SUBMISSION FROM AUSTRALIA (NON-PARTY)

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: <Australia>

☐ Organization: Please specify: <Organization's name>

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. <In regard to the accompanying documents on stacked genes, abiotic stress and mosiquitoes, Australia considers that different organisms and traits do not need different risk assessment methodologies to be developed and should be deleted. The assessment method should remain the same, although the data used will differ depending on the context (trait, organism and environment). Risk management measures will be devised to manage risks identified in the risk assessment and should be proportionate to the level of risk identified.>

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: <Many would argue that "sound science" is based on falsifiability, which is not mentioned. Transparency is not a widely cited criterion for "sound science". The section on uncertainty does not provide any useful guidance on when, how and to what degree uncertainty should

	be considered. This could encourage 'paralysis through analysis' and result in reduced confidence in the risk assessment. It is recognized "that uncertainty cannot always be reduced by providing additional information", but does not mention that certain types of uncertainty can never be reduced by additional information (eg variability and linguistic uncertainty), only better characterised. Furthermore, there always remains uncertainty regarding the level of risk. This guidance material, however, does not provide indicators as to when additional information should be sought or additional management measures applied.>
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The introduction fails to give adequate regard to the wealth of experience, familiarity and scientific knowledge that already exists for the parent species (typically well know crop plants), plant breeding of similar traits, properties of the introduced genes and extensive worldwide commercial releases of LMOs since 1995, as well as, the multitude of field trials and laboratory experiments since the late 1970s. For example, no mention is made that there are no reports of adverse effects from LMOs that meet the roadmap criterion of sound science: "Sound science is based on transparency, verifiability, and reproducibility (e.g. reporting of methods and data in sufficient detail, so that the resulting data and information could be confirmed independently), and on the accessibility of data (e.g. the availability of relevant, required data or information or, if requested and as appropriate, of sample material), taking into account the provisions of Article 21 of the Protocol on the confidentiality of information." There is no mention of controls and limits that form part of the context for risk assessment of field trials. Previous releases and risk assessments can also be important for informing the context and scoping of the risk assessment. The fourth dot point in the context section on the nature and level of the information should read 'For small scale field releases, especially at early experimental stages, less information may be available or necessary compared to the information available for large scale environmental release, and for commercial scale planting.' In practice, less information is required for small scale field trials due to the controls to restrict the spread and persistence of the LMO.>
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: <The text lacks definitions of risk assessment terms such as risk, likelihood and consequences. In addition, there is widespread use of jargon that is undefined such as baseline, transgene, protection goals, assessment endpoints, risk thresholds, scientific quality.

	The dot points under “Context and scoping of the risk assessment” need subtitles and to be rearranged as they are difficult to follow.>

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: <This section is a check list approach that does not provide guidance to determine when and what information is relevant.>
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <This section should include descriptions of: the central role of conceptual models (risk scenarios or causal pathways) in identifying risks; the relationship between adverse effects and assessment endpoints; and alternative baselines (eg where the parental organism is an LMO or the LMO is the result of a cross between two different species). The use of the terms 'predicted' and 'unpredicted' are not in general use. Their meaning and relevance to risk assessment should be elaborated.>
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: <Steps 1-5 would benefit from some plain English explanations such as ‘What could go wrong?’ could be used to describe step 1. Like most other sections this section requires extensive editorial work. For example “The novel characteristics of the LMO to be considered can be genotypic or phenotypic, biological.” Is grammatically incorrect and the use of biological is ambiguous. The paragraph “The type and level of detail of the information required in this step may vary from case to case depending on the nature of the modification of the LMO and on the scale of the intended use of the LMO. For small scale field releases, especially at early experimental stages, less information may be available and some of the resulting uncertainty may typically be addressed by risk management measures” is very similar to one of the dot points in the previous section and therefore is repetitive. Part (c) is confusing (eg (ii) levels of expression [of what]; there is lack of a subject between (b) and (i); and footnote 17 refers to interaction between two (or more) genes, whereas the relevant interactions are typically between the RNA, protein or metabolite products of the introduced genes and not the genes

