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Fifth meeting
Nagoya, 11 - 15 October 2010
Item 13 of the provisional agenda*

ANALYSIS OF THE OPEN-ENDED ONLINE EXPERT FORUM ON RISK ASSESSMENT AND RISK MANAGEMENT [1]

I. INTRODUCTION

1. The Parties to the Protocol established an Open-ended Online Expert Forum on Risk Assessment and Risk Management (referred hereafter as "Online Forum") through the Biosafety Clearing-House (BCH) with the view to identifying major issues related to specific aspects of risk assessment and risk management of living modified organisms (LMOs). The Parties further requested the Executive Secretary to convene ad hoc online discussion groups and at least one real-time online conference per region prior to each of the two meetings of the Ad Hoc Technical Expert Group (AHTEG). [2]

2. To implement the various elements of the decision in a systematic manner, the Secretariat, with the approval of the Bureau of the Conference of the Parties serving as the meeting of the Parties to the Protocol, made the necessary arrangements for 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.

3. Experts in risk assessment were nominated to the Online Forum by Parties, other Governments and relevant organizations by using the common format for nomination of Biosafety Experts. The Secretariat screened nominations for completeness and ensured that the nominees met the criteria and minimum requirements for biosafety experts as set forth in decision BS-IV/4.

4. 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 organized under the Open-ended Online Expert Forum on Risk Assessment and Risk Management.

[1] This document has also been publishes as document UNEP/CBD/BS/AHTEG-RA&RM/1/2.

[2] Decision BS-IV/11.

* UNEP/CBD/BS/COP-MOP/5/1.

/…

5. The present document provides an analysis of the discussion groups and real-time conferences prepared by the Secretariat with a view to assisting the work of the AHTEG as requested by the Parties in decision BS-IV/11. The complete transcripts of the discussion groups and regional real-time conferences are available in separate documents. [3]

II. DISCUSSION GROUPS

6. The objective of the discussion groups was to identify major issues related to specific aspects of risk assessment and risk management. A total of eight topics of discussion were chosen on the basis of recommendations made during previous risk assessment workshops. [4] These topics were:

(a) Risk assessment and risk management of transgenic fish;

(b) Risk assessment and risk management of transgenic trees;

(c) Risk assessment and risk management of transgenic microorganisms and viruses;

(d) Risk assessment and risk management of transgenic pharmaplants;

(e) Risk assessment and risk management of LMOs with stacked genes or traits;

(f) Post-release monitoring and long-term effects of LMOs released into the environment;

(g) Risk assessment and risk management of specific receiving environments; and

(h) Flowchart ("Roadmap") for risk assessment: the necessary steps to conduct risk assessment according to Annex III of the Protocol.

7. The discussion groups were organized in two rounds of four simultaneous topics, and discussions were open for 3 weeks on each topic during the period from 10 November to 19 December 2008. By the launching of the discussion groups, a total of 147 national experts from 48 countries and 36 observers had been registered to the Online Forum. Eighty-eight interventions were posted in the eight discussion groups.

III. REAL-TIME ONLINE CONFERENCES

8. Four regional real-time online conferences (referred hereafter as "real-time conferences") took place under the Online Forum. The provisional agenda, its annotations and the reports including the full transcripts of these conferences are available on the website of the Secretariat. [5]

9. The following three substantive issues were discussed during the real-time conferences:

(a) Development of a "roadmap", such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with the Annex III of the Protocol;

(b) Development of further guidance material on specific aspects of risk assessment and risk management;

(c) Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the roadmap.

[3] UNEP/CBD/BS/FORUM-RA&RM/1/1 (Discussion Groups) and UNEP/CBD/BS/REGCONF-CB-RA&RM/1/2–5 (Real-time conferences).

[4] UNEP/CBD/BS/COP-MOP/4/INF/13 – 17.

[5] Provisional agenda: UNEP/CBD/BS/REGCONF-CB-RA&RM/1/1; Annotations to the provisional agenda: UNEP/CBD/BS/REGCONF-CB-RA&RM/1/Add.1; Reports including full transcripts: UNEP/CBD/BS/REGCONF-CB-RA&RM/1/2 – 5.

