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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
Seventh meeting
Pyeongchang, Republic of Korea, 29 September-3 October 2014
Item 12 of the provisional agenda*

ANALYSIS OF THE RESULTS OF THE TESTING OF THE "GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS"

Note by the Executive Secretary

A. BACKGROUND

1. In decision BS-VI/12, the Conference of the Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety (COP-MOP) commended the progress made on the Guidance on Risk Assessment of Living Modified Organisms, clearly understanding that:

(a) The Guidance is not prescriptive and does not impose any obligations on Parties;

(b) The Guidance will be tested nationally and regionally for further improvement in actual cases of risk assessment and in the context of the Cartagena Protocol on Biosafety.

2. Furthermore, with regard to the testing of the Guidance, the COP-MOP:

(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.

[1] This document was previously published as UNEP/CBD/BS/AHTEG-RA&RM/5/2 on 20 May 2014.

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

3. 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.

4. Furthermore, the COP-MOP also mandated the Open-Ended Online Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management 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.

5. The first round of moderated online discussions of the Open-ended Online Forum on the topic of the testing of the Guidance was held in January 2013 and focused on an exchange of views for the development of tools to structure and focus the testing process. Taking into account the outcomes of that discussion, the Secretariat prepared a draft concept note and a draft questionnaire based on the criteria set out for testing the Guidance in actual cases of risk assessment as per decision BS-VI/12, paragraph 5(b): (i) practicality, (ii) usefulness/utility, (iii) consistency with the Cartagena Protocol on Biosafety, and (iv) the extent to which the Guidance takes into account past and present experiences with LMOs.

6. Further rounds of online discussion were held by the Open-ended Online Forum and AHTEG in April 2013, and by the AHTEG alone in May 2013 to assist the Secretariat in the development of tools to structure and focus the process of testing the Guidance.

7. 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, as tools to structure and focus the process of testing the Guidance.

8. The questionnaire comprised two types of questions to gather both quantitative and qualitative feedback, i.e. (i) close-ended questions using a 5-level Likert scale,[2] marked as mandatory questions, to evaluate to what extent each section of the Guidance is practical, useful and consistent with the Protocol, and takes into account past and present experience with LMOs, and (ii) open-ended questions, which were marked as optional, to gather comments and suggestions for improvements, if any, on each of the tested criteria.

9. All tools to structure and focus the testing, as well as the Guidance, were made available in the six official languages of the United Nations.[3] The concept note is appended to this document in annex 1.

10. On 19 June 2013, a notification was sent to Parties, other Governments and relevant organizations inviting them, 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. A further notification was sent on 23 December 2013 extending the deadline for the submission of testing results to 31 March 2014.

B. OVERVIEW OF THE SUBMISSIONS

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 (Fig. 1). Among the submissions from Parties were 28 from developing countries.

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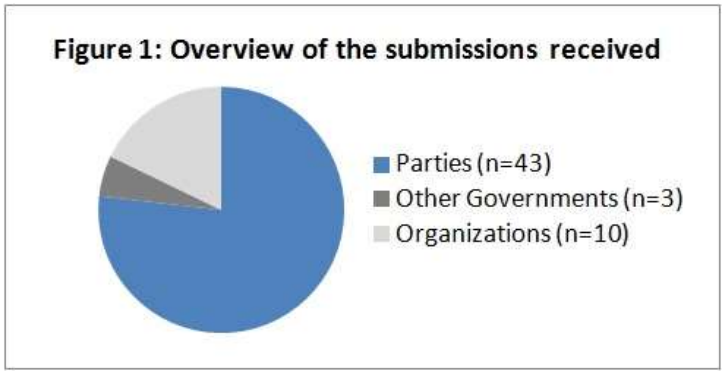
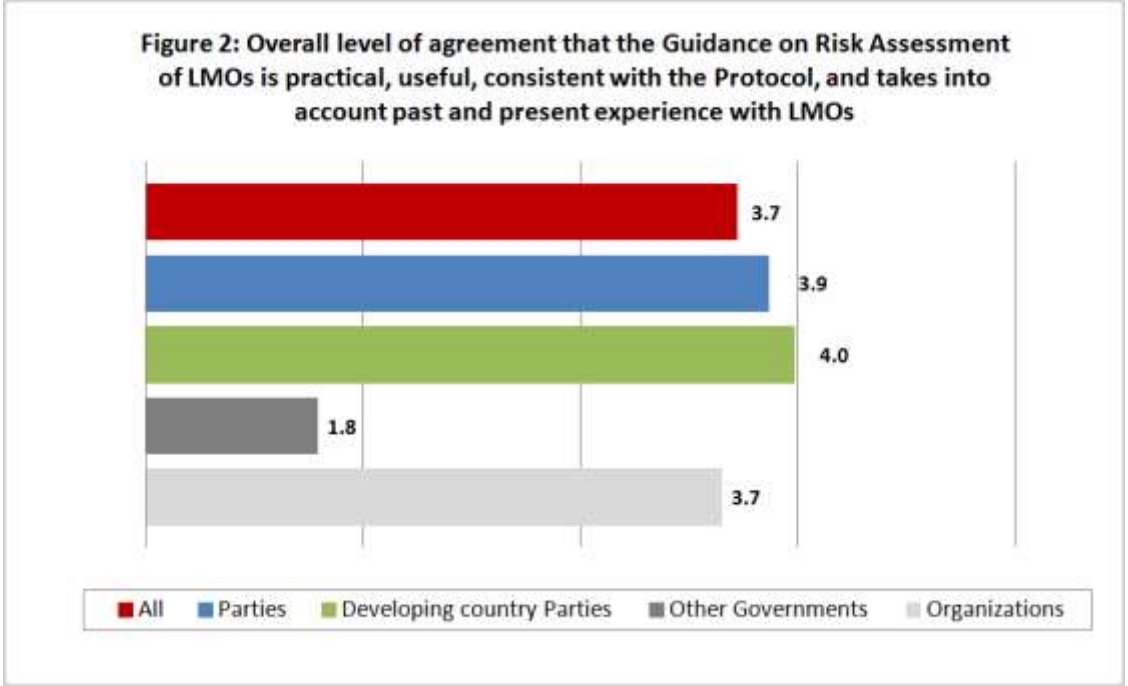
[2] The format of the Likert scale used in the testing questionnaire was: 1 - Strongly disagree; 2 - Disagree; 3 - Neutral; 4 - Agree and 5 - Strongly agree. Additional information on the use of Likert scales may be found at http://en.wikipedia.org/wiki/Likert_scale.

