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CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY
Eighth meeting
Cancun, Mexico, 4-17 December 2016
Item 11 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. In decision BS-IV/11, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) established the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management and an open-ended online forum on specific aspects of risk assessment (Online Forum)[1] through the Biosafety Clearing-House. The Online Forum and AHTEG were subsequently extended by COP-MOP at its fifth, sixth and seventh meetings.

2. In decision BS-VI/12, COP-MOP commended the progress made on the resulting "Guidance on Risk Assessment of Living Modified Organisms" (Guidance) and encouraged Parties, other Governments and relevant organizations to test the practicality, usefulness and utility of the Guidance in actual cases of risk assessment and share their experiences through the Biosafety Clearing-House. In the same decision, the COP-MOP established a process for testing of the Guidance on actual cases of risk assessment.

3. At its seventh meeting, in decision BS-VII/12, COP-MOP invited Parties, other Governments and relevant organizations to test or use, as appropriate, the Guidance in actual cases of risk assessment and as a tool for capacity-building activities in risk assessment, extended the mandate of the Online Forum and the AHTEG with revised terms of reference and established a mechanism for revising and improving the Guidance on the basis of the feedback provided through the testing process, established in decision BS-VI/12, with a view to having an improved version of the Guidance by its eighth meeting.

*UNEP/CBD/BS/COP-MOP/8/1.

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

4. As per its terms of reference, the Online Forum is submitting its report for consideration by the eighth meeting of COP-MOP. Accordingly, this note contains a summary report of the activities and outcomes of the Online Forum during the intersessional period. This note was prepared by the Secretariat in consultation with the Online Forum.

II. COMPOSITION OF THE ONLINE FORUM

5. In paragraph 8 of decision BS-VII/12, COP-MOP invited Parties, other Governments and relevant organizations to confirm the nominations of their experts who are currently participating in the Online Forum, and requested the Executive Secretary to remove the records of experts whose nominations are not confirmed. Parties, other Governments and relevant organizations were further invited to nominate additional experts to join the Online Forum using the format for the nomination of experts to the Roster of Experts.

6. Accordingly, in October 2014, the Secretariat issued a notification[2] inviting Parties, other Governments and relevant organizations (a) to confirm the nominations of experts from their country or organization, as appropriate, who are currently participating in the Open-ended Online Expert Forum on Risk Assessment and Risk Management, and (b) to nominate additional experts from their country or organization, as appropriate, who are actively involved in risk assessment and risk management, to participate in the Forum.

7. The following table summarizes the changes in the composition of the Online Forum as a result of the actions described in paragraphs 5 to 7 above.

	Parties		**Other Governments**		**Organizations**		**Total**	
	countries	participants	countries	participants	institutions	participants	countries/ institutions	participants
Before*	53	214	6	21	58	82	117	317
After*	53	213	4	19	26	34	83	266

* Before/After the nominations of participants to the Online Forum were confirmed by the respective Parties, other Governments and organizations.

III. SUMMARY OF THE ACTIVITIES OF THE ONLINE FORUM

8. In their terms of reference (decision BS-VII/12, annex), the Online Forum and AHTEG were mandated to revise and improve the Guidance, taking into account the results of the testing process established in decision BS-VI/12, in accordance with the following mechanism:

(a) The Secretariat would group the original comments provided through the testing of the Guidance in the form of a matrix based on the following categories: (i) statements that do not trigger changes; (ii) editorial and translational changes; (iii) suggestions for changes without a specified location in the Guidance; and (iv) suggestions for changes to specific sections of the Guidance (sorted by line numbers);

(b) The AHTEG was then to review the grouping of comments arranged by the Secretariat and work on the suggestions for changes;

(c) The AHTEG was then to streamline the comments by identifying which suggestions were to be taken on board and provide justification for those suggestions that were not taken on board. The

[2] Notification 2014-125, Ref. No. SCBD/BS/MPM/DA/83988, available at https://www.cbd.int/doc/notifications/2014/ntf-2014-125-bs-en.pdf.

AHTEG was also to provide concrete text proposals for the suggestions to be taken on board with a justification where the original suggestion was modified;

(d) The Open-ended Online Forum and the AHTEG would subsequently to review all comments and suggestions with a view to having an improved version of the Guidance for consideration by COP-MOP at its eighth meeting.

