



Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/AHTEG-RA&RM/5/6

10 June 2014

ORIGINAL: ENGLISH

AD HOC TECHNICAL EXPERT GROUP ON RISK
ASSESSMENT AND RISK MANAGEMENT UNDER
THE CARTAGENA PROTOCOL ON BIOSAFETY
Bonn, 2-6 June 2014

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

INTRODUCTION

1. In its decision BS-VI/12, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) decided to bring to a close the previous Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management and establish a new AHTEG on Risk Assessment and Risk Management. In that same decision, COP-MOP decided to extend the Open-ended Online Forum on Risk Assessment and Risk Management (hereinafter the “Online Forum”).

2. In accordance with the terms of reference annexed to the decision, the Online Forum and AHTEG were mandated to work primarily online on the following issues in the given order of priority:

(a) Provide input, inter alia, to assist the Executive Secretary in his task to structure and focus the process of testing the guidance, and in the analysis of the results gathered from the testing;

(b) Coordinate, in collaboration with the Secretariat, the development of a package that aligns the Guidance on Risk Assessment of Living Modified Organisms (e.g. the Road map) with the training manual “Risk Assessment of Living Modified Organisms” in a coherent and complementary manner, for further consideration of the Parties, with the clear understanding that the Guidance is still being tested;

(c) Consider the development of guidance on new topics of risk assessment and risk management, selected on the basis of the needs of Parties and their experiences and knowledge concerning risk assessment.

3. Through the joint activities above, the Online Forum and AHTEG were expected to develop and achieve the following:

(a) Moderated online discussions relating to the testing of the practicality, usefulness and utility of the Guidance;

(b) A package that aligns the Guidance on Risk Assessment of Living Modified Organisms (e.g. the Roadmap) with the training manual “Risk Assessment of Living Modified Organisms” in a coherent and complementary manner; and

(c) A recommendation on how to proceed with respect to the development of further guidance on specific topics of risk assessment, selected on the basis of the priorities and needs indicated

by the Parties with the view of moving toward the operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes.

4. In responding to the COP-MOP requests, several activities were held in the form of online discussions of the Online Forum and AHTEG between December 2012 and May 2014. In an online discussion held in May 2013, the AHTEG elected Mr. Helmut Gaugitsch as the Chair of the Group.

5. In finalizing the process to achieve the outcomes as contained in decision BS-VI/12, the AHTEG held its face-to-face meeting in Bonn, from 2 to 6 June 2014. The list of participants to the meeting is annexed hereto as annex I.

ITEM 1. OPENING OF THE MEETING

6. The meeting was opened on Monday, 2 June 2014 at 9.00 a.m. by the Chair of the AHTEG.

7. In his opening remarks, Mr. Gaugitsch welcomed the participants to the AHTEG, emphasized the importance of the work ahead of the Group and elaborated on the need for establishing a way forward in implementing the mandate of the Group.

8. Mr. Charles Gbedemah, on behalf of Mr. Braulio Dias, Executive Secretary of the Convention on Biological Diversity, welcomed the AHTEG members, noting the importance of the work ahead and thanked the Government of Germany for providing financial support and hosting the meeting. He also thanked the European Union for its financial support.

9. In his opening statement, the Secretary of State of the Federal Ministry of Food and Agriculture, Mr. Robert Kloos, welcomed the participants in the AHTEG and noted the potential benefits of LMOs in worldwide commercial applications, particularly in the areas of food and agriculture. He also noted the importance of advancing the implementation of the Cartagena Protocol through the development of guidance as tools to assist Parties in conducting risk assessments.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Election of a Rapporteur

10. The Chair invited the Group to elect a Rapporteur. Ms. Francisca Acevedo, from Mexico, was elected as the Rapporteur for the Group.

2.2. Adoption of the agenda

11. The Chair invited the Group to consider and adopt the provisional agenda circulated by the Secretariat as document UNEP/CBD/BS/AHTEG-RA&RM/5/1. The agenda was adopted without amendments.

2.3. Organization of work

12. The Group agreed to proceed on the basis of the organization of work contained in annex II to the annotations to the agenda prepared by the Secretariat in consultation with the AHTEG Chair and circulated as document UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1.

