SUBMISSION FROM THE PROGRAM FOR BIOSAFETY SYSTEMS (ORGANIZATION)

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: Program for Biosafety Systems (PBS)

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	☐	☐	☒	☐	☐
• Risk assessment of living modified organisms with stacked genes or traits	☐	☐	☒	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☐	☒	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☒	☐	☐

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 in a scientifically sound and case-by-case manner?

	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	☐	☒	☐	☐	☐
• Risk assessment of living modified organisms with stacked genes or traits	☐	☒	☐	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☒	☐	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☒	☐	☐

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	☐	☒	☐	☐	☐
• Risk assessment of living modified organisms with stacked genes or traits	☐	☒	☐	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☒	☐	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☒	☐	☐

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	☐	☒	☐	☐	☐

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. This roadmap for risk assessment and the additional guidance documents are thoughtful and thorough documents; However, in an effort to incorporate the views and opinions of many, the documents have lost much of their utility. This prompts an overall rating for the roadmap of 'poor' as a tool for assisting countries. While the principles may be scientifically sound, they are not described in a way that is practical. Risk Assessment must be a practical exercise as well. These guidance documents do not reflect what has worked in practice where risk assessment based on sound science has been used to make regulatory decisions.

PBS is concerned that inexperienced risk assessors would still have too many questions to be able to use this roadmap as a tool without a great deal of assistance. We believe further testing of the roadmap to evaluate its practical usefulness is still necessary. The documents could be improved significantly based on the results from this type of testing.

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: It is difficult to answer the questions

	on this form as 'yes or no'.
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment:
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: In AnnexIII of the protocol it is not clear where in the risk assessment process the adverse effects should be identified nor that they should be identified in this Step 1. The description of Step 1 in the roadmap attempts to combine identification of adverse effects with identification of novel changes that may cause adverse effects. It would be better to include a separate section on identification of adverse effects. An understanding of protection goals and identification of the adverse effects associated with those protection goals based on the modifications in the organism at the beginning of the risk assessment is a critical step in the risk assessment process and can be difficult. Some of this is captured in the section in the roadmap on context and scoping of the risk assessment. In the roadmap, the distinction between 'adverse effects' in the description of Step 1 and 'consequences' in the description of Step 3 is not clear.
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☐ No. Please comment:
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: An additional point to consider should be added here, as follows: "In the case of field trials, the level and kind of exposure in the receiving environment is likely to be minimized due to the small size of the planting, the temporary state of the planting, and the additional measures that will be imposed on the trial to maximize control over the material, minimize the possibility of gene escape, and prevent persistence of the plant material following the trial. Therefore,

	the size, duration, and confinement measures associated with the field trial are critical characteristics of the receiving environment to consider when assessing the likelihood of adverse effects associated with a field trial."
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: An additional point to consider should be added here, as follows: "In the case of field trials, it may not be possible or necessary to determine the consequences of an adverse effect associated with the cultivation of the crop plant (e.g., impacts on nontarget organisms or impacts from increased weediness following gene flow), but this may be acceptable if the exposure will be minimized sufficiently by the size, timing, and confinement measures associated with the field trial."
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: The distinction between identification of adverse effects and evaluation of consequences is not clear in this step of the roadmap.

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: Stacked genes can be assessed in the same way as other traits. This additional guidance does not explain how these traits should be evaluated differently.
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: Traits for abiotic stress toerance can be assessed in the same way as other traits. This additional guidance does not explain how these traits should be evaluated differently.
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. *As a capacity buidling organization working with countries in Africa and in Asia to build functional biosafety systems, PBS is in a position and would welcome the opportunity to assist with the evaluation through testing and*

revision based on those tests of these guidance documents, and to develop and provide relevant training materials.

Based on experience with capacity building for regulafing field trials, PBS does not see that these documents are particularly relevant to risk assessment that will aid decision-making for transboundarymovement of LMOs for 'confined field trials' for research.

Better guidance on identification of 'adverse effects' according to protection goals, and a more clear distinction between 'adverse effects' and 'consequences' is necessary. This can be one of the most critical aspects of the risk assessment, and is challenging to understand.
