SUBMISSION FROM CANADA (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: <Canada

☐ 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.

The document would benefit from further work to more effectively fulfil the objective of providing additional guidance to annex 3, especially if the intended audience includes inexperienced risk assessors. The guidance of the Roadmap would be enhanced through alignment with current practice, appears overly prescriptive and would benefit from the acknowledgement of the importance of familiarity, and the experience with other, related LMOs. The inclusion in the Roadmap of an appendix on related issues to consider that includes reference to liability and redress, coexistence and ethical considerations while relevant to decision making, its appropriateness in terms of guidance on risk assessment is not clear.

The Roadmap is meant to apply to all LMOs yet many of the sections use specific plant and agriculture considerations but without the mitigating considerations of familiarity and deployment into agricultural ecosystems. As a consequence the Roadmap does not comprehensively represent the risk assessment of plant LMOs for agriculture nor is their adequate context for other types of non plant LMOs.

The flow chart is useful in understanding the Roadmap but not an entirely accurate description of the process of a risk assessment of an LMO.

Specific concerns:

- Some qualifying text about where data may not apply to small scale experimental field trials has been included but a full risk assessment of this type would not apply to the plant LMOs for release into a small field trial in an agricultural setting. In these cases, the release is risk managed through reproductive isolation. This document would not apply to accepted approaches for conducting a risk assessment for a small scale experimental field release of a plant LMO into an

agricultural setting. The considerations for experimental release of a non-plant LMO are outside the scope of the considerations in this document. The Roadmap should clearly state that the guidance is for large scale commercial release to avoid confusion. It would be helpful to include an introductory paragraph that explains the context for the guidance provided, e.g. it is general and may not apply to some situations such as small scale experimental field release of a plant LMO into an agricultural setting.

- The guidance is prescriptive, suggesting that there are accepted international standards for data gathering while no standards have been agreed upon yet. There is extensive text about uncertainty. More important, there is limited flexibility in the guidance to build on familiarity or existing knowledge on similar LMOs or make use of a range of unmodified comparators for the risk assessment.
- The Roadmap would benefit from inclusion of state of the art current practice in countries with well established regulatory systems. The guidance on molecular analysis is excessive and leaves the impression that extensive molecular analysis can be used to predict adverse environmental effects. In practice, risk assessors rely heavily on the phenotypic analysis of the LMO in the environment and measure its environmental interactions when compared to the unmodified comparator.
- The Roadmap includes a section on horizontal gene flow. With relation to LMO plants, the regulatory community has seriously questioned consideration of this issue. The document should specifically highlight for which types of LMOs this is an issue, explain why and provide specific guidance.
- The stacked trait document would benefit from consideration of existing extensive experience with conventional plant breeding. It exceeds reasonable guidance on the conventional breeding of plants with transgenes.
- The guidance on stress tolerant traits should consider the experience from conventional breeding. The document includes the assumption that genomic techniques are predictive and can be used to extrapolate on the behaviour of the stress tolerant phenotype. This assumption should be validated with current technology, practice and experience. The best tool for the risk assessor will be the range of comparators.

iii. Section-by-section review

*Please select **only one** of the boxes for each question*

PART I: THE ROADMAP FOR RISK ASSESSMENT

1. INTRODUCTION

☐ Yes

☒ No. Please comment .

Q6. Are all the concepts in this section relevant and accurate from a scientific point of view?	The Introduction needs to be more focused to deliver the intended message, which is the context in which the risk assessment takes place. Many concepts are introduced here without interpretation or explanation such as “endpoints” and “protection goals.” As a consequence the context for the risk assessment is not clear. While the steps of a risk assessment are described in the Roadmap, a significant enhancement would be to begin with an explanation of the concepts of risk and risk assessment as well as

	an overview of the risk assessment process. The subsection "*The risk assessment process"* is confusing. An effective addition would be an explanation of the core concepts of conducting a risk assessment, including hazard identification, assessment and evaluation. With respect to the subsection on "Overarching issues in the risk assessment process", the section on data requirements provides excessive detail compared to the rest of this section and is overly prescriptive. This section also leaves the impression that there are accepted international standards for data gathering.
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: In the subsection on "Overarching issues in the risk assessment process" the discussion on data requirements does nor reflect the "case by case" principle. This section on data also leaves the impression that there are accepted international standards for data gathering. In this section it would be helpful to mention that useful information can also be gained from the experience of farmers, seed growers, international seed production standards, agronomists guides and communication with experts. In the guidance document, risk assessors are asked to set "criteria for relevancy" without any links to protections goals or endpoints. There is no indication of what this might actually mean in real terms or how those criteria may be related to the actual process of conducting the risk assessment. Is this point really necessary? The value of the section on uncertainty needs to be more explicit. The mixture of concepts from risk assessment, risk management and risk communication in the discussion of uncertainty is somewhat confusing. It would be helpful to add an explanation as to how uncertainty is linked to risk assessment. The overall impression from this section is that a standard process of uncertainty analysis is part of the risk assessment of LMOs. While there is ongoing discussion amongst risk assessors on how to communicate the uncertainty in a risk assessment to risk managers and decision makers, an agreement or standard process is not yet in place. The guidance suggested should reflect existing international practices.
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 section on context and scoping would benefit from increased clarity and definition of basic concepts such as "endpoints, management strategies and risk thresholds. An explanation of how policy and regulation fits into the scoping process, why stakeholders would be involved or how this involvement would occur would be helpful elements to include. For an inexperienced risk assessor the useful concepts of familiarity and making use of existing experience with an LMO are not acknowledged and explained.