13. The Group further agreed to work in plenary and to break into smaller groups, if needed.

ITEM 3. SUBSTANTIVE ISSUES

14. The Group was invited to deliberate on the substantive issues in accordance with the agenda for the meeting, taking into account the background documents, which were made available by the Secretariat.

15. The Chair, in his introductory remarks, recalled that the AHTEG is a multi-stakeholder consultative process led by the members from the Parties.

3.1. Analysis of the results gathered from the testing of the “Guidance on Risk Assessment of Living Modified Organisms”

16. Under this agenda item, the Chair recalled the terms of reference for the AHTEG, as set out in decision BS-VI/12. This was followed by a brief overview of the relevant activities that took place prior to the face-to-face meeting with the view to responding to the requests made in the decision.

17. The Chair invited Ms. Angela Lozan, moderator of the final round of discussion on this issue under the Online Forum, to provide a summary of the conclusions and recommendations emerging from that discussion, as outlined in section A of annex I to document UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1.

18. This was followed by a presentation by Ms. Manoela Miranda, of the Secretariat of the Convention on Biological Diversity, on the process that led to the development of tools to structure and focus the testing of the Guidance. Ms. Miranda also presented the analysis of the results of the testing, as contained in document UNEP/CBD/BS/AHTEG-RA&RM/5/2, and noted that some Parties are already using the Guidance for the purpose of conducting risk assessments. She noted that a compilation of all comments and suggestions for possible improvements submitted through the testing is available as document UNEP/CBD/BS/AHTEG-RA&RM/5/3, and the original submissions from Parties, other Governments and relevant organizations are available through the Biosafety-Clearing House.¹

19. Following these introductions, the Chair invited the Group to a general discussion on the analysis of the results of the testing and proposals on possible ways forward on the issue.

20. After the initial round of discussions, a majority within the Group concluded that the Guidance, in its current version, is useful, practical and consistent with the Protocol, and takes into account past and present experiences with LMOs. These members were of the view that the Guidance, in its current version, should be endorsed and put to practical use.

21. The Group also took note of the comments provided during the testing of the Guidance, and agreed on the importance to recommend a mechanism for analysing the comments provided with a view to updating the Guidance in a transparent manner. The Group was invited to brainstorm on how such a mechanism could take place.

22. Based on the emerging views of the Group, the Chair presented a proposal for an operational plan with regard to the mechanism for updating the Guidance, as follows:

(a) After the seventh meeting of COP-MOP, the Secretariat will group the original comments provided through the testing of the Guidance and, after the eighth meeting of COP-MOP, the comments provided through the third national reporting system. The grouping will be done in the form of matrices based on the following categories:

(i) Statements that do not trigger changes;

1 Available at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

- (ii) Editorial and translational changes;
 - (iii) Suggestions for changes without a specified location in the Guidance;
 - (iv) Suggestions for changes to specific sections of the Guidance (ordered by line numbers).
- (b) A sub-group of the AHTEG composed of 5 members representing the Parties, taking into account regional and gender balance, will be formed to review the grouping of comments done by the Secretariat and work on the suggestions for changes referred to in (iii) and (iv) above;
- (c) The sub-group will:
- (i) Streamline the comments by identifying which suggestions may be taken onboard, and providing a justification for those suggestions that may not be taken onboard;
 - (ii) Provide concrete text proposals for the suggestions to be taken onboard with a justification where the original suggestion was modified.
- (d) The AHTEG will review all comments and suggestions with a view to presenting an updated version of the Guidance for consideration by COP-MOP at its ninth meeting;
- (e) A progress report will be submitted to the eighth meeting of the COP-MOP.

23. In response to the suggested mechanism outlined above, in particular paragraph 22(b), the Chair noted that the Group could take advantage of the face-to-face setting and invited the Group to establish a sub-group to assist the Executive Secretary in his task to develop matrices that would form the basis for the grouping of the comments outlined in paragraph 22(a).

