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Mr. William Kennedy
Executive Director
Secretariat
Commission for Environmental Cooperation
393 St. Jacques Street West, Suite 200
Montréal QC H2Y 1N9

Dear Mr. Kennedy:

Canada is pleased to offer its comments on the draft Article 13 report "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico" and trust they will be carefully considered by the Secretariat and the expert Advisory Group in the preparation of the final report.

The Government of Canada looks forward to continuing the dialogue with the governments of Mexico and the United States on issues related to agricultural biotechnology products and their impacts on the environment.

Yours sincerely,

A handwritten signature in black ink that reads "Norine Smith".

Norine Smith
Assistant Deputy Minister
Policy and Communications

c.c.: Mr. Jose Manuel Bulas
Ms. Judith Ayres



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**“Maize and Biodiversity: The Effects of Transgenic Maize in Mexico”
Canadian Comments on the CEC Secretariat’s Article 13 Report**

The Government of Canada would like to acknowledge the work of the CEC Advisory Group on Maize and Biodiversity in examining and writing of the report on this complex issue, characterized by diverging and, at times, opposing points of view. We note that this is an independent Article 13 report prepared by the CEC Secretariat. The key findings and recommendations are those of the Advisory Group and do not necessarily reflect the views of the CEC Council or the governments of Canada, Mexico or the United States. In these comments, we wish to share our observations and concerns and continue the dialogue on this matter.

Overview

In general, we found the report’s scientific key findings to be balanced and consistent with our scientific understanding, our regulatory approach, and accepted international standards. We are concerned, however, that some of the report’s recommendations do not appear to be supported by the scientific evidence presented in its key findings.

Canada believes the impacts of modern, non-transgenic maize hybrids should be the basis of comparison for determining the potential effects of transgenic maize. This baseline for comparison is often reflected in the key findings. However, this crucial context appears to have been largely disregarded in formulating the recommendations. We draw your attention to Annex 1 for a number of specific examples of these points.

Canada also suggests that this report could be more informative and complete if it took into fuller account the existing domestic regulatory approaches and international obligations of all three North American governments. Overall, Canada’s comments reflect our position that questions on importing transgenic maize should be decided by a country’s own science-based risk assessment and taken pursuant to a regulatory system which respects a country’s right to set its own level of protection in a manner consistent with its international obligations. Please refer to Annex 2 for more detail on this consideration.

Finally, you will find a number of specific comments in Annex 3. We wish, in particular, to draw your attention to comment 8 addressing the consideration of socio-economic factors and on comments 14 and 15 which deal with a country’s NAFTA and WTO obligations under a moratorium and considerations in the use of labelling.

Canada trusts these comments will be carefully considered by the Secretariat and Advisory Group in the preparation of the final report on the effects of transgenic maize in Mexico.

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Annex 1 The relationship between Key Findings and Recommendations

We are concerned that some recommendations are not supported by – and do not appear to be based on – the evidence presented in the key findings. We found this is particularly pronounced in the recommendations on gene flow 1 through 6 and recommendation 8. These recommendations acknowledge that gene flow to landraces of maize does occur. However they (i) imply assumptions that all traits that are derived from transgenes present the same risks and (ii) make no mention of the effect of the gene flow that occurs between other, non-transgenic varieties. The lack of consensus that the flow of transgenes adversely affects biodiversity or the environment is ignored in these recommendations. Specifically, the recommendations are contrary to some of the report's key findings that transgene flow must be considered in terms of (i) the historical context of how landraces have interacted with introduced varieties and (ii) a single trait's effect on the environment. We offer the following specific examples for your consideration:

Recommendations on gene flow:

Gene flow recommendation number 1 does not reflect key findings 11 and 16, or the stated mandate and scope of the study. Instead, the focus of this recommendation is placed equally on all transgenes, regardless of their potential impact on the environment, and to the exclusion of an examination of the presence or impact of fitness traits from conventional maize hybrids. Other recommendations in the report, such as number 2 on biodiversity and number 2 on gene flow, do acknowledge that information is needed about the impact of both transgenic and conventional maize. Since gene flow from either transgenic or conventional cultivars could transfer traits to landraces, the environmental risks of the introduced traits must be assessed on a case-by-case basis for the conditions of the likely potential receiving environment.

- Gene flow recommendation number 2 does not follow from key finding 16, which acknowledges that transgenic and conventional maize may have similar impacts on the genetic diversity of landraces or teosinte. Again, we note that research should focus on the potential for significant impact of the trait on fitness of the plant, regardless of the source of the trait.
- Gene flow recommendation number 4 describes gene stacking as the presence of multiple transgenes. As discussed above, the key findings indicate that the potential impact of both transgenic and conventional maize should be considered. The presence of multiple fitness traits may have different consequences in a population than individual fitness traits, but this is dependent on the biology of the plant and its environment (as indicated by key findings 2 and 12, not whether the trait is transgenic. In any case, an environmental safety assessment and approval process carried out according

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to internationally accepted criteria would address the likelihood and consequences of stacking a new transgene with other genes or transgenes already present in cultivated or wild plants.