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



12. Based on the quantitative feedback of all the responses, on a scale of 1 to 5, where 1 represents "strongly disagree" and 5 represents "strongly agree", the results indicated an overall level of agreement that the Guidance is practical, useful and consistent with the Protocol, and takes into account past and present experience with LMOs of 3.7 among all submissions, 3.9 among Parties, 4.0 among developing country Parties, 1.8 among other Governments and 3.7 among organizations (Fig. 2).[4]



13. A large number of comments and suggestions on possible improvements to the Guidance were provided as feedback in the form of free text during the testing of the Guidance. The total array of comments and suggestions from all the respondents to the testing are available online at http://bch.cbd.int/protocol/testing_guidance_RA.shtml. In addition, the AHTEG may wish to take note of document UNEP/CBD/BS/AHTEG-RA&RM/5/3, "Compilation of the suggestions for improvements to the 'Guidance on Risk Assessment of Living Modified Organisms'", in its consideration of a mechanism for the improvement of the Guidance.

[4] Calculated as the average rating from 1 ("strongly disagree") to 5 ("strongly agree") among all responses within each type of submission, i.e. all submissions, Parties, developing country Parties, other Governments and organizations.

14. The comments and suggestions for improvement of the Guidance highlighted throughout this document have been randomly selected by the Secretariat to give the AHTEG a flavour of the feedback received.

15. The following is a sample of the list of general comments and suggestions that are applicable to the Guidance:

(a) The Guidance could specify more clearly that the intended target audience are regulators involved in the risk assessment process, and that its objective is not to provide a single methodology for the risk assessment process but rather to assist the regulators in navigating through different options;

(b) The Guidance provides a good conceptual review in identifying a number of relevant issues, but in many instances it does not propose ways to address them. Novice risk assessors are often familiar with the basic elements of risk assessment, but may lack the experience to deal with specific cases. To enhance the usefulness of the Guidance in guiding risk assessors on how to conduct a risk assessment on a case-by-case basis, a more in-depth discussion of methodological and conceptual aspects could be added to the Roadmap. In Part II, practical examples drawn from actual cases could be proposed for each of the specific types of LMOs and their intended uses (e.g. field trials, commercial cultivation, vaccines) to show how different regulators have addressed the different situations;

(c) The information presented in Part II does not follow the structure of the respective steps in Part I (the Roadmap), and it is unclear whether or how the Roadmap is to be used in parallel with the guidance on specific types of LMOs or traits. There is a need to explain how the information and points to consider provided under Part II would help in asking the right questions at each step of the risk assessment and, in particular, during step 1. For example, it could be more clearly stated that, for specific types of LMOs and traits, the points to consider raised under Part II are to be considered in addition to those with the Roadmap;

(d) Potential adverse effects to biodiversity arising from changes in cultural and management practices such as application of herbicides or fertilizers associated with the introduction of the LMOs could be further elaborated;

(e) The text could be revised to use language that is simpler, more user friendly and less prescriptive, including changing the text from “points to consider” to “points that may be considered”;

(f) The quick link option to the “Use of Terms” section is very helpful and should be offered in more instances throughout the text;

(g) Additional examples, in particular those from a regional context, and publications in languages other than English could be added;

(h) Links could be provided to the text of all referenced articles of the Protocol for easier and quicker access;

(i) The background documents throughout the Guidance need to be re-examined for relevance to the actual final text;

(j) Revising the use of certain terms in the versions of the Guidance in languages other than English to ensure that the original meaning of the terms is retained in the translated versions.

C. SECTION-BY-SECTION ANALYSIS OF THE RESULTS

i. Part I: The Roadmap for Risk assessment of LMOs

16. All 56 submissions received included results for the testing of the Roadmap for Risk Assessment of LMOs.

17. Among 43 submissions from Parties, the average ratings for the Roadmap in relation to the four tested criteria were: practicality – 3.6; usefulness – 3.9; consistency with the Protocol – 4.0; and accounting for past and present experience with LMOs – 3.7. Among the developing country Parties, as indicated by 28 submissions, the average ratings for the Roadmap were: practicality – 3.7; usefulness – 4.0; consistency with the Protocol – 4.0; and accounting for past and present experience with LMOs – 3.8.

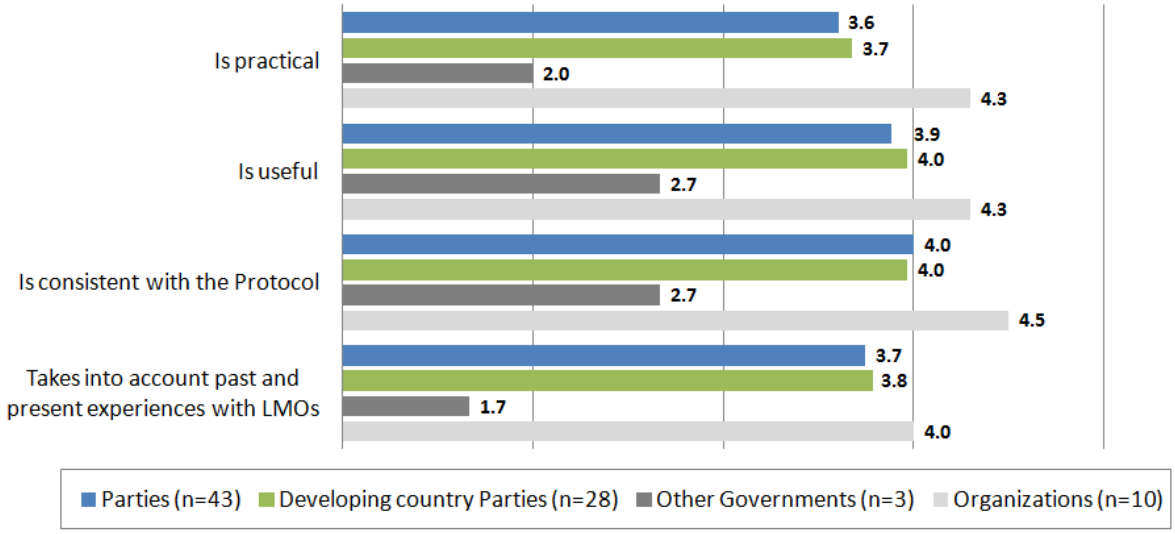
18. Among other Governments, as indicated by 3 submissions, the average ratings were: practicality – 2.0; usefulness – 2.7; consistency with the Protocol – 2.7; and accounting for past and present experience with LMOs – 1.7.

