Sub-category: Audience

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 197 (RM) and ID 49 (General comments): Both comments ask for clarification of the audience; and discuss experienced vs novice risk assessors.  (Also ID 39 – Abiotic and ID 17 -LM trees refer to novice-unexperienced risk assessors). | The RM is a guidance document and should be used together with the background material, not only as a stand-alone document. We could make reference to the training manual and its use in training situations. If necessary, we could add something about the importance of training, emphasize team-work and usefulness of different disciplines when performing RA, doing RA is a complex task that one needs to study (that is the purpose of the background material). | See preface and background (paragraph 1) |

Sub-category: Scope

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:** ID 185, 219, 237, 300, 341, 483, 487  There is a need to clarify the importance of scale and duration of a release; The difference of field trials vs F&F import only vs cultivation (see step 1 in particular); The relevance of confined vs unconfined; Difference in data requirements of field trials vs cultivation; Likelihood estimation in field trials vs cultivation (see step 3); *Spillage during handling and transport not addressed.*  **Roadmap**: ID 390 and ID 391  Restricted to GM-plants. | We need to make sure that there is a clear understanding of differences between field trials, F&F import only and cultivation (scale, duration, confinement, data requirements, purpose, estimation of likelihood). This is pointed out in several parts of the RM. Let’s see if and how this can be further clarified.  It is stated that the guidance is for all GMOs but we have most experience in GM plants.  Let’s try to further clarify this. | This has been pointed out in several parts of the RM – see for instance page 9, paragraph 3; page 11, first paragraph (field trials); page 12, third bullet point (scale, duration; F&F import only; field trials); page 15, point (h) (scale, duration and level of confinement)  See page 9, background, paragraph 2 |

Sub-category: Relevancy of points to consider

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap**:  ID 126, 217, 309; How to use available information and points to consider to ask the relevant questions (problem formulation); Add problem formulation section; outline protection goals, assessment endpoints, measurement endpoints, | ID 105, 236, 237, 392; clarify that points to consider are considered case by case, and not relevant to all cases  ID 126, 217, 309; problem formulation (PF) is one way to structure the RA (the phase in which the goals of the assessment are defined and the methods specified). PF approach commonly includes integrating available information, identification of hazards, defining assessment endpoints, conceptual models (plausible scenarios and risk hypotheses) and an analysis plan.  I suggest that we “introduce” PF as one approach/tool in RA. In RM the approach has been to have a separate step on context and scope. We could make a comparison chart/bullet points/provide text of different approaches to structure RA (e.g. GW Suter II 2007).  ID 137: Needs clarification. These points to consider relate to characterization of the LMO.  ID 191: Add explanatory text. Clarify text. | See page 14, first full paragraph.  PF is mentioned on pages 13 (paragraph 2) and 14 (paragraph 2 under rationale. Protection goals, assessment endpoints, plausible scenarios and risk hypotheses are mentioned e.g. on page 9 (Intro, paragraphs 2 and 3), page 12 (Establishing the context and scope, paragraph 1) and page 14 (paragraph 2 from bottom up).  Also, the RM clearly states that asking for additional information shall contribute to better evaluations (page 11, paragraph 2 from bottom up) |

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

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 22, 126, 484: How to link different steps (1-5)?  ID 126, 391: Link between sections I and II missing; how to use them consequently?  ID 197, 217, 220: How to formulate the problem, how to link it to assessment endpoints, how to link points to consider to steps 1-5.  ID 223, 309: Iterative seen as an ambiguity, outline and clearly define protection goals, assessment endpoints, measurement endpoints. Clarify what information is needed?  [ID 391: See stacked genes in part II]  ID 417: simplify and re-structure.  ID 428: clarify that assessment process needs to be carried out for each adverse effect.  ID 483: information needs and likelihood assessments of confined releases differ from commercial releases. | All RA frameworks are described as steps. The steps are iterative i.e. if needed the steps can be repeated to improve the assessment.  The single steps of the RM refer to consequent steps (see page 14, last paragraph; page 15 first paragraph; page 17, first and third paragraph, first paragraph under points to consider; page 18, first and third paragraph under rationale … etc.).  But it is clear that this has to be further clarified. Again I suggest a chart/bullet points/additional text. And possibly reference to other frameworks?  As discussed, concrete examples could be useful. Refer to/check the Training Manual. | See notes in relevancy of points to consider. |