24. The Group agreed to establish a sub-group, taking into account geographic distribution and gender balance, composed of Ms. Marja Ruohonen-Lehto representing the Western European and Others Group (WEOG), Ms. Francisca Acevedo representing the Latin American and Caribbean Group (GRULAC), Mr. Wei Wei representing the Asia and the Pacific region, Mr. Abisai Mafa representing the Africa region, and Ms. Angela Lozan representing the Central and Eastern Europe (CEE) region.

25. The sub-group met with members of the Secretariat for an initial discussion on the structure of the matrices referred to in paragraph 22(a) above.

3.2. Development of a package that aligns the Guidance on Risk Assessment of Living Modified Organisms (e.g. the Roadmap) with the training manual “Risk Assessment of Living Modified Organisms”

26. Under this agenda item, the Chair recalled the terms of reference for the AHTEG as set out in decision BS-VI/12, as relating to this issue. This was followed by a brief overview of the activities that took place under this agenda item to date with the view to implement the requests made in the decision.

27. The Chair invited Ms. Marja Ruohonen-Lehto, moderator of the final round of discussion on this issue under the Online Forum, to provide a summary of the conclusions and recommendations emerging from that discussion, as outlined in section B of annex I to document UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1.

28. In her remarks Ms. Ruohonen-Lehto stated that the Online Forum recommended that the Guidance and the Training Manual on Risk Assessment of LMOs (hereinafter the “Manual”) remain as independent documents and that, within the Guidance, only the Roadmap would be aligned to the Manual. She noted that the outcome of this exercise, as mandated in decision BS-VI/12, is the draft graphic alignment of the Roadmap and the revised Manual.

29. The Chair invited Ms. Miranda to introduce the most recent version of the draft graphic alignment² to the Group. She noted that the graphic alignment will be further developed into an interactive learning tool as requested in decision BS-V/12.

30. The Group was then invited to consider ways to improve the graphic alignment. During the discussions participants praised the work carried out by the Secretariat in drafting the graphic alignment, and provided a few suggestions for its improvement. These suggestions included adding more visual elements to the graphic alignment and an introductory section to explain the history of its development.

31. The revised version of the draft graphic alignment will be submitted for the consideration of COP-MOP at its seventh meeting.

3.3. Recommendation on how to proceed with respect to the development of further guidance on specific topics of risk assessment

32. Under this agenda item, the Chair recalled the terms of reference for the AHTEG as set out in decision BS-VI/12, as relating to this issue. This was followed by a brief overview of the activities that took place under this agenda item to date with the view to implement the requests made in the decision.

33. The Chair invited Ms. Francisca Acevedo, moderator of the final round of discussion on this issue under the Online Forum, to provide a summary of the conclusions and recommendations emerging from that discussion, as outlined in section C of annex I to document UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1.

34. A presentation on the results of a dedicated survey on the status of the implementation of operational objectives 1.3, 1.4 and 2.2 of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011–2020 was given by Ms. Miranda.³ The results of the survey show that the majority of Parties, in particular developing countries and countries with economies in transition, consider that the existing guidelines do not satisfy their needs on specific topics of risk assessment and risk management of LMOs.

35. The AHTEG was invited by the Chair to discuss a possible way forward for the development of further guidance on specific aspects of risk assessment. This was followed by a discussion to consider the topics for the development of further guidance that were identified in the Online Forum, as well as the priorities and needs indicated by the Parties in the survey referred to in paragraph 34 above.

36. After a discussion on a possible way forward, it was agreed that the Online Forum and the AHTEG would work together, primarily online, with the view to developing further guidance on prioritized specific topics of risk assessment. This work would require the establishment of AHTEG sub-groups, development of draft texts, rounds of revisions, as well as inviting external experts to provide input to assist in different steps of the process, as appropriate, with a view to submitting the developed further guidance for consideration by COP-MOP at its eighth meeting.

2 Available at http://bch.cbd.int/protocol/cpb_art15/training.shtml.

3 Available as document UNEP/CBD/BS/AHTEG-RA&RM/5/5.

37. The AHTEG then prioritized topics for the development of further guidance on the basis of the priorities and needs indicated by the Parties with the view of moving towards achieving the operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes, as follows:⁴

- (a) Risk assessment of living modified organisms introduced in centres of origin and genetic diversity;
- (b) Risk assessment of living modified microorganisms and viruses;
- (c) Risk assessment of living modified fish.

