SUBMISSION FROM THE AFRICAN BIOSAFETY NETWORK OF EXPERTISE (ORGANIZATION)

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: African Biosafety Network of Expertise (ABNE) / African Union-NEPAD Planning and Coordinating Agency >

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 the precautionary focus will stall decision making in many countries trying to implement new biosafety processes and the text is too complex to assist countries starting out with risk assessment of LMOs. The text is too complex for capacity building in countries where there is little or no risk assessment experience. As such, the Roadmap will be a valuable reference for experienced risk assessors, but will be largely incomprehensible for those wishing to learn about risk assessment. The writing styles of the four sections of the Roadmap differ markedly. A simplified text with clear explanations that is illustrated by examples would be a much better capacity building tool.

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: The content is mostly scientifically sound, but the wording implies the need for information that will not always be available for new events and this needs to be clarified upfront in the text. As the document stands now, new reviewers might terminate a risk assessment review before they

	get to the sections that enable them to deal with applications that do not have a complete information package. This very precautionary stance will prevent developing countries, such as those in Africa, from accessing or testing technology that may be beneficial to their communities and have very little negative impact on human health or the environment, or which have an acceptable level of risk taking into consideration the benefits and the ability to manage risk. Similarly, the text suggests that monitoring is required for safe management, but this option is rarely needed and is very expensive. The cost of unnecessary monitoring can be an obstacle to adoption in developing countries. Monitoring should only be considered when there is a specific need and an effective methodology for obtaining useable results in a cost effective manner. The Introduction talks about 'an absence of risk', but does not explain that there is no such thing as zero risk - it is not an attainable goal.
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: By not distinguishing between levels of release right at the start of the risk assessment, the content implies a requirement for complex data that will not be available for field trials of new events that have not yet had approval in any country. This will make it very difficult for developing country governments to approve field trials for local assessment of available LMO events. It would be important to explain at the start that risk is always present and that risk assessment evaluates the risks of an activity and applies risk management to reduce risk to an acceptable level. There is need to describe what an acceptable level of risk is and how this will vary from product to product and among cultures and communities.
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: Language is too complex and there is no glossary of terms to help new users. For instance, terminologies such as 'protection goals' and 'assessment end-points' are unexplained jargons.
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: <The content is largely scientifically sound but point (f) needs to be right at the start of the section to help identify data that will not be needed for ensuring the safety of a confined release (field trial). Much of the molecular data noted in point (c) will not be available for the large numbers of events that will be evaluated in field trials during the event evaluation process of GMO development. Also in this section, it is not clear why stability is a safety issue. While this may be a concern for some specific constructs, it is

	mostly a commercial concern to ensure that the trait remains stable in all planting materials. Gene instability is a natural phenomenon and should not be deemed "unsafe". Point c (a) (i) is an unusual requirement. Most RA reviews look at the biology of the parent organism which includes its sexually compatible relatives. It would be more logical for risk assessors to consider point (ii) and then point (iii) and only contemplate the biology of sexually compatible species that both occur in the release environment and introgress with the LMO. This biology need not be exhaustive, but would consider the weediness and invasiveness of these plants and whether the trait would cause them to impact negatively on the release environment. The requirement for consideration of uncertainty in point (n) is so vague that it is likely to stall the development of RA recommendations for inexperienced risk assessors. This should be dealt with as an over-arching issue in this document with a clear explanation of how risk assessment is used to enable the precautionary approval of activities even when there is incomplete knowledge and some uncertainty. It would be useful for the section on dealing with uncertainty to be separate from the RA steps and to have an example of how uncertainty has been addressed using risk management measures.
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Step 1 does not clearly distinguish between levels of release such as confined, unconfined and imports for food, feed or for processing. These are important distinctions to be made early in the RA so that unnecessary data requirements can be eliminated from the RA. There is no discussion on the importance of 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).>
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 is far too complex and there is no glossary of terms to help new users. While this sets a broad outline of what might be included in risk assessments, it is not easily comprehensible to the learner and will have little value to capacity building efforts in its current format.
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: While the content is largely scientifically accurate, it is not clearly and simply explained for easy implementation by new users. The requirement for consideration of uncertainty in point (n) is so vague that it is likely to stall the adoption of RA recommendations by inexperienced risk assessors. Uncertainty should be dealt with as an over-arching issue in this document with a clear explanation of how risk assessment is used to enable the precautionary approval of activities even when there is incomplete knowledge and some uncertainty. The inclusion of uncertainty as a consideration for each step is not necessary and is problematic. This focus suggests that uncertainty is a

