Testing of the Guidance on Risk Assessment of Living Modified Organisms

#5

COMPLETE

Collector: BCH website (Website Survey)
Started: Friday, December 20, 2013 3:20:13 AM
Last Modified: Friday, December 20, 2013 4:07:02 AM
Time Spent: 00:46:48

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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	Netherlands
Q3: **Person submitting this questionnaire:**	
Full Name:	Marco Gielkens
Email Address:	marco.gielkens@rivm.nl
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies), Other (please specify) Scientific Advisory Body
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/attachment/?id=11351
Risk Assessment 2:	http://bch.cbd.int/database/record.shtml?documentid=102141
Risk Assessment 3:	http://bch.cbd.int/database/record.shtml?documentid=101474
Q7: **In what language was the Guidance tested?**	English

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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*

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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) — Strongly 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:**

- Part I states that the information it presents is relevant to the risk assessment of all types of LMOs and uses (Roadmap lines 180 – 81). It also notes that the Roadmap has been developed largely based on LM crop plants (lines 181 – 2). This causes a strong bias in the rationale and approach of this Part, leaving Part I of low practicality for other LMOs (e.g. LM fish and micro-organisms).
- In some cases, this is compensated for by the sections in Part II presenting information on specific types of LMOs or traits (LM mosquitoes). However, the Guidance leaves ambiguity how to mutually use Parts I and II for the specific types of LMOs and traits discussed in Part II (e.g. LM trees).
- Part I does not provide instructions how to use the available information and presented points to consider to ask the relevant questions for the purpose of performing the consecutive steps of the risk assessment, in particular Step 1 (problem formulation).

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

(no label)	Agree

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:

Respondent skipped this question

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 presented information is largely focused on unconfined commercial releases. Field trials are addressed insufficiently to yield the Guidance practical for this particular use. The environmental risk assessment of LMOs in case of spillage during handling and transport is left unmentioned.

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:

- The concept of uncertainty is discussed in general terms only. It omits to address uncertainty in the context of experience in risk assessment and history of use that might have been obtained already with certain LMOs. Such existing experiences directly impact on the level of uncertainty. It also does not address the principal differences how the concept of uncertainty is handled in field trials and unconfined releases.

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

a) To promote a uniform interpretation of the questionnaire during the testing, a further specification has been defined of the terminology used:
“Practicality” is understood as: Does the Guidance Document allow you to perform every step of the Risk Assessment in a consistent manner: does it present concrete information to raise and answer the necessary Risk Assessment questions?
“Usefulness/Utility” is understood as: Does the Guidance Document present relevant information to help you understand and enable you to conduct a Risk Assessment?
“Consistency” is understood as: Does the Guidance Document contain elements that are very Practical or Useful, but are not related to the scope of the Risk Assessment in the Protocol?
“Experience” is understood as: Does the Guidance Document improve our understanding of the Risk Assessment methodology and does the Guidance Document make use of existing information?
b) The Guidance Document was developed in response to a need for further guidance on Risk Assessment of LMOs. As such, the Guidance Document does find its application in the conducting of the Risk Assessment, not the verification of the outcomes. The testing has therefore been performed with the technical and scientific information that was available with the application of the different actual test cases.

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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

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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:

- The scope of this section takes the wrong assumption that a risk assessment is already available for LM plants with the single genes or traits. This leaves many LM plants out of the scope of this section. Also, the availability of a risk assessment for the individual lines is not a necessary prerequisite to allow for a risk assessment of the stacked line.
- For stacked genes or traits the focus in the problem formulation should be on possible interactions that may take place between the individual genes or traits. This is left undiscussed in the section and some of the points to consider that are mentioned lack scientific rationale.
- The presented information does not follow the structure of the respective steps in the risk assessment. It leaves ambiguity how to mutually use Parts I and II for the specific types of LMOs and traits discussed in Part II.
Provide instructions how to use available information and points to consider to ask the right questions for the purpose of performing the respective steps in the risk assessment, in particular Step 1.

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:

- The section on LM plants with stacked genes is not fit for field trials.

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:

Introduce the experiences with LM plants with stacked genes in risk assessment and history of safe.

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

See 17. Under Part I.

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Q40: Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM crops with tolerance to abiotic stress	No

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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*

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

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

(no label)	Neutral

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

- This section does not provide instructions how to use the available information and presented points to consider to ask the relevant questions for the purpose of performing the consecutive steps of the risk assessment, in particular Step 1 (problem formulation).
- The presented information does not follow the structure of the respective steps in the risk assessment.

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

(no label)	Agree

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:**

The specific nature of field trials is not sufficiently addressed in this section. It should be made clear whether the paragraph on risk management strategies applies to field trials and /or commercial unconfined release into the environment.
1667: The heading 'unintentional transboundary movements' is inappropriate legal wording and should be replaced by 'potential for dispersal and methods to prevent this'.

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

(no label)	Agree

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) Neutral

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:

Include reference to past experiences with the SID technique (non LMO self-limiting techniques).
1730 – 5: It is important to include a more explicit mentioning of the relationship between environmental risk considerations of the LM mosquitoes and the human health benefits.

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

See 17. Under Part I.

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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

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Q61: This section of the Guidance is practical.1

(no label) Neutral

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

- This section does not provide instructions how to use the available information and presented points to consider to ask the relevant questions for the purpose of performing the consecutive steps of the risk assessment, in particular Step 1 (problem formulation).
- The presented information does not follow the structure of the respective steps in the risk assessment.
- Include and give proper account to the risk assessment of field trials with LM trees.

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

(no label) Agree

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:

Include and complete several essential considerations (presence of genetic elements, propagation methods).

