CBD

UNEP

Convention on Biological Diversity

Distr.
GENERAL

UNEP/CBD/BS/COP-MOP/7/10/Add.1
11 June 2014

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Seventh meeting
Pyeongchang, Republic of Korea, 29 September-3 October 2014
Item 12 of the provisional agenda*

REPORT OF THE OPEN-ENDED ONLINE EXPERT FORUM ON RISK ASSESSMENT AND RISK MANAGEMENT

Note by the Executive Secretary

I. INTRODUCTION

1. At their fourth meeting, the Parties to the Cartagena Protocol on Biosafety, in 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 of risk assessment (hereinafter, the "Online Forum")[1] through the Biosafety Clearing-House (BCH). The Online Forum was subsequently extended by the COP-MOP, at its fifth and sixth meetings, in decisions BS-V/12 and BS-VI/12, respectively.

2. In accordance with the terms of reference, annexed to decision BS-VI/12, the Online Forum was mandated to work online together with the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management 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 Roadmap) 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;

* UNEP/CBD/BS/COP-MOP/7/1/Add.1.

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

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(c) Consider the development of guidance on new topics of risk assessment and risk management, selected on the basis of the Parties' needs 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. Moreover, according to its terms of reference, the Online Forum shall submit its final report detailing the activities, outcomes and recommendations for consideration by the seventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol.

5. Accordingly, this report was prepared by the Secretariat and summarizes the activities of the Online Forum, its outcomes and recommendations during the inter-sessional period between December 2012 and May 2014 on the three substantive issues listed in paragraph 2 above.

II. SUMMARY OF THE ACTIVITIES AND OUTCOMES OF THE ONLINE FORUM

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

6. In decision BS-VI/12, the COP-MOP set out a process for testing the Guidance on Risk Assessment of LMOs, whereby it:

(a) Encouraged Parties, other Governments and relevant organizations, as appropriate, to translate the Guidance into national languages and to make such translated versions available through the Biosafety Clearing-House for wide dissemination, in order to facilitate the testing of the Guidance at national, regional and subregional levels;

(b) Also encouraged Parties, other Governments and relevant organizations, through their risk assessors and other experts who are actively involved in risk assessment, to test the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House and the open-ended online forum;

(c) Invited Parties, other Governments and relevant organizations to provide financial and technical assistance to developing country Parties and Parties with economies in transition to undertake, as appropriate, the testing activities referred to above.

7. In that same decision, the COP-MOP requested the Executive Secretary to:

(a) Develop appropriate tools to structure and focus the testing of the Guidance;

(b) Gather and analyse, in a transparent manner, feedback provided as a result of testing on the practicality, usefulness and utility of the Guidance, (i) with respect to consistency with the Cartagena Protocol on Biosafety; and (ii) taking into account past and present experiences with living modified organisms; and

(c) Provide a report on possible improvements to the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

8. In the initial response to the COP-MOP requests regarding the testing of the Guidance, both Online Forum and AHTEG held three rounds of online discussions between January 2013 and May 2013, focusing on the development of tools to structure the testing of the Guidance in actual cases of risk assessment as mandated by the COP-MOP decision.

9. On the basis of the input provided by the two expert groups, the Secretariat developed a concept note and a questionnaire which were made available both offline and online, in the six official languages of the United Nations.[2]

10. In June 2013, Parties, other Governments and relevant organizations were invited to test the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House and the Open-Ended Online Forum. The testing was ongoing for 9 months and ended in March 2014.

11. A total of 56 submissions were made on the results of the testing of the Guidance from 43 Parties, 3 other Governments and 10 organizations. Among the submissions from Parties, 28 were from developing countries. All submissions are available online at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

12. A final round of online discussion was held in the Online Forum in April 2014 focusing on the analysis of the results of the testing of the Guidance with a view to providing input to the AHTEG at its face-to-face meeting.[3] The conclusions and recommendations emerging from that discussion are summarized in section III.A below.

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"

13. Seven rounds of online discussions were held by both the Online Forum and AHTEG between December 2012 and December 2013 focusing on how to best align the Guidance (e.g. the Roadmap) and the Manual.