	themselves). Points to consider (a) to (d) do not explain their relevance to risk assessment. Suitable examples would be useful.>
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 rationale should include reference to baselines.>
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The points to consider should include: • predetermined controls (eg buffer/isolation zones, flower removal, fencing, disposal etc) that will affect the chance of interactions with the receiving environment, particularly in the case of field trials • reference to factors that affect spread of the LMO (eg reproductive ability, including time to seeding, number of seed and vegetative propagules; spread by natural means including birds, wild animals, wind, water; and spread by people including deliberate spread and accidental spread by machinery, mixed produce or farm/domestic animals) if they are increased relative to the parent organism • reference to factors that affect persistence of the LMO (eg ability of seedlings to establish amongst existing vegetation and ability to be controlled by standard managements practices) if they are increased relative to the parent organism>
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: <The second and third paragraphs overlap with each over and with point to consider (b). Points to consider (c) and (d) are closely overlapping.>
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: <There appears to be some confusion in distinguishing likelihood and consequences. For example, point (a) refers to several factors that relate to spread and persistence, a likelihood consideration. Similarly, invasiveness in point (c) is defined in many jurisdictions in terms of spread and persistence and therefore is a likelihood consideration.>
Q16. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <It could be useful to include in point (c) short and long term, and reversible and irreversible adverse effects.

	Examples of assessment endpoints could assist less experienced evaluators (eg increased competitiveness, reduced yield of crops, reduced quality of services or products such as reduced status of a nature reserve, increased habitat (food, shelter, or a suitable host) for undesirable organisms such as weeds, pests or pathogens; reduced habitat for desirable organisms; increased soil salinity; reduced water table levels; ill health in people or other desirable organisms etc).>
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: <There is varied use here and elsewhere of "non-modified recipient" and "non-modified organism of the same species".>
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 first and last sentences of the rationale contradict each other. By failing to provide any guidance on how to estimate the level of risk using widely adopted methods (eg use of a risk matrix) then a crucial decision making point is unclear and the foundations for assessing the significance of uncertainty become arbitrary. In contrast, reference is made to "indeterminate due to uncertainty or lack of knowledge". This is an obscure use for arriving at an estimate of the level of risk. Furthermore, the logic of this statement implies a tautology as 'indeterminate' and' lack of knowledge' are both forms of uncertainty. The alternative perspective that any uncertainty (including lack of knowledge) can justify an estimate of indeterminate risk is misleading. Finally, the typical interpretation of indeterminancy (as in Heisenberg uncertainty) cannot be resolved by further information.>
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The points to consider (a) – (f) are all considered previously (points (d) and (e) should have been considered at step 1). There is no indication of how these points are considered differently at step 4.>
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: <See answer to Q18.>
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: <It is misleading to suggest that "risk management options can be identified that have the potential to remove the identified risks" as zero risk is not compatible within the risk paradigm.

	The statement “Some uncertainties may be reduced by ……implementing the appropriate risk management options” is not correct as risk management accommodates uncertainty, not reduces it as the uncertainty remains.>
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: <Without definitions of “protection goals, assessement end-points and risk thresholds” (assessment is misspelt) it is difficult to understand this sentence.>
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 related issues are all to do with decision-making, their relationship to risk assessment and Annex III is not clarified. If this section is in fact ‘Related issues to decision-making’ then it would seem to be outside the scope of the Roadmap and therefore should be deleted.>
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 order of the start and overarching issues is reversed from that in the text. The processes and consequences of NO and YES responses in step 5 of the flowchart do not match the text. The flowchart is overly complicated.>
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: <The issues raised here are examples of considerations that have been raised in the Roadmap and may be better served by being referred to there. This is reinforced by the statement "LMOs with multiple transgenic traits resulting from re-transformation, co-transformation or transformation with a multigene cassette should be assessed according to the Roadmap." These can give rise to the same issues as raised in this section for stacked genes generated by crossbreeding. Pg 15 “Although recombination, mutation and rearrangements are not limited to LMOs, the combination of transgenic traits via

