Testing of the Guidance on Risk Assessment of Living Modified Organisms

#1

COMPLETE

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Q1: **Type of submission:**	Other Government

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Q2: Name of the Party:	*Respondent skipped this question*
Q3: Person submitting this questionnaire:	*Respondent skipped this question*
Q4: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q5: Context in which the testing was conducted	*Respondent skipped this question*
Q6: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q7: In what language was the Guidance tested?	*Respondent skipped this question*

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Q8: **Name of the other Government:**	Canada
Q9: **Person submitting this questionnaire:**	
Full Name:	Olivier Morin
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Q10: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q11: **Context in which the testing was conducted**	Individual exercise(s)

Q12: **Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.**	
Risk Assessment 1:	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2006-59/eng/1311614163773/1311614524215
Risk Assessment 2:	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2011-86/eng/1331650522962/1331653085996
Risk Assessment 3:	http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/dd2010-82/eng/1331755614111/1331755683913
Risk Assessment 4:	http://www.dfo-mpo.gc.ca/csas-sccs/Publications/ScR-RS/2013/2013_023-eng.pdf
Q13: **In what language was the Guidance tested?**	English

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Q14: Name of the organization:	*Respondent skipped this question*
Q15: Person submitting this questionnaire:	*Respondent skipped this question*
Q16: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q17: Context in which the testing was conducted	*Respondent skipped this question*
Q18: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q19: In what language was the Guidance tested?	*Respondent skipped this question*

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Q20: **Would you like to submit an evaluation of the following section of the Guidance: Part I: The Roadmap for Risk Assessment**	Yes

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Q21: **This section of the Guidance is practical.1**	
(no label)	Disagree

Q22: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The general guidance provided by the document is not conducive to the very specific recommendations that appear frequently. Specific recommendations for a general case are not useful or helpful. A good example is the extensive list of specific elements provided as points to consider for only the molecular characterization (line 440-452). There is no link to why any of these aspects may be important or a recognition or how many of these components, if any, would be required if the risk assessor has high familiarity with the trait and organism and/or the phenotype is well characterized. The cases considered in the testing treated the molecular characterization in terms of how they related to the expressed product and possible routes of exposure. Aspects such as the copy number, and site of insertion are generally irrelevant to that assessment. A consideration of phenotypic and genotypic changes is only relevant if it has a realistic linkage to a harm Many of the molecular characterization element identified may very well be irrelevant in all but a very few specialized cases but they are presented as "point to consider" although they would be rarely be points to consider and function more to encourage unfocussed data collection. Concentrating on small changes in genotype (line 453) is not a useful exercise unless linked to a hypothesis. Product efficacy features such as in the points to consider in Line 451 are not part of the risk assessment. Genotypic or phenotypic instability would rarely be a hazard but more frequently a product failure and does not warrant consideration unless it can be linked to a specific harm. Similarly, herbicide tolerance is an aspect of the applied pesticide product not the LMO and in any case is not a hazard but an inevitable outcome of product use and would only be significant if it resulted in the failure of all possible control options, a high unlikely scenario.(line 469). In the cases tested, evolution of herbicide tolerance in weed populations is considered in the context of management advice to a user rather than a point to consider for the risk assessor. – Overall, the "points to consider regarding characterization of the LMO" (lines 432 to 456) would be more practical if it was guiding the evaluators to determine the potential harms rather than to collect information for an extensive list of parameters. For example, instead of listing the various components of a thorough molecular characterization, the guidelines could trigger the evaluator to (1) determine if any toxic sequences have been inserted into the host organism, (2) determine if any endogenous toxic gene could have been upregulated resulting from the genetic modification, (3) determine if any antibiotic resistance gene sequence have been inserted into the host genome that have clinical significance, (4) determine if potential genotypic instability could result in a specific hazard, etc. Such an approach would allow for incorporation of concepts such as long history of safe use and familiarity and would also avoid collection of information that would not be useful for the risk assessment, such as information related to product efficacy. The purpose of the data collected for a risk assessment is not the same as data collection to satisfy scientific curiosity ("need to know vs. nice to know"). This fundamental concept has not been captured anywhere in the guidance despite its critical importance to the risk assessment.

