Testing of the Guidance on Risk Assessment of Living Modified Organisms

#3

COMPLETE

Collector: BCH website (Website Survey)
Started: Tuesday, April 01, 2014 9:26:38 AM
Last Modified: Wednesday, April 02, 2014 6:50:24 AM
Time Spent: 21:23:46

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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:**	United States of America
Q9: **Person submitting this questionnaire:**	
Full Name:	Michael Trulson
Email Address:	TrulsonMC@state.gov
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.aphis.usda.gov/brs/aphisdocs/09_05501p.pdf
Risk Assessment 2:	http://www.aphis.usda.gov/brs/aphisdocs/09_05501p_com.pdf
Risk Assessment 3:	http://www.aphis.usda.gov/brs/aphisdocs/04_26401p.pdf
Risk Assessment 4:	http://www.aphis.usda.gov/brs/aphisdocs2/04_26401p_com.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:

Overall, the Roadmap document (Part I of the Guidance) is not as practical as it could be for the novice risk assessors, for the following reasons:
1. The document does a very poor job of setting the context for comparative risk assessment by making clear our extensive experience in dealing with non-LMOs, not only non-LMOs modified by human intervention but also non-LMOs that are continually evolving without human intervention. As a consequence, our extensive experience with evaluating and dealing with potential environmental risks with non-LMOs is largely ignored in the document, even though this experience is key to using our prior knowledge to evaluate LMOs. The document gives the impression that the occurrence of outcrossing and instability of genotypes or phenotypes are something unique to LMOs (and that these phenomena are indications of environmental risk).
2. The document does not acknowledge the existing experience of over 40 years in evaluating potential environmental risks from LMOs. In contrast, the document gives the impression that there is a great deal of uncertainty and inexperience worldwide.
3. The document does a very poor job of providing practical guidance on risk assessment related to limited or confined environmental releases of LMOs (with LM plants, these are often referred to as field tests). This is relevant for the document discussion of topics beginning at line 218 and extending through the remainder of the document. The document says that some information may not be needed for confined environmental releases, but there is no tie-in with the concepts described elsewhere in the document (especially in the discussion on the likelihood of an adverse effect occurring).
4. The section on “uncertainty” uses the term in a manner different from the way that the term is used in the Protocol. Paragraph 8(f) of Annex III states “Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.” The underlined emphasis is added to highlight that according to Annex III the level of risk is determined at the end assessment, not with each step and consideration.
5. The document introduces additional terminology that is not consistent with the Protocol text, and the new terminology is not well explained. Perhaps the most striking examples of this occur in the section “conducting the risk assessment”, especially the use of “hazard identification”, exposure assessment, hazard identification, etc., rather than the text in Annex III of the Protocol (see lines 376-380 and onward through following pages). Additional terms are used, yet their meaning in relationship to the text in Annex III of the Protocol is not explained, including “causal link and pathway”, “non-target organisms”, “target organisms”, etc. No guidance is provided in the document to explain that in many cases there will be no target non-target organisms (e.g., LM-plant modified to tolerate drought conditions).

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:

Perhaps one of the most useful and practical suggestions for novice risk assessors is not addressed in the guidance document at all, and it would require extensive additional text to elaborate on the need for risk assessors to use relevant experts who know about the non-LMO versions of the organism and can set the context and extent of worldwide experience with confined releases and unconfined releases of the species of the organism in question. There is an over-emphasis throughout the document on the predictive utility to risk assessors of molecular genetic characterization of the LMO. In actual practice, the phenotype of the LMO is of far greater predictive utility in assessing potential environmental risks, and this approach has the added benefit of drawing upon our experiences with evaluating and using non-LMO organisms that have similar or identical phenotypes.
In order to increase the usefulness of this document, it should describe how confinement approaches for such releases serve to minimize the likelihood of adverse environmental impacts from the LMO release, even when detailed information on the specific LMO is not available. This is a well understood principle with testing LMOs and non-LMOs, and its value should be more extensively developed in the document.

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:

In the recapitulation of the reason for the guidance, this document focuses primarily on the potential problems with LMOs, whereas the Protocol and the parent convention emphasize the role of biotechnology in providing environmental benefits (and the need for a Protocol to enable sharing of these benefits, even before countries have their own regulatory mechanisms in place to facilitate the necessary transboundary movements of LMOs). This is primarily a case of missed opportunities to set the tone of the document in the Preface and Background sections.

