SUBMISSION FROM THE UNITED STATES OF AMERICA (NON-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: <Country's name>

☒ Other Government. Please specify: United States of America

☐ 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	☐	☒	☐	☐	☐
• 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 falls short in helping the target audience, namely those who have little or no experience in conducting risk assessments (RA) of LMOs in the context of the Protocol. It would be better to finish the main Guidance (Roadmap) before adding the additional guidance documents. The reasons for issuing these additional documents does is unclear if the main Guidance is supposed to cover all LMOs. Moreover, the Guidance fails to acknowledge that there is considerable experience in numerous countries that have evaluated the biosafety of LMOs for decades, and that environmental releases of LMOs are routinely done around the world, building upon the extensive experience in other areas of risk assessment of organisms.

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: <Annex III states "Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms." This idea of the

RA supporting informed decisions by competent authorities is key for the context of the RA, but it is not made clear here or elsewhere. As a consequence, the Guidance in its current form does not give adequate emphasis to the point that the competent authority will make a decision, and the RA should be both well-reasoned based upon the best available information, as well as sufficiently clear in its reasoning to be useful to the competent authority responsible for making the decision regarding the transboundary movement of the LMO. Numerous countries have, in fact, conducted appropriate RAs related to the biosafety of LMOs that were able to inform the decisions.

Regarding the use of appropriate comparators, the Guidance restricts comparison to the non-modified recipient organism, but in many cases it will be more useful to compare an LMO with another similar LMO that has already been well characterized (e.g., a new BT-crop that has been modified with the same or similar genetic construct would be a very useful comparator).

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

☐ Yes

☒ No. Please comment: < The guidance does not adequately explain whether the guidance pertains to environmental releases of LMOs that are confined and of limited duration (e.g., field tests of LMO plants) as well as the unconfined environmental releases that would be associated with introducing a new LMO plant variety into agricultural practice. This is an especially important consideration for RA practitioners with limited experience, because they may not realize that many of the information elements and scientific data described in the guidance are not available when someone asks for permission to bring an LMO into the country to conduct a limited field test evaluation.

Furthermore, the Guidance should be more explicit that it is not in fact "the" definitive guide, but rather reflects the views and experience of the members of the AHTEG that had an opportunity to provide input into its development. The introduction gives the impression that the AHTEG member's views were evaluated equally on their merit, without regard to whether the expert represented a Party, non-Party, or observer. The Chairman of the AHTEG made clear in the latter sessions of the AHTEG that the opinions of AHTEG members of Parties would have precedence over those of non-Parity and observer members. The approach of this Chair was in stark contrast to the way the Chair of the first AHTEG on RA handled the discussions and contributions from all members of that AHTEG.

The introduction should also provide the reader with additional context on the technical qualifications of the experts serving on the AHTEG. Such a suggestion was made by a non-Party member of the AHTEG in an effort to provide increased transparency regarding the qualifications of AHTEG members, but the idea was rejected by the Chair of the AHTEG. Such transparency may assist the target audience in evaluating the validity of the Guidance overall. It would be useful if the Guidance included an annex that included the technical qualifications that accompanied the nominations for AHTEG members (and upon which the Secretartiat based in part its decision on AHTEG membership).

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: <It is assumed that the primary target users of this guidance are those who have little or no experience in conducting RA under Annex III, since this was the implied charge (target group) in the terms of reference for the AHTEG. Many of the key concepts in this section are not clearly made. For example, the statements about potential adverse effect from LMOs apply to non-LMOs (i.e., non-LMOs can present potential for adverse environmental effects, as occurs with alien invasive species). This context is missing from the introduction and would be more useful to the target audience, instead of the statements that are covered later in the document about the steps of risk assessment, etc. In this section, and throughout the Guidance, there are too few clear examples to illustrate the points being made. There is restatement of text from the Protocol, but little explanation about how numerous countries have conducted specific RAs to support decision-making by competent authorities. Here and elsewhere in the Guidance, the discussion of uncertainty lacks adequate context, specifically that uncertainty is not unique to LMOs, but rather a consideration in the scientific process itself and the way by which we evaluate scientific information in the light of existing practices.

