THE IDENTIFICATION OF LIVING MODIFIED ORGANISMS THAT ARE NOT LIKELY TO HAVE ADVERSE EFFECTS ON THE CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY, TAKING ALSO INTO ACCOUNT RISKS TO HUMAN HEALTH

Submitted by Canada

May 14, 2012

Under the provisions of the medium-term programme of work, decision BS-I/12 paragraph 7 (a) (i), further elaborated in decision BS-V/12 as adopted by the Fifth Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (Nagoya, 11-15 October 2010), the Secretariat of the Convention on Biological Diversity has requested Parties and invited other Governments and relevant organizations to submit scientifically sound information on the identification of living modified organisms (LMO) that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Paragraphs IV.12 and 13 of BS-V/12 state:

> 12. *Requests* Parties and *invites* other Governments and relevant organizations to submit to the Executive Secretary (i) information on risk assessments, carried out on a case-by-case basis with regards to the receiving environment of the living modified organism, that might assist Parties in the identification of living modified organisms that are not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and (ii) the criteria that were considered for the identification of such living modified organisms;
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> 13. *Requests* the Executive Secretary to compile the information received and prepare a synthesis report for consideration by the Parties at their sixth meeting.

Canada has over 20 years of experience in conducting scientifically sound assessments on the safe handling and environmental release of LMOs. These risk assessments, many of which predate the coming into force of the Cartagena Protocol, are completely consistent with the principles enunciated in Annex III to the Protocol.

To date, most environmental releases of LMOs have been crops for food and livestock feed production. Canada has also conducted environmental assessments and authorized the environmental release of a recombinant live vaccinia virus as a vaccine to control raccoon rabies. This LMO virus has also been subject to comprehensive field testing and

environmental safety assessments in the EU and the US with positive outcomes. A newer version of this recombinant vaccine has recently been assessed and authorized for environmental release in Canada.

It has been nearly three decades since LMO crop plants first entered regulatory processes in the world. The application of molecular biological tools has allowed plant breeders to rapidly introduce traits that would have been difficult or impossible to introduce via more traditional breeding techniques. This has broadened the scope of genetic changes that can be introduced into plants to achieve specific breeding objectives, although it does not inherently result in plants that are less safe than those produced by more conventional techniques.

In Canada, regulatory oversight for biotechnology products is based on a regulatory approach that considers the novelty of a product, not its method of production, as the trigger for regulatory review. For example, a new agricultural product may be considered novel if it has one or more new traits or one or more changed traits, or if it has a new use. To date, the general scientific consensus is that the method used to produce a new plant variety (either conventional breeding techniques or genetic engineering) is not necessarily an effective predictor of the plant's environmental impact, although new proteins may raise unique food concerns, such as the occurrence of allergens. To date there have been no documented cases of an LMO that has been authorized for commercial release in Canada where any harm to biodiversity has been observed.

Canada has assessed and authorized more than 70 LMO crops for unconfined environmental release including varieties of canola, maize, potatoes, soybeans, squash and sugar beets[1]. Canada's experience mirrors that of other countries where many of the same products have been subject to rigorous reviews and the environmental safety of those products affirmed[2].

Highly domesticated crop species, such as those listed above carrying agronomic traits that protect against herbicide damage, insect feeding damage, virus infection, as well as those with alterations to oil composition or producing enzymes for more efficient feed processing, have been shown to be environmentally safe by one or more competent authorities, representing a wide range of environments[3].

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[1] For a complete list with information on the status of regulated plants, with novel traits in Canada see: http://active.inspection.gc.ca/eng/plaveg/bio/pntvcne.asp

[2] Decision Documents on authorized products in Canada describing the risk assessment criteria and regulatory decisions for all products can be found at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236.

[3] For global approvals see: http://cera-gmc.org/index.php?action=gm_crop_database

LMOs intended for environmental release in Canada are regulated and undergo a rigorous environmental risk assessment and, where necessary, risk management that takes into consideration any negative effects on the functions of an ecosystem[4]. In accordance with Canada's responsibilities as a Party to the Convention on Biological Diversity, environmental risk assessments specifically address potential impacts on biodiversity. The risk assessments conducted by Canada are consistent with Annex 3 of the Cartagena Protocol and therefore, are relevant to the request by the Secretariat to identify LMOs that do not pose an unacceptable risk to biodiversity. Commonality in information requirements used by many national biosafety authorities is a strong argument for the portability of data between jurisdictions and may support the possibility of applying risk assessments either in whole or in part to a number of regulatory jurisdictions.

Canada is of the view that LMOs such as those currently approved in Canada for unconfined release, particularly where those approvals have been confirmed in more than one country with similar functioning regulatory systems, provide a starting point in identifying LMOs unlikely to cause a risk to biodiversity, also recognizing that further analysis may be required. The supporting data can easily be generated from the Biosafety Clearing House and will not be cited here.

Canada would propose that additional analysis in support of this work program should focus on LMOs which have already been approved in more than one country based on the principles enunciated in Annex III to the Protocol in order to:

I. Identify common characteristics/traits of LMOs unlikely to cause a risk to biodiversity; and

II. Review the commonality in information requirements and the portability of the science of risk assessment between Parties and Governments for LMOs unlikely to cause a risk to biodiversity in order to consider the merits of the portability of data and the possibility of applying risk assessments either in whole or in part to a number of regulatory jurisdictions.

[4] Assessment criteria for determining environmental safety of plants with novel traits, as contained in Canada's Regulatory Directive Dir94-08, can be found here: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08/eng/1304475469806/1304475550733