MAIZE AND BIODIVERSITY

The Effects of Transgenic Maize in Mexico

Key Findings and Recommendations

Secretariat Article 13 Report

Commission for Environmental Cooperation
of North America

8 November 2004

The Commission for Environmental Cooperation (CEC) was established by Canada, Mexico and the United States when these Parties signed the 1994 North American Agreement on Environmental Cooperation (NAAEC). The CEC's broad mandate is to facilitate cooperation and public participation to foster conservation, protection and enhancement of the North American environment for the benefit of present and future generations, in the context of increasing trade and social links among our three countries.

Position of the Parties

The following report was prepared independently of the three Parties to the NAAEC by the Secretariat of the CEC pursuant to Article 13 of the NAAEC with the assistance of a designated Advisory Group on Maize and Biodiversity.

Publication of this report does not constitute endorsement of its contents by the Council of the CEC or the governments of Canada, Mexico or the United States.

The Parties' comments are appended to the report. These comments include observations that some of the recommendations contained therein do not reflect the report's scientific findings, but rather reflect cultural and social perspectives of the Advisory Group and other entities.

This report is published in the three languages of the CEC: English, French and Spanish. However, as the text was originally prepared in English and thereafter translated, in the case of disputed meaning, reference should be made to the English version.

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Preface

When it was reported in 2001 that genetically modified corn had spread among native maize land races in the high valleys surrounding Oaxaca, the familiar controversy and debate over genetically modified, or *transgenic*, crops suddenly took root in Mexico. More recently, testing sponsored by the government of Mexico has confirmed the appearance of transgenic material in the maize fields of the Sierra Norte region and elsewhere.

Peasant farmers and many others know that open-pollinated plants like maize easily share their genes, so they were naturally concerned with questions about the effects of transgenes. Were they safe? What impact would the spread of transgenes to native races—and perhaps their wild relatives—have on both Mexico's rich genetic diversity and this important global resource?

In 2002, members of Mexican civil society, international organizations and, in particular, indigenous and peasant groups from Oaxaca, requested that the CEC Secretariat initiate an independent enquiry to determine the facts.

Keeping in mind the single, common environment shared by North America's three countries, we agreed to study and report upon this issue pursuant to Article 13 of the North American Agreement on Environmental Cooperation. This article provides the Secretariat of the CEC with the opportunity to prepare occasional reports on important environmental matters for the CEC Council, the environment ministers or equivalent of each country.

This report, the fifth such Article 13 report completed by the Secretariat, comes at the 10-year anniversary of the CEC. It follows the June 2004 *Puebla Declaration* in which the CEC Council noted its continuing support for our work to identify and assess such emerging issues. As with previous Article 13 enquiries, this report is an example of how the CEC Secretariat can focus North American and world expertise upon such an important environmental issue.

There is urgency to our work. Worldwide, genetic modification holds the promise to improve agricultural productivity, increase resistance to disease and decrease reliance on pesticides. If peasants have access to transgenic varieties that are perceived as valuable, they will crossbreed these with traditional varieties—spreading the transgenes and their traits among their landrace fields. On the other hand, the long-term impact on the environment, health, Mexican traditional landraces and wild species is unknown.

The complexity of this issue and lack of scientific consensus can easily leave the public perplexed. In Mexico—a world center of origin and diversity of maize—the issues are particularly acute. Despite the significant controversy surrounding this matter we are heartened by the fact that the recommendations to the CEC Council set out in this report represent the unanimous conclusions of our international, independent, and multi-stakeholder advisory group. We trust this report will contribute to a better understanding of, and informed response to, these issues on the part of the public and decision-makers alike.

William V. Kennedy

Executive Director, CEC Secretariat

Acknowledgements

The CEC Secretariat would like to acknowledge the many individuals and organizations that contributed time and energy to the successful completion of this Article 13 report. Special mention goes to the CEC Advisory Group on Maize and Biodiversity, chaired by Dr. José Sarukhán, whose members have worked under a very tight deadline to agree on the key findings and recommendations for the CEC Council that represent the core of this Secretariat report (see listing of Advisory Group members in **Table 1**). Each member was instrumental in preparing this report and the Secretariat would like to thank each one of them for their extraordinary dedication and collegiality over the course of the last two years. The writers of the four discussion papers that were developed at the beginning of the process (see **Table 2**), the 18 authors who wrote the 10 chapters in the background volume to this report and the 26 external reviewers of those chapters (see **Table 3**) are also gratefully thanked. The CEC Secretariat would also like to thank the many government and public commentators who provided written comments and oral comments at the symposium.

The CEC would also like to acknowledge and thank the many citizens of Canada, Mexico and the United States who responded to our calls for comments, attended public meetings, and improved our work and our process for their interest, engagement, and belief in the CEC.

This initiative, conducted under the authority of Article 13 of the North American Agreement on Environmental Cooperation that gives the Secretariat the authority to address key environmental issues, would not have been possible without the coordinating work of Chantal Line Carpentier, head of the CEC's Environment, Economy and Trade program, the support of Hans Herrmann, head of the CEC's Conservation of Biodiversity program and of our many colleagues at the CEC, including Vic Shantora, Tim Whitehouse, Manon Pepin, Doug Wright, Evan Lloyd, Geoffrey Garver and Hernando Guerrero. Finally, the Secretariat would like to acknowledge the staff of the CEC Communications Department who have handled the editing and translation of the various documents prepared for this Article 13 initiative with their usual professionalism, patience, and collegiality.

Introduction

This report comprises key findings and recommendations to the CEC Council concerning maize and genetic diversity in Mexico. The context, mandate, process, and guiding framework for arriving at these conclusions are outlined below. A glossary of technical terms is also attached. For further information on the historical and contemporary context, as well as the discussion papers and background volumes assembled in the course of this study please consult the CEC's web site at <http://www.cec.org/maize/>.

The Context

In April 2002, the CEC was petitioned by 21 indigenous communities of Oaxaca and three Mexican environmental groups, Greenpeace México, the Mexican Center for Environmental Law (*Centro Mexicano de Derecho Ambiental*—Cemda), and the Union of Mexican Environmental Groups—eventually supported by more than 90 letters from organizations and institutions throughout the three NAFTA countries, urging an analysis of the impacts of transgenic introgression into landraces of maize in Mexico. (See the executive summary of the original petition in the appendix.) This issue was considered of great potential environmental importance, given that Mexico is a center of origin and diversity for maize and that maize is so intrinsically linked to Mexican culture, especially that of Mexican indigenous groups.

Writing this report was a difficult task. There remain many questions that science has not resolved concerning transgenic maize, including even the regional extent of transgenic maize introgression in Mexican landraces. Also, there are widely divergent convictions regarding the possible risks such genetically modified organisms (GMOs) may pose to the environment and to animal and human health, as well as possible advantages associated with them. The questions of social, cultural, economic, and trade impacts of technological and other changes in agriculture are also subjects of dynamic debates. These questions assume particular importance in Mexico, where maize was domesticated from teosinte and where it remains genetically highly diverse. Recognizing these difficulties, the CEC created a 16-member Advisory Group to represent stakeholders from academia, industry, NGOs, and community and indigenous groups and guide the development of the report (see **Table 1**). Members were invited based on their personal expertise in the field they represent and not as representatives of any particular organization or institution. A declaration of no conflict of interest was submitted by all members of the Advisory Group at the onset of this effort.

Table 1. Advisory Group on Maize and Biodiversity

Member	Organization	Country
José Sarukhán, Chair	*Instituto de Ecología, Universidad Nacional Autónoma de México*	Mexico
David A. Andow	Department of Entomology, University of Minnesota	United States
Mindahi Bastida-Muñoz	*Consejo Mexicano para el Desarrollo Sustentable* and member of the CEC Joint Public Advisory Committee	Mexico
Andrew Baum	SemBioSys Genetics Inc.	Canada
Susan Bragdon	International Plant Genetic Resources Institute	United States
Conrad G. Brunk	Department of Philosophy, Director of the Centre for Studies in Religion and Society, University of Victoria	Canada
Don S. Doering	Winrock International	United States
Norman Ellstrand	Department of Botany and Plant Sciences, and Director, Biotechnology Impacts Center, University of California at Riverside	United States
Amanda Gálvez Mariscal	*Facultad de Química, Universidad Nacional Autónoma de México*	Mexico
Luis Herrera-Estrella	*Centro de Investigación y Estudios Avanzados del Instituto Politécnico Nacional*	Mexico
Julian Kinderlerer	Institute of Biotechnological Law and Ethics, Law Department, University of Sheffield	England
Lilia Pérez Santiago	*Unión de Comunidades Productoras Forestales Zapotecas-Chinantecas de la Sierra Juárez UZACHI*	Mexico
Peter W. B. Phillips	Department of Political Studies and College of Biotechnology, University of Saskatchewan	Canada
Peter H. Raven	Missouri Botanical Gardens	United States
Allison A. Snow	Department of Evolution, Ecology and Organismal Biology, Ohio State University	United States
José Luis Solleiro Rebolledo	*Centro de Ciencias Aplicadas y Desarrollo Tecnológico (CECADET), Universidad Nacional Autónoma de México*	Mexico

Mandate and Scope of the Study

This report analyzes the likely effects of current and future uses of transgenic maize, as compared to non-transgenic maize production, upon: the genetic diversity of landraces and wild relatives of maize, agricultural and natural biodiversity, human health, and social values and cultural identity.

The focus of this report is on the possible impacts of cultivation of current and near-term commercial transgenic maize varieties on landraces of maize and teosintes and the possible introgression and effects of transgenes into those taxonomic entities. Likely future transgenic maize varieties are also considered to ensure the present report serves future policy making and scientific research. In considering the effects of transgenic maize cultivation, the Advisory Group aimed to identify and assess both the risks and benefits to interested and affected parties and to maize biodiversity in Mexico. Several of the 10 chapters of the background volume to this report examine issues related to gene flow, both direct and indirect, from transgenic varieties of maize to Mexican landraces and their wild relatives, and the conservation of maize biodiversity near its center of origin. They also deal with the context and background on wild and cultivated maize in Mexico, present a framework for judging potential benefits and risks, on understanding benefits and risks, help our understanding of the biology of maize and community values to improve communication and participation, and discuss managing potential risks and enhancing potential benefits. Other chapters cover the potential effects of transgenic maize on biodiversity, genetic diversity, agriculture, society and culture, and human health. Time and resources were not available to complete an economic analysis of transgenic maize in Mexico.

Issues related to the distribution of risks and benefits among affected parties are also considered. The Advisory Group recognized that such assessments and management strategies need to take into account scientific knowledge, a complex agricultural and social system and inherent uncertainty. Chapters contained in the background volume are not intended to reflect the views of the Advisory Group, the CEC Secretariat or Council. Given the number and diversity of experts that contributed to the background chapters, differences of interpretation as well as contrasting points of view may occur in the texts.

Process

The Advisory Group on Maize and Biodiversity committed itself to the highest standards of scientific accuracy and objectivity, transparency, communication, and participation of stakeholders in the development and review of this report. The intention was for the group to guide the Secretariat through the analysis and to provide recommendations to the three NAFTA countries that reflect diverse perspectives, are analytically rigorous and conceptually bold, and provide a basis for action by national scientific and policy agencies. The steps followed to accomplish this were to: a) develop discussion papers (see **Table 2**) to help define the scope and breadth of the work, b) map this into chapter topics and their detailed outlines, c) select the authors and give them clear guidance on the scope of their chapters as well as editorial supervision, d) submit chapters to a peer review process and ensure that the comments in those reviews were adequately addressed, e) organize an open, public symposium where summaries of the chapters would be presented and comments and reactions to the draft chapters collected and considered, and f) develop a report that incorporated key findings and recommendations. The key findings and recommendations of this report are thus derived from a variety of sources. These include the background chapters as prepared for the CEC Secretariat and reviewed externally, the professional expertise of the Advisory Group members themselves, comments received at the public symposium and subsequently, and the comments of the Parties to the NAAEC on the background chapters and the preliminary draft of this report.