9. While revising and improving the Guidance, an attempt was to be made to take into account the topics prioritized by the AHTEG, on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan[3] and its outcomes, for the development of further guidance.

10. Also in decision BS-VII/12, COP-MOP invited Parties to submit (a) information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms (LMOs), and (b) existing guidance on specific topics of risk assessment of LMOs; and agreed to consider, at its eighth meeting, the need for the development of further guidance on topics prioritized on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes.

A. Grouping of comments provided through the testing of the Guidance

11. In implementing the mechanism set out by COP-MOP in decision BS-VII/12 to revise and improve the Guidance, the Secretariat grouped the original comments provided through the testing of the Guidance into five categories: (a) comments that do not trigger changes (i.e. comments related to the testing process as such); (b) overall evaluation of the Guidance; (c) suggestions for editorial and translation changes; (d) suggestions for substantive changes without a specified location in the Guidance; and (e) suggestions for substantive changes to specific sections of the Guidance.

12. Following the grouping exercise, the AHTEG was invited to provide feedback, through an online discussion,[4] on the grouping of the comments done by the Secretariat and to propose practical ways to take the comments on board. In reviewing the grouping of comments, the AHTEG reflected positively on the work done by the Secretariat and made proposals for revisions of the categories under which some of the comments were grouped.

13. The following general issues were identified by the AHTEG and its subgroup[5] as emerging from the comments of the testing of the Guidance:

(a) Defining the audience;

(b) Defining the scope of application (i.e. for field trial and/or full release of LMO);

(c) Clarifying when the “points to be considered” are relevant and why;

(d) Linking the five risk assessment steps;

(e) Clarifying that risk assessors can draw on knowledge and experience gained from non-LMO risk assessments;

(f) Improving the language of the Guidance;

[3] The Strategic Plan for implementation of the Cartagena Protocol on Biosafety (2010-2020) is available at http://bch.cbd.int/protocol/issues/cpb_stplan_txt.shtml.

[4] Online discussions were held from 16 February to 2 March 2015 (see http://bch.cbd.int/onlineconferences/ahteg_ra.shtml).

[5] The Group, at its face-to-face meeting held in Bonn from 2 to 6 June 2014, agreed to establish a subgroup to revise and improve the Guidance on the basis of the comments provided throught the testing (UNEP/CBD/BS/AHTEG-RA&RM/5/6, para. 24).

(g) Describing the role of the different actors in a risk assessment and mechanisms of communication;

(h) Clarifying consistency with the Protocol if needed;

(i) Providing "real-life" examples of LMO risk assessment and/or effects;

(j) Elaborating on issues related to human health during environmental risk assessments.

B. Improvements to the Guidance taking into account the results of the testing process

14. Subsequently, the Online Forum held an online discussion from 27 April to 11 March 2015 to provide feedback on the general issues that could be incorporated or improved in the Guidance.[6] A total of 44 interventions were made in that discussion. There was general agreement among the participants in the Online Forum that the general issues identified by the AHTEG and its subgroup were an appropriate reflection of the issues raised through the testing of the Guidance. Some participants also provided more detailed feedback on those general issues for consideration by the subgroup in future work. A summary of the discussion prepared by the moderator is available in section A of the annex to this report.

15. In moving forward with its task and taking into account the suggestions made by the Online Forum, the AHTEG and its subgroup undertook further rounds of online discussions to streamline the suggestions for changes provided through the testing and make revisions to improve the Guidance.[7]

16. The AHTEG held its first face-to-face meeting in the intersessional period from 16 to 20 November 2015 in Brasilia, where it deliberated on each of the substantive and editorial suggestions for changes to the Guidance as proposed by the subgroup and the Secretariat, respectively, on the basis of the comments from the testing, and discussed online by the AHTEG prior to its face-to-face meeting. The proposed changes based on comments provided through the testing of the Guidance were accepted, modified or rejected, with the necessary justification, as appropriate, taking into account the contribution from the Online Forum. The resulting updated Guidance, with a new title: "Guidance on risk assessment of living modified organisms and monitoring in the context of risk assessment", is contained in annex II to the report of the November 2015 AHTEG meeting and served as the basis for further revisions and improvements.[8]

17. At the same meeting, the AHTEG decided that the following topics could be addressed prior to the eighth meeting of COP-MOP by adding relevant information boxes or sentences under the relevant sections of the Roadmap:

(a) "LMOs introduced in centres of origin and genetic diversity" and "LMOs intended for introduction into unmanaged ecosystems" (the two topics will be addressed together);

(b) "LMOs created through use of dsRNA techniques, engineered to produce dsRNA or exposed to dsRNA" and "LMOs containing RNAi" (the two topics will be addressed together);

(c) "Integrating human health into the environmental risk assessment" taking into account the topics "Nutritionally altered living modified plants" and "LMOs that produce pharmaceutical products", as appropriate;

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[6] The calendar of activities held by the Online Forum and AHTEG during the intersessional period is available at http://bch.cbd.int/onlineconferences/calendar_ra.

