*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: Ireland<br>☐ Other Government. Please specify: <Country's name><br>☐ 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><br>Type of meeting: ☐ Face-to-face ☐ Online<br>☒ Individual exercise. Please provide your name, occupation and affiliation: Dr. John O'Neill, Environment Policy Advisor, Department of Environment and National Focal Point for Protocol<br>☐ Other: Please specify: <Type here> |
| Q4. Which sections of the Guidance were tested? | ☒ Part I: The Roadmap for Risk assessment of LMOs<br>Part II: Specific types of LMOs or Traits:<br>☒ Risk assessment of LMOs with stacked genes or traits<br>☒ Risk assessment of LM crops with tolerance to abiotic stress<br>☒ Risk assessment of LM mosquitoes |

| OVERALL EVALUATION | Very poor | Poor | Neutral | Good | Very good |
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| *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.*

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| Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol? | ☒ Yes<br>☐ No | Comments: The roadmap does provide useful guidance however it could be improved in respect of how the document is structured and in providing further clarity in certain areas so that the document could go beyond being "useful". |
| Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment? | ☒ Yes<br>☐ No | Comments: Please see comments above for Q8 and below for Q10. The document could be improved for ease of use for the end user. |
| Q10. Is the Roadmap organized in a logic and structured manner? | ☒ Yes<br>☐ No | Comments: Improvement could be made on the structure. For example the text is quite dense in places which can be confusing for the reader. In the preface it should very much stand out that part I is the Roadmap and the illustrative flowchart should be introduced at the outset (i.e. background section) rather than as an annex on page 16. The fact that the report is broken into Part(s) 1 & 2 with the latter having subsections (A, B & C) is not helpful to the overall structure either and it might be preferable to have the main document referred to as the Roadmap with A,B & C placed in Annexes. Such an approach might give more prominence to the "roadmap concept. A table of contents would also be helpful in providing additional clarity. |
| Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? | ☒ Yes<br>☐ No | Comments: Please see comments above. |
| Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)? | ☒ Yes<br>☐ No | Comments: It is noted that roadmap has been based largely on LM crop plants and therefore this "limitation" should be acknowledged in the overall context of the guidance. |
| 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<br>☐ No | Comments: Again as per Q12 there might exist a general applicability which might be limited in respect of catering for "all types of introductions". |
| Q14. Is there any other issue or concept that you would like to see included in the Roadmap? | ☐ Yes<br>☒ No | Comments: <Type here> |
| Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap? | ☒ Yes<br>☐ No | Comments: <Type here> |

| 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<br>☐ No | Comments: Again the section is useful, however improvements could be made on presentation which could provide further clarity - a visual chart may help in this respect. |
| 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<br>☐ No | Comments: Useful to a certain extent but must also take into account comments in Q16 & Q19. |
| Q18. Is this section of the Guidance organized in a logic and structured manner? | ☐ Yes<br>☐ No | Comments: Please see comments in Q16 & Q19. |
| Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? | ☒ Yes<br>☐ No | Comments: Yes, but only to a certain extent. The continuous cross referencing to roadmap text is not that user friendly and an alternative approach could be considered. |
| Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance? | ☐ Yes<br>☒ 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<br>☐ No | Comments: Again it is useful however improvements could be made on presentation and bringing further clarity .As commented previously, a visual chart may help in this respect. |
| 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<br>☐ No | Comments: Useful to a certain extent but must also take into account comments in Q21 & Q24. |
| Q23. Is this section of the Guidance organized in a logic and structured manner? | ☒ Yes<br>☐ No | Comments: Please see comments in Q21 & Q24. |
| Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? | ☒ Yes<br>☐ No | Comments: Yes but only to a certain extent. The continuous cross referencing to roadmap text is not that user friendly and an alternantive approach could be considered. |
| Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance? | ☐ Yes<br>☒ 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<br>☐ 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<br>☐ No | Comments: <Type here> |
| Q28. Is this section of the Guidance organized in a logic and structured manner? | ☒ Yes<br>☐ 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<br>☐ No | Comments: Yes but only to a certain extent. As previously noted the continuous cross referencing to roadmap text is not that user friendly and an alternative approach could be considered. |
| Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance? | ☐ Yes<br>☒ 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. In the preface and on line 11 it could be helpful to state, in respect of Article 15, "that risk assessments shall be carried out in a scientifically sound manner and shall be based at a minimum …" thus giving prominence to relevant text of Art 15 from the outset.

Also for clarity would it be helpful to list steps referred to in line 251 (page 7) so as to improve overall structure?

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