Testing of the Guidance on Risk Assessment of Living Modified Organisms

#2

COMPLETE

Collector: BCH website (Website Survey)
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PAGE 1

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

PAGE 2

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*

PAGE 3

Q8: **Name of the other Government:**	Australia
Q9: **Person submitting this questionnaire:**	
Full Name:	Peter Thygesen
Email Address:	peter.thygesen@health.gov.au
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://bch.cbd.int/database/record.shtml?documentid=105380
Risk Assessment 2:	http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/dir102-3/$FILE/dir102rarmp.pdf

Q13: **In what language was the Guidance tested?**	English

PAGE 4

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*

PAGE 5

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

PAGE 6

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:

Lines 324-328 does not provide any practical guidance on what differences might apply and why.

Lines 351-370 are impractical in most circumstances. In most cases it is the species that is used as the comparator with an emphasis on cultivated varieties as these provide the most information and the best relevant indicators of risks posed by the non-modified parental organism. This is also the level at which most biology documents are prepared for use in risk assessments of LMOs. For most indicators of risk varietal differences are not significant. For those few indicators such as levels of endogenous toxins that may be relevant (more typically in food safety testing), the range of values in cultivated varieties gives a more realistic indication of acceptable levels than a single (near-)isogenic line, which may be aberrant in some way. In practice, many LMOs released are made from backcrossing into elite varieties from the original transformant that may be no longer cultivated, and therefore not relevant as the non-modified comparator.

Lines 428-431 should carefully distinguish between field trials and commercial releases as several of these types of effect do not seem relevant to field trials (as tested on Australian case study DIR 102).

Lines 460-461 do not provide practical guidance in the absence of what is meant by 'sufficient data' or 'meaningful baseline'.

Lines 519-522 do not work in practice. For example, a toxin expressed by a plant may have multi-trophic effects, such as the plant is consumed by an insect, which is eaten by another invertebrate, which is then eaten by a bird, which in turn might be eaten by an animal (e.g. a snake), which may then be affected by the toxin. The level of uncertainty increases the higher up the trophic scale we go. Therefore, from lines 519-522 we should assign 100% likelihood of an adverse effect to the snake if we have not specifically tested the toxins effects on the snake? This is not done in the two Australian case studies.

Lines 523-525, 580-582, 615-618 and 623-626 are not practical if clear criteria are not established during the planning (context) phase. In particular, the use of 'indeterminate' risk (line 624) is impractical as there is always incomplete knowledge and so would be applied for all risks all of the time. This is out of step with the two Australian case studies and regulatory risk assessment methodology in general where uncertainty is already considered as part of the likelihood and consequence assessments.

Lines 619-622 are particularly confusing and difficult to put into practice as no guidance is given on what is meant by 'multiple lines of evidence', 'quantitatively or qualitatively weighted', or 'combined'. Practical examples would help.

Lines 630-636 are missing the key point in practice, namely, how the estimates of likelihood and consequences are going to be combined to give a level of risk either individually or overall.

Lines 633 and 635-636 are already catered for in practice in step 1 as seen in the two Australian case studies.

Line 634 does not clearly distinguish risk management strategies that are established as part of the context and those that arise from evaluation of the overall level of risk. For the field trial case study (DIR 102) the controls proposed by the applicant for restricting spread and persistence form part of the risk context and then used in step 1 as consistent with Annex III, not at step 4 as suggested by this guidance.

Lines 672-677 can be confusing in a regulatory setting where monitoring normally refers to monitoring for compliance with licence conditions. No mention is made to distinguish these uses of the term monitoring in practice. Nor is there mention of other monitoring related activities that form part of the licence conditions in the two Australian case studies, namely, adverse effects reporting obligations and contingency plans.

Line 683. An additional point to consider as important in practice is whether or not a proposed risk management measure may introduce additional risks or increased level of identified risks.

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

(no label)	Disagree

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:

Lines 200-201 is confusing as determination of what is considered an adverse effect is used to derive assessment endpoints, not the other way round. Also, this provides little useful guidance if legislative protection goals are broad, such as, 'to protect the environment'.

Lines 290-296 give the misleading impression that all uncertainties are significant and should be dealt with. Instead the focus should be restricted to uncertainty sources that impact on the overall risk in a way that may significantly affect decisions.

