SUBMISSION FROM THE EUROPEAN FOOD SAFETY AUTHORITY (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 Food Safety Authority (EFSA)>

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	☐	☐	☐	☐	☐
• Risk assessment of living modified organisms with stacked genes or traits	☐	☐	☐	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☐	☐	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☐	☐	☐

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	☐	☐	☐	☐	☒
• Risk assessment of living modified organisms with stacked genes or traits	☐	☐	☐	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☐	☐	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☐	☐	☐

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	☐	☐	☐	☒	☐
• Risk assessment of living modified organisms with stacked genes or traits	☐	☐	☐	☐	☐
• Risk assessment of living modified crops with tolerance to abiotic stress	☐	☐	☐	☐	☐
• Risk assessment of living modified mosquitoes	☐	☐	☐	☐	☐

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	☐	☐	☐	☒	☐

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 "Guidance on Risk Assessment of Living Modified Organisms" is considered very well written and organised, is concise, provides a detailed, clear and straightforward overview of the safety assessment requirements of LMOs as well as the principles and recommendations to follow when conducting an environmental risk assessment.

The Roadmap describes the key principles and concepts that should be followed when conducting an environmental risk assessment. These principles and concepts are accurate and well described. In addition, the points for consideration given in the Roadmap enable a concrete and practical translation of these general principles and concepts. The approach followed in the Roadmap is very helpful.>

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: <We note that the Roadmap does not cover or provide guidance on the following issues: relevant statistical principles to follow for experimental risk assessment studies (e.g., statistical power of environmental risk assessment

	studies; the use of prospective power analysis; size effects on environmental risk assessment; number of replications for field trials; sample sizes; and specific statistical methodologies for data analysis of environmental risk assessment studies), the use of models and scenario analyses, or the selection of appropriate comparators. We sense it may be helpful to consider these elements in the text. >
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 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: < The risk assessment approach proposed is driven by identified hazards, as the first risk assessment step focuses on the identification of differences between the GM plant and its comparator. Does this approach enable the consideration of unanticipated unintended effects? It is also interesting to note that 'the context and scoping of the risk assessment' is kept separated from the Risk Assessment process itself. Recent papers on problem formulation tend to integrate elements of the context and scoping into the first step of risk assessment. In doing so, problem formulation is frequently described as the critical first step of environmental risk assessment. The problem formulation step proposed in these papers is not limited to the identification of hazards, but also take into account the operationalisation of protection goals, the definition of assessment and measurement endpoints, the identification of exposure profiles, etc.. In the list of points to consider, two issues might be included "effect on target organisms" and "effects of altered farm management practices".>
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	☒ Yes ☐ No. Please comment: <Type here>

view?

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: <In the list of points to consider, the "impact of potential horizontal gene transfer" might be added.>
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: <The Roadmap recommends using the terms "major, intermediate, minor or marginal" in order to qualify the magnitude of the consequence of adverse effects. However, no clear definitions are provided in the Roadmap to define these terms. If considered useful, reference can be made to the definitions used in the Commission Decision 2002/623/EC, which supplements Annex 2 of Directive 2001/18/EC for the terms "high, moderate, low, negligible".>

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: <In the list of points to consider, point "e" is a risk management action, which is not related to risk assessment and therefore might be removed. >
Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <It the list of points to consider, it would be useful to add one bullet point "Measure the efficacy and effectiveness of the proposed risk mitigation measure" as was the case for the GM mosquitoes.>
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: <It would be useful to add the "post-market environmental monitoring" in the list of bullet points in the box related to Step 5.>

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: <It is confusing to consider issues related to the detection and identification of GM plants in a risk assessment context. Guidance for the selection of appropriate comparators in the case of a LMO with stacked genes is missing and would be useful.>
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: In the section "Assessment of combinatorial…", last sentence, the issue of "effect on target organisms" and the consequences of any interaction on the evolution of resistance in target organisms should also be considered and included. >
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: <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: Concerning the section Issues to be considered in the risk assessment for "(a) description of the genetic modification" it might be useful to highlight sequences which might influence the mobility of the insert in the insect (such as transposable elements)
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 Part I, section "Overarching issues in the risk assessment process", a section is dedicated to the consideration of uncertainty. However, guidance on how to express the incertainty is not given and it might be useful to provide guidance on this specific aspect (e.g. qualitative, quantitative estimation) or link to where information could be finf in the document.

In the reference list, the latest EFSA scientific opinion on Guidance on the environmental risk assessment of GM plant (2010), which was finalized and published in November 2010, could be added. Full reference is given below: EFSA Panel on Genetically Modified Organisms (GMO); guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 2010;8(2011):1879.[111pp.]. doi:10.2903/j.efsa.2010.1879. >