Testing of the Guidance on Risk Assessment of Living Modified Organisms

#3

COMPLETE

Collector: BCH website (Website Survey)
Started: Wednesday, December 11, 2013 10:24:41 PM
Last Modified: Wednesday, December 11, 2013 10:56:25 PM
Time Spent: 00:31:44

PAGE 1

Q1: **Type of submission:**	Party

PAGE 2

Q2: **Name of the Party:**	Malaysia
Q3: **Person submitting this questionnaire:**	
Full Name:	Dr Mohana Anita Anthonysamy
Email Address:	anita@nre.gov.my
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q5: **Context in which the testing was conducted**	Group event(s) (e.g., w orkshop, training course, meeting)
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.**	
Risk Assessment 1:	http://bch.cbd.int/database/record.shtml?documentid=101474 and http://bch.cbd.int/database/record.shtml?documentid=101480
Q7: **In what language was the Guidance tested?**	English

PAGE 3

Q8: Name of the other Government:	*Respondent skipped this question*
Q9: Person submitting this questionnaire:	*Respondent skipped this question*
Q10: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q11: Context in which the testing was conducted	*Respondent skipped this question*
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.	*Respondent skipped this question*

Q13: In what language was the Guidance tested?	*Respondent skipped this question*

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:**

Please refer to response in #12

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:

GENERAL COMMENTS
1. It is a difficult document to read. We suggest that a more user friendly document is developed.
2. Points mentioned should be separated/differentiated to what is essentially needed and what is good to have.
3. Language used is too complicated. It should be simplified.
4. Content is repetitious and too wordy.
5. Case examples should be extracted out from the main document.
6. For countries looking at assessment of LMOs for the purpose of Food, Feed and Processing only, this document is not useful at all.
7. Use bullet points in the formatting to enhance clarity.
8. Have sections and numberings so that it will be easier for any cross references.
9. A lot of information can be put in appendices/explanatory notes. Keep the main document simple…with headers, etc. Examples, options, alternatives should be mentioned in appendix.
10. “Points to consider" are all useful points. May avoid listing this points using alphabets. Use numbering so that it is easy for reference and to break it up into smaller segments if necessary.

SPECIFIC COMMENTS
1. Title of the Document TITLE - it may be changed to “Guidelines” as it serves as an option only
2. Line 195 - Put the 3 items in bullets
3. Line 218 OVERARCHING ISSUES - Change title to – BASIC PRINCIPLES FOR RISK ASSESSMENT PROCESS
4. Line 219 and Line 225 - a number of “issues” is stated. The term “issues” gives a negative connotation. Use more neutral language. Positive language will get better co-operation from scientists. Terms like issues. Suggestion is to replace with “points”.
5. Line 241 - Have a header for the paragraph – information linked to protection goal. It is too wordy. Suggest changing into a more clearly structured format. Shorter paragraphs.
6. Line 237 and line 244 - There must be consistency of words – “data”, “information”, “relevant data” are all used in this document. Too many repetitive terms. Suggestion is to use “information” and explain that information includes data, raw data and others. All unnecessary explanations can be put in glossary.
7. Line 266-274 Identification and Consideration of Uncertainty - Rather lengthy explanation of uncertainty. Suggest putting as appendix.
8. Line 275-277 - Suggest removing line 275 – 277. It provides unnecessary justification to do a risk assessment. It is already mentioned in the main CBD document that uncertainty is a concern.
9. Line 299-340 - PLANNING PHASE OF THE RISK ASSESSMENT. Instead of providing lengthy possibilities, have a short concise checklist. Have a summary document on how to do a risk assessment.
10. Line 343-370 - CHOICE OF COMPARATORS. Suggest shifting this part to Appendix. Just simply mention in the main document that the appropriate comparator must be chosen and provide a cross reference to the Appendix.
11. Line 365-370 - Suggest removing line 365-370. It’s confusing, and there is no need to refer to “other risk assessment”. The paragraph seems ambiguous and does not add value or any useful information. It may cause confusion.
12. Line 371 - 387 - CONDUCTING THE RISK ASSESSMENT. Explanatory notes should not be in the main document. Just keep to main steps.
13. Line 272-387 - Suggest putting in explanatory notes as Appendix.
14. Line 393-431 Step 1 - Simplify the rationale; keep to one page, just the main points. Any additional information can be put in Appendix.
15. Line 500-525 Step 2 - Rationale can be simplified some more.
16. Line 519-522 - It is not logical to “assign a likelihood of 100% that an adverse effect will occur…”
There is an inconsistency in the terminology used as the assessment described is qualitative (Line 523-525). There should not be a percentage value that is used for uncertainty (quantitative value) but instead a qualitative value description should be used for consistency.
17. Line 526-557 - Points to consider – can reduce the explanation and examples. If there is already a Training Manual that complements this document, then there is no need for so much of explanation and examples.
18. Line 561-582 Step 3 - Rationale can be simplified some more.
19. Line 611-628 Step 4 - Rationale can be simplified some more.
20. Line 641-682 - Rationale can be simplified some more.
21. Line 707 - Is this supposed to be risk/benefit analysis or scientific benefit analysis?

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 training manual developed was not consistent with Annex III or the requirements as listed in this Guidance document.

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:

1. Some items in the document are impossible for developing countries to adopt. There is financial constraint to do some of the requirements
2. It is not a practical working document to conduct a risk assessment. However, it can be used as an additional reference.
3. A lot of information that is needed is not essential to make a decision. The document may be misinterpreted that everything that is listed must be done.
4. How much data would be considered enough from the list? The items for consideration cannot be generalized that it is applicable to all.
5. It is not a practical document to conduct a risk assessment for an experimental field trial. For countries that are trying to develop their modern biotechnology capacity, these requirements are overwhelming.
6. The document is not a print-friendly document as there are a lot of links attached. It will not be easy for a third world country with limited internet access to fully access the document with all the links.

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 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*

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**	No

PAGE 10

Q41: This section of the Guidance is practical.1	*Respondent skipped this question*
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	*Respondent skipped this question*
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	*Respondent skipped this question*
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	*Respondent skipped this question*
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:	*Respondent skipped this question*
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**	Yes

PAGE 12

Q51: **This section of the Guidance is practical.1**

(no label)	Disagree

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:**

Please refer to General Comments response in #12

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

(no label) Disagree

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:

Please refer to General Comments response in #12

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) Agree

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:

The points to consider are quite comprehensive and based on the case study that was used to test the guidance document, all relevant points have been taken into consideration.

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*