

**POSSIBLE WAYS FORWARD TO ADDRESS CHALLENGES IDENTIFIED IN THE TESTING OF THE GUIDANCE
ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS**

(AHTEG Sub-group discussion 25 May – 22 June 2015)

Sub-category: Audience

Identified challenges	Possible ways forward
<p>The targeted audience is not clearly stated ; the Guidance does not provide adequate guidance for non-experts; need to clarify the audience and how the novice/less experienced risk assessors can use the guidance</p>	<p>It should be emphasized that only persons with least knowledge of biology can apply this guidance other than lay people.</p> <p>Reference can be made to the training manual and its use in capacity building. Relevant examples are provided in the Training Manual under the respective sections.</p> <p>Emphasize the importance of training, team-work and usefulness of different disciplines when performing RA, doing RA is a complex task that one needs to study (that is the purpose of the background material).</p>

Sub-category: Scope

Identified challenges	Possible way forward
<p>Need to clarify how the intended use (e.g. food/feed import or release), scale and duration of a release (e.g. for field trial or commercial cultivation) may affect the risk assessment, that information requirements and availability for field trials <i>versus</i> commercial releases, and the difference of estimating the likelihood and consequences in field trials versus commercial cultivations.</p> <p>Problems arising from spillage during handling and transport are not addressed in the Guidance.</p> <p>The Roadmap is restricted to LM plants.</p> <p>Forest trees and fruit trees should be treated differently in the document</p>	<p>Although these issues are pointed out in several parts of the Roadmap, an attempt could be made to further clarify differences between field trials, food/feed import, and cultivation (scale, duration, confinement, data requirements, purpose, estimation of likelihood). Set up appropriate paragraphs in each document to define the scope and the complementation to other documents.</p> <p>Describe how confinement approaches for such releases serve to minimize the likelihood of adverse environmental impacts from the LMO release, even when detailed information on the specific LMO is not available.</p> <p>Mention the consequences of spillage and mixing (e.g. of seeds).</p> <p>The Roadmap has been developed with focus on LM plants in view of the available experience (see lines 181-183). However this linkage was not established in part II and needs to be reviewed.</p> <p>Assess if a clearer separation of forest trees vs fruit trees is needed in the document, or if the document could focus only on forest trees.</p>

<p>In the LM mosquito section, do the management strategies apply to field trials and/or commercial unconfined releases?</p> <p>The section on Stacked LMOs is limited to LMOs obtained through crossing and assumes that risk assessments are available for the individual parents which is often not the case.</p> <p>Clarify the relationship between the outcome of the risk assessment and monitoring (monitor only if uncertainty in RA)</p> <p>Case-specific versus general monitoring (make clear distinction in each part of the document, when applied and to what type of LMOs); Difficult to establish a causal link between changes found through general monitoring and an LMO</p> <p>The document confuses the monitoring of changes with the monitoring of LMOs – these are two different things</p> <p>Elaborate on problem formulation with a view to assist in developing a more focused monitoring plan.</p>	<p>Make attempt to further clarify this.</p> <p>Explain why the scope on stacks is restricted to those obtained through traditional crossing/breeding, and how to go about when risk assessments are not available for the parental LMOs.</p> <p>Elaborate on the requirements in article 16.</p> <p>Emphasize the role of case-specific monitoring and further clarify the difference between case-specific and general monitoring (it has been clarified – see page 54); different types of releases and monitoring (see pages 53, para objective and scope; page 54, full para 1 and 2).</p> <p>The Protocol’s mandate for general monitoring and its relationship especially to observing effects on biodiversity (long-term, cumulative, etc) should be clarified.</p> <p>Take up suggestions in the comments.</p>
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Sub-category: Relevancy of points to consider

Identified challenges	Possible way forward
How to use available information and points to consider and ask relevant questions (problem formulation).	Clarify that the points to consider serve as references for the risk assessment and the assessor must choose which points to consider are applicable to each case according to the rationales provided in the document, the specific needs of the risk assessment, well as the available of information. Provide reasons for the points to consider, referring literatures when necessary.
A problem formulation section is missing.	Introduce a section on problem formulation as one of the approaches/tools used in RA. A comparison (chart/bullet points/text) of different approaches to structure the risk assessment could be added (e.g. GW Suter II 2007). (Problem formulation is one way to structure the risk assessment (the phase in which the goals of the assessment are defined and the methods specified). The problem formulation approach commonly includes integrating available information, identification of hazards, defining assessment endpoints, conceptual models (plausible scenarios and risk hypotheses) and an analysis plan.)
The role of protection goals, assessment endpoints, measurement endpoints during the risk assessment are not properly explain.	Further elaborate on protection goals, assessment endpoints and measurement endpoints
[Stacked LMOs section] Lack of scientific rational in some points to consider.	Check more critically each point to consider in this section.