	cross breeding may further change the molecular characteristics of the inserted genes/gene fragments…" This is a remote risk that does not appear to be LMO specific as crossbreeding may change the molecular characteristics of any gene and in any type of cross, non-LMO x non-LMO, non-LMO x LMO or LMO x LMO. Furthermore, every individual progeny can have potentially unique genetic changes of the inserted sequences just through natural mutation, but in practice these rare changes are swamped by the selection process in any breeding program. Pg15 "The reappraisal of the molecular sequence at the insertion sites, and the intactness of the transgenes may be confirmative to the molecular characteristics of the parental LMOs, but may also be a basis for assessing any intended or unintended possibly adverse effects on the conservation and sustainable use of biological diversity in the likely potential receiving environment and of potential adverse effects on human health." This is a confusing statement whose logic is unclear. Why may a reappraisal of the insertion sites/transgenes form a basis for assessing any intended or unintended effects etc? Pg16 "The extent of the reexamination may vary case by case and take into account the results of the parental LMO risk assessment." The reexamination should definitely take into account the parental LMO risk assessment. Pg 17 "development of specific methods for distinguishing …." does not seem to fit step 5, point to consider (d) of the Roadmap and is not clear that this is a risk assessment issue, but relates more to definitional issues of what is a specific LMO that should be part of the context and scoping considerations. >
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: <Pg14 "In addition to the crosshybridising of two LMOs --- through crossbreeding of two or more LMOs" Perhaps the text should consistently use one term – "crosshybridising" or "crossbreeding" (unless these terms are meant to be different). Pg16 "For example, it should be assessed whether the different transgenes affect the same biochemical pathways or physiological processes, or are expected to or may have any combinatorial effects that may result in potential for new or increased adverse effects relative to the parent LMOs." The English grammar of this sentence needs some adjusting.

	Following is a suggested text: "For example, relative to the parent LMOs, it should be assessed whether the different transgenes in the StaEv affect the same biochemical pathways or physiological processes, or may have combinatorial effects in the StaEv that would result in the potential for new or increased adverse effects." Pg17 "Intentional and unintentional StaEvs may have altered environmental impacts as a result of cumulative and combinatorial effects of the stacked traits prevalent in different LMOs of the same species in the receiving environment." It is unclear how the second part of this sentence, beginning with the word 'prevalent', links into the first half of the sentence.>
B. RISK ASSESSMENT OF LIVING MODIFIED CROPS WITH TOLERANCE TO ABIOTIC STRESS	
	☐ Yes ☒ No. Please comment: <The concepts are relevant, but most of them are not unique to plants which have been modified with an abiotic stress trait. As such, the question of the relevance of this section arises. Consideration should be given to omitting this section unless the concepts can be justified as sufficiently different than those which form the basis of the risk assessment of other LMOs which are plants. For example: Pg18 "Questions that may be relevant to the risk assessment of LM crops with tolerance to abiotic stress in connection with the intended use and receiving environment include" then followed by four dot points.
Q29. Are all the concepts in this section relevant and accurate from a scientific point of view?	Much in the four accompanying dot points is not unique to plants modified with tolerance to abiotic stress. It could be applied to any LMO which is a plant. Pg 19 It is unclear how "transcriptomics" and "metabolomics" will be able to detect novel allergens or anti-nutrients. Pg19 (b) "Likelihood of gene flow to wild or domestic relatives" This issue would have to be considered for any transgenic plant. Pg20 "It is also possible the LM crops with enhanced tolerance to an abiotic stress could have changes in seed dormancy, viability, and/or germination rates under other types of stresses." Although these chages may be more likely to occur in LMOs with stress tolerances, these issues would have to be

considered for any transgenic plant.

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: <This section requires a number of editorial changes to assist understanding.>

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: <The material here is more useful as background information on the biology of mosquitoes and does not provide additional material that is already covered by the Roadmap.>
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: <This section requires a number of editorial changes to assit understanding>

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 text should be written consistently in British English (eg crosshybridising, pg14) or US English (eg characterization, pg 6).>