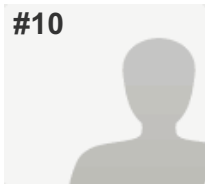


# Testing of the Guidance on Risk Assessment of Living Modified Organisms

#10



**COMPLETE**

**Collector:** BCH website (Website Survey)

**Started:** Saturday, February 08, 2014 2:10:14 AM

**Last Modified:** Saturday, February 08, 2014 2:24:38 AM

**Time Spent:** 00:14:23

## PAGE 1

**Q1: Type of submission:**

Party

## PAGE 2

**Q2: Name of the Party:**

Germany

**Q3: Person submitting this questionnaire:**

Full Name:

Volker Matzeit, Federal Ministry of Food and  
Agriculture Division 222 for New Technologies

Email Address:

volker.matziet@bmelv.bund.de

**Q4: Institution(s) or organization(s) that participated in the testing:**

Government authority(ies),  
Other (please specify)  
Federal Office of Consumer Protection and Food Safety; and  
Federal Agency for Nature Conservation

**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=101390>

**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*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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)

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:**

- Line number 127: The Cartagena Protocol is mentioned as “protocol” without further explanation. To the uninitiated reader it is not self-evident which Protocol is meant. Therefore, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity should be referred to as such in this first sentence of the Preface of the Road map.

- General: All mentioned articles should be linked to their respective texts for easier and quicker access to relevant text passages.

- General: Especially in Part I, the structure of the document might be more easily navigated by lettering or numbering the headings.

- General: The quick link option to the “Use of Terms” section is very helpful and should be offered with more consistencies.

- Line number 263-265. Information is confusing. It is implicated that only independent experts can perform the risk assessment. Changing the wording to e.g. „Independent experts with the relevant background in the different scientific disciplines can serve in an advisory function during the risk assessment process or even perform the risk assessment themselves.” might be more appropriate and clear.

- Footnote 11: This explanatory document could also be mentioned earlier and more clearly.

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

- Footnotes 12 and 13 should link to the respective text passage.
- Line number 343 ff: Sadly, an alternative to the comparative approach is not discussed but may become necessary considering future LMOs.
- Line number 370: Link to references is missing (cp. Line 297-298).
- Line number 371 ff: The mentioned Annexes and Paragraphs should be linked for easier access and understanding.
- Line number 421: "(iv) transfer genes to other organisms/populations, and (v) become genotypically or phenotypically unstable" are per se no adverse effects and should therefore be omitted in the list. Still the mentioned processes may be part of a causal link or pathway to a secondary adverse effect and could be mentioned in this relation.
- Line numbers 422-424: It is emphasized that the LMO should be considered in context of a comparator. It should be mentioned, that in special cases, where it is difficult to identify an appropriate comparator, the applicability of comparative approach may be limited.. An introductory guideline such as the road map might also propose solutions (maybe in a future revision of the road map?)
- Line numbers 452/ 2173-2174: The given definition of 'unintended gene products' is not helpful. Maybe one or two examples would be advantageous (e.g. potential protein encoding sequences crossing the plant-construct insertion sites or elongation of the intended protein due to faulty or lacking terminator sequences etc.)
- Line numbers 460-461: Should read for practicality reasons: "Availability of data on the likely receiving environment which may serve as a basis for the risk assessment" since neither "sufficient" nor "meaningful baseline" is sufficiently well defined in this context to be useful for practical risk assessments.
- Line number 491-492: To simplify reading and implementation point (p) should be reduced to "(p) Potential adverse effects of the incidental exposure of humans to (parts of) the LMO (e.g., exposure to modified gene products in pollen)". The naming of "the toxic or allergenic effects that may ensue" is redundant to "Potential adverse effects" and can therefore be omitted. The second part of the point should be placed in a separate point, since agricultural practices that may be used are not directly connected to the issue of "incidental exposure". Moreover (p) might be better placed under Step 2 (exposure assessment)
- Line numbers 493-494: new point (q) may read: "Potential adverse effects of changes in agricultural practices such as type of irrigation, number and amount of pesticide applications, methods for harvesting and waste disposal, etc, induced by use of the LMO. Where use of other regulated products or practices are changed interplay with the respective risk assessments and regulations needs to be considered." . Practicality of the risk assessment approach may be impaired, if no clear separation to risks from other regulated products is kept.
- Line number 501: It is slightly confusing that the first sentence starts with a reference to step 4. The first sentence in explaining what should be done in step 2 should maybe start with: "In this step the risk assessor evaluates the likelihood that each of the potential adverse effect identified in step 1 will occur."
- Line numbers 519-522: should read: "If the likelihood of adverse effects being realized is difficult to assess it may be useful to reverse order of Steps 2 and 3 (s. Line 567 and Fig 1)." An assumption of 100% likelihood may lead to an erroneous indication of high risk although not supported by facts.
- Line numbers 527 and elsewhere: the term "likely potential receiving environment" is difficult to comprehend and to a certain degree redundant.
- Line numbers 560 ff: Again, the evaluation of consequences should be done in context of adverse effects caused by a comparator. There are no hints given on what should be done if no comparator is available.
- Line number 598: The terms "combinatorial and cumulative effects" should be linked directly to "Use of Terms" like all other terms before and not via footnote.
- Line numbers 716-720: The respective articles should be linked.
- Annex: Flow chart for the risk assessment: The instructions in the flow chart should be concise and brief and should inform the reader on what each step is about. Further information is given in the text and it is not necessary to repeat it here.

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

(no label)

Agree

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**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*

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

(no label)

Agree

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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:** *Respondent skipped this question*

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

(no label)

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

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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# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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*

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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

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*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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)

Agree

**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:**

- Part I "Conducting the risk assessment" introduces steps of a risk assessment. The same heading is also used in the Part II documents, but only specific issues of risk assessment are covered in those. Thus, it might be more accurate to change the Part II headings to „Conducting the risk assessment – special points to consider“.

- Line numbers 1234-1236: It is pointed out that a comparative approach may be challenging for LM tree species for which there is little or no information with regard to their ecological functions or interactions in the likely receiving environment. The need for alternative approaches should be addressed.

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

(no label)

Strongly 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:**

- Footnote 25: It is slightly irritating that it is mentioned that some experts are of the opinion that fruit trees should not be included. As they are included, it does not matter to the uninitiated reader that there was a dispute concerning them. Also, as the dispute is not further explained (do fruit trees have other, special concerns?) this information is unneeded.

- The text of footnote 27 should be included in the paragraph.

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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:**

- Line number 1357: The consequences of the cultivation of whole LM trees on ecosystem functions and biodiversity should be considered and not only the consequences of the modified trait. We suggest rephrasing this sentence accordingly .

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

(no label)

Strongly Agree

**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*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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.<sup>1</sup>

*Respondent skipped this question*

**Q82:** This section of the Guidance is useful or has utility.<sup>2</sup>

*Respondent skipped this question*

**Q83:** This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.<sup>3</sup>

*Respondent skipped this question*

**Q84:** This section of the Guidance takes into account past and present experiences with LMOs.<sup>4</sup>

*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*