Line 275 is not useful as it is highly contentious and is even contradicted by the example on lines 519-522 as assigning a likelihood of 100% that an adverse effect will occur whenever there is a high level of uncertainty (e.g. experimental trials described in lines 254-259) can be expected to be scientifically invalid on most occasions. Uncertainty is central to the concept of risk. Therefore, the risk assessment provides a systematic framework to consider uncertainty. It would be better to say that explicit considerations of uncertainty provide transparency in the decision making process.

Lines 343-370 would be assisted by acknowledgment that the non-GM comparator have associated risks (e.g. gluten in wheat and barley, glycoalkaloids in potatoes, gossypol in cotton, weediness in rice), which serves as a baseline to determine if the GM version has

barley, glycoalkaloids in potatoes, gossypol in cotton, weediness in rice), which serves as a baseline to determine if the GM version has additional or increased risks. In addition, there should be recognition that in some circumstances, the appropriate comparator may be a GMO (e.g. with new forms of GM cotton in environments where GM cotton is already the standard cultivated form of cotton).

Lines 377-378 'risk assessment is defined as a science-based process…..' should delete 'defined as' as parts of the Roadmap that describe adverse effects and risk acceptability rely on policy (i.e. non-science). In the two Australian case studies the adverse effects identify the values that are affected (i.e. constitute harm) and expressed in the Risk Analysis Framework (OGTR 2013, see http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/42D3AAD51452D5ECCA2574550015E69F/$File/raffinal5_2.pdf). Only after explicit description of these values is evidence (including science-based evidence) used to test if these values are affected.

Lines 401-406 are confusing and do not fit well with the simple, clear sentence at line 398. The two Australian case studies are more consistent with line 398.

Lines 410-413 and 417-421 only discuss changes without specifying what an adverse effect might be. The two Australian case studies put emphasis on what the potential adverse effects might be.

Lines 412,413 – the term 'target' should be replaced by 'assessment endpoint' as it could lead to confusion with 'non target organisms' and 'target organisms' used elsewhere, eg line 419.

Lines 426-427 – should also include behavioral changes.

Lines 428-431 are not useful without clear examples provided using existing LMOs. It also involves ambiguous use of effects. Are combinatorial and cumulative effects shorthand for combinatorial and cumulative adverse effects?

Lines 469-470 are highly contentious. This is not meaningful without stating the protection goals. If they are protection of agricultural yield or food security then they may be relevant. However, in the Australian context, as described for these two case studies, the protection goal is the environment. These suggested adverse effects would be considered as economic/stewardship issues, not environmental adverse effects.

Lines 476-481 are very confusing as they mix together different types of consideration (use, intended receiving environment/receiving environment due to potential for spread and persistence, nature of the receiving environment, pathways to adverse effects, and adverse effects) in an incoherent manner. Each point to consider should be simple and clear.

Lines 509-514 seem to indicate that risk hypotheses/scenarios can be established in the absence of a causal link, which is very likely when there is no actual causal link. It also contradicts the clear statements at lines 415-416 and 505-506.

Lines 547-552 can be misleading by confusing likelihood of adverse effects occurring with the likelihood of a single link in the causal pathway to an adverse effect. It could be made clearer by adding 'as a step in a pathway to an adverse effect', after 'compatible species', in line 547.

Lines 564-565 – as for lines 509-513, this text describes factors which should have already been taken into consideration in development of the risk scenarios – this should be clarified in the text.

Lines 586-597 are not clear that they indicate magnitude of the consequences as they do not explicitly describe an adverse effect, but seem more to do with step 1 or 2.

Lines 598-599 are not clear if this is referring to effects or adverse effects? Without examples this does not seem useful.

Line 604 is not clear what the adverse effect is as invasive plants (i.e. spread and persist) do not necessarily give rise to adverse effects (as is the case in the two Australian case studies). Suggest rewording to indicate that data from field trials could provide information about potential for invasiveness and impacts in the environment.

Lines 612-636 give little useful guidance on the notion of level of individual risks as opposed to overall level of risk and how these are actually achieved. As uncertainty is considered in both likelihood and consequences, it will already be reflected in the level of risk estimated from the combination of these two elements. As discussed currently, it sounds like a new consideration.

