Environment and Climate Change Canada | Environnement et Changement climatique Canada

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Dr. Cristiana Paşca Palmer
Executive Secretary
Secretariat of the Convention on Biological Diversity
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Ref.: SCBD/SPS/DC/MPM/MW/86376

July 28, 2017

Dear Dr. Cristiana Paşca Palmer:

In response to CBD notification 2017-035 titled "Submission of information requested in decision VIII/12 on Risk Assessment and Risk Management" , Canada would like to provide the below information related to decision VIII/12 wherein 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 to take the Guidance on Risk Assessment of Living Modified Organisms into account as a voluntary tool to assist in conducting risk assessment in accordance with the Cartagena Protocol while acknowledging that other guidance documents and national approaches can also assist in conducting risk assessment in accordance with the Protocol.

(a) Information on their needs and priorities for further guidance on specific topics of risk assessment of living modified organisms;

Canada does not support the development of further international guidance on specific topics for the risk assessment of LMOs under the Cartagena Protocol on Biosafety. The CBD Secretariat should instead focus its efforts on developing a single, practical guidance document based on current risk assessment practices that could be used for all types of ``case-by-case`` assessment. Given the continued increase in the use and diversity of biotechnology products, a single scientifically-sound guidance on risk assessment is, in Canada's view, the most practical and feasible approach to undertake.

Noting the decision at COP-MOP 8 not to endorse the general Guidance on Risk Assessment of LMOs developed by the Ad Hoc Technical Expert Working Group (AHTEG), Canada is of the view that Parties should strive to achieve consensus on the fundamental elements of

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environmental risk assessments for LMOs, rather than start new work on new guidance. There is also no need to develop specific guidance for products of synthetic biology as all known organisms of synthetic biology are LMOs.

With more than 20 years of experience in conducting LMO risk assessments, Canada has developed generic guidance on risk assessments that we would be pleased to share with the Secretariat.

(b) Proposals on criteria, including the technical justification, that may facilitate the selection of topics for the development of further guidance; and

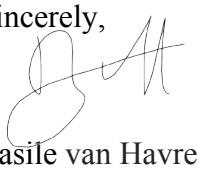
Canada strongly supports the further development of science-based, case-by-case, product- not process- triggered, regulatory systems. Canada is not aware of any scientific rationale that would support the selection of new topics for guidance. Efforts should be focused on developing a general Guidance that is acceptable to all parties, and that can be used for decision making on all types of LMOs.

(c) Views on perceived gaps in existing guidance materials.

There is currently a wide range of existing guidance material that can be used to help countries conduct risk assessments for LMOs. Some of these documents have been developed by countries either domestically, regionally, or internationally. For example, there is the work of the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology (specific to environmental release) and the work of the International Life Sciences Institute Research Foundation. Countries with experience regulating LMOs have also developed their own approval approaches, which other countries could draw upon for advice and guidance.

Canada looks forward to further discussions on this topic at the Twenty-second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice scheduled for July 2018.

Sincerely,



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