Dear colleagues—

Although travelling, I wanted to join in this robust discussion we are having on risk assessment under the Protocol. I hope my comments are not too disjointed as a result, however.

Some comments submitted to these discussions could be useful to more than one thread; in addition, a simultaneous discussion is going on regarding “socio-economic considerations” under Art 36 which I am have been involved in. I hope participants have the time to try to access and integrate all this material (I hope the staff of the Secretariat will help us to do so).

1. Very little research has been done on the impacts of LMOs and published in the peer-reviewed open literature. And most of what exists has been sponsored by industry and thus of suspect validity due to normal conflict-of-interest cautions. The most survey of this work is: ”A literature review on the safety assessment of genetically modified plants,” by José L. Domingo and Jordi Giné Bordonaba, Environment International 37 (2011) 734–742. Some relevant conclusions:

"In spite of the notable increase in the number of citations, those concerning specifically to studies focused on demonstrating the health safety of GM foods remain very limited."

On the greater number of refereed health studies from industry, despite the possible conflict of interest: "Anyhow, this represents a notable advance in comparison with the lack of studies published in recent years in scientific journals by those companies (Domingo, 2007). The scientific community
may finally be able to critically evaluate and discuss all that information, which was not possible until now. Scientists know quite well how different may be the information published in reputed international journals, which has been submitted to peer-review processes, from those general comments/reports not submitted to this selective procedure."

Overall: "In the period here reviewed, October 2006–August 2010, a few reviews on health risks of GM foods/plants have been also published (Dona and Arvanitoyannis, 2009; Magaña-Gómez and de la Barca, 2009; Key et al., 2008). In general terms, all these authors agree in remarking that more scientific efforts are clearly necessary in order to build confidence in the evaluation and acceptance of GM foods/plant by both the scientific community and the general public. Especially critical is the recent review by Dona and Arvanitoyannis (2009), who remarked that results of most studies with GM foods would indicate that they may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects, and might alter the hematological, biochemical, and immunologic parameters. These authors also concluded that the use of recombinant GH or its expression in animals should be re-examined since it has been shown that it increases IGF-1 which, in turn, may promote cancer. A harsh response to that review was recently published in the same journal (Rickard, 2010). This is indeed only an example on the controversial debate on GMOs, which remains completely open at all levels."

Countries should make an effort to fund such research and should also require applicant corporations to conduct it (in open and transparent fashion) in order to build up solid information for decision-making. In this regard, I second the caution offered by Dr Ossama—many of the studies which have been done are NOT based on an examination of the “holistic system” of the actual LMO in the actual receiving environment; instead they often are “managed systems” where, for example, instead of looking at a real Bt plant, only the active chemical produced by the Bt is investigated, thus rendering extrapolations shaky.

Andrade cautions against “speculative hypotheses” and urges us to rely on actual references. In this regard I would make two comments—more research on LMO impacts needs to be funded and “thinking outside the box” or speculation has been recognized since the earliest days of assessment studies in the 1970s as a fruitful way to anticipate unexpected situations and to reduce uncertainty (coupled, of course, with the admonitions of the Precautionary Principle, that in the face of great uncertainty the wisest course is to not act).

1. In the face of commercial pressures to utilize LMOs, we should encourage a posture of modesty (this is also embodied in the Precautionary Principle, included twice in the Protocol). Recent studies have concluded that LMOs are NOT needed to “end hunger” (one of the most frequent arguments for pressing ahead without adequate assessment). I refer to the International Assessment of Agricultural Knowledge, Science and Technology for Development , IIAASTD (see <http://www.agassessment.org> ) and the recent report by the UN’s Rapporteur on Hunger, Prof Oliver de Schutter (<http://www.srfood.org/index.php/en/component/content/article/1-latest-news/1174-report-agroecology-and-the-right-to-food> ). Despite the industry’s repeating of the mantra of the “risks of doing nothing” (which should, of course, be specifically assessed in each case), the general opinion of those knowledgeable and without any institutional bias is that doing nothing in regard to introducing LMOs is often the preferred course of action.
2. A risk assessment performed under the Protocol must include all impacts reasonably flowing from the subject action (i.e, the importation, transit, use etc of LMOs). Impacts (or consequences) are indirect as well as direct; these so called “second and higher order effects” may well be what is driving the introduction of the LMO (eg, profits to the manufacturing corporation or patent-holder) and/ or stimulating opposition. It is therefore imperative that the assessors trace out these “impact chains” to capture all impacts that are important to the decision to be made, not just those which are merely proximate. In this, I agree with Mme. Flandroy’s posting.
3. Risk assessment must also take into account the distribution of the costs/risks/benefits. One cannot simply add up the positives and negatives in an algebraic sense. After all, the whole push to develop and deploy LMOs is based on benefits to a narrow class of actors (the industry) even if they are attempted to be justified on the basis of claimed benefits to wider slices of society. The costs and risks usually fall on other social segments. This reality means that all risk assessments—no matter how dispassionate and professionally conducted—exist in a political context.
4. As regards to the separation between risk assessment and risk management, I agree with Gough that this is somewhat artificial even though it is a frequent mantra. The reality in practice is that there is overlap and substantial iteration between the policy/political function of the managers and the more technical work of the assessors. The Codex materials referenced by Dr Yoshikura are clear on this interaction.
5. The discussions about “substantial equivalence” or “conventional counterpart” are really about ANALOGY. Analogies involve difference as well as similarity (otherwise the two items would be identical, not analogous), and the problem with reliance upon substantial equivalence is that it ignores such differences which may be of critical importance. In the literature review cited above, it is noted that

