

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

#52



**COMPLETE**

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

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## PAGE 1

**Q1: Type of submission:**

Party

## PAGE 2

**Q2: Name of the Party:**

Norway

**Q3: Person submitting this questionnaire:**

Full Name:

Bjarte Rambjør Heide

Email Address:

Bjarte.Rambjor.Heide@miljodir.no

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

Government authority(ies), Academic institution(s)

**Q5: Context in which the testing was conducted**

Group event(s) (e.g., workshop, training course, meeting)

**Q6: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. <http://bch.cbd.int/database/record.shtml?documentid=104904> and <http://bch.cbd.int/database/record.shtml?documentid=104905>) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.**

Risk Assessment 1:

<http://bch.cbd.int/database/record.shtml?documentid=104904>

Risk Assessment 2:

<http://bch.cbd.int/database/record.shtml?documentid=104905>

**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*

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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 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:

The practicality of the Roadmap may be improved by articulating the inter-linkages of the risk assessment process with risk management and risk communication. Furthermore, describing the risk assessment process in the context of decision-making more fully, as illustrated in the flow chart, would improve the practicality of the Roadmap.

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:

Text Line 273 "There is no internationally agreed definition of "scientific uncertainty", nor are there internationally agreed general rules or guidelines to determine its occurrence." does not provide the user with anything useful, the same can be said of many terms defined in this guidance. A more useful phrasing in our view would be to replace the last two sentences, that starts on Line 271 with a hybrid sentence "The issue of uncertainty and the determination of its occurrence is dealt with – sometimes differently – in each international instrument incorporating precautionary measures." In relation to the descriptions, particularly in the rationale to step 1, are in some places unnecessarily complicated english, should be simplified here and throughout the Roadmap to enhance the understanding of non-native language users.

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

**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 issue of baselines is relevant here in the context of the Protocol's focus on the receiving environment. Thus it is not only a comparison of a LMO and a non-LMO in the receiving environment that is important, but changes to the receiving environment itself resulting from the release of the LMO that must be additionally considered. We suggest adding in line 424, to read, "...in the likely potential receiving environment, or baseline environmental conditions prior to the release of the LMO". This is important to reinforce the subsequent points to consider in (g) and (i).

**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:**

The section "choice of comparators" could better elaborate on the impact of different choice of comparators may have on the analytical robustness of the comparative assessment. Therefore we suggest the addition of the following sentence at the end of the paragraph on line 371; "The impact of using additional comparators that are not (near)isogenic lines on the level of analytical rigour of the comparative assessment may be taken into consideration when deciding on appropriate comparators".

**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*

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

**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.<sup>1</sup>** *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.<sup>2</sup>** *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.<sup>3</sup>** *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.<sup>4</sup>** *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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# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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

PAGE 14

**Q61: This section of the Guidance is practical.1**

*Respondent skipped this question*

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

*Respondent skipped this question*

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

*Respondent skipped this question*

**Q64: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:**

*Respondent skipped this question*

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

*Respondent skipped this question*

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

**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

PAGE 16

**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:**

Although it is clearly stated that monitoring for human health is part of the guidance, its description contains little information that would allow practical human health monitoring. Therefore the sentence starting on line 1794 should be amended to conclude "...yet may require additional methods or approaches".

**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:**

A more detailed description of how existing monitoring networks could be utilized in monitoring would improve the usefulness of the guidance. Suggest replacing the term "programmes already established" from line 1831 with "existing monitoring networks".

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

(no label)

Strongly 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:**

As human health is an important protection goal under the Protocol, and for Norway, the consistency of the monitoring guidance with the Protocol could be improved by the inclusion of points related guidance to human health monitoring where possible.

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

(no label)

Strongly Agree

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**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:**

It may be useful to the reader to highlight that existing experience on LMO monitoring is very limited, and as evidenced from prior environmental monitoring efforts in other fields has shown that the monitoring plan must be carefully considered and sufficiently detailed to make sure the outcomes are meaningful to the stated objective, or will likely not yield useful results.

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**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*