14. During the online discussions, it emerged that the Roadmap and the Manual need to be aligned in such a way that the two documents would remain independent rather than being merged into a single document. Taking into account the fact that the testing of the Guidance, which comprises the Roadmap, was still in progress and the fact that the COP-MOP may wish to establish a process for its update, the alignment between the contents of the Roadmap and the Manual was limited to revising and restructuring the Manual alone while keeping the Roadmap untouched throughout the process.

15. On the basis of the online discussions and the resulting revised Manual, the Secretariat prepared a draft graphic alignment of the Roadmap and the revised Manual.

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2 Available through the Biosafety Clearing-House at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

3 The face-to-face meeting of the AHTEG was held in Bonn, Germany from 2 to 6 June 2014.

16. A final round of online discussion on the development of a package aligning the Roadmap and the Manual was held in April 2014 focusing on improvements to the draft graphic alignment with a view to providing input to the AHTEG at its face-to-face meeting. The conclusions and recommendations emerging from that discussion are summarized in section III.B below.

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

17. An initial round of online discussions was held by both the Online Forum and AHTEG in February 2013 with a view to brainstorming 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]

18. A final round of online discussion on recommendations on how to proceed with respect to the development of further guidance on specific topics of risk assessment was held in February 2014. The conclusions and recommendations emerging from that discussion are summarized in section III.C below.

3.4. Other matters

19. A discussion on "other matters" was held by the Online Forum and AHTEG in May 2014 with a view to offering participants an opportunity to raise and discuss any other issues relevant to the subject matter of their mandate. During that discussion, issues were raised reiterating some of the views and recommendations included in section III of the present report.

III. RECOMMENDATIONS

20. In accordance with paragraph 8(d) of decision BS-VI/12, all online discussions held by the Online Forum were moderated to enhance their efficiency.

21. The following summaries were prepared by the moderators of the final discussions on each of the three substantive issues set out in decision BS-VI/12 and contain the views and recommendations of the Online Forum.

A. Analysis of the results gathered from the testing and possible improvements to the "Guidance on Risk Assessment of Living Modified Organisms"

22. In opening the discussion, the moderator of the discussion recalled decision BS-VI/12 where the COP-MOP requested the Executive Secretary of the CBD to:

> *(a) Develop appropriate tools to structure and focus the testing of the Guidance;*
>
> *(b) Gather and analyse, in a transparent manner, feedback provided as a result of testing on the practicality, usefulness and utility of the Guidance, (i) with respect to consistency with the Cartagena Protocol on Biosafety; and (ii) taking into account past and present experiences with living modified organisms; and*
>
> *(c) Provide a report on possible improvements to the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.*

[4] The Strategic Plan for implementation of the Protocol is available at http://bch.cbd.int/protocol/issues/cpb_stplan.shtml.

23. The moderator reminded the Online Forum of its role in the testing of the Guidance, as mandated by the COP-MOP, to "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".

24. The moderator further noted that 54[5] submissions were received at that time as a result of the testing of the Guidance. Among these, 41 were from Parties (including 26 from developing countries), 3 from other Governments and 10 from organizations. The moderator also stated that the original submissions including comments and suggestions for the improvements of the Guidance were made available by the Secretariat at http://bch.cbd.int/protocol/testing_guidance_RA.shtml.

25. Twenty nine comments were posted during the two-week discussion which focused on the analysis of the results gathered from the testing, aggregation of suggestions and comments to facilitate further discussions and a process for improving the Guidance.

26. In considering the ***number of submissions***, it was noted that a sample size of 54 submissions at the time was adequate to determine the robustness of the results and usefulness and practicality of the Guidance.

27. It was also noted that, while there was a high number of submissions from Parties for such a demanding task, there was a need to take into account that only 25% of the Parties to the Protocol took part in the testing of the Guidance. Nevertheless, it was further noted that the high level of agreement among the different categories of submissions provides strong indication of the emerging trends, which would only be corroborated in the event that further testing takes place.