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

(no label) Agree

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

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

(no label) 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:

Introduce the experiences with LM trees in risk assessment and history of safe.

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

See 17. Under Part I.

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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:

Make clear why and when specific or general monitoring applies to what types of LMOs.
Introduce practical guidance as to how monitoring should be carried out.
Distinguish between monitoring of field trials and commercial releases.
Adjust this section to make it applicable to all types of LMOs.
Address the relationship between the outcomes of the risk assessment and monitoring.

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

(no label) — 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: — *Respondent skipped this question*

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

(no label) — 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:

- Monitoring for the use of LMOs field trials is not discussed properly. Most of the suggested elements for a monitoring plan do not apply to field trials or the requested information will not be available. However, especially for field trials monitoring plays an important role in data gathering about uncertainties.

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:

No experiences gained with LMOs in risk assessment and history of use have been included in this Part of the Guidance.

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

See 17. Under Part I.

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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:

This questionnaire presents the results of The Netherlands of the testing of the Guidance on Risk Assessment of LMOs in accordance with Decision-VI/12 of COP-MOP. The main findings are reported with the respective questions in the questionnaire. Below, a recommendation for further improvement of the Guidance is presented.

Explanatory notes on the testing procedure followed by The Netherlands
The testing has been performed by risk assessors and risk assessment experts from governmental authorities in their personal capacity. The testing was done in two consecutive workshops: in workshop 1 the context, objectives and execution of the testing were framed and the actual cases were selected. Workshop 2 presented the results from the individual testing by the workshop participants and concluded on recommendations to further improve the Guidance Document.

To promote a uniform interpretation of the questionnaire during the testing, a further specification has been defined of the terminology used:
“Practicality” is understood as: the Guidance Document allows you to perform every step of the Risk Assessment in a consistent manner: it presents concrete information to raise and answer the necessary questions to perform each step of the Risk Assessment.
“Usefulness/Utility” is understood as: how informative is the Guidance Document. Does it present relevant information.
“Consistency” is understood as: the Guidance Document contains elements that may be very Practical or Useful, but are not related to the scope of the Risk Assessment in the Cartagena Protocol.
“Experience” is understood as: 1. the Guidance Document improves our understanding of the Risk Assessment methodology, and 2. the Guidance Document makes use of existing information.

The Guidance Document was developed in response to a need for further guidance on Risk Assessment of LMOs. As such, the Guidance Document does find its application in the conducting of the risk assessment, not the verification of the outcomes. The testing has therefore been performed with the technical and scientific information that was available with the application of the different actual test cases (rather than the information of the risk assessment evaluation reports).

Recommendations by The Netherlands on improvements of the ‘Guidance on Risk Assessment of LMOs’.
Concentrate the further improvement of the Guidance on the elaboration of easy-to-use standalone sections for specific types of LMOs and traits:
1. Give priority to the development of case-specific sections in Part II of the Guidance for specific types of LMOs and traits, which gives recognition of the need to raise special points to consider, uncertainties and monitoring requirements that come with their unique nature and characteristics.
2. Ensure a standalone nature of the case-specific sections that gives proper account of the different uses (field trial and commercial releases).
3. Adhere to a concise and consistent format for the case-specific sections to preserve the readability and improve the effectiveness of the Guidance:
o In the setup of the sections follow the structure of the respective steps in the risk assessment;
o Support the problem formulation with the use of appealing examples and clear instructions how to use available information and points to consider to ask the relevant questions for the purpose of performing the consecutive steps of the risk assessment, in particular Step 1.
o Use a clear text structure, maximum size (6 pages) and make reference to additional literature where relevant (including Part I Roadmap, Part III Monitoring and BCH background documents).
o Provide a scheme in which the aspects of risk assessment are presented in a visual manner. Add numbers (e.g. paragraph numbers) to the scheme to allow for easy navigation to necessary information in the Guidance.
4. Identify and rank specific types of LMOs and traits that demand the elaboration of case-specific sections.
5. Focus Part I (Roadmap) on the step-wise approach of the risk assessment methodology with reference, where relevant, to the Training Manual on Risk Assessment of Living Modified Organisms.
6. Keep Part III (Monitoring) as a separate document with individual chapters for specific types of LMOs and traits. Address explicitly the nature, needs and conditions of monitoring for different uses (unconfined commercial release and field trials) and explain the relationship between monitoring and risk assessment and risk management, in particular in relation to the concept of uncertainty.

Rationale
The Guidance aims to assist in implementing the risk assessment of LMOs. To maximize the practicality and usefulness/utility the information presented in the Guidance has to be easy to use.
The testing revealed that these conditions are not met in the current Guidance.
Parts I and III present an all-inclusive reference on the conducting of a risk assessment and monitoring for all LMO types and traits, possible uses and receiving environment. This has led to an already bulky, yet incomplete, document.
The testing revealed that Parts I and III still lack necessary information, both for specific types of LMOs, traits and possible uses (in particular field trials). Adding this information will further expand the document and challenge the easy to use condition.
Part II of the Guidance recognizes that specific LMO types and traits can raise unique or special points to consider, uncertainties and monitoring requirements that merit a separate section (“emphasis to issues that may be particularly relevant when assessing the risks of the respective types of LMOs and traits”; lines 757 – 8).
The testing revealed that, in some cases, the individual sections in Part II improve the practicality and usefulness/utility of the Guidance. This case-specific approach links up to the case-by-case principle of the risk assessment methodology.

More information is available at : http://www.cogem.net/showdownload.cfm?objectId=A1B0E481-0607-F1E0-B96C7C00F9E6635A&objectType=mark.hive.contentobjects.download.pdf