Testing of the Guidance on Risk Assessment of Living Modified Organisms

#4

COMPLETE

Collector: BCH website (Website Survey)
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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	Belgium
Q3: **Person submitting this questionnaire:**	
Full Name:	Didier BREYER
Email Address:	didier.breyer@wiv-isp.be
Q4: **Institution(s) or organization(s) that participated in the testing:**	Other (please specify) Biosafety and Biotechnology Unit (SBB) of the Institut scientifique de Santé Publique (WIV-ISP)
Q5: **Context in which the testing was conducted**	Individual exercise(s)
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=103066
Risk Assessment 2:	http://bch.cbd.int/database/record.shtml?documentid=102120
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

PAGE 6

Q21: **This section of the Guidance is practical.1**

(no label)	Neutral

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

The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the practicality of the Roadmap were expressed amongst people.

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:

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the usefulness and utility of the Roadmap were expressed amongst people.
- Line 190: The comparative approach is an important aspect of the risk assessment of LMOs. That could be highlighted already in the introduction. We propose to change the end of line 190 as follows:
“…and on a case-by-case basis in relation to the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.”
- Line 585: We suggest adding under “points to consider”: “Relevant knowledge and experience with non-modified organisms with similar phenotypic characteristics in the likely potential receiving environment.” This is particularly relevant for LM plants tolerant to abiotic stress.
- Lines 654-659 (“In evaluating the acceptability of the overall risk of the LMO, it is important to consider whether risk management options can be identified that could address identified individual risks and the estimated overall risk as well as uncertainties. The need, feasibility and efficacy of the management options, including the capacity to enact them, should be considered on a case-by-case basis. If such measures are identified, the preceding steps of the risk assessment may need to be revisited in order to evaluate how the application of the proposed risk management measures would change the outcome of the steps”).
More attention should be drawn on the importance of this paragraph, especially the re-conduction of the overall risk assessment, revisiting every steps of the risk assessment of the LMOs including the risk management options. This is of great importance as the final recommendation may be highly influenced by the presence/absence of risk management options.
- The scale and duration of the environmental use is an important point to consider to determine the nature and level of detail of information that is needed for the risk assessment, and to identify and verify plausible risk hypothesis. Although this point is highlighted on page 10 and briefly addressed in step 2 (lines 533-535) and in step 3 (lines 569-570) of the Roadmap, it is not enough stressed and considered in the further description of the 5 steps of risk assessment (in particular step 1), including the points to consider. This leads to insufficient distinction between the environmental risk assessment of field trials (in which different types of trials could also be distinguished) and commercial releases.

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 testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the consistency of the Roadmap were expressed amongst people.

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

(no label)	Neutral

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:	*Respondent skipped this question*

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

- The roadmap is straightforward, well-structured (cfr. 3 sections: overarching issues; planning phase; conducting phase) and comprehensive (cfr. listing of potential points to consider in the risk assessment). It represents a practical and useful tool to learn how to make a risk assessment of LMOs for inexperienced risk assessors.

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

PAGE 8

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

Q32: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q33: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q34: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q35: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q36: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q37: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q38: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

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

PAGE 10

Q41: **This section of the Guidance is practical.1**

(no label)	Neutral

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

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the practicality of this section of the Guidance were expressed amongst people.

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

(no label)	Neutral

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:

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the usefulness and utility of this section of the Guidance were expressed amongst people.
- Lines 1009-1050: As outlined in the document, the choice of comparators and the experimental design (stress vs. non-stress conditions) may present specific challenges for this type of LM plants. Although the Guidance provides some explanation on how to deal with this issue, it is a bit confusing and unclear with regards which comparator(s) and which comparative endpoint(s) should be used in which case(s) and under which condition(s). Providing some concrete (even theoretical) examples would certainly be very useful.
- Lines 1040-1043: The possible use of “Omics” in the comparative assessment is not specific to LM plants with tolerance to abiotic stress. We suggest moving this sentence to the relevant section of the Roadmap.

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

(no label) Neutral

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

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the consistency of this section of the Guidance were expressed amongst people.

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

(no label) Neutral

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:

Since the current experience with the risk assessment of LM plants with tolerance to abiotic stress is very scarce, an update of this section of the Guidance will probably be needed after more experience has been gained.

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

This Guidance is practical and useful by pointing in a few pages to the specific issues related to LM plants with tolerance to abiotic stress. The problematic of potential “pleiotropic effects” in these LM crops is well explained and helpful for the risk assessment.

