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| **Sub-category** | **Section** | **Priority given by sub-group** | **Challenge** | **Possible way forward** |
| Define audience  | Entire Guidance | High | The Guidance is useful to those who have less experience in risk assessment but too general, therefore, less useful to those who are more experienced in LMO risk assessment. | Explain that the Guidance is meant as a tool to explore the fundamental principles and criteria of the risk assessment of LMOs, and the specific points to be considered when assessing specific types of LMOs and traits. As compared with other guidelines on the environmental risk assessment of genetically modified plants, the Guidance is more straightforward and concise and therefore easier to read for a novice risk assessor. However, it may be less useful for applicants for which a more detailed Guidance is needed. it is important to note that the Guidance is not meant as a self-sufficient document to conduct a risk assessment, on the contrary, it points at other relevant sources of information that may be consulted through lists of relevant background documents.  |
| Define scope of application (i.e. for field trial and/or full release of LMO) | Roadmap, Stacked genes | Medium/High | The Guidance is supposed to cover all LMOs and all scopes of application, including risk assessments for confined field trials. However, the points to consider outlined in each of the steps are very broad and it is not immediately obvious what points would be applicable to a specific product or to a certain scope. The Protocol does not distinguish between “field trials” and “commercial” releases.  | Emphasize/explain, in the Guidance, that the information needed in order to conduct a risk assessment of an LM crop intended for field trial is less than that for a risk assessment for commercial release. In the majority of cases, the objective of the field trial is to generate information that will help risk assessors characterize the level of risk. Often, the lack of information prior to the risk assessment is compensated by measures to limit the exposure of the environment to the LMO under trial. This clarification could be done in the form of a “box” which could include concrete examples of how countries conduct risk assessments for field trials.  |
| Clarify when the ‘points to be considered’ are relevant and why  | Roadmap | Medium | The information contained in the points to consider provides little practical help when conducting a risk assessment for a specific LMO. A lot of information listed in the points to consider is not essential to make a decision. The points to consider make it difficult, in particular for an inexperienced risk assessor or user, to formulate appropriate testable hypothesis that support risk characterization. To verify that all relevant information has been provided in a dossier and that all risk hypotheses are adequately tested, it is important to be able to formulate meaningful hypotheses on the basis of the points to consider. Otherwise, the points to consider could lead risk assessors to develop many scientific hypotheses that, although broadening scientific knowledge, would not really inform the risk assessment ('nice to know' vs. 'need to know'). | The points to consider could propose concrete questions to help risk assessors in the “problem formulation”\* process. This could be done by proposing specific examples of adequately formulated risk hypotheses, including selection of assessment endpoints and ways of collecting relevant data supporting the risk assessment. In addition, examples illustrating the implementation of the guidance and the risk assessment methodology for specific cases could be a way forward to improve the utility of the guidance. For example, some points to consider could pose questions regarding the type of pest in question and its relationship with the environment, how the pest is dealt with under conventional (non-LM crops) conditions, what is the susceptibility of non-target organisms, etc.\* “Problem formulation” needs to be understood as a composite of protection goals, assessment endpoint and measurement endpoints; the latter are not even mentioned in the Guidance, yet they are necessary in enabling the translation of protection goals into concrete measureable indicators and parameters. |
| Link the five risk assessment steps | Roadmap | High | While the guidance is useful in the sense that it includes different steps to be followed, it does not provide adequate instructions for following the different steps when applied to a specific problem. For example, in Step 1, the Guidance lists the points to consider, but when it moves to the other steps, 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 characterisation). So the Guidance almost becomes a list of potential hazards and exposure scenarios without context and with no clear guidance on how to integrate the various pieces of information for performing a risk assessment in practical terms. This approach does not allow a necessary connection between each phase of the risk assessment, and may generate confusion and lack of harmonization between risk assessments. For instance, for non-target organisms, although the Guidance takes both risk and exposure into account, it is not clear on how to combine everything and follow the process of specific assessment.Moreover, the way risk assessment is introduced gives the wrong impression that there must always be risks (e.g. language such as 'the risk posed by the LMO'). This is underlined by the flow chart which in all cases ends with 'consideration of risk management'. | One of the important elements that could be improved is the introduction of a problem formulation step (mentioned in the Guidance but not developed or explained in detail). This step would help risk assessors in focusing the risk assessment according to the product type, the receiving environment and the scope. This would also help in clarifying the key areas to assess, given national protection goals, what information is already available and relevant for the assessment and what information is missing to complete the assessment. The Guidance could be structured in such a way that allows a separate risk assessment (where a hazard and exposure characterization are conducted) of each issue, such as weediness potential and effects on non-target organisms, considered by the country important to their environmental protection goals. This allows for risk assessments that are easier to understand, where the problem under assessment is clearly defined (problem formulation), information already available is considered and an analysis is conducted to determine what additional information may be needed to complete the risk assessment. Another potential improvement would be to re-structure the Guidance or provide examples to clarify how the Steps described fit together for the assessment of a particular risk or issue under consideration. |
| Simplify language | Roadmap | High | The language is very dense and of a ‘legal negotiation’ type, with often sentences of several lines that are extremely difficult to follow for non native English speakers. |  |
| Clarify that risk assessors can draw on knowledge and experience gained from non-LMO risk assessments | Roadmap, Stacked genes, Abiotic stress, LM trees | Medium/High |  |  |
| Describe mechanisms of communication between risk assessors and risk managers | Roadmap | High | One of the critical elements of a risk assessment is to facilitate the communication between the risk assessor and the risk manager, so the risk assessor can outline in a clear way what problems were addressed, what information was used to address them, what were the conclusions and what information supports these conclusions. The Guidance in its current form fails to provide this. The Guidance is useful in that it describes the critical distinctions between hazard and exposure and the need to consider both to characterize risk. However the Guidance does not offer much practical support to risk assessors as it is not clear how to match relevant hazard data with relevant exposure data to assess the risk for a particular area of assessment.  |  |
| Clarify consistency with the Protocol, if needed | Roadmap, Stacked | Medium | While the broad structure and the 5 steps outlined in the document are consistent with the steps in Annex III to the Protocol, the text of the Guidance is not in conformity. Annex III is based on scientific considerations, whereas the Guidance extends into policy considerations and administrative issues. For example under the section on 'Overarching issues in the risk assessment' sub section ‘quality and relevance of information’, several points/terms being used are administrative in nature. The terms such as 'independent review', sufficient quality of information etc are administrative/operational procedures and subject to different interpretations. In addition the use of new terminologies is not consistent with the CPB. |  |
| Provide “real-life” examples of LMO risk assessment and/or effects (including, inter alia, human health related issues) | Roadmap, Monitoring | High |  |  |
| Clarify what to do in cases where risk assessments are not available for the individual events | Stacked genes | High | The scope of this section takes the wrong assumption that a risk assessment is already available for LM plants with the single genes or traits. This leaves many LM plants out of the scope of this section. Also, the availability of a risk assessment for the individual lines is not a necessary prerequisite to allow for a risk assessment of the stacked line. | Clarify that the section on stacked genes should be used when risk assessments for the parental LMOs was conducted in accordance with the Roadmap. In the event that the parental LMOs have not yet been assessed, the Roadmap could be used together with the section on stacked genes in the risk assessment of the stacked line. |