"Probably, one of the most important problems related with the lack of studies (at least not published in the scientific literature) on the safety assessment of GM foods/plants was the use of the “substantial equivalence” concept. This notion is based on the principle: “if a new food is found to be substantially equivalent in composition and nutritional characteristics to an existing food, it can be regarded as being as safe as the conventional food” (SOT, 2003).
Although application of the concept is not a safety assessment per se, it enables the identification of potential differences between the existing food and the new product, which should then be further investigated with respect to their toxicological impact. Why must it be thought that two plants (GM and non-GM) with the same nutritional capacity should also imply
similar health risks (or absence of risks)? Why a similar principle is not used, for example, for chemical substances of commercial interest such as pesticides, drugs, food additives, etc.?
In fact, the “substantial equivalence” principle is a starting point rather than an end point (Kuiper et al., 2002). If this seems to be reasonably obvious, and taking into account the great controversy generated by the debate about GM plants safety, why the published information is so scarce?"

The researchers add that:

"The conclusions of our 2006 review concerning the doubts on the use of the principle of “substantial equivalence” in GM plants, as well as the lack of toxicological studies (Domingo, 2007), were quite in agreement with the conclusions of other reviews (Zdu\_czyk, 2001; Bakshi, 2003; Pryme and Lembcke, 2003), as well as with those of our previous review (Domingo, 2000;
Domingo-Roig and Gómez-Arnáiz, 2000). In a recent paper (Dona and Arvanitoyannis, 2009), it was reported that the results of most studies with GM foods indicated that they might cause some
common toxic effects. There is no doubt that one of the main issues concerning GM food safety assessment is based upon detection of their potentially toxic properties, which could provoke unintended effects of the genetic modification (Tyshko et al., 2007)."

More research needs to be done by direct testing of the LMO without such comparisons, such as is done for new drugs; counties should either fund it or demand it from companies applying for permits.

1. There have been some expressions of concern that conducting an assessment under the Protocol may run afoul of the WTO agreements. In fact, this is not the case.

A recent major study by authors coming from “pro-LMO” backgrounds is clear that the WTO allows countries to articulate protective goals and seek to implement them. See Thorn and Brosch, “The Cartagena Protocol on Biosafety and the World Trade Organization-- Implementing a WTO-Consistant Biosefty Regulatory Framework: Guidelines for Biosafety Regulators” 15 December 2005“ (DTB Associates):



 In addition, a posting on the discussion about Socio-Economic Considerations has observed:

With respect to the WTO Agreements, which are legally-binding for its Members, and over which there is some concern about whether decisions which take into account socio-economic considerations are WTO-consistent, it is worth pointing out that the WTO is not about “trade at any cost”. WTO Agreements have a context for trade. For example, the preamble of the Marrakesh Agreement Establishing the World Trade Organization (1994) affirms “…the objective of sustainable development, seeking both to protect and preserve the environment…”.

Article XX of the General Agreement on Tariffs and Trade (GATT) 1994, which provides general exceptions to trade liberalization, is also of importance. Article XX contains several general exceptions, among them for trade-restricting measures:
- “necessary to protect public morals”;
- “necessary to protect human, animal and plant life and health”;
- “relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption”.

This means that WTO Members may adopt or enforce measures for these purposes, even though they restrict trade. Thus, there is scope for WTO Members to take protective measures and to restrict trade of certain products, including agricultural products, for moral, environmental and health purposes.

How this will play out in the case of a dispute involving socio-economic considerations for LMO products has yet to be tested, as there has been no such case yet. The WTO Agreements do not a priori exclude socio-economic aspects, although more analysis is needed on the specific agreements to identify the flexibilities and policy space available.

For example, risk assessment under the SPS Agreement can already involve a mix of scientific and economic considerations. When assessing risks to animals and plants, “Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks” (Article 5.3). (There is no similar reference to economic concerns in relation to impacts on human health.)

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And another:

. . . this is a joint reply from several of the participants nominated by Norway. Dr. Casper Linnestad of the Ministry of the Environment, Dr. Anne I. Myhr from GenØk - Centre for Biosafety and Dr. Nina Vik from the Directorate for Nature Management have discussed this topic.

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With regards to obligations according to the WTO we would just like to refer to pages 14-15 in the proceedings of the International Conference on GMOs in European Agriculture and Food Production, 25-26 Nov, 2009, The Hague, The Netherlands. These pages refer to the presentation "The GMO Debate Under the Rules of the World Trade Organization" by Mr. Joost Pauwelyn (Professor of International Economic and WTO Law, Graduate Institute of International Studies, Switzerland). We include here the reference to Mr. Pauwelyn's presentation in the proceedings:

"The WTO allows more regulatory measures by national governments than is generally perceived. Mr. Pauwelyn highlighted that WTO rules do not allow any discrimination in favor one of several sources of the same product. Any measure should be rationally motivated, that is, related to a legitimate objective and based on scientific or other evidence. In developing their line of argumentation countries need to define socioeconomic aspects as risk-, health- or trade-related to make them subject to either of three WTO Agreements, each of which represents a specific ‘box’ of arguments.

1. The WTO Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement)
2. The General Agreement on Tariffs and Trade (GATT)
3. The Agreement on Technical Barriers to Trade (the TBT Agreement)

Examples showed that restrictions based on concern for “public morale” are sometimes allowed under the WTO.

In the discussion, specific aspects of both legal frameworks were covered. It is clear that in WTO terms, “risk” has to be defined ‘in the real world’, beyond laboratory tests. Socio-economic criteria are not a priori excluded, as long as they are verifiable and transparent".