



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

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OFFICE OF
INTERNATIONAL AFFAIRS

William Kennedy
Commission for Environmental Cooperation
393 rue St-Jacques Ouest, Bureau 200
Montreal, Quebec, Canada H2Y1N9

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.

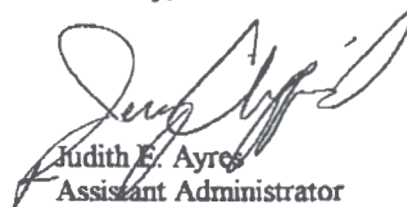
The United States believes the Article 13 provision, if properly implemented, can be an important component of the CEC Secretariat's responsibilities. The United States fully supports the production and release of Article 13 reports that provide scientifically credible, useful and accurate information 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

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.**