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

(no label)	Strongly 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:

As mentioned in comments above, the current content of the document gives the erroneous impression throughout that LMOs are likely to pose risks to biodiversity that differ from those posed by non-LMOs, yet this is not supported by global experience to date in both confined environmental releases of LMOs or in unconfined releases of LMOs. There are numerous places in the document where the facts could be made clearer, but one specific example would be to note the actual experience with LM plants on line 182. The text could cite the experiences worldwide that there have been no substantiated adverse effects on biodiversity arising from either confined or unconfined LM plants. Such environmental releases have occurred over the past 30 years at tens of thousands of sites worldwide. This type of information would be very useful in the early parts of the document to set the context for the overall discussion of risk assessment that follows. It would also pave the way for a more well-developed explanation that it is not the technique of genetic modification that is of primary interest in risk assessment, but rather the phenotype of the organism resulting from the genetic modification.
The discussion on centers of origin, gene flow, etc., found throughout the document need to correct the impression left for readers of this version of the guidance that gene flow poses risks in and of itself (and that LMOs are unique in posing potential adverse effects on biodiversity). This is a pervasive short-coming of the document that cannot be pinpointed to a few lines, but they appear prominently in the section on Conducting the Risk Assessment (lines371-723) and the Flow chart (Figure1, lines 726-731).

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

The Roadmap should be revised to present a more balanced view of existing experience in doing environmental risk assessments of LMOs. It should also make clear that global experience with non-LMOs can provide a useful context for considering whether the phenotype of an LMO is likely to cause adverse effects to the environment. It would be best to revise the Roadmap before attempting any further topic-driven documents, such as those in Parts II and III of the guidance. Preparation of guidance on specific risk assessment topics should be done when there is a body of experience upon which to base the specific guidance. The topics in Parts II and III were chosen because of interest in the topics, rather than whether there was sufficient experience from numerous risk assessments upon which to base a document providing sound guidance. Until such a body of experience is developed, it is more prudent to continue with the case-by-case approach.
It is unclear whether the statement in lines 152-154 state that the guidance is a “living document” is the aspiration of the authors or the Parties to the Cartagena Protocol on Biosafety. After more than 5 years’ work by the AHTEGs and online experts to arrive at this rather weak draft of the guidance document, it seems worth considering whether this is the best mechanism for novice risk assessors to gain a better appreciation of how to conduct environmental risk assessments in a manner consistent with Annex III of the Protocol.

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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 — Yes

PAGE 8

Q31: This section of the Guidance is practical.1

(no label) — Strongly Disagree

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:

This section on stacked genes or traits is focussed solely on LM plants, yet the rationale for developing a guidance section on this topic is lacking. In fact, experience from doing safety assessments on non-LM plants would not suggest any need to evaluate the environmental safety of the offspring of two plants when each of the parents are considered to be environmentally safe. This is the first faulty premise of this section, that such guidance is logical or needed. It is not logical to advocate such a guidance section on stacked traits in LM plants, nor does it have any basis in the evidence of centuries of plant breeding and selection done by humans. Therefore, this does not seem to be a topic suitable for development of a guidance section. We understand that the AHTEG had only a very brief deliberation when choosing this and the other special topics for developing guidance sections, and that there was disagreement on these decisions. It is unfortunate that so much effort has been expended on this topic, and it is advisable to retract this section.
In addition to these shortcomings, the section provides no practical advice to risk assessors evaluating requests for confined environmental releases.

Q33: This section of the Guidance is useful or has utility.2

(no label) — Strongly Disagree

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:

As stated in the comment above, this section is likely to mislead novice risk assessors that there is some inherent reason why environmental risk assessments need to be done for the offspring of two parents who have already been deemed unlikely to pose adverse effects on biodiversity. Such a notion is contrary to worldwide experience with plant breeding over thousands of years.

