



## 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

Second meeting

Ljubljana, 19-23 April 2010

Item 2 of the provisional agenda\*

### 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, in its 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”)<sup>1</sup> through the Biosafety Clearing-House (BCH) in accordance with the terms of reference annexed to that decision and reproduced in annex I below for ease of reference.

2. The Executive Secretary was requested, in the decision, to convene two meetings of the AHTEG prior to the fifth meeting of the COP-MOP, in October 2010. The Executive Secretary was also requested to convene *ad hoc* discussion groups of the Open-ended Online Forum and at least one real-time online conference per region prior to each of the meetings of the AHTEG.

3. During the first meeting of the AHTEG held in Montreal from 20 to 24 April 2009, the Group considered the need for further guidance on specific aspects of risk assessment and prioritized topics for subsequent development of guidance documents.

4. The Group agreed on the following specific topics and established four sub-working groups (SWG) to focus on each of the topics during the period before the second meeting of the Group:

- (a) Roadmap for risk assessment;
- (b) Risk assessment and risk management of living modified mosquitoes;
- (c) Risk assessment and risk management of living modified crops tolerant to abiotic stress;

and

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\* UNEP/CBD/BS/AHTEG-RA&RM/2/1.

<sup>1</sup> Available at [http://bch.cbd.int/onlineconferences/forum\\_RA.shtml](http://bch.cbd.int/onlineconferences/forum_RA.shtml).

(d) Risk assessment and risk management of living modified organisms with stacked genes or traits.

5. At its first meeting, the Group also produced an action plan 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. The action plan is attached hereto as annex II below.

6. Concurrently to the AHTEG process, online discussion groups and regional real-time online conferences were held under the Open-ended Online Forum to provide further input to the work of the AHTEG SWGs. An analysis of the main outputs of the Open-ended Online Forum (UNEP/CBD/BS/AHTEG-RA&RM/2/2) is available for consideration by the AHTEG.

7. The results of the work of the AHTEG will be included in its final report to the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to be held in Nagoya, Japan, from 11 to 15 October 2010.

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

8. The meeting will be opened by Mr. Helmut Gaugitsch, Chair of the AHTEG, at 9 a.m. on 19 April 2010. The opening of the meeting will be followed by welcoming remarks from a representative of the Government of Slovenia and an opening statement from Mr. Ahmed Djoghla, Executive Secretary of the Convention.

## **ITEM 2. ORGANIZATIONAL MATTERS**

### ***2.1. 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 of the AHTEG (UNEP/CBD/BS/AHTEG-RA&RM/2/1).

### ***2.2. Organization of work***

10. The Group will be invited to consider the proposed organization of work as contained in annex III 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**

11. Under item 3, issues arising from paragraph 1 (e) of the terms of reference for the AHTEG will be considered.

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

### **3.1. Development of guidance on specific aspects of risk assessment**

#### **A. Finalization of the draft guidance documents**

13. Under item 3.1 (a), the Chairs of the AHTEG sub-working groups will be invited to introduce the latest draft versions of the guidance documents developed by the sub-working groups (UNEP/CBD/BS/AHTEG-RA&RM/2/4).

14. In its deliberations on the final draft guidance documents, the Group may wish to consider the documents for adoption and subsequent consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting.

#### **B. Recommendations on a mechanism for integrating the AHTEG guidance documents and tools for retrieval of reference guidance materials in the Biosafety Clearing-House**

15. For its second meeting, the AHTEG, was mandated by the Conference of the Parties serving as the meeting of the Parties to the Protocol to 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.

16. During the Open-ended Online Expert Forum, some participants including AHTEG members, recommended that reference guidance materials be provided through the Biosafety Clearing-House not only for the roadmap, but also for the other documents produced by the AHTEG on specific aspects of risk assessment. It was also recommended that the lists of reference guidance materials may be updated and improved over time.