10. Under item (a), participants in the real-time conferences were invited to consider (i) information that may be needed in developing a roadmap/flowchart other than that contained in paragraphs 7 to 9 ("Methodology" and "Points to consider") of Annex III to the Cartagena Protocol; and (ii) guidance materials that are directly applicable to the steps and points to consider listed in paragraphs 8 and 9 of Annex III to the Protocol.

11. Under item (b) participants were invited to prioritize the topics of earlier discussion groups, taking into consideration the availability of scientific information on these topics, the main knowledge gaps, and any other specific aspects of risk assessment and risk management that may be considered for the development of guidance materials.

12. Under item (c) the participants were invited to provide recommendations to the AHTEG on how to design an action plan for the development of guidance materials and the roadmap. According to the terms of reference of the AHTEG, this action plan should include the details of a process for monitoring and reviewing the progress in each of the issues dealt by the Group. The action plan is to be reviewed at the second meeting of the AHTEG to ensure that the terms and procedures established in its first meeting were followed.

13. The participants in the real-time conferences were also asked if they would be available to assist the AHTEG in achieving their mandate during the period prior to its second meeting, and, if so, in which areas they would be able to provide assistance. Participants showed a strong support to the work of the AHTEG as evidenced by the high level of readiness to offer assistance. A table with the compilation of the areas in which the experts expressed their availability to collaborate with the work of the AHTEG is annexed to the present document.

14. The real-time conferences took place on 28 January (Europe), 3 February (Latin America), 10 February (Africa) and 17 February 2009 (Asia). A total of 49 national experts from 32 countries and 12 observers took part in the four real-time conferences and 910 interventions were posted.

IV. SUBSTANTIVE ISSUES

15. The discussion groups and real-time conferences focused on topics that were relevant to the work of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management. Interventions during the discussion groups and real-time conferences expressed a variety of views on each of the substantive issues. The following synthesis attempts to summarize the most prominent views that emerged from the Online Forum. The transcripts of the original interventions are available in separate documents. [6]

A. Development of a roadmap for risk assessment in accordance with Annex III of the Cartagena Protocol on Biosafety

16. The views expressed during the discussion groups and real-time conferences were in agreement that the roadmap should be a practical guide to assist risk assessors and decision makers on how to implement the provisions set out in the Annex III of the Protocol. The roadmap is envisaged to provide additional detailed guidance on how to conduct risk assessment of LMOs on the basis of the steps of the "methodology" and "points to consider" listed in paragraphs 8 and 9 of Annex III. Furthermore, the roadmap is to serve as a reference to guidance materials that are relevant to each step or point to consider. It is also envisaged that such a guide could also be helpful in the process of developing human capacity, particularly in countries where risk assessment frameworks are not yet well established.

17. While there was agreement that the roadmap must be based on the methodology and points to consider listed in Annex III of the Protocol, some views diverged as to whether or not there is a need for additional steps to those listed therein.

[6] UNEP/CBD/BS/AHTEG-RA&RM/1/INF/3 and UNEP/CBD/BS/REGCONF-CB-RA&RM/1/2 – 5.

18. A number of interventions suggested the use of a "matrix approach" for each introduced gene and potential adverse effect identified in a systematic manner. Some participants suggested that problem formulation and hazard identification should be added to the first step of risk assessment in the roadmap.

19. It was also suggested that the roadmap would provide guidance on how to (i) account for incomplete knowledge or uncertainty on the nature/consequences of the hazard as well as its probability; (ii) identify the appropriate comparators for each of the different steps of the process, including how to establish good indicators for biodiversity and ecosystem; and (iii) identify the right non-target organisms important for a particular receiving environment and how to assess the effects of the LMO on the non-target organisms.