Q35: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Strongly Disagree

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:

If "consistency with the Cartagena Protocol on Biosafety" means supporting its intentions as well as its words, this section of the guidance falls far short. The Cartagena Protocol does not advocate using poor science or accumulated knowledge in risk assessment, yet this section does not use logic or accumulated knowledge. As stated in the comment above, experience from conducting safety assessments on non-LM plants would not suggest any need to evaluate the environmental safety of the offspring of two plants when each of the parents are considered to be environmentally safe. There is nothing inherent in the techniques of modern biotechnology that would contradict observations from non-LM plants. It would be best to discontinue work on this section, since its fundamental premise is scientifically flawed and unsupported by empirical and experimental knowledge.
Repeatedly in this section, the authors say that certain evaluations "may be considered" or "may be relevant", yet there are no concrete examples from experience in which these actually indicated that the plants with stacked traits were likely to pose an increased risk to biodiversity. Such guidance is not constructive, in that it sends risk assessors on a path to request and evaluate information that does not bring them closer to a valid assessment of actual likely risks. As such, these faulty guidance recommendations prevent countries from being able to conduct a timely evaluation and reach a decision on the transboundary movement of LM plants. Such delays inhibit the ability of countries to share the benefits of modern biotechnology, a chief goal of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety.
These vague statements regarding what "may be considered" likewise give no practical advice on how to conduct a risk assessment when someone wants to conduct a confined, short-term field test with LM plants with stacked traits. This failure hinders the goal of the Protocol to provide a way for countries to have transboundary movements of LMOs for research and development, and thereby accrue some of the benefits that others have been able to realize.

Q37: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

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:

In the instances in which countries have done assessments of LM plants with stacked traits, it has not been for the purpose posited in this section. Lines 880-882 make the erroneous statement: "Likewise, the evolution of resistance in target organisms (e.g., insect pests) to such stacked LM plants could happen faster than the development of resistance to the parental LM plants." Stacking of insect resistance traits is done to slow the development of resistance in inset populations. In any event, the development of resistance in pest and pathogen populations occurs with non-LM plants, too. In fact, most of the phenomena that this section ascribes or implies as unique to LM plants are common to non-LM plants, also. The section on methods to distinguish stacked trait plants from mixtures of non-stacked parental lines is disingenuous when it states in lines 943-944: "Based on the considerations above, the detection of each and all individual transgenes in a stacked event, if needed or required, may become a challenge and may need special consideration." In fact, there are no such reliable, practical methods, to use in the case of LM plants in agriculture.

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

Please see the previous comments and suggestion to retract this section. The scientific rationale is consistently weak or lacking.

PAGE 9

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:

In the Introduction to this section, lines 957-959 state: “While the same general principles used in the risk assessments of other types of LMOs also apply to LM plants with increased tolerance to abiotic stress, there are a number of specific issues that may be of particular importance when assessing the risks of LM plants tolerant to abiotic stresses”. In fact, none of the specific issues cited subsequent to this are unique to LM plants modified to tolerate abiotic stress. The issues around pleiotropic effects and potential changes in invasiveness are not unique to LM plants modified for increased tolerance to abiotic stresses, nor are they unique to non-LM plants crossed with other non-LM plants. The authors provide no context of how such issues of pleiotropic effects or potential invasiveness are evaluated in non-LM plants, and that would have been useful information to place the evaluation LM-plants in context.
This section does not provide any practical distinctions to aid risk assessors when evaluating requests for confined environmental releases of LM plants modified to tolerate abiotic stresses.

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:

Consistent with the comment above, this section of the guidance does not introduce any new topics that are not already addressed in the overall Roadmap (Part I of the guidance). Most of the Roadmap was written with a strong focus on LM plants, and the discussion in this section adds little to the information presented previously in the Roadmap. Like the Roadmap and other sections on LM plants, this section lacks information that is useful or helpful to the novice risk assessors trying to decide what information is relevant for confined environmental releases as compared to unconfined environmental releases. It would have been useful if this section made clear global experience with non-LM plants, as well as existing varieties bred and selected for their ability to tolerate abiotic stresses. This is a common occurrence with many non-LM crop plants, forages, ornamentals, and forest trees, but the text neglects to make this as clear as it could be.

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

(no label) Strongly Disagree

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:

If “consistency with the Cartagena Protocol on Biosafety” means supporting its intentions as well as its words, this section of the guidance falls far short. The text follows the same recipe for restating the elements found in Annex III of the Protocol, but it does little to clarify when and why it may be relevant to consider certain attributes of the LM plants modified to tolerate abiotic stresses. The text of this section, like the rest of the guidance, is written in a manner that gives the reader the impression that these traits and their potential effects on biodiversity are unique to LM plants, thereby inhibiting researchers, developers, and governments from pursuing modern biotechnology techniques to achieve plants which can tolerate abiotic stresses, such as drought, flooding, and increased salinity.