[7] Further information on the work carried out by the AHTEG and its subgroup is available in document UNEP/CBD/BS/RARM/AHTEG/2015/1/2 (http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=5545).

[8] The report of the AHTEG meeting held in Brasilia from 16 to 20 November 2015 is available at http://www.cbd.int/doc/meetings/bs/bsrarm-ahteg-2015-01/official/bsrarm-ahteg-2015-01-04-en.pdf.

(d) "Synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs".

18. Following the face-to-face meeting of the AHTEG, the Online Forum held an online discussion from 1 to 15 February 2016 to gather views, relevant guidance and sources of information on the topics identified in paragraph 18 above. A total of 107 interventions were made during the discussion. A summary of the discussion prepared by the moderator is available in section B of the annex to this report.

19. A final round of online discussion focusing on improving the existing Guidance was held by the Online Forum from 25 April to 9 May 2016 with a view to gathering feedback on the further revisions to the Guidance for consideration by the AHTEG at its second face-to-face meeting in the intersessional period (Mexico City, July 2016). A total of 55 interventions were made during that discussion by 31 participants of the Online Forum. A summary of the discussion prepared by the moderator is available in section C of the annex below.[9]

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

20. At its first meeting during the intersessional period (November 2015), in taking into account the topics prioritized for the development of further guidance, the AHTEG decided to recommend to COP-MOP the development of additional guidance on "risk assessment of LM fish" and "risk assessment of LMOs produced through synthetic biology". The AHTEG also decided to prepare outlines on the two topics for consideration by COP-MOP at its eighth meeting in order to facilitate its deliberations on further development of the topics as separate guidance.

21. Following the AHTEG meeting, the Online Forum held online discussions to gather views, information and sources of information or references on the two topics, and to provide feedback on the draft outlines for further guidance, as follows:

(a) Submission of views, relevant guidance and sources of information on risk assessment of LM fish (22 February to 7 March 2016);

(b) Feedback on the draft outline for further guidance on risk assessment of LM fish (11 to 25 April 2016);

(c) Submission of views, relevant guidance and sources of information on risk assessment of organisms developed through synthetic biology (9 to 23 May 2016);

(d) Possible considerations during the environmental risk assessment of LMOs developed or created through approaches commonly referred to as "synthetic biology" (13 to 27 June 2016).

22. The summaries of the final discussions regarding the development of outlines on risk assessment of LM fish and on risk assessment of organisms developed through synthetic biology for consideration of COP-MOP are available in sections D and E, respectively, of the annex below.

[9] Following the last online discussion of the Online Forum, the AHTEG met face-to-face for a second time during the intersessional period from 25 to 29 July 2016 in Mexico City, Mexico. The report of the meeting is available at http://www.cbd.int/doc/meetings/bs/bsrarm-ahteg-2016-01/official/bsrarm-ahteg-2016-01-06-en.pdf and will be made available for consideration by COP-MOP at its eighth meeting as information document UNEP/CBD/BS/COP-MOP/8/INF/3.

Annex

SUMMARY OF ONLINE DISCUSSIONS HELD BY THE ONLINE FORUM (2015-2016)[10]

A. Feedback on the general issues identified by the AHTEG Sub-Group that may be incorporated or improved in Guidance (27 April - 11 March 2015)

Summary of the moderator, Ms. Stacy Scott

Comments related to topics for further risk assessment guidance have been posted - i.e. to combine guidance on LMOs created using dsRNA, LMOs that produce or are exposed to dsRNA, and LMOs that contain RNAi into one topic (from Jack Heinmann); and to develop guidance on LMOs for bioremediation (from Veronica O. Sinohin).