	primary consideration for decision making. However, uncertainty is an over arching issue that should be explained at the start of the document only. Importantly, risk assessment and risk management are the precautionary tools used to enable informed decisions even when there is uncertainty and incomplete information. By promoting these considerations at each stage, inexperienced risk assessors are very likely to be overwhelmed by the uncertainty and pull back from making a decision. We have seen this in Africa. While this approach is favoured by nations not wanting to adopt the technology, the result of this overly precautionary approach in countries wishing to evaluate GMOs is that inexperience and lack of confidence will greatly restrict the access of African farmers and communities to new technology that could be tested safely. It would be useful for the section on dealing with uncertainty to be separate from the RA steps and to have an example of how uncertainty has been addressed using risk management measures.
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Step 2 (a) does not clearly distinguish between levels of release such as confined, unconfined and imports for food, feed or for processing. These are important distinctions to be made so that likelihood can be evaluated in relation to size and duration of the release and, in the case of food grain imports, where the grain is not intended for planting. >
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: Language is too complex and there is no glossary of terms to help new users. This document might guide the development of capacity building curricula, but would not have value for teaching in its current format.
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: While the content is largely scientific, there are some omissions and again no clear differentiation between the types of releases which will establish the information necessary for evaluating consequences. The inclusion of point (e) will be a stumbling block for inexperienced assessors trying to develop safety recommendations. This should be dealt with as an over arching issue in this document with a clear explanation of how risk assessment is used to enable the precautionary approval of activities even when there is incomplete knowledge and some uncertainty. It would be useful for this separate section on dealing with uncertainty to have an example of where uncertainty has been dealt with using risk management measures.
Q16. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The rationale should include mention that consequences can be temporary or long term and can be

	reversible or irreversible. Point (a) under Points to consider, should start with a consideration of the type of activity as the size and duration of release during confined, unconfined and grain import activities have very different impacts on the consequence of environmental impact.
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 too complex and there is no glossary of terms to help new users. This document might guide capacity building curricula, but would not have value for teaching in its current format. (A measure of successful instruction in risk assessment could be the ability of the students to read, understand and apply this document.)

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: In practice, many risk assessors would look at risk management measures to mitigate unacceptable risks before moving to step 4. This seems like a logical process as the 'estimation of overall risk' can only be determined when the risk management options are presented. The inclusion of point (f) will be a stumbling block for inexperienced risk assessors and should be dealt with as an over arching issue for risk assessment. The risk assessment process is designed to deal with uncertainty and incomplete knowledge and this focus is overtly precautionary.
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: This section focuses on assessing the potential risk in the absence of risk management, which is not a realistic measure. The 'estimation of overall risk' can only be determined when the risk management options are presented. The guidance needs to include risk management considerations before 'overall risk' is evaluated, or else many easily managed risks will remain unacceptable without management options. This means that the risk assessment recommendations will be overly precautionary and will stall the progress of relatively low risk LMOs into African field testing. Risk management considerations should be inserted between steps 3 and 4 to ensure realistic evaluations of overall risk and to ensure pragmatic recommendations.
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: As mentioned before, the language in this section is complex and largely inaccessible to those wishing to learn about risk assessment. The content 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: From a practical point of view, the determination of risk management measures and the recommendations to decision makers are two separate activities. Risk management should precede Step 4 and be included in the recommendations to decision makers. 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 used.
Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: Risk management should be considered prior to the evaluation of overal risk and should be

	separate from the drafting of the recommendations for decision makers. The first point to consider should be the nature of the release and this determines the duration of the release and plays an important role in estimating acceptable risk levels. The recommendations sent to the decision makers should include a summary of the risk assessment and, highlight those risks most likely to be realised during the activity. The recommendations should clearly state the type of risk management measures that are recommended for the activity to be implemented safely.
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 trainees 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: Risk levels cannot be evaluated without the consideration of appropriate risk management measures. 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. The type of activity is important here, because short duration field trials will not impact on any of these issues (other than risk management, which should be included as part of the risk assessment recommendation process).
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 links risk management considerations and decision making as separate from risk assessment, but RA recommendations cannot be made without consideration of practical and effective risk management measures.