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 text does a poor job of depicting the knowledge gained from non-LM and LM plants modified for increased tolerance to abiotic stresses. There is virtually no information in the text nor its references cited to inform novice risk assessors of the vast array of stress tolerant non-LM plants used, bred, and selected around the world. The case of LM-plants is not much better in the text, yet there have been numerous plant species evaluated and tested in confined field tests around the world in response to pressing needs in agriculture, horticulture and forestry. Some LM plants for abiotic stress have completed the risk assessments at the commercialization phase, as well, but the text makes no mention of them.

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

As with other sections of the guidance, any section on LM plants for abiotic stress should be emphasizing for the novice risk assessor the relevant characteristics that might be of concern. Other than the vague discussion on pleiotropic effects, the other points to consider focussed on issues relevant to weed risk assessment, a topic that is well-developed for non-LM plants. This section should have highlighted the extant weed risk assessment models, how they are used, which data are most relevant, and how recommendations are reached for non-LM plants. This would help to set a constructive context for risk assessors of the LM plants modified for abiotic stress tolerances.

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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	No

PAGE 12

Q51: This section of the Guidance is practical.1	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q53: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
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	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q59: 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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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) Strongly 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:

Consistent with the comments above for other sections of the guidance, this section of the guidance on LM trees does not introduce any new topics that are not already addressed in the overall Roadmap (Part I of the guidance). A number of statements are made in this section that imply that the characteristics of some trees warrants a unique section of the guidance, but a rationale for this suggestion is not given.

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

(no label) 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:

The usefulness of this section of the guidance is hindered by confusion in the scope that echoes at various places through the document. The problem of scope begins with the apparent contradiction of line 1169 which states: “Forest biodiversity is one of the seven thematic programmes of work under the Convention on Biological Diversity (CBD).” Yet in the following paragraph, lines 1177-1180, the authors state that the scope of this section is not limited to forest trees, but rather encompasses all true trees. The contradictory echoes reappear throughout this section, especially with the generalizations that seem to describe primarily forest trees (lines 1182-1212), yet the text compares trees to annual crop plants rather than non-trees.

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

(no label) Disagree

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:

As with other sections of the guidance, the section on LM trees follows the organization of Annex III with “points to consider”. However, the rationale for certain statements and assumptions to support the “points to consider” is lacking or faulty throughout this section.

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

(no label) Strongly 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:

The text does a poor job of depicting the knowledge gained from non-LM and LM trees. As mentioned above, there are a number of sweeping generalizations in the text that imply that these characteristics are unique to tree species (especially long life, symbiotic relationships, complex ecological relationships, etc., mentioned lines 1182-1212). There is virtually no information in the text nor its references cited to inform novice risk assessors of the vast array of non-LM trees used, bred, and selected around the world in horticulture, fruit and nut production, wind and soil erosion control, and pulp and timber production. The case of LM-trees is a bit better in the text, describing some of the tree species evaluated and tested in confined field tests around the world in response to pressing needs in agriculture, horticulture and forestry. Some notable LM trees have completed the risk assessments at the commercialization phase, as well. It is disappointing that this section gives little attention to the benefits that plant breeders see in using modern biotechnology techniques to introduce traits that otherwise take decades to incorporate into tree species. In some cases, such as the resistance of papaya to papaya ringspot virus, there were no known sources of resistance which breeders can turn to for resistance to this pathogen that attacks papayas wherever they are grown.

Q69: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

Overall, there is little unique information presented in this section that is not already in the Roadmap (Part I) of the guidance. The general statements (lines 1181-1212) introducing the reader to trees are not enough to inform readers who are unfamiliar with trees, and overly generalized for those who know about trees. The existing information, including OECD biology documents on specific tree species provides more practical information for risk assessors, and there are more informative resources on various tree species that could be cited in addition to the OECD consensus biology documents.

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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

Yes

PAGE 16

Q71: This section of the Guidance is practical.1

(no label) Strongly Disagree

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:

This section of the guidance does not seem to be very practical for use in real situations in which countries are trying to achieve the protection goals of the Cartagena Protocol on Biosafety. This section of the guidance seems to confuse detection of LMOs (lines 1775-1778) and monitoring adverse effects of LMOs released into the environment (lines 1786-1788). The document chooses to categorize monitoring as either case-specific monitoring or general monitoring (lines 1798-1799) and explains in the accompanying footnotes that some of the experts in the online forum and AHTEG thought that general monitoring should not be part of the guidance. In terms of practicality, the general monitor approaches are not well-designed to yield information that would reliably indicate a causal relationship between the environmental release of an LMO and some purported adverse effect. This conceptual shortcoming, and lack of expert agreement on general monitoring, should be more clearly highlighted in the text (i.e., more than a footnote should warn of the weak basis for advocating general monitoring). It is good that the text of line 1800 directs the reader to the purpose of monitoring as described in paragraph 8(f) of Annex III of the Protocol, but it is not very practical if the subsequent text of this section doesn't provide some real-life examples of environmental monitoring that was useful in detecting the levels of risk identified in the risk assessment, i.e., the levels of adverse effects to biodiversity. The text in lines1822-1831 states that general monitoring is used in some approaches, but does not resolve the inability of such general monitoring to link an adverse effect to the release of the LMO.