Lines 620-621 have little use and provide less insight than the parent statement at paragraph 8(d) of Annex III. Multiple lines of evidence may well be used to obtain the likelihood and consequences ratings, but what has this got to do with combining these to obtain an estimated level of individual risks, which are then combined in some unexplained way to obtain an overall level of risk. In the two Australian case studies the likelihood and consequences are combined through a risk matrix that can be more clearly linked to Annex III than to these lines.

Lines 664-668 are confusing as only relevant if it affects the estimates of the overall level of risk.

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

(no label)	Disagree

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:

Lines 178-179 are open to misinterpretation as going beyond the scope of Annex III. Paragraph 2 of Annex III states that "Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms." Therefore, the primary target group should be competent (national) authorities. Any use beyond this group should be seen as an unintended benefit, not its primary objective. Risk assessment of LMOs in the two case studies used here (DIR 102 and 108) were done by the Australian competent national authority.

Lines 204-205 states that risk assessment methodology is a 'tiered process', which implies a hierarchy rather a flat, albeit connected, process as described in Annex III. Both Australian case studies are consistent with Annex III rather than a 'tiered process'. Would be better described as a 'stepwise process'.

Line 269 is missing and/or to be a strictly correct quote from Annex III.

Lines 219-296. This section is not consistent with paragraphs 3-6 under "Guiding principles" of Annex III, which would seem to fill an equivalent role.

The section 'Quality and relevance of information', lines 222-265, seems to misinterpret "Risk assessment should be carried out in a scientifically sound and transparent manner…." in paragraph 3 of Annex III. Instead the Roadmap restricts attention regarding scientifically soundness and transparency to information used in a risk assessment rather that to the overall process of risk assessment itself. Indeed, nothing is provided in the Roadmap to indicate scientific validation of its own guidance.

Similarly, the discussion in the section 'Identification and consideration of uncertainty', 266-296, seems to be restricted to matters related to uncertainty regarding the level of risk as addressed in the methodology section of Annex III, paragraph 8(f), rather than uncertainty in the overarching sense as discussed in paragraph 4 of Annex III.

Both sections of the Roadmap, 'Quality and relevance of information' and 'Identification and consideration of uncertainty' are important considerations in risk assessment. However, as described here, they would be better suited in the section 'conducting the risk assessment', line 371, and with a more appropriate title such as 'risk assessment methodology under the microscope'. However, this would highlight the absence of guidance on the section, "Guiding principles" in Annex III. Part of this gap could be filled in part by substituting lines 219-296 with lines 343-370 of the Roadmap. However, lines 346-364 are problematic (see below) and new text would still be needed to provide guidance on paragraphs 3, 4 and 6 of Annex III.

The Australian case studies are consistent with Annex III, but not the Roadmap in these matters.

Lines 346-364 are inconsistent with lines 344-345, which is a direct quote from paragraph 5 of Annex III. The context (comparator) is risks posed by the non-modified recipients or parental (missing in line 333) organism. This implies a comparative risk assessment in which risks posed by the LMO are considered against the risks posed by the non-modified recipients or parental organism. The Roadmap limits discussion to changes of genotype and phenotype in the LMO, rather changes in the nature and level of risks. These risks should be considered in the context relevant and appropriate to the organism under consideration, and does not imply that comparisons require 'the same time and location, and under the same environmental conditions', line 352. For example, risks regarding potential adverse effects to beneficial organisms may be compared between the LMO (e.g. a Bt crop) and the non-modified recipient under different environmental conditions (e.g. different pesticide types/application regimes) if these are appropriate to differences in standard management practices that are expected to apply under normal production conditions.

Lines 466-468. It is not clear that the Protocol makes a clear distinction between biological diversity in centres of origin and centres of genetic diversity (emphasised in the Roadmap) as opposed to biological diversity elsewhere (e.g. nature reserves or World Heritage areas).

Lines 586-597 and line 604 are inconsistent with 8(c) as they are not about the consequences of adverse effects but about causal pathways to potential adverse effects.

Lines 605-606 should be consequences of adverse effects not consequences of effects.

The Australian case studies are consistent with Annex III, but not the Roadmap in these matters.

Lines 620-621 are misleading. Estimating the level of overall risk (as well as individual risks) is "based on the evaluation of the likelihood and consequences of the identified adverse effects being realized", paragraph 8(d) of Annex III, not a 'best estimate of risk from multiple lines of evidence'. It uses non-evidential methods to combine likelihood and consequence assessments.

The Australian case studies are consistent with Annex III, but not the Roadmap in this matter.

