Sub-category: Audience

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 197 +17 + 49 (RM)  They all suggest somehow that the targeted audience is not clearly stated and/or that the guidance must be for X or Y audience in a prevalent manner.  ID 39 (A) vague discussion on pleiotropic effects | Looking at and rereading the roadmap, it is clear to me that this is not necessary. The section on “objective and scope” as well as “Part I/ background” make it very clear what the roadmap is meant to accomplish/ the roadmap´s function.  No further clarification is really needed.  My suggestion is to explain this as clearly as possible, maybe reiterate what the roadmap clearly states.  ID 39 the whole section is pretty well constructed, although I believe many of the points made also could be included en the Roadmap because they are not only specifically relevant to “LMO with tolerance to abiotic stresses” |  |

Sub-category: Scope

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 185 (RM) + 219 + 300 + 341 + 483 + 487 Need to emphasize scale issues in the roadmap (time and space) through the steps when conducting a RA so it is sufficiently comprehensive, and correct context in relation to needed info for the risk assessment process  ID 390 (RM) + 391 mostly plants although roadmap should be universal for all LMO  ID 68 (S) no need for the section if Roadmap corrected  ID 11 (A) make a distinction for confined field trials and commercial market use | ID 185+ 219 + 300 + 341 + 483 + 487 must take this into account  ID 390 + 391 this problem and limitation is already mentioned in Part I “Background” recognizing that it is with LM plants where most experience exists ….revisit Part II  ID 68 probably so for some issues, but this special section on stacks is relevant on its own, there are certain issues that are specific to stacks  ID 11 I don´t think this is relevant for risk assessment purposes, Q´s must be made from the start……if I understood the comment correctly | General note from Francisca: it may be necessary to explain why the scope on stacks is restricted to those obtained through traditional crossing/breeding. |

Sub-category: Relevancy of points to consider

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 105 (RM) does not sustain for itself  ID 126 (RM) need to better structure part II relative to part I; also explain that the guidance is not by itself a standalone methodology, but a “guidance”  ID 137 (RM) difficulty in understanding the relevance of the points to consider  ID 191 (RM) no challenge  ID 217 + 309 (RM) “problem formulation” is suggested to be added…the guidance does mention the concept although does not explicitly develop it (see para 2 step 1).  ID 236 (RM) not well sustained  ID237 (RM) what I find relevant is the need for examples, rest is not well sustained  ID 309 (RM) suggest clarifying what info is actually needed in the process  ID 392 (RM) does not sustain for itself  ID 8 (S) does not sustain for itself  ID 15 (S) look at interactions that have been left not attended  ID 24 (S) questions the scientific grounds of the whole section  ID 28 (S) does not sustain for itself  ID 32 (A) several criticisms that can be analyzed, including questioning related to a “the difficulty of identifying comparators”, criticism related to using “omics” in risk assessment, and a lack of enough development of the “cross talk issue” between gene constructs in stacks.  ID 39 (A) argue relevancy at learning from non GM abiotic stress tolerance in plants | ID 105 Dismiss  ID 126 Reevaluate order part II in relation to part I  ID 137 Dismiss  ID 191 yes this is OK  ID 217 + 309 This para could be clearer, it is a bit confusing. Adding some clearness might help those proposing problem formulation to be explicitly dealt with.  ID 236 Dismiss  ID 237 I find the roadmap an easy document to read on the whole, It might be useful to bring to the front of the document the flow chart and highlight the part of the flow chart for each section  ID 309 take into consideration to try to make this clearer through elaborating a bit more perhaps?  ID 392 Dismiss  ID 8 Dismiss  ID 15 Revisit the section, all though this sections does discuss and point them out as relevant issues to be dealt with  ID 24 Revisit the section to see in which cases they have a point  ID 28 Dissmiss  ID 32 difficulty in id comparators is real not only for “abiotic stress tolerant modified organisms”, use of omics is not unnecessary but not only relevant for “abiotic stress tolerant plants”, cross talk issue might be further developed.  ID 39 agreed, risk assessment must draw on all possible similar experience | See “conducting the risk assessment”….it explicitly mentions that “relevance” depends on the case being assessed |

