Annex

QUESTIONNAIRE FOR THE TESTING OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

GENERAL INFORMATION ABOUT THE TESTING	
Q1. These results are being submitted on behalf of a:	☒ Party. Please specify: México ☐ Other Government. Please specify: <Country's name> ☐ Organization: Please specify:
Q2. When was the testing of the Guidance conducted?	Please enter date: NOV 30TH, 2011>
Q3. Type of event where the testing of the Guidance was conducted?	☒ Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: <The present response to the Questionnaire includes different activities (1 training workshop , meeting among evaluators at the National Insitute of Ecology and individual responses to the questionaire among experts participating in a group on charge of generating the Mexican stardard on risk assessment) > Type of meeting: ☒ Face-to-face ☐ Online ☐ Individual exercise. Please provide your name, occupation and affiliation: J. ☐ Other: Please specify: <
Q4. Which sections of the Guidance were tested?	☒ Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: ☒ Risk assessment of LMOs with stacked genes or traits ☒ Risk assessment of LM crops with tolerance to abiotic stress ☐ Risk assessment of LM mosquitoes

OVERALL EVALUATION					
	Very poor	**Poor**	**Neutral**	**Good**	**Very good**
Please indicate the level of agreement you attribute to each of the questions in the left column.					
Q5. How do you evaluate the level of consistency of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	☐	☐	☒	☐	☐
Q6. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs in a scientifically sound and case-by-case manner?	☐	☐	☒	☐	☐
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk	☐	☐	☒	☐	☐

assessments of LMOs introduced into various receiving environments?

PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	☐ Yes ☒ No	Comments: Some of the considerations are not clear, for example the repeated inclusion of uncertainty as a consideration independent of each of the steps. On the other hand the definition of monitoring seems to assume that risk assessment has not been correctly and that the monitor is going to solve.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ☒ No	Comments: Is sufficiently general to serve as a guide, but included aspects that are unclear, as the uncertainty and the monitoring. The choice of the best comparator is not quite clear, for example, does not include cases in which the modified parental may the best comparator to test pleiotropics effects in stacked events. Also the section of Related Issues, for someone with little experience could be confused as those issues are not related to risk asssessment but are still in the guidance document. In addition to the last section of RELATED ISSUES it is not part of the analysis of risk, but policies and it can be confusing for someone with little experience. The roadmap may be easier for those with experience in risk assessment. Clarification of the information that is specified in some of the points considered necessary. We consider that regulators from developing countries must have a intensive trainning course provided by experienced evaluators international organization>
Q10. Is the Roadmap organized in a logic and structured manner?	☐ Yes ☒ No	Comments: In general the structure seems clear how ever there are points to consider that are on the wrong section.
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: However an example of risk assessment would be very helpful. Also, we would appreciate if you provide more real examples of each scenario>
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☒ Yes ☐ No	Comments: <The Roadmap is general enouhg to be applied to all types of LMOs, although it woulb benefit if the use of examples is more balanced and not too centered on LM plants.>
Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?	☒ Yes ☐ No	Comments: But clarification when some information is needed or would be available needs to be enphasized.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ☒ No	Comments: He is considered better to focus only on the points that mark the annex III and article 15 of the Protocol

Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ☒ No	Comments: It is recognized that the process ir risks assessment is iterative, the graph gives the impression that it is a endless cycle.

PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS		
Risk assessment of living modified organisms with stacked genes or traits		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol?	☒ Yes ☐ No	Comments:
Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes of traits?	☐ Yes ☒ No	Comments: <the guidance may be easier for those with experience in risk assessment. Clarification of the information that is specified in some of the points considered is necessary.>
Q18. Is this section of the Guidance organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: <It is considered necessary to clarify some of the concepts contained in the Guide, to facilitate its implementation. >
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☒ Yes ☐ No	Comments:
Risk assessment of living modified crops with tolerance to abiotic stress		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q21. Does this section provide useful guidance when conducting risk assessments of LM crops with tolerance to abiotic stress(es) in accordance with the Protocol?	☒ Yes ☐ No	Comments: <Type here>
Q22. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM crops with tolerance to abiotic stress(es)?	☒ Yes ☐ No	Comments: <Type here>
Q23. Is this section of the Guidance organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: <Type here>
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☒ Yes ☐ No	Comments:

Risk assessment of living modified mosquitoes		
Please answer each of the questions in the left column with "yes" or "no" and add comments if needed.		
Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol?	☐ Yes ☐ No	Comments: <Type here>
Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes?	☐ Yes ☐ No	Comments: <Type here>
Q28. Is this section of the Guidance organized in a logic and structured manner?	☐ Yes ☐ No	Comments: <Type here>
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☐ No	Comments: <Type here>
Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☐ Yes ☐ No	Comments: <Type here>

ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the "Guidance on Risk Assessment of Living Modified Organisms" below.

Q31. *During the round of comments pass in which analyzed the guide point to point, Mexico through the consultation of experts involved in evaluation of risks to the taking of decisions by the competent authorities, made a detailed evaluation in which it expressed the need for clarification and even delve into some of the concepts contained in the Guideparticularly what it refers to the detereminación of uncertainty.*

The risk assessment is a very relevant activity that must be shared with biotech companies. Regulator must check the "available literature" to evaluate the risks. In some cases the problem is that literature is scarse International Organizations must develop some protocolos that must be part of the acompanies research duties during the GMO development as happens with synthetic pesticides.
