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AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY
Second meeting
Ljubljana, 19-23 April 2010

ANALYSIS OF THE OPEN-ENDED ONLINE EXPERT FORUM ON RISK ASSESSMENT AND RISK MANAGEMENT (JUNE 2009 - FEBRUARY 2010)

I. INTRODUCTION

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-IV/11, established an open-ended online forum on specific aspects on risk assessment (referred to hereinafter "the Open-ended Online Forum"[1] through the Biosafety Clearing-House (BCH) and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management in accordance with the terms of reference annexed to the decision.

2. The Executive Secretary was requested to convene two meetings of the AHTEG prior to the fifth meeting of the Parties to the Protocol, to be held in Nagoya, Japan from 11 to 15 October 2010. The Executive Secretary was also requested to convene ad hoc discussion groups of the Open-ended Online Forum and at least one real-time online conference per region prior to each of the meetings of the AHTEG.

3. To implement the various elements of the decision in a systematic manner, the Secretariat, with the approval of the COP-MOP Bureau, established a continuous process comprising: (i) an open-ended online forum; (ii) discussion groups on specific topics; (iii) two series of regional real-time online conferences (one prior to each AHTEG meeting); and (iv) two meetings of the AHTEG.

4. The first phase of the Open-ended Online Forum took place, November 2008 to February 2009, prior to the first meeting of the AHTEG held in Montreal, Canada, from 20 to 24 April 2009. During this first phase, a total of eight ad hoc online discussion groups on specific topics of risk assessment and risk management, as well as four regional real-time online conferences (Europe, Latin America, Africa and Asia) were held under the Open-ended Online Forum. An analysis of the above events was prepared by the Secretariat for the consideration of the AHTEG at its first meeting.[2]

5. The second phase of the Open-ended Online Forum took place, June 2009 to February 2010, prior to the second meeting of the AHTEG, to be held in Ljubljana from 19 to 23 April 2010.

6. As of February 2010, a total of 229 experts had been registered in the Open-ended Online Forum. Among these, 153 experts were nominated by 48 Parties, eleven experts by a total of five non-Party countries and 65 experts registered as observers.

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

[2] Available as document UNEP/CBD/BS/AHTEG-RA&RM/1/2.

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7. The present document, prepared by the Secretariat, provides an analysis of the ad hoc discussion groups and real-time online conferences that took place during the second phase of the Open-ended Online Forum.

II. AD HOC DISCUSSION GROUPS AND REAL-TIME ONLINE CONFERENCES

8. The Secretariat convened ad hoc discussion groups and regional real-time online conferences for deliberations among the experts of the Open-ended Online Forum on the substantive issues that are analysed under section III below.

9. A total of ten discussion groups were held in two rounds of events scheduled, 22 June to 12 July and from 23 November to 14 December 2009, under the Open-ended Online Forum. A total of 219 interventions were posted in the discussion groups.

10. The Second Series of Regional Real-time Online Conferences on Risk Assessment and Risk Management were also held under the Open-ended Online Forum. Four regional real-time online conferences took place for: Africa (2 February), Asia and the Pacific (4 February), Western European and Others and Central and Eastern Europe (9 February) and Latin America and the Caribbean (11 February 2010). A total of 42 national experts and 22 observers took part in the four real-time conferences with 914 interventions posted.

11. The full transcripts of the discussion groups as well as the provisional agenda, annotations and the full transcripts of the real-time online conferences are available online through the Biosafety Clearing-House.[3]

III. SUBSTANTIVE ISSUES

12. The discussion groups and real-time online conferences focused on the following topics which form the core discussions of the second AHTEG meeting:

(a) Roadmap for risk assessment;

(b) Risk assessment and risk management of living modified crops resistant or tolerant to abiotic stress;

(c) Risk assessment and risk management of living modified mosquitoes;

(d) Risk assessment and risk management of living modified organisms with stacked genes or traits;

(e) Modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and

(f) The way forward for the development of further guidance on risk assessment and risk management of living modified organisms.

13. There were a variety of views expressed during both the discussion groups and real-time online conferences on each of the substantive issues. The following synthesis attempts to summarize the most pertinent views that emerged from the interventions made under the Open-ended Online Forum between June 2009 and February 2010.

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[3] The full transcripts of the Discussion Groups are available at: http://bch.cbd.int/onlineconferences/archived_discussions_ra.shtml . The documents (provisional agenda: UNEP/CBD/BS/REGCONF-CB-RA&RM/1/1 and annotations to the provisional agenda: UNEP/CBD/BS/REGCONF-CB-RA&RM/1/Add.1) and full transcripts of the Real-time Online Conferences are available at: http://bch.cbd.int/onlineconferences/realtime_ra.shtml.

A. Roadmap for risk assessment

14. Three main broad issues were discussed during the discussion groups and real-time online conferences with regard to the Roadmap: (i) the content of the draft text; (ii) testing the Roadmap; and (iii) how to link relevant reference materials to specific sections of the Roadmap.

