Ref.: SCBD/BS/CG/MPM/jh/77649 23 September 2011

N O T I F I C A T I O N

Testing of the "Guidance on Risk Assessment of Living Modified Organisms"

Dear Madam/Sir,

At the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP), the Parties welcomed the collaborative efforts of the Open-ended Online Expert Forum and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management that resulted in the "Guidance on Risk Assessment of Living Modified Organisms" (hereinafter "the Guidance").[1]

Further, the Parties noted that the Guidance is a document in evolution with an objective to provide a reference that may assist Parties and other Governments in implementing the provisions of the Protocol with regards to risk assessment, in particular its Annex III and, as such, the Guidance is not prescriptive and does not impose any obligations upon the Parties. The Parties also noted that the first version of the Guidance required further scientific review and testing to establish its overall utility and applicability to living modified organisms (LMOs) of different taxa introduced into various environments.

Between 4 February and 15 March 2011, a scientific review was carried out by Parties, other Governments and relevant organizations. A total of 33 submissions were received, of which 18 were from Parties, three from other Governments and 12 from organizations. All submissions received through the scientific review are available in the Biosafety Clearing-House (BCH).[2] The scientific review was followed by two rounds of online discussions under the Open-ended Online Expert Forum[3] and a face-to-face meeting of the AHTEG[4] to revise and improve the Guidance.

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1 Additional information on the development of the "Guidance on Risk Assessment of Living Modified Organisms" may be found in document UNEP/CBD/BS/COP-MOP/5/12.

2 Available at http://bch.cbd.int/onlineconferences/guidance_ra/review.shtml .

3 Online discussions on the revision of the Guidance took place under the Open-ended Online Forum between 28 March and 18 April 2011 and between 18 July to 6 August 2011. The comments are available at http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml .

4 The third meeting of the AHTEG was held in Mexico City, Mexico from 30 May to 3 June 2011. The report of the meeting is available at http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=4736 .

National Focal Points of the Cartagena Protocol on Biosafety (CBD when no CPB designated)
Relevant Organizations

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As a result of the above deliberations, a draft revised version of the Guidance (dated 15 September 2011) was developed and is available for the testing of its overall utility and applicability at http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml .

Accordingly, I am pleased to invite you to provide the Guidance to the experts of your country or organization involved in risk assessment of LMOs to test for its overall utility and applicability. It is noted that testing initiatives may be conducted either as a group or individual exercise, such as face-to-face meetings, workshops or online discussions, and the results are to be reported back using the attached questionnaire in order to facilitate a coordinated analysis of the results. The completed questionnaire is to be mailed to the Secretariat at riskassessment.forum@cbd.int **as a MS Word document as soon as possible but no later than 30 November 2011.**[5]

The results from testing initiatives by Parties and other Governments are to be submitted with the endorsement of the National Focal Points and those by organizations through headquarters offices.

The results of the testing, when available, will be made public through the BCH at http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml .

Please accept, Madam/Sir, the assurances of my highest consideration.

Ahmed Djoghlaf
Executive Secretary

[5] This notification and questionnaire are also available online at http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml .

Annex

QUESTIONNAIRE FOR THE TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

GENERAL INFORMATION ABOUT THE TESTING	
Q1. These results are being submitted on behalf of a:	☐ Party. Please specify: <Country's name> ☐ Other Government. Please specify: <Country's name> ☐ Organization: Please specify: <Organization's name>
Q2. When was the testing of the Guidance conducted?	Please enter date: <Text>
Q3. Type of event where the testing of the Guidance was conducted?	☐ Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: <Type here> Type of meeting: ☐ Face-to-face ☐ Online ☐ Individual exercise. Please provide your name, occupation and affiliation: <Type here> ☐ Other: Please specify: <Type here>
Q4. Which sections of the Guidance were tested?	☐ Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: ☐ Risk assessment of LMOs with stacked genes or traits ☐ Risk assessment of LM crops with tolerance to abiotic stress ☐ Risk assessment of LM mosquitoes

OVERALL EVALUATION	Very poor	Poor	Neutral	Good	Very good
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	☐	☐	☐	☐	☐
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in a scientifically sound and case-by-case manner?	☐	☐	☐	☐	☐
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs introduced into various receiving environments?	☐	☐	☐	☐	☐

PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ☐ No	Comments: <Type here>
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ☐ No	Comments: <Type here>
Q10. Is the Roadmap organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ☐ No	Comments: <Type here>
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	☐ Yes ☐ No	Comments: <Type here>
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ☐ No	Comments: <Type here>
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ☐ No	Comments: <Type here>

PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS		
Risk assessment of living modified organisms with stacked genes or traits		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol?	☐ Yes ☐ No	Comments: <Type here>
Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes of traits?	☐ Yes ☐ No	Comments: <Type here>
Q18. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>
Risk assessment of living modified crops with tolerance to abiotic stress		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q21. Does this section provide useful guidance when conducting risk assessments of LM crops with tolerance to abiotic stress(es) in accordance with the Protocol?	☐ Yes ☐ No	Comments: <Type here>
Q22. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM crops with tolerance to abiotic stress(es)?	☐ Yes ☐ No	Comments: <Type here>
Q23. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>

Risk assessment of living modified mosquitoes		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol?	☐ Yes ☐ No	Comments: <Type here>
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	☐ Yes ☐ No	Comments: <Type here>
Q28. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>

ADDITIONAL COMMENTS	
Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.	
Q31.	<Please type your comments here>