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:

Lines 227-234 are important as studies purporting adverse effects from LMOs have typically shown shortcomings in these aspects. So the addition of some of these examples would be useful.

Lines 275-289 are an idiosyncratic treatment of uncertainty that is not applied in the regulatory setting, including the two Australian case studies. In fact, the implied nature of 'incomplete knowledge' in the sentence at lines 286-288 contradicts the majority position in risk analysis, which treats incomplete knowledge as a form of epistemic uncertainty and reducible (to some degree in principle) by obtaining additional information.

Lines 237-238. Sample material has never been required by the Australian competent national authority. Instead, relevant information is requested about the sample material from the applicant.

Lines 222-265 ignores the reality that competent national authorities such as Australia provide the necessary independence for assessing the information either through regulatory staff, enlisted expert advice and consultation. Also, relevant information is determined by legislation.

Lines 300-340 ignore the importance of other key parameters for establishing the context and seen in the two Australian case studies, namely the risk criteria for the likelihood and consequence assessments, and for combining the two; information from previous risk assessments of the same or similar LMOs; and proposed limits and controls to restrict spread and persistence of the LMO (particularly relevant for field trials).

From experience in the Australian context and also shown in the two case studies, molecular information (lines 443-456) have not provided clear examples for identifying substantive risks; this is particularly marked for field trials.

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

PAGE 7

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) 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: *Respondent skipped this question*

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

(no label) 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: *Respondent skipped this question*

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

(no label) 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: *Respondent skipped this question*

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

(no label)	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:	*Respondent skipped this question*

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

This part of the Roadmap was tested on DIR 108, a commercial release of a stacked LM canola. The same issues that apply to the Roadmap also apply here and if corrected would allow application to stacked traits without the need for additional guidance. More specific comments include the following.

Lines 794-817 are not relevant as the comparator is the species Brassica napus. Therefore the issues of choice of non-modified comparator are straight forward and the innate heterozygosity part of the normal considerations and are not particular to a stacked event.

With regards to conducting the risk assessment, the methodology was consistent with Annex III but followed little of the guidance material.

Lines 819-869 were considered of little relevance and did not give rise to any realistic risk scenario.

In lines 870-900, only lines 877-878 were considered relevant, but did not give rise to an identified risk that warranted detailed consideration.

In the Australian context lines 901-949 are part of all risk assessments and therefore subject to the normal considerations that form part of the Roadmap.

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)	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:	*Respondent skipped this question*

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

(no label)	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:	*Respondent skipped this question*

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

(no label)	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:	*Respondent skipped this question*

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

(no label) 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:

This part of the Roadmap was tested on DIR 102, a field trial of abiotic stress tolerant LM wheat/barley. The same issues that apply to the Roadmap also apply here and if corrected would allow application to abiotic stress tolerant traits without the need for additional guidance. More specific comments include the following.

This guidance material does not acknowledge the extensive experience with introducing abiotic stress tolerance through conventional breeding and other (indiscriminate) forms of mutagenesis. In practice these are considered desirable traits that potentially allow more uniform yields to be produced in existing agricultural areas, not to extend growing into even more marginal zones (lines 1083 and 1151-1156), where there is competition from better adapted species.

Lines 1009-1050 are not relevant as the standard methods using the parental species as the comparator and comparing risks.
Lines 1052-1162 were largely irrelevant as this case study is a field trial, which identified risk scenarios that are typical of LM plants and did not need special considerations. Nevertheless, the introduced characteristics were considered in terms that might affect proposed controls to restrict spread and persistence of the LMOs (e.g. lines 1135-1136), which apply to all LM plant applications. No additional controls were deemed necessary other than those determined of the basis of the biology of the non-modified parental species.

Furthermore, data is expected from these field trials that might answer some of the issues raised in lines 1052-1162. In addition, Australia applies a weed risk assessment methodology that covers unintended effects, which would encompass pleiotropic effects, cross-talk and unintended effects from genes introduced and intended to provide abiotic stress tolerance. Therefore, there would be no need for the “omics” technologies suggested at lines 1040-1043.

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

PAGE 11

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*

PAGE 13

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**	No

PAGE 14

Q61: This section of the Guidance is practical.1	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q63: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
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:	*Respondent skipped this question*
Q65: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
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	*Respondent skipped this question*
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*

PAGE 15

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*

PAGE 19

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*