19. Among the organizations, as indicated by 10 submissions, the average ratings were: practicality – 4.3; usefulness – 4.3; consistency with the Protocol – 4.5; and accounting for past and present experience with LMOs – 4.0.

20. The following graph summarises the results of the testing of the Roadmap with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 3).

Figure 3: Roadmap for Risk Assessment of LMOs

Level of agreement that this section of the Guidance:



21. The following paragraphs include a sample of the list of comments and suggestions that emerged from the testing exercise with a view to improving the Roadmap.

22. To improve the *usefulness* of the Roadmap, some suggestions include:

(a) The Roadmap could be improved in order to become more flexible and applicable to different situations, regardless of the methodology of modification (e.g. RNAi), recipient organism (e.g. LM animals and microorganisms) or modified trait;

(b) The section on the identification and consideration of uncertainty would be better served by outlining components for describing each identified uncertainty, namely its nature, source and level; providing some common, simplified approaches which are currently in use for dealing with uncertainty; and providing examples that more information may result in more uncertainty;

(c) The Roadmap could provide more guidance on how to integrate the various pieces of information when performing a risk assessment in practical terms, for example, by providing links on how the information obtained from the "points to consider" in Step 1 (hazard identification) can be used with information in Step 2 (exposure assessment) and Step 3 (hazard characterization) to complete Step 4 (risk characterisation);

(d) Examples of methodological approaches to "hazard identification," "exposure assessment", "hazard characterization", and "risk characterization" could be included into the Roadmap;

(e) The Roadmap could also include information on how to use the "points to consider" to formulate questions, particularly in Step 1, which would guide the evaluators to determine potential adverse effects, and how these questions can be relevant to the subsequent steps of the risk assessment. Instead of listing the various "points to consider" out of context, the Roadmap could focus on questions that would trigger the evaluator to determine if the LMO could cause potential adverse effects;

(f) There could be a stronger focus, in the Roadmap, on issues of human health in the context of risk assessment of LMOs;

(g) Making an appropriate distinction between risk assessment considerations for small scale experimental releases for the purpose of field trials or large scale/commercial releases.

23. Regarding improvements to the practicality of the Roadmap, some suggestions include:

(a) Making use of tools which are commonly used to assess the overall risk such as "worst-case scenarios", "decision trees", "risk matrices", etc;

(b) Articulating the inter-linkages between the processes of risk assessment, risk management and risk communication;

(c) Placing much of the information, such as examples, options or alternatives, in appendices/explanatory notes to simplify the main document;

(d) The "Points to consider" could be split into smaller segments and the letters could be replaced by numbers for ease of reference;

(e) Using lettering and/or numbering in the headings of each section for easier cross-referencing.

24. To increase the consistency of the Roadmap with the Protocol, some suggestions include:

(a) Strengthening the link to the precautionary approach;

(b) Adding a reference to Article 10 paragraph 6 of the Protocol when describing appropriate ways to deal with identified uncertainties;

(c) Reflecting the provisions of Annex III of the Protocol with respect to information and characteristics of the donor organism(s);

(d) The Roadmap should address the potential adverse effects to human health in more detail;

(e) Removing issues that are focused on policy elements that are not within the scope of a risk assessment (e.g., the section on "related issues", data quality, consultation with stakeholders, selection of experts) or outside the scope of the Protocol (e.g., co-existence, ethical issues);

(f) Avoiding the use of prescriptive and policy-based statements;

(g) Including the notions that access to and transfer of biotechnology are essential elements to attain the objectives of the CBD (article 16 of the CBD), Parties agree to promote and advance priority access to the results and benefits arising from biotechnologies (articles 19.1 and 19.2 of the CBD), and that modern biotechnology has great potential for human well-being (preamble of the Protocol).

25. To improve the extent to which the Roadmap takes into account *past and present experiences with LMOs*, some suggestions include:

(a) Explaining that a risk assessment process can be simplified on the basis of available experience and providing more guidance on how to identify what information is needed and relevant;

(b) Addressing uncertainty in the context of experience in risk assessment and the history of use that might have already been obtained with certain LMOs, as well as the principal differences between how the concept of uncertainty is handled in small-scale field trials and large-scale/commercial releases;

(c) Including key and long established concepts for LMO risk assessment such as familiarity;

(d) Removing speculative risks such as those arising from indirect effects, synergistic and combinatorial effects, horizontal gene transfer among plants, and persistence of the gene product in the environment as they ignore the long history of experience with LM crops where these risks have not been realized.

