I appreciate this opportunity to contribute to this discussion of the evolving work of the AHTEG. These comments are addressed to the latest version of the Roadmap and to some points raised by colleagues in previous postings.

My understanding is that the Roadmap is intended to be somewhat more detailed than Annex III, elaborating its terms, particularly in order to provide guidance to countries and personnel who do not have a history of doing frequent assessments or evaluating them (see lines 35-37). Unlike a number of other international regimes, the Protocol does not make the somewhat artificial distinction between risk assessment and risk management (and also risk communication). This is wise because there is continuous interaction among the three sorts of activities.

In particular, as I think I noted in my contribution during the comment period on the previous version of the document, no matter how many times certain governments intone the mantra of “scientific risk assessment,” risk assessment itself is not wholly free of *values and subjective elements*. To understand this is not to ignore that a great deal of scientific information is necessary for an adequate assessment and should play a clear and major role in the process. But any investigation of the circumstances as well as the content of the approvals of LMOs which have already occurred will show that non-scientific factors (power of corporate sponsors, trade considerations, and the like) have been heavily weighted in the process. Indeed, *many governments do not actually do assessments* but merely accept those proffered by the sponsoring corporations. In addition to violating democratic principles (that public authorities should retain oversight regarding public health) such shortcuts conflict with mandates of the Protocol (that governments have an obligation to protect biodiversity).

The result is that *a great many prior “assessments” are really scientifically invalid*, since not enough resources have been put into actually investigating risks (I have called this “don’t look/don’t find”). A recent example is the paper entitled “A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health” by de Vendômois JS, Roullier F, Cellier D, Séralini GE. Int J Biol Sci 2009; 5:706-726. <http://www.biolsci.org/v05p0706.htm>. The accompanying press release notes: “In what is being described as the first ever and most comprehensive study of three major GMOs about assessing the effects on mammalian health, researchers from CRIIGEN and Universities of Caen and Rouen have

highlighted a number of new sex and often dose dependent side effects linked with their consumption. Their study of the 90-day feeding trials data of insecticide producing Mon 810, Mon 863 and Roundup herbicide absorbing NK 603 varieties of GM maize clearly underlines adverse impacts on kidneys and liver, the dietary detoxifying organs, as well as different levels of damages to heart, adrenal glands, spleen and haematopoietic system. Ironically, the confidential raw data of Monsanto about feeding trials on rats that these researchers have analyzed allowed the international authorization of these three commercialized GMOs in different parts of the world.” The main sponsoring research Institute, CRIIGEN, “denounces in particular the past opinions of EFSA, AFSSA and CGB, committees of European and French Food Safety Authorities, and others who spoke on the lack of risks on the tests which were conducted just for 90 days on rats to assess the safety of these three GM varieties of maize. While criticizing their failure to examine the detailed statistics, CRIIGEN also emphasizes the conflict of interest and incompetence of these committees to counter expertise this publication as they have already voted positively on the same tests ignoring the side effects.” **The systemic problems of most existing assessments may be listed as:**

* **Failure to investigate all plausible risk scenarios;**
* **Reliance on company data which may be inadequate, based on faulty research design, or even partial due to suppression;**
* **Conflicts of interests existing between assessors and LMO promoters.**

**How can the Roadmap overcome these limitations?** This is the major question AHTEG must address. And, unfortunately, I do not think that it meets the challenge.

In addition, here are some specific observations:

In line 41, the adjective in the phrase “living guidance document” might be replaced by “evolving” in order to be more clear.

In the “Overarching issues” section, the problem of “uncertainty’ is raised (and it is the subject of a number of comments which have been posted). The reference on l. 76 to “uncertainty analysis” is vague, since the user of the Roadmap is likely not to know what that means (indeed, I am not sure I am clear on what is being referred to here). One purpose of a risk assessment is to *identify uncertainties.* Sometimes the assessors also need to understand that , in the words of Donald Rumsfeld (whom I so rarely agree with), “we may not know what we don’t know.” We should be frank and note that there is a class of risks (possible dangers) that risk assessment may not be able to uncover.

In line 85, we should note that the Precautionary Principle is also mandated in Arts 11 and 15 which give rise to the need to do the sort of risk assessment we are discussing. The Principle is thus not merely a general suggestion to the assessors but one of the fundamental bases of the assessment.