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

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| Identified challenges | Possible way forward | Notes (if needed) |
| (RM) ID 22+126 + 309 + 391 +483 ? + 484  ID 15 (S) interactions left unattended  ID 16 (S) dismiss  ID 24 (S) no need for analyzing stacks | ID 22+126+309 + 391 + 483? + 484 + Need to elaborate on the relationship between the points to consider in the different sections of the roadmap (conducting a …….) as well as assuring same logical steps/sections between Parts I and II of the Guidance  ID 15 These are discussed but can be revisited  ID 16 the section is not meant to stroll you through the whole process but just complement it (the roadmap)  ID 24 reasonable to guide ourselves reading literature cited that says stacks do not need to be analyzed further than the individual LMO….. |  |

Sub-category: Experience with LMO & conventional practices

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| Identified challenges | Possible way forward | Notes (if needed) |
| (RM) ID 22+ ID 24 + 300 + 401 (?) + 412 + 459 + 481 The roadmap repeatedly mentions framing the risk assessment steps in previous knowledge and known context, see in planning phase, in conducting the risk assessment step 1 (h) and footnote 19, also (l), step 2 also considers past experience as well as step 5 (a)  ID 49 (RM) gives good examples to think of related to “real life case studies”  ID 414 (RM) does not sustain for itself  ID 485 (RM) point out that the RM conveys the idea that outcrossing, as well as phenotypic and/or genotypic instability are not natural phenomenon  ID 24 (S) does not convey that traditional breeding practices looks for stacking as much desired characteristics as possible  ID 49 (S) + 51 introduce history of safety with stacked events  ID 19(A) + 28 + 32 + 33 + 39 neglects drawing from previous knowledge from abiotic stress tolerant plants, the text ignores the concept of familiarity | (RM) ID 22+ ID 24 + 300 + 401 (?) + 412 + 459 + 481 revisit and see if an extra mention is needed  ID 49 Try to get a grip on some of these possible examples  ID 414 (RM)  ID 485 (RM) Dismiss, the whole point of risk assessment in relation to the release of LMO into the environment is that what is new is a genetic combination in a receptor organism in an X or Y environment, this is what is being evaluated and must be considered in the context of outcrossing, as well as phenotypic and/or genotypic instability  ID 24 this is true but through other mechanisms, not with modern biotech, and what is new and being regulated is the use of modern biotechnology, and it is in this context that the section on stacks is focused on.  ID 49 + 51 include examples  ID 19 + 28 + 32 + 33 + 39 review and mention past experience w/good reviews as additional bibliography |  |

Sub-category: Language

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| Identified challenges | Possible way forward | Notes (if needed) |
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Sub-category: Consistency with the Cartagena Protocol

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 52 + 65 + 91 (M) Question if general monitoring should be included  ID 35 (S) Be non prescriptive | ID 52 + 65 + 91 (M) revisit and consider  ID 35 dismiss, it is not prescriptive, it is ony “guiding a way forward to analyze” |  |

Sub-category: Actors and communication mechanisms

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 94 (M) usefulness of monitoring networks | ID 94 (M) consider introducing usefulness of monitoring networks |  |

Sub-category: Concrete examples

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| Identified challenges | Possible way forward | Notes (if needed) |
| All comments call for concrete examples, for example ID 40 (GC) is very constructive  ID 1(S) +3 + 56 call for examples, use some from LA, including some in spanish | Examples are needed |  |

Sub-category: Human health

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 34 (GC) specify scope of HH issues under ERA | ID 34 not sure how |  |

Sub-category: Others

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 90 (M) + 43 (GC) + 46 (GC) + 50 (GC) Need to check and update ref´s  ID 61 (S) is asking for more info on being able to detect stacked events with a single test | ID 90 (M) + 43 (GC) + 46 (GC) + 50 (GC) it is correct to need to check and update ref´s  ID 61 the whole point is that it might not be possible, or at least rather difficult to assure in a single detection reaction if what you are detecting comes from a mixture of two independently contained events or them being stacked. |  |