17. In its attempt to implement the above, the Secretariat with the help of the Chairs of the AHTEG sub-working groups, and taking into account the bibliography recommended by the AHTEG members and participants to the Open-ended Online Forum, created draft pages in the Biosafety Clearing-House containing links to reference guidance materials that are relevant to each of the AHTEG guidance documents.<sup>2</sup>

18. Under agenda item, 3.1 (b), the Group will be invited to consider the current lists of reference materials and mechanisms for future updates and make recommendations for its maintenance and improvement.

### **3.2. Review of the AHTEG action plan**

19. Under agenda item 3.3 and pursuant to paragraph 1 (e) (iii) of its terms of reference, the Group will be invited to assess its action plan in accordance with the terms and procedures established therein, including the timeline for the tasks of the sub-working groups and the monitoring and review plan, in light of the activities performed by the Group as follows:

(a) Four rounds of online discussions within the AHTEG sub-working groups held for further drafting of the guidance documents and testing of the roadmap (May, September, November 2009 and

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<sup>2</sup>

Available at [http://bch.cbd.int/onlineconferences/references\\_ahteg\\_ra.shtml](http://bch.cbd.int/onlineconferences/references_ahteg_ra.shtml) .

January 2010),<sup>3</sup> and followed by one round of on-line discussions among all AHTEG members for further input to the guidance documents (March 2010);

(b) One face-to-face meeting of the sub-working group on the roadmap (12-14 October 2009, The Hague) for testing the draft roadmap;

(c) Two face-to-face meetings (24 April 2009, Montreal, Canada and 12-14 October 2009, The Hague) and two teleconferences (24 July 2009, 7 April 2010) of the AHTEG Bureau;

(d) Progress reports on the work of the sub-working groups (October 2009);

(e) Ad hoc teleconferences between the AHTEG and sub-working group Chairs; and

(f) Development of at least five draft versions for each of the guidance documents which progressively built upon the input and comments provided through activities of the AHTEG and under the Open-ended Forum.

20. The outcome of this review process may be highlighted in the Group's final recommendations and conclusions.

**3.3. *Consideration of 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***

21. In decision BS-IV/11, recalling the provisions of the medium-term programme of work,<sup>4</sup> the Parties requested Parties and invited other Governments and relevant organizations to submit to the Executive Secretary, scientifically sound information on the identification of 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.

22. A synthesis report of the above submissions prepared by the Secretariat (UNEP/CBD/BS/AHTEG-RA&RM/2/2) is available for the consideration of the AHTEG.

23. Pursuant to paragraph 1 (e) (iv) of its terms of reference, the AHTEG will be invited to 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.

24. In its deliberations, the Group may wish to consider the examples of modalities as suggested in the Open-ended Online Forum and make recommendations to the Conference of the Parties serving as the meeting of the Parties to the Protocol.

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<sup>3</sup> The online discussions of the AHTEG sub-working groups alternated with the activities under the Online Forum, namely, two rounds of online discussion groups (June-July and November-December 2009) and the second series of real-time conferences (February 2010).

<sup>4</sup> Decision BS-I/12, paragraph 4 (b) (iii) on 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, and taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

**3.4. *Recommendations of the AHTEG to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting***

25. The Group will be invited to formulate its recommendations and conclusions on risk assessment and risk management to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting including future actions and development on issues relevant to these topics for its consideration.

26. In its deliberations on this agenda item, the Group may also wish to consider, *inter alia*, the need for development of further guidance materials on specific aspects of risk assessment and risk management, including (i) the list of topics identified in its first meeting, previous workshops and the Open-ended Online Forum; as well as (ii) recommendations provided by the Open-ended Online Forum to the Conference of the Parties serving as the meeting of the Parties to the Protocol and submissions by Parties, other Governments and relevant organizations.

**ITEM 4. OTHER MATTERS**

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

**ITEM 5. ADOPTION OF THE FINAL REPORT OF THE AHTEG**

28. 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 6. CLOSURE OF THE MEETING**

29. The meeting is expected to close at 5 p.m. on Friday, 23 April 2010.

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*Annex I*

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

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, 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, 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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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;<sup>6</sup>
  - (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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<sup>6</sup> 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*

**ACTION PLAN**

The AHTEG agreed on the following 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.

