



environments?

**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.*

Q8. Does the Roadmap provide useful guidance for conducting risk assessments of LMOs in accordance with the Protocol?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments:  * The scope of the guidance given under the term "risk assessment" in this document is generally referred to as "risk analysis" (one of which components is risk assessment) so there is some ambiguity.
Q9. Is the Roadmap useful to risk assessors who have limited experience with LMO risk assessment?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments:  * The approach has not been explained, e.g. risk hypothesis, problem formulation (there are different approaches to PF etc). Without that knowledge and experience in applying this approach in Risk Assessment, some risk assessors may have difficulties.
Q10. Is the Roadmap organized in a logic and structured manner?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
Q11. Is the Roadmap user-friendly taking into account that risk assessment is a complex scientific and multidisciplinary activity?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments: <Type here>
Q12. Is the Roadmap applicable to all types of LMOs (e.g. plants, animals, microorganisms)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments:  * Reference is made to annex III of the protocol stating, "Risks associated with living modified organisms or products thereof should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment" this may not be true for all LMOs. This is recognised in the section "choice of comparators" with regards to LM plants tolerant to abiotic stress, stacked LMOs and certain LM mosquitoes. I would point this out when using the above quote to avoid confusion. In addition I would include pharmaceutical producing plants in addition to the examples mentioned above.
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)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments:  * Yes, but more focus can be placed on decreasing/addressing risk with the use of risk mitigating measures (particularly containment) during small scale releases such as field trials or applications where large scale release is unlikely e.g. pharmaceutical producing plants and animals.
Q14. Is there any other issue or concept that you would like to see included in the Roadmap?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Comments:  * Introducing the concept of using pathways to harm in risk assessments is important (in par 278-283). I

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would recommend fleshing out this section slightly more as it is such an important concept and including a figure to demonstrate the process.

\* A specific example for risk assessment of GM microorganisms.

\* Explain /define terminology, e.g. null hypothesis and risk hypothesis, conceptualization, harm, etc.

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Q15. Does the flowchart provide a useful graphic representation of the risk assessment process as described in the Roadmap?

Yes

No

Comments:

\* The flowchart is very useful as a graphic representation of the Risk Assessment process (again this is actually risk analysis). I would include the text "(including monitoring)" in the sentence "Consideration of risk management strategies, and decision making" so that it reads "Consideration of risk management strategies (including monitoring), and decision making" because monitoring is an important risk management strategy and often a legal requirement, but it is not always clear to regulators how this fits in the process of risk analysis. Including it in the flowchart will make it easier for regulators to see how it fits into the process.

\* It describes the process but I suggest that the diagram of the EFSA environmental consensus document (2010) be considered, that is much clearer as to what ERA entails.

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## 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.*

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|---|--|--|
| Q16. Does this section provide useful guidance when conducting risk assessments of LMOs with stacked genes or traits in accordance with the Protocol? | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments:<br>* A diagram would be helpful 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? | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments: <Type here>  |
| Q18. Is this section of the Guidance organized in a logic and structured manner?  | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> 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?   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> 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?   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments:<br>* This section is curious in that it only deals with ‘breeding’ stacks and not stacks due to multiple gene cassettes. |

### 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.*

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|---|--|---|
| 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? | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> 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)? | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments:<br>* Include a diagram.   |
| Q23. Is this section of the Guidance organized in a logic and structured manner?  | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> 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?               | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments:<br>* More headings.   |
| Q25. Is there any other issue or concept that you would like to see included in this section of the Guidance?   | <input checked="" type="checkbox"/> Yes<br><input type="checkbox"/> No | Comments:<br>* If the tolerance trait does increase the persistence of the plant such as in agricultural areas (when the non modified comparator did not) there needs to be discussion on what constitutes a harm and what negative effects will be acceptable. The choice of |

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comparator becomes important in this example, e.g. other commonly accepted agricultural practices and plants may be used for baseline information.

\* The paragraphs from lines 1031-1042 introduce concepts that may be outside the scope of an environmental risk assessment for GM crops and may be better dealt with at a national level, i.e. through national legislation and policies.

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**Risk assessment of living modified mosquitoes**

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*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>

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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>

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

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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>

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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>

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**ADDITIONAL COMMENTS**

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

Q31.

*\* How is this guidance document positioned relative to the other documents? Does this document become the key guidance document of the Protocol and its signatories? Will adherence to this be enough to protect countries from liability and redress issues?*

*\* The Document is well written and thought out but difficult to apply because of the subjective nature of the assessments. I would suggest that no two people could come up with anything like a similar assessment for an application. An improvement in this direction would be a semi-quantitative approach as described by Morris, 2011. Transgenic Research DOI 10.1007/s11248-010-9480-8.*

*\* The 'approach' taken by this roadmap should be more clearly explained. The leap is too big from the framework/strategy that we are accustomed to.*

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