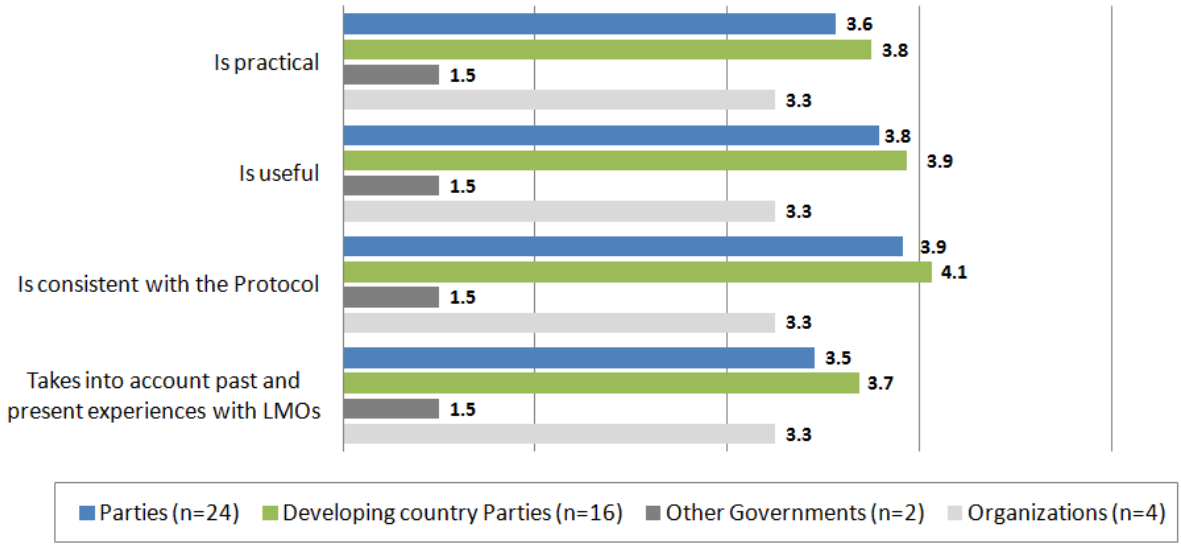
ii. Part II: Specific types of LMOs or Traits – Risk assessment of LMOs with stacked genes or traits

26. Among the submissions received, 30 included results for the testing of the section of the Guidance on "Risk assessment of LMOs with stacked genes or traits". Among these, 24 were from Parties, including 16 from developing countries, 2 were from other Governments and 4 from organizations.

27. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 4).

Figure 4: Risk Assessment of LMOs with Stacked Genes or Traits

Level of agreement that this section of the Guidance:



28. With regards to suggestions on how to improve the practicality, usefulness, consistency with the Protocol and the extent to which this section takes into account past and present experiences with LMOs. The following presents a sample of these suggestions:

(a) The scope of this section should account for the fact that a risk assessment may not be available for the parental organisms of the LMO with stacked genes;

(b) It could be stated more clearly that re-transformation and co-transformation are not considered in this section, and that LMOs developed through these methods should be assessed as single events;

(c) The process of problem formulation under this section should focus on possible interactions that may take place between the individual introduced genes or traits;

(d) Additional explanation or examples are needed to increase the scientific validity of some points to consider in this section;

(e) The current text gives the impression that the "choice of comparators" is the only relevant issue under the planning phase for the risk assessment of LMOs with stacked genes or traits. An explanation could be added to explain that other issues are also relevant but that they are already covered in the Roadmap;

(f) This section should start by "setting the scene" that stacked genes are a natural phenomenon that occurs as a result of conventional breeding. It could include guidance on how to identify cases that go beyond the natural consequences of conventional breeding that could give rise to safety concerns;

(g) This section could provide a better reflection of nearly 20 years of experience with LMOs and issues related to vector sequences, horizontal gene flow, chronic effects, bioaccumulation, persistence of gene products in environment, etc.

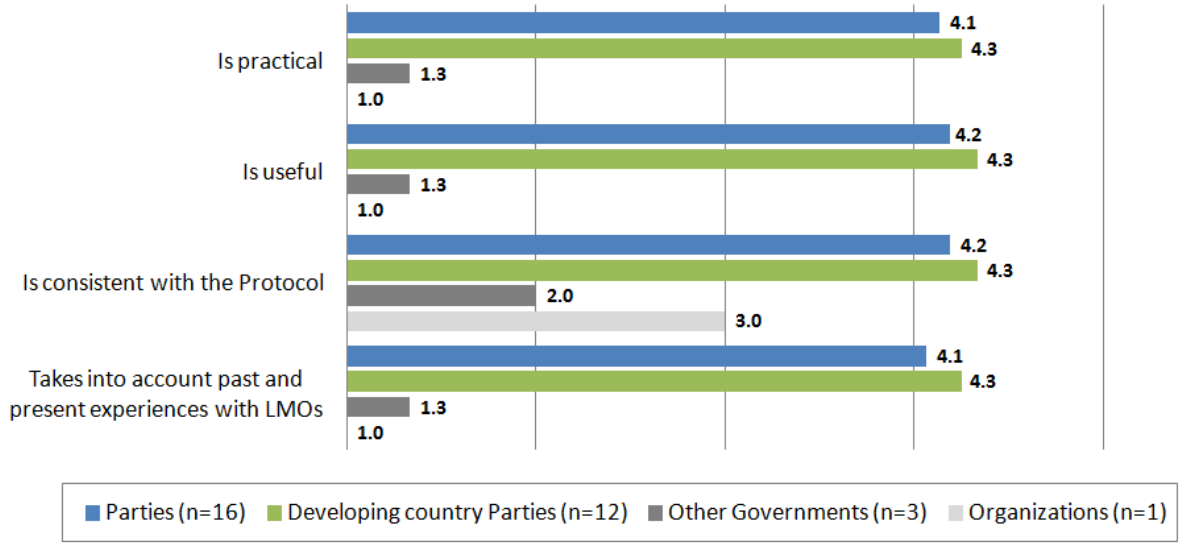
iii. Part II: Specific types of LMOs or Traits – Risk assessment of LM crops with tolerance to abiotic stress

29. Among the submissions received, 20 included results for the testing of the section of the Guidance on "Risk assessment of LM crops with tolerance to abiotic stress". Among these, 16 were from Parties, including 12 from developing countries, 3 were from other Governments and 1 from organizations.

30. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 5).