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 Roadmap outlines five steps that are to be taken "as appropriate". Guidance on how to determine whether a step is required would be helpful. Since the process of risk assessment is not described in the document, an inexperienced risk assessor would have difficulty how to determine whether the steps are appropriate. This section would benefit from linking the process of hazard identification with the information elements listed in the points to consider. There is an extensive and prescriptive list of considerations for molecular characterization however, it would be helpful to identify how knowledge of the insertion site, stability or the transformation method is linked to hazard identification. Molecular information is of limited predictive value and the extensive emphasis on molecular characterization in this section could be misleading.
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The discussion of comparators could be enhanced in terms of its usefulness as guidance. There is the implication that a comparator needs to be a near isogenic line and unmodified. For an LMO derived from the modification of an existing LMO, the risk assessor may use the original LMO as the comparator as well as considering the normal variation in the species. The concept of the comparative risk assessment could be better developed in the Roadmap. This section would be a useful place to explore the concept of the choice and use of a comparator and provide useful guidance.
Q11. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. The list presented as "points to consider regarding the potential adverse effects resulting from the interaction between the LMO and the receiving environment" is confusing since it includes mechanisms by which harm can occur along with the consequences of that harm occurring. The term "nontarget" is only relevant in the context of a target. The discussion on horizontal gene transfer is only applicable to certain LMOs and this should be clarified and the circumstances under which it can occur added for context. It would be helpful if the section on cumulative effects included examples and a description of its context in risk assessment. Consideration of uncertainty is inherent to the entire process. And hence not a separate consideration. The guidance would be more comprehensive if it addressed the type of uncertainty or how to deal with uncertainty.

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. Establishment and spread is considered as a potential pathway to harm and the potential for adverse effects should this occur is considered.
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Establishment and spread are identified here as potential pathways to harm. Many of the aspects that assist or mitigate these processes are not included such as dormancy, pollen viability, possibility of establishment in unmanaged ecosystems, existing methods of control etc.
Q14. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. Points to consider in step 1 and step 2 seem to be nearly identical. In step 2 the "points to consider" c and d are variations on the same consideration The language throughout this section could be simplified. Some aspects are repeated and key considerations are not present. The clarity of the document could be improved if there was a structure presentation describing how the considerations can be used to construct plausible pathways to harm so that some potential adverse effects can be discarded from further analysis.
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. Some of the points to consider" seem to be out of place and should be in step 1 or 2. It would be helpful to clarify likelihood and consequences. Point b for example, discusses direct, indirect, combinatorial and cumulative effects. These considerations would be better placed in step 1 or 2. Point d seems to be better placed in step 1.
Q16. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Consequences need to be evaluated in context and considering protection goals and endpoints. This would be an ideal area to illustrate and give examples of endpoints. This section would also be the ideal place to expand the concept of the comparator and place harm in context. A discussion on uncertainty does not fit here.
Q17. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. See comments above.

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. The risk assessor has been led to step 4 without an understanding that a probable pathway to an identifiable risk needed to be identified in the preceding steps. It is important to include this key point in the description of this step. Points d and e are incorporated at earlier stages in the risk assessment and it would be helpful to identify how they fit here. In addition, these would seem to be considerations only under a narrow set of circumstances but they might be helpful to illustrate specific examples.
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. The concepts of protection goals and endpoints introduced here would benefit from an explanation as to how these are applied in the steps of the risk assessment or how the risk assessor makes use of them. Practical guidance on evaluation of risk or any examples of how this is accomplished in practice would also be helpful.
Q20. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. See comments above. Practical examples and further elaboration would be beneficial to the target audience.
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. Characterizing step 5 as an interface between risk assessment and risk management is inaccurate since the processes are interlinked. The management options outlined in this section such as insect resistance management and herbicide tolerant management are examples of product stewardship, not risk management. It is inaccurate to state that uncertainty will be reduced with risk management options since the uncertainty will remain with the implementation of the risk management.
Q22. Does this section include all the necessary relevant concepts?	☒ Yes ☐ No.
Q23. Are all the concepts in this section expressed in a language that could be easily	☐ Yes ☒ No.

understood by the target users?	Clarifying the references to protection goals and risk thresholds would render this guidance much more useful.
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. The related issues have no relevance to the risk assessment and fall into the realm of policy and decision making. The relevance of this section should be reconsidered or better clarified.
4. FLOWCHART	
Q25. Does the flowchart provide an accurate graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ☒ No. While the flow chart is a good representation of the existing text, the usual steps taken by a risk assessor in undertaking an assessment could be better captured in the flow chart.

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. : This consideration should be covered in the Roadmap since it is intended to cover all LMOs and there is already a consideration of "combinatorial effects". It is not scientifically valid to require that the document only consider stacked LMOs that are the consequence of breeding between LMOs. This document would benefit from consideration and acknowledgement of the extensive body of literature on conventional plant breeding.
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. See comments above Q26
Q28. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. Relevant information has been omitted (see Q26). These omissions limit the utility of this section.
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. The value of this section should be made more explicit since the scope of the Roadmap was intended to cover all LMOs. Potential risks are already covered in the Roadmap. If the document considered actual products, it could be more useful.
Q30. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. The guidance would be enhanced by considering the experience from conventional breeding. The document includes the assumption that genomic techniques are predictive and can be used to extrapolate on the behaviour of the abiotic stress tolerant phenotype. This assumption should be validated with consideration of current technology, practice and experience. The best tool for the risk assessor will be the range of comparators.
Q31. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☐ Yes ☒ No. The document would be more comprehensive if it addressed the idea of the comparator and its usefulness as guidance for the risk assessor.

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. *<Please type your comments here>*