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 10 (T) + 33 comments are made regarding differentiating confined trials vs release into the environment at a larger scale (commercial) and what needs to be taken into account  ID 23 (T) + ID 24 emphasis is made on differences between orchard fruit trees and forest tree plantations  ID 15 (Mosq) asks for differentiating what is needed in a confined trial vs commercial release  ID 15 (Monit) + ID 23 + ID 30 + ID 34 + ID 56 + ID 65 + ID 74 + ID 77 + clarify relationship between general and specific monitoring and when in Part III each applies  ID52 (Monit) + 91 suggests deleting “general monitoring” in Part III altogether  ID 33 (Monit) seems to focus on LMO detection instead of detecting changes  ID 45 (Monit) parameters only refer to commercial/large scale environmental releases  ID 46 (Monit) suggestion of highlighting how problem formulation would reduce monitoring requirements  ID 47 (Monit) questions the focus of the section and the way it is developed  ID 85 (Monit) (???) | 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  ID 10 + 33 this varies between regulatory frameworks, might not be useful to make this distinction….but just make sure these types of Q´s are asked and resolved during the lifespan of testing related to Risk Assessment  ID 23 + 24 nevertheless they are trees and have common issues……could include a paragraph pointing this out.  ID 15 as I have stated before, different regulatory systems differ in what is required when, these are elements that must be taken into consideration during the risk assessment process on the whole….  ID 15 + ID 23 + ID 30 + ID 34 + ID 56 + ID 65 + ID 74 + ID 77 discuss, specially the relevance of general monitoring related to detecting “adverse effects”….  ID 52 + 91 discuss  ID 33 I don´t have the same perception reading the document, nevertheless it might be useful to emphasize that detecting changes is what monitoring is about  ID 45 discuss  ID 46 not sure this is convenient  ID 47 discuss | 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 14 (T) + 22 + 34 several issues that are put forward relevant for tree risk assessment  ID 26 (T) rationale for certain points to consider lacking  ID 12 (Mosq) argue speculation under “unintentional effects”  ID 10 (Monit) points to consider with no internationally agreed guidance | 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  ID 14 + 22 + 34 check which can be incorporated into the section on Trees  ID 26 my opinion is that the rationale is not lacking  ID 12 dismiss, to me it is reasonable to think in all the possibilities and discard the ones that in X or Y case are very unlikely……this is the whole point of the “guidance” and the section on mosquitoes does a very good job  ID 10 Dismiss | 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 2 (T) + 8 + 9 + 34 argue lack of linkage between steps in Roadmap and Trees section and in the Trees section also  ID 6 (Mosq) does not have the same structure than the Roadmap  ID 15 (Monit) address relationship between outcomes of risk assessment and monitoring  ID 48 (Monit) suggests making reference to sections in the roadmap that mention “monitoring”  ID 58 (Monit) suggests clearly articulating the link between risk management and monitoring (by including it in the roadmap at the end of risk management)  ID 62 (Monit) clarification as to whether the proposed monitoring can actually indicate a causal relationship between the environmental release of the LMO and the observed adverse effect  ID 69 + 73 (Monit) suggestion of highlighting how problem formulation to ID info/monitoring requirements so as to focus monitoring  ID 74 (Monit) questions general monitoring in its capacity of id adverse effects related to the release of an LMO into the environment  ID 77 (Monit) ????  ID 83 suggests mentioning monitoring strategies in the case of 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…..  ID 2 + 8 + 9 + 34 check but this section is meant to complement the roadmap, not develop all the steps described  ID 6 not relevant, pretty well structured and indicates what part of the roadmap is related to  ID 15 relevant if not already there….maybe make it more explicit  ID 48 OK, take on board  ID 58 OK, take on board  ID 62 discuss, circular  ID 69 not sure this is convenient, you reduce scope…..  ID 74 Discuss  ID 83 agree |  |

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  ID 29 (T) + 30 draw from previous experience  ID 33 (T) argues that too much info asked for in confined releases,  ID 14 (Mosq) + 26 + 28 + 34 all suggest using past experience, including knowledge on non modified mosquitoes, further guidelines on the selection of comparators, the SID technique, previous risk assessment already undergone, as well as management of LM releases that have already taken place  ID 70 (Monit) + 71 suggests including past experience in real LMO releases in relation to monitoring  ID 81 (Monit) suggests including that there has been limited experience with LMO monitoring and that it is absolutely necessary to carefully consider the monitoring plan and make it sufficiently detailed to make sure the outcomes are meaningful to the stated objective | (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  ID 29 + 30 include previous experience from non LMO trees as well as from regulated cases in confined and released conditions  ID 33 depends on regulatory system in place, the section mentions info needed through the process to do a risk assessment and be able to evaluate, each regulatory system should consider according to its needs  ID 14 + 26 + 28 + 34 all are relevant comments that should be analyzed. Mexico had a confined trial release with a very good risk assessment presented by the applicant (even though it was not going to be released into the environment at all)….this one (if publicly available) could be also referenced as an example  ID 70 + 71 OK  ID ID 81 OK |  |

Sub-category: Language

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| Identified challenges | Possible way forward | Notes (if needed) |
| ID 11 (T) too technical and high level language | ID 11 Dismiss |  |

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 (Monit) + 91 delete “general monitoring”  ID 65 (Monit) questions “general monitoring” | ID 52 + 65 + 91 (M) revisit and consider  ID 35 dismiss, it is not prescriptive, it is ony “guiding a way forward to analyze”  ID 52 + 91 discuss  ID 65 discuss |  |

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 25 (Monit) only place with “role players”  ID 94 (Monit) suggests explaining how existing monitoring networks could be utilized | ID 94 (M) consider introducing usefulness of monitoring networks  ID 25 discuss what to do  ID 94 OK |  |

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  ID 2 (Mosq) + 8 + 17 + 28 + 35  ID 71 (Monit) suggests that actual experience should be taken as a model  ID 74 (Monit) points out that there are no examples on how general monitoring might point out how a LMO release can actually cause an adverse effect | Examples are needed in general,  ID 71 OK  ID 74 discuss |  |

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 57 (Monit) suggests including reference to monitoring adverse effects related to human health issues with respect to LMO releases | ID 34 not sure how  ID 57 discuss how to take on board |  |

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 13 (T) + 14 interesting additional ideas presented  ID 17 (T) missing concepts  ID 28 taking action in the ideas presented  ID 31 missing benefits of using technology on plant breeding  ID 33 (Mosq) incorporate description of aspects specific to the risk assessment from the perspective of epidemiology  ID 39 (Mosq) link with the effort of OECD Mosquito Biology Consensus document under development by the Working Group on Harmonization of Regulatory Oversight in Biotechnology  ID 2 (Monit) suggests adding additional references  ID 26 (Monit) worried about costs  ID 27 (Monit) “post monitoring relevant” but adds costs, give guidance on the matter  ID 63 (Monit) monitoring is not verifying compliance, but several ref´s give this impression  ID 90 (Monit) suggests several ref´s need to be re-examined | 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.  ID 13 + 14 take on board  ID 17 consider  ID 28 OK  ID 31 check and consider including…although does not have much to do with risk assessment as such  ID 33 take on board  ID 39 link and reference  ID 2 discuss and propose the already settled system to do so  ID 26 Indeed, monitoring has costs related to it…..derived from using modern biotech and the possible identified effects that need to be studied  ID 27 discuss  ID 63 discuss and maybe dismiss  ID 90 discuss |  |