- In the first paragraph about the identification and consideration of uncertainty (lines 267-274), it is important to clearly state that the consideration of uncertainty and its importance to effective decision making is subject to a great deal of discussion and the importance will be variable, depending on where uncertainty occurs.
- In the section about the identification and consideration of uncertainty (lines 267-297), it would be more accurate to say that "Communicating uncertainty adds precision to the communication of outcomes of the risk assessment" rather than "Considerations of uncertainty strengthen the scientific validity of a risk assessment" as the degree of uncertainty can be helpful to risk managers and decision makers when they weigh options.

The section on uncertainty from 267-297 was unhelpful in practice and seemed more geared to confound a clear process then to enhance the end product. Although reviewers did not consider all of the literature referenced, it really did not provide much additional clarity on the practical application in risk assessment process. It is unclear how an uncertainty analysis, especially considering that this is generally a subjective judgment, strengthens the "scientific validity of the risk assessment" (line 275). The science, if sound, will stand on its own merits but communicating the degree of uncertainty can be helpful to risk managers and decision makers when they weigh options. It would be more accurate to say that communicating uncertainty adds precision to the communication of the outcomes of the risk assessment. The acknowledgment in this section that more information can result in more uncertainty is useful but no examples are provided. This could be helpful for context and highlight the pitfalls in unfocussed data requests.

Uncertainty is inherent and associated with risk assessment (not "an inherent and integral element" as stated in line 267). This section is more likely to paralyze a novice risk assessor with indecision since complete information will never be available and both the importance and degree of uncertainty is highly subjective, despite the many attempts at quantification and it is not at all clear that extensive considerations of uncertainty really do enhance the final risk assessment as affirmed in this section.

Q23: This section of the Guidance is useful or has utility.2

(no label)	Neutral

Q24: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

In practice, risk assessors in Canada found the guidance confusing and unworkable for most cases considered. The LMO risk assessments considered for testing did not follow the format of the Roadmap in their reporting or the hazards considered. The language is confusing and inconsistent with the terminology generally used. Speculative hazards such as those discussed in line 431 where gene products combine for an unexpected hazard has never been identified in any of the cases reported on the BCH. The addition of these terms on several points in the guidance is not useful. The points to consider format suggests that normal phenomena such as gene flow to wild relatives is a hazard.

Line 180 refers to the broad intended applicability of the Roadmap, including to limited scale releases and field trials. In testing the Roadmap was only marginally applicable for risk assessment of field trial of an LMO plant. Much of the information identified in the Roadmap would be unknown or irrelevant in the context of a confined field trial release. For example, potential for vertical gene transfer (line 482) is a relevant consideration for field trials, but other considerations listed in the documents, as potential changes to existing agronomic or pest management practices (line 478), are not. Other important considerations for the receiving environment (line 471) for a field trial of an LM plant, as control of land and proximity to the related cultivated species are not included at all in the document. In general, considerations of larger landscape effects are irrelevant in the context of a small scale field trial with limited duration. The objective of field trials is generally to learn about the LMO and generate the information that is under consideration in the Roadmap in contrast to a request for larger scale release where most information about the LMO should be known. In this context the Roadmap has little applicability to a confined field trial. Small scale research field trials have different considerations that are mostly related to inspection, monitoring and risk management. Since this Roadmap has limited utility for risk assessment related to field trials, we suggest removing the paragraph beginning at line 184. Directive Dir 2000-07: Conducting Confined research Field Trials of Plant with Novel Traits in Canada: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-dir2000-07/eng/1304474667559/1304474738697 provides guidance to risk assessors on how to determine necessary and sufficient information and to applicants who wish to conduct field experiments. Many other competent authorities have similar guidance.

Gene transfer is not a hazard, it is a characteristic of living organisms, but the outcome of gene transfer may be. The concept of combinatorial and cumulative effects has not been captured in guidance or risk assessment of LMOs elsewhere. These speculative and unresolved concepts in terms of a LMO risk assessment add little value to the process of hazard identification and in fact these concepts add confusion and hamper utility.