38. In addition to the three prioritized topics above, the AHTEG also identified the following list of topics for future consideration, if and when appropriate:⁵

- (a) Risk assessment of living modified animals;
- (b) Risk assessment of LM insects;
- (c) Risk assessment of living modified organisms created through use of dsRNA techniques, engineered to produce dsRNA or exposed to dsRNA;
- (d) Risk assessment of living modified organisms containing RNAi;
- (e) Risk assessment of living modified organisms produced through cisgenetics;
- (f) Risk assessment of living modified organisms that produce pharmaceutical and industrial products;
- (g) Risk assessment of nutritionally altered living modified plant;
- (h) Risk assessment of living modified organisms produced through synthetic biology;
- (i) Risk assessment and management of LMOs intended for introduction into unmanaged ecosystems;
- (j) Co-existence between LMOs and non-LMOs in the context of small scale farming;
- (k) Guidance on integrating human health into the environmental risk assessment;
- (l) Guidance on health impacts of LMOs and herbicides that are part of the technology package that accompanies them;
- (m) Guidance on the synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs.

3.4. Mechanism for updating the background documents to the “Guidance on Risk Assessment of Living Modified Organisms”

39. Under this agenda item, the Chair of the AHTEG introduced the topic by outlining the experiences and challenges encountered while updating the lists of background documents linked to the Guidance during the last intersessional period in accordance with paragraph 6 of decision BS-VI/12.

40. The Group was then invited to consider possible ways to improve the existing mechanism based on the aforementioned experiences.

⁴ The topics listed are not ranked in any particular order.

⁵ The topics listed are not ranked in any particular order and include topics that were originally in documents UNEP/CBD/BS/AHTEG-RA&RM/5/1/Add.1 and UNEP/CBD/BS/AHTEG-RA&RM/5/5, noting that some topics were removed from the original lists as they are already being addressed by other fora under the Protocol.

41. In the course of its discussion the Group proposed the following as possible improvements to the existing mechanism:

(a) The period for commenting on the background documents will be extended to three weeks and an automatic reminder could be sent after two weeks;

(b) The Secretariat could raise awareness of the background documents linked to the Guidance by, for example, adding information and links in the BCH and inviting experts in the specific topics of the Guidance to submit background documents;

(c) The Secretariat could improve the online-based workflow for background documents in such a way that the reviewing mechanism would only be triggered when changes made to a record affect how a document is linked to the Guidance;

(d) The background documents could be indexed for author affiliation (e.g. government, academic institutions, non-governmental organizations and business).

42. Furthermore, the Group recommended the following criteria to assist in the implementation of the mechanism:

(a) Documents must be of acceptable scientific quality, and relevant to risk assessment or to specific topics of the Guidance;

(b) A document should be referenced only in those sections of the Guidance where it is directly relevant;

(c) Taking into account an approach based on inclusiveness, where there is disagreement among the members of the Group, the Chair has the ultimate responsibility to accept or reject a document.

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

43. Under this agenda item, the Chair invited the AHTEG members to formulate their recommendations, including future actions on risk assessment and risk management, for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

44. The Chair established a stepwise approach in which he invited all AHTEG members to brainstorm on possible recommendations for COP-MOP. The Chair synthesized the views and proposed a set of draft recommendations for further consideration. The members from Parties agreed on the set of recommendations attached hereto as annex II for consideration by the Parties at their seventh meeting.

ITEM 5. OTHER MATTERS

45. The possibility to discuss issues relevant to the work of the AHTEG, as well as risk assessment and risk management in general, during the Special Session on Implementation of the Protocol was discussed. The Chair encouraged members of the AHTEG to share the experience in developing and applying the Guidance during the preparation phase for the Special Session as well as during the meeting of COP-MOP. The Chair noted that the use of the Guidance can contribute to the fulfilment of the obligations under the Protocol.

ITEM 6. ADOPTION OF THE MEETING REPORT

46. The draft report was introduced to the Group by the Rapporteur. The Chair invited the Group to consider the report, which was adopted as amended.