Sub-category: Link between steps or sections of the Guidance

Identified challenges	Possible way forward
Part I does not provide instructions on how to use information that is available and points to consider to ask the relevant questions for the purpose of performing the steps of the risk assessment, in particular Step 1 (problem formulation). Realistic pathways from hazard to harm are missing.	<p>Explain how to use the information that is available and points to consider. Clarify, improve the link between steps. How to move from step 1 to step 2, etc.</p> <p>The definition of the problem and the endpoints need to be clarified.</p> <p>Development of a succinct section on problem formulation, as well as further explanation on how to determine what information is relevant to characterize exposure and hazard.</p> <p>Possibly add references to other frameworks. Concrete examples</p>

<p>Guidance is ambiguous on how to use Parts I and II simultaneously.</p> <p>[Stacked LMOs section] Lack of focus in the problem formulation should be on possible interactions that may take place between the individual genes or traits.</p> <p>Clarify the relationship between risk assessment, risk management and monitoring</p>	<p>could be useful. Refer to/check the Training Manual.</p> <p>Provide explanation in the text linking the Roadmap and the different sections in Part II. Reconsider the structure/form of the document.</p> <p>Development of a succinct section on problem formulation</p> <p>General monitoring and causal link to possible adverse effect observed (see text on page 54, on general monitoring). Clarify further.</p>
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Sub-category: Experience with LMO & conventional practices

Identified challenges	Possible way forward
<p>Need to elaborate on: risk assessment of LMOs in comparison to common practices of agriculture; conventional agricultural practices; use and benefit from experience with non-LMOs; how pathogens are dealt with in conventional practices; experience with conventional breeding experience; the concept of familiarity; 20 years of experience with LMOs.</p> <p>[Stacked LMOs section] The need to explain what happens in nature and with conventional breeding; Guidance does not convey that traditional breeding practices looks for stacking as much desired characteristics as possible.</p> <p>[LMOs with resistance to abiotic</p>	<p>Include a statement that past experiences are important and could be useful but the nature of the modification of the LMOs should be the priority in risk assessment.</p> <p>Attempt to further clarify these issues in the preface and throughout the document, as appropriate, e.g. provide explanation of what happens in nature and with conventional breeding.</p> <p>Emphasize the importance of the background materials and risk assessment summaries in the BCH.</p> <p>Add more details about the level of heterozygosity among the non-modified recipient organisms used to produce the parental LM plants; phenotypic variability among non-modified hybrids produced through crosses between the non-modified recipient organisms; Number of crossings and the use of intermediate stacked LM plants as additional comparators; Phenotypic changes that may indicate underlying changes to any of the transgenes and genetic elements present in the stacked LM plant. Add examples.</p> <p>Mention past experience. Emphasize the importance of the</p>

stress section] The need to compare with non-LM plants with abiotic stress tolerance and weed risk assessment models.	background materials and risk assessment summaries in the BCH. Check if additional relevant materials could be added to the list.
[LM mosquito section] The need to elaborate on past experience with the management of non-LM mosquitoes; guidance on comparators.	Check if additional relevant materials could be added to the list.
[LM trees section] The need for more information on non-LM trees and commercial use, breeding and selection of trees (also in the context of LM-trees).	Check background material and clarify/check the corresponding parts in the document.
[Monitoring section] The need to highlight the limited experience with LM monitoring.	Check and clarify. Highlight the background documents.

Sub-category: Language

Identified challenges	Possible way forward
Complicated (“repetitive” and “too wordy”) and prescriptive language.	The fact that RA is complicated and a demanding task to perform cannot be changed, but check if language can be simplified, e.g. by shortening the sentences. Refer to Training Manual and background documents.
[LM Trees section] The language too technical.	Check if the language in this section can be simplified.
Need for further clarification of terms (clear reference to the use of terms).	Check the use of terms section. Consider using footnotes or boxes in the text to clarify some concepts/terms.