Table 2. Discussion Papers

Title	**Author(s)**
Issues Summary	Chantal Line Carpentier and Hans Herrmann, CEC
Ecological and Biological Aspects of the Impacts of Transgenic Maize, Including Agro-Biodiversity	Dr. Elena R. Alvarez-Buylla, *Laboratorio de Genética Molecular, Desarrollo y Evolución de Plantas, Instituto de Ecología, UNAM*
Sociocultural Aspects of Native Maize Diversity	Miguel A. Altieri, Department of Environmental Science, Policy and Management, University of California, Berkeley
Economic Valuation	Scott Vaughan, Unit for Sustainable Development and Environment, Organization of American States

The detailed outline for each chapter was developed under the guidance of the Advisory Group and posted for public comment on the CEC web site on 6 May 2003. Names of potential authors for the chapters were then requested from the Advisory Group and the public. The Advisory Group then selected the best authors available to write the chapters through a blind voting process. An effort was made to ensure that Mexican experts be authors or co-authors to fully capture the complexity of maize production, consumption, and appreciation in Mexico. In total, 18 authors were selected to author and co-author these ten background chapters. Once written, chapters were reviewed by a lead Advisory Group member before being submitted to an external review process (see **Table 3**). Lead Advisory Group members were responsible for ensuring that all comments had been addressed, either in the chapters directly or by a response to reviewers that appears with the original comments in an appendix on the CEC web site. A rigorous and transparent review process similar to that applied for the Intergovernmental Panel on Climate Change reports or the future Millennium Ecosystem Assessment report was followed in each case. The names of the authors and reviewers appear on each chapter. On average, each chapter was reviewed by four or five external reviewers, in addition to Advisory Group members, for a total involvement of 26 external reviewers. This transparency in the review process has helped underline areas where there is no scientific consensus and allows for a presentation of the various points of view in a specific area of inquiry. Comments and chapter reviews, along with the original chapters, can be found on the CEC's web site at <www.cec.org/maize>.

Table 3. Background Volume—Chapter Titles, Authors, and Reviewers

Chapter	Author	Co-author	Advisory Group Reviewers	External Reviewers
Chapter 1 Context and Background on Wild and Cultivated Maize in Mexico	Antonio Turrent (INIFAP)	José Antonio Serratos Hernández (Cimmyt)	José Sarukhán (lead) Peter Raven	Flavio Aragón Al McHughen Rafael Ortega Paczka Margaret Smith Garrison Wilkes
Chapter 2 Understanding Benefits and Risks	Paul Thompson (Michigan State University)		Don Doering (lead) Conrad G. Brunk Peter Phillips Lilia Pérez Santiago José Luis Solleiro	Elena Álvarez-Buylla Maarten Chrispeels Barry Commoner Al McHughen
Chapter 3 Assessment of Effects on Genetic Diversity	Julien Berthaud (IRD)	Paul Gepts (University of California, Davis)	Norman Ellstrand (lead) Peter Raven Allison Snow José Luis Solleiro	Lesley Blancas Rafael Ortega Paczka Marilyn Warburton Garrison Wilkes
Chapter 4 Assessment of Effects on Natural Ecosystems	Lillian LaReesa Wolfenbarger (University of Nebraska, Omaha)	Mario González-Espinosa (Ecosur)	Peter Raven (lead) José Sarukhán	Deborah Letourneau Angelika Hilbeck Daniel Piñero Garrison Wilkes
Chapter 5 Assessment of Biological Effects in Agriculture	Major Goodman (North Carolina State University)	Luis Enrique García Barrios (Ecosur)	David Andow (lead) Peter Raven José Luis Solleiro	Elena Álvarez-Buylla Flavio Aragón Angelika Hilbeck Eric Van Dusen Garrison Wilkes Mark E. Whalon
Chapter 6 Assessment of Social and Cultural Effects Associated with Transgenic Maize Production	Stephen Brush (University of California, Davis)	Michelle Chauvet (Universidad Autónoma Metropolitana)	Julian Kinderlerer (lead) Mindahi Bastida-Muñoz Peter Phillips José Sarukhán José Luis Solleiro	Kirsten Appendini Rafael Ortega Paczka Garrison Wilkes
Chapter 7 Assessment of Health Effects	Héctor Bourges, M.D. (UNAM)	Samuel Lehrer (Tulane University Medical Center)	Amanda Gálvez Mariscal (lead) Luis Herrera-Estrella Peter Raven José Luis Solleiro	Barry Commoner David Miller Armando Sadajiko Shimada
Chapter 8 A Framework for Judging Potential Benefits and Risks	Mauricio Bellon (Cimmyt)	George Tzotzos (UNIDO) Paul Thompson	Peter Phillips (lead) Conrad G. Brunk Julian Kinderlerer Amanda Gálvez Mariscal José Luis Solleiro	Gary Comstock Michelle Marvier Kathleen McAfee Eric Van Dusen
Chapter 9 Understanding Complex Biology and Community Values: Communication and Participation	Jorge Larson (Conabio)	Michelle Chauvet (Universidad Autónoma Metropolitana)	Julian Kinderlerer Mindahi Bastida-Muñoz	Rosa Luz Gonzáles Aguirre Bill Hallman
Chapter 10 Managing Potential Risks and Enhancing Potential Benefits: Identification and Analysis of Management Tools and Policy Options	Reynaldo Ariel Álvarez Morales (Cinvestav)	John Komen (ISNAR)	David Andow (lead) Susan Bragdon Don Doering Amanda Gálvez Mariscal	George Khachatourians Michelle Marvier Luciano Nass Stuart Smyth Marilyn Warburton

Draft chapters were presented at the CEC symposium on maize and biodiversity, 11 March 2004, in Oaxaca, Mexico, to allow the public to provide comments and opinions that would be considered for a final version of the chapters, as well as for inclusion in the recommendations. The symposium was attended by 384 persons, 280 from Mexico, 51 from the United States and 43 from Canada, representing all sectors of society. It was one of the rare occasions where companies producing hybrid seeds, academia, government, environmental and other NGOs, community groups *and* campesinos were in the same room to learn and debate on the subject in Mexico. Additional comments on the chapters and on potential recommendations were also received up to 10 April 2004, and forwarded to the authors and Advisory Group members.

The final Secretariat report was presented to the CEC Council for technical review on 14 May 2004. Although certain modifications were made following that review, the key findings and unanimous recommendations of the Advisory Group remain unchanged.

The sections comprising key findings and recommendations are organized according to themes: 1) transgenic maize and gene flow, 2) impacts on biodiversity, 3) impacts on health, and 4) sociocultural impacts in Mexico. In making its recommendations, the Advisory Group was cognizant of the Parties' adherence to various international agreements and treaties related to transgenic maize, as listed in **Table 4**, and of the countries' national approaches to overseeing biotechnology. The Advisory Group was guided by the best scientific knowledge available, in all aspects where it is applicable, in drawing its findings and recommendations. However, the Advisory Group also recognizes that a number of important social and cultural issues are also at play. The Advisory Group has attempted to give its best evaluation of sociocultural issues but yet keep those considerations distinct from the scientific evidence about health or environmental impacts.

Frameworks and Approaches Considered in the CEC Maize Study

The Advisory Group considered that policy options may include the following non-exclusive approaches of risk avoidance, risk mitigation, and risk tolerance. Examples of risk avoidance are options that restrict the import and commercial planting of GM maize. Risk mitigation might include policies to remove transgenes from affected maize varieties. Risk tolerance options include communication of risk and involvement of interested and affected parties in development of management strategies that maintain the risk within limits acceptable to those parties.

Table 4. International Agreements and Treaty Obligations of the NAFTA Countries

	Canada	Mexico	United States
North American Free Trade Agreement	Party	Party	Party
Convention on Biological Diversity	Party	Party	Signatory
Cartagena Protocol on Biosafety	Signatory	Party	—
CODEX ALIMENTARIUS Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology	Member	Member	Member
International Treaty on Plant Genetic Resources for Food and Agriculture	Ratified	—	Signatory
International Union for the Protection of New Varieties of Plants (UPOV Convention)	Signatory (1978 Act)	Signatory (1978 Act)	Signatory (1991 Act[1])
World Trade Organization (including TRIPS Agreement)	Party	Party	Party

Canada, Mexico and the United States are members of the World Trade Organization. Any recommended policy must conform to the principles of the Sanitary and Phytosanitary (SPS) Agreement, such as those specifying that SPS measures cannot offend the principle of non-discrimination, are least trade restrictive, and are presumed consistent with the SPS agreement if they conform to major international standards. The Technical Barriers to Trade (TBT) Agreement was considered, which provides that technical standards must be nondiscriminatory (Article 2.1) and not more trade restrictive than necessary to realize a legitimate objective (Article 2.2). Governments are also encouraged to seek equivalence of technical matters and mutual recognition of conformity assessment procedures to reduce the restrictiveness of the measure.

The Advisory Group considered the Convention on Biological Diversity (CBD), ratified by Mexico and Canada and signed but not ratified by the United States, which encourages respect for indigenous peoples and wider application of their traditional knowledge and equitable sharing of benefits arising from it [according to Article 8(j)], and endorses a precautionary approach to risk assessment [in Article 8(g)].

Such a precautionary approach is furthered in the Cartagena Biosafety Protocol under the CBD, which applies to transboundary movement, transit, handling and use of all living modified organisms (LMOs) (Article 4), in such provisions as are found in Article 10.6

[1] With a reserve pursuant to Article 35(2).

"Decision Procedure,"[2] Article 11.8[3] and, particularly, as are set forth in the Protocol's Annex III, which suggests that risk assessment be carried out on a case-by case basis that depends on the living modified organism, its intended use and the likely potential receiving environment. Mexico and Canada have both signed the Protocol and Mexico has ratified it, binding itself to the Protocol's requirements and obligations. While neither Canada nor the United States is party to the Protocol, both have indicated they will work with parties to it to address concerns related to trade in LMOs (Living Modified Organisms). The Protocol provides for socioeconomic issues to be taken into account in the regulation of the transboundary movement of living modified organisms: parties "may take into account, consistent with their international obligations, socioeconomic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities" (Article 26).

The Advisory Group considered the principles developed by the Canadian Biotechnology Advisory Committee that precautionary measures should be: (1) proportional to the potential severity of the risk being addressed and be effective, taking into account the benefits and costs of actions or lack of actions; (2) subject to reconsideration on the basis of the evolution of science, technology and society's views about the acceptable level of protection; (3) non-discriminatory between situations presenting similar risks and consistent with measures taken in similar circumstances; (4) the least trade-restrictive option where more than one option exists; and (5) administered in a transparent and accountable way, providing for public involvement.

The Advisory Group considered the principles and practices developed by the United States government for the regulation and oversight of biotechnology, as proposed by the Office of Science and Technology Policy (OSTP) in 1986 and modified subsequently by the OSTP, US Department of Agriculture, US Environmental Protection Agency, and Food and Drug Administration.

The Advisory Group considered the provisions of Article 282 of the General Law of Health, enforced by the Mexican Ministry of Health, which establishes a mandatory requirement of notification of the intention to introduce a biotechnology product into the market. This requirement is met by the exporter throughout the submission of a food safety analysis dossier to be revised by the Federal Commission for the Prevention of Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*—Cofepris). Cofepris communicates the end resolution of the assessment and publishes a "positive list" of the transgenic crop and specific trait approved for consumption (see <http://www.cofepris.gob.mx/pyp/biotec/biotec.htm>).

[2] Article 10.6 of the Protocol states: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects."

[3] Article 11.8 states: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects."

The Advisory Group also considered the trilateral arrangement "Documentation Requirements for Living Modified Organisms for Food or Feed, or for Processing (LMOs/FFPs)," signed in October 2003 between Canada, Mexico and the United States in order to clarify documentation requirements such that they fulfill the objectives of the Cartagena Protocol on Biosafety without unnecessarily disrupting commodity trade (see <http://www.agr.gc.ca/itpd-dpci/english/topics/bsp_trilateral.htm>)

Finally, the Advisory Group considered that, as of the end of 2003, the United States has registered or deregulated approximately 20 transgenic maize varieties for commercial use, while Canada currently has approximately 10, and Mexico has authorized six varieties for importation as food feed or for processing but none for commercial cultivation. Therefore, imports might contain a mix of authorized and unauthorized varieties. These discrepancies highlight a clear need for capacity building of the Mexican Health Sector for detection and food safety risk assessment see (see <http://bch.biodiv.org/database/record.aspx?searchid=122521&recordid=1358>).

