Discussion items

These discussion items are listed here for use in the Internet Forum from 22 June through 6 July 2009.

They may not be part of the final text of the Roadmap.

Discussion item 1:

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.

1. Glossary is good idea if everybody agrees easily in terminology. If not, it could be a tiring process that would delay the outcome document. My suggestion is to try to add a simple definition/description along some of the terms that might be confusing.

Discussion item 2:

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?

1. Subjective quantification or qualification of risks assessment levels is something that should be avoid, since risks assessment is supposed to be based on scientific knowledge it should be as objective as possible. This would include a recognition of the uncertainly involved in the process but not on the unwanted subjectivity. If we mention that including scientifically based criteria to assign risks levels on a case by case basis, this could contribute to objectivity and at the same time to transparency.

Discussion item 3:

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?

1. Yes, examples of those are OECD documents.

Discussion item 4:

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.

How do you feel about taking on board this kind of statements that go beyond the risk assessment process?

1. The need for a dialogue with stakeholders could be seen as the risk communication stage that, together with the risk assessment and risks management stages, is part of the whole risk analysis process. I agree that the public awareness usually is not part of risk assessment, however communication between risks assessors and risks managers as well as communication with relevant stake holders is an important part of the whole process. Maybe is could be important to notice that in some countries the same group (or the same person) does all the analysis, but when there is more people involved there is a need of communication.

Discussion item 5:

‘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.

1. I think that all this discussion and examples are too centered on GM crops and agriculture, if we want to make the roadmap useful for all types of LMOs we need to be more general with the examples. Also if this roadmap will have a wide use and examples for GM crops are used we should also consider the different scales of environmental releases as well as the time a living modified organism is going to “stay” en in the receiving environment, because these are factors that affect the risks levels.

Discussion item 6

It has been pointed out that in Annex III it is stated that “to fulfill its objective, risk assessment entails, as appropriate, the following steps”. This can be interpreted that it will not be necessary in all cases to perform all the steps in order to fulfill the objective of risk assessment.

I am not certain that this is the case: all steps will be performed, but the level of detail of performing each step may be very different, depending on then experience that a risk assessor has with the particular LMO and the conditions of use. This may look like you are ‘skipping a step’, but as a matter of fact it means that the step has already been performed many times for the LMO in question, and the risk assessor is using his/her familiarity with the problem and its solution.

1. Yes, I agree that the way it is written make it seem like there are steps that are not needed or appropriate to be taken, the idea should be that there are cases when some steps are not as relevant because the different reasons (i.e. biologically contained), and this is a different interpretation could be avoided with a small clarification.

Discussion item 7 (embedded in footnote 10):

I would prefer to add this enumeration to the text, but as it is now, it is too extensive to do that. We may need further reflection on the necessary detail of the attributes mentioned, in order to make it more concise.

Do you have text proposals?

Discussion item 8

Do you agree that this paragraph may be deleted, as it appears to be redundant, given the detailed description in paragraph (d).

1. Yes, also because the examples are too focused on agro ecosystems.

Discussion item 9:

One important purpose of the Roadmap is, that it can serve as a structure on which we can ‘attach’ information documents that are available in the BIRC of the BCH, that provide information that is useful and important for specific steps in the risk assessment process. One information document may be useful in one particular step, but it may also be useful in different steps, and may therefore figure in different places in the document. At this moment only a few documents are shown in the text, and you are invited to add references to other documents, and if necessary indicate why you think they are relevant.

1. There are also cases when the relevant documents only apply to a single species as for example the biology documents. In these cases a single reference to the OECD biology documents where you could find the one for the organism needed, would be better than “attach” all the different biology documents for all the species or genera available.

Discussion item 10: There is discussion whether the points on a conclusion are clear and useful. Conclusions, and the way they are formulated, are directly linked to decision making, and are the responsibility of the Party. The terms used (‘highly likely, likely, unlikely, highly unlikely’ for likelihood, and: ‘major, intermediate, minor, marginal’ for consequence) are open to subjective interpretation.

It is argued that this step finishes with a number of assumptions (not conclusions) that are taken along to the next step, like step 1, that finishes in a similar way.

1. Including scientifically based criteria to assign risks levels on a case by case basis, could contribute to objectivity and at the same time to transparency. It would also help if we add a statement that clarifies that decision making in some countries could consider other things besides the risk assessment outcome.

Discussion item 11:

There is some difference of opinion on the rationale behind Step 3.

To some this step is a summary evaluation integrating step 1 and 2. However, I think that this integration is done in step 4, where the likelihood is taken into account.

To me the essential point in this step seems to be the comparison of the consequences with the ‘baseline’.

What is your opinion?

1. I agree with your interpretation, this is the step for comparison with “baseline” or common practices.

Discussion item 12:

The issue of risk / benefit may also in addition be taken on board in the chapeau. The purport of the text should be, like it is now, that potential benefits are not taken into account in risk assessment under the Protocol.

Should there be a paragraph in the chapeau, and do you agree in general with the way I suggest the risk / benefit question should be approached?

1. I think that it is important to include the risk / benefit issue, even if the potential benefits are not taken into account explicitly on risk assessment, results from risk assessment could include identifying positive effects to biodiversity or to the environment from the Use of a LMO in comparison with previous practices. In part it is the fact that that there are potential beneficial effects of LMOs, that make us consider their use.

Discussion item 13:

The issue of co-existence concerns the potential economic loss and the impact of the admixture of GM and non-GM crops; one item in this discussion concerns the appropriate management measures to minimize admixture.

The co-existence discussion as such does not have a direct relation to environmental risk assessment, but management strategies adopted for co-existence issues may be also be relevant also for reduction of environmental impacts of LMOs. In my opinion that is what is meant in this paragraph.

Examples of such strategies would include: additive measures to prevent pollen flow to neighboring fields that may have synergistic effect: scheduling different flowering times, use of crop varieties with reduced pollen production, pollen traps, hedgerows, combined with isolation distances between fields with the same crops.