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AD HOC TECHNICAL EXPERT GROUP ON RISK
ASSESSMENT AND RISK MANAGEMENT UNDER
THE CARTAGENA PROTOCOL ON BIOSAFETY

Third meeting

Mexico City, 30 May - 3 June 2011

ANALYSIS OF THE ONLINE DISCUSSIONS UNDER THE OPEN-ENDED ONLINE EXPERT FORUM ON RISK ASSESSMENT AND RISK MANAGEMENT (MARCH - APRIL 2011)

Note by the Executive Secretary

A. Introduction

1. At their fourth meeting, the Parties to the Cartagena Protocol on Biosafety, in their decision BS-IV/11, established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management and an open-ended online forum on specific aspects on risk assessment (hereinafter, “the Open-ended Online Forum”)¹ through the Biosafety Clearing-House (BCH) in accordance with the terms of reference annexed to that decision.
2. The Secretariat, with the approval of the Bureau of the fourth Conference of the Parties serving as the meeting of the Parties to the Protocol, established a continuous process, comprising three types of activities: (i) ad hoc online discussion groups; (ii) regional real-time online conferences; and (iii) face-to-face meetings of the AHTEG, to realize the outcomes as established in decision BS-IV/11.
3. The outcomes of this process are summarized in document UNEP/CBD/BS/COP-MOP/5/12² and include the “Guidance on Risk Assessment of Living Modified Organisms” (hereinafter “the Guidance”).
4. At their fifth meeting, in decision BS-V/12, the Parties welcomed the Guidance and noted that its first version requires further scientific review and testing to establish its overall utility and applicability to living modified organisms (LMOs) of different taxa introduced into different environments. In this context, the Parties requested the Executive Secretary to: (i) translate the first version of the Guidance into all United Nations languages with a view to enabling a large number of experts to take part in the review process; (ii) coordinate with Parties and other Governments, through their technical and scientific experts, and relevant organizations, a review process of the first version of the Guidance; and (iii) make the comments of the review process available through the Biosafety Clearing-House.
5. The Guidance was translated into all six United Nations languages, and a scientific review was carried out by Parties, other Governments and relevant organizations between 4 February and 15 March 2011. A total of 33 submissions were received, of which 18 were from Parties, two from other Governments and 12 from organizations. All submissions received through the scientific review are available in the Biosafety Clearing-House.³

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

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

³ See http://bch.cbd.int/onlineconferences/guidance_ra/review.shtml.

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

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

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

8. In implementing this request, the Secretariat convened a round of online discussion groups under the Open-ended Online Forum from 28 March 2011 to 18 April 2011 on the following topics derived from the expected outcomes listed in paragraph 6 above:

- (a) Revision of the “Guidance on Risk Assessment of Living Modified Organisms”;
- (b) Possible mechanisms, including criteria, for future updates of the lists of background materials;
- (c) New specific topics of risk assessment for the development of further guidance.

9. A total of 160 interventions were posted on the three topics of discussion. All contributions received in these discussion groups are available through the Biosafety Clearing-House.⁴

10. Below is a short analysis of the main outputs of each of these discussion groups for consideration of the AHTEG at its third meeting to be held in Mexico City, Mexico from 30 May to 3 June 2011.

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

11. Under discussion topic (a) referred to in paragraph 8 above, participants in the Open-ended Online Forum and AHTEG were invited to make proposals for revising and improving the current version of the Guidance on the basis of the results of the scientific review process.

12. A total of 121 interventions were made on possible improvements to the guidance.

13. On the basis of the interventions made in this online discussion and the results of the scientific review by Parties, other Governments and relevant organizations, the AHTEG Chair, in consultation with the AHTEG Bureau and Secretariat, prepared a Chair’s draft for the revision of the Guidance (UNEP/CBD/BS/AHTEG-RA&RM/3/3).

