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: <Brasil> ☐ Other Government. Please specify: <Country's name> ☐ Organization: Please specify: <Organization's name>
Q2. When was the testing of the Guidance conducted?	Please enter date: <12/12/2011>
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: <Type here> Type of meeting: ☐ Face-to-face ☐ Online ☒ Individual exercise. Please provide your name, occupation and affiliation: <Luciana Pimenta Ambrozevicius - Federal Inspector - Ministry of Agriculture, Livestock and Food Supply (MAPA); Edilson Paiva - President of National Biosafety Committee (CTNBio); Sharon Lisauskas Campos, Ph.D, Ministry of Science, Technology and Innovation (MCTI)> ☐ Other: Please specify: <Type here>
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: A more deitaled description of Step 1 is missing in the Guidance. The definition of a risk hypothesis as "a theory that predicts the likelihood of harmful outcomes to assessment endpoints" is critical to the success of Risk Assessment and the process to elaborate this hypothesis and to analyse it based on the presented data should be better explained. Besides, The National Biosafety Committee is of the view that the RoadMap establishes criteria not foreseen in the Cartagena Protocol especially with regard to risk assessment for the environment.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ☒ No	Comments: The National Biosafety Committee is of the view that the usefulness of the RoadMap to risk assessors is affected by the absence of a common thread between questions as well as a confusing language. Besides, the RoadMap doesn't seems to consider the scientific evolution in the sector nor the history of safe use of GMOs as an element of assessment. Some Brazilian risk assessors had difficulties in using the RoadMap, especially with regard to the selection and integration of essential information listed in the "points to consider" in a logical way to make the right questions about how the assessment endpoints will respond as a result to the exposition to the LMO; the use of the data presented by the applicant to answer those questions; the evaluation if the data presented was enough refined to reduce uncertainty and if the results from some field trials can be extrapolated for the potential receiving environment in the RA.
Q10. Is the Roadmap organized in a logic and structured manner?	☐ Yes ☒ No	Comments: According to the National Biosafety Committee the most critical point of the RoadMap structure is the formulation of the problem. for MAPA, although all the steps of a RA process are presented in a structured way, some aspects, like the problem context and scope are described apart from the Conducting RA section and they are indeed essential when applying step 1 of the process. Moreover, uncertainty is presented as a concept that is part of all "points to consider" without any consideration of how the uncertainty can be reduced in the LMO RA>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☒ Yes ☐ No	Comments: According to MAPA, the way it is structured with a general description of each step and the points to consider in topics the Guidance can be considered clear . Nevertheless, according to CTNbio the Roadmap could be more user-friendly if the sutructure and the language were less confusing.

Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☐ Yes ☒ No	Comments: According to CTNBio, the Roadmap doesn't seem to consider the biological peculiarities of all types of LMOs. Most part of the aspects of the RoadMap are strictly related to plants and mosquitos. Besides, according to MCTI, the Guidance should introduce the subject of genetically modified animals and microorganisms within the generation of recombinant proteins, and some assessments could be applicable as analysis and parental effects on the environment when compared to LMOs.
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: According to CTNBio, the RoadMap does not address adequately the issues related to scale. Besides, the document seems to be primarily directed to plants and animals, disregarding microorganisms. In MAPA's view, for a risk assessor with limited experience it will be difficult to select which information will be essential for a RA of a small scale release, considering that not all the information in the guide is required in this case.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☒ Yes ☐ No	Comments: According to CTNBio, the formulation of the problem could be develop in a different manner, taking into account, inter alia, the following aspects: target of protection, parental transgenic biology, identification of the receiving environment, genetic construction with emphasis on expression of GMOs, history of safe use of genes and hosts and familiarity of the biological expected behavior. Besides, the definition of risk levels should be clearly indicated. CTNBio also suggests the table prepared by FAO as an example. For MAPA the problem formulation (Step 1) should be better adressed in the Guidance. Although all the necessary information for the PF is listed in the Step 1, there is a lacking of descrition about how to link this information in a logical way to set up a exposure scenario and generate a risk hypothesis. Also the concept of "familiarity"in the RA should be better exploited. MCTI suggest the insertion of animal, microorganisms and public perception of LMOs. >
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☐ Yes ☒ No	Comments: The flowchart is showed according to the process described in the Guidance, but again, all the steps listed in the Annex III and detailed in the Guidance could be further elaborated allowing the assessor to select and use the information listed in the "Points to consider" and to evaluate if the data presented is enough to make assumptions and predictions about how the new trait of a LMO could affect an assessment endpoint. According to CTNBio, the formulation of the problem is not in the 'flowchart', although it is the most important step in risk assessment. The absence of tables that define the level of risk in the flowchart makes the Step 2 very difficult to implement. Besides, since Steps 2 and 3 refer to the same object, it would be more appropriate to include a table in the flowchart to integrate these two elements.

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: <Type here>
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: <Type here>
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	☒ Yes ☐ No	Comments: Special attention should be given to events whose genetic material segregate. Polygenic traits exhibit different phenotypes according to the inherited genetic block. In this case the LMO should be assessed individually, particularly its interaction with human and animal health and the environment. If the event is unique and is the multiplication of genetic material occurs by cloning, from the same founding event, the analysis will be unique and ends in the genotype and phenotype of this event, and the interactions with human and animal health and the environment .
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	☒ Yes ☐ No	Comments: <Type here>

scientific and multidisciplinary activity?

Q25. 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>
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: In the field of geneticaly modified mosquitoes, the paratransgenia is under development to control, reduce or eliminate the ability of mosquitoes to transmit pathogens, mainly but not exclusively, by blocking the development of the pathogen in the vector. The paratransgenia is being focused on the use of insect symbionts, which can be genetically modified to express molecules inside the mosquito that are harmful to the pathogens they transmit. In this sense, this technique could be used and analysed case bu case tasking into consideration that vertical transfer of genes will not occur between the mosquitoes.

ADDITIONAL COMMENTS

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

Q31. With regard to Part I, the evaluation about the level of consistency of the Guidance with the Protocol was "poor" because it goes beyond the definitions of the Protocol. Besides, the Guidance takes into consideration other aspects listed in the "Related Issues" that are not part of the objective of risk assessment according to the Annex III of the Protocol. The separation of the "Setting the Context and Scope" in the so called "Planning Phase" make it difficult to understand the importance of the establishment of the "assessments endpoints" as the fundamental tool to define the risk hypothesis. An inappropriate risk hypothesis may misdirect the whole risk analysis process and lead to the imposition of unnecessary controls to reduce risk. As for Part II, Brazil appreciates the efforts made so far but believes that the text related to specific types of LMOs need to be improved in order to better address the specificities of each type of LMOs.