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: <There should be a greater emphasis on what this step means in actual practice by those conducting RAs, specifically that identification of potential adverse effects (in many RA models described as "hazard identification") is a key step that can save a great deal of time in the overall RA. If there is no hazard identified, the rest of the RA is not really needed. This point is often not appreciated by novice risk assessors, and the Guidance should describe this concept with some clear examples based upon actual experience.
Q10. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <This section would be clearer to the target audience if there were examples that illustrate how our experience in evaluating the phenotype or characteristics of organisms bears more relevance than focusing on the technique by which the organism derived the characteristics. Here and elsewhere, such examples would make the concept much clearer for the novice assessor. This would be a chance to provide a more useful description of how comparators are used throughout the RA process.
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: <There is an over-reliance on merely quoting the Protocol. There should be more examples given of LMOs that have already been reviewed and are being used in

	the environment. There are many such examples upon which to draw, and the experience to date around the world is that there have been no scientifically verifiable adverse environmental effects among LMOs approved for environmental release. A number of LMO crops have been reviewed in multiple countries and are now being used in agricultural production systems. Such examples would be very useful illustrations to make the concepts come alive. There is little explanation of the jargon (and too few clear examples to illustrate). For example, outcrossing and flow of transgenes is just one example of the items listed in the "points to consider" that have inadequate explanation. Actually, the text here gives the erroneous impression that transgenes flow without the rest of the LMO genome going along.
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: <The Guidance text gives the impression that likelihood evaluation is of equal weight in each risk assessment. That is not the case,and the text should provide some examples drawn from experience of countries that conduct RA associated with limited environmental releases that are part of the field trials used in plant variety development for both LMOs and non-LMOs . If the focus is primarily on LMO plants, as stated in the introduction, the discussion of horizontal gene transfer is regarded as largely irrelevant by scientists and risk assessors around the world. Here is a case where the guidance might describe why this is irrelevant for LMO plants.
Q13. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The Guidance text is too brief when it states "the intended scale and duration of the environmental release." This section could have been a very good place to describe how RA/RM for limited environmental releases (e.g., field trials) can be applied in a way that differs from the RA/RM for unconfined environmental releases that might be part of agricultural production using an LMO crop variety. Specifically, the example could explain that RA for a confined release can be done with less information in the hazard identification (Step 1) if it is possible to limit the likelihood of interaction of the LMO with the environment during and following the environmental release. This is the standard practice used for RA at the early field trial stage, but this point is not made sufficiently here or elsewhere in the Guidance.>
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: Here and elsewhere, there is extensive use of terminology and jargon with little explanation or examples given to illustrate the point. Outcrossing and flow of transgenes is just one example of the items listed in the "points to consider" that have inadequate explanation. Actually, the text here gives the impression that transgenes flow without the rest of the LMO genome going along. Again, the text refers the reader to a long list of potential references, but the novice risk assessor is unlikely to sort this out in a way that is meaningful

	(that was the job of the AHTEG, according to the terms of reference established for the AHTEG at MOP4).
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: <The items listed in the "points to consider" section give the impression that these will typically come into play, but that is not necessarily the case. As described above in the comments to Step 1, the lack of identified potential hazards at that step will mean that these points in Step 3 are not needed. Again, the point that should have been made in Step 1 should also be made here. The overall risk hypothesis or problem formulation approach is not apparent in the way the Guidance is laid out, and it is likely to result in the target audience getting the impression from the Guidance that these "points to consider" will come into play.>
Q16. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: The Guidance should emphasize here and elsewhere that the comparative approach in the risk assessment does not limit the choice of appropriate comparator organism to non-LMOs either in theory or in actual practice. The comparative approach is part of Annex III and other guidance on RAs, and it calls for comparing the risks posed by the LMO to an appropriate comparator organism, typically one that is similar in many respects to the LMO.
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 phrase "combinatorial and cumulative effects" is unclear. The discussion of uncertainty is unclear as presented, especially as it lacks the context of how this relates to the scientific process, how risk assessors typically use a "weight of evidence" approach to combat potential uncertainty about the reliability of particular data. As presented in the text, this sounds like a huge hurdle for the risk assessor, and it is presented with no practical approach that the risk assessor can use. In actual practice, uncertainty about data on LMOs and non-LMOs are addressed adequately, but the Guidance text does not make this clear to the target audience.

