SUBMISSION FROM NEW ZEALAND (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: New Zealand

☐ Other Government. Please specify:

☐ 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	☐	☐	☐	☒	☐
• 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.

New Zealand recognizes that preparation of the Guidance for Risk Assessment of LMOs (the Guidance) has been a substantial undertaking. We also acknowledge that this version is an improvement over earlier versions. Nevertheless there remain areas of concern regarding the usefulness of the Guidance, as it stands, for those seeking to conduct risk assessment under the Cartagena Protocol on Biosafety.

One of the concerns about the document is that while its stated purpose is "to provide further guidance on using Annex III [of the Cartagena Protocol on Biosafety] with additional background material and links to useful references relevant to risk assessment.", it appears to simply elaborate on the wording in Annex III without providing guidance for a novice or inexperienced analyst about the nature of risk assessment, what it involves, and how to undertake it.

It seems to infer that risk assessment is a series of mechanical steps that can be conducted in a purely objective manner. The essence of risk assessment is that it requires thorough analysis of the system/activity and of the identified risks, and this cannot be undertaken in any generic sense. Thus thorough knowledge of the system/activity is an essential pre-requisite. That risk assessment is undertaken by practitioners with the necessary experience and understanding is key.

The following comments relate to the material under the heading 'PART 1: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS'.

Part 1 of the Roadmap, essentially a Preface, appears confusing with respect to aims, objectives and purpose.

The process of risk assessment outlined in Annex III is on the one hand generic (concerned with estimating risk based on identifying likelihood and consequences) and on the other hand quite specific ("…identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity…"

There is a question in each section about whether the concepts are expressed in a language that could be easily

understood by the target users. The general answer to this is 'no'. A good way of improving the language would be to identify a representative member of the target audience and to write to that person. A good start would be to remove the use of the passive voice, and to reduce the length of the sentences.

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:

The presentation in this section appears confusing. Since the section headed "THE RISK ASSESSMENT" simply follows the headings in Annex III this section contains a range of concepts and valuable material that should presented in a way that established a sound foundation for the risk assessment.

The material under 'General introduction' would fit better under the first section which is essential a Preface.

The remaining material could be renamed "Background and Context" in which case it would be logical to:

(a) Rename 'General introduction' as 'Background'; and

(b) Combine the 'Overarching issues' and 'Scoping and Context' sections as 'Context'.

The precautionary approach is given significant emphasis in this section which is interesting as is the objective for the protocol, not for risk assessment under the Protocol.

An important context that is not addressed in this section is that while risk assessment is commonly used to inform decisions, it does not follow that this either requires or follows from adopting a precautionary approach, which should be a different process or consideration.

The INTRODUCTION is complex and in places unclear. For example It is hard to understand the message it is trying to project. "What is considered an adverse effect depends on protection goals and assessment end-points taken into consideration when scoping the risk assessment. The choice of protection goals…". There are two important concepts contained in this section that are not properly explained, i.e. protection goals and endpoints. .

Paragraph 5 under *Background* is another example of the presentation of concepts without adequate explanation. It simply repeats a section from Annex III without explaining what might be meant by "acceptable risk" or case-by-case risk assessment.

The subsection "*The risk assessment process"* should be very important, but this material does not explain risk, or risk assessment as a general concept. A section discussing the basic concepts of identification, analysis/assessment and evaluation would be of considerable value to the target audience and allow

