

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: <Country's name>

Other Government. Please specify:

Organization: Please specify: Federal Office of Consumer Protection and Food Safety, Germany, <http://www.bvl.bund.de>

Q2. When was the testing of the Guidance conducted? Please enter date: 09.12.2011

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: <Type here>

Other: Please specify: Joint action of various scientific officers in the department

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
<i>Please indicate the level of agreement you attribute to each of the questions in the left column.</i>					
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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 <u>scientifically sound and case-by-case manner</u> ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Q7. How do you evaluate the usefulness of the Guidance as a tool to assist countries in conducting and reviewing risk assessments of LMOs <u>introduced into various receiving</u>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: Focus on comparative assessment and guidance on assessment endpoints is missing.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: See comments above
Q10. Is the Roadmap organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: It contains parts that are too speculative and do not contain guidance, e.g. application of "omics"-techniques for risk assessment or future possibilities of PCR-discrimination between single events and stacks.
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
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)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: Characterization of all possible environments for large scale commercialisation is unrealistic.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Better discrimination between safety issues due to genetic modification and others more related to agriculture in general.
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
Q18. Is this section of the Guidance organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: see comments under Part I
Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> 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?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: All aspects are completely covered by the guidance on risk assessment of LMOs.
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)?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: see comments above
Q23. Is this section of the Guidance organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: <see comments above>
Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: see comments above

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.