To briefly summarise the comments on the task at hand - to provide "Feedback on the general issues identified by the AHTEG sub-Group that may be incorporated or improved in Guidance" – it is beginning to emerge that participants believe the general issues identified by the sub-Group (see opening message) reflect the general issues raised by the testing of the Guidance.

Some participants have provided more detailed feedback on these general issues, including Franco Teves who commented that a) the LMO's comparator(s) be evaluated in the non-native receiving environment before the LMO, b) the evaluation of likelihood and consequence should be always be undertaken together, in perhaps a semi-quantitative way, when considering risk (semi-quantitative risk expression can indicate whether LMO risk is the same or higher than its comparator), and c) rather than assigning a likelihood of 100% when there is a high level of uncertainty, efforts should be focussed on adequately identifying and characterizing the hazard/cause of hazard. Further, Angela Lozan, Hari Sharma and Galina Mozgova have commented that the five risk assessment steps could be linked using text and graphics (i.e. use a flowchart). Galina also commented that the 'points to be considered' sections could in-text reference real-life examples.

In this forum, feedback on the general issues identified by the sub-Group has been provided, including specific suggestions on how to address these issues.

Additionally, comments related to the list of topics for further risk assessment guidance have been posted, and in some instances, have sparked debate.

Taken together, your efforts in this forum will assist the sub-Group in its next task, "Streamlining which suggestions for changes provided through the testing of the Guidance will be taken onboard during the revision of the Guidance, and providing a justification for each of the suggestions that will not be taken on board" (please seehttps://bch.cbd.int/onlineconferences/calendar_ra/), and will ultimately inform how the general issues with the Guidance will be addressed.

B. Gathering views, relevant guidance and sources of information on topics identified by the AHTEG for inclusion in the existing Guidance (1 - 15 February 2016)

Summary of the moderator, Ms. Francisca Acevedo Gasman

I am very satisfied with our past discussion on gathering views, information and sources of reference on four topics and for that I would like to thank all who have actively participated.

We have a rich and diverse community of very capable experts in our Forum which helped me learn a great deal about the four topics during the two weeks of discussion. It is quite obvious that there are different points of view among us on how to proceed but, in my personal opinion, it is this very diversity

[10] All discussions, including the summaries of the moderators, are available at http://bch.cbd.int/onlineconferences/onlineconferences/forum_ra/discussion.shtml. The summaries by the moderators are presented in the form and language in which they were posted in the online discussion.

that adds value to this type of discussion and that is precisely the greatest strength of such online platforms.

We had much participation in all four topics for which information was solicited and for each of them we have read different viewpoints. In the following lines I will attempt to provide a "flavor" of some of the views shared, without any intention of providing an exhaustive list of the issues that were raised during the discussion.

- Under the topic "*LMOs introduced in centres of origin and genetic diversity*" and "*LMOs intended for introduction into unmanaged ecosystems*" (the two topics will be addressed together), among other issues, we read about how outcrossing and introgression of the transgene into sexually compatible plants could have an impact on wild genetic resources and/or in situ germplasm collections; about the potential impact of LMOs on the domestication processes of wild relatives; the importance of monitoring activities in centres of origin and genetic diversity; and how the introduction of LMOs in centres of origin and genetic diversity would be closely inter-linked with socio-economic considerations, particularly the contribution of farmers and indigenous peoples in such centres of origin and centres of genetic diversity.

On the other hand, we also read that these are issues considered in any ERA process of LM crops for cultivation via protection goals and problem formulation. The particularities of a receiving environment are an intrinsic part of the risk assessment and are already captured by many Elements for Consideration presented in the Roadmap and the inclusion of specific consideration on centres of origin would be redundant.

- On the topic of integrating "*Integrating human health into the environmental risk assessment*" taking into account the topics "*Nutritionally altered living modified plants*" and "*LMOs that produce pharmaceutical products*", as appropriate, we read that when considering human health as the protection goal, the safety assessment of foods derived from LM plants improved for nutritional or health benefits can be conducted according to the Guideline elaborated by the Codex Task Force on Foods derived from Biotechnology. Furthermore, it was noted that it is quite unlikely that nutritionally altered LM plants would pose special considerations for the environment since they are specifically developed for nutritional or health benefits. It was also noted that many pharmaceutical compounds are derived from plants that are not LMOs, and that the potential for a pharmaceutical compound to cause harm in the environment is not related to its use as a pharmaceutical.

