SUBMISSION FROM AUSTRIA (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: Austria

☐ Other Government. Please specify: <Country's name>

☐ 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. *Further development to elaborate the specificity of the guidance is supported; see specific comments below.*

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: <Type here>
Q7. Does this section include all the necessary relevant concepts?	☒ Yes ☐ No. Please comment: <Type here>
Q8. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>

2. THE RISK ASSESSMENT

Step 1: "An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health"

Q9. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: We appreciate the roadmap for RA, however it should explicitly stress that the scope of the assessment of adverse effects on biodiversity in step 1 is also addressing broad level issues including effects on species distribution at a broader landscape scale, effects on food webs, effects on biogeochemical aspects of the environment such as soil characteristics and fertility, among others. Concerning the points to consider regarding adverse effects resulting from the interaction between the LMO and the receiving environment, point h) (line228-232): The consideration should not be limited to the LMO and its dispersal, but should also include effects resulting from specific (agricultural) management of a LMO.
Q11. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>

Step 2: "An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism"

Q12. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q13. Does this section include all the necessary relevant concepts?	☒ Yes ☐ No. Please comment: <Type here>
Q14. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>

Step 3: "An evaluation of the consequences should these adverse effects be realized"

Q15. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q16. Does this section include all the necessary relevant concepts?	☒ Yes ☐ No. Please comment: <Type here>
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: <Type here>

Step 4: "An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized"	
Q18. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q19. Does this section include all the necessary relevant concepts?	☒ Yes ☐ No. Please comment: <Type here>
Q20. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>
Step 5: "A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks"	
Q21. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: We support that during step 5 it should be indicated how uncertainties were taken into account and how remaining uncertainties may be addressed by monitoring (Lines 369-372). However the roadmap should indicate that while monitoring is a means to address assumptions made during RA and to validate the conclusions of RA on a wider (e.g. commercial) level of application, it is not an appropriate risk management tool to reduce risks, but it can only serve as an early warning instrument for management. The guidance for Step 5 should also acknowledge that concluding a single recommendation might not be the way how to best address all cases of LMOs. For assessments associated with higher degrees of uncertainties, ambiguities and potential ignorance it is imperative that the difficulties associated with the RA are made transparent to the decision makers. It may also be favourable to provide an analysis of alternative management options for decision making in such cases. (e.g. see Stirling, A. (2010). Keep it complex. Nature 468, 1029–1031, doi:10.1038/4681029a). This should also be reflected in the description of Step 5 in the flowchart for the roadmap.
Q23. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>
3. RELATED ISSUES	
Q24. Does the "Related Issues" section include all relevant issues related to risk assessment and decision-making process but that are outside the scope of the Roadmap?	☒ Yes ☐ No. Please comment: <Type here>

4. FLOWCHART

Q25. Does the flowchart provide an accurate graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ☒ No. Please comment: The flowchart is highly appreciated, however the description (e.g. text to Figure 1) should better indicate that the procedure is an iterative process (specifically if the evaluation step indicates that not all objectives and criteria have been met, or new information or consequences of identified Risk Management Options would impact the RA).

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: <Type here>
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <It is supported that multitrait LMOs generated by other means than cross breeding between different Transformation Events should be assessed like other "newly" generated LMOs, making use of the Roadmap for Risk Assessment (see Line 11-12). However it needs to be stressed that the RA for Stacked Events (StaEv) should also be conducted according to the (general) principles outlined in the roadmap, but take into account specific issues for RA of StaEv as outlined in the StaEv-document. We therefore strongly support that the guidance requires a comprehensive assessment of the StaEv in comparison with near isogenic-varieties of the non-modified recipient species (Lines 79-82). Due to the specific nature of the StaEv, additionally further supporting data on the StaEvs might be required as outlined (Lines 83-85). However the assessment should be based on data generated for the StaEvs itself for all issues considered. The StaEv document indicates that the transgenes present in the StaEv may be unlinked and thus may segregate independently. This is specifically the case if the transgenes are inherited from different parental LMOs (see Line 33-36). However the document should stress in more detail, that a set of StaEv with different combinations of transgenes might arise in the environment upon propagation of the StaEv in question. This is due to segregation patterns of the transgenes in a specific StaEv, taking into account unintentional stacking and secondary linking of transgenes due to recombination effects. The assessment should address effects by all such StaEv with different combinations of transgenes.
Q28. Are all the concepts in this section expressed in a language that could be easily understood by the target users?	☒ Yes ☐ No. Please comment: <Type here>
B. RISK ASSESSMENT OF LIVING MODIFIED CROPS WITH TOLERANCE TO ABIOTIC STRESS	
Q29. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q30. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The guidance presents a general outline for considerations for LMOs with tolerance to abiotic stress, however it needs to be stressed that more detailed guidance is necessary for the assessment of modifications,

	which impact a range of key features of the plant, such as reproduction, composition and interaction with other species. Regarding such LMOs a variety of different consequences need to be assessed and the possibility that introduction of these LMOs into the environment might be irreversible should be considered. The points to consider concerning increased persistency (Lines 120f) should indicate this consideration: e.g. the need for and the feasibility of control measures should be considered for LMOs with traits, which might increase or establish the potential for irreversible persistence. Further guidance needs also to be developed with regard to the assessment of LMOs with tolerance to abiotic stress that cannot be assessed comprehensively by a comparative approach. The document needs to stress that while the comparative approach should be used to assess whether these LMOs have any fitness advantages (or in general: any adverse characteristics) under non-stress conditions additional approaches (and comparators) for ERA need to be implemented for assessing potential adverse effects under 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: <Type here>
C. RISK ASSESSMENT OF LIVING MODIFIED MOSQUITOES	
Q32. Are all the concepts in this section relevant and accurate from a scientific point of view?	☒ Yes ☐ No. Please comment: <Type here>
Q33. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The guidance is outlining a general framework for the assessment of LM mosquitoes, incorporating the necessary elements, incl. mentioning of appropriate risk management and monitoring considerations. However additional specific guidance is needed to better address the different applications of GM mosquitoes, which are currently under development, namely self-limiting versus self-propagating applications. Since the latter contain gene-drive systems, which promote the spread of the transgenic traits through populations (of the same or sexually compatible species), assessment needs and criteria should be specific to the characteristics of the different applications. Further development of guidance for LM mosquitoes should take into consideration that similar applications (e.g. RIDL applications for population suppression) are developed in other arthropod species. The development of further guidance should therefore target other insect species too. Additionally paratransgenic modification of mosquitoes and other arthropod species is in development as are applications to modify the characteristics of mosquitoes with non-transgenic symbionts/parasites. Since the assessment of such applications will be different from the assessment of LM mosquitoes, the development of specific guidance for such applications is also necessary.

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. <