IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CENTER FOR FOOD SAFETY 660 Pennsylvania Ave., SE Suite 302 Washington, DC 20003, Plaintiffs, v. **ANDREW C. VON ESCHENBACH**, in his official capacity as, Acting Commissioner of Food and Drugs, Food and Drug Administration, 5600 Fishers Lane, Room 1471 Mail Stop HF-1 Rockville, MD 20857, Defendant.	Civil Action No. _____

COMPLAINT FOR DECLARATORY RELIEF
AND WRIT OF MANDAMUS OR OTHER ORDER

1. This is an action for declaratory judgment and mandamus relief challenging the failure of the defendants, and others acting under his authority, to respond substantively to plaintiff Center for Food Safety's (CFS) petition for rulemaking concerning the regulation of genetically engineered foods (GE Foods Petition).

2. Defendant's failure to respond substantively to the GE Foods Petition violates the Administrative Procedure Act, 5 U.S.C. § 555(b).

JURISDICTION AND VENUE

3. This court has jurisdiction over this action pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 706(1), as well as, 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1346 (United States as a defendant), and 28 U.S.C. § 1361 (mandamus).

4. The relief requested is specifically authorized pursuant to 28 U.S.C. § 1651 (writs), 28 U.S.C. § 2201 (declaratory relief), 28 U.S.C. § 2202 (further relief), 28 U.S.C. § 2412 (costs and fees). Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. §§ 701 - 706.

5. Venue is proper pursuant to 28 U.S.C. § 1391(e) because the defendant resides in this district and a substantial part of the events and omissions which gave rise to this action occurred in this district.

PARTIES

6. Plaintiff Center for Food Safety (CFS) is located at 660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003. Plaintiff is a tax-exempt, non-profit, membership organization incorporated in the District of Columbia. Since the organization's founding in 1997, the activities of CFS have been centered in several areas including addressing the environmental, economic, and ethical concerns raised by the development and commercialization of agricultural and food processing technologies.

7. CFS develops and disseminates to its members, policymakers, members of local, state and federal government, international governmental officials, non-profit organizations and interested members of the general public a wide array of educational and informational materials that address the environmental, economic and social and public health impacts associated with use of genetically engineered foods. These materials include, but are not limited to, reprints of news articles and agency regulatory positions, press releases, fact sheets, action alerts, electronic mail alerts and investigative and technical reports. CFS's materials often analyze the legal and regulatory means taken by federal agencies to address the various economic, environmental, public health and social impacts associated with agricultural biotechnology.

8. Along with its capacity as an informational clearinghouse, CFS also serves in an

advocacy function to, *inter alia*, protect human health and the environment from the impacts and risks raised by the use of genetically engineered foods. Accordingly, CFS's activities seek to encourage full public participation in local, state and federal policymaking and rulemaking proceedings so that public concerns over the use of agricultural biotechnology are considered and acted upon by governmental decisionmaking bodies.

9. To achieve its goals, CFS participates extensively in federal agency decisionmaking processes through comments on agency rulemaking, calls for formal investigations, other administrative actions and appeals, meetings with agency officials, petitions for rulemaking, and litigation when agencies fail to meet statutory environmental, human health and/or procedural requirements. CFS also expends financial resources to facilitate and encourage public participation during various governmental decisionmaking processes.

10. The interests of CFS are being, and will be, adversely affected by defendant's actions complained of herein. In particular, defendant's unreasonable delay in responding to the GE Foods Petition injures CFS by, *inter alia*, abridging the organization's procedural right to petition a federal agency for rulemaking under the APA. The defendant's unreasonable delay also directly harms CFS's goals and functions by impeding the organization's ability to further facilitate public involvement in governmental decisionmaking and foreclosing the statutory right that allows for public participation through petitions for rulemaking.

