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: The Netherlands ☐ 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: December 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: <Type here> ☒ Other: Please specify: Discussion in Government Office
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: However, the guidance, in particular the guidance on the steps in de ERA process , is extremely complicated. This is mainly caused by the fact that the document tries to cover many discussions that are current in the Parties that have 'hands on' experience with LMO risk assessment. This would be acceptable, if the document would at least also focus on the basics of the ERA, for instance in step 1, the assessment of the new traits in the LMO. When trying to apply the guidance to a specific application (MON810 market application) we felt that the document does not offer the basic guidance that is needed for deciding exactly what new traits there are in the LMO, and what could be the potential adverse effects caused by these traits. The document should in the first place deal with these kinds of basic questions, and only in the second place focus on the myriad of secundary discussions that are ongoing amongst more experienced Parties. However, this is a problem that can only partly be solved by revising the text of the Roadmap. We think that the text, being a general guidance, will never be able to fully inform the uninitiated about all the intricacies of environmental risk assessment of the specific case that they are dealing with. For that reason, the Roadmap refers to background documents, so that the available experience of others can be taken into account. For the usefulness of the document it will be vital that a mechanism is devised for continuously assembling lists of references, and for updating and managing these lists. This is a task for the AHTEG, and it is of vital importance that the AHTEG delivers a thoroughly considered proposal for a process that takes this issue into account, especially taking into account the needs of uninitiated users of the Roadmap.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	☐ Yes ☒ No	Comments: See Q8
Q10. Is the Roadmap organized in a logic and structured manner?	☒ Yes ☐ No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	☐ Yes ☒ No	Comments: See Q8
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	☒ Yes ☐ No	Comments: Yes, but only in principle. The Roadmap focuses mainly on GM plants, but is applicable, mutatis mutandis, to any type of GMO.

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: <Type here>
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	☐ Yes ☒ No	Comments: <Type here>
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	☒ Yes ☐ No	Comments: Yes, although discussions on details remain necessary.

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: <Type here>
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: <Type here>
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: <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: <Type here>

ADDITIONAL COMMENTS

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

Q31. For the testing process we have put an actual application (the original application for placing on the market of MON810) side by side with the Roadmap, and we have tried to put ourselves in the position of regulators that have not before done an environmental risk assessment of this type. We agree with the test results that were posted by the UK.