Q73: This section of the Guidance is useful or has utility.2

(no label) Strongly Disagree

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:

Throughout this section of the guidance, the authors have incorrectly confused monitoring for the presence of LMOs with monitoring for the adverse effects arising from the environmental release of LMOs. The Protocol states the purpose of environmental monitoring when there is uncertainty in the level of risk identified in the risk assessment. The text needs to clarify that (1) not all environmental releases of LMOs are likely to cause adverse effects on biodiversity (then give specific cases illustrating this point both from examples of confined and unconfined environmental releases of LMOs), (2) monitoring is done to address uncertainty in the level of risk from a risk assessment and therefore needs a clear scientifically plausible hypothesis to test, and (3) any parameter or indicators need to have a strong basis for indicating likely adverse effects, not merely measuring some change in the environment.

Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Strongly Disagree

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:

The text is inconsistent with the Protocol when it states in lines 1833-1835 that: "A monitoring plan is developed when the recommendation of a risk assessment and/or the national biosafety policy calls for monitoring activities to be carried out in conjunction with the environmental release of the LMO." This differs from what is stated as the purpose of environmental monitoring (lines 1779-1782 correctly direct the reader to paragraph 8(f) of Annex III for the purpose). The text in lines 1833 brings national policies into the discussion, and this is clearly beyond the scope of the Protocol text.
It is strongly suggested that the authors revise the text so that the reader can clearly understand that change in some parameter does not mean that there an adverse impact on biodiversity has occurred (e.g., the section on Choice of indicators and parameters, lines 1857-1879). Among other things in this section, line 1859 should make it clear that in order to be consistent with the Protocol, the monitoring is for adverse effects, not just effects. Further clarification is needed throughout this section to address whether the proposed monitoring can actually indicate a causal relationship between the environmental release of the LMO and the adverse effect observed.
Monitoring in the sense of the Protocol is not verifying compliance with laws and regulations governing LMOs, but there are places in which novice risk assessors and others are likely to get this impression from many of the supporting documents cited for this section. Such background documents are not appropriate for this section.
In addition, monitoring in the sense of the Protocol is not detection of LMOs, and these discussions should be clarified or removed from the text (lines 924-944, 1775, 1847-1849) and supporting documents cited for this section of the guidance (too numerous to cite here).

Q77: **This section of the Guidance takes into account past and present experiences with LMOs.4**

(no label) Strongly Disagree

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:**

As mentioned in the comment above, this section of the guidance does not provide a strong rationale for why the described "general monitoring" approach is likely to yield reliable information as to whether an environmental release of an LMO has actually caused an adverse impact on biodiversity. There are no examples cited in the text of when such general monitoring has yielded such information, yet the authors seem to advocate such an approach. The section on establishing baselines (lines 1916-1929) is rather vague about how such baseline information has actually been used to indicate that the release of an LMO has caused adverse impacts on biodiversity. Here, as elsewhere in this section, the authors have incorrectly implied that change equals likely adverse effects to biodiversity. It needs to be clarified consistently in this and other sections of the guidance that mere change does not mean that there are adverse effects to biodiversity.

Q79: **Here you may provide further details to explain your answers in evaluating this section of the Guidance:**

This section of the guidance does not appear to be well supported by knowledge gained through actual use. Most of the background documents cited for this section illustrate the problems with using reports that are not subsequently substantiated. This is the case for almost all of the background documents cited for the section heading. For the background documents cited for the subheadings of this section on monitoring there are two additional cited documents, namely one abstract (by two members of the AHTEG on RA, "Observational science in the environmental risk assessment and management of GMOs [2012]") and a food safety study on pigs (Carman, et al, A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet [2013]). In general, the background documents here and throughout the guidance need to be re-examined for relevance to the actual final text.

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

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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:** *Respondent skipped this question*