On the other hand, we also read that a useful and practical addition to the Guidance would be to focus on the 'how' aspect of integrating human health into the environmental risk assessment. The intention with the inclusion of human health considerations in a more appropriate manner would not be to duplicate a health risk assessment or a safety assessment carried out in accordance with the Codex Principles and Guidelines, but to provide further information that is relevant to the assessment of the LMO and to fill the gaps of the food safety assessment. For example, the effects on human health related to the environmental risk assessment of an LM plant relates to possible immediate and/or delayed effects on human health resulting from potential direct and indirect exposure to the LM plant. Exposure pathways to be assessed would include those arising from the environmental release, such as alterations that may affect pollen in plants, leading to inhalation and contact exposures. In case of detection of potential chimerical ORFs a bioinformatics analysis should be done to establish possible similarity with known toxins or allergens. Moreover, it was noted that in the case of nutritionally altered LM plants and LMOs that produce pharmaceutical substances, potential challenges for traditional comparative risk assessment approaches could be created. Another aspect was the risk that LMOs producing pharmaceuticals may accidentally enter the food supply.

- Concerning the topic "*LMOs created through use of dsRNA techniques, engineered to produce dsRNA or dsRNA*" and "*LMOs containing RNAi*", we read that it would be important to note in the Guidance that the risk assessment of RNAi LMOs may require the use of different risk hypothesis or scenarios, taking into account the resilience of the RNA molecule in the environment, the potential of

dsRNA to produce heritable silencing effects (through epigenetic transmission), and the ability of dsRNA to be taken up and further amplified, and potential toxicity which may need to be investigated through genome-wide microRNA screening. It was also suggested that the title of this topic should be changed to "LMO possessing a transgene(s) capable to induce an RNA silencing response". The need to define relevant terms was also noted.

On the other hand, we also read some views that risk assessments of these types of LMOs follow the same paradigm as other LM plants and, therefore, no additional guidance on this topic is needed.

- And, finally, on "*Synergistic impacts of different herbicides that are part of the technology package that accompanies certain LMOs*", on the one hand, we heard that this topic is outside of the scope of the environmental risk assessment of an LMO crop under Annex III of the Cartagena Protocol and covered by other regulatory frameworks, which also assess the safety of herbicides as applied to LMOs.

On the other hand, we also heard that the focus of this topic is on LMO risk assessment and some of the specific considerations would include the choice of comparators, synergistic effects, potential of multi-herbicide resistant LM plants to establish as weeds, changes in the management related to the use of herbicides which is induced by the characteristics of the LMO: amount of herbicides, the time of the application and the combination of different herbicides if applied combined at the same time or on the same field at different times, as well as potential "joint action" of two or more herbicides being used in connection to an LM crop.

With regard to the format, the suggestions include adding text boxes, additional sentences in line with the existing text and/or examples. Also, a number of relevant references were proposed. There were also views that the addition of more examples focusing on specific LMOs in "boxes" or with additional sentences would not improve the flexibility of the Guidance but rather create confusion for novel risk assessors.

Furthermore, some participants were of the view that some of the topics warrant the development of entire separate sections of the Guidance (i.e. under Part II), while others called for efforts to focus on improving the existing Roadmap and argued that boxes or additional text on the four topics are unnecessary and would add complexity to the Guidance.

It is important at this point to remember why we have been discussing on these matters, and I therefore will permit myself as the moderator to add the following reference text extracted from the COP-MOP 7 decision BS-VII/12:

"Annex

TERMS OF REFERENCE FOR THE OPEN-ENDED ONLINE FORUM AND AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT

Methodology

[…]

2.While revising and improving the Guidance, an attempt should be made to take into account the topics prioritized by the AHTEG, on the basis of the needs indicated by the Parties with a view to moving towards operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes, for the development of further guidance."

Expected outcome

[…]

5. An improved version of the Guidance on Risk Assessment of Living Modified Organisms."

I also include the link to the page were operational objectives 1.3 and 1.4 of the Strategic Plan and its outcomes can be directly visited: http://bch.cbd.int/protocol/issues/cpb_stplan_txt.shtml#oo1_3

We in this online forum had the objective of gathering views, relevant guidance and sources of information on the four topics shown above so as to be incorporated into the existing Guidance, by creating text boxes or adding text, as appropriate, in the "Roadmap for Risk Assessment of LMOs" (Part I of the Guidance). Discussing if the topics should be taken on board at all, or if they had to be further developed into complete documents (Part II of the Guidance) was out-of-scope of this exercise.