11. The failure of the defendant to provide an answer to the GE Foods Petition (and the substantive information contained therein) impedes CFS's daily operations by impairing the organization's use of the petitioning process to obtain a complete and comprehensive agency interpretation of the FDA's legal authority to regulate genetically engineered foods under statutes such as the Federal Food Drug and Cosmetic Act. CFS's technical reports and policy analyses rely upon the

receipt of such federal agency interpretations of their statutory authority. The information provided to CFS by federal agencies in their responses to petitions for rulemaking play a critical role in the organization's ability to provide informative and novel genetically engineered food policy proposals designed to comply with the current federal regulatory agency interpretations of their statutory mandates and requirements. Defendant's failure to provide an answer to the GE Foods Petition deprives the organization of the information necessary to create and analyze policy proposals concerning genetically engineered foods that conform to the agency's current statutory interpretation. Additionally, defendant's unreasonable delay adversely affects CFS's ability to disseminate the agency's current statutory interpretation of, *inter alia*, the Federal Food Drug and Cosmetic Act to the public, state and local governments, policymakers and others interested in the possible use of existing federal laws as regulatory tools for addressing the public health and environmental impacts associated with the use of genetically engineered foods.

12. The economic interests of CFS are being and will be adversely affected by defendant's actions complained of herein. After the filing of a citizens petition, defendant's petitioning process allows the solicitation of public comments to inform and aid its response to a filed petition. In pursuit of its organizational goal of encouraging public participation in governmental decisionmaking processes, plaintiff CFS expended significant resources to print, distribute and send to thousands of members of the public materials designed to encourage their participation in the defendant's commenting process. Defendant's failure to answer the GE Foods Petition has rendered these expenditures futile.

13. The interests of CFS's members are being, and will be, adversely affected by defendant's actions complained of herein. FDA's unreasonable delay in responding to the GE Foods Petition and regulating genetically engineered foods has inflicted, and will continue to inflict, physical, economic and aesthetic injuries on CFS members in many ways. CFS's members consume tomatoes, potatoes, soy

products, cotton seed oil, squash, canola oil, corn, papaya and other food products that may currently be genetically engineered. FDA's failure to respond to the GE Foods Petition and, thus to regulate and label genetically engineered foods, allows genetically engineered organisms, and substances and ingredients derived from them, into interstate commerce as whole foods and food ingredients that can cause unpredictable changes to the characteristics of certain foods that are difficult for consumers to detect. These changes may include unintended alterations to the foods so that they contain novel allergens, new toxins, elevated levels of inherent toxins, degraded nutritional quality and other harmful changes. As a result, absent FDA's response to the GE Foods Petition CFS's members will continue to be exposed to numerous food products that are unknowingly altered and pose potentially harmful impacts to their health.

14. Defendant Andrew C. Von Eschenbach is sued in his official capacity as Commissioner of the United States Food and Drug Administration with its principal office located at 5600 Fishers Lane, Rockville, MD 20857. As FDA Commissioner, defendant Von Eschenbach has the ultimate responsibility for the activities of the FDA, including those actions complained of herein.

STATEMENT OF FACTS

15. Genetic engineering encompasses a wide range of new techniques that allows scientists to create novel foods whose molecular biology has been altered using genetic material from unrelated organisms. Unlike traditional plant breeding, these techniques artificially breach natural reproductive barriers and combine genes from distant species in ways that could never occur in nature.

16. To create these novel foods, creators of these foods must forcibly insert the new genetic material into the DNA of the targeted host plant. To do so, scientists have to create a "cassette" of genetic material which may include marker genes for antibiotic resistance, viral promoters, and terminators, specifically designed to breach the host plant's species boundary. The inserted "cassette"

may then disturb the function of the region of the host plant's DNA into which it has been spliced in order to confer the desired, engineered trait.

17. Creation of these genetically engineered plants is not a precise science. Scientists cannot control the location where the "cassette" is inserted and, because the effect of a gene in the host plant is significantly governed by its location, this is a significant cause of unexpected effects. Additionally, scientists cannot guarantee stable expression of the inserted genetic material. More than one copy of a "cassette" may be inserted, genes in the host plant may be switched off or varied from their normal expression. The end result is an inability of scientists to predict the full effect of the introduction of new genetic material into previous known foods. Furthermore, the protein produced by the inserted gene may interact with the plant's proteins in unpredictable ways that can cause harmful results.

