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4 February 2011

NOTIFICATION

Scientific review of the “Guidance on Risk Assessment of Living Modified Organisms”

Madam/Sir,

At the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), the Parties welcomed the “Guidance on Risk Assessment of Living Modified Organisms” developed through collaborative efforts between the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.¹

The Parties also noted that the first version of the “Guidance on Risk Assessment of Living Modified Organisms” requires further scientific review and testing to establish its overall utility and applicability to living modified organisms of different taxa introduced into various environments. The Executive Secretary was therefore requested to:

- (i) Translate the first version of the “Guidance on Risk Assessment of Living Modified Organisms” into all United Nations languages to enable a large number of experts to take part in the review process;
- (ii) Coordinate with Parties and other Governments, through their technical and scientific experts, and relevant organizations, a review process of this first version of the “Guidance on Risk Assessment of Living Modified Organisms”;
- (iii) Make the comments of the review process available through the Biosafety-Clearing House.

Accordingly, I am pleased to invite you to undertake a **scientific review** of the “Guidance on Risk Assessment of Living Modified Organisms” among technical and scientific experts of your country or organization. The guidance document is available in all the six official languages of the United Nations at http://bch.cbd.int/onlineconferences/guidance_ra/. Attached is a review form (Annex I) to help facilitate the process in a coordinated manner. The review form should be mailed to the Secretariat at riskassessment.forum@cbd.int as soon as possible but **no later than 15 March 2011**. **Reviews from Parties and other Governments are to be submitted by their National Focal Points. Reviews from organizations are to be submitted through their head offices.**

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.

To: Cartagena Protocol on Biosafety (CPB) National Focal Points
CBD National Focal Points (where CPB focal points have not yet been designated)
Relevant organizations

At fifth meeting of the COP-MOP, the Parties also extended the current Open-ended Online Expert Forum and the AHTEG on Risk Assessment and Risk Management and mandated these groups to work together with the view to developing and achieving the following outcomes:

- (i) A revised version of the “Guidance on Risk Assessment of Living Modified Organisms”;
- (ii) A mechanism, including criteria, for future updates of the lists of background materials;
- (iii) Further guidance on new specific topics of risk assessment, selected on the basis of the priorities and needs by the Parties and taking into account the topics identified in the previous intersessional period.

The COP-MOP also urged Parties and invited other Governments and relevant organizations to nominate additional experts with experience relevant to risk assessment to the Open-ended Online Expert Forum on Risk Assessment and Risk Management and to actively participate in the online discussions.

I would like to take this opportunity to note that nominations of scientific and technical experts to the Forum may be done online at http://bch.cbd.int/onlineconferences/forum_RA.shtml . Nominations will be accepted on an ongoing basis for as long as the Forum is active, but it is strongly recommended that experts join the Forum before mid-March 2011 when the next round of online discussions is tentatively scheduled to start.

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

Ahmed Djoghlaif
Executive Secretary

Annex I

**FORM FOR THE SCIENTIFIC REVIEW OF THE
GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS**

The Guidance for Risk Assessment of Living Modified Organisms (the “Guidance”) was developed through collaborative efforts between the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.*

The aim of the Guidance is to further elaborate the methodology for risk assessment of living modified organisms (LMOs) in accordance with the Cartagena Protocol on Biosafety, and in particular in accordance with Annex III of the Protocol.

The Guidance is intended to be a “living document” that will be improved with time as new experience becomes available and new developments occur in the field of applications of LMOs, as and when mandated by the Parties to the Cartagena Protocol on Biosafety.

At the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), the Parties to the Protocol welcomed the first version of the Guidance and noted that it requires further scientific review and testing to establish its overall utility and applicability to living modified organisms of different taxa introduced into various environments.

The Executive Secretary was therefore requested to coordinate a review process of this first version of the Guidance among Parties and other Governments, through their technical and scientific experts, and relevant organizations.

The following questions are aimed at seeking views to assist the Open-ended Online Expert Forum and the AHTEG in revising the Guidance.

The completed review forms are to be mailed to the Secretariat at: riskassessment.forum@cbd.int . Reviews from Parties and other Governments are to be submitted by their National Focal Points. Reviews from organizations are to be submitted through their head offices.

* 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 (see “Official Documents” at <http://www.cbd.int/doc/?meeting=MOP-05>).

i. Reviewer's information

Please select **only one** of options below

This scientific review of the Guidance on Risk Assessment of Living Modified Organisms is 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>

ii. Overall evaluation

Please select **only one** answer for each section

Q1. How do you evaluate the level of consistency of the following sections of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q2. How do you evaluate the usefulness of the following sections of the Guidance as tools for assisting countries in conducting and reviewing risk assessments of LMOs <u>in a scientifically sound and case-by-case manner?</u>	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q3. How do you evaluate the usefulness of the following sections of the Guidance as tools for assisting countries in conducting and reviewing risk assessments of LMOs introduced into various receiving environments?

	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Q4. How do you evaluate the usefulness of the “Roadmap” as a tool for assisting countries in conducting and reviewing risk assessments of LMOs of different taxa?

	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

ADDITIONAL COMMENTS ON THE OVERALL EVALUATION

Please add any additional comment you may have regarding the overall evaluation of the first version of the “Guidance on Risk Assessment of Living Modified Organisms” below.

Q5. <Please type your comments here>

iii. Section-by-section review

Please select **only one** of the boxes for each question

PART I: THE ROADMAP FOR RISK ASSESSMENT

1. INTRODUCTION

Q6. Are all the concepts in this section relevant and accurate from a scientific point of view?

- Yes
 No. Please comment: <Type here>

Q7. Does this section include all the necessary relevant concepts?

- Yes
 No. Please comment: <Type here>

Q8. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

- Yes
 No. Please comment: <Type here>

2. THE RISK ASSESSMENT

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”

Q9. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q10. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q11. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

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

Q12. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q13. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q14. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

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

Q15. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q16. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q17. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

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”

Q18. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q19. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q20. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

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”

Q21. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q22. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q23. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

3. RELATED ISSUES

Q24. Does the “Related Issues” section include all relevant issues related to risk assessment and decision-making process but that are outside the scope of the Roadmap? Yes
 No. Please comment: <Type here>

4. FLOWCHART

Q25. Does the flowchart provide an accurate graphic representation of the risk assessment process as described in the Roadmap? Yes
 No. Please comment: <Type here>

PART II: SPECIFIC TYPES OF LMOs AND TRAITS

A. RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS WITH STACKED GENES OR TRAITS

Q26. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q27. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q28. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

B. RISK ASSESSMENT OF LIVING MODIFIED CROPS WITH TOLERANCE TO ABIOTIC STRESS

Q29. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q30. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q31. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

C. RISK ASSESSMENT OF LIVING MODIFIED MOSQUITOES

Q32. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes
 No. Please comment: <Type here>

Q33. Does this section include all the necessary relevant concepts? Yes
 No. Please comment: <Type here>

Q34. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes
 No. Please comment: <Type here>

ADDITIONAL COMMENTS ON THE SECTION-BY-SECTION REVIEW

Please add any additional comment you may have regarding particular sections of the first version of the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q35. <Please type your comments here>