At the last COP-MOP meeting, the Parties agreed that, in parallel to revising the Guidance in response to the comments from the testing, an attempt would be made to take into account the topics prioritized by the previous AHTEG. Adding some sentences or boxes on the specific topics in the existing Roadmap and/or other parts of the Guidance is already a compromise solution, which was reached at the last COP-MOP, between Parties who wanted full guidance to be developed on those topics and Parties who did not want any additional guidance to be developed. Therefore, discussing whether the new topics should be developed as an entire section of the Guidance or not be developed at all not only is a step back, but it also goes against what was already decided by the Parties.

I would also like to recall that the topics prioritized by the previous AHTEG are not their own input but rather the result of several requests and inputs from Parties over the years, which were streamlined by the previous AHTEG as the list that was sent to the last COP-MOP meeting. Interestingly, but by no means a coincidence, the call to add more information into the Guidance on two of the topics prioritized by the AHTEG (centres of origin and human health) were also made by different Parties during the testing of the Guidance, further emphasizing the importance of those topics. The most important in this debate is not how the list came to be, but rather the fact that Parties mandated us to take into account that particular list of topics as prioritized by the previous AHTEG. Therefore we should turn back to the discussion on “how” to integrate these topics in the current version of the Draft Guidance rather than discussing if this should be done or not.

The main challenge now is to reconcile the different views; we should go beyond weighing one view against the other, but instead should distil and make sense of them all into something that helps the users of the Guidance. With this thought in mind, the Sub-group will make its best attempt to reconcile the views and the result will be discussed at a later stage by the entire AHTEG and Online Forum. I recognize that other suggestions were made, which are not being included in this summary, and that is because they were not directly related to the topic of discussion and I will leave them for consideration by the AHTEG and/or Secretariat, as appropriate.

Finally, I would like to again thank the Secretariat on having selected me as moderator in such a process to help out in what I believe a very important instrument for the implementation of the Cartagena Protocol. I would like to thank you all as well for participating in the Online Forum.

C. Feedback on the proposed revisions to the Guidance (25 April - 9 May 2016)

Summary of the moderator, Mr. Helmut Gaugitsch

I would like to thank all participants who shared their views during the last two weeks of discussion and the subgroup members for their hard work leading up to the discussion.

We had quite an intense discussion in which 31 participants posted comments.

Among the comments, I am very glad to see so many concrete proposals to improve the text. These proposals will undoubtedly improve the quality and usefulness of the Guidance.

As you are well aware, in some situations it is rather challenging to reconcile different views, for example among those who wished to delete the text boxes and those who wish to keep them. In this context, I appreciate the proposals that seek a middle-ground between the different views, such as the

proposals to harmonize the text boxes and provide links to them in the text. Based on your views, the AHTEG at its face-to-face meeting in July 2016 will follow an inclusive approach to explore all possibilities to reach a middle ground on the various outstanding issues, including by harmonizing the text boxes, for example by categorizing the different types of boxes, and explaining the purpose of each type of box at the beginning of the guidance. We will also endeavor to add links or references to the boxes in the appropriate passages of the text.

Reflecting upon the work done and what remains to be done, I recognize that some parts of the text need to be further improved, for example when referring to problem formulation which is a crucial element of risk assessment.

I also recognize the concerns of some participants with regard to the process, in particular with regard to difficulties in following the process and lack of transparency, not having a chance to comment on all changes, previous suggestions not being reflected in the text, comments in categories B and D that still remain to be addressed, and limited time to review documents and provide comments.

Although the focus of this online discussion was not on procedure, and these types of comments distract from the main task, they must also be taken seriously and I would like to respond to them as follows:

(a) As noted in a few interventions, the process set out in decision BS-VII/12 is complex and demanding. On the one hand, the task provided by the COP-MOP is rather challenging and demands a considerable amount of time and dedicated work. On the other hand, we are a large group of people with many different views. Nevertheless, one aspect of the process that cannot be overly emphasized is that the entire work leading up to the current version of the Guidance, including the many iterations of the work of the sub-group, is publicly available for anyone to see (as per my introductory message to this discussion, the discussions of the sub-group are available in their entirety at http://bch.cbd.int/onlineconferences/RA_ahteg_subgroup). While I recognize that reviewing the work of the sub-group is time consuming due to the amount of information generated in the multiple steps of the process, this challenge cannot and must not be used as a reason to claim lack of transparency in the process.