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: <The brief, generalized description of this step omits the key consideration that only when potential adverse effects have been identified can the steps 2-4 be conducted. In addition, it is misleading to the target audience to suggest here and elsewhere that risk assessors just tack on the phrase "also taking into consideration any relevant uncertainty that emerged in the preceding steps" to each consideration throughout the RA. See previous comments about the use of the "uncertainty analysis" in various parts of the Guidance. As presented in the text it is confusing and misleading.
Q19. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <This section would benefit from some specific examples of how this step is applied in practice. The examples should be drawn from actual cases in which risk assessors have used this approach as part of a risk assessment that was used by competent authorities to make decisions related to the transboundary movement and introduction of an LMO into the environment. As written, there is not enough concrete information for the target audience (RA novices) to understand how this step fits into the overall RA.
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: <Here and elsewhere in the Guidance, many terms are not explained, including "protection goals, assessment endpoints and thresholds." Clarity of these terms are especially relevant in this section, since the Guidance is invoking other national laws and statutes. Additionally, with this statement, the risk assessor is now given the impression that the scope of the RA is not in fact as described in the introductory sections of the Guidance (namely that this is guidance for conducting a RA under the Cartagena Protocol). This drifting of the scope of the document is not limited to this section.
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: The "points to consider" section of Step 5 states "The criteria for the establishment of acceptable/unacceptable levels of risk, including those set out in national legislation or guidelines, as well as the protection goals of the Party, as identified when setting the context and scope for a risk assessment." This is again taking the the scope of this Guidance beyond the bounds established by the Parties in the terms of reference for this AHTEG, since this text suggests that the RA is to be done with a scope greater than that described in Annex III of the Protocol. It is clear from this part of the Guidance text that the drafters confused risk assessment with decision-making.

Q22. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: <The text of Step 5 misses the opportunity to use some particularly clear examples to illustrate how RAs consider the LMO in the context of current practices. These examples can be drawn from many countries' experiences, particularly those who have found a benefit from using BT-crop varieties instead of relying solely on chemical insecticides to control insect pests of crop species (the examples in the Philippines are particularly compelling). Likewise, numerous countries could cite how they factored into their RA how herbicide tolerant LMO crops enabled the benefits for controlling soil erosion and greenhouse gas generation, as well as improved use of water and mineral nutrition of crops. The concepts of the Guidance can be far clearer if it were to include such examples that are readily grasped regardless of the experience that the target audience may have in conducting RAs of LMOs.
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: <The target audience is likely to be unclear what the authors mean by risk management or monitoring strategies. Do the authors mean monitoring for the LMO's effects on biodiversity? There is no discussion about what is meant by risk management, nor are there clear examples given in the text. The mention of "refuge areas" to protect against the development of resistance to an insecticidal protein needs much more discussion, especially since many see this not as mitigation of a risk but rather prolonging the useful life of an insecticide in agriculture. Without the context, this part of the text is likely to be misunderstood. Frequently the reasons have been misunderstood as to why some countries have used such refugia, why this approach is used only in some instances (e.g., not for other pest resistance traits in LMO crop plants) and what the results have been in achieving the desired outcome.
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: The "related issues" section looks like the authors could not decide what to say about these headings, so there are just phrases in a list. There is no text to describe what the authors intended with these items, but they appear to be outside the scope of work laid out by the Parties in the Terms of Reference for the Guidance document. It might be best to omit these if they can not be described in the context of the Guidance.
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: The Flowchart is confusing, describes activities which are outside the Terms of Reference for the Guidance document, and also outside the scope of Annex III. Of note, some of the most useful steps that RA practitioners follow in government regulatory systems around the world are not included in the flowchart (and only minimally described in the Roadmap Guidance document). For example, one of the first questions to ascertain is whether the proposed

	environmental release will be confined and limited (e.g., field trial of an LMO plant) or without confinement (e.g., commercial scale use of an LMO variety). Another key question that is typically done early in the process is whether the LMO, or one similar to it, has previously been evaluated in a RA either in one's own country or in another country. Neither of these two items is mentioned in the flowchart. As presented, the flowchart seems unlikely to be helpful to the target audience seeking to follow Annex III to do a RA.
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: The guidance makes an assumption based on poor scientific justification. Why should there be a separate guidance for stacked traits beyond the overall Guidance document? Our experience with non-LMO plants with stacked traits does not indicate a need for a separate evaluation when each of the progenitor plant lines are considered to be safe. The overall Guidance document states that it is supposed to be for all LMOs.
Q27. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: There is inadequate discussion of our experience in plant selection and breeding that relates to the supposed need for additional RA of stacked trait plants when each parent is safe. There should be a thorough discussion of hybrid variety development during the past 70 years and how that relates to the need or lack thereof for additional RA for plants with stacked traits.
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: The terminology is nonstandard, especially with the description of what is meant by "stacked traits." It is unclear why the consideration only includes those traits that were introduced by rDNA techniques or cell fusion beyond the taxonomic family. The logic and argumentation throughout are not convincing.
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: <The concepts are not sound from a scientific perspective, especially since the focus is primarily on the method of genetic modification rather than the resultant phenotype. The description of phenotypes is overly simplistic, as are the suppositions about the potential environmental effects.
Q30. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: LMO plants with tolerance to abiotic stress should be discussed in context with the appropriate comparators, e.g., non-LMO varieties that are tolerant to abiotic stress. There are numerous examples in the scientific literature of non-LMO plants that tolerate abiotic stress, but these are not

