

PART I: ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS

Please answer each of the questions in the left column with “yes” or “no” and add comments if needed.

<p>Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: Step1 is a step to examine what adverse effects could occur, why and how(line 270), and to identify the scientifically plausible scenarios and risk hypotheses(line278-280). Many points to consider are listed. However, it is difficult to understand where each of points to consider should be used in the examining process of this step. As it would be thought that points to consider depend on the kind of adverse effects, it might become more understandable to exemplify what kind of adverse effects (e.g. “gene transfer” or “weediness” as shown in the Scale-up document of OECD(1993)) will happen, and to explain points to consider in each case of adverse effect.</p> <p>Although it seems (k) in points to consider is similar to (n), they are not listed side by side. What rule is applied to ordering points to consider? As many points to consider exist, the way of ordering should be reexamined.</p>
<p>Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: <Type here></p>
<p>Q10. Is the Roadmap organized in a logic and structured manner?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: <Type here></p>
<p>Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: <Type here></p>
<p>Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: As the Roadmap has been developed based largely on living modified crop plants (line 54-56), it could not to say that it is fully applicable to all types of LMOs at this stage.</p>
<p>Q13. Is the Roadmap applicable to all types of introductions into the environment (e.g. small- and large-scale releases, placing on the market/commercialisation)?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: <Type here></p>
<p>Q14. Is there any other issue or concept that you would like to see included in the Roadmap?</p>	<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments: As stated in the “background” in Part I , the Roadmap complements Annex III of the Protocol. It would become more understandable if a table which shows the relationship between Annex III and the steps of the Roadmap would be added in this part.</p>
<p>Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?</p>	<p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p>	<p>Comments: The meaning of the both sided arrow between Step2 and Step3 in the flowchart cannot be understood. There is no description of the relationship between Step2 and Step3 in the text of Step2, neither in the text of Step3. As it is stated in</p>

the explanation of Figure1 that “the box around steps 2 and 3 shows these steps may sometimes be considered simultaneously or in reverse order”, the both sided arrow seems to have different implication.

It is stated in the text that Step4 is a step to determine the level of the overall risk based on all information from Step1, Step2 and Step3. However, there is no arrow from Step1 to Step4. It is inconsistent with the text.

PART II: SPECIFIC TYPES OF LIVING MODIFIED ORGANISMS OR TRAITS

Risk assessment of living modified organisms with stacked genes or traits

Please answer each of the questions in the left column with “yes” or “no” and add comments if needed.

Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol? Yes No Comments: <Type here>

Q17. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LMOs with stacked genes or traits? Yes No Comments: <Type here>

Q18. Is this section of the Guidance organized in a logic and structured manner? Yes No Comments: <Type here>

Q19. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? Yes No Comments: <Type here>

Q20. Is there any other issue or concept that you would like to see included in this section of the Guidance? Yes No Comments: <Type here>

Risk assessment of living modified crops with tolerance to abiotic stress

Please answer each of the questions in the left column with “yes” or “no” and add comments if needed.

Q21. Does this section provide useful guidance when conducting risk assessments of LM crops with tolerance to abiotic stress(es) in accordance with the Protocol? Yes No Comments: <Type here>

Q22. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM crops with tolerance to abiotic stress(es)? Yes No Comments: <Type here>

Q23. Is this section of the Guidance organized in a logic and structured manner? Yes No Comments: <Type here>

Q24. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? Yes No Comments: <Type here>

Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance? Yes No Comments: Examples of “biotic conditions”(line983) should be shown in the text.

Risk assessment of living modified mosquitoes

Please answer each of the questions in the left column with “yes” or “no” and add comments if needed.

Q26. Does this section provide useful guidance when conducting risk assessments of LM mosquitoes in accordance with the Protocol? Yes No Comments: <Type here>

Q27. Is this section of the Guidance useful to risk assessors who have limited experience with risk assessments of LM mosquitoes? Yes No Comments: <Type here>

Q28. Is this section of the Guidance organized in a logic and structured manner? Yes No Comments: <Type here>

Q29. Is this section of the Guidance user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity? Yes No Comments: <Type here>

Q30. Is there any other issue or concept that you would like to see included in this section of the Guidance? Yes No Comments: <Type here>

ADDITIONAL COMMENTS

Please add any additional comment you may have regarding the “Guidance on Risk Assessment of Living Modified Organisms” below.

Q31.

(1) Part I Roadmap for risk assessment of living modified organisms

1) line63-64,line177-178:

In order to consistent with the Annex III of the Protocol and the line 221-222 of the Roadmap, and to make it clear that the assessment is performed by comparative way, “in relation to the likely potential receiving environment” should be replaced to “in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment”.

2) line123:

The sentence of “Where appropriate, in the risk assessment and be described in the risk assessment report.” may be incomplete sentence.

3) line 350:

As the changes caused by the change of farm management practices, such as the change in the herbicide application followed with adoption of LMO, are not effects of the LMO, those effects should be out of the objective of assessment in the Roadmap. Therefore the words of “changes in farm management practices” should be deleted.

4) As the cumulative effects of LMO would not be the common understanding of the Parties,

a) line365:The words of “Cumulative effects with any other LMO present in the environment” should be deleted.

b) line 469:The words of “and cumulative” should be deleted.

c) line507-508:The words of “, including cumulative effects due to the presence of various LMOs in the receiving environment” should be deleted.

5) line543:

The sentence of “Monitoring can be applied as a tool to detect unexpected and long-term adverse effects” should be deleted.

It is recognized that the General Surveillance (GS), which is shown in the first draft of Monitoring Document distributed on Aug.30, is based on this part.

GS will cover the monitoring of particular indicators or parameters that reflect important protection goals where no particular hypothesis for an adverse effect has been established. On the other hand, the monitoring in the Roadmap is quoted from Annex III, paragraph 8(f) of the Protocol, and is implemented where there is uncertainty regarding the level of risk (line147-150). Thus the monitoring in the Roadmap, which is implemented in case that the uncertainty exists after the risk assessment based on the risk hypothesis, is different from GS, which has no risk hypothesis.

Therefore this part is beyond the Annex III. It is not appropriate to contain this sentence in the Roadmap which complements Annex III.

(2) Part II A. Risk assessment of living modified plants with stacked genes or traits

1) As the cumulative effects of LMO would not be the common understanding of the Parties,

a) line725,739,756:The words of “and cumulative” should be deleted.

b) line765-766:The words of “and DNA fragments that could result in cumulative effects” should be deleted.

2) line741-743:

As the changes caused by the change of farm management practices, such as the change in the herbicide application followed with adoption of LMO, are not the direct effects of the LMO, those effects should be out of the objective of assessment in the Roadmap. Therefore the sentence of “Also, indirect effects due to changed agricultural management procedures, combined with the use of the transgenic event LMOs, may occur.” should be deleted.