Lines 299-340 on the planning phase of the risk assessment describe processes which differ from country to country and are rooted in law and derived regulations. The division in roles between risk assessment, risk management and decision making is rooted in policy and institutional structure. Although some competent authorities use consultative mechanisms, this is a function of policy and rooted in regulation, often as a requirement for public transparency and is not a condition for conducting a risk assessment of an LMO. With the wide divergence of models for implementation, the guidance offered is of limited utility and provoked more questions than practical guidance. Risk assessors are required to identify risks and their acceptability is decided by risk manager. The rest of the suggested steps would either be primary steps in developing regulations or guidelines or a special case where an LMO was proposed for release and these primary steps had not already occurred. This section should be eliminated as it is not generally applicable and adds extensive confusion.

- Lines 335 to 337 should be more specific and include categorization of the likelihood, magnitude of consequences, and the matrix to be used to estimate risk.

Defining the quality of scientific information, (line 229-239) is a policy decision by competent authorities and the guidance here is prescriptive in terms of policy guidance but vague in scientific terms. For example, there is guidance to use appropriate statistical methods but no guidance as to what those may be. The Roadmap acknowledges that there is no international guidance document but fails to acknowledge that risk assessors will bring professional expertise to bear and will be capable of making those determinations more effectively on their own using their own standards. The recommendation that methods be transparent and sufficiently detailed for independent verification (line 235) is unrelated to the quality of data submitted but rather addresses whether the competent authority wishes to verify submitted information. In Canada, Developers are responsible for the data they submit and misrepresentation would constitute a breach of the regulations. Independent verification does not take place. This policy recommendation is well outside of the scope of the Roadmap.

Q25: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q26: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

The Roadmap is structured in close alignment with the Annex 3 and captures concepts such as case by case, comparative risk assessments. Where it strays is the in inclusion of factors outside of risk assessment and risk management such as product efficacy (described above.) and the extensive discussion of policy elements such as data quality, consultation with stakeholders and selection of experts. (line 263)
The section on risk management blurs the line between decision making and risk management and as in many other areas of the document, recommends policy. This is not in line with Annex 3. The last section on related issues has no place in this document. It is not complete enough to be useful, is subjective in the topics chosen and is far outside of the scope of the Roadmap which is intended to enhance the guidance in Annex 3.

Q27: **This section of the Guidance takes into account past and present experiences with LMOs.4**

(no label) Disagree

Q28: **Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:**

- Include key and long established concepts for LMO risk assessment such as the use of familiarity to increase potential utility. Risk assessments are not linear but rather horizontal processes where hazards are considered in context, familiarity factors into the information required and the degree of hazard identification undertaken This is apparent in the LMO risk assessments posted on the BCH.
- Line 367 suggests that the use of a non-modified counterpart may not be sufficient to assess the risk of a stress tolerant plant. For countries that have conducted risk assessments on these types of crops, there has been no evidence to date that this is the case. It is difficult to follow the scientific logic behind this statement and as practice to date contradicts this statement, it is counter-productive to include this in guidance. Since Annex 3 states unequivocally that LMO risk assessments are comparative it also departs from the guidance in Annex 3. Even if there is significant divergence from the usual domestic phenotype, the process would still be comparative as described in Annex 3, therefore this paragraph should be deleted. The inclusion of extensive text on indirect effects, synergistic and combinatorial effects ignores the long history of experience with LM crops where these risks have not been realized and provides no context for when they might be. The recurring emphasis on these speculative risks without actual context is counterproductive and confusing.

Q29: **Here you may provide further details to explain your answers in evaluating this section of the Guidance:**

The cases considered in the testing are those were conducted by experienced risk assessors but at least one risk assessor had no familiarity with the cases chosen. None reported that the guidance was helpful. All noted that steps suggested in the planning phase, and overarching issues sections did not seem to be reported in the LMO risk assessments' at least for LM plants on the BCH. There seemed to be both prescriptive and vague guidance combined and the depth of detail was not consistent. It was felt that the document needed to be reconfigured to better reflect the information contained in reports on the BCH and thus the accepted practice of competent authorities.