20. A number of interventions pointed out the importance of including, in the roadmap, guidance on how to extrapolate results from small-scale field trials of short duration to commercial-scale, long-term situations, as well as from one receiving environment to others. Some interventions recommended that guidance on how to properly delimit the geographical scope of the risk assessment, particularly for LMOs that may present high mobility, such as fish, insects or algae, also be included in the roadmap.

21. A few interventions expressed the need to include provisions for socio-economic impacts of LMOs in the roadmap as part of the decision-making process.

22. With regards to the information provided in the risk assessment report submitted by the applicant, the roadmap is also expected by some participants to include guidance on how to evaluate the quality and credibility of the data that is needed for informed decision-making.

23. On the question of availability of guidance materials relevant to each step or issue in the roadmap, the participants of the real-time conferences suggested that it would be useful to classify the different documents linked to the roadmap (e.g., published scientific papers, technical reports and other non-peer reviewed material, project of guidelines, approved guidelines or guidance material). Some participants raised questions as to how documents with divergent or conflicting views could be handled and whether a mechanism could exist to validate and review the materials linked to the roadmap.

24. An example of how the roadmap could look like was posted in a discussion group: [7]

Step 1: An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health

Points to consider:

(a) The biological characteristics of the recipient organism (e.g. its taxonomic status, its origin, centres of origin and centres of genetic diversity, and a description of the habitat where the organisms may persist or proliferate) relevant for its interaction with the likely receiving environment (Annex III, 9 (a)).

Examples of supporting material:
http://www.oecd.org/document/51/0,3343,en_2649_34387_1889395_1_1_1_1,00.html,
http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/env-jm-mono(2003)11 and
http://www.olis.oecd.org/olis/2006doc.nsf/LinkTo/NT00000B8E/$FILE/JT03206674.pdf

(b) Characteristics of the vector (its identity, and its source or origin, and its host range) if used, and in as far as present in the LMO (Annex III, 9 (c)). Example of supporting material: information submitted by applicants.

(c) Characterization of the insert(s), including, as appropriate, the gene products, their level of expression, their function and physiological effect on the recipient (Annex III, 9d).

Examples of supporting material: http://www.olis.oecd.org/olis/2007doc.nsf/LinkTo/NT00002DF6/, http://bch.cbd.int/database/attachedfile.aspx?id=1904 and

[7] UNEP/CBD/BS/AHTEG-RA&RM/1/INF/3.

http://www.aphis.usda.gov/brs/canadian/usda03e.pdf.

(d) The biological characteristics of the donor organism(s) relevant for the characterization of the donor gene(s) and its genotypic and phenotypic effects in the recipient (Annex III, 9 (b)). Characterization of the resulting LMO, with a focus on identifying differences in biological characteristics between the LMO and those of the recipient organism (Annex III, 9 (e)).

Example of supporting material:
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/gmo_guidance_gm_plants_en,0.pdf

(e) Conclusions regarding the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism.

Step 2: An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism.

Points consider:

(a) Information relating to the intended use of the LMO (e.g. confined field trial, or unconfined large scale cultivation) (Annex III, 9 (g)). *Supporting information:* information submitted by applicants.

(b) Likely potential receiving environment: information on the relevant characteristics (e.g. geographical, climatic and ecological characteristics) of the likely potential receiving environment (Annex III, 9 (h)).

Step 3: An evaluation of the consequences should these adverse effects be realized.

Point to consider:

(a) Characteristics of the likely potential receiving environment (Annex III, 9 (h)), and of experience with similar consequences of traditional practices (e.g. agricultural practices, pest management) as a baseline.

Example of supporting material:
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/gmo_guidance_gm_plants_en,0.pdf

Step 4: An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized.

Example of supporting material:
http://www.efsa.europa.eu/cs/BlobServer/Scientific_Document/gmo_guidance_gm_plants_en,0.pdf

Step 5: A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks.

Points consider:

With regard to acceptability of identified risks:

(a) Likely potential receiving environment (Annex III, 9 (h)), and experience with similar consequences of traditional practices, as a baseline.

Supporting information: baseline data.

(b) Evaluation of the risk associated with the LMO in the context of the risks posed by the non-modified recipients in the likely potential receiving environment (Annex III, 9 (e)).