Figure 5: Risk Assessment of LM Crops with Tolerance to Abiotic Stress

Level of agreement that this section of the Guidance:



31. The following is a sample of comments and suggestions that emerged from the testing exercise with a view to improve this section of the Guidance:

(a) More clarification is needed as to when and why it may be relevant to consider certain attributes of the LM plants modified to tolerate abiotic stresses;

(b) Concrete examples could be provided to explain various points to consider. This could be done by adding links to publications on this type of LMO;

(c) The current text gives the impression that the "choice of comparators" is the only relevant issue under the planning phase for the risk assessment of LM crops with tolerance to abiotic stress. An explanation could be added to the effect that other issues are also relevant but that they are already covered in the Roadmap;

(d) In addition to the explanation already given in the section on the "choice of comparators", it would be useful to provide concrete (or even theoretical) examples of which comparator(s) and which comparative endpoint(s) could be used in which case(s) and under which condition(s);

(e) This section of the Guidance does not acknowledge the extensive experience with introducing abiotic stress tolerance crops through conventional breeding and mutagenesis and ignores the concept of familiarity. It could be useful if this section made clear comparisons with non-LM plants, as well as existing varieties bred and selected for their ability to tolerate abiotic stresses;

(f) Issues related to pleiotropic effects or potential invasiveness in non-LM plants could be added to place the evaluation LM plants into context;

(g) This section would require a revision to establish the distinction between guidance in cases of releases for field trials and for placing an LMO on the market;

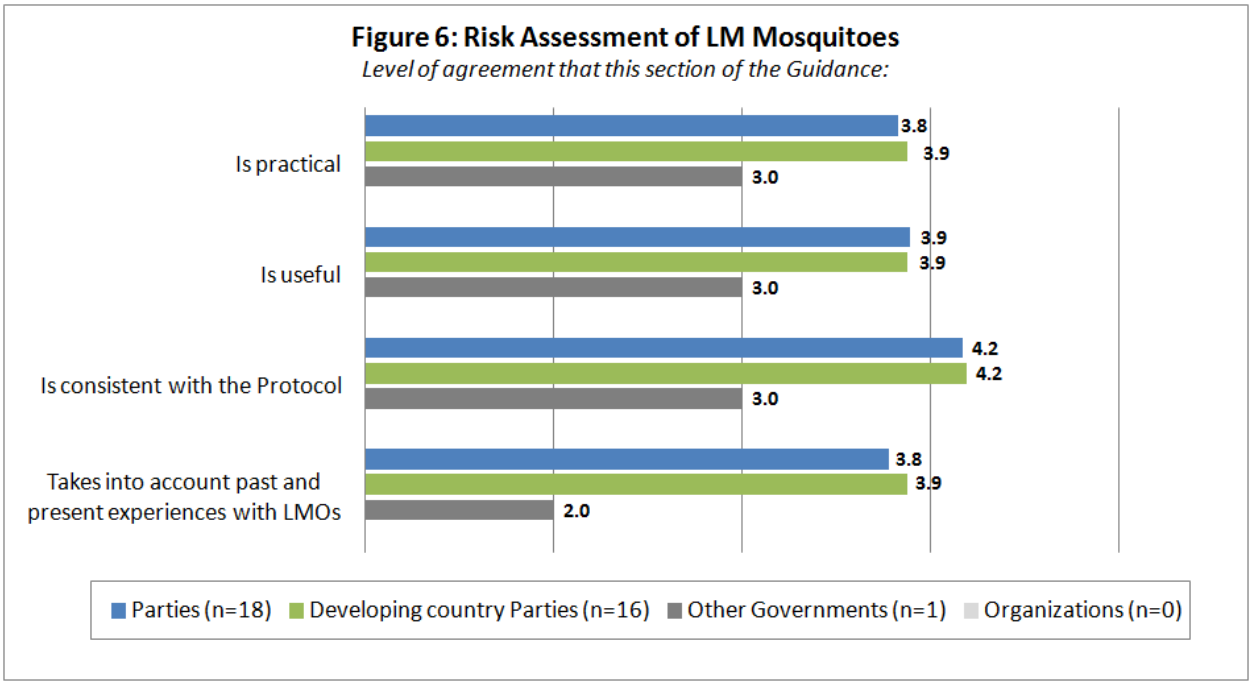
(h) The discussion on cross talk in stress tolerance mechanisms should be contextualized to potential adverse effects;

(i) The sentence about "omics" technologies could be moved to the relevant section of the Roadmap since their possible use is not restricted to LM plants with tolerance to abiotic stress. On the other hand, this sentence could be eliminated, unless a clear explanation of how "omics" technologies could help evaluate the risks of LM crops tolerant to abiotic stresses.

iv. Part II: Specific types of LMOs or Traits – Risk assessment of LM mosquitoes

32. Among the submissions received, 19 included results for the testing of the section of the Guidance on "Risk assessment of LM mosquitoes". Among these, 18 were from Parties, including 16 from developing countries, and 1 was from other Governments. There were no submissions from organizations regarding this section of the Guidance.

33. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 6).



34. The following is a sample from the list of comments and suggestions that emerged from the testing exercise with a view to improve this section of the Guidance:

(a) The issues under this section could be addressed in more practical, rather than theoretical, terms by, for example, referencing data from previous field trials of LM mosquitoes;

(b) The title of this section could be changed to reflect that the scope of this section is limited to LM mosquitoes that are important as vectors of human and animal pathogens and parasites;

(c) A sub-section on 'Containment' could be added to address some uncertainties with the possible effects of LM mosquitoes;

(d) The heading "unintentional effects" contains a number of speculative issues that could be addressed. Only the most plausible "points to consider" should be kept;

(e) Instructions could be provided on how to use the information and points to consider under this section to ask the relevant questions, in particular during Step 1 (problem formulation), for the purpose of performing the consecutive steps of the risk assessment in accordance with the Roadmap;

(f) Additional guidance could be given on the selection of comparators, including the possible need for alternative comparators to the non LM parental line;

(g) The specific nature of field trials could be better addressed in this section. Moreover, it could be made clear whether the paragraph on risk management strategies applies to field trials and/or large-scale/commercial release into the environment;

(h) References to past experiences with non LMO self-limiting techniques (e.g. sterile insect technique) could be added;

(i) The relationship between considerations of the environmental risks of LM mosquitoes and human health benefits should be mentioned more explicitly;

