Of course I appreciate the good work which has gone into the creation of this draft. The comments below express concerns/suggestions I wish to have the ATHEG consider. Many are responsive to comments colleagues have already posted.

**General Considerations**

\*Footnote 4—this is only one interpretation of the scope of the Protocol, and I think (having participated in all the negotiations) far too narrow. Direct adverse effects on human health from an LMO are encompassed in the document’s provisions. Certainly, humanity residing in a local ecosystem are part of its biodiversity! Also, Article 26 on socioeconomic considerations definitely encompasses human health.

* In the bullet points: the last one (and **Discussion Item 4**)—Public involvement and dialogue is not a “one-way street” in which the officials put out information to concerned members of the public. The public needs opportunities to supply input and the procedures should embody a commitment for the officials to seriously consider and respond to such imput. In addition to being in accord with democratic principles, such mechanisms assure that many the existence and extent of impacts which may be known only to the local population (e.g., changes in crop plants, outbreak of a disease cluster, etc) actually get considered. The identification and evaluation of the extent of any damages definitely requires imput by affected people.
* Next to last bullet point, about uncertainity. This should definitely mention the **Precautionary Approach** (or Principle) which is explicitly recited twice in the Protocol’s text. This should guide the work of the assessment.

**Step 1**

**(d)** This is perhaps the central and most important principle for a Risk Assessment Roadmap—a rejection of the reductionist approach which is, unfortunately, too often followed currently if any assessment is done at all. There has been far too much discussion of “substantial equivalence” or the “comparator” without realizing that the basis of the assessment is because there may be important **differences**. Logical reasoning from knowledge about the component elements in not an adequate substitute for actual test data from the growing and evaluation of the engineered organism (eg, animal studies may be appropriate).

**(e)** Footnote 11 needs to explicitly cover human health considerations—eg, do the people in the receiving environment have impaired immune systems due to poverty and poor nutrition. We are not just concerned about the plants and non-human animals in this environment.

**Step 2**

The “possible displacement of species” is not the only impact path of interest. What if the LMO increases other species (like pest organisms, etc.?) This section needs to be cast in wider terms.

**(d)** What is “incidental exposure”? The dictionary suggests it means “unplanned” or “secondary”. The word should be eliminated and a sentence added that “Exposure may occur directly or indirectly, intentionally or unintentionally, etc but all pathways may produce consequences nonetheless and need to be investigated.” The wording in Step 3 is inadequate, since the concepts embodied respectively in steps 2 and 3 have been separated by the drafters of this text.

**Step 3, Points to Consider, Rationale**

In the real world, effects may not only exist but they will have particular **patterns of distribution.** Thus certain sub-populations are more heavily impacted than others, and this result shapes the social and political concerns about these impacts, their assessment, the estimation of damages, etc. For example, are the affected persons infants, of a particular gender or ethnicity (due to ethnic-linked genomic factors), of a particular social/economic class, those in poor health with compromised immune systems, and the like. The existing text includes nothing about this reality, projecting a false picture that all are equally affected.

Without this level of analysis, it is impossible to seriously undertake the “severity of the consequences” called for under the Rationale.

**Related Issues**

It should be noted someplace that consequences can be both positive and negative—benefits and damages. Although the aggregation of such information about the impacts is a process for Risk Management, there ought to be a sentence recognizing the relationship of the work of the assessors (and how it is presented) to the decision-making process which the Managers must undertake.

ATHEG should look at he Guidelines published by the Codex Alementarius for assessing GE foods as providing some model elements, suitably expanded to cover all LMOs and to take into account environmental and social factors. These were accepted by 168 countries, without reservations, at the Codex Commission. See “Guidelines” (below “Standards” in the table) #44-46, 68 (as amended) at

<http://www.codexalimentarius.net/web/standard_list.do?lang=en>

We need to give special attention to assessments of crops engineered with stacked genes and “pharmacrops” that produce drugs and industrial chemicals. They are not being adequately assessed currently although there is research in the literature that reasonably suggests they may pose special risks to human health, wildlife, and the environment. In addition, there are real social and economic risks presented by such GE crops to the increasingly important organic sector and to and conventional family farmers

Despite repeated assurances that pharmaceutical and industrial GE crops would be subjected to increased monitoring, reporting, oversight, and management, the USA, for example, has rejected scientifically sound approaches that would have banned outdoor cultivation of GE pharmaceutical-and chemical-producing crops. But such bans are the only way to ensure that untested drugs and industrial chemicals do not end up in our food and environment. Furthermore, food crops should *never* be the host species for production of drugs or industrial chemicals. These elements should be indicated in the roadmap.