	them to 'place' this version of risk assessment alongside other everyday analyses with which they may be involved. We would suggest some editing of the material under subheading '*The risk assessment process*". The first paragraph is about the process of risk assessment, whereas the second paragraph is about data. The material in the second paragraph seems out of place. It may be too specific for background and perhaps should be under the main process section (The risk assessment). The confusion with headings is highlighted here as well. The subsection currently named "*Overarching issues in the risk assessment process*" is about the context for the risk assessment. The first three bullet points are about data. While all of this may be useful, it is highly specific. The fourth bullet point is 'Identification and consideration of uncertainty'. There are some important points contained in this section. However, the material could be better organised (e.g. paragraph 3 belongs before paragraph 2) and there are some mixed messages (e.g. paragraph 4 is partly about communication and partly about analysis). Following on from this, we would suggest the first sentence in paragraph 4 "considerations of uncertainty strengthen the confidence and scientific soundness of a risk assessment" should be removed. If not then we would suggest, at a minimum, deleting "the confidence and" and substituting "scientific soundness" for "scientific validity". We view that the concept of 'source of uncertainty' introduced in paragraph 5 is not explained especially well and that paragraphs 5 and 6 appears to mix concepts. It would be better to remove the 'source' and 'nature' aspects. While uncertainty with respect to information, models and parameters is an important consideration in risk assessment for LMOs, it should not be treated as something that is totally independent, and it would be useful to have more discussion of what to do when there is a lack of information or knowledge under the separate steps in the process discussion later in the document. Under the current subheading '**Context and scoping of the risk assessmen**t' a number of useful points are listed. However, again there is a mixture of general and highly specific aspects. Bullet point 5 appears too specific for this list. Bullet point 6 is a partial duplication of earlier material and in general a misuse of the word 'criteria' (how do you establish criteria for the manageability of risks?).
Q7. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: See above for missing concepts including • Baselines and marginal effects • Protection goals • Endpoints • Case-by-case (in this context) • Acceptable risk • Criteria • Hazard • Risk – including the components of risk (magnitude of

effect and likelihood/probability)
- Risk assessment
- Tolerable risk
- Pathways
- Cumulative effects/risks
- Uncertainty

In addition, the concept of establishing the context needs to be explicit rather than just implicit.

The section on "**Overarching issues..."** may confuse those aspects that need to be taken into account in the scoping/planning establishing the context stage of the risk assessment and concepts relating the making decisions about the assessed risks.

The guidance recognizes that uncertainty cannot always be reduced by providing additional information. As an example, it is indicated that new uncertainties may arise as a result of the provision of additional information. However, in many cases more information will not contribute to a better understanding of the potential effect. Risk assessors should look to ensure that any additional information required will contribute to better evaluations and better decisions, rather than simply being more information for its own sake.

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:

There is repetition of the Protocol and Annex III without apparent explanation (for example paragraph 1 under the bullet point 'Identification and consideration of uncertainty', and the whole discussion of the precautionary approach).

The language is complex (see sentence beginning "Sound science is based on transparency…" sub bullet point 3 under bullet point 2 under "Overarching issues…") and may not be suited to an explanatory guide that may be used by people for whom English is not their first language. The explanatory examples given in this paragraph are themselves complex.

This part of the document could be made more accessible by a careful review of its structure and perhaps a 'terminology' section concentrating on the concepts introduced.

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:

No specific view.

There is no space given to comment on the introduction to this section.

General comment: The lack of guidance about the nature of risk and its components is highlighted by the statement that "This step is similar to the 'hazard identification step' in other risk assessment

	guidance. For the novice assessor this statement will likely be confusing. It would be better to ensure that 'risk' and 'hazard' are introduced and given a meaning in the context of this guidance at an earlier stage. It is indicated that "risk assessment is performed in five steps, as appropriate" with no indication as to how to determine the appropriateness of these step i.e. it may not be necessary to perform each of the five steps in a mechanical way but there is no guidance given as to when it may be "appropriate" to do so. All steps include "consideration of uncertainty" under the "Points to be considered". While this is valuable it reinforces the need to review the discussion of uncertainty in the INTRODUCTION and to make sure that it goes beyond consideration of uncertainty in data to other aspects such as measurement uncertainty and modelling uncertainty, and the connection between uncertainty and variability.
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: It would be useful to have more discussion on potential comparators, and how to determine the appropriate comparator/baseline (see comment above about missing concepts).
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: No specific view

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: This section introduces 'risk characterisation' without explaining what this is. It also states that "the likelihood of each adverse effect being realized has to be assessed and evaluated beforehand". This suggests confusion in risk assessment terminology that could be overcome by an introduction to the risk assessment process being applied and possibly a table showing links between the different terminologies used in different jurisdictions such as the OIE, IPPC, CODEX, ISO and the USEPA. It is important to note that it is the likelihood of the specific level of adverse effect that needs to be assessed – not just the likelihood of any adverse effect (since this may lead to the overstatement of the risk). The other important concept that could be better explained is that of a plausible pathway between the hazard or source of effect and the endpoint.
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: See above

