**Marja Ruohonen-Lehto, Finland**

**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).  **ID 39 (Abiotic), ID 17 (LM trees), ID 49 (General comments)**  Worry on how the novice/less experienced risk assessors can use the guidance(s) | 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 my comments on the RM section. | 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.  -------------------------------------  **-----------------------------------------**  **ID 15 (LM mosquitoes):** Management strategies paragraph – applies to field trials and/or commercial unconfined releases?  ---------------------------------------  **ID 10, 33 (LM trees):** RA of field trials should be included; point out that not all information is available for field trials  **ID 23, 24:** Forest trees and fruit trees should be treated differently in the document  **ID 33:** Practice of confinement needs clarification  ---------------------------------------  **ID 15, 23, 30, 33, 45, 46, 56 (Monitoring):**  \*Case-specific vs general monitoring (make clear distinction in each chapter/comment; when applied and to what type of LMOs)  \*Field trials vs commercial releases  \*Practical guidance how to monitor  \*Relationship between RA outcome and monitoring  \*General monitoring and causal relationship with a possible risk difficult to achieve  \*Monitor changes, not LMOs – two different things  \*Problem formulation – to assist in developing a more focused monitoring plan  **ID 34, 47, 52, 65, 74, 91 (Monitoring):**  \*Remove general monitoring to a footnote  \*Monitor only if uncertainty in RA  \*No need for/questioning the purpose of general monitoring | 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.  -------------------------------------------  **General comments:**  **ID 33, 45:**  Very many useful comments that we need to consider when working on text changes suggestions later.  -----------------------------------------  **General about all part II documents:** We should maybe consider how to streamline the format of all four documents. And how to better highlight the specific issues/RM complementing issues.  -------------------------------------------  **ID 68 (Stacked):** I think we should (maybe again with a help of a flowchart/bullet points) highlight better what are the specific issues in the case of a stacked event.  ------------------------------------------  **ID 11 (Abiotic):** We need to clarify differences between field trials and commercial releases (scope and scale; data requirements etc.)  -------------------------------------------  **ID 15:** My understanding is that for both but has to be clarified.  ------------------------------------------  **LM trees:** About field trials, see my comments on RM.  We need to clarify confinement and how this is taken into account in RA&RM.  We need to think if a clearer separation of forest trees vs fruit trees is needed in the document.  ---------------------------------------  ID 15, 23, 30, 33, 45, 46, 56:  My summary of the comments would be:  We need to clarify the objectives/interpretation of the Protocol, especially Article 16 (para 2 and 4) which give strong support for general monitoring.  And again – the guidance is not binding or prescriptive.  Let’s clarify further specific vs general (it has been clarified – see page 54); different types of releases and monitoring (see pages 53, para objective and scope; page 54, full para 1 and 2).  Additional suggestions to be considered in later phase of redrafting (check and update when appropriate).  34, 47, 52, 65, 74, 91:  I think that there is clear mandate for general monitoring in the Protocol. Let’s try to clarify this. It’s relationship especially to observing effects on biodiversity (long-term, cumulative …).  ID 85: I do not quite understand what this comment asks for.  ID 33: Useful, specific comments when drafting text changes. | 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 15 (Stacked):**  Possible interactions between genes and traits not discussed.  Lack of scientific rational in some points to consider.  ------------------------------------------  ----------------------------------------- | 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.  -----------------------------------------  **ID 8, 28 (Stacked ):** We need to clarify that points to consider are considered case-by-case (see my comments in RM).  **ID 15:** see sections “Potential interactions …” on page 27 and “Combinatorial and cumulative effects”.  Lack of scientific rational – difficult to comment while no concrete examples given.  **ID 24:** As stated above (in scope), we need to highlight better what are the specific issues in the case of a stacked event. The criticism on points to consider (too many, lack of basis) – we need to check this with a critical reading.  ----------------------------------------  **ID 32 (Abiotic):** I cannot agree to this statement while I think that e.g. examples of possible hazards/risks are given. And the document is based on scientific literature.  **ID 39:** It is a little difficult to understand the suggestions of this comment; again, not all points to consider are relevant to all cases.  -----------------------------------------  **ID 12 (LM mosquitoes):** We need to clarify the meaning of unintended vs uncertainty (?). Again, what points to consider depends on the case.  ------------------------------------------  **ID 14, 22 (LM trees):** Very specific suggestions that need to be considered/looked at when we work on textual changes later on.  **ID 26:** Needs to be considered; difficult with no specific suggestions.  **ID 34:** If I understand correctly, we need to highlight/emphasize better the specific issues that we include in this LM trees document to complement the RM.  -----------------------------------------  **ID 10 (Monitoring):** Clarify that points to consider are considered case-by-case. | 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.  -----------------------------------------  **ID 47 (General comments):** Realistic pathways from hazard to harm missing  **ID 49 (General comments):** Clarify, improve the link between steps. How to move from step 1 to step 2 …  -----------------------------------------  **Monitoring:**  **ID 15**: relationship between RA and monitoring  **ID 58**: Link between RA, management and monitoring missing. | 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.  ------------------------------------------  **General comments:**  **ID 33:** see my comment under scope.  **ID 47:** Look into this. In connection with introducing problem formulation and other approaches to focus RA.  **ID 49:** Clarify. Possible examples should relate to this. Needs discussion within the group. Check the Training Manual.  **---------------------------------------**  **ID 15** **(Stacked):** see relevancy to points to consider.  **ID 16:** We need to clarify the relationship between part I and II. Clarify how to link information and points to consider particularly, to step I.  **ID 24:** See relevancy to points to consider.  ------------------------------------------  **ID 5, 6 (LM Mosquitoes):** Clarify how to link information and points to consider particularly, to step I. Reconsider the structure/form of the document (see my earlier comments).  ------------------------------------------  **ID 2, 9 (LM trees):** Again, the link between the RM and this specific document has to be clarified/improved.  **ID 8:** Clarify how to link information and points to consider particularly, to step I.  **ID 34:** See relevancy to points to consider.  -----------------------------------------  **ID 15:** clarify (there is text on this already in the Guidance: page 53, introduction and objective and scope …).  **ID 23**: separate specific vs general; see my comments in scope.  **ID 46, 73**: Problem formulation step; see my comment in scope.  **ID 48**: refer to RM – ok, to be done.  **ID 58**: Clarify!  **ID 62, 74:** General monitoring and causal link to possible adverse effect observed (see text on page 54, on general monitoring). Clarify further.  **ID 83:** Link monitoring to stacked events too – clarify! | 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]  ------------------------------------------  **ID 24, 49, 51 (Stacked):** Experience with LMOs; 20 years of experience should be pointed out more clearly.  -----------------------------------------  **ID 19, 28 (Abiotic):** clear reference to experience of non-LM plants with abiotic stress tolerance  **ID 33, 39:** Make reference to non-LM plants with abiotic stress tolerance; also to weed risk assessment models.  -----------------------------------------  **ID 14, 26, 28, 34 (Mosquitoes):** Past experience with non-LM mosquitoes; additional advice on comparators; include experience on non-LM mosquitoes management  **ID 29, 30, 33 (LM trees):**  Include more information on non-LM trees and commercial use, breeding and selection of trees; also on LM-tree RA.  **ID 70, 71, 81 (Monitoring):**  Experience with LM RA and use; highlight the limited experience with LM monitoring. | 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?  -----------------------------------------  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.  ---------------------------------------  **ID 32:** See my comment under points to consider.  **ID 33, 39:** Check this in the background material. Make reference in the text where appropriate.  -----------------------------------------  **ID 14, 26, 28, 34:** Check background material and clarify/check the corresponding parts in the document. Good suggestions as such.  **ID 29, 30, 33:** Check and clarify. Highlight the background documents.  See e.g. above. | 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).  **ID 11 (LM trees):** Language too technical. | 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.  **ID 11:** Check the use of terms section. Elsewhere similar comments. Should we use footnotes, clarifications directly in the text? |  |

