



## Convention on Biological Diversity

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### THIRD SERIES OF REGIONAL REAL-TIME ONLINE CONFERENCES ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY

Latin America and the Caribbean (11 April 2012; 15:00 - 18:00 GMT) (in Spanish)

Western Europe and Others Group and Central and Eastern Europe (12 April 2012; 9:00 - 12:00 GMT) (in English)

Africa (17 April 2012; 10:00 - 13:00 GMT) (in English)

Asia and the Pacific (19 April 2012; 03:00 - 06:00 GMT) (in English)

### 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 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. 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 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.

2. The Executive Secretary was requested, prior to the sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol, to convene (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 online forum for consideration by the Parties.

3. A summary of the activities held to date 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.

4. As a follow-up in this process, the Third Series of Regional Real-time Online Conferences on Risk Assessment and Risk Management, comprising four regional conferences (Latin America and the Caribbean (GRULAC), 11 April; Western Europe and Others Group and Central and Eastern Europe (WEOG and CEE), 12 April; Africa, 17 April; Asia and the Pacific, 19 April 2012), will be held at [http://bch.cbd.int/onlineconferences/realtime\\_ra.shtml](http://bch.cbd.int/onlineconferences/realtime_ra.shtml).

5. The objectives of the real-time online conferences are to address specific issues related to the outcomes (a) and (c)<sup>1</sup> (see paragraph 1 above) for consideration by the AHTEG at its fourth meeting, and to provide recommendations to the Parties at its sixth meeting.<sup>2</sup>

6. The revised “Guidance on Risk Assessment of Living Modified Organisms” and the fifth draft versions of the guidance on “Monitoring of Living Modified Organisms Released into the Environment” and “Risk Assessment of Living Modified Trees” will be made available as background documents for deliberations during the real-time online conferences.

7. Participation is open to those registered in the Open-ended Online Forum.<sup>3</sup> Participants who had been nominated by Parties and other Governments will be automatically registered in their respective regional conferences. Observers representing organisations are invited to indicate one regional real-time online conference in which they may wish to participate.<sup>4</sup>

8. In replicating the first series of real-time conferences, the GRULAC and Africa conferences will be held in Spanish and English respectively due to technical reasons. Experts from English-speaking countries in GRULAC and French-speaking countries in Africa may contact the Secretariat to indicate other regional real-time conferences that they may wish to participate.

9. The conferences will be available to all BCH users wishing to follow the discussions in real-time.

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

10. The conferences will be opened at 3:00 p.m. on 11 April 2012 for GRULAC; 9:00 a.m. on 12 April 2012 for WEOG and CEE; 10:00 a.m. on 17 April 2012 for Africa; and at 3:00 a.m. on 19 April 2012 for Asia and the Pacific (all times are indicated in UTC/GMT).<sup>5</sup>

11. Each conference is expected to last approximately 3 hours.

## **ITEM 2. ORGANIZATIONAL MATTERS**

### *2.1. Adoption of the agenda*

12. The participants to the conferences will be invited to adopt the provisional agenda prepared by the Executive Secretary (document UNEP/CBD/BS/REGCONF-RA&RM/3/1).

13. The third series of regional real-time conferences will be chaired as follows: Ms. Hajara Yusuf Sadiq (Africa), Ms. Vilasini Pillai (Asia and the Pacific), Mr. Helmut Gaugitsch (WEOG and CEE) and Ms. Sol Ortiz García (Latin America and the Caribbean) as approved by the COP-MOP Bureau during the first series of regional real-time online conferences.

<sup>1</sup> Discussions on outcome (b) in paragraph 1 above were conducted under the Open-ended Forum and AHTEG and have already been concluded (see annex 1).

<sup>2</sup> The fourth meeting of the AHTEG is scheduled to take place from 4 to 8 June 2012 in Montreal, Canada. The sixth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP-6) is scheduled to take place from 1 to 5 October 2012 in Hyderabad, India.

<sup>3</sup> Registration to the Open-ended Online Forum are accepted on an ongoing basis. National experts are to be nominated at <http://bch.cbd.int/onlineconferencing/riskAssessment/expertNomination.shtml> (access restricted to National Focal Points), and experts from organisations at [http://bch.cbd.int/onlineconferences/observers\\_ra.shtml](http://bch.cbd.int/onlineconferences/observers_ra.shtml).

<sup>4</sup> The deadline for indicating one of the conferences to be attended is 6 April 2012.

<sup>5</sup> To convert into your local time, please refer to <http://www.timezoneconverter.com/cgi-bin/tzc.tzc>.