Key Findings

Context of GM maize in Mexico

High levels of poverty, dependence upon agriculture by large populations for income and food security, and a significant indigenous population distinguishes rural Mexico from that of Canada and the United States. There is a “rural crisis” in Mexico of poverty, migration, and dislocation as the Mexican economy moves from a rural and agricultural base toward an urban majority and an economy based in manufacturing and services. In the regions of maize landrace cultivation, there is recent cultural memory and political history among the indigenous peoples of perceived inequity and injustice at the hands of Mexicans of Spanish origin, Americans, and powerful elites. The issue of transgenic maize impact on landraces has become entwined with historical issues and grievances affecting rural Mexicans that are not directly associated with either improved maize or traditional landraces. Similarly, those who advocate greater use of genetic engineering and unrestricted trade may have vested interests in aspects of scientific and technical development, trade, political influence, or industrial agriculture in Canada, Mexico and the United States.

All of the above issues have become intertwined in the debate over the impacts of the presence of transgenes in Mexican landraces. Care needs to be taken by decision makers to recognize the impact of broader issues upon the views and interests of proponents and opponents of transgenic maize in Mexico.

Gene Flow

Gene flow among maize varieties and wild relatives in Mexico

1. Gene flow between landraces of maize—as well as between landraces and modern varieties—has been demonstrated to occur experimentally and descriptively. All strains of maize, *Zea mays* subsp. *mays*, are interfertile and produce fertile progeny.
2. Descriptive studies have demonstrated that gene flow between maize and teosinte occurs, but it is not known how long maize genes persist in teosinte populations after hybridization has occurred in the field. The rate at which crop genes enter teosinte populations may be limited by partial genetic barriers and subsequently by the relative fitness of the hybrids.
3. Gene flow is important in the dynamic process of on-farm (*in situ*) management of maize genetic resources in Mexico. Mexican farmers often trade seeds, sow mixtures of seeds from different sources, including the occasional modern hybrid variety, and often allow and intend, cross-pollination between different strains to occur when they grow close together. Despite gene flow, farmers are able to select and perpetuate different landraces and cultivars.

Presence and sources of transgenes in Mexico

4. Transgenes have entered some landraces of maize in Mexico. This finding was confirmed by scientific studies sponsored by the Mexican government. However, no peer-reviewed summaries of this work have been published and information

released to the public has been vague. In any event, there is no doubt that transgenes will spread in Mexican maize, and that they are present now.

5. Transgenes, like other alleles from modern varieties, are expected to enter local landraces once they have been introduced into a given region. Whether novel alleles (transgenic or not) eventually increase or decrease in frequency will depend on a variety of factors (see below).

6. Living transgenic maize is continuously entering Mexico—especially through grain imports, but it may also be carried by migrant workers returning from the United States. The probable primary source of transgenes present in Mexican landraces is maize grain grown in the United States.

7. Based on the proportion of transgenic maize grown currently in the United States, maize imports to Mexico from the United States are likely to be approximately 25 to 30 percent transgenic. Transgenic maize is not labeled or segregated in the United States after harvesting, and it is mixed together with non-GM maize. The two transgenic varieties most commonly grown in the United States have two engineered traits, respectively: (1) Bt transgenes for resistance to certain insect larvae and (2) other transgenes for resistance to certain herbicides <see http://www.isb.vt.edu/>. A few varieties with transgenic male sterility have been deregulated in the United States. Also, some maize varieties that commercially produce industrial compounds are grown in the United States under permit. The planting of transgenic maize in the United States and Canada continues to increase. Likewise, new types of transgenic maize are being developed and are likely to be deregulated in these countries within the next few years.

8. One type of transgenic (Bt) maize known as Starlink™ is no longer allowed to be planted in the United States. In 2000, Starlink™ was grown widely in the United States after it was approved for animal feed only. Starlink™ maize inadvertently entered the US food supply, but no health or environmental harms have been linked to this event. The Starlink™ transgene is still found in the US grain system at low frequencies. It is not known whether the Starlink™ Bt transgene is present in Mexican landraces of maize, although this seems unlikely; however, peer-reviewed publications on this topic are as yet not available.

9. Non-deregulated, non-commercialized maize varieties with dozens of other transgenic traits have been cultivated in small-scale field trials in the United States and Canada (see <http://www.isb.vt.edu/> and <http://www.inspection.gc.ca/english/sci/biotech/gen/pntvcne.shtml>). These transgenes are much less likely to spread into Mexico than the widely grown commercial transgenes because they are grown in small plots and the US Department of Agriculture and the Canadian Food Inspection Agency (which regulate field trials in those countries) require strong confinement of experimental transgenes. It is not known if transgenes from early field trials in Mexico (prior to 1998) are present in Mexican maize, although this may be unlikely.

10. A probable pathway of transgene introgression (i.e., the spread and persistence of transgenes) into landraces is as follows: imported transgenic grain that is shipped to rural communities through a government agency (e.g., Diconsa, S.A. de C.V.) may

be experimentally planted by small-scale farmers. Indeed, small-scale farmers are known to plant Diconsa seeds occasionally, adjacent to their local landraces. Cross-pollination can occur between modern cultivars and landraces that flower at the same time and grow near each other. Farmers save and trade seed, some of which may be transgenic, and thus the cycle of gene flow can be repeated and transgenes can spread further.

Persistence of transgenes in landraces and teosinte

11. Novel alleles introduced by gene flow may or may not persist in recipient populations depending on: (1) whether gene flow is a one time or recurrent event, (2) the rate of gene flow, and (3) whether the novel allele is locally detrimental, beneficial, or neutral and depending on the size of the recipient population. These principles apply to both conventional genes and transgenes.

12. Transgenes that are beneficial or selectively neutral have the potential to persist indefinitely in landraces of maize. Frequencies of transgenes are expected to increase in landraces if farmers have a preference for these traits or if the transgenes confer a reproductive advantage to the plant.

13. Bt transgenes have the potential to be selectively favored in recipient populations if they protect the plants from damage from certain insect pests. Transgenes for herbicide resistance are expected to be selectively neutral unless the recipient population is exposed to the herbicide in question, in which case they would confer a selective advantage. These expectations are based on the assumption that there are no other phenotypic changes in the transgenic variety other than the intended trait.

14. Removing transgenes that have introgressed widely into landraces is likely to be very difficult and may in fact be impossible.

15. It is not known definitively whether transgenes or other crop genes are able to persist permanently in populations of teosinte after hybridization has occurred.

Expected effects of transgenes on the genetic diversity of landraces and teosinte

16. There is no reason to expect that a transgene would have any greater or lesser effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars.[4] The scientific definition of genetic diversity is the sum of all of the variants of each gene in the gene pool of a given population, variety, or species. The maize gene pool represents tens of thousands of genes, many of which vary within and among populations. Transgenes are unlikely to displace more than a tiny fraction of the native gene pool, if any, because maize is an outcrossing plant with very high rates of genetic recombination. Instead, transgenes would be added to the dynamic mix of genes that are already present in landraces, including conventional genes from modern cultivars. Thus, the introgression of a few individual transgenes is unlikely to have any major biological effect on genetic diversity in maize landraces.

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[4] Bellon, M.R., and J. Berthaud. 2004. Transgenic maize and the evolution of landrace diversity in Mexico: the importance of farmers' behavior. *Plant Physiol.* 134(3).

17. Note: Possible ecological effects of transgenes that *might be* different from those of other crop genes are discussed in another section of this report, along with the fact that some people think that transgenes could be deleterious to human health, the landraces themselves, or the environment, and therefore perceive transgenes to be a form of genetic pollution. These issues are distinct from questions about how transgenes affect genetic diversity and future crop breeding.

18. Modern agricultural practices have real and significant impacts on the genetic diversity of Mexican landraces. For example, economic pressures associated with modern agriculture and the current asymmetries and economics of US-Mexican maize trade could cause some small-scale farmers to abandon their use of indigenous landraces. The specific problem of genetic erosion in maize is caused by many interacting socioeconomic factors. The potential direct and indirect effects of transgenic maize on this problem are unclear.

19. A combination of *ex situ* and *in situ* conservation is necessary to optimally maintain the genetic diversity held in landraces. *Ex situ* conservation of landrace diversity alone is not sufficient because landraces are evolving entities. Likewise, *in situ* conservation (by farmers) alone is not sufficient to preserve genetic diversity because it does not necessarily capture the diversity of the past.

Biodiversity

1. Biodiversity is a term that applies to all species, their genetic variability, and the communities and ecosystems in which they occur.

2. According to the Convention on Biological Diversity, biodiversity has “ecological, genetic, social, economic, scientific, educational, cultural, recreational, and aesthetic values” essential for human life.

3. The diversity of maize in Mexico is maintained primarily by local and indigenous farming communities. This system allows the conservation of the maize genetic resources that constitute the basis of food and agricultural production. In the last six or seven decades, institutions in Mexico such as the *Instituto Nacional de Investigaciones Forestales, Agricolas y Pecuaries* (the National Institute for Research in Forestry, Farming and Animal Husbandry—INIFAP), the *Centro Internacional de Mejoramiento de Maíz y Trigo* (International Maize and Wheat Improvement Center—Cimmyt), the institutions of higher education, and some foreign sources, especially the United States, have contributed to this genetic diversity through the generation of a number of novel varieties of maize.

4. The landraces of maize in Mexico have been produced dynamically and are changing continuously as a result of human and natural selection. They are not static or discrete entities, but the term “landrace” refers to the different regional strains of maize in Mexico.

5. With specific reference to maize in Mexico, there are three areas of biodiversity that have special interest:
    - The genetic diversity of maize and the species of teosinte, all of the members of the genus *Zea*.

- The diverse assemblages of plants and animals that regularly occur in the fields where maize is cultivated.
- The biodiversity of neighboring natural communities and ecosystems.

6. All three of these areas pose important concerns and yield the following conclusions:
    - There is no evidence to suggest that the patterns of inheritance of transgenes in Mexican maize or teosintes differ from their behavior in other organisms, or from the behavior of genes and genetic elements, in general.
    - Neither negative nor positive effects of transgenic maize on the plants and animals occurring with them in Mexican maize fields, or milpas, have been reported; however, specific studies have still to be conducted.
    - The biological characteristics of maize and the teosintes are such that they appear very unlikely to spread into neighboring communities, whether they are transgenic or not. However, the effects of GM maize on target and non-target insects moving between maize fields in Mexico and adjacent natural communities are unknown.
    - Agriculture, however practiced, reduces the overall level of biodiversity from its pristine condition. It is an open question whether productive, concentrated agriculture affects biodiversity more than dispersed, less intensive and less productive systems.
7. Scientific investigations and analyses over the past 25 years have shown that the process of transferring a gene from one organism to another does not pose any intrinsic threat over the short or long term, either to health, biodiversity or the environment. It is, therefore, the characteristics of any organism and strain that should be examined in determining the risks or benefits of that organism or strain, regardless of whether the new genes are transgenes or not.

Health

1. There is no empirical evidence that the process of producing GM crops is hazardous or beneficial *per se* to animal or human health. It is the products of transgenic plants, like those of any form of crop improvement, including conventional plant breeding, that need evaluation for their positive and negative effects.
2. The amount and form in which maize is consumed differs greatly between Mexico and most other countries. It is fundamental to the Mexican diet, and both currently approved and future transgenes proposed for introduction in Mexico need special consideration for this reason.
3. Producing pharmaceuticals and certain industrial compounds that are incompatible with food and feed in food crops poses unique risks to human health. This is of special concern in maize, which is a staple food produced following open pollination.
4. Expression of public sentiment at the CEC public symposium and in written comments suggests that there may be levels of concern about toxicity of GM maize among the Mexican public that are significantly high—enough so to require a policy

response that may include specific research as well as public information and education.

Sociocultural Matters

The maize system in Mexico

1. National policy choices and the effects of global maize markets, particularly in relation to US exports into Mexico, account for the fact that Mexico is not currently self-sufficient in maize production.
2. The maize industry is a highly complex and structured system in Mexico (involving actors as varied as millers, importers, transporters, and large- and small-scale tortillería managers). The maize supply chain in Mexico includes extensive mixing, pooling, and exchange of seed and grain among actors.
3. Experimental planting and breeding of maize is a millennia-long tradition that is at the core of the generation of the many native landraces of maize. Mexican landraces are neither genetically static nor genetically homogenous: they are constantly being changed by those who use them. As part of this process, genes from improved/modern varieties are sometimes deliberately or inadvertently introduced into the landraces.
4. Campesinos are smallholder producers who farm less than five hectares of mostly rain-dependent land. Campesinos include private landowners and farmers of communal lands, including *ejidos* and *communidades indigenas*. They constitute over two-thirds of the maize producers in Mexico.
5. Fertile grain in government silos intended for industrial processing and animal feed is accessible to campesinos for unintentional or intentional planting and experimentation.
6. Campesinos regard freedom to exchange seed, to retain seed for future planting, and experimentation with new seeds as fundamental to preservation of their landraces and their cultural identity and communities.
7. In general, there have not been formal systems among campesinos for *in situ* or *ex situ* conservation of landraces for the purpose of preserving genetic diversity. However, there are some formal systems among indigenous communities for *in situ* maintenance of specific maize varieties for cultivation and breeding.
8. Traits in current GM maize varieties of herbicide tolerance and insect resistance have not been specifically demonstrated to be beneficial to campesinos in Mexico and do not appear, in themselves, to address their most pressing needs.

