Dear Helmut,

Thanks very much for volunteering as moderator for this discussion and thanks very much for posting these very clear questions that will focus our discussion for a start.

As participants may remember, I am working in the Netherlands GMO office, where we are, among other things, dealing with environmental risk assessments of LMOs. I have been involved in the discussions that we have had during the past years in the AHTEGs and in the Online Forums.

In the NL we have been giving some thoughts to the questions that you pose, and I would like to try and share these thoughts with you.

1. Who will be the target audience of this package:
o Trainers of RA?
o People learning how to carry out a RA?
o Risk assessors/ Practitioners?

I think the package is aimed at anybody involved in environmental risk assessment of LMOs in the wide context of the CPB (I mean, in any legislation, in particular the legislation of Parties of the CPB). Anybody: be it as trainers, novice risk assessors, or seasoned risk assessors with a lot of experience.

Everybody will read the guidance in the package from a different point of view, though. Experienced risk assessors will look at the guidance in an opinionated way, and they may agree with various issues, or have a (slightly) different view. I think that the present exercise should get those views on the table, for the purpose of mutual learning from each others experience. The basic methodology of the risk assessment is given in the CPB, in particular in Annex III, and that should be the point of departure for all discussions. Trainers will be, ideally, as involved in and knowledgeable about actual risk assessments that they can be involved in these discussions in the same way.

We should keep in mind, however, that such discussions will tend to be at a different level of complexity than what is most helpful for people learning how to do a risk assessment. They should first master the basics, before they get involved in the more complicated discussions.

So, although the guidance will be useful to people at all levels of experience, we should keep in mind that it is the movice risk assessor who should be able to understand the flow of thoughts and can use the guidance in the practice risk assessments.

In the discussion of the package, we should keep that in mind.

2. How can the Guidance and Manual be integrated?
o Should the Manual or the Guidance be used as the basis for this exercise?
o Should the package also provide a step by step guide for risk assessors to use when conducting RA?
o Should the package also be aimed for usage as a reference and background text for RA?

I think the package is very much already all of these, although maybe not as effective as it could be.

The Manual and the Guidance are basically talking about the same process, although the manual is meant to be much more basic and hands-on, while the Guidance tries to go into the details of the risk assessment process, including references to many background documents where the reader may find more information. Hopefully the Guidance provides copntext for all this information, taht is not always in agreement, but it is essential that a risk assessor learns how to deal with conflicting information, too.

Both the Manual as the Guidance (see for instance the flow chart) aim to provide basic information and a step-by-step approach, at different levels. Ideally, understanding the Manual is a prerequisite for understanding the discussion in the Guidance. As it is now, one cannot go without the other.

In the end, the package as whole should function as a starter (Manual) and an advanced course (Guidance) in risk assessment. Therefore the package should aim to be all of the items listed under 2.

3. With respect to the type of language used: which document will have priority as the reference to standardise the language between the two documents?

Given the difference between the two documents: basic and advanced, I am not sure that the language of the documents should be fully harmonised, as explained in the following.

Obviously, the same terms should be used with the same meaning.

Concepts explained in the Manual should coincide with the same concepts used in the Guidance. It may be, though, that a concept is explained basically and in a straightforward way in the Manual, while in the Guidance it may become clear that things can be more complicated – but this is inherent to any science course and scientific discussion, isn’t it?

Therefore, I don’t think there has to be a priority for one or the other document – there is a need for consistency between the two documents.

4. Do we integrate all of the guidance or just the roadmap section?

This, as many things in risk assessment, should, or could best, be done in a step-by-step manner.

The Roadmap was meant to be a general document, applicable to all types of organisms.

The other documents in the Guidance go much more into detail and explain how the Guidance applies to specific cases, or one aims to show how a specific iessue in the Guidance, i.e., monitoring, is understood in (various) current practice(s).

Therefore, there should be some order in the complexity of the language and the explanations, the Manual being in line with a first tutorial, the Roadmap being an advance course and the other guidance documents being an exercise for those that have mastered the Manual and the Roadmap.

I think that is the way that we have also understood it and taken care of it in the AHTEG – at least for the Roadmap and the other guidance documents.

This implies that all documents should be in agreement as to the basics of risk assessment, terminology and concepts, and in order not to be tedious or confusing, there should be minimum redundancy, or only such redundancy as is necessary.

Asd a practical proposal, I would suggest that we start with integrating the Manual and the Roadmap, and, once way have learned from that exercise, we start integrating the Roadmap and the other documents. Let’s also remember that the AHTEG has been aware already about the consistency between the Roadmap and the other documents, and I guess that the authors of the Manual have been similarly aware of the need for consistency. We don’t start from scratch, therefore.

5. Do we include a section on the decision making process in this new package?

Annex III states: “2. Risk assessment is, *inter alia*, used by competent authorities to make

informed decisions regarding living modified organisms.”

So, the conclusions and recommendations of the risk assessment will be used in decision making, but

1. This is not the only information that may be used, see for instance Article 26 on socio-economic considerations.
2. And, Annex III is not prescriptive how the informastion should be used.

In agreement with this, Annex III is talking about risk management (which is something that is *decided* upon in the decision making process) is treated in Annex III and in the Guidance. In the discussions in the AHTEG I think we have agreed that the issue of risk management is treated is a as a *link,* a *window*, to discussions on decision making.

Under the mandate of BS-VI/12 we are supposed to be working on risk assessment and risk management. From what I say above it would follow that we could provide some general views on *that* the risk assessment should aim to be useful in decision making, and we could talk about prerequisites for being useful. One important prerequisite is that risk assessment should be *useful*, but should not be *prescriptive* for decision making, i.e., decisions are not made in the risk assessment. But, then I am already starting to write my section on desicion making – that’s not what I should be doing here.

6. What (practical) experiences have people had with either/ both documents?
o Was one document easier to use/ understand than the other?
o What aspects of one or the other do you think will enhance a user’s understanding of RA?
These questions seem to be on a different topic: this is much more what we should be asking of the people involved in the testing.

These are very general questions, and yes or no answers will give us very little insight in the situation.

We should encourage people at all levels of experience to participate in the testing – but all should be aware of what the testing is meant for.

The Manual is pitched at the novice audience, and as such easier to understand, whereas the Guidance is right in the middle of an advanced level of disussions about risk assessment, without always remembering the audience (mind you, I have been responsible for that, too).

I think the step-by-step approach of further developing the package, described above, will very much enhance the usefulness for the understanding of risk assessment.

As a final remark, all of this is very much the opinion of somebody that has been involved already in all discussions. I would very much like to hear from others, especially people that struggle with the documents, so I can become aware of where I should be doing some more struggeling, too.