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: (as stated in the response to Q12) It is the likelihood of particular levels of adverse effect that need to be evaluated. This is unclear in the Roadmap. The likelihood cannot be determined until one has specified the adverse effect that the likelihood will relate to. Essentially risk analysis has advanced since Annex III was developed.
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: No specific view
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: This section infers that all analysis should be qualitative – this may not be the case. The points to consider are useful, but they do not give guidance as to how they might be taken into account.
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: Points (d) and (e) need elaboration as to the circumstances in which they will be relevant. Given the different ways in which risk can be estimated, this section is short. It might be helpful to have more reference to the range of alternative approaches that might be applied (see answer to Q12)
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: It is difficult to answer this question (and others) with a simple yes/no response. The rationale notes that in step 4 it should be determined whether the assessed risks meet the criteria set out in the protection goals, assessment endpoints and thresholds, as established in relevant legislation of the Party or in its practice. This is the first time since discussing the background of risk assessment that protection goals, assessment endpoints and thresholds are introduced, and there is no guidance as to how to do it. Further, given that Step 4 is the estimation of the overall risk, surely this should be left until Step 5 which is where decisions about acceptability etc are made?

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: Once again the inference is that estimation of the risk will be qualitative. There appears a lack of clarity in that it is unclear as to whether the 'overall' risk is aggregated risk or whether there will be a range or set of 'overall' risks. The statement that "there is no universally accepted method to estimate the overall risk, but rather a number of methods are available for this purpose" would be more helpful with examples.
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: This step indicates a separation between the assessment and management of risk. This is not current best practice in our view. We see modern risk analysis as tending to avoid use of the phrase "acceptability of risks" because of the context aspects. This is alluded to in the 'Points to consider'. This section refers to removing the identified risks (paragraph 2). This appears to demonstrates a misunderstanding of the nature of risk and risk assessment/analysis– first of all you can't 'remove' risk and secondly you probably cannot reduce identified risks (but you can reduce assessed risks). It may simply be a mistake and may mean assessed risk.
Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: See earlier comments on missing concepts including protection goals, assessment end-points and risk thresholds etc. Point (a) under points to consider talks about the criteria for the establishment of acceptable/unacceptable levels of risk – at this stage it is not the criteria for the establishment of these levels that is relevant, it is the criteria for the levels themselves. It is worrying that the concept of acceptability is not given greater prominence. While this will vary from country to country and in many circumstances different concepts such as tolerability may be used, we see it as critical that novice risk assessors be given good guidance as to how to determine these criteria within their own country.
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: Discussing identified risks, the focus is on risks that are not acceptable in relation to the established protection goals, assessment end-points and risk thresholds. In order to apply this, risk assessors would require more information on these essential concepts (see earlier responses).

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: We would suggest this section might be removed and the relevant material placed in other sections of the document.

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: General comment: Context and Overarching Issues are treated separately whereas they are similar, or the same. The related issues box also belongs with Context.

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 difficult to conclude. The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity.

Q27. Does this section include all the necessary relevant concepts?

☐ Yes

☐ No. Please comment:

It is difficult to say. Can't say. The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity.

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:

Overly complicated words and language used – if English was not your first language you would probably struggle. Expected that novice risk assessors would have difficulty understanding this section.

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:

It is difficult to say . The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity

Q30. Does this section include all the necessary relevant concepts?

☐ Yes

☐ No. Please comment:

It is difficult to say.. The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity.

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:

Overly complicated words and language used – if English was not your first language you would probably struggle. Expected that novice risk assessors would have difficulty understanding this

section.

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:

Can't say. The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity.

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

☐ Yes

☐ No. Please comment:

Can't say. The relevant points to be considered during a risk assessment should be determined on a case-by-case basis based on the LMO and activity.

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:

Overly complicated words and language used – if English was not your first language you would probably struggle. Expected that novice risk assessors would have difficulty understanding this section.

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.

No section-specific comments:

We are not clear who the intended audience is for this section of the document as it does not appear to provide clear guidance for the novice risk assessors on how to perform a risk assessment.

It is complicated when you have to move around the document (or go to different documents) to find the information needed.

Where are the references to scientific literature regarding the plausibility of each of the "points to consider" or other issues to be considered?