The sentence in lines 88-89, suggesting that *previous experience with the LMO* may be relevant is a bit “dangerous” in suggesting to a novice more than what can scientifically be sustained. Although this argument has been put forward by some governments, it has been rejected as incomplete, since only if the receiving environments are identical will the prior assessment be really useful. I suggest that this limitation on the use of prior work be specifically stated. The comment is the latter part of that paragraph which might be meant to cover this point seems to be very vague; what is an “ecological situation”?

Lines 95-96 assume that only one scenario will be followed in the real world. In fact, the comparison suggested here is meaningless if the non-modified recipient has never been grown in that environment (not a rare scenario). As an example, if a drought-tolerant rice were to be developed, it needs to be assessed in terms of an environment where, presumably, rice has not been previously grown because of inadequate water; here there would be no “context of the risks posed by the non-modified recipient.”

Someplace in this section there should be language that the assessment must be compared to the *claimed benefits* (which also should be completely assessed, rather than relying merely on the claims of promoters). All of us take risks every day, because we believe they are worth running for the benefits which ensue from our actions. A similar reality faces a nation state.

And there is no mention in the document of the *distribution of risks and benefits* as critically important aspects of an assessment. Population groups do not equally bear the risks of LMOs nor equally reap the benefits. So the equity considerations of one running a risk in order to profit another must be indicated as a relevant aspect of the assessment.

In the section 3, “Context and scoping,” the 3rd bullet point (lines 114-118) is unclear and could be rewritten to make it easier to understand. For example, what is the “applicable guidance” referred to in the last sentence? The 4th bullet point (lines 119-121) could have the word “for’ inserted in 2 places after the “e.g.”: “for a confined environmental release” and “for an unconfined . . .”. BTW, the first of these two phrases is internally contradictory—a “confined release” is one that is NOT into the environment, in general understanding (true, I have seen experimental test plots which are only separated from the rest of the world by a wire fence which is no barrier to insects, rodents, or birds; I would call this an “unconfined environmental release,” despite the fence).

Lines 137-139, the “rationale” in step 1 of the risk assessment indicates a fundamental weakness in the approach being discussed. Comparison with another organism is merely an *analogy*; analogies contain differences as well as similarities (otherwise they would be identities). At the very beginning it is the *differences* which must be stressed in the assessment if one is to be looking for unexpected or unintended or unforeseen consequences.

In line 140, I have already noted above why the term “science-based scenarios” is misleading. Moreover, in the assessment literature, “scenario” refers to speculation about the future (eg, “what if there is an economic recession?”) and therefore is inherently non-scientific.

The “Points to Consider” (lines 146-151) are *reductionistic*; these should be stated as being only *a part* of the characterization; by now it should be evident that an LMO is not a LEGO-constructed entity where the functioning is the addition of the functions of the parts. The fluidity of the genome, the unknown impacts on proteins moderating the functioning of the genome, etc. mean that scientific testing must be done to characterize the modified organism; mental manipulations of exisiting data will give limited, if any, real characterization of it. So, for example, the “levels of expression of newly introduced genes” referred to in lines 218-219 is critically important and requires observation and testing.

Footnote 7, in its text and its function, does not seem to make sense. Whether a release is “commercial” depends in part on the intention of the owner; how this mental state might affect the structure of the assessment itself is not obvious.

Lines 164-167 need to include language acknowledging that activities of the human species in the receiving environment must be included (e.g., is farming occurring?). In most environments, the reality is that very little is known about the interactions among the organisms (e.g., the large number of soil micro-organisms, many of which have never been named or studied).

In lines 214-215, the phrase in the parenthesis is unclear to me.

The “evaluation of the consequences” section is conceptually limited. The relevant comparisons must be not only with other forms of the organism, as noted, but with *alternative ways of achieving the same final result* (e.g., the use of agro-ecological farming practices instead of genetic engineering for example). This is a bedrock aspect of assessment operations, and definitely should be mentioned in this section of the Roadmap. (BTW, this whole section is often considered risk management, but—as I noted above—I think it is highly appropriate to include it since the categorization is artificial in many regards.) In lines 238-239, the Roadmap doesn’t indicate *how* such impacts are to be ascertained /measured/ compared; to people unfamiliar with assessment procedures, this question will loom large. The same is true of the language in lines 277-279; *the acceptability of a risk depends, in the real world, of the risks presented by alternative ways of achieving the same result*. This definitely should be stated. The limitation of the comparison to the LMO and its unmodified parent is not consistent either with good assessment practice nor realistic.

