

SUBMISSION FROM SPAIN (PARTY)

(Translated from the original in Spanish)

FORM FOR THE SCIENTIFIC REVIEW OF THE GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

The Guidance for Risk Assessment of Living Modified Organisms (the “Guidance”) was developed through collaborative efforts between the Open-ended Online Expert Forum and the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management.*

The aim of the Guidance is to further elaborate the methodology for risk assessment of living modified organisms (LMOs) in accordance with the Cartagena Protocol on Biosafety, and in particular in accordance with Annex III of the Protocol.

The Guidance is intended to be a “living document” that will be improved with time as new experience becomes available and new developments occur in the field of applications of LMOs, as and when mandated by the Parties to the Cartagena Protocol on Biosafety.

At the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), the Parties to the Protocol welcomed the first version of the Guidance and noted that it requires further scientific review and testing to establish its overall utility and applicability to living modified organisms of different taxa introduced into various environments.

The Executive Secretary was therefore requested to coordinate a review process of this first version of the Guidance among Parties and other Governments, through their technical and scientific experts, and relevant organizations.

The following questions are aimed at seeking views to assist the Open-ended Online Expert Forum and the AHTEG in revising the Guidance.

The completed review forms are to be mailed to the Secretariat at: riskassessment.forum@cbd.int . Reviews from Parties and other Governments are to be submitted by their National Focal Points. Reviews from organizations are to be submitted through their head offices.

* Additional information on the development of the “Guidance on Risk Assessment of Living Modified Organisms” may be found in document UNEP/CBD/BS/COP-MOP/5/12 (see “Official Documents” at <http://www.cbd.int/doc/?meeting=MOP-05>).

i. Reviewer's information

Please select **only one** of options below

This scientific review of the Guidance on Risk Assessment of Living Modified Organisms is being submitted on behalf of a:

- Party. Please specify: <Spain>
- Other Government. Please specify: <Country's name>
- Organization: Please specify: <Organization's name>

ii. Overall evaluation

Please select **only one** answer for each section

Q1. How do you evaluate the level of consistency of the following sections of the Guidance with the Cartagena Protocol on Biosafety, particularly with its Article 15 and Annex III?	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Q2. How do you evaluate the usefulness of the following sections of the Guidance as tools for assisting countries in conducting and reviewing risk assessments of LMOs <u>in a scientifically sound and case-by-case manner?</u>	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Q3. How do you evaluate the usefulness of the following sections of the Guidance as tools for assisting countries in conducting and reviewing risk assessments of LMOs introduced into various receiving environments?					
	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Q4. How do you evaluate the usefulness of the "Roadmap" as a tool for assisting countries in conducting and reviewing risk assessments of LMOs of different taxa?					
	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

ADDITIONAL COMMENTS ON THE OVERALL EVALUATION

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

Q5. <Regarding Risk Assessment of living modified organisms with stacked genes or traits, it would be interesting to include examples of case studies in order to clarify the different stages, since the provided explanation/rationale is extremely theoretical; therefore it would be interesting to include case studies to illustrate each item>

iii. Section-by-section review

Please select **only one** of the boxes for each question

PART I: THE ROADMAP FOR RISK ASSESSMENT

1. INTRODUCTION

Q6. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes No. Please comment: <Type here>

Q7. Does this section include all the necessary relevant concepts? Yes No. Please comment: <Type here>

Q8. Are all the concepts in this section expressed in a language that could be easily Yes

understood by the target users?

No. Please comment: <Type here>

2. THE RISK ASSESSMENT

Step 1: “An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health”

Q9. Are all the concepts in this section relevant and accurate from a scientific point of view?

Yes

No. Please comment: <Type here>

Q10. Does this section include all the necessary relevant concepts?

Yes

No. Please comment: <Type here>

Q11. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

Yes

No. Please comment: <Type here>

Step 2: “An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism”

Q12. Are all the concepts in this section relevant and accurate from a scientific point of view?

Yes

No. Please comment: <Type here>

Q13. Does this section include all the necessary relevant concepts?

Yes

No. Please comment: <Type here>

Q14. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

Yes

No. Please comment: <Type here>

Step 3: “An evaluation of the consequences should these adverse effects be realized”

Q15. Are all the concepts in this section relevant and accurate from a scientific point of view?

Yes

No. Please comment: <Type here>

Q16. Does this section include all the necessary relevant concepts?

Yes

No. Please comment: <Type here>

Q17. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

Yes

No. Please comment: <Type here>

Step 4: “An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized”

Q18. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes No. Please comment: <Type here>

Q19. Does this section include all the necessary relevant concepts? Yes No. Please comment: <Type here>

Q20. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes No. Please comment: <Type here>

Step 5: “A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks”

Q21. Are all the concepts in this section relevant and accurate from a scientific point of view? Yes No. Please comment: <Type here>

Q22. Does this section include all the necessary relevant concepts? Yes No. Please comment: <Type here>

Q23. Are all the concepts in this section expressed in a language that could be easily understood by the target users? Yes No. Please comment: <Type here>

3. RELATED ISSUES

Q24. Does the “Related Issues” section include all relevant issues related to risk assessment and decision-making process but that are outside the scope of the Roadmap? Yes No. Please comment: <Type here>

4. FLOWCHART

Q25. Does the flowchart provide an accurate graphic representation of the risk assessment process as described in the Roadmap? Yes No. Please comment: <Type here>

PART II: SPECIFIC TYPES OF LMOs AND TRAITS

A. RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS WITH STACKED GENES OR TRAITS

Q26. Are all the concepts in this section relevant and accurate from a scientific point of view?

- Yes
 No. Please comment: <Type here>

Q27. Does this section include all the necessary relevant concepts?

- Yes
 No. Please comment: <Type here>

Q28. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

- Yes
 No. Please comment: <The concepts are described, but their practical application is quite complex; therefore, the addition of examples for each stage is recommended>

B. RISK ASSESSMENT OF LIVING MODIFIED CROPS WITH TOLERANCE TO ABIOTIC STRESS

Q29. Are all the concepts in this section relevant and accurate from a scientific point of view?

- Yes
 No. Please comment: <Type here>

Q30. Does this section include all the necessary relevant concepts?

- Yes
 No. Please comment: <Type here>

Q31. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

- Yes
 No. Please comment: <Type here>

C. RISK ASSESSMENT OF LIVING MODIFIED MOSQUITOES

Q32. Are all the concepts in this section relevant and accurate from a scientific point of view?

- Yes
 No. Please comment: <Type here>

Q33. Does this section include all the necessary relevant concepts?

- Yes
 No. Please comment: <Type here>

Q34. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

- Yes
 No. Please comment: <Type here>

ADDITIONAL COMMENTS ON THE SECTION-BY-SECTION REVIEW

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

Q35. <The importance of the analysis of follow-up plans for authorized modified living organisms when obtaining additional information to complete the initial risk assessment should be emphasized>