

SUBMISSION FROM THE EUROPEAN NETWORK OF SCIENTISTS FOR SOCIAL AND ENVIRONMENTAL RESPONSIBILITY (ORGANIZATION)

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: <Country's name>

Other Government. Please specify: <Country's name>

Organization: Please specify: European Network of Scientists for Social and Environmental Responsibility (ENSSER)

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 type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 in a scientifically sound and case-by-case manner?

	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" 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 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"/>

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 checked="" type="checkbox"/>	<input 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. The Roadmap is written in a very condensed language for a audience rather knowledgeable in GMO risk assessment. To make it really useful for regulators that have no or limited experience in GMO risk assessment, further guidance is necessary. Eg. to explain the concepts of problem formulation, protection goals, give ideas how to develop such concepts in a comprehensive and transparent way, how to involve stakeholders. The term "scoping the risk assessment" will certainly require more guidance to become operational for many risk assessors. Or to give ideas on what type of literature might be needed and useful and what kind of statistics are needed to assess the value of the data received with an application. Checklists are certainly useful for the individual tasks.

more on Q3 and Q4 see extra page before the questionnaire

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: a clearer separation of normative (eg. problem formulation, protection goals) and scientific issues of risk assessment would be useful, and some comments on appropriate procedures for running the different activities

Q8. 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>

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: "no", because the information how to evaluate the different points to consider is not sufficient, for a meaningful guidance, this section should contain more elaborated description

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>

understood by the target users?

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: the issue of comparators could be more elaborated

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: <Type here>

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: the issue of comparators could be more elaborated

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. <Please type your comments here>

Extra page

on Q3: this section would benefit from improving the language and having more background material to explain the concepts.

on Q4: this section would benefit from specific guidance for biosafety-relevant phyla (e.g. arthropods, nematodes or molluscs) and subphyla (e.g. vertebrates) with specific guidance for particular class, order or family (e.g. fish, birds, amphibians, mammals, reptiles). As originally designed for plants, the roadmap is clearly useful for trees and algae, though not ultimately sufficient (encompassing enough), thus development of specific guidance should also be undertaken. A closer look on algae is advisable because

of the planned use of GE algae in synthetic biology applications in facilities close to marine environments.