Sub-category: Consistency with the Cartagena Protocol

Identified challenges	Possible way forward
The Guidance introduces terms that are not in the Protocol; The Guidance goes beyond the recommendations of the Protocol;	The aim of the Roadmap is to provide additional and specific guidance to Annex III which is the over-arching frame. This inevitably introduces new, specific terms and concepts. Nevertheless, when possible or appropriate, refer to Annex III when introducing new terms. Add a note that new terms are being introduced which are not present in the Protocol, refer to the use of terms section.

<p>The tone of the Guidance is different of that of the Protocol; The Guidance is too prescriptive as compared to Annex III.</p> <p>[Monitoring section] General monitoring is not mandatory as per the Protocol.</p>	<p>Highlight with more prominence that the Guidance is not binding, e.g. add a disclaimer box at the beginning of the document. Check if some terms can be replaced by less prescriptive ones, e.g. replace “should” by “may”, as appropriate.</p> <p>Clarify that it is not mandatory as per the Protocol, but put it into the context of Article 16, paragraphs 2 and 4.</p>
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Sub-category: Actors and communication mechanisms

Identified challenges	Possible way forward
<p>Link between risk assessment, risk management and risk communication, and decision making is missing; Need to elaborate on communication mechanisms; Need to clarify different roles of (key)players in the process, including through consultation with NGOs; Need to explain how existing monitoring networks could be used.</p> <p>Elaborate further on other related issues (risk management, capacity building, public awareness and participation, socio-economic considerations, liability and redress);</p>	<p>Consider addressing these challenges by introducing examples of how these are dealt in some national frameworks. Refer to the examples in the training manual.</p> <p>Consider adding text on the usefulness of existing monitoring networks.</p> <p>This is a delicate issue. The current version of the Guidance is the result of a fine compromise between those who called for more text on the related issues and those who called for a strict focus on risk assessment.</p>

Sub-category: Concrete examples

Identified challenges	Possible way forward
<p>Need for “real-life” examples and case-studies on LMO risk assessment; Need for more specific values or criteria; Need for examples of risk to human health; Need for more reference to experience worldwide.</p>	<p>Incorporate the concrete examples to make the evaluation useful and easier for novel risk assessors.</p> <p>Case studies can be referred to in the background documents and training manual, BCH risk assessment summaries. Add selected and relevant case- studies as annexes? Consider adding examples from Latin America, in the Spanish version.</p>

<p>[Stacked LMOs, LM mosquitoes & Monitoring sections] Need for practical examples; More practical guidance on how to use the points to consider.</p>	<p>This is linked to other parts of the Guidance i.e. what type of examples should be included and how and where. Check the Training manual for examples how to move from one step to another. Make full use of the online resources in the BCH. Refer examples among the background documents.</p> <p>Attempt to add more concrete examples in Part II.</p>
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Sub-category: Human health

Identified challenges	Possible way forward
<p>Considerations of human health is lacking throughout the Guidance.</p>	<p>Discuss how to address this issue within Sub-group and entire AHTEG.</p>
<p>Clarify the scope of human health in connection with the environmental risk assessment.</p>	<p>Discuss how to address this issue within Sub-group and entire AHTEG.</p>
<p>[Monitoring section] Lack of consideration of human health in the context of monitoring.</p>	<p>Discuss how to address this issue within Sub-group and entire AHTEG.</p>

Sub-category: Other issues

Identified challenges	Possible way forward
<p>Need to clarify the purpose of the Guidance; Need to elaborate on the benefits of LMOs.</p>	<p>State more clearly that the Guidance is not meant as a method on how to conduct risk assessment. Clarify that the scope of the Guidance is on risk assessment. Benefit assessment is outside the scope of the Guidance.</p>
<p>[Stacked LMOs] Need for more guidance in the section dealing with the detection of stacked LMOs.</p>	<p>Attempt to improve the relevant text. Provide references to available methods and BCH section on LMO detection and identification.</p>
<p>[LM mosquito section] Need to discuss the aspects of epidemiology in the risk assessment.</p>	<p>Check if text can be improved.</p>
<p>[LM trees section] Need to explain the implications of the long lifespan on monitoring.</p>	<p>Check if text can be added to the paragraph mentioning the long lifespan of trees.</p>

<p>[Monitoring section] Need to mention cost implications of setting up a monitoring system.</p>	<p>Add reference among the background documents.</p>
<p>[Background documents] Need to check, streamline and update background documents; Add references throughout the text to relevant background documents.</p>	<p>Check and improve when possible. Consider adding specific references throughout the text in addition to the general background documents.</p>