Supporting information: baseline data.

With regard to manageability of identified risks:

(a) Relevant management practices that are in use for the non-modified recipients, or for other organisms that require comparable risk management.

Example of supporting material: http://www.unep.org/biosafety/Documents/Techguidelines.pdf

(b) Relevant methods for detection and identification of the LMO and their specificity, sensitivity and

reliability (Annex III, 9 (f)).

Example of supporting material:
http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT0000A48A/$FILE/JT00166030.PDF

Step 6: Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Examples of supporting materials:
http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163 and
http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf

B. Development of further guidance materials on specific aspects of risk assessment and risk management

25. During the discussion groups, interventions were made for each topic listed in section II above. Subsequently, during the real-time conferences, views were invited on how to rank these topics in order of priority. [8] During the prioritization process, participants were asked to take into consideration the availability of scientific information on these topics, the main knowledge gaps, and any other specific aspects of risk assessment and risk management that may be considered for the development of guidance materials.

26. Concurrent with the recommendations of previous workshops organized by the Secretariat [9] as well as the Canada-Norway Expert Workshop on "Risk Assessment for Emerging Applications of Living Modified Organisms", [10] the majority of interventions corroborated the need for further guidance on specific issues of risk assessment.

27. The topics discussed were all considered important in terms of developing guidance materials, but the degree of importance varied considerably based on local and personal experiences. Nevertheless, the topics that emerged as the first three in terms of priority were:

(a) Risk assessment and risk management of transgenic trees;

(b) Risk assessment and risk management of LMOs with stacked genes or traits; and

(c) Risk assessment and risk management of specific receiving environments.

28. The following remarks were made under each specific aspect of risk assessment and risk management:

Transgenic trees

29. With regards to risk assessment of transgenic trees, some interventions noted that particular emphasis had to be given to pollen flow, fitness and ecological interactions due to characteristics that were inherent to trees, such as long lifespan, abundant pollen production and lack of domestication. On the other hand, some participants argued that experience drawn from crop plants may directly apply to the risk assessment of trees.

[8] It is noted that the roadmap did not enter the prioritization because this issue is included as a separate task for the AHTEG in its terms of reference.

[9] UNEP/CBD/BS/COP-MOP/4/INF/14 – 17.

[10] UNEP/CBD/BS/COP-MOP/4/INF/13.

30. It was generally agreed that there was a lack in baseline information with regard to forest ecology and clear models to predict the impact of fitness and invasiveness. Many interventions also expressed a need for the development of more baseline information including the biology of parental species and organisms, particularly in tropical environments, for use as indicators of impact.

31. Some interventions proposed that, due to the inherent characteristics of trees (e.g., long lifespan and copious pollen production), risk assessment of transgenic trees should not be limited to a particular environment or geographical location, but rather include all natural or managed forests at a global scale. On the contrary, other interventions argued that transgenic trees were not substantially different from annual crops in their characteristics with respect to risk assessment and consideration of receiving environments thus do not deserve special or more stringent risk assessments due to their potential for gene flow in diverse, wild and feral receiving environments.

32. Some participants identified the need for guidance on which questions should be addressed during the problem formulation step in the risk assessment of transgenic trees, and how to apply modeling approaches to address the temporal and spatial aspects of out-crossing of tree species.

33. The need and feasibility of field trials of transgenic trees was also discussed. A key question seems to be how to extrapolate the results from small-scale and short-period field trials to large-scale and long-term effects.

34. With regards to risk management based on strategies such as isolation and biological containment, some participants noted that the current methodologies may not suffice to prevent gene flow.

LMOs with stacked genes or traits

35. The discussions on LMOs with stacked genes or traits centred primarily on the extent to which the risk assessment of these LMOs may be inferred from the assessments done for the respective parental lines, i.e., those that were crossed for obtaining the LMO with stacked genes. While some participants argued that, if no interaction was expected between the stacked transgenes, the risk assessment of such LMOs may be based primarily on the risk assessments carried out for the parental LMOs, others expressed the view that LMOs with stacked genes had to be treated as new LMOs and, thus, the risk assessment had to be carried out accordingly.