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Q30: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LMOs with stacked genes or traits** No

PAGE 8

Q31: **This section of the Guidance is practical.1** *Respondent skipped this question*

Q32: **Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

Q33: **This section of the Guidance is useful or has utility.2** *Respondent skipped this question*

Q34: **Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

Q35: **This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3** *Respondent skipped this question*

Q36: **Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

Q37: **This section of the Guidance takes into account past and present experiences with LMOs.4** *Respondent skipped this question*

Q38: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

Respondent skipped this question

Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

Respondent skipped this question

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Q40: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM crops with tolerance to abiotic stress

Yes

PAGE 10

Q41: This section of the Guidance is practical.1

(no label) Strongly Disagree

Q42: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The comments on the Roadmap apply to this document as well. Fixing the flaws in the Roadmap would render this document unnecessary.

Q43: This section of the Guidance is useful or has utility.2

(no label) Strongly Disagree

Q44: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

Same comment as above.

Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q46: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

Respondent skipped this question

Q47: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q48: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

The document suggests that the use of a non-modified counterpart may not be sufficient to assess the risk of a stress tolerant plant. For countries that have conducted risk assessments on these types of crops, there has been no evidence to date that this is the case. It is difficult to follow the scientific logic behind this statement and as practice to date contradicts this statement, it is counter-productive to include this in guidance. Those familiar with profiling technologies acknowledge that this is a powerful tool for research but not to generate relevant risk assessment data. The statement about the use of “omics” technologies is attached to speculative risks and unless a clear explanation of how those risks could arise, why that is different from any other LMO plant and how transcrptomics can address those risks, this section should be eliminated. It is scientifically unsound and devalues the document.
The discussion on cross talk in stress tolerance mechanisms is interesting but is not contextualized to any potential resulting harms. Countries have long experience with a wide variety of stress tolerant plants that are derived through conventional breeding. The document makes no mention of existing experience and once again ignores the concept of familiarity.

Q49: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The document has little grounding in the current experience with stress tolerant LM plants or the extensive experience with stress tolerant plants derived through conventional breeding technologies. There is no reference to either current or past experience. As a consequence, it provided little useful guidance to risk assessors.

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Q50: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM mosquitoes

Yes

PAGE 12

Q51: This section of the Guidance is practical.1

(no label) Neutral

Q52: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The title should be changed to reflect what is covered in the text; in other words, that the scope of the guidance is limited to LMO mosquitoes that are important as vectors of human and animal pathogens and parasites. To be practical, the section (not 'document' as used under the heading 'Objective and Scope' lines 1439, 1443 and 1446) on 'Conducting the Risk Assessment' should include a sub-heading on 'Containment' based on the rationale that given the uncertainties with the possible effects of LMO mosquitoes, a limited release (trial) may be desirable and therefore information should be sought on a description of any means of containing or controlling the release. Here is a suggestion:

"Containment (biological, physical, chemical, temporal) of the living modified mosquito

Rational:

Given the uncertainties with the possible effects of widespread release of LM mosquitoes into the environment, limited release in a particular geographic zone may be desirable. Description of any means of containing or controlling the release of the living modified mosquito inside of the intended target zone.

Points to consider:

(a) Description of physical containment and its effectiveness
(b) Description of chemical containment and its effectiveness
(c) Description of biological containment and its effectiveness including success rate of separating sexes or induction of sterility.
(d) Description of temporal or other means of containment and their effectiveness"

There are a number of rather speculative possibilities under the heading 'unintentional effects' that are not practical in risk assessment; if these are of concern, then what would be useful here is some suggestions for a research program that would reduce the uncertainty. Certainly there is closely related research that could be used as a surrogate. Experienced risk assessors are always dealing with some uncertainty. Unacceptable uncertainty provides further rationale for the need for containment and therefore, argues for its addition to the guidance.

Under 'points to consider', is this an exhaustive 'wish-list' of concerns? Only the most plausible should be kept; item (n) relates to a human-driven consequence that is not related to the LMO mosquito and, in most countries, would not be among the considerations for a risk assessment such as this.

