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United States Department of State

Washington, D.C. 20520

To:
Dr. Ahmed Djoghlaif
Executive Secretary
Convention on Biological Diversity
Montreal, Canada

Re: Notification No 2009-103

September 14, 2009

Dear Dr. Djoghlaif,

The United States appreciates this opportunity to provide information relevant to the 28 May 2009 notification from the Secretariat entitled "Submission of scientifically sound information regarding the identification of Living Modified Organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

This question was part of the 2008 notification from the Secretariat, and we commented on this issue in our submission to the Secretariat in January of 2009. Below we reiterate the relevant points in response to this most recent request from the Secretariat.

1. Decisions about the suitability of an LMO should take into account a case-specific risk assessment. In decision BS-IV/11, the Parties asked the AHTEG to "consider possible modalities for cooperation in identifying living modified organisms or specific traits that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

The United States believes that undertaking this task as an *a priori* exercise would violate the established principle set out in Annex III that case-by-case analyses should be used to make decisions about an LMO. The United States notes that Annex III sets out general principles, methodological steps, and points to consider in the conduct of risk assessment. The general principles include, among others, the concepts that:

- Risk assessment should be carried out in a scientifically sound and transparent manner;
- Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk;
- Risks should be considered in the context of risks posed by the non-modified recipients or parental organisms; and that
- Risks should be assessed on a case-by-case basis.

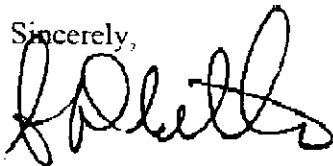
As noted above, the methodology described in Annex III of the Protocol follows the conventional risk assessment paradigm, beginning with identification of a potential hazard, such as characteristics of an LMO, which may have an adverse effect on biodiversity. Risks are then characterized based on combined evaluation of the likelihood of adverse effects, and the consequences should those effects be realized.

Therefore, the task of identifying such LMOs (i.e. "that may have adverse effects on the conservation and sustainable use of biological diversity...") in fact contradicts the very foundation that risk assessment plays in providing scientifically sound assessments to decision makers, regardless of whether the decisions are being made under the Protocol or under a national biosafety legal system. It is not possible to reach valid conclusions on hypothetical LMOs, because there is no real information to analyze, and this analysis would not take into account the particularities of different receiving environments as well as differences in how a particular LMO might be used. Furthermore, it is unclear how such a list of LMOs would relate to Parties' obligations under the Protocol. In addition, such a list would not remove the obligation to make decisions on transboundary movements.

2. The United States supports an alternative approach to making lists of LMOs. Under this alternative approach, the AHTEG might consider modalities for developing a process to examine existing case-specific risk assessments of LMOs in order to extract any consensus conclusions that have been broadly validated by many countries in risk assessments that have been undertaken in a manner consistent with Annex III. Such reviews may be able to identify broad-based consensus on LMOs whose transboundary movement are unlikely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. There are now quite a few LMOs that have been subjected to multiple assessments by different countries, in various receiving environments, and it may be useful for other countries to be aware of the extent of agreement across these risk assessments. This approach would provide a basis for a decision of the Parties as described in Article 7 paragraph 4.

"The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health."

Sincerely,



A. David Miller
Division Chief
National Focal Point
Biosafety Protocol