Cultural significance of maize and public perceptions of GM maize

9. Maize has significant cultural, symbolic, and spiritual values for most Mexicans. This is not the case in Canada and the United States. The risk assessment of transgenic maize in Mexico is inextricably linked to these values.
10. Although teosinte is considered by some to be a weed that reduces productivity, it is kept in milpas in many areas because it is considered the “mother of maize.”

Teosinte is thereby a source of genetic variability for the different wild species of the genus *Zea* and for the planted landraces or varieties of maize.

11. There are a number of Oaxacans, especially campesinos, who consider the presence of any transgenes in maize as an unacceptable risk to their traditional farming practices, and their cultural, symbolic, and spiritual value of maize. That sense of harm is independent of its scientifically studied potential or actual impact upon human health, genetic diversity, and the environment.

12. Furthermore, to many people in rural Mexico, the introgression of a transgene into maize is not acceptable and is considered a "contamination," as expressed in writing and presentations submitted during the Article 13 process.

13. Risk assessment of transgenic maize in Mexico is inextricably linked to the central role of maize in Mexico's history and culture, including the beliefs and value systems of indigenous people.

14. Only a few, insufficient efforts have been made to communicate or demonstrate possible benefits of GM maize to smallhold farmers by crop developers or the Mexican government.

15. So far there is no evidence that introgression of today's GM maize traits poses a significant harm to health or the environment in Canada, Mexico or the United States. However, this has not been studied in the context of Mexican ecosystems.

16. Many campesinos and the community organizers who are most vocal and concerned with transgenic gene flow perceive GM maize as a direct threat to political autonomy, cultural identity, personal safety and biodiversity. Many campesinos do not perceive any direct benefit to them from the current transgenic maize.

Public institutions and processes

17. Just as there is a low level of information about the fundamentals of plant genetics and transgenic technologies in rural communities, so there is also a low level of information about rural social and cultural concerns within scientific and policy communities. These knowledge gaps frustrate the generation of scientifically sound and socially acceptable policies.

18. The introduction of transgenic maize to Mexico through officially legal and sanctioned import of grain from the United States has occurred in the absence of any formal process of information to or consent within rural communities. Lack of consultation is understandable since the introduction of GM maize into rural communities was an unexpected result of its importation as food or through informal seed exchange, and not a part of a government plan to introduce such crops.

19. Many people living in rural communities and many NGOs distrust the governments and the institutions entrusted with biosafety (as expressed in the findings of the Article 13 process). Mexican government regulators have been unable to implement laws, *partly* because some NGOs oppose experimental plantings of transgenic crops. Timely or reliable information to stakeholders on the potential implications of GMO technologies has not been provided.

20. The response in the public symposium organized by the CEC suggests that such forums as may have been hosted by the Mexican government for the expression of public concerns about GM maize or for communication of information about potential benefits have not been adequate for the campesinos in Oaxaca and neighboring areas.

Policy environment in Mexico regarding GM maize

21. The three NAFTA countries have significantly different capacities to undertake scientific research, regulatory assessment and enforcement of policies though Mexico's capacity will be improved by a project of over US$1 million, supported by the United Nations Development Programme and the Global Environment Facility, to assist Mexico to implement its biosafety policies. The official Mexican government positions regarding transgenic maize and the roles and responsibilities of specific government departments to regulate transgenic maize are either unknown or not understood by the public.

22. The maize transgenes that have found their way into Mexico have not undergone risk assessment for environmental, health, social, or economic risks by Mexican national public institutions as they have within the United States and Canada. The regulatory agencies of the United States and Canada do not carry out a formal risk assessment for the consequences of transgenes beyond their borders.

23. There are currently no mechanisms for systematic monitoring of transgenes in Mexico.

24. The policy of a moratorium on commercial transgenic maize planting is undermined by the unapproved cultivation of imported maize and does not accomplish its aim if imports of unlabelled, unsegregated, and fertile GM maize from the United States are allowed.

25. By ratifying the Biosafety Protocol, Mexico demonstrated its commitment to apply the "precautionary approach" *to the regulation of the transboundary movement of living modified organisms*.

26. Though a conventional risk analysis could be conducted for the case of *imported* GM maize in Mexico, it is appropriate in the Mexican context to incorporate precautionary assumptions into the scientific assessment and management of all risks and to recognize the significance of informed consent in the acceptability of the these risks.

27. In the context of international trade agreements, if Mexico wishes to address the socioeconomic concerns of the campesino farmers, there is at least a strong *prima facie* case that it would be "socially acceptable" to protect the campesinos and their landraces as well as the needs of other groups who may be impacted by changes in current policy. It is clear that the maximum reduction of the risks of transgene introgression into Mexican landraces might be accomplished by a total ban on importing living modified organisms in the form of transgenic maize into Mexico. However, the economic price and trade restrictiveness of this measure for both the United States and Mexico would seem to be unacceptably high.

Recommendations

The following unanimous recommendations to the CEC Council are informed not only by the preceding key findings but also by the background volume, comments received throughout the process, including at the March 2004 symposium, and the best professional judgment of the interdisciplinary, multi-stakeholder advisory group that was tasked to formulate these recommendations.

Gene Flow

1. Additional research is needed to determine which specific transgenes have entered Mexican landraces, and perhaps into wild populations of teosinte, and their frequency, with full public disclosure and explanation of the findings, and prompt publication in peer-reviewed scientific journals.
2. In order to develop biosafety policy, biodiversity conservation strategies, and plans for the future potential application of genetic engineering in Mexico, research is needed to determine the extent to which genes from modern cultivars (including transgenes) have entered, backcrossed, and introgressed into landraces and teosinte via pollen and seed flows in the context of modern and traditional maize systems. Theoretical and empirical research should specifically test whether the presence of individual genes from modern cultivars (including transgenes) has any major biological effect on the genetic diversity of maize landraces or teosinte. In addition, researchers should explicitly test the assumption that transgenes from grain supplied by different grain traders, like Diconsa, have been and continue to be the main source of existing transgenes in landraces.
3. Regulatory agencies of the three countries should develop and implement better methods for detecting and monitoring the spread of specific transgenes, such as unique identifying genetic markers (including the specific transgene locus) and the transgene products (such as specific Bt proteins) that can be recognized easily, reliably, and inexpensively.
4. In order to develop appropriate regulatory policy and biodiversity conservation strategies, research is needed to determine the consequences of gene stacking (multiple novel genes, including transgenes) *via* gene flow on the fitness and yield of recipient plants, because the cumulative effects of multiple genes may have different consequences than single genes, and this could influence the persistence of transgenes in recipient populations of landraces and teosinte.
5. Until adequate research and risk/benefit assessments of the effects of gene flow from transgenic maize to landraces and teosinte have been conducted and more information is made available to the campesino farming community, the current moratorium[5] on planting commercial transgenic maize in Mexico should be

[5] The Mexican government lifted the *de facto* moratorium for the experimental field release of GM maize in June 2003. The reason for this was the need to answer specific scientific questions related to the possible presence of GM maize on Mexican territory. The National Institute of Ecology (INE), Semarnat and Conabio have been meeting to generate recommendations for defining guidelines and conditions on conducting experiments with GM maize. In July 2004, INE

enforced. However, this should not apply to carefully planned and contained experimental planting, if good and scientifically sound information is sought to answer most questions dealing with risk assessment of transgenic maize varieties and their potential impacts.

6. Because the persistence and spread of new genes depends so much on the gene flow rate, the Mexican government should strengthen the moratorium on commercial planting of transgenic maize by minimizing the import of living transgenic maize grain from countries that grow transgenic maize commercially. For example, some countries have addressed this problem by milling transgenic grain at the point of entry.
7. The Mexican government should directly notify local farmers that maize grain distributed by Diconsa is likely to contain transgenic materials and should not be planted under existing regulations. This effort should include clear labeling of Diconsa grain bags, containers, and grain silos, and a strong commitment to educating affected farmers about this issue.
8. Potential methods for eliminating transgenes from landraces should be evaluated and developed in case subsequent decisions are made to the effect that such action would be desirable. Small-scale farmers should be involved in the development of these methods.
9. Any policy for managing the spread of transgenes in maize should not interfere with traditional forms of gene flow in the landraces because these promote genetic diversity and are the foundation of local food security.
10. More effective programs are needed to provide both *in situ* and *ex situ* conservation of the genetic diversity of maize.

Biodiversity

1. The changing genetic nature of maize and teosinte populations in Mexico should be monitored on an ongoing basis, both for existing genes, transgenic or not, and new genes that become established in the future. The monitoring system should provide information to the public in a timely manner.
2. The genetic diversity of Mexican races of maize and teosinte should be conserved both in nature and in agriculture, and in *ex situ* cultivation and seed banks. Mexican, international, and private-sector funding should be made available for this exceedingly important effort.
3. Human capacity building in Mexico should be supported for specialists in all aspects of maize study and improvement, from molecular genetics to ecology, including the economics and social sciences involved.

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circulated a draft of these guidelines for revision to experts who had participated in a workshop on the issue last December. In a parallel effort, the Ministry of Agriculture (SAGARPA) has requested the *Subcomité Especializado de Agricultura* (SEA) of CIBIOGEM, in charge of biosafey risk evaluations, to prepare specific guidelines for the experimental release of GM maize. Applications for the commercial release of maize are not currently being accepted in Mexico.

4. Many aspects of the cultivation and improvement of maize in Mexico need further study, with special attention being given to the role and needs of campesinos, which have largely been neglected.
5. The direct and indirect effects of the cultivation of genetically modified maize on the assemblages of plants and animals, many of them useful, which occur with the maize in milpas and other Mexican agricultural systems, and on biodiversity in the neighboring natural communities, need urgently to be examined and evaluated.
6. The further development of maize cultivation in Mexico needs to take into account the needs and the potential benefits and risks for campesinos, small-scale producers, and large-scale commercial agriculture.
7. Farmers of all sorts should be involved in the development of new agricultural practices from the start of the process.

Health

1. Research into the ways in which the consumption of large amounts of maize might amplify hypothetical positive or negative effects from particular varieties or genetically modified strains is urgently needed.
2. The modification of maize to produce pharmaceuticals and certain industrial compounds that are incompatible with food and feed should be prohibited, in accordance with the stated intentions of the Mexican government, and serious consideration should be given to banning such use for maize in other countries.

Sociocultural Matters

1. The Parties to the NAAEC should adopt policies to reduce the risks identified to a level "as low as is reasonably achievable." This safety standard ("ALARA") is a widely recognized and invoked regulatory standard for health and environmental risk in the member countries of NAFTA and elsewhere.[6] Given the fact that certain transgenes are already present in Mexican maize and landraces, and that 'zero-risk' is no longer a feasible standard, the ALARA approach seems most reasonable at this time.
2. Steps should be taken to reduce the probability of unapproved GM maize planting in Mexico by supporting the current moratorium on commercial transgenic maize planting. A significant and 'reasonably achievable' reduction of *any* risks that might

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[6] ALARA is an approach to control or manage exposures (both individual and collective to the workforce and the public) and releases to the environment as low as social, technical, economic, practical, and public policy considerations permit. ALARA is not an exposure limit; it is a practice that has as its objective the attainment of exposure levels as far below applicable limits as possible. This affords a wider margin of error should a control fail or malfunction—one's exposure level may rise but still stay below the acceptable limit. This common-sense approach means that exposure for both workers and the public are typically kept lower than their regulatory limits. ALARA is not simply a phrase, but a work principle, a mindset, a culture of professional excellence. In an ideal world, one could reduce his exposure to hazardous materials to zero. In reality, reducing an exposure to zero is not always possible; certain social, technical, economic, practical, or public policy considerations will result in a small but acceptable level of risk. ALARA practices are mandated for radiation workers by the US Nuclear Regulatory Commission.

be demonstrated could be accomplished by implementation of the following measures:

a. A requirement that maize imported from the United States be labeled as potentially containing GM maize or else certified as GM-free (Canada does not currently export bulk maize to Mexico).

b. A requirement that all maize imported into Mexico from Canada and the United States that is not certified as GM-free be directed without exception to mills for processing. A required system of 'end-use certificates' for all such imports may be an implementation mechanism.

c. Programs to educate farmers to avoid planting seeds that may contain GM maize and not to plant any seeds brought from the United States or other countries where transgenic maize is grown.

d. Implementation of procedures to ensure involvement of smallhold farmers in the development of new Mexican biotechnology policies that are adequate and acceptable to all parties.