Q53: This section of the Guidance is useful or has utility.2

(no label) Neutral

Q54: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

See above. Usefulness is related to practicality so the comments on practicality overlap with those on usefulness. Points to consider (i) and (j) are covered by point (k). Point (n) is not relevant to the RA of the mosquito. The Guidance would be clearer if the heading were 'Points that could be considered'. Lines 1714 to 1718 is a 'point to consider' when talking about containment strategies and should not be placed under RM (see text above regarding containment).

Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label)	Neutral

Q56: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

Respondent skipped this question

Q57: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label)	Disagree

Q58: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

Line 1612 should say: "The likelihood and consequences of this hazard can be gauged by assessing the fitness of the LM mosquito with the transgene should the self-limiting mechanism fail to prevent spread of the transgene."

1703 should begin with "Where a risk has been identified that warrants a response through risk management, risk assessors should consider risk management strategies such as monitoring the LM mosquitoes to ensure that the technology is functioning as intended and to identify any unintended adverse effects."

Paragraph starting at line 1746 should read "There are other issues that may be taken into consideration in the decision for environmental releases of LM mosquitoes used for control of wild-type mosquitoes that are vectors of human and animal pathogens and parasites which are not covered by Annex III of the Protocol. They encompass, inter alia, social, economic, cultural and health issues associated with the use of LM mosquitoes to control wild-type mosquitoes that are vectors of human and animal pathogens and parasites or, alternatively, the use of chemical pesticides or other means to achieve the same result. The use of LM mosquitoes will require broader considerations of how target-disease risk affects human behavior, veterinary medicine, public health practices and national health priorities in order to address the catastrophic human tragedy caused by exposure to wild-type mosquitoes that are vectors of pathogens and parasites of human health and veterinary importance."

Q59: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

In the context of LM mosquitoes for control of wild-type mosquito vectors, one should bear in mind the enormous potential public health good that could be achieved.

The LM mosquito guidance would likely benefit from linking with the OECD Mosquito Biology Consensus document now (2014) under development by the Working Group on Harmonization of Regulatory Oversight in Biotechnology.

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Q60: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM trees

Yes

PAGE 14

Q61: This section of the Guidance is practical.1

(no label)	Disagree

Q62: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

This below information pertains to forest trees. Concerning the section on The likely potential receiving environment specifically the text section, I would recommend including information pertaining to the potential longer life span of LM trees on the landscape, in particular to consider with more detail the potential impact on ecosystem processes (secondary ecological impact, or unintended impact). Ecosystem processes drive the composition and function of forest and include such processes as geomorphological (erosion and sedimentation rates), hydrological cycling (water holding capacity and surface-flow patterns) and biogeochemical cycling (nutrient mineralization and immobilization rates). Impacts on ecosystem processes can have cascading effects (e.g. alterations in atmospheric exchanges (trace gas fluxes and carbon balance) and soil processes (nutrient cycling and microbial diversity)) that can result in an alteration in the integrity of the ecosystem. In the section addressing the likely potential receiving environment(s) point (c) slightly addresses this point, but there should be a more detailed description (as given above).

Additionally it is important to consider potential impacts at a landscape level (secondary ecological impact, or unintended impact). A landscape can be defined as a heterogeneous land area (including heterogeneous habitats) composed of a cluster of interacting ecosystems (Forman and Godron (1986). LMO-related alterations in ecosystems processes over time may impact processes of interacting ecosystems. This level of interaction would be highly complex. This may be an impact that is more relevant when there is an ecologically sensitive ecosystem (e.g. aquatic, wetland, and riparian ecosystem) adjacent to the LMO site.

Additionally under Risk management strategies 'Points to consider:' for this section. An important point to consider should be the potential impact on biodiversity associated with cultural and management practices associated deployment of the LMO (secondary ecological impact, or unintended impact). This could occur due to changes in cultural practices such as application of fertilizer associated with the introduction of the LMO. This could have potential impacts on the environment, including effects on the diversity and ecosystem complexity of non-targeted species.