## 2.2. *Organization of work*

14. The conferences for Africa, Asia and the Pacific, and WEOG and CEE will be held in English. The conference for Latin America and the Caribbean will be held in Spanish.

15. The conferences will take place online in the form of a “chat room” where participants will be able to post written interventions. A list of all participants will be visible to all who are logged in at the time of the conference. Participants will need to request the floor when they wish to make interventions. Participants will be able to consult with the Secretariat in case of technical difficulties through an online “Helpdesk” or by telephone. Prior to the conferences, participants will have the opportunity to test the conference system.

16. Participants are encouraged to prepare their initial interventions for each of the substantive issues in advance based on the following information.

### ITEM 3. SUBSTANTIVE ISSUES

17. In preparing for the discussions on substantive issues, the participants to the Real-time Conferences are invited to consider the latest versions of the following documents to be made available on 2 April 2012:<sup>6</sup>

- (a) Guidance on Risk Assessment of Living Modified Organisms;
- (b) Monitoring of living modified organisms released into the environment;
- (c) Risk assessment of living modified trees.

18. Participants are also invited to consider the reports of the third meeting of the AHTEG and the meeting of the AHTEG Sub-working Groups.<sup>7</sup>

#### ***3.1. Comments on the guidance documents prepared by the Open-ended Online Expert Group and the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management***

19. Under this agenda item, participants will have before them for their consideration the documents listed in paragraph 17 above and discuss whether these documents:

- (a) Provide useful tools to assist countries in conducting or reviewing risk assessments;
- (b) Are consistent with the provisions for risk assessment and risk management under the Protocol; and
- (c) Are comprehensive or have any missing relevant concept and, should this be the case, how the missing concept(s) could be addressed.

#### ***3.2. Format of the Guidance for consideration of the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety at its sixth meeting***

20. To facilitate the discussion under this agenda item, participants of the real-time conferences will be invited to consider how the documents listed in paragraph 17 above could be formatted to facilitate its consideration by the Parties at their sixth meeting.

21. In particular, participants may consider whether and how the two new guidance documents (i.e. on “monitoring” and “living modified trees”) could be integrated into the revised “Guidance on Risk Assessment of Living Modified Organisms”.

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<sup>6</sup> The documents will be made available at [http://bch.cbd.int/onlineconferences/realtime\\_ra.shtml](http://bch.cbd.int/onlineconferences/realtime_ra.shtml).

<sup>7</sup> Available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736> and <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5028>, respectively.

**3.3. *Consideration of the need for development of further guidance on specific aspects of risk assessment and/or risk management of living modified organisms***

22. Under this agenda item, participants will be invited to consider the need for the development of additional guidance on risk assessment and/or risk management of living modified organisms and, if so, what kind of process could be considered for developing any additional guidance.

**3.4. *Recommendations to the Conference of Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety, including considerations for future activities related to the Guidance on Risk Assessment of Living Modified Organisms***

23. Similar to the practice at the face-to-face AHTEG meetings organized by the Secretariat, the participants in the real-time conferences may wish to provide recommendations to the Parties with regard to risk assessment and risk management, including considerations for future activities related to the “Guidance on Risk Assessment of Living Modified Organisms”.

**ITEM 4. OTHER MATTERS**

24. Under this item, the participants in the real-time conference may wish to consider other matters for discussion in accordance with the rules of procedure.

**ITEM 5. CLOSURE OF THE CONFERENCE**

25. It is expected that the conference will be closed by its Chair after three to a maximum of four hours of discussion. The entire transcripts of the conferences will be made available through the Biosafety Clearing-House.

*Annex***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.<sup>8</sup>

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.<sup>9</sup>

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-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

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<sup>8</sup> 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](http://bch.cbd.int/onlineconferences/ra_guidance/review.shtml).

<sup>9</sup> The report of the meeting is available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736>.

organisms introduced into various receiving environments, in a scientifically sound and case-by-case manner.<sup>10</sup>

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.

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

11. 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.

12. 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.

13. 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.

14. 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.

15. The online submission of background materials is ongoing through the BCH.<sup>11</sup>

16. 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***

17. 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.<sup>12</sup>

18. 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:

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<sup>10</sup> The results of the testing of the Guidance are available through the BCH at [http://bch.cbd.int/onlineconferences/ra\\_guidance/testing.shtml](http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml).

<sup>11</sup> At <http://bch.cbd.int/managementcentre/edit/resource.shtml>.

<sup>12</sup> Available at <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736>.

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

19. 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.

20. 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”.

21. 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.

22. 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.

23. 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.

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