**Discussion Items**

**Item (2)** Despite the well-worn mantra to the contrary, risk assessments contain always subjective elements. This is not limited to “some cases.” As I put it at a conference at Harvard (Sept. 2000) chaired by the first Secretary of the CBD, Calestous Juma:

*“It is necessary to establish speedy but reliable risk assessment to implement the Precautionary Principle and at the same time take into account consideration of the socio-economic consequences of modern biotechnology . . . .” German Delegate, CBD COP V, Nairobi, June, 2000*

*\*\*\**

*The modern era of risk assessment can be traced back to Chauncey Starr’s 1969 article in Science, but it was not perhaps until 1976, with the publication of William Lowrence’s Of Acceptable Risk, that the subjective elements of the process began to get a forthright treatment. While Lowrence tried to maintain that “risk” was scientifically objective, his discussion of “safety”—as socially acceptable risk—acknowledged the political nature of the overall context of the evaluation. But it is obvious that even a rigid determination of a clear risk—say of injury from skydiving or of winning the lottery jackpot—cannot, in itself, tell us why only some people will accept the risk and jump from an airplane or buy a ticket. Nor can it tell us the fractional portion of the population willing to undergo such an action.*

*However, we must recognize that risk itself (defined as the probability of a hazard) has subjective elements. And when we affirm this characteristic of risk, the Precautionary Principle can be seen as an inherent aspect of risk assessment, not something alien.*

*Thus, the proposition is the subjective nature of risk itself, and perforce of its assessment.*

*Subjective aspects include:*

* *The choice of phenomena to research [eg, note that only a small amount of public money is devoted to looking at the environmental risks of GMOs];*
* *The definition of what is a “hazard” (ie, undesirable) [eg, is the displacement of peasant farmers by agribusiness part of the “modernization processes” or an instance of cultural annihilation?];*
* *How to actually measure a hazard, especially if it combines different aspects not subject to a single metric [eg, the death of a bee deprives us of both honey and pollination];*
* *How to account for incomplete knowledge, uncertainty, etc. in the nature/consequences of the hazard as well as its probability;*
* *Who has the burden of proof of developing the necessary data—the proponent of the technology, the regulatory agency, or consumer/environmental citizen organizations?;*
* *How to account for the social distribution of risk, since hazards impact different sectors/classes in society differently [Monsanto shares may increase in value while family farmers are driven off the land];*
* *How to discount future events in light of present actions [will an endangered species be driven to extinction before other recovery efforts might be mounted];*
* *How to monitor a risk, and how much surveillance is “worth” in both monetary and non-monetary terms [eg, the absence of a law requiring the labeling of GE food is also a decision that monitoring the long-term cumulative effects of eating such products is not very important to the decision-makers]; and*
* *How to balance risks against “benefits“, since benefits involve all the above factors as well*

*Despite this reality, the current dominant paradigm still claims that risk assessment is a matter for “sound science” rather than politics or social values; these other messy factors must wait until after risk is assessed when they can come into play as part of “risk management.” This bifurcation is historically traceable to William Ruckelshaus’ second tenure as head of the US EPA.*

*Ruckelshaus was brought back into that role as part of the larger Reaganite agenda to role back the “democratic paradigm” of public policy and install a “technocratic” one (in the terminology of David Dickson, a report/editor with Science, Nature, New Scientist). This manoeuvre helped that Administration (and subsequent ones) deflect popular environmental and consumer concerns while calling for endless technical studies, thus delaying substantially any constraints on industry practices (and simultaneously enabling citizen groups to be discredited as anti-rational and selfish, and alienating liberal scientists from those movements to which they otherwise might have given pro bono advice.) “Sound science” thus became a mantra to obscure the exercise of partisan political power.*

**Item (4)** –see above

**Item (6)** –so it should be stated and referenced

**Item (8)** what paragraph is being referred to? Hard to give an opinion, since the paragraph in question is not identified

**Item(9)** See reference to Codex, above.

**Item (10)** on “subjective interpretation”—but the “evaluation” of impacts is often subjective (note the root word is “value”!) There is no objective algorithm telling us how to weigh the reduction in honeybees, for example.

**Item (11).** This is not a function of scientific work alone. See discussion above, for example about affected populations.

**Item (12)** Yes, there should be such a paragraph

**Item (13)** I agree with the recent comment that co-existence (or “non-coexistence”) is always an assessment question, stemming from impacts on the receiving environment.

Philip L. Bereano

Professor Emeritus,

University of Washington &

Vice President

Washington Biotechnology Action Council