Foreman RTT and Godron M. 1986. Landscape ecology. John Wiley and Sons, New York. 619 pp.

This dispersal section is very vague and this can be misleading for forest tree species. I recommend specifically addressing the means of dispersal. For examples, gene flow associated with sexual propagation:

(i) Potential for gene flow to a wild relative. The LMO may hybridize with sexually comparative species (non-targeted species within the same genus and even other genera) and have an impact on the environment through the production of hybrids and their progeny. This form of gene flow is due to the production of transgenic pollen or wild-type pollen may fertilize a transgenic ovary. There are four basic elements associated with the likelihood and consequences for this form of gene flow: a) distance of pollen movement from the transgenic tree; b) synchrony of flowering between the LMO and wild-type species; c) sexual compatibility between LMO and the wild-type species; d) ecology of the wild-type species.
The LMO transgene can become permanently established in the wild-type populations(s) if it becomes introgressed into the genome. The likelihood of this is depended on environmental selection pressures. A transgene which increases fitness will more likely persist in the wild-type population.

(ii) Potential for gene flow of the LMO. Sexual propagation may occur through the formation and dissemination of transgenic seed (transgenic pollen fertilizing a transgenic ovary). This does not involve hybridization with non-targeted species.

3b) Gene flow associated with vegetative propagation:
(i) The potential for gene flow can also involve the dispersal of LMO's vegetative parts and their subsequent establishment. (e.g. stem or root segments).
Note, for 1-3 there may be addition potential impacts related to the length and scale of LMO release, and the LMO population size relative to the wild-type population(s). New unintended impacts may arise due to the release of LMOs on a large scale over long durations, which are related to stochasticity in climatic and biological conditions.

Q63: This section of the Guidance is useful or has utility.2

(no label) Strongly Disagree

Q64: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

There is a significant risk to have all trees (forestry and fruit) addressed in section C. Modern commercial apple production and other orchard fruits, for example, have more in common with field crop production than plantation forestry. Given the consideration of all trees under this section, there are many sweeping generalizations and this can be interpreted as implying that all GE trees may pose the same risks and must be evaluated by the same standards.

Q65: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q66: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*

Q67: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label)	Disagree
Q68: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q69: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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Q70: Would you like to submit an evaluation of the following section of the Guidance: Part III: Monitoring of LMOs Released into the Environment	No

PAGE 16

Q71: This section of the Guidance is practical.1	*Respondent skipped this question*
Q72: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q73: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q74: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q76: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q77: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q78: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 17

Q80: **Would you like to submit an evaluation of the following section of the Guidance: Background Documents**	No

PAGE 18

Q81: This section of the Guidance is practical.1	*Respondent skipped this question*
Q82: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q84: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

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Q85: **Please use the space below if you wish to provide additional feedback regarding the testing of the Guidance on Risk Assessment of Living Modified Organisms:**

The lack of practicality of the Roadmap was well illustrated by the testing process in Canada by experienced risk assessors and some novices. The organization is the key problem as it is difficult to reconcile the organization of the Roadmap with the actual process of conducting a risk assessment. The Roadmap describes an academic exercise that is not an accurate representation of real practice considers hazards without adequate context and requires that risk assessors become policy experts. The process described for the risk assessment is linear, and compartmentalized where the hazards are presented outside of the working context that risk assessors employ where hazards are considered and discarded when there are no realistic pathways from the hazard to any type of harm. This concept appears in the document but is never linked in any coherent way, even in the section on conducting the risk assessment. The document is presented in a way that does not acknowledge the professional judgment that is truly key to effective risk assessment and instead is replaced by prescriptive guidance on data quality. The hazard identification sections are not contextualized and as a consequence look like shopping lists.

Additional points identified:
- The scope of risks to human health in the context of an environmental risk assessment should be specified, e.g., topical exposure, etc.).
- Include list of references at the end of the document as is common practice. Including references as hyperlinks will only be useful when an internet connection is available and when the hypertext links are valid and active
- Part I should be broadly applicable, hence the focus on plants should be removed. This includes references to plants (lines 543-546) and crops (lines 589-592).