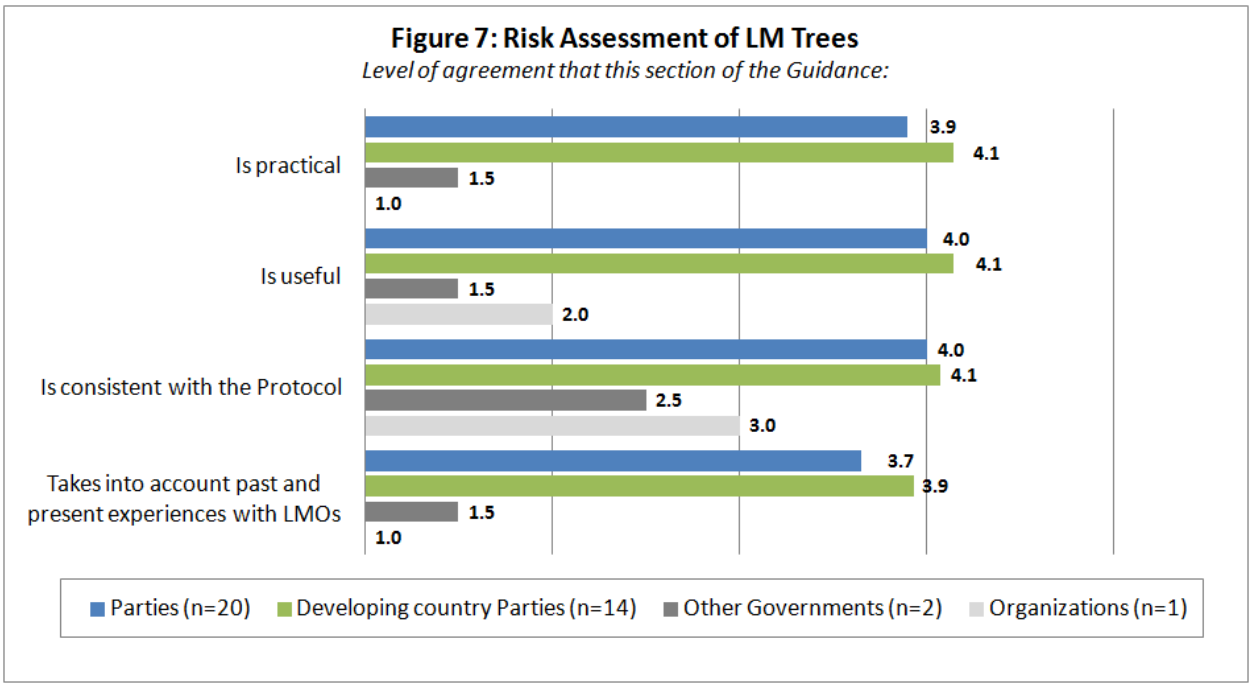
(j) Specific issues related to the epidemiology of the vectors (changes in the vector dynamics, host range, etc.) could be further developed;

(k) This section would likely benefit from linking with the OECD Mosquito Biology Consensus document which is currently under development by the Working Group on Harmonization of Regulatory Oversight in Biotechnology.

v. Part II: Specific types of LMOs or Traits – Risk assessment of LM trees

35. Among the submissions received, 23 included results for the testing of the section on "Risk assessment of LM trees". Among these, 20 were from Parties, including 14 from developing countries, 2 were from other Governments and 1 from organizations.

36. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 7).



37. The following is a sample from the list of comments and suggestions that emerged from the testing exercise with a view to improve this section of the Guidance:

(a) The scope of this section could be further clarified by not mixing issues relevant to forest trees and orchard trees. Likewise, it should be clearly indicated that the considerations under this section are not applicable to all LM trees, and that the relevance of each point to consider will vary from case to case;

(b) This section of the Guidance is very academic and does not provide practical "hands-on" advice. This could be improved by providing scientifically-sound rationales to support certain statements and assumptions under some points to consider;

(c) Parts of this section are too concise and poorly elaborated and could be improved by linking background documents to address specific issues;

(d) Examples of methodological approaches could be added to the "planning phase of the risk assessment" under this section;

(e) More information on the biology of non-LM trees could be added to this section from OECD documents;

(f) Modelling strategies and systems could be proposed as a tool that can be used to predict potential long-term adverse effects to biodiversity and ecosystem processes;

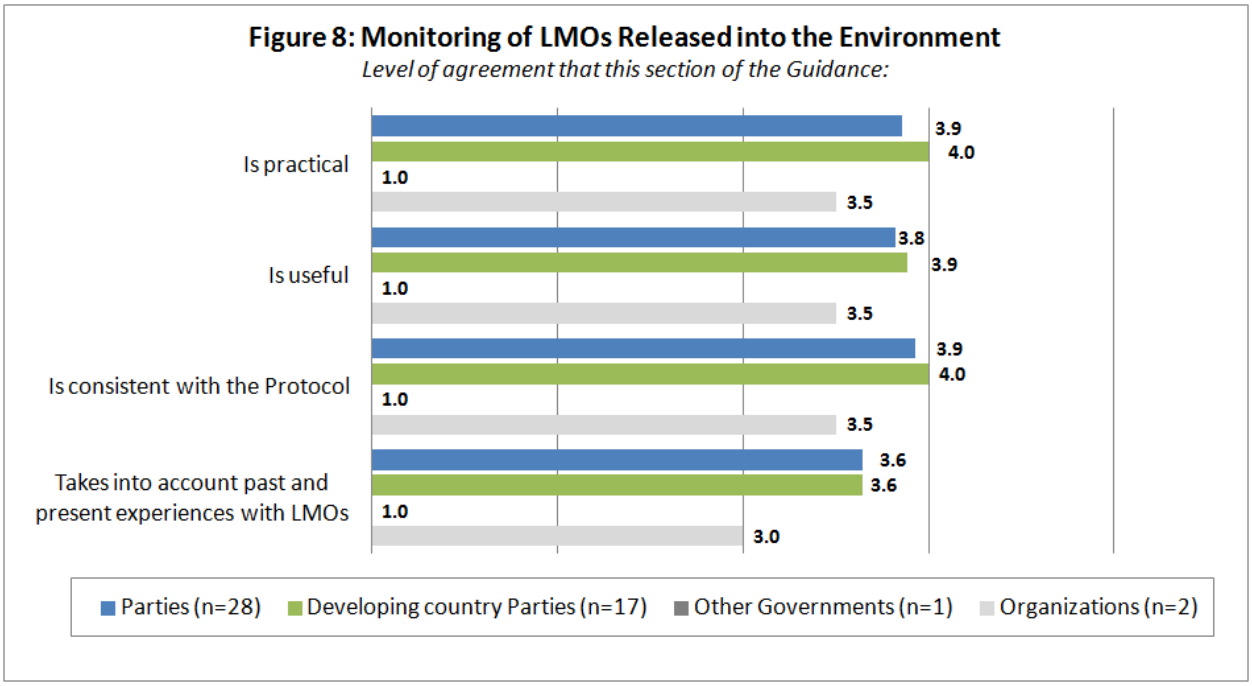
(g) The likelihood and consequences of gene flow between LM trees and non-LM trees could be further elaborated on;