3. The Mexican government should initiate a communication and consultation program with campesinos on the benefits and risks of transgenic maize.

4. Campesinos should be supported in their efforts to protect and preserve the unique biodiversity in Mexican landrace maize. This may involve direct payments to farmers who are willing to sustain their traditional farming operations and adopt breeding practices that preserve landraces in a way that prevents or minimizes the introgression of genes from other sources and localities.

5. A quality assured landrace seed program should be developed. Campesino farmers may submit their own seed and any other materials they intend to use for breeding to labs for investigation of the presence of any GM traits. This measure may also require regional registration of campesino breeders and the development of a management system (which could provide a basis for campesinos protecting their traditional knowledge, creating the base for a differentiated food product). If effective, this would both limit introgression of new transgenes and detect and also allow for the removal of any transgenes currently in campesino seeds.

6. Increase public support of *in situ* conservation of landrace diversity. Provide support of community seed banks, farmer training and extension, registration and codification of local and traditional knowledge, and greater scientific research into landrace character and identity.

7. Harmonize the assessment and management of biosafety risks through greater coordination of research and regulatory policies in Canada, Mexico and the United States, as proposed under the North American Biotechnology Initiative. Information and knowledge on the attributes and risks of any new crop cultivated in all three countries is needed before such a crop is commercialized. This information is required to determine what, if any, confinement methods may be needed to prevent the movement of certain LMOs across international boundaries. This may ideally involve product proponents making a coordinated application for regulatory review in all three markets but in many cases it may not be commercially appropriate to

release a new product simultaneously in all markets. To ensure complete regulatory oversight, there should be greater information exchange among regulators in the three countries in order that no products are released without the knowledge of all three governments. Ideally, harmonization should address risks both specific to individual countries and those common to one or more of the countries.

Appendix: Petition to the Commission for Environmental Cooperation to Produce an Article 13 Report under the North American Agreement on Environmental Cooperation (Executive Summary)

24 April 2002

The petitioners, communities affected by the genetic contamination, are requesting that the Secretariat of the Commission for Environmental Cooperation (CEC) prepare a report on the potential direct and indirect environmental impacts on biodiversity caused by the release of genetically engineered maize in Oaxaca. The petitioners are requesting preparation of this report according to Article 13 of the environmental cooperation side agreement of the North American Free Trade Agreement (NAFTA).

Background on maize contamination

In September 2001, Mexican government officials reported contamination of local varieties of maize with transgenic sequences in communities in the states of Oaxaca and Puebla. In January 2002 the Mexican government further reported that in 11 of the communities, contamination levels were between three and 13 percent; in four localities, levels of contamination found were much higher—between 20 percent and 60 percent. In Diconsa (the Mexican government food distribution agency) stores, 37 percent of the grains were found to be transgenic.

This contamination cannot be considered merely a national problem. Impacts on the genetic diversity of Mexican maize could have direct repercussions on the diversity of maize and ecosystems in all of North America and the rest of the world. Mexico is one of the centers of origin for maize. To lose a variety of maize in Mexico is to lose it throughout the planet.

Moreover, the contaminating genes will certainly have broader impacts on biological diversity in Mexico. One of the potential contaminating genes produces a pesticide—the Bt toxin—that is known to have effects on organisms other than the target pests found in the United States.

Because of the international nature of the impacts of this genetic contamination, the petitioners have taken the case to the regional environmental body that was established under NAFTA, the Commission for Environmental Cooperation (CEC).

What is the Commission for Environmental Cooperation?

The North American Commission for Environmental Cooperation is a body composed of the top environmental officials from Canada, Mexico and the United States, set up under the North American Agreement on Environmental Cooperation (NAAEC), an environmental side agreement to the North American Free Trade Agreement (NAFTA). The NAAEC was intended to ensure that each government is effectively enforcing [its] environmental laws.

As it has the authority to examine environmental threats that may be occurring on a regional level or across national borders, the CEC provides an important mechanism for citizens to raise concerns about the enforcement of environmental laws within the three NAFTA countries.

What is the Article 13 process and why is it being used now?

Under Article 13 of the NAAEC, the CEC Secretariat has the authority to initiate independent investigations and prepare reports on environmental issues that are within its broad work program. Several Article 13 reports have been prepared in the past, including others that were initiated following a petition from citizens and nongovernmental organizations, such as the 1995 report on the massive bird kill at the Silva Reservoir in the state of Guanajuato in Mexico. The CEC may also examine environmental issues outside of its work program, unless blocked by two of the three NAFTA parties.

In preparing a Secretariat report under Article 13, the CEC is charged with gathering information from a variety of sources, including through public consultations with affected communities and from submissions from nongovernmental organizations. Once completed, the CEC Secretariat submits a report to the Council of the CEC, and makes it public within 60 days, unless the Council decides otherwise.

Although the NAAEC does not provide for legally binding obligations to be imposed, the process will generate international attention to the direct and indirect impacts of genetic pollution—in this case, contamination from the environmental release of genetically engineered maize in Mexico—that can be useful for putting public pressure on the offending countries.

What are the petitioners specifically requesting from the CEC?

The petition that is being filed is a request under Article 13 of the NAAEC asking the CEC Secretariat to prepare a report to examine direct and indirect environmental impacts that could occur if transgenic maize escaped in the state of Oaxaca. The petitioners have specifically asked for the following points to be considered in the report:

1. Carry out a valuation of the possible environmental impacts on maize biodiversity and ecosystems of Oaxacan communities that might arise from contamination by release of genetically engineered maize.
2. Carry out an analysis of the direct and indirect effects of gene flow from engineered maize on the genetic diversity of maize that exists in the affected communities in Oaxaca.
3. Carry out a valuation of the environmental impacts caused by the transgenic maize on ecosystem biodiversity where the contamination is found.
4. Determine the sources of contamination of native varieties of maize by genetically engineered varieties.
5. Analyze the risks of spreading the contamination of native maize varieties by the unintentional release of genetically engineered maize seeds.
6. Issue recommendations to the Mexican government to address the harm caused to native maize varieties by the release of genetically engineered maize.

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Glossary of Useful Terms[7]

(Cross-referenced terms are indicated in boldface type.)

allele – One of two or more alternate forms of a gene occurring at the same position (locus) on a **chromosome**, which control the expression of the **gene** in different ways. A cell or organism is homozygous when it contains identical alleles at a given locus, or heterozygous when there are two different alleles present. A gene for height, for example, may exist in two allelic forms, one for short and one for tall.

***Bacillus thuringiensis* (Bt)** – A group of soil bacteria found worldwide, which produce a class of proteins highly toxic to the larvae (immature forms) of certain taxonomic groups of insects. Bacterial spores (resistant forms) containing the toxin are used as an environmentally benign commercial pesticide favored for its high specificity. Bt strains (over 20,000 known) produce "cry" (crystal) endotoxin **proteins** that disrupt digestive function and lead to death in moths, butterflies, and certain other insects, including corn borers, cabbage worms, cotton bollworms, and other agricultural **pests**. Since 1989, genes expressing the cry proteins have been introduced into plants (see **Bt crop**) to confer insect resistance. Bt also refers to the insecticidal toxins.

biodiversity – The total variability within and among **species** of living organisms and their habitats, first used in 1986 to denote biological diversity. Usually refers to all heritable variation at all levels, and is generally divided into three levels: genetic (**genes** within a local population or species), taxonomic (the species comprising all or part of a local community), and ecological (the communities that compose the living parts of ecosystems). Human cultural diversity is sometimes viewed as a form of biodiversity. (See also **genetic erosion**; **genetic resource**.)

biosafety – The goal of ensuring that the development and use of **transgenic** plants and other **genetically modified organisms** (and products of **biotechnology**, in general) do not negatively affect plant, animal, or human health**, genetic resources**, or the environment.

biotechnology – The scientific or industrial manipulation of life forms (organisms) to produce new products or improve upon existing organisms (plants, animals, or microbes), first coined to apply to the interaction of biology and human technology. In recent usage, refers to all parts of the industry that creates, develops, and markets a variety of products willfully manipulated on a molecular and/or cellular level. While gene splicing (see **recombinant DNA** technology) is a major technique, the term generally includes other areas such as plant tissue culture, plant meristem culture, embryo transfer, cell fusion, enzyme systems, fermentation, and immunology. (Bioengineering is generally synonymous, although some use this term more narrowly to mean **genetic engineering** or **recombinant DNA** technology.)

Bt crop – A crop plant genetically engineered to produce insecticidal toxins derived from the bacterium ***Bacillus thuringiensis***. Current commercial Bt crops include Bt cotton, Bt corn, and Bt soybeans. (See also **pest-protected plant**.)

chromosome – A discrete, highly compact, thread-like structure carrying thousands of **genes** arranged in linear sequence. In higher (nucleated) organisms, including plants and animals and excluding bacteria, chromosomes are arranged in pairs and are found in the nucleus of every cell.

coat protein (CP)-mediated resistance (or protection) – Resistance of a plant to virus infection, obtained by splicing into the plant **genome** a viral **gene** expressing the coat (capsid) **protein** from a

[7] Adapted and supplemented (as indicated) from *Transgenic Crops: An Environmental Assessment.* Henry A. Wallace Center for Agricultural and Environmental Policy at Winrock International (January 2001). Used by permission.

(usually) related virus. The most widely used form of pathogen-derived resistance (PDR), shown to be effective across a number of crops and for a variety of RNA viruses, although the mechanism is poorly understood. With transformed plants containing virus-protective **transgenes**, which may be co-infected naturally by multiple viruses, **biosafety** concerns include creation of new viruses, expanded viral host ranges, or more severe viral diseases.

cultivar – A group of individual plants within a species which collectively is genetically distinct from any other, which is uniform in its overall appearance and which remains stable in its attributes.

DNA (deoxyribonucleic acid) – The basic genetic material found in all living cells (and some viruses), providing the blueprint for construction of **proteins**. When not actually being replicated (regenerated) within the cell, DNA exists as the so-called "double helix": double-stranded, chain-like molecules composed of nucleotide base pairs (the specific carriers of genetic information) and condensed into compact structures known as **chromosomes**. (See also **gene**.)

***ex situ* plant conservation –** Literally, "out of place"; referring to the conservation of plants outside their original or natural habitats, including gene banks or **seed banks**. National and international gene banks worldwide hold millions of plant accessions (distinct samples) for short or long-term storage, for the purposes of study, distribution, or use. Most gene bank collections provide unrestricted access to *bona fide* users (e.g., plant breeders). (Compare ***in situ* plant conservation**.)

fitness – A relative measure of an organism's reproductive efficiency (i.e., the relative probability of reproduction of a genotype), generally referring to Darwinian fitness. Components of fitness include survival, rate of development, mating success, and fertility, and pathogenicity in the case of microbes. Fitness is germane to hazard assessment of organisms engineered to contain foreign **genes**. Also called adaptive value. (See also **risk assessment**.)