ITEM 7. CLOSURE OF THE MEETING

47. The meeting was closed on Friday, 6 June 2014 at 11:15a.m.

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*Annex II***RECOMMENDATIONS TO THE CONFERENCE OF PARTIES SERVING AS THE MEETING OF PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY**

Having noted that:

(a) The dedicated survey on the status of the implementation of operational objectives 1.3, 1.4 and 2.2 of the Strategic Plan for the Cartagena Protocol on Biosafety for the period 2011–2020, conducted in accordance with decision BS-VI/12, considered, inter alia, existing guidelines on risk assessment and risk management;

(b) The results of the survey show that the majority of Parties, in particular developing countries and countries with economies in transition, consider that the existing guidelines on risk assessment and risk management on living modified organisms (LMOs) do not satisfy their specific needs, and that further guidance is needed;

(c) The results of the survey also show that some Parties among developing countries and countries with economies in transition are currently using and applying the “Guidance on Risk Assessment of LMOs” (hereinafter “the Guidance”) and the “Training Manual on Risk Assessment of LMOs” (hereinafter the “Manual”);

(d) The Guidance has undergone numerous revisions by the Online Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management, scientific review and editing, as well as two testing exercises;

(e) The majority of Parties, in particular developing countries and countries with economies in transition, who participated in the testing of the Guidance concluded that the Guidance is useful, practical and consistent with the Protocol, and takes into account past and present experiences with LMOs;

(f) Many comments were provided during the testing of the Guidance for its further improvement.

1. On the basis of the above, the AHTEG on Risk Assessment and Risk Management recommends the following:

Regarding the “Guidance on Risk Assessment of Living Modified Organisms”

2. Endorsement of the Guidance, and support for its use and application, in its current version, in actual cases of risk assessment and as a tool for capacity building activities in risk assessment.

3. Formulation of questions regarding the use of the Guidance into the format of the third National Report on the implementation of the Protocol including suggestions for possible improvements.

4. Establishment of a mechanism for updating the Guidance as described in paragraph 22 in this report, having taken into account the notion that the Guidance is intended to be a “living document”, with a view to presenting an updated version of the Guidance for consideration by COP-MOP at its ninth meeting.

5. Consideration, at its ninth meeting, of the need for a medium or long-term mechanism for future updates of the Guidance.

Regarding the development of a package aligning the Roadmap and Manual

6. Endorsement of the package that aligns the Guidance and Manual as a useful online tool for, *inter alia*, capacity building in risk assessment.
7. Requesting to the Secretariat, subject to the availability of funds, to conduct capacity building activities in risk assessment using the aligned package to facilitate the use and implementation of the Guidance, in its current version.
8. Inviting the Global Environmental Facility, Parties, other Governments and international organisations to provide funds and in-kind assistance to implement the capacity building activities in risk assessment.

Regarding the development of further guidance on specific aspects of risk assessment

9. Establishment of a process as outlined in paragraphs 36 to 37 of this report for the development of further guidance on the following topics prioritized on the basis of the needs indicated by the Parties with the view of moving toward the operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes:
 - (a) Risk assessment of living modified organisms introduced in centres of origin and genetic diversity;
 - (b) Risk assessment of living modified microorganisms and viruses;
 - (c) Risk assessment of living modified fish.

Mechanism and criteria for updating the background materials linked to the Guidance

10. Requesting the Executive Secretary to implement the improvements to the mechanism for submitting and retrieving background documents linked to the Guidance as outlined in paragraph 41 of this report.
11. Addition of the following criteria to assist in the implementation of the mechanism for regularly updating the list of background materials linked to the Guidance as established in decision BS-VI/12, paragraph 6:
 - (a) Documents must be of an acceptable scientific quality, and relevant to risk assessment or to specific topics of the Guidance;
 - (b) A background document should be referenced only in those sections of the Guidance where it is directly relevant;
 - (c) Taking into account an approach based on inclusiveness, where there is disagreement among the members of the Group, the Chair has the ultimate responsibility to accept or reject a document.

12. The goals of the recommendations in paragraphs 2 to 11 above could be achieved by extending the Open-ended Online Expert Forum on Risk Assessment and Risk Management and the AHTEG on Risk Assessment and Risk Management to work primarily online with revised terms of reference.