

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: España <input type="checkbox"/> Other Government. Please specify: <Country's name> <input type="checkbox"/> Organization: Please specify: <Organization's name>
Q2. When was the testing of the Guidance conducted?	Please enter date: Noviembre 2011
Q3. Type of event where the testing of the Guidance was conducted?	<input type="checkbox"/> Group event (e.g., workshop, training course, meeting). Please provide the title of the event and name of organizer: <Type here> Type of meeting: <input type="checkbox"/> Face-to-face <input type="checkbox"/> Online <input type="checkbox"/> Individual exercise. Please provide your name, occupation and affiliation: <Type here> <input checked="" type="checkbox"/> Other: Please specify: Grupo de trabajo interno
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

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 <u>a 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 assessments of LMOs <u>introduced into various receiving environments</u> ?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

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: La hoja de ruta constituye una herramienta útil aunque probablemente necesite acompañarse de talleres específicos que la desarrollen, aclarando dudas prácticas y dando claridad a todos los conceptos. Para poder establecer la valoración de los riesgos hay que apoyarse en análisis de información procedentes de estudios, experimentos, etc. La guía permite identificar la lógica del proceso de la evaluación de riesgos y los pasos a seguir pero no siempre cómo conseguir la información para realizar las estimaciones.
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 checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
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: La hoja de ruta es aplicable a cualquier tipo de organismos vivos modificados, no obstante parece especialmente orientado a plantas, quedando otros organismos vivos modificados como animales, árboles o microorganismos menos representados.
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: El documento se centra más en los casos de las liberaciones voluntarias al medio ambiente de cultivos pero se adapta razonablemente bien a otro tipo de actuaciones y organismos vivos modificados
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Comments: <Type here>
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: El gráfico resulta muy útil, clarificando todo el proceso de un solo golpe de vista, ayudando a entender la importancia de cada paso de la evaluación de la riesgos

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. En general nos parece que la nueva revisión de la guía aporta numerosas mejoras, a destacar la mayor claridad y mejor estructura de los ejemplos o el apartado nuevo con el glosario de términos.

Nos parecería positivo añadir en este último apartado alguna definición suplementaria, como la de heterocigosidad , isogénico, re-transformación y co-transformación

Consideramos que la monitorización y los planes de seguimiento son un elemento clave para la mejora continua de las evaluaciones de riesgo ya que supone el elemento clave de contraste entre los datos teóricos o de laboratorio con la experiencia real en campo, lo que permite una fuente muy valiosa de información de cara a rectificar la evaluación de riesgo o emprender evaluaciones nuevas. Por ello, convendría que fuera claramente indicada en el texto de la guía.

Por último, creemos que es importante seguir con el trabajo emprendido y desarrollar nuevas guías específicas, considerando como prioritarias por su importancia y desarrollo actual las referentes a peces, microorganismos y virus.