Sub-category: Audience

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| Identified challenges | Possible way forward | Notes (if needed) |
| The guidance should be aimed at all Parties, but with a greater emphasis on Parties that still lack a solid regulatory and/or technical framework for risk analysis.  This document will not provide adequate guidance for non-experts. | The guidance must provide step-by-step instructions for formulating the problem in the context of the scientific method.  It should have highlighted the risk assessment models  This is to provide real life case studies for a range of LMOs (from GM animals, plants, trees and microorganisms, viruses) and uses (from field trials, commercial cultivation, vaccines) to show how different regulators actually carried out the risk assessment.  Suggestion: Such models, real case studies and examples is relevant to be provided in the Training Manual under the respective sections. |  |

Sub-category: Scope

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| Identified challenges | Possible way forward | Notes (if needed) |
| L14-65:  To determine the nature and level of detail of information that is needed for the risk assessment  Insufficient distinction between the environmental risk assessment of field trials (small scale) and commercial releases (large scale).  For countries looking at assessment of LMOs for the purpose of Food, Feed and Processing only, this document is not useful at all  In part II for Guidance on Stacked Events it does not highlight / demonstrate (I) how a risk assessment is actually conducted (i) how the risk assessment process can be simplified using the available experience and (ii) risk assessment may not be applicable to all Protection Goals or end points.    L. 79-149:  The specific nature of field trials is not sufficiently addressed.  The general monitor approaches are not well-designed to yield information that would reliably indicate a causal relationship between the environmental release of an LMO and some purported adverse effect. | L 14-65: Suggested that a more user friendly and easy reading document developed.  Case examples should be extracted out from the main document.  Use bullet points in the formatting to enhance clarity.  Have sections and numberings so that it will be easier for any cross references.  A lot of information can be put in appendices/explanatory notes. Keep the main document simple…with headers, etc. Examples, options, alternatives should be mentioned in appendix. 10. 'Points to consider' are all useful points. May avoid listing this points using alphabets. Use numbering so that it is easy for reference and to break it up into smaller segments.  it would require extensive additional text to elaborate on the need for risk assessors to use relevant experts who know about the non-LMO versions of the organism.  It should 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.  RM has been developed with focus on LM plants in view of the available experience (refer line 181-183) with LM plants. However this linkage has not been established in Part I and part II and needs to be reviewed.  L 79-149: A clear distinction should be made for guidance in case of releases for confined field trials and guidance for placing on the market.  Distinction between 'case specific' monitoring and 'general monitoring' should be done more clearly.  Some text contradictions should be eliminated (trees-forests).  Make clear why and when specific or general monitoring applies to what types of LMOs. Introduce practical guidance as to how monitoring should be carried out. Distinguish between monitoring of field trials and commercial releases. Address the relationship between the outcomes of the risk assessment and monitoring.  It is advised to start this section (Monitoring) with a listing of the various uses of monitoring, and to stick to monitoring changes.  1. Give priority to the development of case-specific sections in Part II of the Guidance for specific types of LMOs and traits  2. Ensure a standalone nature of the case-specific sections that gives proper account of the different uses (field trial and commercial releases).  3. Adhere to a concise and consistent format for the case-specific sections:  - Support the problem formulation with the use of appealing examples  - Use a clear text structure,  - Provide a scheme in which the aspects of risk assessment are presented in a visual manner.  4. Identify and rank specific types of LMOs and traits that demand the elaboration of case-specific sections.  5. Focus Part I (Roadmap) on the step-wise approach of the risk assessment methodology with reference, where relevant, to the Training Manual  6. Keep Part III (Monitoring) as a separate document with individual chapters for specific types of LMOs and traits. Explain relationship between monitoring and risk assessment and risk management, in particular in relation to the concept of uncertainty. |  |

Sub-category: Relevancy of points to consider

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| Identified challenges | Possible way forward | Notes (if needed) |
| L.5-33:  Guidance leaves ambiguity how to mutually use Parts I and II for the specific types of LMOs and traits discussed in Part II (e.g. LM trees).  - Part I does not provide instructions how to use the available information and presented points to consider to ask the relevant questions for the purpose of performing the consecutive steps of the risk assessment, in particular Step 1 (problem formulation).  L68-119:  For stacked genes or traits the focus in the problem formulation should be on possible interactions that may take place between the individual genes or traits.  The document does not give any guidance how to identify cases that go beyond what happens in nature and with conventional breeding.  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. | L5-33:  Linkage between Part I and Part II.  Instructions how to use the available information and presented points to consider.  The definition of the problem and the so-called endpoints need to be inferred.  Development of a succinct section on problem formulation is recommended, as well as further explanation on how to determine what information is relevant to characterise exposure and hazard.  The 'prescriptive' tone and policy-based statements in the Guidance should be revised.  L68-119:  The problem formulation should be done with the reference on possible interactions that may take place between the individual genes or traits.  The document should give any guidance how to identify cases that go beyond what happens in nature and with conventional breeding.  Important point to consider should be the potential impact on biodiversity associated with cultural, ecological and management practices associated deployment of the LMO |  |

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

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| Identified challenges | Possible way forward | Notes (if needed) |
| There is a lack of clarity on how to relate the different steps of the assessment.  Guidance leaves ambiguity how to mutually use Parts I and II for the specific types of LMOs and traits discussed in Part II (e.g. LM trees).  There is no clear link on how information from Step 1 (hazard identification) is used with information in Step 2 (exposure) and Step 3 (hazard) to complete Step 4 (risk characterization). | Make clear how the different steps of assessment are related.  Make possible to mutually use Parts I and II for the specific types of LMOs and traits discussed in Part II.  To make clear link on how information from Step 1 (hazard identification) is used with information in Step 2 (exposure) and Step 3 (hazard) to complete Step 4 (risk characterization).  The relevant linkages can be provided in the Training manual. |  |

Sub-category: Experience with LMO & conventional practices

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| Identified challenges | Possible way forward | Notes (if needed) |
| It is an opinion that identified risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms | Suggested that identified risks should be considered in the context of the risks posed by the non-modified recipients or parental organisms.  To be of practical value for risk assessment, any guidance document should therefore: 1) provide a clear explanation of what happens in nature and with conventional breeding.  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. |  |

Sub-category: Language

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| Identified challenges | Possible way forward | Notes (if needed) |
| The Guidance needs re-structuring and simplification. | The Guidance can be revised in terms of the language simplification and understanding, where is relevant. |  |

Sub-category: Consistency with the Cartagena Protocol

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| Identified challenges | Possible way forward | Notes (if needed) |
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Sub-category: Actors and communication mechanisms

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| Identified challenges | Possible way forward | Notes (if needed) |
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Sub-category: Concrete examples

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| Identified challenges | Possible way forward | Notes (if needed) |
| Incorporate the concrete examples to make the evaluation useful and easier for novel risk assessors. | To develop easy-to-use standalone sections for specific types of LMOs and traits: 1. Give priority to the development of case-specific sections in Part II of the Guidance for specific types of LMOs and traits.  2. Ensure a standalone nature of the case-specific sections that gives proper account of the different uses (field trial and commercial releases). 3. Adhere to a concise and consistent format for the case-specific sections to preserve the readability.  Focus Part I (Roadmap) on the step-wise approach of the risk assessment methodology with reference, where relevant, to the Training Manual on Risk Assessment of Living Modified Organisms |  |

Sub-category: Human health

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| Identified challenges | Possible way forward | Notes (if needed) |
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Sub-category: Others

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| Identified challenges | Possible way forward | Notes (if needed) |
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