

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:	<input checked="" type="checkbox"/> Party. Please specify: <Italy> <input type="checkbox"/> Other Government. Please specify: <Country's name> <input checked="" type="checkbox"/> Organization: Please specify: <Istituto Superiore Protezione e Ricerca Ambientale (ISPRA);International Centre for Genetic Engineering and Biotechnology (ICGEB)>
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Q2. When was the testing of the Guidance conducted?	Please enter date: <15 december 2011
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Q3. Type of event where the testing of the Guidance was conducted?	<input checked="" type="checkbox"/> Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: <Ministero dell'Ambiente e della Tutela del Territorio e del Mare Type of meeting: <input checked="" type="checkbox"/> Face-to-face <input checked="" type="checkbox"/> Online <input type="checkbox"/> Individual exercise. Please provide your name, occupation and affiliation: <Type here> <input type="checkbox"/> Other: Please specify: <Type here>
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Q4. Which sections of the Guidance were tested?	<input checked="" type="checkbox"/> Part I: The Roadmap for Risk assessment of LMOs Part II: Specific types of LMOs or Traits: <input checked="" type="checkbox"/> Risk assessment of LMOs with stacked genes or traits <input checked="" type="checkbox"/> Risk assessment of LM crops with tolerance to abiotic stress <input checked="" type="checkbox"/> Risk assessment of LM mosquitoes
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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?	<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 type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <The roadmap is useful to risk assessors with limited experience only if biosafety education and training are provided>
Q10. Is the Roadmap organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <But it should be more schematic>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: The addition of tables and graphs could help to better understand the roadmap
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: <The roadmap is especially applicable to plants, less to the other 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)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: It is lacking in some more specific considerations usefull for placing on the market. An ecosystemic approach should be considered at all level of RA.
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: The concept of baseline status of the receiving environment and the issue "unintended sequences" page 9 line 328
Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: The flowchart should be simplified by using keywords or key concepts

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: Suitable biosafety education and training must be provided to risk assessors who have limited experience apart from the usefulness of this section of the guidance
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: It could be improved with tables and graphics
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> 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)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Suitable biosafety education and training must be provided to risk assessors who have limited experience apart from the usefulness of this section of the guidance
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: It could be improved with tables and graphics
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: Tables, diagrams and graphics

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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> 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?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: Suitable biosafety education and training must be provided to risk assessors who have limited experience apart from the usefulness of this section of the guidance
Q28. 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>
Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: It could be improved with tables and graphics
Q30. 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: Tables, diagrams and graphics

ADDITIONAL COMMENTS

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

Q31. It is suggested:

- (i) the use of examples that include microorganisms and animals;
- (ii) an ecosystemic approach during the RA.

1. To the introduction please add this reference:

Guidance on the environmental risk assessment of genetically modified plants EFSA Journal 2010;8(11):1879 [111 pp.].
<http://www.efsa.europa.eu/it/efsajournal/pub/1879.htm>

2. to para. Step 5: Points to consider related to risk management strategies: monitoring; please add this reference:

Guidance on the Post-Market Environmental Monitoring (PMEM) of genetically modified plants -EFSA Journal 2011;9(8):2316 [40 pp.]. <http://www.efsa.europa.eu/it/efsajournal/pub/2316.htm>

3. To "The Choice of Comparators" please add this reference:

EFSA Guidance on selection of comparators for the risk assessment of genetically modified plants and derived food and feed EFSA Journal 2011; 9(5):2149 [20 pp.]. <http://www.efsa.europa.eu/it/efsajournal/pub/2149.htm>
