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2 April 2004

Office of the United States Trade Representative
Docket No. WTO/DS-291
Via E-mail: FR040@ustr.gov

To Whom It May Concern:

As requested at 69 Federal Register 11927 (March 12, 2004), the Center for Food Safety submits the following comments and attachments concerning the WTO Dispute Settlement Proceeding Regarding Measures of the European Communities Affecting the Approval and Marketing of Biotech Products.

The Center for Food Safety (CFS) opposes the decision taken by the United States Trade Representative (USTR) to file the panel request challenging the pace by which the European Communities' establishes a scientific-based, mandatory pre-market approval system for genetic engineered foods. The filing of the panel request is particularly contradictory considering the U.S. government's failure to address the numerous scientific shortcomings and non-mandatory status of its current 1992 Statement of Policy Foods Derived From New Plant Varieties. 57 Federal Register 22991 (May 29, 1992). Indeed, the United States Food and Drug Administration (FDA) has delayed for over four years in answering a scientifically supported, legal request to establish a mandatory pre-market safety testing regulation for all genetically engineered foods.

Pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(e), and the FDA implementing regulations, the Center for Food Safety and numerous other organizations petitioned the FDA on March 21, 2000, to take action regarding, *inter alia*, the potential human health and environmental impacts associated with the use and commercialization of genetically engineered foods. See Attachment; See also, FDA Docket No. 00-1211. More specifically, the agency has been requested to initiate new rulemaking to establish mandatory pre-market safety, environmental review and labeling regulations for all genetically engineered crops and foods. Since the filing of the petition over four years ago, the FDA has failed take any action concerning the issues presented by the petition.

As the FDA is well aware, the CFS legal petition has received the public support of several hundred thousand individuals. Coupled with the FDA's statutory obligation to ensure the safety our country's food supply, the intense public support for mandatory regulatory oversight of genetically

engineered foods necessitates FDA's immediate response to the petition. Moreover, by refusing to act, the FDA continues to delay in proceeding through the regulatory creation process of establishing a science-based, mandatory review system similar to one the European Communities now seeks to complete. Therefore, it is inappropriate for the USTR to now challenge the pace of the European Communities' actions during the creation of an such approval system.

Furthermore, the Center for Food Safety reminds the USTR that its action in challenging the European Communities' actions in creating a regulatory scheme couple with the excessive and unreasonable delay in addressing the science and regulatory matters on genetically engineered foods brought to the U.S. domestic regulatory agencies' attention over four years ago saps the public confidence in U.S. government's ability to discharge its responsibilities of protecting the human health, welfare and environment of its citizens.

Accordingly, the Center for Food Safety requests that the USTR withdraw its consultation requests filed on May 13, 2003, and all other subsequent filings concerning measures taken by the European Communities concerning products of agricultural biotechnology.

Sincerely,

Joseph Mendelson, III
Legal Director

Attach.