(h) Alternative approaches could be explored in this section of the Guidance for cases where a traditional comparative approach based on the non-modified counterpart would be challenging, such as for an LM tree of a species for which there is little or no information with regard to its ecological functions or interactions in the likely receiving environment.

vi. Part III: Monitoring of LMOs Released into the Environment

38. Among the submissions received, 31 included results for the testing of the section "Monitoring of LMOs Released into the Environment". Among these, 28 were from Parties, including 17 from developing countries, 1 was from other Governments and 2 from organizations.

39. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 8).



40. The following is a sample from the list of comments and suggestions that emerged from the testing exercise with a view to improve this section of the Guidance:

(a) Although it is clearly stated that monitoring for human health is within the scope of this section of the guidance, there is little information that would allow practical human health monitoring. Therefore, to improve this section's consistency with the Protocol more elements could be provided on how to account for issues of human health in the context of environmental monitoring;

(b) Greater emphasis on the distinction between "general monitoring" and "case-specific monitoring" could be applied more consistently within the section by making it clear why and when specific or general monitoring applies to specific types of LMOs, and by adding the definitions of these two terms in the "use of terms" section;

(c) More practical guidance as to how monitoring should be carried out could be provided by, for example, providing a better explanation of the relationship between the outcomes of the risk assessment and monitoring;

(d) Including a section that highlights how "problem formulation" and "option assessment" could be used to reduce the monitoring requirements and allow for a more focussed monitoring plan;

(e) A better distinction between the monitoring of field trials versus the monitoring of commercial releases should be made. Currently, the suggested elements for a monitoring plan do not apply to field trials or the requested information will not be available. Therefore, a clarification should be added that the parameters outlined in this section only refer to commercial/large scale environmental releases. Monitoring of field trials could be discussed better in the document, as it plays an important role in data gathering and addressing uncertainties;

(f) A more detailed description of how existing monitoring networks could be utilized for general monitoring would improve the usefulness of the guidance;

(g) Clarification is needed to avoid confusing issues related to the detection of LMOs (i.e. "detecting LMOs") and monitoring adverse effects of LMOs released into the environment (i.e. "detecting changes");

(h) Real-life examples of environmental monitoring that were useful in detecting the levels of risk identified in the risk assessment could be provided;

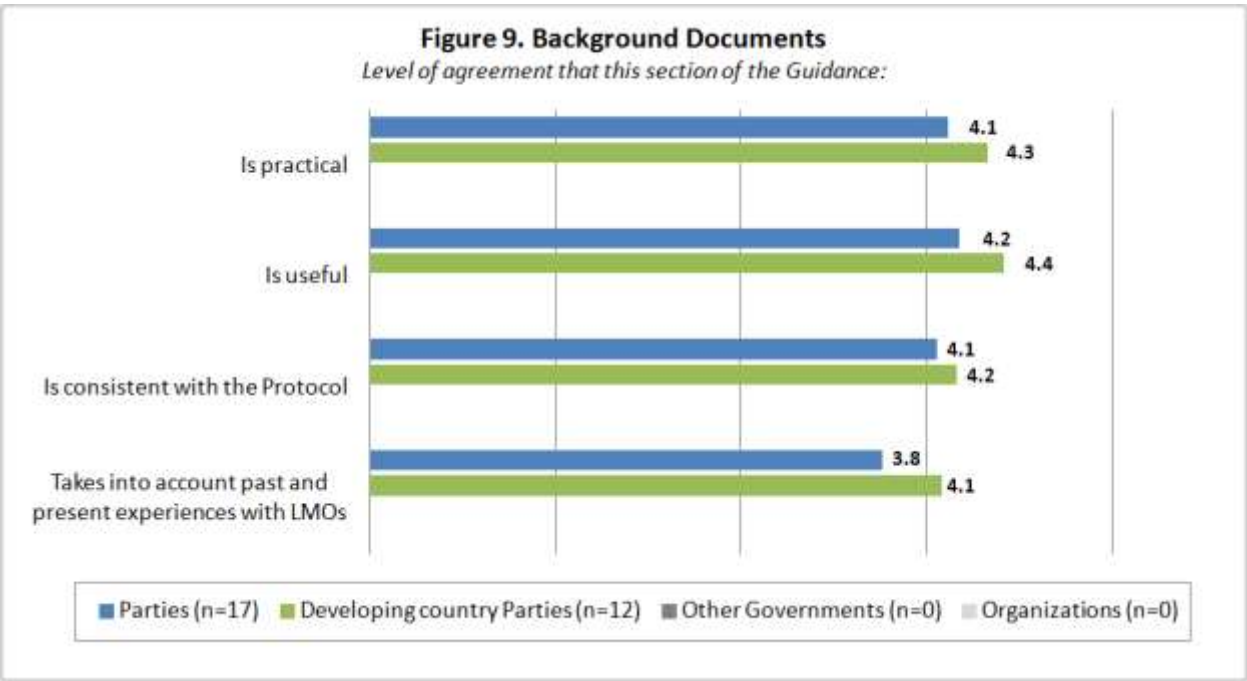
(i) To highlight consistency and interconnections between different parts of the Guidance, reference should be made to the sections contained in the Roadmap which address monitoring requirements;

(j) The terms "notifier", "competent authority", "regulators" are introduced for the first time in this section and could be explained.

vii. Background Documents

41. Among the submissions received, 17 included results for the testing of the section on "Background Documents". These submissions were all from Parties and, among these, 12 were from developing countries.

