.cbd.int/onlineconferences/realtime\\_ra.shtml](http://bch.cbd.int/onlineconferences/realtime_ra.shtml) and

<sup>3/</sup> Annex III to decision VIII/10 of the Conference of the Parties, para. 18.

### **2.3. Organization of work**

12. The Group will be invited to consider the proposed organization of work for the meeting contained in annex II below.

13. The Group may also wish to start its work in plenary, and subsequently break into working groups as appropriate.

### **ITEM 3. SUBSTANTIVE ISSUES**

14. Under Item 3, the issues set out in paragraph 1 (d) of terms of reference for the Ad Hoc Technical Expert Group would be considered after an introduction by the Secretariat of a background document setting out the objective of the Group.

15. To assist in its deliberations on each of the substantive items, the Group will be invited to consider the documents listed in annex III to the present document.

#### **3.1. *Development of a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol***

16. In accordance with paragraph 1 (d) (i) of its terms of reference, the AHTEG is to develop a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol and, for each of these steps, provide examples of relevant guidance documents.

17. Under this item, the Group is invited to consider the interventions made during the online discussions on information that may be needed in developing a roadmap/flowchart other than that contained in Methodology and Points to consider of Annex III to the Protocol, as well as guidance materials that are directly applicable to the steps and points to consider listed in paragraphs 8 and 9 of Annex III to the Protocol.

18. The Ad Hoc Technical Expert Group in formulating its deliberations may also wish to take into consideration the task assigned by decision BS-IV/11 to its second meeting on this same issue 4/.

19. In considering this item, the Group will have before them an analysis of the online discussions on this subject contained in the note prepared by the Executive Secretary (UNEP/CBD/BS/AHTEG-RA&RM/1/2), as well as a compilation of views and/or information from Parties, other Governments and relevant organizations (UNEP/CBD/BS/AHTEG-RA&RM/1/INF/1).

#### **3.2. *Development of further guidance material on specific aspects of risk assessment and risk management***

20. Previous meetings organized by the Secretariat, including one Ad Hoc Technical Expert Group and four regional workshops, established the need for further guidance on certain specific aspects of risk assessment and risk management.

21. Under this item, participants will be invited to consider the establishment of modalities for the development of guidance documents on such specific aspects of risk assessment and risk management.

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4/ Paragraphs 1 (e) (i) and (ii) of the annex to decision BS-IV/11.

22. According to paragraph 1 (d) (ii) of its terms of reference, the Ad Hoc Technical Expert Group, at its first meeting, shall prioritize the need for further guidance on specific aspects of risk assessment and define which aspects should be addressed first, taking also into account the need for and relevance of such guidance, and availability of scientific information.

23. The work of the Ad Hoc Technical Expert Group should be undertaken keeping in mind the previously identified need to develop additional guidance on specific aspects of risk assessment including particular types of (i) living modified organisms (for example, fish, invertebrates, trees, pharmacopants and algae); (ii) introduced traits; and (iii) receiving environments, as well as monitoring of the long-term effects of living modified organisms released in the environment.

24. The Ad Hoc Technical Expert Group is also invited to consider the interventions made during the online discussions on order of priority of specific topics of risk assessment and risk management, the availability of scientific information on these topics, and main knowledge gaps.

25. In considering this item, the Group will have before it the following documents:

(a) An analysis of the online discussions on this subject contained in the note prepared by the Executive Secretary (UNEP/CBD/BS/AHTEG-RA&RM/1/2);

(b) The reports of the regional workshops organized by the Secretariat on capacity-building and exchange of experiences on risk assessment and risk management (UNEP/CBD/BS/COP-MOP/4/INF/14, 15, 16 and 17);

(c) The report of a workshop organized by Canada and Norway on Risk Assessment for Emerging Applications of Living Modified Organisms (fish, trees, pharmacrops and viruses), which was held in Montreal from 4 to 6 June 2007 (UNEP/CBD/BS/COP-MOP/4/INF/13);

(d) A compilation of views and/or information from Parties, other Governments and relevant organizations in preparation for this AHTEG (UNEP/CBD/BS/AHTEG-RA&RM/1/INF/1); and

(e) A list of guidance materials available in the Biosafety Information Resource Centre of the Biosafety Clearing House (UNEP/CBD/BS/AHTEG-RA&RM/1/INF/2).

**3.3. *Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the “roadmap”***

26. The work of the Ad Hoc Technical Expert Group, which will continue until the fifth meeting of the Parties to the Protocol, will be guided by a detailed action plan on how to accomplish the tasks assigned to the Group by the Parties.

