

*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](mailto: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.

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\* 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: Third World Network

**ii. Overall evaluation**

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

<b>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?</b>	<b>Very poor</b>	<b>Poor</b>	<b>Neutral</b>	<b>Good</b>	<b>Very good</b>
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" 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 checked="" type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>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></b>	<b>Very poor</b>	<b>Poor</b>	<b>Neutral</b>	<b>Good</b>	<b>Very good</b>
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" 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 checked="" type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

<b>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?</b>					
	<b>Very poor</b>	<b>Poor</b>	<b>Neutral</b>	<b>Good</b>	<b>Very good</b>
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 checked="" type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<b>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?</b>					
	<b>Very poor</b>	<b>Poor</b>	<b>Neutral</b>	<b>Good</b>	<b>Very good</b>
Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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. The Roadmap section it is a well described document and brings some innovative and well-needed aspects such as the definition of sound science. However, the wording at times does not seem to be very practical for regulators; we believe further descriptions and more concrete suggestions are needed. In particular, this would be useful for novel sections such as "overarching issues" in order to propose evaluation criteria for sound science, transparency and uncertainty. The roadmap is very useful for GM plants/crops and trees but the details are clearly not focussed on different taxa.

Despite having a homogenized writing the documents on specific LMOs are highly variable in their scope, some choose to have a very narrow scope (stacked events-only plants and conventional crossing) and others with no restriction in their scope (eg. GM mosquitoes). This brings rather unequal risk considerations and therefore an imbalanced impact of its use by regulators (ranging from background information to actual guidance).

A section with a standardized list of concepts for the whole document would be a good complement.

**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>

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Q7. Does this section include all the necessary relevant concepts?  Yes  
 No. Please comment: <Type here>

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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>

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## 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>

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

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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: Language can be understood by users, however some concepts are not defined. A list of concepts for the whole document would be useful to create a baseline of definitions.

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**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: The recommended levels of likelihood are not defined with specific criteria or means of evaluation. The points for consideration give support but not sufficient detail to enable adequate guidance on how to create levels of likelihood.

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Q13. Does this section include all the necessary relevant concepts?  Yes  
 No. Please comment: The recommended levels of likelihood are not defined with specific criteria or means of evaluation. The points for consideration give support but not sufficient detail to enable adequate guidance on how to create levels of likelihood.

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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>

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**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>

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Q16. Does this section include all the necessary relevant concepts?

Yes

No. Please comment: <Type here>

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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: Language can be understood by users, however some concepts are not defined. A list of concepts for the whole document would be useful to create a baseline of definitions.

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**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>

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

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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>

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**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>

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

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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>

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**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>

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**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>

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## 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: There is some inconsistency within the proposed references and comparator, sometimes it is described as if a reference can be used as a comparator. There is a clear challenge in this section with regard to the comparative approach, however this is not a reason for not having a clear distinction in concepts.

Profiling techniques could be -always- used as a reference strategy for analysis (regardless of whether or not the comparison with the unmodified counterpart in the stressed environment is available). As it reads, the document gives the impression that the “omics” techniques are not very useful or will only be available in the future, which is certainly not the case.

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: There is a need for a list of concepts and terms in this section.

### 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:

Q33. Does this section include all the necessary relevant concepts?

- Yes  
 No. Please comment: This section could include risk considerations in regards to unintentional transboundary movement.

Gene flow could also arise from the self-limiting strategies themselves, particularly when the techniques allow for a certain percentage of the LMO population to remain. So this is not a consideration based on the potential failure of the management strategy but on the actual reality of

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what the technology is able to offer. Therefore there is a need to properly evaluate the risk considerations of the technology used and its limitations.

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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>

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**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>*

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