36. The issue of whether or not additional provisions was needed for assessing the risks of this category of LMOs featured prominently in the discussions.

37. How to assess the interaction between transgenes (i.e., synergism, antagonism or no interaction), as well as DNA stability, changes in toxicity and allergenicity and segregation of the novel traits in LMOs with stacked genes or traits were mentioned as important issues that need to be addressed while assessing the potential risks.

Specific receiving environments

38. There was a shared consensus that the receiving environment plays a major role in determining potential risks that may arise from LMOs. The receiving environment is also an important factor in the development of risk management strategies for preventing potential risks or minimizing damage.

39. Specific receiving environments mentioned included, among others, centres of origin and diversification, mega-diverse regions, protected areas, areas where *in situ* collections are kept and fragile environments.

40. Some interventions pointed out that factors which may affect the capacity of dispersal of an LMO or parts of it (e.g. pollen, seeds and propagules), such as surface waters, animals and winds, must be taken into account when assessing the risks of introducing an LMO into a particular environment.

41. It was noted that guidance was needed on how to choose the appropriate indicators for a particular receiving environment, including the identification of the non-target organisms in the receiving environment that may be affected by a specific LMO or its traits.

42. With regards to knowledge gaps, it was also noted that there was a lack of baseline information for many types of environments, particularly for tropical and sub-tropical regions relating to non-target organisms, species distribution, as well as traditional agricultural practices against which to compare the possible effects (positive and negative) of an LMO.

43. Some views also emphasized that an ecological approach should be followed, in order to integrate the different aspects of the receiving environment, such as those in the context of biocenosis and the services provided by it as recommended in the ecosystems approach of the Convention on Biological Diversity. [11]

Monitoring and long-term effects of LMOs

44. Discussions on monitoring and long-term effects of LMOs focused mostly on whether or not and at what point a monitoring plan was needed, what potential adverse effects should be monitored, and on the spatial and temporal aspects of long-term monitoring. The standardization of monitoring programmes and how to store and retrieve data also featured actively in the discussions. Questions related to cost effectiveness and feasibility were also raised.

45. There was a general agreement that the objectives of long-term monitoring, as well as the parameters to be monitored should be identified and analyzed through science-based risk assessments. Based on the results of a risk assessment, specific parameters should be selected on a case-by-case basis as part of a plan to monitor long-term effects of LMOs, which may include also non-target environments or ecosystems in the case of unintentional dispersal.

46. Gene flow, invasiveness and cumulative effects of LMOs in complex ecological contexts, such as food webs, for instance, were highlighted as important issues to be considered during the hazard identification step of a risk assessment focusing on long-term monitoring.

47. Also highlighted in the discussions, was the need for more guidance on how to select indicators for LMO monitoring and how to design feasible monitoring plans, including statistical considerations and technical criteria related to frequency and duration.

48. Several participants shared the notion that a harmonization of monitoring methodologies and guidelines would facilitate data collection, interpretation and comparison across different regions.

Transgenic fish

49. Interventions made under this topic underlined the fact that transgenic fish pose potential risks that needed special focus during the risk assessment process in large part due to high level of uncertainty related to the potential adverse effects and the difficulty of remediation.

50. There was also a general agreement that the current experience in environmental risk assessment of transgenic fish using case-specific and ecologically relevant data was very limited, and that systematic and broadly accepted methodologies to assess and manage environmental risks of this type of LMOs are needed.

51. A multidisciplinary approach, which would include molecular biology, population genetics, ecology and other scientific fields, should be applied when assessing risks of transgenic fish.

[11] http://www.cbd.int/ecosystem

52. Information on methodologies for collecting basic biological data (such as ecological niches and local genotypes, identification of critical life stages and critical environmental variables and fitness components), modelling, comparators, case-studies and case-by-case protocols, including those mentioned in the report of the Canada-Norway Expert Workshop on "Risk Assessment for Emerging Applications of Living Modified Organisms",[12] should all be taken into account when developing guidelines on risk assessment of transgenic fish.