*Composition of the sub-working groups and Bureau*

**Sub-working group on the roadmap for risk assessment**

*Chair:* Hans Bergmans.

*Core-group (Parties):* Ossama Abdel-kawy, Michael DeShield, Rufus Ebegba, Mahaman Gado Zaki, Angela Lozan, Leticia Pastor Chirino, David Quist, Beatrix Tappeser and Wei Wei.

*Non-Parties and Observers:* David Heron, Paul Keese, Phil McDonald, Piet van der Meer and Thomas Nickson.

**Sub-working group on risk assessment and risk management of living modified crops with resistance or tolerance to abiotic stress**

*Chair:* Kazuo Watanabe.

*Core-group (Parties):* Branka Javornik and Sol Ortiz García.

*Non-Parties and Observers:* David Heron, Paul Keese, Jack Heinemann, Piet van der Meer, Esmeralda Prat and Ricarda Steinbrecher.

**Sub-working group on risk assessment and risk management of living modified mosquitoes**

*Chair:* Eliana Fontes.

*Core-group (Parties):* Michael DeShield, Leticia Pastor Chirino and Vilasini Pillai.

*Observer:* Esmeralda Prat.

**Sub-working group on risk assessment and risk management of living modified organisms with stacked genes or traits**

*Chair:* Beatrix Tappeser.

*Core-group (Parties):* Ossama Abdel-kawy, Kok Gan Chan, Branka Javornik, Sol Ortiz García, Vilasini Pillai, David Quist, Kazuo Watanabe and Jelena Žafran Novak.

*Non-Parties and Observers:* David Heron, Phil McDonald, Jack Heinemann, Thomas Nickson and Ricarda Steinbrecher.

**Bureau**

A Bureau consisting of the Chair and Rapporteur of the AHTEG and the Chairs of the four sub-working groups (SWGs) was formed.

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*Timeline for the tasks of the Sub-working groups on the roadmap and specific topics*

<b>Dates</b>	<b>Sub-working group on roadmap</b>	<b>Sub-working groups on specific topics (abiotic stress, mosquitoes and stacked genes)</b>
<b>April – 8 May 2009</b>	SWG Chair to assign tasks, in consultation with the core-group, with regard to further drafting of the roadmap and call for comments from the sub-working group participants.	
<b>April – end-May 2009</b>		<p>SWGs to gather information and supporting documents on the specific topic identified and submit of background materials to the Secretariat in preparation for the discussion groups under the Open-ended Online Expert Forum on Risk Assessment and Risk Management, including:</p> <ul style="list-style-type: none"> <li>a. Initial outline of the guidance documents;</li> <li>b. Initial bibliography on the topics; and</li> <li>c. Questions to be put forward to the discussion groups in the Open-ended Online Expert Forum on Risk Assessment and Risk Management.</li> </ul>
<b>27 May 2009</b>	Deadline for submission of comments to the SWG chair.	
<b>8 June 2009</b>	<p>Deadline for submission of background materials to the Secretariat in preparation for the discussion groups under the Open-ended Online Expert Forum on Risk Assessment and Risk Management. The background materials may include:</p> <ul style="list-style-type: none"> <li>a. Introduction to the work of the SWG;</li> <li>b. Advance draft of the roadmap; and</li> <li>c. Questions to be put forward to the discussion group.</li> </ul>	
<b>22 June – 6 July 2009</b>	SWG to participate along with other experts of the Online Forum in the discussion groups organized by the Secretariat for the preparation of the roadmap testing and on the specific topics	
<b>7 – 31 July 2009</b>	SWG to develop the operational details of the testing phase by the SWG.	
<b>7 July – end-August 2009</b>		SWGs to incorporate the suggestions made in the discussion groups and prepare a preliminary draft of the guidance documents.
<b>31 July 2009</b>	SWG Chair to submit the operational details of the testing phase to the AHTEG Chair.	