	a significant part of the discussion in this guidance document. The limited attention to the issue in the Guidance making it challenging for the target audience to appreciate how the information regarding non-LMO comparator plant's interaction with the environment would factor into a RA for the LMO plant modified for abiotic stress tolerance. There is a rich scientific literature on non-LMOs that has not been included in the guidance that would provide useful context for those doing RAs on LMO plants which tolerate abiotic stress.
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: There is inadequate development of most of the ideas and concepts in this annex. Without clear examples, the relevance and relationship of this annex to the overall Guidance document is not clear. In general, the concept of familiarity could be a useful discussion to include, especially to the intended target audience who will likely be familiar with numerous examples of the safety of non-LMO plant varieties and how they can actually promote biodiversity by preserving the productivity of crop land under changing conditions of abiotic stress.
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: This topic had inadequate technical expertise on the AHTEG, and the limited time for its preparation meant that only a few of the world's experts in this area had a chance to contribute during the online sessions. The AHTEG drafters of this annex on mosquitoes did their best with available experience in this area, but it is not possible to conclude that it contains all scientifically relevant and accurate information on this topic. As a consequence, the current version is very limited.
Q33. Does this section include all the necessary relevant concepts?	☐ Yes ☒ No. Please comment: There is incomplete discussion of the potential impacts on the role that LM mosquitoes (LMM) would have on controlling mosquito-vectored pathogens of humans and other animals. It seems that this topic is being addressed more thoroughly and extensively by other internationally recognized groups of scientists and government officials. These concepts have not been fully considered in this annex. There needs to be some acknowledgement that different types of LMM are under development. Some of these are sterile (at least for practical purposes) and are not expected to spread beyond the release area. These are the type that has been released thus far. Other LMM are being engineered to contain some form of gene drive (weak or strong). These will differ in their ability to persist in the environment and to spread their transgenes into the local mosquito population. LMM with gene drive are not yet available. The concept that all LMM will not have the same risk characteristics with respect to persistence and moving transgenes into the environment is not well conveyed. The risks of LMM need to be considered in the context of

	benefits, especially with respect to human health. It is important that the text also reflect the other consideration here regarding the risks posed by conventional mosquito and vector control methods. For mosquito control, current methods are based on use of broad spectrum insecticides and on land management activities (such as drainage and landfilling), both of which also have environmental implications.
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: The language in this section introduces several concepts only briefly, and these are concepts that will relate to all phases of RA/RM. These include epidemiology of dengue and malaria, as well as the ecology of mosquito breeding. Many users of this document will find it puzzling that the term "cross-fertilisation" is used for the mating of mosquitoes. The text refers to the "risk of horizontal gene flow", but it never identifies the hazard or likelihood of this (this is inconsistent with how risk is estimated in RA). There is no identification of potential adverse effects (hazard identification) regarding horizontal gene transfer. The guidance mentions "quality control" of the released LMO mosquitoes but does not elaborate on this in the context of identifying hazards, likelihoods, consequences, and overall risk. Without such context, the guidance misses an opportunity to address what this issue of "quality control" means in the overall RA.

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. Throughout the Guidance document there is a lack of examples to illustrate how Annex III can be applied in various cases of doing a RA for an LMO. There are now many cases that have been done around the world, and many LMOs have been reviewed multiple times and subsequently approved for environmental releases. Many LMO crops are used as part of agricultural production around the world, but the Guidance document gives the impression that we know very little about LMOs or how to evaluate their biosafety as part of a systematic, yet flexible approach to RA that is consistent with Annex III of the Protocol.

It will not be apparent to the target audience reading this Guidance document that Annex III was written to be broadly applicable to various LMOs and compatible with a range of national regulatory frameworks to address biosafety. That's a significant shortcoming in the Guidance as it stands now.