

<p><b>Discussion item 1:</b></p> <p>We propose to add a glossary of terms, that explains terms and concepts that are not straightforward. We ask you to provide suggestions for items that could be mentioned in the glossary.</p>	
<p><b>Discussion item 2:</b></p> <p>The notion that evaluation and quantification of the level of risk may be subjective in some cases has been brought up, as an issue that should also be mentioned, as a separate paragraph, in this Chapeau section. Do you agree that this is an issue to be mentioned here; if so, do you have a text suggestion?</p>	<p>Since risk assessments should always be as objective as possible, no paragraph on „subjective decisions“ should be integrated in this section of the roadmap; decisions are always taken objectively based on the facts accessible.</p>
<p><b>Discussion item 3:</b></p> <p>Annex III, 3 states that “Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations”, but does not specify any particular standards, e.g. for transparency, accessibility, reproducibility, relevance or quality. Still, it is clear that these standards will (have to) be set, e.g. by Parties or by standard setting bodies. Do you agree that we can refer to standards against this background?</p>	<p>I agree that we can refer to standards, e.g. to standards set by the OECD.</p>
<p><b>Discussion item 4:</b></p> <p>It has been pointed out that the need for a dialogue with stakeholders and the promotion of public awareness is a statement on procedures governing the risk assessment process, not on risk assessment itself.</p> <p>How do you feel about taking on board this kind of statements that go beyond the risk assessment process?</p>	<p>Risk assessment should be a merely scientific process based on data produced by the scientific community. In my opinion, any roadmap for risk assessment should be as precise and short as possible, and focus on risk assessment itself, to ensure legibility and practical use of the document.</p>
<p><b>Discussion item 5:</b></p> <p>‘Ecological function’, or ‘ecological services’, provided by an organism refers to the role of this organism in ecological processes. For example organisms may be part of the decomposer network playing an important role in nutrient cycling in soils or be important as pollen source for pollinators and pollen feeders. In relation to LMO risk assessment, the ecological functions of the parental organism may trigger specific concerns, e.g. if pollen of the LMO is an important source for a pollen feeding insect, the exposure of the insect to the LMO (or at least to its pollen) could be high. It has been pointed out that any crop that is grown in a field as such will dominate what happens with carbon/nutrient cycles, pollinators, hydrologic cycles, etc. All these are however (potential) in-field effects, that can be handled as a separate question from the out-of-field or off-site considerations. On the other hand there will be a gradient: in-field, border rows, broader area around the field, out-of-field. The gradient may be different for different aspects: e.g. effects on mineral cycling in the soil vs. pollen flow.</p>	<p>U:\Sekretariat2-(202004)\405\BCH\Cartagena_Protokoll\Roadmap to Risk Assessment\remarks on advance roadmap for risk assessment</p>

Guidance questions	
<ul style="list-style-type: none"> <li>Does the Roadmap provide a clear description of the risk assessment process in the context of Annex III?; do you have suggestions for improvement?</li> </ul>	The risk assessment process is described in detail and well structured.
<ul style="list-style-type: none"> <li>Is the Roadmap useful for you, to improve your grasp on the LMO risk assessment process, and for capacity building purposes; do you have suggestions for improvement?</li> </ul>	This roadmap may be useful for anyone with little experience on biosafety assessment and represents an excellent guideline
<ul style="list-style-type: none"> <li>Could you consider the discussion items that are referred in several footnotes in the document, and that are listed at the end of the document, and provide us with your points of view and reflections on these items? Your textual comments and comments on content, e.g. items or considerations that are missing, as well as further discussion items that you feel should be considered, are very much appreciated.</li> </ul>	
<ul style="list-style-type: none"> <li>Do you see value in the Roadmap as a structure for the effective use of information and guidance documents on risk assessment, as explained above; do you have suggestions for improvement?</li> </ul>	In this form, the roadmap presents a highly instructive document.
<ul style="list-style-type: none"> <li>Could you please provide us with more examples of information documents, and indicate where in the Roadmap they should be assigned?</li> </ul>	

### **additional comments:**

“general considerations – uncertainty”: The question arose if uncertainty on a specific subject necessitates additional information, before potential risk management strategies and the monitoring measures are considered (page 2, overarching issues).

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In our opinion, any available information has to be taken into account during the risk assessment process. Remaining substantial concern results in the need for further risk management and monitoring strategies.