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: This section implies the need for reassessment of molecular and expression data. In fact, a consideration of the potential impacts of stacking should occur first. Assessement of events in field trials should be the first level of safety assessement for unintended effects. Only if phenotypes indicate changes, should additional assessment be necessary. If specific risks are identified, then it should be determined how these could be assessed and how the information would be used to improve safety. If new information is unlikely to improve safety, then collecting it is a waste of effort and time.
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The section needs to discuss the relevance of information in assessing safety and to clarify that collecting information without clear safety goals does not advance the aims of biosafety. Working from the assumption that risks introduced by conventional breeding will be identified and eliminated during event evaluation and selection (as for traditional crops), it is not necessary to include additional testing unless there is evidence of unintended effects during field trials, or if there is a potential for significant negative effects from a theoretical review of possible gene interactions in StaEv.
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: The language remains too complex for capacity building with new risk assessors and the 'use of terms' section does not include enough terms to improve readability for new risk assessors (see para 1, p.15).
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: Many of the issues cited here are routinely checked for all new LM crops and should not be included in a test that is specific to abiotic traits. E.g., p.19, para one, points (a) to (d); p.19, last para. (b); p.20, para 4; p.20 point (c); p.20 'Increased persistence and invasiveness' - the whole section; p.21 points (a), (b), (c) and (e) - only (d) is relevant. The suggestion to test LM crops with improved abiotic stress for all other abiotic stresses is excessive. This should only be required if there is a scientific reason to suggest that additional tolerance may be conferred by the new traits and then, only for those abiotic stresses that occur in the release environment. From a practical perspective, point (iv) in para 3, page 18, should be point (i) as it is the first questions regulators will ask.

	P.18, bullet 1: '…the LM crop that causes adverse effects to other organisms' - what does this mean, here? p.18, bullet 3: this need only be a consideration if there is a possibility that the LMO will reach other environments after release (e.g.,it is not relevant for confined field trials) P. 19, para. 4, last sentence: '…has never been grown' should be changed to '… cannot be grown'. (If it has never been grown, but can grow, then use it as the comparator.) p.19, para 5: remove all references to 'omics' as they have, to date, provided more questions than answers for risk assessors and should not yet be considered as a viable tool for LMO safety assessments. When the 'omics' are able to interpret risk changes, they can then be added to the document. Placing 'omics' in the document creates the impression that these technologies have relevance for risk assessment and the experts clearly state that this is not yet the case. p.20, 1st paragraph: change '… adverse effects should be identified' to '... adverse effects should be investigated'. It is not scientifically reasonable to indentify all unintended effects - only those that impact on the performance of the plant will be identified and these are the ones that are important in safety assessment. p.20 first para,last sentence: change ' … may cause adverse effects' to '…may raise new risk considerations' - p.20 para 3: What does the last sentence mean? ('Such LM crops may also transfer genes for stress tolerance at higher frequencies than observed in non-modified crops'.) Increased fertility? More pollen production? These issues are routinely investigated in all new LM crops. p.20. para 4: change '.. stresses may exist in plants.' to '… stresses do exist in plants.'
Q30. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: This section includes many concepts that are already covered in the risk assessment roadmap and should not be repeated 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: The language in this section is easier to understand, but the content is much weaker. Until the content is improved, it will have little value for capacity building in countries preparing to initiate biosafety processes.
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: Page 23, para 2: remove points (a), (b) and (c), which are in the RA roadmap, and keep only the last 2 points (d) and (e), which are specific to LM mosquitoes.

	p.25, para 1 line 4: explain 'gene drive systems' and give examples of 'other' mechanisms for horizontal gene flow. p.25, point (a) under points to consider: Change text in brackets to read 'whether or not it is an intended strategy'. p.26, first set of 'points to consider': need to provide guidance input on acceptable comparators for these studies. E.g., … as compared to untransformed mosquitoes of the same species...
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 language is more accessible than the Roadmap, but some terminology definitions would be useful. This section would make a useful capacity building tool.

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. *R*egulators in Africa need to assess risks effectively to enable farmers to test new technology for improved food production, disease control, and environmental protection. Much of the overly precautionary text in the Roadmap will make farmer evaluation of a new technology impossible on the continent. While the Roadmap will serve countries that wish to restrict the use of genetic modification, it will severely hamper the ability of developing countries to undertake safe and responsible evaluations. This effectively imposes the precautionary preference of some countries onto many developing countries that are looking for ways to feed their populations, protect the available natural resources and cope with climate change.