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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

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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)	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:

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the practicality of this section of the Guidance were expressed amongst people.

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

(no label)	Neutral

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 testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the usefulness and utility of this section of the Guidance were expressed amongst people.
- With respect to the field trial with LM poplar used as case-study, one could notice that important principles, such as the duration and the scale of the intended use have been mentioned in the Guidance (e.g. lines 1343-1347 (“In determining the likelihood of an adverse effect of an LM tree, an assessment of the exposure to the LM tree should take into account the expected duration of the trees’ presence in the receiving environment, the nature of the transgenic traits, the intended use of the LM tree (e.g., processing, trade routes), as well as dispersal mechanisms. Given the late onset of reproductive maturity of a number of tree species, pollen and seed production may not occur during field trials”). This is done in a very concise, ‘poor’ elaborated way, which is understandable if the Guidance is considered as a framework through which links refer to background document with more detailed and specific information. However, it remains questionable whether these points will sufficiently capture the attention of inexperienced risk assessors or non-specialized users so as to allow them to address these aspects with appropriate consideration in their risk assessment.
- The capacity of vegetative propagation is mentioned in line 1298 but could already be mentioned in lines 1187-1188. This characteristic is not specific to trees but it could have a big impact in the overall risk if one take into account specific characteristics of trees (perennial, height, etc.).

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

(no label)	Neutral

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

- The testing was conducted as an individual exercise. Different levels of agreement/disagreement (i.e. “Neutral” or “Agree”) with regards to the consistency of this section of the Guidance were expressed amongst people.

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

(no label) Neutral

Q68: **Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

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

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

PAGE 16

Q71: **This section of the Guidance is practical.1** *Respondent skipped this question*

Q72: **Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

Q73: **This section of the Guidance is useful or has utility.2** *Respondent skipped this question*

Q74: **Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

Q75: **This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3** *Respondent skipped this question*

Q76: **Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

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

Q78: **Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:** *Respondent skipped this question*

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

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Q80: Would you like to submit an evaluation of the following section of the Guidance: Background Documents Yes

PAGE 18

Q81: This section of the Guidance is practical.1

(no label) Neutral

Q82: This section of the Guidance is useful or has utility.2

(no label) Neutral

Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Neutral

Q84: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Neutral

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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:

- Broadly speaking, the Guidance is a useful tool to learn about the fundamental principles and criteria of the risk assessment of LMOs, and the specific points to be considered when assessing specific types of LMOs and traits. As compared for example with the EFSA Guidance on the environmental risk assessment of genetically modified plants (EFSA Journal 2010;8(11):1879), it is more straightforward and concise and therefore easier to read for the risk assessor. It might be less useful for applicants for which a more detailed Guidance is needed.
- The Guidance is not self-sufficient to conduct a risk assessment. Other relevant sources of information should be consulted.
- The Guidance lists many potential points to be considered in a risk assessment. This led to different feedbacks from individuals who were involved in the testing:
On the one hand, the messages are useful to understand the principles and criteria of the risk assessment of LMOs. This gives inexperienced risk assessors the opportunity to avoid missing important points to be considered in a risk assessment. As potential point to be considered in a risk assessment cover a wide range of study areas, it is very useful to start screening them on basis of a list which is as comprehensive as possible.
On the other hand the information remains of poor help when practically conducting a risk assessment for a specific LMO. It makes difficult, in particular for an inexperienced risk assessor or user, to formulate appropriate testable hypothesis really supporting the risk characterization. To verify that all data have been provided in a dossier and all risk hypotheses adequately tested, it is important to be able to verify these hypotheses. Risk assessors could developed many scientific hypothesis that, although broadening scientific knowledge, would not really inform the risk assessment ("nice to know" vs. "need to know"). In that respect, the Guidance could be more efficient by proposing specific examples of adequately formulated risk hypotheses, including selection of assessment endpoints and ways of collecting relevant data supporting the risk assessment. In addition, examples illustrating the implementation of the guidance and the risk assessment methodology for specific cases could be a way forward to improve the utility of the guidance.
- One of the main added-value of the Guidance is that it provides a structured access through a single link to many references that can give more details about specific aspects of the risk assessment. A potential difficulty with the current system is that the list of background documents is in some cases very long and the scientific quality and relevance of the documents very variable. In consequence the use of these background documents might not be very efficient, in particular for non-specialized users.