SUBMISSION FROM GENWATCH (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: GeneWatch UK

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. There are a number of important omissions, which are discussed in more detail below:

(i) Over-emphasis on plants and an assumption that release of the non-modified organism is safe. There are many examples (e.g. mosquitoes) where release of the unmodified organism is acknowledged to pose hazards. In such cases, Step 1 should require identification of mechanisms by which failure of the novel genotypic and phenotypic characteristics could cause adverse effects. Annex II para 5 of the Protocol requires the RA to consider risks "in the context" of non-modified recipients: it does not (as Step 1 appears to do) assume that release of the non-modified organism into the same environment would be harmless.

(ii) Aspects where impacts on human health have not been fully considered e.g. effects on human or animal immunity of LMOs designed to alter populations of disease vectors; bioaccumulation of hazardous substances in plants.

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:
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 wording of Step 1 is too narrowly based on the assumption that release of the non-modified organism is safe. It refers to identifying changes which could cause adverse effects, but not to identifying changes that are intended to (but fail to) mitigate adverse effects. There are many examples (e.g. agricultural pests, vectors for human disease, invasive plant species) where release of the unmodified organism is acknowledged to pose hazards and the modification is intended to mitigate any harmful effects to some purpose (e.g. reduction of insect pest populations; reduction in disease transmission by mosquitoes; allowing planting of modified invasive species in areas where the unmodified species would be hazardous). Where release of the unmodified organism may be potentially hazardous Step 1 should require identification of mechanisms by which failure of the novel genotypic and phenotypic characteristics (intended to mitigate these harms) could cause adverse effects. Potential adverse effects should also include: Effects on animal and human disease vectors and diseases (viruses, pathogens and parasites), including any evolutionary effects and effects on human immunity due to altered disease transmission.
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:

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: Step 2 should include (g) Impact of interactions between the LMO and environment on ecosystems and human health (e.g. increases in non-target pest populations; bioaccumulation of hazardous metals from soil); (i) Whether the LMO is a vector of human or animal disease and, if

	so, any impacts on disease transmission, including long-term evolutionary impacts and altered immunity; (h) Long-term impacts on pest and weed management practices (e.g. development of herbicide or pest resistance). The likelihood of transnational spread must also be considered (this is particularly likely with releases of GM insects, including agricultural pests and mosquitoes). The Parties may need to consider a mechanism for international consultation or approval in such circumstances.
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: This section appears to have been written with plants in mind not other species such as insects or fish. Add (a)(iii) the behaviour of relevant wild-type populations of unmodified animal or insect species, including interactions between predators and prey, disease transmission and interaction with humans or animal species. Add f) Recognition that ecological models require validation with experimental data, sensitivity testing and thorough testing of theoretical assumptions and conceptual models.
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: Whether health risks are acceptable or not is not purely a matter for Contracting Parties under the CBD. This section presumes that any adverse health effects are secondary to impacts on biodiversity (presumably because, in the case of plants, they result from consumption of the crop, which may require an additional approvals process and/or other regulatory requirements such as traceability and labelling). This is not the case for the release of disease vectors such as GM mosquitoes which are a public health-related intervention intended to alter disease transmission. Any experimental or commercial-scale open release of disease vectors must conform to additional requirements, in particular to the Helsinki Declaration, which requires informed consent prior to any such medical experiment. Step 5 should refer explicitly to the Helsinki Declaration and any other relevant international instruments. As it stands, Step 5 wrongly implies that a recommendation under the CBD is sufficient in such circumstances.
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: Other issues include: (i) The transnational nature of GM insect releases and how to make decisions in such circumstances; (ii) Lack of transparency regarding decision-making on LMOs that are not intended for direct use as food or feed, especially GM mosquitoes.
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: <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: <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>