53. With regard to knowledge gaps, some interventions stated that: (i) there was a lack of baseline information on basic biology, physiology and ecology of many fish species; (ii) methods for quantifying the environmental impacts of transgenic fish in the wild were lacking, and measurements of a specific environmental impact, such as the effect on escaped farmed fish on the local food chain, could be very challenging; and (iii) gaps also exist in human and institutional capacity needed to conduct science-based risk assessments of transgenic fish.

Transgenic pharmaplants

54. The potential risks associated with the introduction into the environment of pharmaplants captured some attention during the discussions on pharmaplants (i.e., plants that were genetically engineered to produce pharmaceutical compounds). Interventions mentioned that risks arising from gene flow within and among species, effects on non-target organism, including human exposure to allergens, were all of particular importance.

55. Some participants argued that the production of pharmaceutical proteins in plants in the environment would introduce novel risks as compared to other LMOs, and would, therefore, require specific considerations in the framework of risk assessment. On the other hand, other participants argued that the potential risks of pharmaplants were no greater than those of some transgenic crop plants that were currently being commercialized.

56. With regards to risk management strategies, the discussions focused on the efficiency of current strategies for physical and biological containment. Some participants were of the view that high levels of containment and special handling are likely to mitigate or eliminate any significant hazard to biodiversity, whereas others expressed that current containment technologies would not be sufficient to stop the flow of transgenes and, therefore, for the foreseeable future, pharmaplants should only be allowed under contained laboratory conditions.

Transgenic microorganisms and viruses

57. Discussion on this topic focused on the release of transgenic microorganisms and viruses into the environment. Some participants argued that the current knowledge on ecological and evolutionary aspects of microorganisms and viruses was not sufficient to conduct proper risk assessments of these LMOs.

58. Selection was noted to be the overall key issue that determined the potential unintended impacts of a transgenic microorganism or virus coupled with their long-term survival or of their DNA molecules. Risk assessments of transgenic microorganisms and viruses had to also consider the relevant tempo-spatial population dynamics.

59. It was also noted that limited understanding of key environmental processes presented a challenge to risk assessment of transgenic microorganisms and viruses. A better understanding of the various aspects of evolution and population dynamics of microorganisms and viruses was highlighted as crucial for the development of baseline information that could be used for risk assessments.

60. The difficulties in monitoring the distribution of microorganisms and viruses once they had been released into the environment, particularly due to their ubiquitous presence in a wide range of substrates were also noted.

[12] UNEP/CBD/BS/COP-MOP/4/INF/13.

Need for guidance on additional specific aspects of risk assessment and risk management of LMOs

61. In addition to the topics mentioned above, the need to develop further guidance materials was also expressed with regard to other specific aspects of risk assessment. The development of further guidance materials was suggested for the following topics:

- Risk assessment/management of transgenic plants for biofuels;
- Transgenic animals, particularly those used for food;
- Transgenic organisms for bioremediation, taking into account the accumulation of toxic compounds in the LMOs themselves;
- Methodology concerning uncertainty analysis as an important part of the overall risk assessment;
- How to assess the issue of "co-existence" between LMOs and non-LMOs in the context of small-scale and "mosaic" farming;
- Problem formulation and hazard identification, including the definition of hazard;
- How to quantify data and apply statistical analyses;
- How to infer a global risk once individual risk factors have been analyzed;
- How to indentify LMOs (or traits/genes) that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in the context of paragraph 4 or Article 7 of the Protocol.

C. Defining an action plan for the development of guidance materials on specific prioritized aspects as well as the roadmap

62. The participants in the real-time conferences recommended that the AHTEG may wish to undertake parallel paths for the development of the roadmap and further guidance materials on the prioritized specific aspects of risk assessment. This implied the establishment of small working groups or tasks forces to tackle each of the issues during the period prior to the second meeting of the Group in 2010. These small working groups could comprise of participants of the AHTEG as well as other experts who had offered their assistance.