The points contained in lines 251-258 are very important and are well-presented.

My comments in regard to colleagues’ postings already made:

1. I agree with Yoshikura-san that “new varieties of non-modified recipients have not been systematically subjected to extensive environmental assessment,” and that systematic evaluation of traditional varieties [and other species in the receiving environment]often have not been performed either, as I discuss above. The Roadmap needs to inform novices that often the needed information is not available, mainly because neither governments nor industry have funded the necessary research (or released the data if it is claimed to be “confidential business information”). Also, what is an “adverse” effect; an effect may be adverse to certain segments of society and simultaneously beneficial to others (climate change presents many obvious examples). So, in addition to a need to define “adverse,” as I have mentioned above, the distributional (equity) aspects of impacts must be included in the assessment.
2. The references to “Adventitious Presence” (Drs. Wei, Nickson): first of all, this is merely a euphemism for *contamination*, often covering up shoddy business practices which fail to maintain adequate segregation of the varieties. Secondly, since the Protocol deals with transboundary movements, if such a movement (say a shipment) is contaminated, of course this needs to be assessed as part of the overall protection of biodiversity (which is the purpose of our work). The Codex Commission Task force on Foods from Modern biotechnology, which Prof. Yoshikura admirably chaired over a period of 7 or 8 years produced a Guideline specifically directed to this problem. It should be among the documents referenced by the Roadmap.
3. Dr. Yogo’s posting raises the reality that assessments must be done for all of the relevant *risk scenarios*  which reflect differing future realities. In other words, any assessment needs to actually be a multiple set of evaluations, each resting on a different set of assumptions about the future (eg, population estimates, climate conditions, etc).
4. I do not agree with the emphasis in Dr. Roberts’ contribution (see also Dr Gough’s first posting). Under the Protocol we deal with transboundary movements, whether intended or inadvertent, small scale or large (small scale movement can have a large impact), etc. In a case-by-case analysis, “existing guidance and information” may in fact be non-existent, as I noted above. Similarly, I disagree with Dr. Hokanson—the distinction is not between “full releases” and field trials; the Roapmap must apply to all transboundary movements of whatever type.
5. I am in substantial disagreement with Dr. Watanabe that existing practices and experiences provide much of a necessary data base, etc. As I have indicated at several places above, existing practices are generally not, in fact, adequate (and I refer to a recently published paper to illustrate this problem). They do not investigate relevant scenarios or assume lack of impacts, and they do not account for the variability in the receiving environments. The Protocol respects the sovereign prerogative of each country to determine the adequacy and relevancy of existing information, and this is particularly embedded in the precautionary approach referred to several times.
6. Uncertainty. I have presented a sketch of my views above. I certainly cannot share the optimism of Dr Pillai, but I appreciate his raising the subject. On what experience can we base optimism? And I disagree with Dr. Sarrazin that ignorance is not a source of uncertainty and that it will not be overcome by risk management measures—one of the objectives of doing an assessment is to better understand what you do not know in order to decide whether to sponsor research in that area. This is specifically recognized by international agreements (see, for example, the SPS agreement of the World Trade Organization, article 5(7)). My experience is in accord with that reported by Dr. Beech—teaching about uncertainty and what to do about it is a difficult subject. But it won’t go away in the real world by ignoring it. Dr gough’s second posting is useful in suggesting how the Roadmap might approach this topic.
7. “Context” is not just a risk management issue set by national governments, a social/political concept. The context of a transboundary movement can be environmental, developmental, social, climatic, etc.
8. Dr. Beech helpfully raises the “consideration of other alternatives.” This is a fundamental aspect to assessment practice. For example, an alternative to an LMO might be a non-LMO approach to achieving the same objective—e.g., through MAS or selective interbreeding. Thus, the acceptability of a course of action is always to be understood in terms of the alternatives it is being compared to. I.e., **all risk assessment is comparative**.

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12 December 2009