



**United States Department of State**  
*Bureau of Economic and Business Affairs*  
*Office of Agricultural Policy*  
*Washington, D.C. 20520*

16 August 2017

Ms. Cristiana Paşca Palmer  
Executive Secretary  
Secretariat of the Convention on Biological Diversity  
413 St. Jacques Street West, Suite 800  
Montreal, Quebec  
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CANADA

Dear Ms. Palmer,

In decision VIII/12, the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) invited “interested Parties, other Governments and relevant organizations that have used the Guidance and/or other guidance documents and national approaches to share an assessment of their applicability and usefulness through the Biosafety Clearing-House.”

The United States Government respectfully submits the following experience with risk assessment of living modified organisms (LMOs) to the Secretariat of the Convention on Biological Diversity (CBD). This information has also been uploaded into the Biosafety Clearing-House (BCH).

Sincerely,

A handwritten signature in black ink, appearing to read "Samuel Crowell".

Samuel Crowell, Ph.D.  
U.S. National Focal Point  
for the Cartagena Protocol on Biosafety

### **Assessment of the “Guidance on Risk Assessment of Living Modified Organisms”**

The Ad Hoc Technical Experts Group (AHTEG) on risk assessment and risk management developed the “Guidance on Risk Assessment of Living Modified Organisms” (the Guidance) to provide a reference for conducting risk assessments in line with Annex III of the Cartagena Protocol on Biosafety (the Protocol). After eight years of work, Parties at COP-MOP8 decided not to endorse the Guidance in decision VIII/12. Instead, Parties acknowledged that other guidance documents and national approaches can also assist in conducting risk assessment in accordance with the Protocol. The United States supports the Parties on both of these decisions.

The original intent of the Guidance document was to establish a “roadmap” of general principles to help Parties perform environmental risk assessments of LMOs. Providing Parties with the broad tenets of a sound risk assessment would allow countries to flexibly conduct assessments of new LMOs on a case-by-case basis, in line with their national legislations, perceived needs, and the scope of the Protocol as outlined in Annex III. However, the Guidance developed by the AHTEG expanded to become a lengthy, self-contained document which in our view contains fundamental flaws that go beyond the scope of Annex III. We believe the Guidance does not accurately reflect how science-based risk assessments are conducted in practice, and that it infringes on standards and guidance published by other international standard-setting bodies.

In short, in our considered view the Guidance contains untested approaches that are confusing, and in some cases impossible, to implement. As a result, we anticipate that continued use or expansion of the Guidance will create confusion and potential conflicts in implementing national biosafety systems. The Protocol and the CBD are not standard setting bodies and we believe they would best serve the Cartagena Parties by deferring to other international organizations with expertise in these areas when providing guidance to Parties on performing environmental risk assessments.

### **Other risk assessment approaches and guidance documents**

The U.S. Government has over 25 years of experience in using science-based risk assessment approaches to evaluate products of modern biotechnology, including living modified organisms (LMOs). The United States strongly advises against expanding the Guidance or developing additional guidance for risk assessment of LMOs and other products of modern biotechnology. At the time of this submission, there are over 1800 entries within the Biosafety Clearing-House (BCH) regarding risk assessments of LMOs. These assessments have been conducted by diverse countries on a wide range of LMOs released into different environments. We consider that it is critical for Parties to the Protocol and the CBD to recognize these experiences and strongly encourage the Parties to attempt to achieve consensus on the broad elements of a sound environmental risk assessment.

We believe that sound risk assessment practices are critical to maximizing benefits and minimizing potential risks associated with any technology. Annex III of the Protocol outlines several key features that all sound risk assessments share, regardless of the technology being considered. First, risk assessments should be carried out using the best available science in a transparent manner, and products should be evaluated on a case-by-case basis. When considering

whether a product poses a potential risk to the environment, a risk assessment should in our view consider the likelihood of adverse effects being realized, the consequences those adverse effects may pose, and whether or not potential risks are acceptable or manageable. Finally, we do not believe that a lack of scientific knowledge or consensus should necessarily be interpreted as indicating a particular level of risk.

In actual practice, conducting a risk assessment for an LMO is akin to conducting assessments of non-LMOs with the same or similar characteristics. Risk assessment standards have already been developed by numerous international bodies: the International Plant Protection Convention (IPPC), the Organization for Economic and Cooperative Development (OECD), the World Organization for Animal Health (OIE), and the World Health Organization (WHO) (websites below). In short, there is no need for the Protocol or the CBD to continue developing guidance on risk assessments when a wealth of information and experiences already exist, and as indicated we believe Cartagena Parties would be best served by making use of the information already available instead of creating their own, potentially contradictory/inconsistent guidance.

**Existing Resources to support Environmental Risk Assessments:**

United States Environmental Protection Agency (EPA):

- <https://www.epa.gov/risk/risk-assessment-guidelines>

International Plant Protection Convention (IPPC):

- <https://www.ippc.int/en/core-activities/capacity-development/training-material-pest-risk-analysis-based-ippc-standards/>
- <http://www.fao.org/docrep/009/a0450e/a0450e00.htm>
- [http://www.acfs.go.th/sps/downloads/34163\\_ISPM\\_11\\_E.pdf](http://www.acfs.go.th/sps/downloads/34163_ISPM_11_E.pdf)

Organization for Economic and Cooperative Development (OECD):

- <http://www.oecd.org/chemicalsafety/biotrack/oecdandriskassessmentinmodernbiotechnology.htm>

World Organization for Animal Health (OIE):

- <http://www.oie.int/en/our-scientific-expertise/specific-information-and-recommendations/invasive-alien-animal-species/>

World Health Organization (WHO):

- <http://www.who.int/tdr/publications/year/2014/guide-fmrk-gm-mosquit/en/>