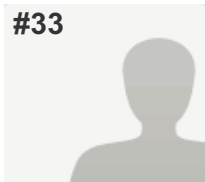


# Testing of the Guidance on Risk Assessment of Living Modified Organisms

#33



**COMPLETE**

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

**Started:** Monday, March 31, 2014 9:58:39 AM

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**Time Spent:** 00:09:33

## PAGE 1

**Q1: Type of submission:**

Party

## PAGE 2

**Q2: Name of the Party:**

Japan

**Q3: Person submitting this questionnaire:**

Full Name:

NIKAIDO Takahiko

Email Address:

takahiko\_nikaidou@nm.maff.go.jp

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

Government authority(ies)

**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://www.bch.biodic.go.jp/>

**Q7: In what language was the Guidance tested?**

Other (please specify): Japanese

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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*

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

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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. <a href="http://bch.cbd.int/database/record.shtml?documentid=104904">http://bch.cbd.int/database/record.shtml?documentid=104904</a> and <a href="http://bch.cbd.int/database/record.shtml?documentid=104905">http://bch.cbd.int/database/record.shtml?documentid=104905</a> ) 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)	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:  This guidance contains several "Points to consider" unable to consider since there is NO internationally agreed guidance of how to address the issue and NO technical consultation has been made regarding the issue. These following "Points to consider" should be deleted: "baseline" in line 460 to 461, "Potential adverse effects concerning target organisms such as pests developing resistance to the target trait and weeds developing resistance to the herbicide" in line 469 to 470, "changes in farm management practices; dispersal of the LMO through mechanisms such as seed dispersal or outcrossing within or between species, or through transfer into habitats where the LMO may persist or proliferate; as well as effects on species distribution, food webs and changes in bio-geochemical characteristics" in line 478 to 481, "Cumulative effects with any other LMO present in the environment" in line 495, "long-term adverse effects related to the exposure to the LMO" in line 529 to 530, (iii) in line 595 to 597, (b) in line 598 to 599, "Individual risks and any interaction among them, such as synergism or antagonism" in line 633, "Broader ecosystem and landscape considerations, including cumulative effects due to the presence of various LMOs in the receiving environment" in line 635, and (g) in line 704 to 706. Also, "non-target organisms" in line 489 and line 593 is NOT clearly defined and it is unable to consider. Also, "agronomic practices" in line 594 has nothing to do with LMO. Also, since there are so many "agricultural practices," "dissemination of the recipient organism," and "abundance of volunteers" in line 589 to 590, it is quite difficult to take all in.	
Q23: This section of the Guidance is useful or has utility.2 (no label)	Disagree
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:  As stated [above], "Points to consider" unable to consider make this guidance less useful; they need to be solved.	

# 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)

Disagree

**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:**

1) RA under the CPB is "to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity". (Annex III 1) On the other hand, RA explained in the Roadmap seems to identify and evaluate broader adverse effects on the whole environment caused not only by LMOs but also by agricultural practices. In order to be consistent with the CPB, at least the following parts beyond the CPB should be revised.

- In line 172, line 177, line 182 : "environmental risks"

- In line 635 : "Broader ecosystem and landscape considerations"

- In line 573-575 : "the adverse effects associated with the existing practices or with practices will be introduced along with the LMO (such as various agronomic practices, for example, for pest or weed management)" --- Those are not the adverse effects caused by LMOs.

2) Monitoring under the Annex III of the CPB is the monitoring of the assessed LMO in the receiving environment where there is uncertainty regarding the level of risk. (Annex III 8(f)) Such monitoring does not include "general monitoring". In order to be consistent with the CPB, at least the following parts related to "general monitoring" should be deleted.

- In line 676-677 : "Monitoring can also be applied as a tool to detect effects that were not anticipated in the risk assessment and long-term adverse effects." --- Such monitoring is not the "monitoring" stated in the Annex III.

- In line 692 : "general monitoring"

3) The words which have no scientific consensus among the Parties, such as "cumulative effects", should not be used in the Roadmap. At least the following parts should be revised.

- In line 429, line 495, line 598, line 635 : "cumulative"

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

(no label)

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:**

As stated [above], this guidance is filled with several "Points to consider" unable to consider and we see no practicality in this document. We are not sure whether those who were involved in preparing this guidance had been involved in risk assessment in reality. If no, it would be required to have such person in this process.

**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**

Yes

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**Q31: This section of the Guidance is practical.1**

(no label)

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:**

This guidance contains several "Points to consider" unable to consider since there is NO internationally agreed guidance of how to address the issue and NO technical consultation has been made regarding the issue. These following "Points to consider" should be deleted: (a) in line 890 and "some of which may persist or accumulate (e.g., via the food chain) in the environment" in line 897.

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

**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:**

As stated [above], "Points to consider" unable to consider make this guidance less usefull. They should be deleted.

**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:**

1) RA under the CPB is "to identify and evaluate the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity". (Annex III 1) On the other hand, RA explained in the Roadmap seems to identify and evaluate broader adverse effects on the whole environment caused not only by LMOs but also by agricultural practices. In order to be consistent with the CPB, at least the following part beyond the CPB should be revised.

- In line 884 : "adverse effects (e.g., due to changes in agricultural practices)" --- Those are not the adverse effects caused by LMOs.

2) The words which have no scientific consensus among the Parties, such as "cumulative effects", should not be used in the Roadmap. At leaset the follow ing parts should be revised.

- In line 870, line 873, line 883, line 885, line 898 : "cumulative"

**Q37: This section of the Guidance takes into account past and present experiences with LMOs.4**

(no label)

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:**

Same as w hat is stated [above]

**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*

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

**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*

**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

**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

**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

**Q71: This section of the Guidance is practical.1**  
(no label) Disagree

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

**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:**

This guidance contains several "Points to consider" unable to consider since there is NO internationally agreed guidance of how to address the issue and NO technical consultation has been made regarding the issue. These following "Points to consider" should be deleted: (d) in line 1874, "cumulative" in line 1902, "in the context of broader environmental monitoring" in line 1904, and (d) in line 1905 to 1906.

**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:**

As stated [above], "Points to consider" unable to consider make this guidance less usefull. They should be deleted.

**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:**

1) Monitoring under the Annex III of the CPB is the monitoring of the assessed LMO in the receiving environment where there is uncertainty regarding the level of risk. (Annex III 8(f)) Such monitoring does not include "general monitoring". In order to be consistent with the CPB, at least the following parts related to "general monitoring" should be deleted.

- In line 1783-1784 : "The Convention on Biological Diversity (CBD) covers in its article 7, "Identification and Monitoring" --- Such monitoring is not the "monitoring" stated in the Annex III.

- In line 1798-1799, line 1822-1831, line 1936-1937 : "general monitoring"

2) The words which have no scientific consensus among the Parties, such as "cumulative effects", should not be used in the Roadmap. At least the following parts should be revised.

- In line 1816, line 1902 : "cumulative"

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

(no label)

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:**

Same as what is stated [above]

**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.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*

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

**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*