GE crop (GM crop) – See **biotechnology**; **genetic engineering**; **GMO**; **transgenic**.

gene – The functional unit of heredity (the physical basis for the transmission of characteristics from parents to offspring), and the basic unit of biological diversity. A gene consists of a segment (locus) on a **chromosome** that corresponds, in most organisms, to a specific sequence of **DNA** subunits (nucleotide base pairs) and encodes for a specific product or has an assigned function. Some genes direct the synthesis of one or more **proteins**, while others have regulatory functions (controlling the expression of other genes). (See also **allele**; **biodiversity**.)

gene flow – The exchange of genes (in one or both directions) at a low rate between different (usually) related and sexually compatible populations of organisms; gene exchange results from the dispersal of gametes (mature reproductive cells, also called sex cells). In plants, gene flow usually occurs via transfer of pollen (male gametes), and includes the natural transfer of **genes** from genetically modified plants to wild relatives. Gene flow may threaten the diversity of **landraces**. Also called gene migration. Sometimes more loosely called gene transfer, but the latter term is more appropriately applied to transfer of genes via **genetic engineering** methods. (See also chloroplast **genome**; **non-target effect**; **transgene**; **transgenic**.)

gene (genetic) marker (or marker gene) – Any **DNA** segment that can be identified, or whose location on the **chromosome** is known, so it can be used as a reference point to map the location of other **genes**. A selectable marker gene produces an identifiable phenotype (i.e., observable characteristics) that can be used to track the presence or absence of other genes (e.g., genes of commercial interest) on the same piece of DNA transferred into a cell. (See also **genetic transformation**.)

genetic engineering (genetic modification) – The selective, deliberate alteration of an organism's **genome** by human intervention, by introducing, modifying, or eliminating specific **genes** through molecular biology techniques. Includes alteration of the genetic material of an organism in order to produce endogenous (internal) **proteins** with properties different from the unmanipulated organism, or to produce entirely different (foreign) proteins, as well as changes accomplished by less direct, less precise methods, such as induced mutation by application of chemicals or radiation. Some use "genetic engineering" (and synonyms) to mean gene splicing and **recombinant DNA** technology, although in more precise usage these latter terms specifically refer to joining DNA from different sources or species (e.g., plants and microbes) and introducing nonnative DNA (**transgene**) into an organism. (See also **transgenic**.) Conversely, some use "genetic engineering" more broadly to include any human intervention, including classical, conventional breeding techniques for crop improvement and other means of artificial selection. (See also **biotechnology**; **GMO**; **LMO**.)

genetic erosion – For agricultural crops, the process that diminishes genetic diversity in the gene pool (all **genes** within a population) of a particular crop plant. Forces leading to genetic uniformity—a narrowing of crop **germplasm—**include the widespread replacement of local **landraces** with more uniform modern varieties grown in monoculture (see also **Green Revolution**), habitat destruction, and socioeconomic changes.

genetic resource – Genetic material serving as a resource for present and future human use. For plants, includes modern cultivars (varieties), **landraces**, and wild and weedy relatives of crop species. Plant breeders rely on a broad, diverse genetic base to enhance crop yields, quality, or adaptation to environmental extremes. (See also **biodiversity**; **DNA**; **germplasm**.)

genetic transformation – The process whereby free **DNA** (i.e., nonchromosomal and associated with a **vector**) from a donor organism is transferred directly into a competent (i.e., receptive) recipient cell to produce a **transgenic** organism. (See also **recombinant DNA**.)

genome – The entire hereditary material of a cell or a virus, including the full complement of functional and nonfunctional **genes**. In higher organisms (including plants, animals, and humans) the genome comprises the entire set of **chromosomes** found within the cell nucleus. Sometimes refers to the complete (haploid) set of chromosomes carried by a gamete (sex cell).

genomics – The scientific field of study that seeks to understand the nature (i.e., **DNA** sequences) and specific function of **genes** in living organisms; in combination with bioinformatics, can be applied to development of **transgenic** crops and other biotechnologies. Includes mapping genes and genetic combinations.

germplasm – The total genetic variability available to a particular population of organisms, represented by the pool of germ cells (sex cells, the sperm or egg) or plant seeds. Also used to describe the plants, seeds, or other plant parts useful in crop breeding, research, and conservation efforts, when they are maintained for the purpose of studying, managing, or using the genetic information they possess (same as **genetic resources**). Also called germ plasm. (See also **biodiversity**.)

GMO (genetically modified organism) – The broad term used to identify organisms that have been manipulated by molecular genetic techniques to exhibit new traits. Also known as genetically engineered organism or GEO. (See also **genetic engineering**; **living modified organism**; **transgenic**.)

Green Revolution – The technological advancements in developing-country agriculture after 1960, usually referring to the development and use of high-yielding modern varieties of grain crops (especially rice and wheat) and associated use of chemical pesticides, herbicides, and fertilizers, and irrigation technology. Sometimes used more generally to indicate a capital-intensive approach to agricultural development, along with innovations in hybrid-seed technology (and accompanying displacement of locally adapted **landraces**).

herbicide-tolerant crop – A crop able to survive the application of one or more synthetic chemical herbicides, many of which are toxic to both crops and weeds. Includes those naturally tolerant and those **genetically engineered** to contain genes that make them insensitive to or able to detoxify herbicides, as an approach to chemical weed control. Also called herbicide-resistant crop.

hybridization – In crop science, the production of offspring (hybrids) from genetically unlike parents, by natural processes or by human intervention (i.e., artificial selection). In plant breeding, includes the process of cross-breeding two different varieties to produce hybrid plants. Hybrids may be less or more fit than either parent; the former condition is termed **outbreeding** depression, and the latter is called hybrid vigor (or heterosis). Hybrid offspring may result from pollen flow (**gene flow**) between **transgenic** crops and wild relatives. (In molecular biology, the term refers to fusing two unlike cells to produce monoclonal antibodies, and alternatively to the binding of complementary strands of **DNA** or RNA.)

***in situ* plant conservation** – Literally, "in its natural place," an approach to plant conservation using methods that include maintenance of wild plant **genetic resources** where they occur naturally, or maintenance of domesticated materials where they were originally selected and further developed. May include designating existing parks, wildlife refuges, or other protected areas as *in situ* reserves. Generally recognized as a strategy to complement ***ex situ* plant conservation**.

landrace – A crop variety having a broad genetic base (highly heterozygous in genetic terms) and resulting from centuries of development and adaptation to particular soil types and microclimates. Landraces have been improved by local farmers using traditional selection processes, rather than by professional plant breeding methods, and are an important source of diverse **genes** for plant breeders. (See also **allele**; **gene flow**; **genetic resource**; **race**.)

living modified organism (LMO) – As defined by the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, any living organism possessing a novel combination of genetic material obtained through the use of modern **biotechnology** (i.e., here defined as *in vitro* nucleic acid techniques, including **recombinant DNA** methods, and cell fusion techniques that overcome natural reproductive barriers). Some may use term as synonym for genetically modified organism (**GMO**).

non-target effect – Generally, an ecological effect stemming from intentional introduction of plants, chemicals, or microbes to natural, agronomic, or forest ecosystems, and including various effects on non-target organisms (or **species**), the unintended recipients affected by an introduced product. Non-target effects may result from deliberate release of genetically engineered plants, microbes, or other life forms. (See also **gene flow**; **risk assessment**.)

outbreeding – Sexual combination between distantly related members of the same **species**, in contrast to inbreeding, mating between closely related members. Same as outcrossing. In outbreeding plants, pollen and egg come from plants that are genetically different, permitting **gene flow** in and out. Breeding systems in plants occur along a continuum, from exclusive outbreeding to exclusive inbreeding (self-pollination), e.g., some plants are largely inbred but occasionally outcross at low rates. (See also **hybridization**.)

pest – Any species that interferes with human activities, property, or health, or is otherwise objectionable. Economically important pests of agricultural crops include weeds, arthropods (including insects and mites), microbial plant pathogens, and nematodes (roundworms), as well as higher animals (e.g., mammals and birds).

pesticide – Any substance or agent employed to destroy a **pest** organism. Common pesticides include insecticides (to kill insects), acaricides (mites and ticks), herbicides (weeds), fungicides (fungi), and nematicides (nematodes). Pesticides are commonly classified as conventional chemical compounds and biopesticides (or biological pesticides) derived from natural materials. Biopesticides include microbial (i.e., living organisms), biochemical (e.g., pheromones), and plant-pesticides (e.g., **Bt crops**). (See also **pest-protected plant**.)

pest-protected plant – Any crop plant genetically engineered to contain **genes** that express a pesticidal trait, whether by conventional or transgenic technologies. **Bt crops** are currently the most widely used **transgenic** pest-protected plants. (See also **pest**; **pesticide**.)

plant breeders' right (PBR) – The form of intellectual property rights that is legally accorded to plant breeders by laws or treaties, and intended for cultivated plants. PBRs require distinctness, uniformity, and stability (DUS). Also know as plant variety right, and similar to patent law for inventors.

protein – Any of a class of high-molecular weight polymer compounds, each the ultimate expression product of a **gene**. Proteins act in specific ways (as enzymes, regulators of gene activity, transporters, hormones), their specificity residing in characteristic three-dimensional shapes determined by their subunits, amino acids arranged in precise sequences and joined by peptide linkages.

race – A group of organisms within a species that are genetically or physiologically distinct from other members of the species. In anthropology the term is used to describe distinct human types such as Caucasian, Negroid and Mongoloid. **Landraces** are cultivated varieties that have been produced locally by informal artificial selection by farmers (sometimes living only a few kilometers apart) of crop plants showing characters that make them suited to particular growing conditions. There are estimated to be over 120,000 landraces of rice. (From: *The New Penguin Dictionary of Science,* M. J. Clugston 1998).

recombinant DNA (rDNA) – The product of **gene** splicing through **genetic engineering** techniques, joining together genes from different sources, and typically across **species** lines. (See also **recombination**; **transgenic**.)

recombination – The joining of **genes** (i.e., **DNA** segments), sets of genes, or parts of genes into new combinations, either biologically or through laboratory manipulation (e.g., **genetic engineering**). Genetic recombination is classified as intrageneric (within **species** of the same genus) or intergeneric (across species boundaries). In plants, recombination occurs naturally during sexual reproduction as the **chromosomes** form new associations.

risk assessment – For genetically engineered organisms, the process of predicting the behavior of the modified organism. For transgenic plants, refers to gauging the overall likelihood that their deliberate release into the environment will cause environmental harm, including adverse impacts on natural and agricultural ecosystems, or introduce new risks to public health. Harm may result from direct effect of a modified plant (e.g., enhanced weediness, or allergenicity), or from **gene flow** to unrelated plants and its consequences.

seed bank – A term (often used loosely) to denote a collection of seed and other **germplasm** from a broad cross-section of plants, and serving as a form of ***ex situ*** **plant conservation**. Also called gene bank, although the latter term is more accurate in describing many plant collections that contain non-seed, propagative materials, as well as seeds. (Seed bank also refers to a store of dormant and viable seeds in the soil, which germinate when environmental conditions are favorable.) See also **genetic resource**.

species – A taxonomic category of life forms, usually consisting of organisms that are sexually compatible and may actually or potentially interbreed in nature. The scientific (or Latin) name of a species includes the genus name and species designation, with the genus placed first (e.g., *Bacillus thuringiensis*). (See also **biodiversity**.)

substantial equivalence – A regulatory concept emerging in the 1990s for genetically modified (GM) foods; if a GM food is shown by molecular characterization and other tests to be substantially equivalent to its "natural" antecedent, it can be assumed to pose no new health or safety risks (thus requiring no additional biochemical or toxicological testing) and hence is acceptable for commercial use. (See also **biosafety**; **genetic engineering**; **GMO**; **risk assessment**.)

sui generis – In referring to a system of intellectual property rights, an alternative, unique form of IPR protection designed to fit a particular context and needs. Literally, "of its own kind."

teosinte – *Zea mexicana*, a tropical American fodder plant in which the seeds are not united on a cob. Rather, the female inflorescence (the ear) consists of a single row of six or more seeds, each of which contains a hard, flinty endosperm, like popcorn, covered by a tough shell (the cupule). Teosinte is one of the genetic forebears that contributed to the development of modern maize. (Adapted from <http://waynesword.palomar.edu/plapr99.htm#teosinte> and other sources.)

transgene – A "package" of genetic material (**DNA**) that is inserted into the genome of a cell via gene splicing techniques, including genes moved across **species** lines into the **genome** of a host organism. Along with the genes of interest (i.e., those expressing a novel **protein**), a transgene may contain promoter, other regulatory, and marker genetic material. A transgene may consist of a gene (or genes) from a dissimilar organism (i.e., foreign DNA), or artificially constructed genes. (Compare **gene flow**; see also **gene marker**; **recombinant DNA**; **vector**.)

transgenic – An organism containing novel genetic material (**DNA**) derived from an organism other than the parents or in addition to the parental genetic material; includes the offspring of a genetically engineered organism. The foreign (nonnative) DNA is incorporated early in development and present in germ cells (reproductive cells, sperm or egg) and somatic cells, and is inherited by offspring in a Mendelian fashion. A transgenic plant usually contains DNA from at least one unrelated organism, including a virus, bacterium, animal, or other plant. (See also **genetic engineering**; **pest-protected plant**.)

TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement – Under the World Trade Organization (WTO), governs the patenting of biotechnological processes and certain resulting products, to ensure at least minimal national standards for intellectual property protection on traded goods. Article 27.3(b) is the clause under which member countries are permitted to exclude plant varieties from being patentable, provided other effective IPR protection is available (***sui generis*** system), such as **plant breeders' rights**. (See also **biotechnology**; **UPOV Convention**.)

UPOV Convention – The Convention of the International Union for the Protection of New Varieties of Plants (an intergovernmental membership organization based in Switzerland) whose aim is to "protect new varieties of plants by an intellectual property right," thus establishing **plant breeders' rights** (PBR), and serving as an example of a ***sui generis*** system for plant variety protection (PVP). The UPOV Convention aims to balance protection of the rights of farmers to replicate seeds on the farm, and the rights of plant breeders to use and develop plant **genetic resources** for commercial benefit. Initially adopted in 1961 and based on several European nations' PVP systems, the Convention was revised in 1978, and again in 1991. The 1978 version of UPOV protected farmers' traditional use of protected plant varieties for propagation activities on their own holdings. The 1991 version extends protection of the options and incentives of plant breeders to innovate, by extending breeders' IPRs to harvested materials (e.g., seeds), as well as propagating materials of protected varieties, while removing farmers' rights to replicate, exchange, or replant protected seed varieties. (See also **TRIPS Agreement**.)

variety – A category used in the classification of plants and animals below the species level. A variety consists of a group of individuals that differ distinctly from but can interbreed with other varieties of the same species. The characteristics of a variety are genetically inherited. Examples of varieties include breeds of domestic animals and the races of man.
(from: *A Dictionary of Biology*, Oxford University Press, Market House Books, Ltd. 2000.)

vector – A self-replicating agent used to carry new **genes** into cells to produce **recombinant DNA**. Includes plasmids (i.e., circular, nonchromosomal DNA found in bacteria), as well as viruses and other forms of **DNA**. (In plant pathology, a vector is an organism capable of transmitting a pathogen from one host to another, such as plant-feeding insects that transmit viruses.) See also **chromosome**; **transgene**.

weed – In general, any unwanted plant that interferes with human activities (including agricultural systems) or natural habitats. The concept of a weed is fairly subjective; plants may be considered weeds for diverse reasons (e.g., rapid growth, persistence, invasiveness, toxicity to livestock). **Herbicide-tolerant crops** intended for improved weed control may potentially contribute to weed severity. (See also **pest**.)

Attachment: Comments of the Parties to the North American Agreement on Environmental Cooperation

Canada

Environment Canada
Gatineau, QC K1A 0H3

4 November 2004

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

Dear Mr. Kennedy:

The Government of Canada supports the official release of the Article 13 report, "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico".

I must note that the process outlined in the North American Agreement on Environmental Cooperation provides for the release of the report, normally within 60 days, unless Council decides otherwise. The Government of Canada was in the process of preparing a response to the report when it was made public by Greenpeace well before the expiration of the 60-day period. Needless to say, Canada is very disturbed by this breach of process.

That being said, the Government of Canada would like to acknowledge the many individuals and organizations that contributed, under the leadership of the Secretariat of the Commission for Environmental Cooperation (CEC), to the extensive work on Maize which culminated in this Article 13 report. Special mention goes to the CEC Advisory Group on Maize and Biodiversity for its various contributions and dedication to the project.

Canada appreciates the challenges of writing a report on such a complex issue, characterized by diverging and, at times, opposing points of view. The report notes that there are a wide range of views on the possible risks such genetically modified organisms may pose to the environment and to animal and human health, as well as possible advantages associated with them.

We would like to note in particular that the Maize Report is an independent report prepared by the CEC Secretariat pursuant to Article 13 of the North American Agreement on Environmental Cooperation. The key findings and recommendations are those of the Advisory Group and do not necessarily reflect the views of the CEC Council nor the governments of Canada, Mexico or the United States.

I would also note that the draft report was presented to the CEC Council for comment on May 14, 2004. Canadian government experts reviewed the draft report with great care and provided detailed comments to the CEC Secretariat on July 30. Although some modifications were made to the report following the comments provided by Council, Canada notes that the key findings and recommendations of the Report remained unchanged. In the interest of transparency, Canada requests the CEC Secretariat to append this letter and our comments from July 30 in their entirety to the final report as published and as made available on the CEC web site.

The following paragraphs reiterate certain key observations outlined in our comments on the draft report with a view to contributing to the dialogue on the effects of transgenic maize.

In general, Canada finds the scientific key findings contained in the report to be balanced and consistent with our scientific understanding, our regulatory approach, and accepted international standards. We note, however, that some of the report’s recommendations do not appear to be supported by the scientific evidence presented in the key findings. It is noted in the report that the recommendations were informed by the key findings, and also a number of other inputs, including from comments received throughout the process and based on the personal judgment of members of the Advisory Group. While we do not question the expertise of those who have contributed to the report, it is impossible to completely assess the soundness of the recommendations because we do not have the benefit of all the information that the drafters took into account in developing them.

In particular, Canada sees a disconnect between the key scientific findings and some recommendations on the issue of gene flow. Some of the gene flow recommendations imply that all traits derived from transgenes present the same risks and make no mention of the effect of the gene flow that occurs between other, non-transgenic varieties. This appears inconsistent with key findings that transgene flow must be considered in terms of the historical context of how landraces have interacted with introduced varieties and in terms of a single trait's effect on the environment. Without having all the inputs that have informed the development of these recommendations, it is difficult to reconcile this apparent discrepancy.

Overall, the Government of Canada is of the view that questions on importing transgenic maize should be decided by a country’s own science-based risk assessment and in the context of a regulatory system which respects a country’s right to set its own level of protection in a manner consistent with its international obligations. We believe the report could have been more informative and complete, providing a better framework for the recommendations, if there had been a more thorough discussion of the existing domestic regulatory approaches and international obligations of the three governments. 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.

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,

Norine Smith
Assistant Deputy Minister
Policy and Communications

c.c.: Mr. Jose Manuel Bulas, SEMARNAT

Ms. Judith Ayres, U.S. EPA

Note : This response is published in the three languages of the Commission: English, French and Spanish. However, as the text was originally prepared in English and thereafter translated, in the case of disputed meaning, reference should be made to the English version.

Environment Canada
Gatineau, QC K1A 0H3

30 July 2004

Mr. William Kennedy
Executive Director
Secretariat
Commission for Environmental Cooperation
393 St-Jacques Street West, Suite 200
Montreal 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,

Norine Smith
Assistant Deputy Minister
Policy and Communications

c.c.: Mr. Jose Manuel Bulas

Ms. Judith Ayres

"Maize and Biodiversity: The Effects of Transgenic Maize in Mexico"

Canadian Comments on the CEC Secretariat's Article 13 Report*

30 July 2004

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.

* These comments are published in the three languages of the Commission: English, French and Spanish. However, as the text was originally prepared in English and thereafter translated, in the case of disputed meaning, reference should be made to the English version.

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 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.

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 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."

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 <u>that policy must conform to</u> 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.

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 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.

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

Mexico

30 July 2004

Comments by CIBIOGEM Technical Committee on the report "Maize and Biodiversity: Effects of Transgenic Maize in Mexico." Report of the Secretariat of the North American Commission for Environmental Cooperation in accordance with Article 13. Preliminary version of 13 May 2004.

We reviewed the Spanish version alongside the English version and found various inconsistencies between the two. We therefore suggest that extreme care be taken to ensure the equivalency of the two versions.

We suggest that the report discuss the possible benefits of genetically modified maize for the development of agriculture in Mexico (consider elements of Chapter 2, "Identification of Possible Benefits and Risks," section 2.3).

We would like to know whether the report's authors took cognizance of NOM-056-FITO-1995, which forms a part of the legal framework for biosafety in Mexico (http://web2.senasica.sagarpa.gob.mx/xportal/nom/noms/Doc74/NOM056.doc).

We want to clarify that the *de facto* moratorium existing in our country concerned applications for environmental release of genetically modified maize. Therefore, we request a clarification from the authors on the sense of recommendation 6 regarding biodiversity.

This moratorium was lifted on 13 August 2003, and work is currently being done to establish policies and guidelines for experimental release of genetically modified maize. This work is being done, on the one hand, by a group of experts under Semarnat and, on the other, by the Specialized Agriculture Subcommittee (*Subcomité Especializado de Agricultura*). The moratorium was lifted by virtue of an agreement with CIBIOGEM that states: "The moratorium on transgenic maize is hereby lifted and comments made by Semarnat shall be received and considered."

Regarding recommendation 2(a) on sociocultural aspects [Ed. note: p. 27, English version], we request clarification on whether this refers to the provisions of Article 18(2)(a) of the *Cartagena Protocol* on the identification of GMO shipments for food, feed, or processing, or whether the reference is to the product's labeling.

With a view to preserving the objectivity of the report, we suggest reconsidering the language used to avoid value judgments such as the following: *"…In the regions of maize landrace cultivation, there is recent cultural memory and political history among the indigenous peoples of perceived inequity and injustice at the hands of Mexicans of Spanish origin, Americans, and powerful elites." […] "Similarly, those who advocate greater use of genetic engineering and unrestricted trade may have vested interests in aspects of scientific and technical development, trade, political influence, or industrial agriculture in Canada, Mexico and the United States.*" (From Conclusions on Sociocultural Aspects, first paragraph of section on background to GM maize in Mexico [Note: p. 23, English version]).

Be careful with the translation, for example paragraph 11 of the section titled "Cultural significance of maize and public perceptions of GM maize" [Note: these passages are found on [p. 24, English version]: *"Gran cantidad de oaxaqueños, sobre todo campesinos, consideran que la presencia de cualquier transgén en el maíz constituye…"* whereas the English version says "There are a number of Oaxacans,…" Even the section title illustrates this point: "*Importancia cultural del maíz y percepciones ciudadanas en* *torno al maíz GM*" versus "Cultural significance of maize and public perceptions of GM maize." Another example: paragraph 11 in the Spanish version corresponds to two paragraphs in the English 11 and 12. This division changes the meaning of the English version.

Yet another example of translation problems is in paragraph 18 of the sociocultural section [note: p. 25, English version], where the Spanish reads *"introgresión"* for the English "introduction," completely changing the meaning of the sentence.

United States

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of
International Affairs

4 November 2004

William Kennedy
Executive Director
Commission for Environmental Cooperation
393, rue St-Jacques Ouest, Bureau 200
Montreal, Quebec, Canada H2Y 1N9

Dear Mr. Kennedy:

Enclosed is the United States Government response to the Secretariat's Article 13 report on "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico," received on September 14, 2004.

The United States concurs with the other Parties in making this report publicly available. We request that you include on the front of this report the following disclaimer language that has been agreed to by the Parties:

> *Position of the Parties*
>
> *The following report was prepared independently of the three Parties to the North American Agreement on Environmental Cooperation (NAAEC) by the Secretariat of the Commission for Environmental Cooperation (CEC) pursuant to Article 13 of the NAAEC with the assistance of a designated Advisory Group on Maize and Biodiversity.*
>
> *Publication of this report does not constitute endorsement of its contents by the Council of the CEC or the governments of Canada, Mexico or the United States.*
>
> *The Parties' comments are appended to the report. These comments include observations that some of the recommendations contained therein do not reflect the report's scientific findings, but rather reflect cultural and social perspectives of the Advisory Group and other entities.*

In addition, we request that you append to the report this transmittal letter and the enclosed response, as well as our response and transmittal letter of July 23, 2004, concerning the draft report.

The United States has been at the forefront of efforts to unlock the promise of agricultural biotechnology and ensure its safe use. The United States conducts robust scientific reviews of all biotech products to ensure that they are safe for human health and the environment. We recognize the importance of preserving biological diversity that will allow global agriculture to continue to thrive, and may provide key insights into solving challenges for food production. We are a major contributor to efforts to preserve the genetic diversity of crop plants in their centers of origin, including maize.

Thus, we are deeply disappointed that the CEC Secretariat has produced an Article 13 report that ignores key science about biotechnology and fails to focus on efforts that will preserve maize genetic diversity, the stated goal of the report. We look forward to working together with the Secretariat and the other Parties to improve procedures for implementing Article 13.