- Gene flow recommendations number 5, 6 and 8 do not follow from key findings 11 and 16, which acknowledge that rates of gene flow and impacts on the genetic diversity of landraces or teosinte must be considered equally for both transgenic and conventional maize. Each line of transgenic maize and each line of conventional maize may have a unique impact on the environment or on biodiversity. Therefore, recommendations meant to be applied broadly to all transgenic maize are not science-based. Canada uses a case-by-case approach to assessing the environmental safety of novel plants in a product-based approach, such that environmental safety assessments are performed on novel plant varieties regardless of the method used to produce them.

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Annex 2 Domestic regulations and International obligations

Recognizing Domestic Regulations

We believe that many of the recommendations would be better framed with a more fulsome discussion of the existing regulatory approaches in Canada, Mexico and the United States. For instance, examining the potential consequences of gene flow and the potential impacts on biodiversity are central to Canada's environmental safety assessment process for novel plant varieties.

To our knowledge, Mexico has not yet finalized a regulatory process to carry out environmental risk assessments to approve or reject transgenic crops, such as maize. For this reason, Mexico has put into place a moratorium on the planting of transgenic maize. Consistent with our approach to risk assessment, we believe Mexico should develop its own risk assessment decisions on transgenic maize appropriate for the Mexican environment as the centre of origin of maize. To promote this effort, Canada supports regulatory capacity building initiatives to enhance domestic regulatory protocols in other countries.

Recognizing International Agreements

While this report should recognize countries' domestic actions, it should also note ongoing work amongst nations internationally on matters related to those raised in this report.

In particular we suggest that some recommendations could benefit from taking into full account international obligations under the Convention on Biological Diversity, the North American Free Trade Agreement, the World Trade Organization Agreements and the Cartagena Protocol on Biosafety. To that end Canada offers the following specific comments for consideration:

Convention on Biological Diversity (CBD)

Canada notes that the concerns of local and indigenous communities were the primary reason for the CEC Secretariat to prepare this report. As a party to the Convention on Biological Diversity, Canada recognizes that the CBD calls on Parties to respect and preserve the practices of indigenous and local communities, and gives priority to species of social and cultural importance. Furthermore, Article 8(g) of the Convention on Biological Diversity requires Parties to "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity [...]". Canada

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honors its obligation under Article 8(g). Canada also recognizes the commitment outlined in Article 8(j) to respect and preserve the practices of indigenous and local communities.

World Trade Organization (WTO) and North American Free Trade Agreement (NAFTA)

Canada supports science-based risk assessments and regulations for genetically modified (GM) products. Decisions based on science are an obligation for WTO members under both the Agreements on the Application of Sanitary and Phytosanitary (SPS) Measures and on Technical Barriers to Trade (TBT) and are also required under NAFTA chapters on SPS and TBT. Both Agreements also require that measures are no more trade restrictive than necessary to fulfil the objectives of protection of human, animal or plant life or health, or the environment. In cases where there is insufficient data upon which to base a decision, obligations under the WTO require members adopting a provisional measure to continue to seek to obtain additional information within a reasonable period of time. The SPS and TBT Agreements also require countries to base their measures on relevant international standards, where available.

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is aimed at assisting developing countries to make informed decisions on living modified organisms (LMOs) through establishing Biosafety frameworks. Canada supports the objective of the protocol and its effective and practical implementation.

Voluntary Trilateral Arrangement on documentation requirements for living modified organisms for food or feed, or for processing (LMO/FFP's)

In the absence of clarity regarding documentation requirements under the Protocol, Canada, Mexico and the United States have entered into a trilateral arrangement that specifies the conditions under which exporters should document shipments of LMOs that are destined for food, feed or for processing (FFP). Under the interim arrangement, exporters have to provide documentation on the commercial invoice accompanying a shipment which stipulates that: "This shipment may contain LMOs intended for direct use as food, feed or for processing, that are not intended for intentional introduction into the environment."

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**Annex 3
Specific comments**

We are pleased to provide the following specific comments:

Disclaimer, page 3:

1. A word is missing in the first sentence as follows. "This Article 13 [report] was prepared by the CEC Secretariat.

Section: "Mandate and Scope of the Study"

2. We note that the mandate and scope of the study originally included two areas for analysis which were not completed: a) impacts on animal health, and b) economic impacts. The report should be clear whether it is the intention of the Secretariat to pursue analysis in these areas.
3. We also note that the scope would have benefited from consideration of the potential impact of new maize varieties, developed using *conventional* methods, on biodiversity in Mexico.
4. The last sentence in the section states that "This report comprises key findings and recommendations to the governments of Mexico, Canada and the United States." The recommendations should be directed to the CEC Council.

