SUBMISSION FROM THE GLOBAL BIOSAFETY SPECIALIST (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: Global Biosafety Specialist

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. The scientific guidance is mostly sound, but overall risk evaluations without prior consideration of risk management options will be overly precautionary and this will stifle the testing of even low risk GMOs in African environments. The consideration of risk management should be inserted between steps 3 and 4 of the Roadmap to ensure that assessors evaluate risk in full recognition of possible risk management measures. Unless this is done the recommendations will be focused on unmanaged risk and will not be a true reflection of the planned activity.

Also, uncertainty should be dealt with as an over arching issue during the introduction, and not at each step in the RA. It should be explained that risk assessment and risk management are specifically designed to enable informed decision making even when there is uncertainty and incomplete information.

The text is too complicatedfor training new assessors. A simplified training tool with examples will be needed to build capacity.

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

☐ Yes

☒ No. Please comment: The level of activity should be

view?	determined at the start of a RA review as this establishes the information requirements. The roadmap implies the need for information that will not be available for new events. If this is not set out clearly at the start, inexperienced reviewers might terminate a RA review early believing that they do not have the complete information package. This will prevent developing countries, e.g., Africa, from being able to test GMOs that may be beneficial to their development. 'Absence of risk' is not an attainable goal and should be removed or clarified. Similarly, monitoring is given too much focus - it is rarely needed and expensive - another barrier to adoption that suits some countries, but will impede others who have identified GMOs as valuable technology. The Roadmap appears to be forcing the EU precautionary stance onto all countries. This will be to the detriment on poor countries.
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Avoiding early consideration of levels of release (confined; unconfined, etc.) will make it very difficult for inexperienced assessors to approve field trials for local evaluation of GMOs. The Roadmap should clarify that there is always risk and that the aim of RA is to understand the risks associated with a planned activity and to apply risk management measures to reduce risk to an acceptable level. The document should describe 'acceptable' risk and how this varies in different communities, different cultures and in the face of different needs.
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: There is a lot of unexplained jargon and the language is too complex for new users or as a training tool.
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: Phenotypic, genotypic, molecular, stability, etc., characteristics are largely unavailable for the multiple new events that will be evaluated in field trials. Without clarifying the nature of the release at the start of the RA review and determining what information is needed for a safe activity, inexperienced reviewers will become bogged down with questions that have no relevance to the safety of the planned activity. Much of the data highlighted in this section will not be available for early trials. This needs to be clarified. The instability of genes is a natural phenomenon and should not be deemed "unsafe". Specific genes may raise safety issues if they are unstable. Only with a clearly identified risk should this become an information requirement. BUT, not at the testing stage, only prior to general release. The order in point (c) is incorrect: first assess (ii); then assess

	(iii); if sexually compatible relatives occur in the release environment, then assess (iii). If gene flow can be managed, then (iii) is not necessary. This is a good example of the need for a tiered approach to what data is needed. The Roadmap does not make this clear and without it, the data requirements are impractical. (i.e., an example of technical barriers to trade).
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Consideration of uncertainty should be dealt with at the start of the Roadmap, not in each Step. RA is designed to be able to deal with incomplete data and uncertainty. RA and risk management are precautionary steps taken to ensure sound decision making. In practice, the evaluation of each potential risk takes into account uncertainty. An example of how RA and RM manage uncertainty and deal with incomplete information would be useful. There is no guidance on identifying data that are required to assess safety (need-to-know) and data that are not required but would add a level of comfort for the decision makers (nice-to-know, but not needed for safety). Step 1 does not distinguish levels of release such as confined, unconfined and imports for food and feed processing. This distinction is made early in any GMO RA so that unnecessary data requirements can be eliminated from the information requirements.
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: This will be useful information for experienced risk assessors but is too complex for new users or for training. A simplified training version would be better for capacity building and could include examples of each point.
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: Uncertainty - see comment above. 'Likely receiving environment' - there is no clear consideration of this in Step 2, which would be fine if this question was asked right at the start. See comments above.
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Step 2 (a) should distinguish clearly between levels of release such as confined, unconfined and imports for food and feed processing. These distinctions are important so that likelihood can be evaluated with respect to the size and duration of the release and whether the release is intended for planting / reproduction in the environment.
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: See above: A glossary of terms would be useful. A training format would be needed for capacity building in developing countries.

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: The size and duration of the release is relevant to estimating the consequences of an adverse effect. Consequences can also be permanent or temporary; reversible or irreversible. Uncertainty -see previous comments.
Q16. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The size and duration of the release should be the first consideration when estimating the consequences of the release. The consequences need to be evaluated in comparison to what is currently in use - i.e., the untransformed counterpart of the GMO, and/or other technology that is currently in use.
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 language is complicated, which will make the concepts difficult to grasp for those in trianing.