18. The unpredictability of this novel food technology may produce unanticipated and unknown side effects impacting human health. The genetic engineering of foods may produce new toxins (or elevate existing toxins to harmful levels), create new allergens, exacerbate resistance to antibiotics, cause immuno-suppression, and alter the level of nutrients in such food.

20. Since May 29, 1992, the FDA has voluntarily assessed genetically engineered foods under its "Statement of Policy: Foods Derived From New Plant Varieties." The policy determined that all transferred genetic material and the resulting food products derived from genetically engineered plant varieties were considered generally recognized as safe (GRAS). As a result, genetically engineered food producers were encouraged to consult with the defendant concerning potential safety and regulatory questions concerning genetically engineered foods. However, genetically engineered food products derived from genetically engineered plants can now appear in interstate commerce without labeling, without pre-market notification to the FDA, without producer submission of a food additive petition and without final FDA safety evaluation approving the food additive petitions. Indeed, under the

policy, a genetically engineered food is not subjected to any mandatory pre-market safety review.

21. A number of incidents have revealed that the FDA's voluntary consultation policy is inadequate. In 2001, public interest organizations, including the plaintiff, tested consumer products and found the illegal presence of a genetically engineered corn, known as StarLink, in food products throughout the United States. The U.S. Environmental Protection Agency (EPA), one of the federal agencies with regulatory jurisdiction over this particular type of genetically engineered crop, had approved this variety of corn for use only as an animal feed. Subsequent to the discovery of the corn's presence in the food supply, EPA determined that the Cry9C protein found in StarLink corn had a medium likelihood of being a human allergen. Prior to the EPA review, the genetically engineered corn containing the Cry9C protein had been reviewed by the defendant under its current voluntary review policy and the agency failed to identify or address any potential allergenicity concerns. Eventually, the EPA's determination triggered one of the largest food recalls in history.

22. More recently, research continues to indicate that mandatory testing and labeling regulations for genetically engineered foods should be required. For example, in 2005, government researchers in Australia found that when a gene was transferred from a bean to a pea the protein encoded by the transferred gene unexpectedly gained the ability to cause immunological reactions similar to allergies in humans. The researchers detected the genetically engineered pea's immunological properties through procedures and testing protocols that are not in anyway recommended or mandated through the current voluntary FDA review policy.

23. To address the inadequacies of FDA voluntary consultation policy and the potential impacts of genetically engineered foods on consumers, on March 21, 2000, the plaintiff CFS (joined by numerous other organizations) filed the Petition Seeking the Establishment of Mandatory Pre-Market Safety Testing, Pre-Market Environmental Review & Labeling for All Genetically Engineered Foods

(GE Foods Petition).

24. The GE Foods Petition asks FDA to make certain regulatory amendments and take other actions as required under the Federal Food Drug and Cosmetic Act and National Environmental Policy Act in order to create, *inter alia*, a mandatory, pre-market regulatory review system for all genetically engineered foods.

25. On March 22, 2000, the FDA acknowledged receipt of the GE Foods Petition and assigned the petition docket number 00P–1211/CP1.

26. On December 3, 2001, plaintiff CFS sent a letter to Acting Principal Deputy Commissioner Bernard A. Schwetz stating that the agency must substantively respond to the GE Foods Petition and that, if no such response was received by CFS, the agency could be legally found to have unreasonably delayed in providing a response. The FDA did not respond to the letter or provide a substantive response to the petition.

27. On March 27, 2002, plaintiff sent a letter to Deputy Commissioner Lester Crawford and Joseph Levitt, Director, FDA/Center for Food Safety and Applied Nutrition (CFSAN) again requesting that the FDA provide a substantive response to the GE Foods Petition. The FDA failed to respond to this letter or provide a substantive response to the petition.

28. On October 15, 2002, plaintiff sent a third letter to Deputy Commissioner Crawford and CFSAN Director Levitt requesting that the FDA provide a substantive response to the GE Foods Petition. The letter stated that if no such response was received by November 15, 2002, CFS would consider the agency to have unreasonably delayed in providing a response The letter was sent via certified mail first class mail with return receipt. The return receipts were sent back to the plaintiff, but FDA has neither responded to the content of the letter nor provided a substantive response to the petition.

