

**SUBMISSION FROM THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND
(PARTY)**

**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: <UK

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

Organization: Please specify: >

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

	Very poor	Poor	Neutral	Good	Very good
• Roadmap for risk assessment	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified organisms with stacked genes or traits	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified crops with tolerance to abiotic stress	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
• Risk assessment of living modified mosquitoes	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input 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 checked="" type="checkbox"/>	<input 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. In general, the focus of the guidance tends too much towards identifying issues that could be considered in risk assessments without linking these to specific risk hypotheses. More emphasis is needed on the process of risk assessment, including but not limited to that laid out in the flowchart e.g. the use of tiered approaches. Otherwise, the guidance may lead to disproportion and a non-evidenced based approach that will not aid in decision making.

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: The use of worst case scenarios can be a useful tool in risk assessment. For example, in considering the consequences of a trait from the LMO being transferred to other organisms by horizontal gene transfer. Tiered approaches

may be helpful in characterising risks e.g.in determining whether beneficial organisms in the same taxonomic Order as the pest targeted by an insecticidal LM plant could be adversely affected.

Yes

No. Please comment: We are not convinced that those with little experience in risk assessment will understand what is meant by assessment endpoints and risk thresholds. These terms are not used in Annex III. Examples would help.

The first sentence in paragraph 3: Annex III does not refer to unintended effects and their mention here does not explain their significance to risk assessors. For example, it would be useful to explain that unintended effects can be divided into 2 categories i.e. those that can be foreseen and those that are genuinely unanticipated and if / how these categories can be dealt with in risk assessments.

The flowchart refers to determining risk thresholds in the context of scoping the RA - this is missing in the paragraph that deals with identifying assessment endpoints. It would be useful if the guidance explained when it is important to define a level of change in a particular variable that can be taken as conferring an unacceptable risk to biological diversity (taking into account human health). Otherwise, data on biodiversity in particular are likely to show differences that do not have any meaning for decision-makers.

Q8. Are all the concepts in this section expressed in a language that could be easily understood by the target users?

The reference to the key steps in RA and their possible relevance to each other is vague. The guidance should refer to the flowchart and make sure these relationships are clear in the sections dealing with the particular steps - this is not the case at present (see below).

It is helpful that the guidance points out that the provision of additional information does not necessarily help to reduce uncertainty and can make decision-making more difficult. However, this statement needs to be linked to other bullet points i.e. (i) the importance of framing the risk hypothesis accurately so that the data generated answer the question (i.e. meet the criteria for relevancy). (ii) In some cases it might be that the nature of the uncertainty means that it can't be addressed through the provision of more data in the risk assessment but may need to be dealt with by monitoring or possibly risk management.

Bullet point 4 on page 5 states that less information may be available - this is not relevant. It's the nature and level of detail of information that is required, which is relevant and amongst other things, this will depend on the biology/ecology of the recipient organism and the scale of environmental exposure e.g. whether its for import only, field testing or commercial cultivation.

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: <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: The points to consider in (a) are not helpful without examples or rephrasing e.g. changes in the non-modified recipient's taxonomic relationships and changes in its centres of origin that could lead to adverse effects. Points to consider in (c) would also be more helpful with examples. The text explains that the availability and relevance of information may vary but it is not clear where/ how particular information may be useful in hazard identification e.g. data on levels of expression and stability. Similarly in (d) it would be useful to include an example of where data on transcript levels (rather than changes at the translational level) would be useful in hazard identification. Without these types of examples the guidance lacks a sense of proportion and does not encourage a strategic use of information that facilitates decision-making. In (h) it might be worth including 'effects of altered management regimes of the LMO'.

It is important to emphasise the need to define an adverse effect as far as possible and a casual link between a characteristic of the LMO and this effect or the next steps will generate information that will not help in decision-making.

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: It would be useful to emphasise a systematic approach to problem formulation i.e. relate this step to step 1 and explain why steps 2 and 3 should be considered in parallel.

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:

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: >

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

- Yes
 No. Please comment: <But it is important to recognise that steps 2 and 3 are carried out in parallel because it will not be

necessary to consider likelihood/ exposure in any detail if no adverse consequences have been identified (e.g. through geneflow) and vice versa. As discussed above it is important to link this step to step 1. At present, the distinction between steps 1 and 3 is not clear when reading the 'points to consider' in the respective steps.

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: >

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: <>

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: Are the risk management strategies referred to in decision-making the same as those referred to in step 5?

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:

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: <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: <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:

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

- Yes
 No. Please comment: T

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>