63. Due to budgetary constraints, it was recommended that online tools could be the primary choice of instrument to assist the work of the AHTEG. Among these, real-time online conferences could be used as a tool for discussions on targeted and concrete questions. E-mail exchange could also be used as preparatory work for the real-time discussions, for instance, to formulate, as appropriate, guiding questions to facilitate the real-time conferences. Questionnaires and videoconferences were also mentioned as possible tools to facilitate the exchange of information.

64. It was also noted that dedicated online spaces (i.e., webpages) could be established for each of the issues being addressed, possibly through the BCH, where the AHTEG and other experts may share and discuss views, upload documents, follow-up on the progress, etc.

65. With regard to the process for monitoring and reviewing of the progress of the AHTEG on each of the issues, a recommendation was made to consider the use of an approach called "Plan-Do-Check-Act cycle", which is a problem-solving method typically used for process improvement that constantly monitors the results and adjust actions as appropriate.

66. The participants of the Online Forum also suggested that the AHTEG may wish to consider a recommendation to the Parties to the Protocol to extend the development of further guidance materials and, as appropriate, the roadmap into more harmonized guidelines. It was also suggested that, at a more advanced stage of drafting of the guidelines, virtual expert consultation meetings could be held for each of the topics, followed by face-to-face AHTEG meetings. The outcome could then be submitted to the Parties to the Protocol during its sixth and subsequent meetings.

Annex

COMPILATION OF PLEDGES BY EXPERTS TO ASSIST THE AD HOC TECHNICAL EXPERT GROUP [13]

Expert	Affiliation	Details
Roadmap		
Wendy Hollingsworth	Barbados – Party	Roadmap
Eliana Fontes	Brazil – Party	Roadmap, for instance, for improving risk assessment, knowledge gaps, methodologies to be developed or analyzed, including non-target organisms
Leticia Pastor Chirino	Cuba – Party	Roadmap
Maria de Lourdes Torres	Ecuador – Party	Roadmap in mega-diverse regions
Ossama Abdel-kawy	Egypt – Party	Roadmap (e.g. with respect to the improvement of RA, knowledge gaps, etc)
Beatrix Tappeser	Germany – Party	Roadmap e.g. with respect to the improvement of RA, knowledge gaps, methodologies to be developed or discussed, including monitoring methodologies
Marja Ruohonen-Lehto	Finland – Party	roadmap
Adriana Otero-Arnaiz	México – Party	Roadmap or flowchart
Hans Bergmans	Netherlands – Party	Roadmap
Halimatu Saadiyya Idris	Nigeria – Party	Development of the roadmap
Ricarda Steinbrecher	Federation of German Scientists (Vereinigung Deutscher Wissenschaftler) – Observer	The whole RA roadmap in general
Hector Quemada	Program for Biosfety Systems/Calvin College – Observer	Developing the steps of the roadmap
Michael Schechtman	United States of America – Non-Party	Roadmap
Camilo Ignacio Rodriguez-Beltran	Independent scientific researcher/consultant Biosafety programme – Observer	Roadmap based on the methods used at INBI-Genok
Transgenic fish		
Behzad Ghareyazie	Islamic Republic of Iran – Party	Transgenic fish
Transgenic trees		
Adriana Otero-Arnaiz	Mexico – Party	Trees
Ricarda Steinbrecher	Federation of German Scientists (Vereinigung Deutscher Wissenschaftler) – Observer	RA/RM of transgenic trees, particular questions regarding uncertainty and evidence validity, where and how best to set baselines
Transgenic microorganisms and viruses		
Halimatu Saadiyya Idris	Nigeria – Party	Microbiological aspects
Remi Akanbi	AfricaBio – Observer	Microbiological aspects of RA

[13] This list includes some participants of the AHTEG because, at the time of the real-time conferences, the list of participants in the AHTEG had not yet been defined.