29. On April 4, 2003, the FDA withdrew a proposed rule that would have altered the type of actions that could be requested through its citizen petition process. In support of its rule withdrawal, the agency stated that the agency has made improvements in handling citizen petitions and that the agency's current response rate is equal to, and sometimes exceeds, the number of citizen petitions its receives. Despite these improvements, the agency still has failed to provide a substantive answer to the GE Foods Petition.

30. Since the filing of the GE Foods Petition, the FDA has engaged in a number of activities that support a positive substantive response to the plaintiff's requests contained therein. Both the U.S. Government and FDA officials have participated in the development of genetically engineered foods assessment protocols at the Codex Alimentarius Commission, the global foods safety standard setting organization of the United Nations. The standards set at the Codex are recognized by the World Trade Organization as international norms when resolving trade disputes under the GATT.

31. During its participation in Codex task forces and meetings, United States and FDA officials have joined in endorsing and approving three documents creating state of the art safety assessment approaches for the pre-market review of genetically engineered foods. These documents are: Principles for the Risk Analysis of Foods Derived From Modern Biotechnology (CAG/GL 44-2003); Guidelines for the Conduct of Food Safety Assessment of Foods Derived From Modern Biotechnology (CAG/GL 45-2003) and Guidelines for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms (CAG/GL 46-2003). All three of these documents have been voted on and approved as official Codex guidelines and each makes clear that all genetically engineered foods should go through rigorous safety assessment procedures prior to their allowance on the market. The FDA's current policy does not follow the guidelines adopted at Codex.

32. Additionally, numerous countries throughout the world have adopted mandatory pre-

market approval and labeling systems for genetically engineered foods. These include but are not limited to: Australia, Brazil, China, India, Japan, New Zealand, South Korea and all member nations of the European Union.

33. Over six years since the filing of the GE Foods Petition, after the submission of three letters seeking action on the petition, and after the international regulatory community has developed consensus standards on the oversight of genetically engineered foods, plaintiff CFS now seeks to compel FDA to provide a substantive response to its petition.

CAUSE OF ACTION

34. Plaintiffs incorporate by reference all allegations contained in paragraphs 1 through 33 *supra.*

35. Pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(e) and the Food and Drug Administration's implementing regulations found at 21 C.F.R. §§ 10.20, 10.30, plaintiff CFS presented a petition for rulemaking entitled "Petition Seeking the Establishment of Mandatory Pre-Market Safety Testing, Pre-Market Environmental Review & Labeling for All Genetically Engineered Foods." To date, FDA has failed to provide the plaintiff with a substantive answer to the GE Foods Petition.

36. The Administrative Procedure Act, 5 U.S.C. § 555(b) requires the Comissioner of the FDA "within a reasonable time . . . proceed to conclude a matter presented to it."

37. Food and Drug Administration regulation, 21 C.F.R. § 10.30(e)(2) provides that "[t]he Commissioner shall furnish a response to each petitioner within 180 days of the receipt of the petition."

38. The Administrative Procedure Act, 5 U.S.C. § 706(1) further provides that a reviewing court shall "compel agency action unlawfully withheld or unreasonably delayed."

39. FDA's failure to provide a substantive answer to the GE Foods Petition within a reasonable period of time is a violation of the Administrative Procedure Act, 5 U.S.C. § 555(b).

RELIEF REQUESTED

WHEREFORE, plaintiff respectfully requests that this Court enter an Order:

(1). Declaring that defendant's unreasonable delay in responding to the GE Foods Petition is a violation of the Administrative Procedure Act;

(2). Ordering FDA to provide a substantive answer to the GE Foods Petition within sixty (60) days after the entrance of this Order;

(3). Retaining jurisdiction of this action to ensure compliance with its decree;

(4). Awarding plaintiff's attorney's fees and all other reasonable expenses occurred in pursuit of this action; and

(5). Granting other such relief as the Court deems just and proper.

Respectfully submitted,

/s/

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