<b>Dates</b>	<b>Sub-working group on roadmap</b>	<b>Sub-working groups on specific topics (abiotic stress, mosquitoes and stacked genes)</b>
<b>31 August</b>	SWG Chairs to submit a progress report to the AHTEG Chair and agree on a date to schedule a teleconference or face-to-face meeting, pending availability of funds, with the view to scheduling an event (e.g. real-time conference) with the whole AHTEG to (i) discuss the progress of the SWGs; (ii) adjust the action plan as needed; and (iii) where not yet in place, review a process for the inclusion of additional experts and follow-up of the work.	
<b>October – November 2009</b>		Second round of discussion groups on the specific topics followed by further drafting based on the contributions made in the discussion groups (tentative).
<b>October 2009</b>	Launching of the testing phase and, pending availability of funds, face-to-face meeting of the SWG.	
<b>Mid January 2010</b>	A final report on the work of the SWGs, including the guidance materials developed, will be submitted by the Chairs of the SWGs to the AHTEG Chair by mid-January 2010 in order to make it available to the regional real-time online conferences organized by the Secretariat.	
<b>February 2010</b>	Participation to the regional real-time online conferences organized by the Secretariat, prior to the second AHTEG meeting.	
<b>April 2010</b>	Second meeting of the AHTEG (tentative date).	

*Note:* Real-time online conferences and online discussion groups may be freely used by the AHTEG or by the Sub-working Groups through the BCH. Opportunities for teleconference or limited face to face meetings may be discussed with the Secretariat.

### ***Monitoring and review plan***

Based on the progress reports of the SWGs, the Bureau will review the action plan, and may adjust the activities and timelines, as appropriate. This is to ensure that the expected outcomes set out in the terms of reference of the AHTEG are met.

*Annex III*

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

***Monday, 19 April 2010***

9 a.m.	Opening of the meeting (agenda item 1)
Morning	Organizational matters (agenda item 2) and Substantive issues (agenda item 3)
Afternoon	Development of guidance on specific aspects of risk assessment and risk management: (a) Finalization of the draft guidance documents (agenda item 3.1 (a))

***Tuesday, 20 April 2010***

Morning	Development of guidance on specific aspects of risk assessment and risk management: (a) Finalization of the draft guidance documents (agenda item 3.1 (a)) ( <i>continued</i> )
Afternoon	Development of guidance on specific aspects of risk assessment and risk management: (b) Recommendations on a mechanism for integrating the AHTEG guidance documents and tools for retrieval of reference guidance materials in the Biosafety Clearing-House (agenda item 3.1 (b))

***Wednesday, 21 April 2010***

Morning	Review of the AHTEG action plan (agenda item 3.2)
Afternoon	Consideration of 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 (agenda item 3.3)

***Thursday, 22 April 2010***

Morning	Recommendations of the AHTEG to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting (agenda item 3.3)
Afternoon	Recommendations of the AHTEG to the Conference of the Parties serving as the meeting of the Parties to the Protocol at its fifth meeting (agenda item 3.3) ( <i>continued</i> )

***Friday, 23 April 2010***

Morning	Other matters (agenda item 4) and Adoption of the final report of the AHTEG (agenda item 5)
Afternoon	Adoption of the final report of the AHTEG (agenda item 5) ( <i>continued</i> )
5:p.m.	Closure of the meeting (agenda item 6)

*Annex IV*

**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/2/1	Provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/2/1/Add.1	Annotations to the provisional agenda
UNEP/CBD/BS/AHTEG-RA&RM/2/2	Submissions on the identification of 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
UNEP/CBD/BS/AHTEG-RA&RM/2/3	Analysis of the open-ended online expert forum on risk assessment and risk management (from June 2009 to February 2010)
UNEP/CBD/BS/AHTEG-RA&RM/2/4	Draft guidance documents on risk assessment

**Information and 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
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Additional relevant information documents are listed in annex III to the annotations to provisional agenda for the first meeting of the AHTEG (UNEP/CBD/BS/AHTEG-RA&RM/1/1/Add.1).<sup>1</sup>

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Available at <http://www.cbd.int/doc/?meeting=BSRARM-01> .