



Ref.: SCBD/BS/CG/MPM/jh/77649

23 September 2011

## NOTIFICATION

### 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”).<sup>1</sup>

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).<sup>2</sup> The scientific review was followed by two rounds of online discussions under the Open-ended Online Expert Forum<sup>3</sup> and a face-to-face meeting of the AHTEG<sup>4</sup> to revise and improve the Guidance.

<sup>1</sup> 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.

<sup>2</sup> Available at [http://bch.cbd.int/onlineconferences/guidance\\_ra/review.shtml](http://bch.cbd.int/onlineconferences/guidance_ra/review.shtml).

<sup>3</sup> 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](http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml).

<sup>4</sup> 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

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](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](mailto:riskassessment.forum@cbd.int) as a MS Word document as soon as possible but no later than 30 November 2011.<sup>5</sup>

**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](http://bch.cbd.int/onlineconferences/ra_guidance/testing.shtml) .

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

Ahmed Djoghlaif  
Executive Secretary

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<sup>5</sup> This notification and questionnaire are also available online at [http://bch.cbd.int/onlineconferences/ra\\_guidance/testing.shtml](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:	<input type="checkbox"/> Party. Please specify: <Country's name> <input type="checkbox"/> Other Government. Please specify: <Country's name> <input checked="" type="checkbox"/> Organization: Please specify: Haut Conseil des biotechnologies
Q2. When was the testing of the Guidance conducted?	Please enter date: November 2011
Q3. Type of event where the testing of the Guidance was conducted?	<input checked="" type="checkbox"/> Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: Examen par le Comité scientifique du Haut Conseil des biotechnologies Type of meeting: <input type="checkbox"/> Face-to-face <input checked="" type="checkbox"/> Online <input type="checkbox"/> Individual exercise. Please provide your name, occupation and affiliation: <Type here> <input type="checkbox"/> Other: Please specify: <Type here>
Q4. Which sections of the Guidance were tested?	<input checked="" type="checkbox"/> Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: <input checked="" type="checkbox"/> Risk assessment of LMOs with stacked genes or traits <input checked="" type="checkbox"/> Risk assessment of LM crops with tolerance to abiotic stress <input checked="" type="checkbox"/> Risk assessment of LM mosquitoes

**OVERALL EVALUATION**

	Very poor	Poor	Neutral	Good	Very good
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*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?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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 <u>a scientifically sound and case-by-case manner</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving environments</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

## 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.*

<p>Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: Le texte a toutefois été jugé trop général dans l'ensemble.</p> <p>Points critiques soulevés par le CS du HCB:</p> <ul style="list-style-type: none"> <li>- Les exigences en termes d'analyses statistiques devraient être plus développées.</li> <li>- Il devrait être clarifié que les résultats bruts doivent pouvoir être obtenus sur demande s'ils ne sont pas inclus dans le dossier.</li> <li>- Problèmes éventuels liés aux pays non signataires du P de C (ex: obtention de données supplémentaires d'une société d'un pays non signataire? obtention de méthodes de détection / identification de LMO importé d'un pays non signataire?) à clarifier.</li> <li>- Définir "ecological function" (p. 6 l. 207).</li> <li>- La question des méthodes de détection/identification des LMOs devrait être développée.</li> </ul>
<p>Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: Les commentaires exposés à la question précédente sont également valables ici.</p> <p>Définir "Party involved" (l. 187 et suivantes)</p>
<p>Q10. Is the Roadmap organized in a logic and structured manner?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: &lt;Type here&gt;</p>
<p>Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: &lt;Type here&gt;</p>
<p>Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: &lt;Type here&gt;</p>
<p>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)?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: Lacunes identifiées par le CS du HCB:</p> <ul style="list-style-type: none"> <li>- le cas des essais expérimentaux n'est pas abordé</li> <li>- la surveillance des points d'entrée et voies de transports lors d'introduction de LMO pour transformation et alimentation n'est pas développée</li> <li>- les cas particuliers de LMO destinés à des usages industriels spécifiques, des utilisations pharmaceutiques ou de la phytoremédiation, ne sont pas discutés.</li> </ul>
<p>Q14. Is there any other issue or concept that you would like to see included in the Roadmap?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: Lacunes identifiées par le CS du HCB: les plans de surveillance post-commercialisation</p>

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Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?

Yes

No

Comments: <Type here>

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## 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 or 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: Il aurait toutefois été judicieux de ne pas limiter tous les exemples de stress abiotique à la tolérance à la sécheresse et à la salinité.

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:

### 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Le terme de moustiques est vague. Culicidae serait plus approprié.
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Les Culicidae se nourrissent de nectar mais leur impact sur la pollinisation devrait être décrit avec plus de précision.
Q28. Is this section of the Guidance organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Il est toutefois important de souligner le risque majeur de résistance aux insecticides dans la première partie du texte. Ce point n'est décrit que brièvement à la fin du paragraphe. Même remarque concernant le risque de dissémination par rapport au contexte environnemental (tout endroit où l'eau stagne suffisamment longtemps pour permettre le développement larvaire de l'insecte).
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: La diversité des problèmes associés aux moustiques GM est bien décrite, mais il n'y a pas d'échelle des différents risques mentionnés. L'importance de la pollinisation devrait être mieux décrite (ex: limitée ou non).
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: L'importance de l'habitat dans la capacité des moustiques de se disperser et de se multiplier n'est pas suffisamment soulignée. L. 122: Dire qu'il y a peu d'études n'est pas totalement correct: plus de 200 articles ont été publiés sur la biologie des Culicidae.

### ADDITIONAL COMMENTS

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

Q31. Remarque annexe :

La question de la coexistence est mentionnée (p. 15 l. 590) comme un sujet pouvant être pris en compte dans le processus de prise de décision en plus de l'évaluation des risques. Le CS du HCB remarque que le sujet n'est pas abordé dans le Protocole.

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