42. The following graph summarises the results of the testing of this section of the Guidance with regard to its practicality, usefulness, consistency with the Protocol and accounting for past and present experiences with LMOs (Fig. 9).



D. CONCLUDING REMARKS

43. As per decision BS-VI/12, the testing of the Guidance in actual cases of risk assessment focused on four criteria, i.e. its practicality, usefulness, consistency with the Protocol and the extent to which past and present experiences with LMOs are taken into account.

44. On average, there was a high level of agreement that the Guidance is practical, useful, and consistent with the Protocol taking into account past and present experience with LMOs.

45. When the results were segmented according to the type of submission, the level of agreement that the different sections of the Guidance are practical, useful and consistent with the Protocol taking into account past and present experience with LMOs was generally the highest among the Parties, followed by organizations and thirdly by other Governments.

46. Among the submissions by Parties, the level of agreement that the different sections of the Guidance fulfil the criteria tested was higher among developing countries. It is noted that, in a recent survey to gather information corresponding to the indicators in the Strategic Plan for the Protocol, seven Parties (i.e. Croatia, Pakistan, Finland, Malaysia, Peru, Sri Lanka and Tajikistan) reported that they are using the Guidance on Risk Assessment of LMOs for the purpose of conducting risk assessment or for evaluating risk assessment reports submitted by notifiers.[5] Among these Parties, six are developing countries. Taken together, the results of the testing of the Guidance and the survey on the indicators of the Strategic Plan suggest that the Guidance on Risk Assessment of LMOs is useful to Parties, in particular those that are developing countries.

47. For most sections of the Guidance, the criteria of usefulness and consistency with the Protocol were rated higher than the criteria of practicality and taking into account past and present experiences with LMOs. Therefore, improving the practicality and the extent to which the Guidance takes into account available experience with LMOs could be the primary focus of further improvements, as appropriate, including, as recommended by several respondents, simplifying the language of the Guidance and adding examples of real cases throughout the text.

[5] The results of the survey on the indicators of the Strategic Plan will be forwarded for consideration of the COP-MOP at its seventh meeting.

Annex 1

Concept note regarding the testing of the Guidance on Risk Assessment of LMOs

1. In decision BS-VI/12,[6] the Conference of the Parties serving as the meeting of Parties to the Cartagena Protocol on Biosafety (COP-MOP) commended the progress made on the Guidance on Risk Assessment of Living Modified Organisms, clearly understanding that:

(a) The Guidance is not prescriptive and does not impose any obligations on Parties;

(b) The Guidance will be tested nationally and regionally for further improvement in actual cases of risk assessment and in the context of the Cartagena Protocol on Biosafety.

2. Furthermore, with regard to the testing of the Guidance, the COP-MOP:

(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.

3. 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.

4. Furthermore, the COP-MOP also mandated the Open-Ended Online Forum and the AHTEG on Risk Assessment and Risk Management 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.

5. Accordingly, the Secretariat is setting up the process of testing the Guidance as follows:

Testing process:

(a) The objective of the testing is to evaluate the practicality, usefulness and utility of the Guidance on Risk Assessment of Living Modified Organisms with respect to consistency with the Cartagena Protocol on Biosafety, in particular Article 15 and Annex III, and taking into account past and present experiences with living modified organisms;

(b) The testing may be conducted by Parties, other Governments and relevant organizations through their risk assessors and other experts who are actively involved in risk assessment;

[6] Available at http://bch.cbd.int/database/attachment/?id=13599.

(c) The testing may be conducted by individuals or as a group initiative (e.g. workshops);

(d) The Guidance is to be tested using actual cases of risk assessment conducted in accordance with Annex III of the Cartagena Protocol, noting that the actual case of risk assessment itself is not the subject of the testing;

Actual cases of risk assessment:

(e) The technical and scientific data of actual cases of risk assessment used in the testing may originate from various sources. These sources may include application dossiers, and previous or ongoing risk assessment processes. Alternatively, the summaries of notifications may also be used;

(f) Irrespective of the source of the technical and scientific data in (e) above, the actual cases of risk assessment used in the testing must be clearly identified either through references to Risk Assessment Records in the Biosafety Clearing House (BCH), or hyperlinks to their original source;

(g) The BCH Risk Assessment Records referring to the actual cases of risk assessment used in the testing may be generated either through the regulatory process of a country or through an independent or non-regulatory process;[7]

Reporting the results of the testing:

(h) The results of the testing are to be submitted through the BCH using the questionnaire common format that is made available for this purpose;

(i) The BCH Risk Assessment Records or hyperlinks to webpages containing information on the actual cases of risk assessment used in the testing are to be linked to the questionnaire;

(j) The results of the testing conducted by Parties and other Governments are to be submitted by their respective BCH National Focal Points and those by relevant organizations through their head offices;

(k) Each Party, other Government or relevant organization may test the Guidance with as many actual cases of risk assessment available but may only complete and submit one questionnaire reporting their results.

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[7] The BCH contains two broad categories of records: "National Records" and "Reference Records". Risk assessment records generated through a regulatory process are "National Records" created and maintained by the country submitting the record, as per Article 20 paragraph 3(c) of the Cartagena Protocol on Biosafety. Risk assessment records generated through a non-regulatory or independent process are "Reference Records", which are created through means other than a country's regulatory processes, e.g. a risk assessment conducted by a relevant organization, such as a business, non-governmental or academic organization, including risk assessments that may trigger the regulatory process of a country. BCH Risk Assessment Records may be searched at http://bch.cbd.int/database/riskassessments/.