Testing of the Guidance on Risk Assessment of Living Modified Organisms

#6

COMPLETE

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Q1: **Type of submission:**	Party

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Q2: **Name of the Party:**	Austria
Q3: **Person submitting this questionnaire:**	
Full Name:	Dr. Michael Eckerstorfer
Email Address:	Michael.eckerstorfer@umweltbundesamt.at
Q4: **Institution(s) or organization(s) that participated in the testing:**	Government authority(ies)
Q5: **Context in which the testing was conducted**	Other (please specify) Collaborative effort of risk assessors from Environment Agency Austria
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://www.efsa.europa.eu/en/efsajournal/pub/3135.htm
Risk Assessment 2:	http://www.efsa.europa.eu/en/efsajournal/pub/3443.htm
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)	Agree

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:

Practicality was considered in regard to the targeted purpose. Specifically the Roadmap was regarded as an instrument to introduce a basic concept for risk assessment, i.e. indicating important elements of a risk assessment framework (policy), rather than a document presenting very detailed guidance for individual case-specific risk assessments. As a reference document relevant for the development of an appropriate overall approach to risk assessment by risk assessors it is considered to be of very high overall practicality. Specifically the points to consider included in the Roadmap connect to aspects which need to be complemented by further guidance available/developed at the level of implementation to address practical details of assessments. In case of our testing we considered that highly consistent additional guidance is available at the EU level (EFSA (2010): Guidance on the environmental risk assessment of genetically modified plants. EFSA Journal 8 (11): 1879).

Line 178: The above consideration should be underlined in the indicated ways of use of the Roadmap. We suggest to include respective formulations:
“The Roadmap may be useful as a reference for designing and planning risk assessment approaches and identifying the need for development of further guidance by risk assessors. It may also be of help for risk assessors when conducting risk assessments and as a training tool in capacity-building activities.”

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

(no label) Strongly 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:

Line 185: include for completeness of argument:
…, including those of limited duration and scale as well as long-term and large-scale releases.

Line 204: avoid “tiered”. Suggestion for formulation:
“The Roadmap describes the risk assessment process as a sequence of five steps, in which the results of one step are relevant to the other steps. This step-wise structure is drawn from the outline presented in Annex III, Para 8 of the Protocol.”

Line 229 - 231: The expression “Data quality should be consistent with the accepted practices of scientific evidence-gathering and reporting and may include independent review of the methods and designs of studies” is not sufficiently clear. We suggest to use the following wording: “An independent review of the design and methods of studies used for risk assessment, and the quality of reporting may be included to ensure appropriate data quality”.

Line 260 - 265: The two bullet points listed under “Additional considerations with regard to scientific information” target different issues, the latter one addressing availability of scientific expertise for conducting risk assessments. It is suggested to include both considerations as separate statements.

Line 398 ff: We propose to use the term “risk hypotheses” throughout for clarity –in substitution for “risk scenarios” (Line 399), “scientifically plausible scenarios” (Line 407). In our opinion the statement in Line 407 can be shortened to:
“In this step, risk assessors develop meaningful risk hypotheses….”

Line 415: We suggest to change to:
It is important to identify direct or indirect links or pathways between a characteristic of the LMO and possible adverse effects, to generate information during risk assessment that will be useful for decision-making”
The chapter on “The choice of comparators” (Lines 343 ff) is regarded very important and crucial for implementation of the guidance. However testing indicated that to appropriately assess effects in managed ecosystem comparisons need to include specific management conditions. This is considered relevant for most applications of LM crop plants and given the importance of these LMOs (cf. Line 181 – 183) should be explicitly indicated with reference to related chapters (e.g. Line 476 ff).

Additionally we suggest to include in Line 424 ... taking into consideration the new trait(s) of the LMO, "and associated changes in management”.

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

(no label) Strongly Agree

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 case study used for testing underlined the importance of the concept included in the Roadmap - consistent with the Protocol - that "special attention (should be paid) to protected areas and centres of origin and centres of genetic diversity" (cf. Line 564, footnote 16). The testing case exemplifies that a conclusive assessment of relevant risk hypotheses, e.g. potential impacts on non-target-organisms, including effects on "rare, endangered, protected species and/or species of cultural value" (footnote 16), needs to be conducted to be able to devise appropriate risk management strategies.

Line 267 - 270: To increase consistency with the Protocol reference should also be made to Article 10 para 6 when describing appropriate ways to deal with identified uncertainties.

Lines 290 – 293: The case-study used for testing identified that identification of uncertainties associated with the potential occurrence of specific adverse effects can result in determining that the respective data basis is not allowing completion of a specific assessment. In such a case no specific conclusions regarding that risk issue can be drawn. Such a possibility should be identified in the text of the indicated paragraph.

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

(no label)	Strongly Agree
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:	*Respondent skipped this question*

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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

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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**	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**	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	No

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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*

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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

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Q71: This section of the Guidance is practical.1

(no label) — Strongly Agree

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:

Practicality was considered in regard to the targeted purpose. Part III (Monitoring of LMOs released into the environment) was regarded as an instrument to introduce important elements of a monitoring framework, and thus highly relevant for the development of appropriate monitoring approaches for specific LMOs. Therefore it is considered to be of high overall practicality.

The points to consider included in chapters 1-4 are providing reference to aspects which need to be elaborated when drafting monitoring plans for implementation. In case of our testing we considered that complementing additional guidance providing additional detail is available at the EU level (EFSA (2011): Scientific Opinion of the Panel on Genetically Modified Organisms on the annual Post-Market Environmental Monitoring (PMEM) report from Monsanto Europe S.A. on the cultivation of genetically modified maize MON810 in 2009. EFSA Journal 9(10), 2376. doi:10.2903/j.efsa.2011.2376).

Line 1822 ff: General Monitoring
Against the background of EU requirements for monitoring few information is provided concerning general monitoring. Taking into account that the general focus is laid on issues, which are highly connected with other parts of the guidance, e.g. the Roadmap on risk assessment (cf. Lines 672 – 677) this is considered acceptable.

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

(no label) — Strongly Agree

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:

Line 1865: Monitoring of the exposure to LMOs is considered an important aspect to address potential uncertainties regarding estimates for exposure used for risk assessment (cf. Roadmap e.g. Lines 323, 505ff & 556ff).

Therefore we suggest to add: “Monitoring of the exposure to LMOs may be a highly relevant element of an overall monitoring approach.”

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

(no label) — Agree

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:**

To highlight consistency and interconnections betw een different parts of the guidance reference should be made to text sections contained in the Roadmap w hich address monitoring requirements (e.g. Roadmap Lines 267ff, 672-677, 689-693).

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

(no label)	Agree

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**	No

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Q81: This section of the Guidance is practical.1	*Respondent skipped this question*
Q82: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q84: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

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Q85: Please use the space below if you wish to provide additional feedback regarding the testing of the Guidance on Risk Assessment of Living Modified Organisms:	*Respondent skipped this question*