28. There were diverging views among the participants of the discussion- as to how much emphasis could be placed on either the quantitative or the qualitative feedbacks during the analysis of the results of the testing. It was noted that, as with similar types of surveys, the rating scales (i.e. quantitative feedback) are mandatory and constitute the core of the results while the optional written comments (i.e. qualitative feedback) constitute a means of clarifying issues and understanding some aspects of the quantitative feedback. On the other hand, it was also noted that surveys based on rating scales may not give meaningful insights and that the analysis of the results need to focus primarily on the qualitative feedback.

29. With regard to the ***quantitative feedback***, it was noted that the highest level of agreement that the Guidance is useful was among the Parties that participated in the testing, among which over half were developing countries.

30. It was also noted during the discussions that despite the overall numbers indicating, on average, a high approval of the Guidance, the distinction between "developed" and "developing" countries does not assist in the analysis of the results and in quantifying the usefulness of the Guidance and the Roadmap. There were suggestions that more useful conclusions could be drawn if the analysis were based on a comparison of the responses between countries that conduct risk assessments on a routine basis and countries with less experience in risk assessment.

31. Some participants noted that the quantitative results seem to show a trend that countries that conduct risk assessments on a routine basis do not consider the Guidance and the Roadmap useful, whereas countries with little experience in risk assessments considered the Guidance more useful. It was also noted that the different ratings provided in the quantitative feedback may also result from the different approaches to risk assessment as a whole, rather than a simple reflection of their experience in conducting risk assessments.

[5] Two additional submissions were made after the discussion bringing the total number of submissions to 56.

32. Further, it was suggested that in order to determine if there is a correlation between the level of experience of countries in conducting risk assessments and how they evaluate the Guidance, a full weighted average could be presented, where the averages under each category are weighted in relation to the number of respondents.

33. With regard to the ***qualitative feedback***, there was a general agreement that the results of the testing indicate that the testers engaged in a constructive dialogue which could lead to the improvement of the Guidance, and that there is a needs for a mechanism to be put in place where the comments emanating from the testing can be meaningfully used and taken into account in a transparent manner. Participants also noted that, considering the extensive effort that has gone into the testing process, very detailed analysis needs to be made of the feedback so as to capture all the salient points carefully in the improvement of the Guidance.

34. Some participants were of the view that the analysis prepared by the Secretariat was an over-simplification of the qualitative feedback and may not necessarily capture the details of the multitude of suggestions for improvements. These participants requested that the analysis document produced by the Secretariat for consideration by the COP-MOP needs to include a paragraph which indicates that the sample lists of the suggestions for improvements are incomplete and interpretive of the original comments.

35. A way forward for further improvement of the Guidance on the basis of suggestions submitted as part of the testing exercise was proposed and supported by several participants. The following step-wise process of actions were suggested:

(a) Grouping the original suggestions proposed during the testing of the Guidance into categories, e.g. editorial comments and those related to translation issues, applicable to all sections of the Guidance versus comments on a specific section, general versus specific comments, regarding the methodology of risk assessment process and methodology, etc.

(b) Streamlining and condensing the suggestions above into concrete text proposals for possible improvement of the Guidance, while establishing a mechanism to ensure transparency which would show how each suggestion for improvement was dealt with and explaining why some suggestions were modified or not considered. This could be done in small groups of 2-3 people per section of the Guidance;

(c) Requesting feedback on the concrete text proposals from the online forum through multiple rounds of online discussions, closely moderated, in an attempt to reach consensus on the proposed changes;

(d) Revising the Guidance to introduce the changes where consensus could be reached among the experts representing the Parties;

(e) Adding a question to the national report format on the implementation of the Protocol where Parties could indicate if they are using the Guidance and include any suggestions for possible improvements.

36. Additional remarks on a way forward with regard to improving the Guidance included:

(a) Making use of available experience outside of the Online Forum during the process for improving the Guidance;

(b) Prioritizing the improvement of the Roadmap before improving the sections on specific types of LMOs or traits (Part II) and before embarking on the development of additional guidance documents;

(c) Noting that as with any such evolving documents, when new information becomes available, a process for improvements needs to be in place while noting also the dire needs identified by developing countries for guidance on risk assessment, the mechanism in place for improvement must not however delay the adoption of the Guidance;

(d) Questions to monitor the percentage of Parties adopting and using the Guidance could be added to the next national reporting cycle.