15. A number of specific recommendations were made with the view to improving the content of the Roadmap. Some topics generated intensive debates, for example:

(a) Some experts noted that the text on "uncertainty analysis" was complex and needed simpler language for better understanding. While others suggested that 'uncertainty assessment' should be better articulated to include the notions of: (i) what uncertainty is; (ii) how and where uncertainty arises; and (iii) different ways in which uncertainty may be addressed in the risk assessment process;

(b) Different views were also expressed with regards to the establishment of causation. Some experts suggested that establishing a "credible causal pathway" for each adverse effect is an important part of the risk assessment as this relates to determining the likelihood in step 2. On the other hand, other experts noted that while there is value in establishing pathways as a basis for further understanding, particularly for risk management options, the pathways should not be applied as criteria for hazard identification because the event leading to an adverse effect is not always known, and a credible pathway may not necessarily provide information on the likelihood of the event occurring;

(c) Different views were expressed as to whether or not co-existence is part of the risk assessment process. While some views noted that co-existence is not part of the risk assessment to identify potential adverse effects to biodiversity, others noted that when co-existence is in place, outcrossing from an LMO to sexually compatible relatives may lead to adverse environmental effects, in which case the issue needed to be addressed in the Roadmap;

(d) A number of experts were in favour of making a distinction between risk assessments for commercial releases and those for field trials in the Roadmap. In this regard, it was noted that the principles of risk assessment are the same for either commercial releases or field trials, thus the Roadmap should address all types of introduction into the environment;

(e) Many interventions suggested the inclusion of a glossary of terms in the Roadmap with some of the definitions derived from existing guidance materials, such as those published by the Organisation for Economic Co-operation and Development (OECD). On the other hand, some interventions suggested that the development of a glossary of terms be done only after the Roadmap is finalized. Adding illustrative examples throughout the text was also proposed as an alternative to a glossary;

(f) The extent to which risk management should be included in the Roadmap and whether the Roadmap sufficiently addresses the relationship between risk assessment and ways of managing risk were also points of discussion. Some views recalled that Annex III of the Protocol includes a reference to risk management strategies and this notion should, therefore, be included in the Roadmap;

(g) There was a general agreement that the inclusion of a flowchart summarizing the different steps of the risk assessment process would increase the overall understanding and user friendliness of the Roadmap.

16. In the testing of the Roadmap, experts were asked by the Chair of the AHTEG Sub-Working Group on the Roadmap to complete a questionnaire. Actual cases of risk assessment were made available to assist in the testing process. The results of the testing exercise expressed a general consensus that the Roadmap is a useful tool and that it is well structured and consistent with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III. There was also some agreement that the draft Roadmap is broadly applicable to cases involving LM crops and their introduction into the environment for commercial purposes, but there was less agreement with regard to the applicability of the Roadmap to other types of LMOs (e.g., animals, fungi, bacteria, viruses, etc) or for their introduction into the environment for field trials. Some experts however noted that the Roadmap may be of limited use to less experienced risk assessors. It was also noted by a number of experts that, at the time when the testing was done, the language of the draft Roadmap was too complex for the less experienced risk assessors and should be simplified to facilitate the understanding of the concepts.

17. With regards to how the Roadmap should be linked to reference guidance materials, particularly those in the Biosafety Information Resources Centre (BIRC) of the BCH, it was noted that: (i) it is crucial to maintain an easily accessible set of reference guidance materials linked to the Roadmap but not as an integral part of it; (ii) the guidance documents should be relevant, factual and current; and (iii) a mechanism was necessary for ensuring the current of the reference guidance materials, taking into account what references should be made available and who should validate them.

B. Risk assessment and risk management of living modified crops resistant or tolerant to abiotic stress

18. The issue of how and whether the comparative approach can be used to characterize living modified crops resistant to abiotic stress in the likely receiving environment featured prominently in the discussions under this topic. Several interventions highlighted that, in the case of LMOs that are resistant to abiotic stress, including living modified crops, a straight forward comparative approach between the LMO and a non-modified organism may not be possible because the non-modified organism may never have been grown in the receiving environment where the stress conditions can prevent or severely affect the growth of the non-modified organism. Therefore, choosing good comparators could become a challenge. To address this challenge, additional molecular and phenotypic analyses of the living modified crop were recommended to characterize the LMO as a novel genotype in the receiving environment and the use of techniques for large-scale genome profiling (for example, "transcriptomics" and "metabolomics") was suggested.

19. On the other hand, some views emphasized the importance of looking at the phenotype of the LMO rather than performing a detailed genotypic characterization (e.g., sequences, insertion sites, etc) because much of the genotypic information may not be predictive enough of the resultant phenotype.

20. It was noted in some interventions that climatic changes may alter the capacity of LM crops resistant to abiotic stress to spread to and establish in climatic and geographic zones beyond those initially considered as the likely or potential receiving environments and noted that such possibilities should be taken into consideration during the risk assessment.