27. In this regard, the terms of reference for the Ad Hoc Technical Expert Group specify that, at its first meeting, the Group shall define an action plan to produce, prior to the second meeting of the Group, modalities for the development of guidance documents on the specific aspects that were identified as priorities and for testing of the roadmap.

28. The action plan should include the details of a process for monitoring and reviewing the progress in each of the issues dealt by the Group and will be reviewed at the second meeting of the Ad Hoc Technical Expert Group to ensure that the terms and procedures established in its first meeting were followed.

29. The Group is invited to identify strategies to accomplish the expected outcomes as set out by the Parties, including activities carried out through electronic means between its two meetings.

30. The Group is also invited to consider the recommendations on the action plan for the development of guidance materials and the roadmap made during the online discussions.

31. The Group may wish to consider the availability of experts who have expressed their willingness to cooperate in its work on the development of guidance materials and the roadmap between its two meetings.

32. In considering this item, the Group will have before them the analysis of the online discussions on this subject contained in the note prepared by the Executive Secretary (UNEP/CBD/BS/AHTEG-RA&RM/1/2), as well as a compilation of views and/or information from Parties, other Governments and relevant organizations in preparation for the current meeting (UNEP/CBD/BS/AHTEG-RA&RM/1/INF/1).

#### **ITEM 4. ADOPTION OF THE REPORT**

33. The Ad Hoc Technical Expert Group will be invited to consider and adopt its progress report, on the basis of a draft to be presented by the Rapporteur with the support of the Secretariat.

34. The progress report shall contain a detailed summary of the terms and procedures for reviewing the modalities for the development of guidance documents to be followed prior to the second meeting of the Group.

#### **ITEM 5. OTHER MATTERS**

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

#### **ITEM 6. CLOSURE OF THE MEETING**

36. It is expected that the meeting will be closed at 5 p.m. on Friday, 24 April 2009.

*Annex I*

**TERMS OF REFERENCE FOR THE AD HOC TECHNICAL EXPERT GROUP ON RISK  
ASSESSMENT AND RISK MANAGEMENT 5/**

1. The Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management shall:

(a) Include experts selected on the basis of their expertise on the issues relevant for the mandate of the Group, based on a standardized common format for submission of CVs from experts nominated by Parties, respecting geographical representation, in accordance with the consolidated *modus operandi* of the SBSTTA of the Convention on Biological Diversity (decision VIII/10 of the Conference of the Parties, annex III);

(b) Include observers in accordance with the rules of procedure for meetings of the Conference of the Parties serving as the meeting of the Parties to the Protocol;

(c) Meet twice, pending availability of funds, with an interval of not less than ten months between meetings and prior to the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, and perform necessary tasks between the two meetings to achieve the proposed outcomes outlined herein;

(d) During the first meeting, the Group shall:

(i) Develop a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol and, for each of these steps, provide examples of relevant guidance documents;

(ii) Taking into consideration the identified need for further guidance on specific aspects of risk assessment, including particular types of: (i) living modified organisms (for example, fish, invertebrates, trees, pharmaplants and algae); (ii) introduced traits; and (iii) receiving environments, as well as monitoring of the long-term effects of living modified organisms released in the environment, prioritize the need for further guidance on specific aspects of risk assessment and define which such aspects should be addressed first, taking also into account the need for and relevance of such guidance, and availability of scientific information;

(iii) Define an action plan to produce, prior to the second meeting of the Group, modalities for development of the guidance documents on the specific aspects that were identified as priorities and for testing of the roadmap. This action plan should include the details of a process for monitoring and reviewing the progress in each of the specific aspects;

(iv) Prepare a progress report containing a detailed summary of the terms and procedures for reviewing the modalities for the development of guidance documents to be followed prior to the second meeting of the Group;

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5/ As contained in the annex to decision BS-IV/11 of the Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Cartagena Protocol on Biosafety.

- (e) During the second meeting, the Group shall:
- (i) Revise and finalize the “roadmap” for the effective use of guidance documents on risk assessment;
  - (ii) Make recommendations to the Secretariat on how to integrate the “roadmap” and tools for retrieval of guidance materials available in the Biosafety Information Resources Centre of the Biosafety Clearing-House that are relevant at the different stages of risk assessment;
  - (iii) Review the action plan referred to in subparagraph 1 (d) (iii) of this annex on specific aspects of risk assessment and risk management developed in accordance with the terms and procedures established in the first meeting of the Group;
  - (iv) Consider possible modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health;
  - (v) Prepare a report for consideration by the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol;
2. The deliberations of the Ad Hoc Technical Expert Group shall be based primarily on:
- (a) Submissions received in accordance with paragraph 5 of this decision; 6/
  - (b) The reports of the regional and sub-regional workshops on capacity-building and exchange of experiences on risk assessment and risk management of living modified organisms (UNEP/CBD/BS/COP-MOP/4/INF/14-17) and the report of the Canada-Norway Workshop on Risk Assessment for Emerging Applications of Living Modified Organisms (UNEP/CBD/BS/COP-MOP/4/INF/13);
  - (c) Contribution received through the open-ended online forum, ad hoc discussion groups and real-time online regional conferences;
  - (d) Guidance materials available in the Biosafety Information Resource Centre of the Biosafety Clearing-House;
  - (e) Any other relevant materials made available by the Secretariat.