Section: "Frameworks and Approaches Considered in the CEC Maize Advisory Group Recommendations"

5. Table 4: International Agreements and Treaty Obligations of the NAFTA Countries. For Canada, the Cartagena Protocol on Biosafety should indicate "**signed**" only.
6. Second paragraph: The third sentence should read "We have also considered that policy must conform to the TBT agreement" for consistency. Policies must conform to the principles of both the SPS and the TBT.
7. Fourth paragraph: sentence: "While Canada has not ratified the treaty and the US is not a Party [...]". Neither Canada nor the US is a Party to the Protocol. To clarify, Canada has ratified the parent Convention on Biological Diversity and signed but not ratified the Protocol on Biosafety, whereas the US has done neither.

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Section: "Key Findings and Recommendations"

- 8 Canada is of the view that risk assessment should be based solely on science. If a risk is identified, socio-economic factors may be considered when implementing an appropriate risk management strategy. Canada also recognizes that the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm. Canada recognizes that countries, when making decisions about whether or not to import, have the right to choose their own level of protection in adopting regulation to protect the environment and animal, human and plant health in a manner consistent with their international commitments.
9. We believe that many of the recommendations made in the report to the CEC Council would be better framed with a short discussion about the existing regulatory approaches in the three countries. For instance, examining the potential consequences of gene flow, and the potential impacts on biodiversity are two pillars of the Canadian environmental safety assessment process for novel plant varieties.
10. Some recommendations imply that Canada is exporting maize to Mexico. These should be corrected to reflect the fact that Canada does not currently export bulk maize/corn to Mexico.

Section: "Findings on Gene Flow"

11. Finding number 4 states that "[...] there is no doubt that transgenes will spread in Mexican maize, and that they are present now." However, this is contradicted in finding number 5 where the possibility of no spread is created with the statement "*Whether* they eventually increase and spread -or decrease in frequency- will depend [...]". Finding number 5 appears more scientifically objective unless there is data to back up the assertion made in number 4. We would suggest rewording finding number 4 to "[...] In any event, transgenes are present in Mexican maize and some transgenes may spread."
12. Finding number 9 we would suggest rewording "may be unlikely" to "is unlikely".
13. There is no scientific evidence, presented in this report or elsewhere, to support generalized statements about the impacts of transgenes as a group. Individual transgenes will have unique modes of action and unique corresponding traits, the impact of which must be considered on a case-by-case basis. For example, even individual Bt proteins have highly specific modes of action that limit their effectiveness to the control of certain classes of insects, and it should be clarified that any individual Bt

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protein will not afford protection against more than a very small range of herbivores. We suggest the first sentence in gene flow key finding number 13 should be reworded to read "Bt transgenes have the potential to be selectively favored in recipient populations if they protect the plants from specific, population-limiting insect pests."

Section 'Recommendations on Gene Flow'

14. Recommendation 5: SPS Article 5.7 allows for an exception to the obligation to base sanitary measures on a risk assessment only 'in cases where relevant scientific evidence is insufficient' to permit a final decision on the safety of a product or process. The provisional measure must take into consideration available pertinent information. The Member adopting the measure must seek to obtain the additional information necessary for a more objective assessment of risk, and must review the SPS measure within a reasonable period of time. Thus, as currently proposed recommendation number 5 that states: "[...] the current moratorium on planting commercial transgenic maize in Mexico should be enforced" could be considered to be in contradiction of NAFTA and WTO obligations.

15. Recommendation 7: Canada does not believe that labelling is an alternative to direct regulation and enforcement where legitimate health and/or safety concerns exist. However, where a product is approved for a specific use such as for food and feed, but not for planting, labelling may be an appropriate risk management tool to ensure a product is used properly. With regard to the labelling of foods derived through biotechnology, Canada considers the use of labelling to indicate health or safety issues to be a legitimate objective, and Canada supports labelling to convey this important information to consumers. Canada is, however, concerned about the use of mandatory method-of-production labelling when other, less trade-restrictive, options are available. The use of mandatory labelling to indicate the method of production (when this does not pertain to the characteristics of a product) could be used in a discriminatory way and could represent a technical barrier to trade. Non-discrimination is a key principle in the WTO Agreement and NAFTA.

Section: "Socio-Cultural Recommendations"

16. The report would flow better if the sub-sections: "Context of GM Maize in Mexico" and "The Maize System in Mexico" were moved ahead of the Key Findings and Recommendations. Some of the explanations there - such as what a '*campesino*' is - would be useful to the unfamiliar reader in advance of the presentation of the details of the report.

7. Recommendation 2 implies that Canada is exporting maize to Mexico

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This should be corrected to reflect the fact that Canada does not currently export bulk maize/corn to Mexico.

18. Last paragraph: We would like to note that Canada supports greater harmonization of biosafety regulations among the North American countries. For example, the North American Biotechnology Initiative (NABI) was established in 2002 to facilitate sharing of information and cooperation on biotechnology issues. A bilateral agreement on assessment and regulation of agricultural biotechnology between Canada and the United States signed in 1998 and expanded in 2001 is being considered for extension to include Mexico under NABI. We strongly support this initiative and consider it an important mechanism for trilateral sharing of information and cooperation on biotechnology issues.