21. It was also noted that the guidance document on abiotic stress encompasses a broad range of LMOs and thus may become too descriptive and theoretical.

C. Risk assessment and risk management of living modified mosquitoes

22. Under this topic, the discussions focused mainly on the identification of possible hazards arising from the introduction of living modified mosquitoes aiming at combating vector-borne diseases, and possible management strategies to prevent unintended adverse effects.

23. Among the possible hazards arising from the introduction of living modified mosquitoes are: (i) transgenic mosquitoes may become vectors to parasites or viruses that cause diseases other than those being targeted; (ii) strategies for the introduction of living modified mosquitoes into the environment and their subsequent establishment may not be compatible with other vector-management strategies currently in use that aim at eradicating the mosquitoes; or (iii) an increase may occur in the abundance of other species of mosquitoes that are disease vectors as a result of a population replacement.

24. Several management options were discussed as means to minimize the risks of the living modified mosquitoes after being introduced into the environment. There was a general agreement on the need for environmental monitoring and having in place mitigation strategies in the event of unforeseen adverse effects.

25. It was also noted that the genetic stability of the living modified mosquitoes must be evaluated and the characterization of the living modified mosquitoes should include a comprehensive description of the intended LMO and the anticipated variant forms (recombinants, loss-of-function mutants, etc.) that could also be introduced into the environment as well as an analysis of the possible risks of such variant forms.

D. Risk assessment and risk management of living modified organisms with stacked genes or traits

26. Under staked genes or traits, the discussions focused primarily on the extent to which new molecular characterization of the stacked events should be undertaken and the possible interactions between the stacked inserts and their products.

27. Some participants argued that it is important to confirm that the insertion loci of the individual transformation events are stable in the stacked LMO in order to appropriately assess the risks. This may be achieved by checking that the presence and structure of the individual inserts and their inheritance mode. On the other hand, other participants argued that there is no need for additional molecular characterisation after cross breeding individual transformation events to produce stacked LMOs.

28. With regards to the molecular characterization of the stacked LMO, it was noted that it is important that the individual inserts can be detected by using existing event-specific molecular markers.

29. It was further noted that consideration should be given to specific information on the potential for interactions between the stacked proteins or modified traits in the stacked LMO.

E. Modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health

30. Under this topic, the views expressed suggested that the identification of LMOs that may have adverse effects on biodiversity is not an easy task due to the complexity of the issue and the case-by-case nature of the risk assessments.

31. Recommendations were made to split this task into a number of more specific questions, and some interventions proposed possible modalities for cooperation such as regional workshops and meetings, online discussions, coordinated research projects, monitoring and surveillance plans, including the involvement of regional detection laboratories, and information sharing.

32. With regards to information sharing, some interventions highlighted the importance of submitting to the Biosafety Clearing-House information on LMO applications that have been rejected on the basis of possible adverse effects posed by the LMO.

33. It was also recommended that questions be assembled to assist in the identification of LMOs or traits that may have adverse effects. A further recommendation is the setting up of criteria for validation for any such findings.

F. The way forward for the development of further guidance on risk assessment and risk management of living modified organisms

34. Under this topic, experts of the Open-ended Forum were invited to make recommendations to the Parties to the Protocol at their fifth meeting regarding the need for further development of guidance materials on specific topics of risk assessment and/or risk management, and, if they were of the view that there is a need for further development of guidance, what kind of process(es) could be considered to address this need.

35. In making recommendations to the Parties, the majority of views expressed that the development of additional guidance on risk assessment and risk management should be pursued. The possibility of incorporating information on specific cases of risk assessment into the Roadmap instead of developing further separate guidance materials was also proposed.

36. Specific topics of risk assessment and risk management that were identified during the online discussions and at the first AHTEG meeting[4] were recommended as a starting point for the development of further guidance. There were also a few additional topics identified, for example, guidance on: (i) specific types of risks pathways; (ii) risk management, including post-release monitoring of the impacts of LMOs released into the environment; (iii) uncertainty and variability analysis; (iv) a "checklist" containing critical elements of the risk assessment process; and (v) how to better link the risk assessment process under the Protocol to provisions and decisions under the Convention on Biological Diversity.

37. It was further recommended that, in the development of new guidance, a consultation among Parties be conducted. The existence of guidance developed by other international bodies (e.g. OECD, IPPC) is also recommended to be taken into consideration.

38. With regard to the mechanism for the development of further guidance, a large number of experts recommended an AHTEG, online discussions and information exchange through the BCH, or a combination of these. Additional examples of mechanisms to address the development of guidance included consultation among experts and a pool of resource experts to implement follow-up training once the guidance is developed.

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[4] Lists of specific topics of risk assessment and risk management identified during the first phase of the Open-ended Online Forum and at the first AHTEG meeting may be found in documents UNEP/CBD/BS/AHTEG-RA&RM/1/2 and UNEP/CBD/BS/AHTEG-RA&RM/1/3.