CFIA Comments on the CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico 16 April 2004

CFIA Comments on chapters 1, 2, 4, and 5

Chapter 1: Context and Background on Wild and Cultivated Maize in Mexico

- 1. This chapter provided extensive background information that is very useful for the topic.
- 2. However, the detail provided in the section entitled "Presence of Transgenic Maize in Mexico exceeded the scope of this chapter. This topic might better be left to subsequent chapters that go into some detail on the consequences of transgenic maize in Mexico.

Chapter 2: Understanding Benefits and Risks

- 1. This chapter was a good overview of approaches to benefits and risks, as indicated by the title.
- The chapter went on to discuss transgenic crops and agricultural biotechnology specifically. Some of this may or may not apply to transgenic maize in Mexico, particularly with respect to unintentional adventitious presence.
- 3. In Section 2.2, the last paragraph states that "many" products commercialized over the next decade will be pharmaceutical, biologic or industrial compound-producing crops. These crops are mentioned in Section 2.3 also. These references could be misleading, since commercial production of such crops is with very few exceptions still hypothetical, and their importance in the future utterly unknown. Furthermore, in countries with relevant regulatory systems in place, both field trials and commercial production of these crops are under strict control to mitigate against accidental entry into food or feed supply chains.

Chapter Four: Assessment of Effects on Natural Ecosystems

 In the introduction, the relationship between biodiversity and ecosystem function might be better documented, and its relevance to transgenic maize in Mexico more clearly substantiated. The implication that the introduction of genetically engineered organisms "intersects" with losses of biodiversity and changes in land use should be better defined and supported. (Page 1) It is not clear what if anything would relate genetic engineering in general to changes in biodiversity; in fact, any environmental impacts would be related to the introduced trait and not to genetic engineering itself.

CFIA Comments on the CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico 16 April 2004

- 2. It may be helpful to clarify whether risks of unintentional, adventitious introduction of transgenes into landraces or intentional adoption of transgenic varieties are being considered in this paper. The consideration of ecological impacts of changes in farming practices, for example, will depend on which situation is being evaluated. The question raised in the summary on page 14, "Will the introduction of transgenes have a positive or negative effect on natural ecosystems in Mexico?", will be easier to answer if it can clarified whether unintentional or intentional introduction is being discussed.
- 3. The scientific controversies raised on page 15 regarding the measurement and understanding of biodiversity and its effects on ecosystem function are all good, outstanding questions. The discussion of unresolved issues here is also balanced and logical. However, it is still not clear what might be a scientific basis for expecting genetically-engineered plants to have an effect on biodiversity and other parameters mentioned. It should be emphasized that any environmental impacts of a transgenic crop plant would depend on the trait introduced and would not be related to genetic engineering itself.

Chapter 5: Assessment of Biological Effects in Agriculture in Mexico

- This chapter provides extensive and very relevant background information on maize agriculture in Mexico and its socio-economic status. It also provides a reasonable discussion of advantages and disadvantages of various transgenic crop traits for Mexican agriculture, from both an environmental safety and a socioeconomic view. Perhaps the title of the chapter could be changed to more accurately fit the apparent objective of the chapter.
- 2. The discussion on stacking of transgenes in Section 2.8 is somewhat unclear. The reference on page 11 to potential problems of inserting 10 to 20 or more genes in one cassette is not particularly relevant here, given that associated technological problems would need to be overcome by the developer before a commercial product could be launched. The potential risks when "farmers themselves accidently stack transgenes by accumulating multiple ones in their landraces" would depend on the traits involved, but this point is not made clear.
- 3. Furthermore, The reference to "chromosomal abnormalities" on page 11 of Section 2.8 is not clear. Are the authors suggesting that these abnormalities will arise with stacking? Or that they would be associated with individual transgenes? In either case, scientific substantiation should be provided.
- 4. In Section 3.3, the first phrase on page 16 stating "The general trend in farming operations is to have the farmer serve as contracted labor..." is unclear. Moreover, how the use of transgenic seeds could advance this trend is unclear.

CFIA Comments on the CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico 16 April 2004

5. The last paragraph of Section 3.3 also makes reference to selective disadvantages accruing to transgenic plants, particularly those related to the process of regenerating from tissue culture on page 17. As mentioned above for multiple gene cassettes (comment 2), these disadvantages are not particularly relevant here since they are fitness problems that would have to be addressed by the developer in order to produce a viable commercial product.

CFIA Comments on CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico 16 April 2004

CFIA comments on chapters 7 and 8

Chapter 7: Assessment of Human and Animal Health Effects

The following revisions need to be considered:

- On the website's table of contents, chapter 7 of the report is titled "Assessment of Human and Animal Health Effects". This should be changed to "Assessment of Human Health Effects" which would match the actual document's title as there is no discussion of animal health effects in chapter
- "The transference of a 2S albumen protein from Brazil nut into soybean...that was then withdrawn from human consumption". This allergen was detected at the research stage and was never approved or introduced into the food chain. (page 14)
- "The Guardian published a note indicating that a new illness (fever, respiratory and skin reactions) is being investigated in Philippines that could be related to Bt maize. Of course, this finding must go through the necessary steps to test." (pages 14, 18) The effects of Bt maize have not been investigated. This article is unsubstantiated.
- 4. The fifth paragraph on page 14 mentions the appearance of new diseases for which no treatment is available is a concern regarding transgenic foods. The CFIA has not previously heard this raised as a concern. It is difficult to see how this could be related to genetic engineering.
- 5. Professor Barry Commoner's review for this chapter regarding the importance and frequency of unexpected and unanticipated issues should be removed from the document as it is not substantiated. (page 15)
- The CFIA does not support the following statement and suggests it be removed: "It is a fact that current technologies modify allergenicity of foods." (page 16, second last paragraph)
- 7. On pages 19 and 20 there is a discussion on effect of transgenes on landraces. If incorporated, transgenes will not be maintained unless there is a selective pressure. There is also much concern about 3rd generation molecular farming plants; however, these have not been commercialized yet and the discussion seems to assume they have been commercialized.
- 8. Pages 31 and 32 includes a discussion on unintended effects of recombinant DNA techniques. This discussion fails to consider recombinant DNA in the context of traditional plant breeding and treats it in isolation.

CFIA Comments on CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

- 16 April 2004
- 9. The following statements are not supported by references:
- a) "...The growing evidence of genetic instability of purportedly 'successful' transgenic plants" (page 33)
- b) "faithful replication of both the transgene and the new host's DNA may be sufficiently disrupted by transgenic process to result in an overwhelming proportion of unpredictable, unintended, unexpected and usually adeverse genetic changes" (page 33)
- c) "Accordingly, the only feasible way of protecting Mexican agriculture from this hazard would be to end the commercial production of maize in the United States, Canada and Latin America." (page 37-38)
- 10. The discussion of different DNA polymerase systems in different species and the effect on mutation frequencies is a theoretical argument that is not supported by the fact that many transgenes have been inserted successfully into plants, which are replicated faithfully. The author makes sweeping conclusions from specific references. Specific evidence is not demonstrated to support this. Cross species transfer of genes occur in nature. (page 33)
- 11. In the following statement, "...Final marketed product does in some cases such as Bt soybeans exhibit unexpected changes in DNA nucleotide sequence in the region of the transgene," the reference refers to a Roundup ready soybean, not a Bt expressing soybean. Secondly, it is important to differentiate the difference between rearrangement of DNA around an insert which is not a safety concern as opposed to the expression of a protein which may be a safety concern. In the case of the RR soybean there was no corresponding protein changes thus no impact on safety. (page 36)
- 12. As part of the safety assessment performed, the composition of all modified plant is examined in detail. Thus, this comment "There are.. major uncertainties about the composition of transgenic plants and their potential effect on human and animal health..." on page 36 is not supported by the CFIA.
- 13. There are grammatical and spelling errors present throughout the document. For instance, "low-fitate", shoul be replaced by "low phytate". (page 13)

CFIA Comments on CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico 16 April 2004

Comments on Chapter 8: A Framework for Judging Potential Benefits and Risks

- 1. This chapter gives a good, brief review of philosophical approaches to risk management discussed in Chapter Two. It then goes on to overview risk assessment methodologies. These are for the most part sound and balanced discussions.
- 2. The chapter goes on to discuss the implications for Mexico. Some of the considerations here are a bit vague or not clearly substantiated. For instance, it is stated on page 17 that transgenes could move from varieties grown by commercial farmers into landraces grown by campesino farmers. While this is certainly true, the nature of the potential negative consequences are not clear. Since the campesino farmers do not export their grain, they will not be affected by market concerns around adventitious presence of transgenes. The impacts of adventitious transgenes in landraces on environmental safety would depend on the population genetics (rate of inflow of alleles and selection) and on the trait in question. These points have been omitted from this discussion.
- 3. Similarly, the potential risks of gene stacking are likely to be related to management issues, such as management of volunteers in the case of stacked herbicide tolerances, or possible incompatible planting strategies to slow development of insect resistance in the case of stacked Bt traits; but not necessarily to the fact that the transgenes "were never tested together" (page 18). This point was not made clear. Furthermore, transgenes that are not intended to enter the human food chain would be a problem on their own, even if not stacked.
- 4. Also discussed in this section (such as on page 18) were the risks associated with recombination or segregation of multiple transgenes within a single released variety. This is not likely to be an issue since, if there were any anticipated adverse effects of recombination or segregation of multiple transgenes, they would be addressed if not by the developer than by the assessment process prior to approval.
- 5. On page 19, there is a discussion of the uncertain and unpredictable fate of transgenes in landraces under the control of campesino farmers. It should be noted that this is also true for any genes flowing into landraces, for example from conventional commercial varieties. In addition, the quote repeated from Chapter Ten, page 3, stating that "the introduction of transgenes into an open pollinated crop... will inevitably lead to the widespread distribution of transgenes among these crops..." is a serious exaggeration. The distribution of the transgenes within landraces, once introduced, will depend very much

CFIA Comments on CEC Article 13 initiative on Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

16 April 2004

on the rate of inflow, the fitness of the hybrids and the selection pressures for or against the trait.

6. What is also notably absent from this discussion is the context of the consequences of these transgenes. As mentioned, the presence of the transgene itself does not necessarily imply a socioeconomic or environmental safety risk. The impact, if any, will depend on the trait.