Sincerely,

Judith E. Ayres

Alternate Representative of the United States

4 November 2004

United States Government Response to Article 13 Maize Report

"Maize and Biodiversity: The Effects of Transgenic Maize in Mexico:

Key Findings and Recommendations"

Recognizing the significant current and potential benefits of agricultural biotechnology, the U.S. has been at the forefront of efforts to ensure its safe use. Agricultural biotechnology has already produced environmental benefits by reducing soil erosion and pesticide use. Scientists around the world agree that we must continue with research and application of biotechnology. As noted by the national science academies of Mexico, the United States, the United Kingdom, China, Brazil and India in a joint report: "GM technology should be used to increase the production of main food staples, improve the efficiency of production, reduce the environmental impact of agriculture, and provide access to food for small-scale farmers."[*]

The United States government has consistently ensured that these new products undergo the most rigorous scientific and technical reviews possible. All transgenic maize varieties on the U.S. market have been subjected to a thorough environmental, human health and food safety review. These reviews incorporate strict scientific standards and extensive input from academia, industry, and the public. The process has been an open and transparent one with multiple opportunities for public input. The United States has been and will continue to be a leader in international efforts to harmonize standards to assess the safety of biotechnology and to build capacity for scientific assessment and decision making for biotechnology.

Further, the United States recognizes the importance of preserving genetic diversity in order to allow global agriculture to continue to thrive, and to provide key insights into solving challenges for food production. The U.S. government is a major contributor to efforts to preserve the genetic diversity of crop plants in their centers of origin, including maize.

Given U.S. leadership in this area, we are deeply disappointed that the CEC Secretariat has produced an Article 13 report that ignores key science about biotechnology and fails to focus on efforts that will preserve maize genetic diversity, the stated goal of the report. First, many of the recommendations of the report are inconsistent with its own scientific findings that biotech maize and other modern maize hybrids behave similarly in the environment. Second, the authors failed to perform an economic analysis of their recommendations, despite the fact that implementing these recommendations would harm U.S. corn producers and deprive Mexican livestock producers and consumers of the economic benefits of U.S. corn exports. Third, the report fails to consider the feasibility of its recommendations and the many different stakeholders that the NAFTA governments serve as well as the significant work undertaken by those governments to protect biodiversity and ensure the safe use of biotechnology.

Recommendations Ignore Science

The central scientific findings of the report clearly state that "there is no reason to expect that a transgene would have any greater or less effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars." In fact, the findings further note, "[thus] the introgression of a few

[*] "Transgenic Plants and World Agriculture," Report prepared under the auspices of the Royal Society of London, the USA National Academy of Sciences, the Brazilian Academy of Sciences, the Chinese Academy of Sciences, the Indian National Academy of Sciences, the Mexican Academy of Sciences and the Third World Academy of Sciences, pp. 6., http://www.nap.edu/books/NI000227/html/

individual transgenes is unlikely to have any major biological effect on genetic diversity in maize landraces." This finding is also consistent with those offered by other recognized scientific organizations. Yet several of the CEC report recommendations urge that transgenic maize be treated differently from other modern hybrids. It is clear that these recommendations are inconsistent with findings of the report and are unlikely to have any effect on conserving maize biodiversity. If implemented, these recommendations would unnecessarily limit NAFTA farmers' access to high-quality U.S. corn exports, as well as the environmental benefits that biotech corn provides.

Report Does Not Consider Costs and Benefits

No economic analysis was performed in the preparation of this report. The report fails to consider how the recommendations might be implemented, and does not weigh the costs and benefits of any of the recommended measures. Moreover, the report does not evaluate whether tangible economic benefits could accrue to Mexican farmers as a result of the use of biotechnology. While the recommended actions respond to the concerns of some stakeholders, they are likely to significantly increase costs for livestock producers and consumers throughout Mexico. For example, requiring U.S. corn exports to Mexico to be milled at the border would increase the cost of U.S. corn significantly, negatively affecting Mexico's livestock producers and consumers. Furthermore, the report does not consider logistical considerations, such as whether it is, indeed, feasible to mill at border facilities the roughly 6 million tons of maize that Mexico imports annually. The scientific findings of the report acknowledge that these measures, both draconian and costly, would be unlikely to protect maize biodiversity.

Report Ignores Key Stakeholders

It is the responsibility of governments to balance the values and needs of different, often-competing stakeholders, to consider the feasibility of implementation, and to comply with the realities of international trade agreements. The CEC Secretariat's Advisory Group chose not to balance these demands and many of their recommendations attempt to respond solely to socio-cultural perceptions of one specific group of stakeholders, while ignoring the needs of others. Indeed, the report itself states that for these stakeholders: "That sense of harm [from biotechnology] is independent of its scientifically studied potential or actual impact upon human health, genetic diversity, and the environment." Views of those sectors of society which may welcome biotechnology options and their potential benefits are not explored or considered. Further, the reader is given no specific references to scientific rationale, or to supporting documentation with which to evaluate the validity of the recommendations.

In addition, the three NAFTA governments have extensive experience and expertise in assessing the safety of and in regulating the products of biotechnology. Yet, no attempt was made by the authors of this report to contact government authorities to explore current regimes, learn from the governments' experiences or discuss benefits and challenges.

The United States has on several occasions expressed concern to the CEC Secretariat about the design of the study and the procedures used in developing this report. Despite repeated requests for greater transparency, predictability, and objectivity in the process, no improvements were made and major substantive and procedural concerns remain. The end result of this flawed process is a seriously flawed Article 13 report.

Considerable resources were invested to evaluate the scientific issues surrounding the potential effects of transgenic maize in Mexico. Unfortunately, scientific analysis did not form the basis for key recommendations in the report. The CEC Secretariat and Advisory Group have neglected a unique opportunity to contribute to our understanding of maize biology and ecology and other related issues and to contribute to improving strategies for preserving maize biodiversity.

The United States is deeply disappointed in this fundamentally flawed report and is concerned that the Article 13 process itself has been undermined by the manner in which this report was developed.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Office of
International Affairs

23 July 2004

William Kennedy
Commission for Environmental Cooperation
393, rue St-Jacques Ouest, Bureau 200
Montreal, Quebec, Canada H2Y lN9

Dear Mr. Kennedy:

Enclosed is the U.S. Government response to the Secretariat's draft Article 13 report on "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico," circulated to the Parties on May 13, 2004. We appreciate the opportunity to provide comments on the draft report.

The enclosed comments will detail specific substantive concerns with the Article 13 report, but it is worth noting that a number of our concerns center around process. The United States believes it is particularly important that studies addressing complex and contentious issues involve all relevant stakeholders, including the Parties, affected elements of the private sector, the public and peer reviewers. Further, the United States feels it is essential that the views of all stakeholders be considered and responded to regarding how the proposed study protocol, peer review, and communication processes are to function.

Unfortunately, the process used to prepare this report was unpredictable and opaque, and did not give adequate opportunity for peer review or for input from stakeholders. These procedural flaws, along with the clear disconnect between the scientific findings of the report and many of the policy recommendations purportedly based on these findings, severely undermine the credibility and usefulness of the final product.

The United States believes the Article 13 provision, if properly implemented, can be an important component of the CEC Secretariat's responsibilities The United States fully supports the production and release of Article 13 reports that provide scientifically credible, useful and accurate information to the governments and the public on issues of environmental importance. The future success of the CEC is determined by the quality and effectiveness of the products which it produces for public use. We believe that a requisite part of this success is ensuring that products/deliverables are held to the highest standards for scientific and technical review while still having policy relevance. We are concerned that if a report is released with such apparent flaws it would call into question the credibility of the CEC as a whole and undermine the integrity of the Article 13 process.

The Secretariat and the Parties it serves share responsibility to ensure the process is transparent and adheres to high professional standards, and that the report is accurate, and recommendations substantiated. We stand ready to work with the other Parties and the CEC Secretariat to improve procedures for implementing Article 13, as well as the content and quality of any future Article 13 reports. The United States urges that the Secretariat take the steps necessary to address the concerns raised in our comments and incorporate appropriate revisions to the draft report before finalizing any work product to be submitted to the Council for its consideration.

Enclosure

Sincerely,

Judith E. Ayres
Assistant Administrator

23 July 2004

U.S. Government Comments to the Secretariat's draft Article 13 report Maize and Biodiversity: The Effects of Transgenic Maize in Mexico

The United States offers the following comments on the process and procedures for preparing this draft report and the technical findings and recommendations contained therein. We also offer comments on the manner in which communications on the study have proceeded.

Process and Communications

The process used to prepare this draft report would have benefited from greater transparency and communication to the Parties as to the intended scope, timeline and peer review procedures of the draft report.

Early in the process, the United States raised concerns about the expanding scope, apparent redundancies and the timeline for the report in detailed comments to the Secretariat on the proposed chapter outlines and the terms of reference. Despite repeated requests for greater transparency, predictability and objectivity in this process, changes were not made to the terms of reference.

To ensure the scientific credibility of the report and provide a strong scientific basis for any policy recommendations that are made, an adequate independent peer review of this draft report is necessary. For example, the background chapters that were prepared contained substantial redundancies, factual discrepancies, and a host of unsubstantiated assertions. The Secretariat released these draft background chapters to the public without a rigorous peer review by the advisory group or an independent panel, and without prior notification to the Council.

- The United States and other stakeholders made great efforts to provide detailed technical comments on the draft chapters subsequent to their public release. However, many of these comments, including comments from members of the expert advisory group, were not adequately considered or acknowledged during the revision process.
- It is of equal concern that preliminary materials were released without adequate indication of their draft status and without disclaimers stating that the chapters reflect the opinions of the authors and not those of the expert advisory group, the CEC Secretariat or the Parties.

Substantive Concerns

The content of the draft report would have been significantly strengthened by a stronger process for stakeholder comment and resolution of key scientific issues, and greater consistency between the report's findings and resulting recommendations.

- Several of the recommendations in the draft report are not supported by the scientific findings or the background chapters. In some cases, these draft recommendations could have serious implications for agricultural trade among the Parties, but do not address the specific concerns identified.
    - For example, the scientific findings of the draft report recognize that gene flow, in and of itself, does not pose risks to biodiversity, and that transgenic maize varieties are no more likely to affect the genetic diversity of landraces than other modern cultivars. Yet, the recommendations are based on the premise that maize that might contain transgenic varieties should be treated differently than non-transgenic maize.
    - The draft report also notes that the sources of transgenes in maize landraces are not precisely known, and that more research is needed to understand when and how farmers obtain and chose to plant transgenic maize. Yet, the draft report recommends that all

imported maize shipments from the United States and Canada be milled immediately upon entry into Mexico. This would be a significant barrier to trade, but, by the draft report's own admission, may not achieve the stated goal of limiting gene flow and would have no greater or lesser effect than placing the same harsh restrictions on other modern cultivars of maize entering Mexico.

- The draft report is internally inconsistent. Many of its recommendations are in conflict with one another and we strongly encourage that the draft findings and recommendations be reconciled so that the recommendations are clearly and strongly supported by the findings presented and that those findings have a uniformly firm scientific grounding. For example, the draft report recommends that Mexico maintain its prohibition on planting transgenic maize, and that programs be implemented to educate farmers not to plant seeds that contain transgenic maize. At the same time, it recommends that the Mexican government initiate a communication and consultation program with the campesinos to demonstrate the benefits and risks of transgenic maize. The draft report recommends that cultivation of maize in Mexico needs further study with special attention to the roles and needs of the campesinos, but subsequently recommends that further development of maize cultivation in Mexico take into account the needs and potential benefits and risks for campesinos, small-scale producers, and large-scale commercial agriculture. These recommendations could be complementary or competitive; at this point, that is not clear.

- The draft report faults existing regulatory and legal regimes for the planting, sales and trade in transgenic maize in the three countries without ever fully discussing or analyzing these regulatory structures. The authors of the draft background chapters and draft report would have benefited from consulting with the relevant government agencies charged with implementing and enforcing these policies. The draft background chapters and draft report make a number of recommendations for future regulation of biotechnology, yet its assertions about the current state of such regulation are not founded in fact. The omission of this critical information and the valuable expertise that could have been provided by government officials who implement these regulations, and industry representatives who comply with them, drastically reduces the relevance of the draft report.

Recommendations for Future Article 13 Reports

- The proposed terms of reference and outlines should be more closely coordinated with the Parties. Likewise, a method should be developed to address differences of opinion that arise on the intended scope, protocol, or procedures for the report.

- A process should be identified whereby comments provided by the Parties on early versions of the draft report are appropriately addressed.