Expert	Affiliation	Details
Transgenic pharmaplants		
Yasuhiro Yogo	Japan – Party	Pharmaplants: weediness, plant physiology and metabolism
LMOs with stacked genes or traits		
Alejandro Hernández Soto	Costa Rica – Party	Gene stacking
Behzad Ghareyazie	Islamic Republic of Iran - Party	Staked traits
Kazuyuki Suwabe	Japan – Party	RA & RM of LMOs with stacked genes and traits
Yasuhiro Yogo	Japan – Party	Stacked genes and traits: plant physiology and metabolism
Sonny Tababa	CropLife Asia – Observer	Stacked/combined genes
Post-release monitoring and long-term effects of LMOs		
Alejandro Hernández Soto	Costa Rica – Party	Monitoring
Jorge Madriz	Costa Rica – Party	Monitoring and inspection
Leticia Pastor Chirino	Cuba – Party	Establishment of inspection and monitoring programmes
Marja Ruohonen-Lehto	Finland – Party	Monitoring issues
Kazuyuki Suwabe	Japan – Party	Post-release monitoring and long-term effects of LMOs released into the environment
Yasuhiro Yogo	Japan – Party	Monitoring and long-term effects: based on the information of soybean, canola and maize in Japan
Adriana Otero-Arnaiz	México – Party	Monitoring
Ricarda Steinbrecher	Federation of German Scientists (Vereinigung Deutscher Wissenschaftler) – Observer	Long-term effects, in particular questions regarding uncertainty and evidence validity, where and how best to set baselines
Specific receiving environments		
Elizabeth Hodson	Colombia – Party	Formulating guidance and other considerations on mega-diverse environments
Ricarda Steinbrecher	Federation of German Scientists (Vereinigung Deutscher Wissenschaftler) – Observer	Specific receiving environments, in particular questions regarding uncertainty and evidence validity, where and how best to set baselines
Yasuhiro Yogo	Japan – Party	Specific receiving environments: based on the discussion in domestic meeting on Cartagena protocol in Japan
General and other issues		
Philippe Baret	Belgium – Party	Systemic aspects of ecology and genetics
Expert	**Affiliation**	**Details**
Pisey Oum	Cambodia – Party	Developing RA and RM guideline in general
Jaroslava Ovesna	Czech Republic – Party	Plant interactions, data analysis, molecular characterization/employment of bioinformatics and related aspects
Maria de Lourdes Torres	Ecuador – Parte	Reviewing guidelines
Ossama Abdel-kawy	Egypt – Party	Other issues

Andi Trisyono	Indonesia – Party	Resistance management and non-target impacts (diversity)
Behzad Ghareyazie	Islamic Republic of Iran—j Party	Effect of LMOs on non target organisms
Maria Antonietta Toscano	Italy - Party	Biological aspects of RA
Francisca Acevedo	Mexico – Party	CONABIO would be able to assist on this process based on its experience on risk assessment, including the use of Geographic Information System (GIS) on risk assessment and the experience on compiling and developing information to support risk assessments
Hans Bergmans	Netherlands – Party	Other issues
Janet Gough	New Zealand – Party	Best practice risk analysis (all aspects). Can also provide access to peer review in some areas that we have experience in
Mahaman Gado Zaki	Niger – Party	Environmental RA
Halimatu Saadiyya Idris	Nigeria – Party	Microbiological aspects
David Quist	Norway – Party	Guidance documents
Flerida Cariño	Philippines – Party	Toxicological risk assessment, molecular data analysis, metabolism, insecticide mode of action and resistance mechanisms
John Kough	United States of America – Non-Party	Expertise on RA & RM that we have done for LMOs approved for use in the US
Remi Akanbi	AfricaBio – Observer	Microbiological aspects of RA
Philip Bereano	Retired, Univ of Washington (WashBAC)	Concern risk management, comparison of alternatives, risk communication, etc.
Hector Quemada	Program for Biosfety Systems/Calvin College – Observer	Gene flow, non-targets and problem formulation
Sonny Tababa	CropLife Asia - Observer	Environmental/food safety RA and RM, detection methods, etc.