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6/ Paragraph 5 of decision BS-IV/11 reads as follows:  
“The Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety  
(...)  
“5. *Invites* Parties, other Governments and relevant organizations to submit to the Executive Secretary, prior to the first meeting of the Ad Hoc Technical Expert Group, information relevant to the work of the Group, particularly on existing guidance documents on risk assessment”.

*Annex II*

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

***Monday, 20 April 2009***

- |           |   |
|-----------|---|
| 9.30 a.m. | Opening of the meeting (agenda item 1)  |
| Morning   | Organizational matters (agenda item 2) and Substantive issues (agenda item 3)   |
| Afternoon | Development of a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol (agenda item 3.1) |

***Tuesday, 21 April 2009***

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| Morning   | Development of a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol (agenda item 3.1) ( <i>continued</i> ) |
| Afternoon | Development of a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol (agenda item 3.1) ( <i>continued</i> ) |

***Wednesday, 22 April 2009***

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|-----------|---|
| Morning   | Development of further guidance materials on specific aspects of risk assessment and risk management (agenda item 3.2)                      |
| Afternoon | Development of further guidance materials on specific aspects of risk assessment and risk management (agenda item 3.2) ( <i>continued</i> ) |

***Thursday, 23 April 2009***

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|-----------|---|
| Morning   | Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the “roadmap” (agenda item 3.3)                      |
| Afternoon | Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the “roadmap” (agenda item 3.3) ( <i>continued</i> ) |

***Friday, 24 April 2009***

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|-----------|--|
| Morning   | Adoption of the report (agenda item 4)   |
| Afternoon | Adoption of the report (agenda item 4) ( <i>continued</i> )<br>Other matters (agenda item 5) |
| 5 p.m.    | Closure of the meeting (agenda item 6)   |



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

UNEP/CBD/BS/AHTEG-RA&RM/1/1	Provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/1/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/1/2	Analysis of the open-ended online expert forum on risk assessment and risk management

*Information and other background documents*

UNEP/CBD/BS/AHTEG-RA&RM/1/INF/1	Compilation of views and/or information in preparation for the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management
UNEP/CBD/BS/AHTEG-RA&RM/1/INF/2	List of guidance materials available in the Biosafety Information Resource Centre of the Biosafety Clearing House
UNEP/CBD/BS/AHTEG-RA&RM/1/INF/3	Transcript of the discussion groups under the open-ended online expert forum on risk assessment and risk management
UNEP/CBD/BS/REGCONF-CB-RA&RM/1/2	Report of the First Regional Real-time Conferences on Risk Assessment and Risk Management: Europe
UNEP/CBD/BS/REGCONF-CB-RA&RM/1/3	Report of the First Regional Real-time Conferences on Risk Assessment and Risk Management: Africa
UNEP/CBD/BS/REGCONF-CB-RA&RM/1/4	Informe sobre la primera conferencia regional en línea en tiempo real sobre la evaluación del riesgo y la gestión de riesgos en el marco del Protocolo de Cartagena sobre Seguridad de la Biotecnología: Latín América
UNEP/CBD/BS/REGCONF-CB-RA&RM/1/5	Report of the First Regional Real-time Conferences on Risk Assessment and Risk Management: Asia
UNEP/CBD/BS/COP-MOP/4/INF/13	Report of the Canada-Norway Expert Workshop on Risk Assessment for Emerging Applications of Living Modified Organisms
UNEP/CBD/BS/COP-MOP/4/INF/14	Report of the African Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms, Addis Ababa, 23-25 August 2007
UNEP/CBD/BS/COP-MOP/4/INF/15	Report of the Central and Eastern Europe Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms, Chisinau, 26-28 November 2007

UNEP/CBD/BS/COP-MOP/4/INF/16

Report of the Latin America and the Caribbean Regional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms, Bridgetown, 10-12 December 2007

UNEP/CBD/BS/COP-MOP/4/INF/17

Report of the Asia Subregional Workshop on Capacity-Building and Exchange of Experiences on Risk Assessment and Risk Management of Living Modified Organisms, Kuala Lumpur, 7-9 April 2008

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