B. 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"

37. In accordance with the terms of reference as outlined in paragraph 1(b) of the annex to decision BS-V/12, and building on earlier online discussions, the moderator recalled the task to develop 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, for further consideration of the Parties, with the clear understanding that the Guidance is still being tested.

38. The moderator further noted that cognizance needed to be taken in the discussions that the text of the Guidance may change, pending a decision of the COP-MOP at its seventh meeting, on the basis of the suggestions for improvements submitted as part of the testing process, but stated that improvements to the graphic component of the alignment between the Manual and the Roadmap (i.e. the "graphic alignment") could be done independently of possible revisions to the Guidance.

39. In opening the discussions, the moderator invited participants to the Online Forum to provide views on the two working documents prepared by the Secretariat: (i) a text alignment between the Manual and the Roadmap, and (ii) a draft "graphic alignment" of the Manual and the Roadmap to be further developed into an online tool that is interactive and more user-friendly.

40. There was a general agreement that the "graphic alignment"[6] of the Manual and the Roadmap is useful, clear, informative and well-designed and could be very useful as an online tool for capacity building. In particular, several participants noted that the pop-up boxes containing examples and figures are useful in that they provide further information on specific topics if needed and contain links to external materials.

41. Some diverging views were expressed regarding the content of the aligned package. On the one hand, some participants expressed their full satisfaction with the alignment as presented. They noted that there is coherence between the Manual and the Roadmap and considered the aligned package as a helpful tool for novice risk assessors. On the other hand, some participants were of the view that, for less experienced risk assessors, the current alignment may be unclear because the Manual and the Roadmap are not always fully coherent.

42. While noting that the alignment is a good model for comparison, some participants found it challenging, at this point in time, to provide further and concrete suggestions to improve the alignment since there may still be considerable changes to the text and structure of the Roadmap as a result of the testing exercise mandated by the Parties.

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[6] Available at http://bch.cbd.int/protocol/cpb_art15/training.shtml.

43. The following recommendations were made for consideration by the AHTEG at its face-to-face meeting and the COP-MOP at its seventh meeting. For ease of reference, the recommendations were grouped in accordance with the various components of the package aligning the Manual and the Roadmap as follows:

Graphic component:

(a) Include more relevant figures and examples, where appropriate, to better illustrate the topics discussed throughout the material and in particular under Module 3 to further explain concepts, such as biological characteristics of a donor organism, specific LMOs, receiving environments, vertical gene flow, management strategies, etc.;

(b) Reduce the amount of text on each slide, possibly by adding further pop-ups and links, especially in the event that the graphic tool is used as a presentation during a training event;

(c) Divide the graphic tool in different modules or chapters to facilitate the direct access to the information of interest to the user;

(d) Offer the final online graphic tool in a format that can be easily downloaded or exported;

Content:

(e) Screen both the Manual and the Roadmap thoroughly for consistency with the Protocol and, as much as possible, use direct and full quotes from the Protocol. For example, the definition of an LMO in slide 8 of the Manual is not consistent with the definition in article 3 of the Protocol;

(f) Ensure consistency between the steps and their points to consider in both the Manual and the Roadmap. For example, Step 1 of the Manual contains resistance management plans, which only appear in Step 5 of the Roadmap;

(g) Improve the alignment between the Manual and the Roadmap, for instance, in slide 45, the two documents are similar at first glance but they emphasize different issues. Also step 1 could be better aligned;

(h) Explain rather than define the terms used in the Manual, as appropriate, by adding a section on "use of terms" similarly to what was done in the Guidance;

(i) Explore ways to show the "points of disagreement" among the members of the AHTEG (especially where there is disagreement about consistency with the Protocol) in the alignment;

Procedure:

(j) Explain in a transparent manner why some suggestions are incorporated in the revised documents while others are not;

(k) Focus on improving the documents that are already available by, for example, either reaching substantial consensus on the substance or explicitly identifying where there are differences of views, rather than focusing on the development of further guidance and aligning the existing documents;

(l) Invite feedback on the usefulness of the aligned package from the target audience, i.e. risk assessors with limited experience.