(b) The online forum plays a crucial role in assisting the AHTEG. In order to move forward with the improvements to the text of the Guidance, each discussion must build on previous work and focus on new revisions to the text. Any attempt to do otherwise, would lead us to move in circles. Any participant who wishes to examine, for informational purposes, all the changes made to date to the text of the Guidance is welcome to use the “compare documents” function in Word or ask the Secretariat to do so. Towards the end of the process later this year and similar to what was done in the last intersessional period, the online forum will have an opportunity to consider a draft report of its work which will be forwarded to the COP-MOP. I expect that the Secretariat will reflect the different views in this draft report, both in terms of substance as well as process.

(c) All views posted in the forum are considered very seriously. However, given the fact that many views are highly polarized, you will all agree with me that it is humanly impossible to reflect every suggestion in the revised text. In cases where the suggestions that were made are mutually exclusive (for example, adding or not adding the text boxes on specific topics), an attempt is made to add some text that reflects all the diverging views.

(d) It is true that the testing comments in categories B and D were not yet taken onboard in a systematic manner but that is what was intended from the onset of the work. It had been decided, in consultation with the online forum, that specific comments would be taken up first, followed by, in a step-wise manner, comments that are more general or of structural/overarching nature. In addressing the specific comments in category E, a large number of the comments that were placed in categories B and D were already indirectly addressed. During the remaining amount of time, as per the calendar of activities, the sub-group with the help of the Secretariat will review all comments in categories B and D, taking into account the views expressed in all past discussions of the forum, and will make proposals in preparation

for the AHTEG meeting. At its meeting, the AHTEG will attempt to reconcile the different views aiming to arrive at a balanced and improved text. As requested by the COP-MOP, explanations on what happened to each comment of the testing will be provided to the COP-MOP.

(e) The question of limited time is a difficult one to address .Here too an attempt is made to strike a balance between what needs to be done and the amount of time that is available to accomplish our task. However, it is necessary to keep in mind that we are all very busy and, no matter how much we try, no amount of time given to an additional task will ever be ideal to our already busy schedules.

Last but not least, I would like to express my heartfelt appreciation to those members of the forum who demonstrated the spirit of compromise that provides the necessary foundation for any intergovernmental and multi-stakeholder process. In particular I would like to thank those who went beyond their own views and preferences and who attempted to find common ground and build upon that to reach compromise among the diverging views.

I kindly invite all of us to refrain from judging too early and in a polarized manner about the results of our efforts but rather to believe in our joint problem-formulation and problem-solving capacity so that we can at the end of this year provide an improved version of the Guidance to the COP-MOP for its consideration. I am looking forward to working with the sub-group, the Secretariat, the AHTEG and the online forum in achieving this challenging goal.

D. Feedback on the draft outline for further guidance on risk assessment of LM fish (11 - 25 April 2016)

Secretariat's summary

In following up on an earlier discussion to gather views, information and references on risk assessment of LM fish, a group of volunteer AHTEG members drafted an outline for the development of further guidance on this topic for consideration by COP-MOP at its meeting in December 2016.

The draft outline served as the basis for an online discussion of the Online Forum that was held from 11 to 25 April. Members of the Online Forum were invited to provide feedback on the draft outline with a view to helping the AHTEG improve the outline before submitting it to COP-MOP. Participants were invited to focus on whether issues that are unique or particularly relevant to the risk assessment of LM fish are whether these issues are adequately covered in the draft outline, as well as on the structure of the outline.

Twenty five interventions were made during the two weeks of discussion. The views expressed by participants of the Online Forum diverged: on the one hand, some participants considered that the Roadmap did not provide enough specific elements to assess the risks of LM fish and, as such, additional guidance would need to be developed. It was also noted that a dedicate guidance on LM fish may help to align the various risk assessment frameworks that originate from different jurisdictions. On the other hand, some participants considered that a separate document was not needed based this on the understanding that a good Roadmap should be a document that guides on the assessment of any LMO. Nevertheless, there was general agreement that a decision on whether or not the development of additional guidance on risk assessment of LM fish is needed lies with the Parties.