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

14. At their fifth meeting, the Parties to the Protocol mandated the Open-ended Online Forum and AHTEG to propose mechanisms for future updates of the lists of background materials linked to the Guidance. The lists of background documents were developed by the Open-ended Online Forum and AHTEG as sources of references that are relevant to the various sections of the Guidance.

⁴ See http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml.

15. With a view to ensuring periodic updates for maintaining the lists in line with the available background materials and current new developments in the relevant subjects, the AHTEG decided to make the list of background materials available through the Biosafety Clearing-House, and make them accessible from the Guidance through web links placed at the end of each section of the Guidance.

16. In the discussion of topic (b) referred to in paragraph 8 above, participants to the Open-ended Online Forum and AHTEG were invited to consider: (i) criteria for the selection of relevant background documents to be linked to the Guidance; and (ii) possible mechanisms for future update of the list of background materials including “who” would be responsible for updating and maintaining the list of background materials, taking into account the long-term sustainability of any proposed mechanism.

17. A total of 19 interventions were made under this topic with recommendations for possible criteria for selection of background materials and mechanisms for future updates to the list.

With regard to possible criteria for selection of background materials,

18. Some participants recommended that some criteria be established to allow only certain types of documents to be included in the lists of background materials (e.g. articles in peer-reviewed journals, acts and reports produced by national biosafety regulatory frameworks, books published by renowned editors/publishers, and internationally recognized guidance materials).

19. Other participants recommended that the criteria for inclusion of background materials be as open and transparent as possible, and also recommended that the background materials be categorized on the basis of their source and content. For example, documents from peer-reviewed publications, risk-assessment reports by regulatory or non-regulatory processes, national or international organizations, industry, non-government organizations, consumer organisations, etc.

With regard to possible mechanisms for future updates,

20. In considering “who” would be responsible for updating the lists of background materials, recommendations included the following possible mechanisms: (i) an AHTEG; (ii) Parties, other Governments and relevant organizations; (iii) national competent authorities; and (iv) a group of experts nominated specifically for this activity by Parties, other Governments and relevant organizations.

21. In considering the periodicity of updates, recommendations were made to add new relevant background documents either on a annually or biennially basis, and to reassess the relevance of existing documents after 5 to 10 years of their addition to the lists with the view of removing outdated publications.

22. A recommendation was made that a search tool be made available to help find documents which are already part of the list of background materials in order to prevent duplications when updates are carried out.

23. In accordance with decision BS-V/12, it was also recommended that the common format for submission of records to the Biosafety Information Resources Centre (BIRC) of the BCH be updated so that relevant background materials can be linked to the specific sections and steps of the Guidance.

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

24. Under discussion topic (c) referred to in paragraph 8 above, the participants of the Open-ended Online Forum and AHTEG were invited to indicate, from the list of topics identified in the previous intersessional period⁵ and taking into account the needs from Parties, which topics are the five most important ones in the order of priority for the development of further guidance.

25. A total of 20 interventions were made under this topic of discussion.

26. The topics identified and prioritized by the participants were given score points from 5 (highest priority) to 1 (lowest priority).

⁵ Available as annex V to document UNEP/CBD/BS/COP-MOP/5/12 (<http://www.cbd.int/doc/?meeting=MOP-05>).

27. According to the participants in the online discussions, the specific topics of risk assessment and risk management with highest priority for further development of guidance are:

- (a) Post-release monitoring and long-term effects of LMOs released into the environment;
- (b) Risk assessment of living modified trees;
- (c) Risk assessment of living modified fish;
- (d) Risk assessment of living modified microorganisms and viruses; and
- (e) Risk assessment and risk management in specific receiving environments.

28. A complete list of specific topics for development of further guidance as prioritized by the participants in the online discussions is annexed hereto.

Annex

**RESULTS OF THE PRIORITY-SETTING OF NEW SPECIFIC TOPICS FOR THE
DEVELOPMENT OF FURTHER GUIDANCE**

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