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: The 'estimation of overall risk' can only be determined when the risk management options are presented. The input of risk management options is needed to reassess the acceptability of risks that without management are unacceptable.
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The overall risk cannot be assessed without consideration of risk management. Before moving onto step 4 the assessors need to have reviewed mechanisms that could be used to mitigate identified risk.
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: The text and language would need to be simplified and explained to make it suitable for capacity building in countries with little or no risk assessment experience.
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: Risk management should be considered before the assessment of overall risk. Then the risk recommendations for decision makers can summarise the identified risks and give the risk management measures that could be used to make the risk of the proposed release safer.
Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The first consideration should be the nature of the release which will define the duration and size of the release and which is essential for assessing the acceptability of risk. The order of the examples for measures that could be used to reduce uncertainty (para.4) should be reversed to reflect the order in which they are most likely to be applied. It is necessary to consider risk management measures prior to the evaluation of overall risk and RM review should be separate from the drafting of the recommendations for decision makers. Recommendations for decision makers usually include both a summary of the identified risks (RA) and those that are mostly likely to be realised during the activity. They also include a summary of the RM measures that will reduce uncertainty, help deal with incomplete information and enable the risks to be reduced to acceptable levels.

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: The language is too complex for students without RA experience.
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: The type of activity must be identified here, because short duration field trials will not impact on any of these issues (As above, risk management, should be taken into consideration before step 3). If the role of the Roadmap is to build RA capacity then it must include the application of risk management to mitigate identified risks and produce sound recommendations for decision makers. Risk levels cannot be evaluated without the consideration of appropriate risk management measures.
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: The chart draws in risk management considerations only in step 5, but overall risk cannot be assessed without RM and RA recommendations must include viable risk management options available for decision making.

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: Consideration of the potential for gene interactions should be undertaken before there is a re-assessment of molecular and expression data. If there is no clear potential impact of stacking genes then additional studies should not be needed. The field trials with the stacked events will be used to assess unintended effects. If phenotypic changes are observed in events that will be moved to general use, then additional assessments may be necessary. If there is no indication of unintended effects, then additional molecular and expression studies are not needed to assess safety.
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: As for traditional crop breeding, risks introduced during crossing of approved events will be evaluated during event selection. It is important to clarify here that collecting information without clear safety goals does not promote higher biosafety levels. Thus, unless there is evidence for new risks that have arisen from the crossing, is should not be necessary to collect additional safety data.
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: While the concepts are useful, the language is too complicated to use this section as it stands for capacity building with new risk assessors .
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: As an addition to the Roadmap there is too much duplication with the main document. This section should refer back to the Roadmap for standard RA considerations and add only those considerations that arise because of the abiotic traits. Again, the 'intended use' should be the first consideration for biosafety, because many of these considerations will not be relevant for small, confined releases. It is excessive to suggest that LMOs with improved abiotic tolerance should be assessed for all other abiotic stresses. This requirement is only necessary if evidence suggests that tolerance may be wider and then, only for those abiotic stresses that will occur in the release environment. Consideration on outcrossing should only be taken into account when outcrossing is possible in the chosen release environment. The comparitor considerations need to be clarified to consider whether standard comparators can be grown in the environment that has a strong abiotic stress. If not, what other comparator could be used to provide acceptable safety information.

	The inclusion of 'omics' is premature. Until there are clear applications of 'omics' to biosafety these should be left out as they currently raise more questions than answers when used for comparisons between plants. If 'omics' are left in the text, new reviewers may infer that data from these platforms is needed to assess safety. Clearly, this is not the case. The section on "unintended effects - Rationale" has a number of technical errors and needs to carefully edited and reworked. Remove considerations that are in the Roadmap and are not specific to abiotic stress.
Q30. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Remove all the references to concepts that are already covered in the risk assessment Roadmap and are not specific to abiotic stress.
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: This language level is much easier to understand, but the content is not as tightly presented - it wanders back and forth between general RA considerations and those that are specific for abiotic stress traits. Improving the content will help to make this a useful tool for capacity building in developing countries.
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: As for the previous section there is still too much inclusion of considerations that are reviewed for general GMOS and it is important for this section to focus on issues specific to GM mosquitoes. Clarity is needed for some of the terminology and further explanation for some broad statements, e.g. what other mechanisms for horizontal gene flow? There is no guidance on the comparators that should be used in these studies.
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: This section uses much simpler language but needs a glossary of terms to help assessors who are new to these GMOs.

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. *The Roadmap takes the very precautionary approach to risk assessment that is seen in countries wishing to use biosafety to restrict the use of GM technology. This is a free choice for countries, but if ultra precautionary language is left in the Roadmap, where it is not needed for ensuring safe releases of GMOs, it will severely restrict*

the ability of regulatory agencies in Africa to enable local farmers to assess new technology for their own use. The impact on agricultural development in countries that critically need to improve food production will be devastating and will reflect negatively on the political intend of this document.