Proposals were made to include the following elements in the outline of guidance on the risk assessment of LM fish for consideration by COP-MOP:

- Earlier experiences in conducting risk assessments of LM fish, including the number of cases of releases of LM fish
- Experiences in conducting risk assessment of LMOs
- Difficulties in conducting risk assessment of LM fish
- Risk assessment aspects that are unique to LM fish

- Recommendations to address the unique aspects
- Reference materials that are "directly" relevant to the risk assessment of LM fish

Other interventions also noted the need to include additional elements that could be added to the outline for guidance on LM fish, such as monitoring, traceability mechanisms, and an overview of relevant work of other relevant international bodies in this field.

The potential for unintentional transboundary movement of LM fish introduced into the environment was also noted as an important consideration.

E. Possible considerations during the environmental risk assessment of LMOs developed or created through approaches commonly referred to as "synthetic biology" (13 - 27 June 2016)

Summary of the moderator, Ms. Maria Mercedes Roca

I thank the Secretariat for their confidence in inviting me again to moderate this most lively and interesting forum that reflects different opinions regarding risk assessment and risk management for synthetic biology (SB). I also sincerely thank the many participants that have shared their opinions and experience with the group, with special thanks to Paulo and Wei Wei for their most valuable interventions, with opposing views.

Before the forum closes tonight, I am sharing with you a moderator´s summary that attempts to reflect the wealth of information and views shared by participants. Although as moderator, I kindly requested that you made comments to the text provided by the Secretariat (Doc1 – Background document Synthetic Biology RARM) and either supported the contents of the document, or not, I agree with Phil that procedure and policy considerations in these issues are very important.

In the spirit of transparency and to give parties a fair view of where the weight of expert opinion lies in this rather contentious issue, I consider that quantifying and qualifying the opinions of participants will provide and more balanced view for parties at COP-MOP to make a decision. It is my hope and my respectful request, that the Secretariat takes these views into consideration, when drafting their report for COP-MOP discussions.

Please feel free to correct any mistakes you find in the following summary:

There were 40 interventions from the following countries and organizations: Brazil, USA, Canada, Mexico, Netherlands, Belarus, Italy, China, Japan, Mauritania and New Zealand. Again, the voice of small developing countries and least developed countries (with the exception of Mauritania) was absent. The discussion was dominated mainly by those countries that have historical and practical expertise in risk assessment of LMOs.

As requested, 7 participants provided alternative text to Doc1. For those 7 submitted documents with alternative text to Doc1, 3 advocated for the development of further guidance for synthetic biology (SB) for future developments, and 4 felt that the development of further guidance is premature, until specific cases of SB are developed.

Although there 41 interventions in total, interventions were made by 17 participants.

11/17 (65%) experts, mostly representing their governments and regulatory agencies from Brazil, Japan, Italy, Canada, the Netherlands, Germany[11] and 2 observer institutions repeated what was the majority view in forum 1: no further guidance is currently required to adequately deal with LMOs developed by SB. On the other hand, 6/17 (35%) participants representing governments (Mexico, Belarus, Mauritania, New Zealand) and two observers advocated for the development of guidance.

[11] A few interventions, supporting the two different points of view, were made after the moderator's summary was posted but before the closing of the discussion. Among these interventions, two were by experts from Germany who were of the view that specific guidance on risk assessment of LMOs developed through synthetic biology is needed.

Although it is not our task to vote and the final decision will be taken by parties at COP-MOP, as moderator, I feel parties would benefit from understanding how experts involved in the discussions arrived at their respective conclusions and why there is no consensus (65% for no further guidance, just review existing one vs 35% to develop new guidance).

On a practical note and to continue with our task, we need to have a working document to discuss at the next AHTEG meeting in Mexico City (I will call this Doc 4). As invited moderator, and in the spirit of transparency, my recommendation to the Secretariat is that Doc 4 should be the submitted document with the most input and support from Forum 2 participants.

I recommend that Doc 4 should therefore be the text originally proposed by Luciana (# 7985) and supported by colleagues from the Brazilian government (#7985, #7997) and reviewed by other participants (#7987, #7990, #7986, #8000, #7991, #7995, #8001, #8002, #8003, #8010, and lastly submitted by Bob Friedman (#8011).

Again, I thank the Secretariat and all participants wholeheartedly again and wish my colleagues from the RARM AHTEG a very fruitful meeting in Mexico City.