**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.  ----------------------------------------  **ID 35 (Stacked):** The Guidance is too prescriptive compared to Annex III.  -------------------------------------------  **ID 52, 65, 91 (Monitoring):**  General monitoring is not mandated / included in 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.  ----------------------------------------  **ID 35:** I think that it is highlighted in many places that the Guidance is not binding, prescriptive.  ------------------------------------------  As stated above, let us clarify the interpretation of Article 16, para 2 and 4. |  |

**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.  ---------------------------------------  **ID 25, 94 (Monitoring):**  Key players mentioned only in this document; a more clear explanation on how existing networks could be used. | Clarify those issues that are clearly linked to RA Guidance.  Possible reference to other related issues in the Preface?  We need to discuss this.  -----------------------------------------  **ID 25, 94**: Let’s see if this can/should be streamlined/ further updated. |  |

**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.  --------------------------------------  **ID 1, 3, 56 (Stacked):** Concrete examples on RA; also on how to deal with points to consider (?)  --------------------------------------  **ID 2, 8, 17, 28, 35 (LM mosquitoes):**  Practical examples needed, incorporate information from countries with experience.  **ID 71, 74 (Monitoring):** Actual examples needed. | 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.  -----------------------------------------  **ID 29, 30, 33:** This is linked to other parts of the Guidance i.e. what type of examples should be included and how and where. As I have commented above, let’s check the Training manual for examples how to move from one step to another. RA examples could be referred to in the background documents, BCH.  -----------------------------------------  See above.  See above, see my comment on scope. |  |

**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.  **General comments:**  **ID 34:** Clarify the scope of human health in connection with the ERA.  **Monitoring:**  **ID 57**: include monitoring human health. | We need to discuss this in the sub-group.  See above.  See above. |  |

**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.  Clarify the purpose of the Guidance; benefits; reference materials  **LM trees:** ID 28, 31: Lifespan – monitoring.  Benefits.  **Monitoring:**  **ID 26, 27**: Cost issues, more specific guidance for developing countries.  **ID 63, 90:** Lack of background documents. | ID 121: ok  ID 212: SEC has a separate assessment process  ID 370: Also separate processes  ID 402: No action needed  ID 431: (Benefits) 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  **Stacked:**  ID 61: clarify the detection methods part.  **LM mosquitoes:**  ID 33, 39: Discuss the aspects of epidemiology in RA? Benefits?  This needs some consideration.  **LM trees:**  ID 13, 14, 17: Additional points to be considered. Clarify certain aspects in the text (more information). Check when drafting text changes.  See my earlier comments.  There is text on the importance on lifespan.  Benefits – how to deal with this has to be discussed. See benefits text in the RM.  **Monitoring:**  ID 26: include as background material.  Consider how to include these comments.  Check and improve when possible. |  |