Sub-category: Experience with LMO & conventional practices

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 22, 31, 300, 459, 481, 485: compare to common practices of agriculture; provide information of agricultural practices; use and benefit from experience with non-LMOs; take note of how pathogens are dealt with in conventional practices; take note of conventional breeding experience.  ID 401, 412, 414, 459, (485): Experience with LMOs; 20 years of experience; introduce familiarity concept to the RM; experience with LMO RA.  [ID 485: see stacked genes section] | I think that this is pointed out in the RM very clearly. We need to see how to clarify this further.  Preface?  This should be clear but we need to clarify this. The importance of background material and RA reports in the BCH must be referred to. Preface/intro? | See page 7, preface, third bullet point; page 10, last para (information); page 12, last bullet point; page 13 – choice of comparators; page 15, first para, point (g); page 18, para 3 under rationale etc.  See page 10, second bullet point under The relevance of information … |

Sub-category: Language

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 221, 224, 237, 365, 417, 419, 431, 441:  Complicated language (”true linguistics” ☺) – repetitious and too wordy.  ”Language” as the tone and way of providing information – comment stating: ”prescriptive tone”.  Clarification of terms (clear reference to the use of terms). | As of the tone of the document: Reference to/checking the principles of RA frameworks. It is based on theory and principles. And it is about risks, hazards, likelihood and consequences.  As of too complex, wordy, difficult language. We need to consider this. The fact that RA is complicated and a demanding task to perform cannot be changed.  Refer to Training Manual and background documents. |  |

Sub-category: Consistency with the Cartagena Protocol

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 161, 365, 366: New terms that are not introduced in the Protocol; The Guidance goes beyond the recommendations of the Protocol; The tone of the Guidance is different of that of the Protocol. | When introducing new terms refer to Annex III when possible. The aim of the RM is to provide additional and specific guidance to Annex III which is the over-arching frame. This inevitably introduces new, specific terms and concepts.  A RA has a certain tone – it assesses risks. But let’s look at this too. |  |

Sub-category: Actors and communication mechanisms

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 129, 169, 186, 454, 468:  articulate inter-linkage of RA, RM and risk communication; link to decision making; elaborate other related issues (RM, CB, PAP, SEC, L&R); introduce communication mechanisms; Clarify different roles of (key)players in the process; suggestion to consult NGOs. | Clarify those issues that are clearly linked to RA Guidance.  Possible reference to other related issues in the Preface?  We need to discuss this. |  |

Sub-category: Concrete examples

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 27, 128, 132, 213, 237, 269, 400, 414:  Real life case studies of LMO RAs; More specific values or criteria to be included; Concrete examples for training and CB; case examples to e.g. annexes; examples of risks to human health; cite experience worldwide. | Case studies can be referred to in background documents; look for examples in the Training manual; also experience in LMO RA is included in background documents and CBD RA reports/summaries.  Need to clarify this in the text. |  |

Sub-category: Human health

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 211, 269, 301, 302, 311, 319, 323, 364, 369:  Human health issues need to be considered. | We need to discuss this in the sub-group. |  |

Sub-category: Others

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| Identified challenges | Possible way forward | Notes (if needed) |
| **Roadmap:**  ID 121, 212, 370, 402, 431, 432, 441, 453: | ID 121: ok  ID 212: SEC has a separate assessment process  ID 370: Also separate processes  ID 402: No action needed  ID 431: Needs further clarification/discussions how to deal with this  ID 432: Non-target organisms: see/clarify if necessary points to consider in RA steps.  ID 441: taken care of by other, earlier comments  ID 453: see my comment on ID 431 |  |