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

44. Recalling decision BS-VI/12 and the outcome to develop "[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", the moderator invited members of the Online Forum and AHTEG to consider a relevant and feasible mechanism for the development of further guidance on a set of topics identified previously by the AHTEG and Online Forum.

45. While some of the views posted during this discussion focused on the moderator's guiding questions, other views deviated considerably. In spite of latter views, the interventions could be grouped into the following three main categories:

(a) Suggestions for the development of further guidance with identified topics;

(b) Suggestions for the establishment of processes for the development of additional guidance only if the existing Roadmap and guidance on specific LMOs and traits are used effectively and

(c) No support for the development of additional guidance at this point in time under the current online/AHTEG processes.

46. Under category (a) above, participants recommended extending the mandates of the Online Forum and AHTEG and their current working setting, which relies primarily on online discussions to provide input to face-to-face meetings. Participants who supported this view suggested a set of topics for the consideration of the Parties for the development of further guidance. These topics are listed below.

47. Under category (b) above, participants were of the view that it is premature to develop further guidance before analyzing the results of the current testing of the Roadmap and specific guidance on their practicality and usefulness. Some participants suggested that i) the priority for further work should be placed on improving the existing Roadmap and guidance before developing further guidance; ii) if gaps exist in the Guidance, a process should be put in place to define criteria for the identification of topics that are relevant to fill these gaps with additional guidance and to assess how to best develop such guidance.

48. In the event that further guidance is needed, participants supported a two-step approach where: in a first step, experts, who are specialized in the particular topics, would present their views on elements to be considered in the development of the guidance and, in a second step, experts in environmental risk assessment would draft the guidance on the basis of the proposals and questions raised in the first step. It was further noted that since the Open-ended Online forum and AHTEG may not have necessary experts on specific topics of risk assessment, other sources may be tapped. Lastly it was proposed that the benefits of developing further guidance must be weighed against the costs involved in this process.

49. Under category (c) above, some participants recommended that further guidance should not be developed at this time. Instead they propose, for example, that the time and resources could be used to better disseminate and raise awareness of the existing guidance. Challenges faced by the Online Forum and AHTEG in developing guidance due to lack of consensus among participants and expertise in specific topics were also noted.

50. Finally, the moderator noted that there may be multiple interpretations from the participants on the several issues discussed and further recommended that these multiple interpretations be taken into account during the discussions by the AHTEG in its face-to-face meeting in order to achieve a fruitful outcome as was requested by COP-MOP-6.

List of topics identified by participants who support the development of further guidance:

- Risk assessment of living modified organisms introduced in centres of origin and genetic diversity;
- Risk assessment of living modified organisms produced through synthetic biology;
- Risk assessment of living modified microorganisms and viruses;
- Risk assessment of living modified organisms created through use of dsRNA techniques, engineered to produce dsRNA or exposed to dsRNA;
- Risk assessment of living modified organisms produced through cisgenetics;
- Risk assessment of living modified animals, including fish Risk assessment and management of LMOs intended for introduction into unmanaged ecosystems;
- Risk assessment of pharmaceutical and industrial products;
- Risk assessment of nutritionally altered living modified plant;
- Socio-economic considerations in the context of environmental risk assessment and in the context of the decision making process;
- Co-existence between LMOs and non-LMOs in the context of small scale farming;
- Co-existence between LMOs and non-LMOs and channel of LMOs distribution;
- Guidance on integrating human health into the environmental risk assessment;
- Guidance on health impacts of LMOs and herbicides that are part of the technology package that accompanies them;
- Guidance on the synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs.

Note: Some participants in the Online Forum expressed concern over the inclusion of some of the topics above, such as co-existence, socio-economic considerations and human health noting that these topics are outside the scope of environmental risk assessment and are issues that are dealt with under other provisions of the Protocol or by other specialized international organizations.
