



Estado Plurinacional de
Bolivia



Plurinational State of Bolivia

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

March, 2011

Additional comments to questions:

1. Introduction

Q6. The current description of sound science, reproducibility and access of data are particularly relevant. Our only comments in relation to the introduction is that the description of scientifically robust would need the inclusion of public participation to achieve precisely more robust and transparent research.

Q7. We would like to applaud the inclusion of the following concepts: Sound science and transparency in RA; implications of lack of scientific knowledge or consensus in relation to valuation of risk; iterative nature of appropriate risk assessment; behaviour of transgenes in different contexts; and identification and consideration of uncertainty. As well the inclusion of different actors and the consideration of customary practices in the "Context and scoping" section.

3. Related issues

Q24. We support the inclusion of "Related issues" as integral part of the Guidelines, and as a suggestion from some of the AHTEG members. The Plurinational State of Bolivia particularly supports the inclusion of socioeconomic considerations, public participation and ethical issues in risk assessment and risk management procedures. In addition, we request the inclusion of cultural issues. We also support the explicit mention of the direct relationship – although not restricted to – of risk assessment and management to liability and redress in the case of damage in the conservation and sustainable use of biological diversity, taking also into account human health.

4. Flowchart

Q25. Practical examples (e.g. specific cases) of the application of the flowchart will be also very helpful.

A. Risk assessment of LMOs with stacked genes or traits

Q26. The title should be "Risk assessment of LM CROPS with stacked genes or traits" (the mention of LMOs is not accurate since it deals only with stacked crops).

B. Risk assessment of Modified crops with tolerance to abiotic stress

Q29. The answer was "no" since it is not clear how the comparative approach will be carried out. It needs further details and clearer text on the use of the comparators and the comparative approach itself. In addition, the risk assessment should not be related only to comparative approaches with non-modified counterparts, but also on the presence of certain substances with known or potential adverse effect. In this sense, the "omics" techniques should have a more relevant role in the suggested risk assessment approach. The "omics" techniques are mentioned as an alternative techniques for future application. We believe that they have present relevance, are central for profiling the molecular characteristics of the LMO in question and appropriately assess potential adverse effects on biodiversity, animal (wild or farm) health and human health.

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: Plurinational State of Bolivia
- 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 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 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 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 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 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 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 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 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"/>
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 type="checkbox"/>	<input checked="" 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 Guidelines will be comprehensively improved if they include socioeconomic considerations as part of the sound science risk assessment of LMOs. The Guidelines also apply to products thereof (PTO) as described in paragraph 5 of Annex III to the Protocol; however, it does not address specific issues to effectively consider PTO along the steps of the Guidelines. This is relevant in the context of other decisions under the Cartagena Protocol e.g. Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, as during the negotiations of its text it was recognized the possibility of a broad interpretation of the application of the Supplementary Protocol in light of the Art. 27, meaning inclusion of resulting from processed materials of LMO origin (UNEP/CBD/BS/COP-5/MOP/5/17 p. 133). Centers of origin are marginally addressed. In general, the text and concepts are dense. It would benefit from the inclusion of examples, glossary and check lists at each step of the Guidelines.

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:

Q7. Does this section include all the necessary relevant concepts?

Yes

No. Please comment: "Protection goals" and "assessment end-points" require more detailed explanations and guidance on what they actually mean, including a reference to the consideration of indirect effects when defining protection goals. Also "informed decisions on RA procedures" require further description of what it actually implies, making reference to public participation and not only public information.

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: The competences and level of training of target users, in this case RA practitioners and decision-makers, vary among countries and individuals based on their fields of expertise. Hence, it would be hard that the Guidelines will be equally understood by the different "target users". The suggestions is to include: i) a glossary of key terms; ii) check lists for each step, and iii) specific examples, either real or hypothetical, to make clearer the application of the concepts and hence, the roadmap.

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:

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

Yes

No. Please comment: The current inclusions are of particular value: unintended and unpredicted characteristics of the LMO and consideration of non-target organisms as well as cumulative effects in relation to points to consider in relation to potential adverse effects. However, in relation to (a) (i) on molecular characteristics of the LMO, it is not clear if it includes the bacterial and plant version of gene products (intended and unintended). It should include both and this should be explicit. In relation to (c) related to the receiving environment, although centers of origin and diversification are listed at the foot note, they should be more explicit in the main text of the Guidelines. In relation to (h) on considerations for unmanaged and managed ecosystems, it should include "taking into account traditional customary uses and management of ecosystems particularly of indigenous and local communities". This since indigenous communities implement certain natural resources management approached that might be consider as "unmanaged" (when they actually are) from other perspectives (e.g. long "resting time" of wilderness up to several years). Finally, (k) on cumulative effects, the description on the food note - from our view - refers more to "combinatorial" effects due to the presence of multiple LMOs in the environment. This is different from "cumulative" that occur in a time scale. We believe that both should be consider adding to (k) "cumulative and combinatorial effects".

Q11. Are all the concepts in this section expressed in a language that could be easily

Yes

No. Please comment: Yes, all concepts are clear for people

understood by the target users?

fully familiar and experienced with the RA terminology. However LMO risk assessors do not necessarily have this level of experience in developing countries. We suggest to include a glossary of key terms, particularly to those that are likely to have significantly different interpretations, e.g. "gene product", "intended and unintended effect", "cumulative vs. aggregate effect", "unmanaged ecosystem", etc.

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: We applaud the inclusion of (a) consideration of "user habits", (b) "Levels of expression in the LMO and persistence and accumulation in the environment" and f) uncertainty. However, under rationale, paragraph 3 (i) in relation to the potential of the LMO to spread mentions "(in particular into protected areas)", it should include also "and centers or origin and genetic diversification". In addition, the points to consider require further guidance on how to put them into practice.

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: The relevant concepts are included in Step 3; however more specific considerations to consequences of adverse effects in centers or origin and diversification need to be included. In addition, it requires criteria to define what is 'major', 'intermediate', 'minor' or 'marginal' adverse consequence (in this regard, again particular focus need to be placed in centers of origin and diversification).

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: "No" only because in points to consider under (e) should mention "combinatory" effects and not restrict to "cumulative" effects only.

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

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: The example in (f) related to management options is somehow misleading in the sense that does not leave clear room to "avoidance" of potential adverse effects by prohibition of the LMO in question. In our view, these concepts (avoidance and prohibition) should be mentioned as options for managing risk.

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:

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: It does not cover all issues and steps included in the Guidelines. it requires further development making a better use of the steps summarized in the flowchart. Inclusion of key questions relevant to the risk assessment will be very useful.

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:

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: A glossary specific to LMOs tolerant to abiotic stress is needed e.g. "omics" technology, transcriptomics, metabolomics, non-modified comparator.

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: It is missing a reference on the risks for transboundary movement of LM mosquitoes. It should also include an analysis of the existence of environmental factors that may increase the risks for adverse effects resulting from LM mosquitoes (e.g. presence of certain substances, such as antibiotics, with capacity of desactivating specific introduced traits that may result in increased LM mosquito survival). A glossary specific to LM mosquitoes is needed

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. *In general, the specific types of LMOs and traits cover different parts of the Guidelines and the flowchart. They require a more consistent format to apply as much as possible the different sections of the Guidelines and flowchart.*
