

The Foundation on Economic Trends

1130 17th St., NW, Suite 630, Washington, DC 20036 — (202) 466-2823 — Fax (202) 429-9602

3 November 1993

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

LS:G... 6-10-93
COMMUNICATIONS SECTION

To Commissioner Dr. David Kessler:

Pursuant to 21 C.F.R. Part 10.30, this is a petition submitted on behalf of the Foundation on Economic Trends and its president, Jeremy Rifkin, requesting that the Food and Drug Administration (FDA) postpone all rulings and the issuance of any regulations pursuant to Calgene's Food Additive Petition for Aminoglycoside 3'-Phosphotransferase II (APH(3')II) in tomatoes, cotton and rapeseed pending the completion of the FDA's Statement of Policy: Foods Derived From New Plant Varieties (Docket 92N-0139).

STATEMENT OF FACTS

Calgene is an agribusiness biotechnology company that is developing improved plant varieties and plant products for the seed, food and specialty chemical industries. Since its 1991 request for an FDA Advisory Opinion on the status of its FLAVR SAVR (TM) tomato, Calgene has sought FDA regulatory approval allowing for the introduction of genetically altered foods into the marketplace.¹

On January 4, 1993 Calgene converted an original Request for an Advisory Opinion on the Safety and Use in the Production of Genetically Engineered Plants using the kan^r Gene (Docket 90A-0416) to a Food Additive Petition (FAP) for Aminoglycoside 3'-Phosphotransferase II (APH(3')II) in Tomatoes, Cotton and Oilseed Rape.² The FAP seeks FDA approval for use of APH(3')II, a protein

¹ The FDA is currently reviewing Calgene's August 1991 request for an Advisory Opinion considering the status of the FLAVR SAVR (TM) tomato as a food.

² Letter from Donald L. Emlay, Director, Regulatory Affairs, Calgene, to Dr. Alan M. Rulis, Director, Office of Premarket Approval, Food and Drug Administration, January 4, 1993.

93P-0423

CP1

used for the purpose of plant selection during the genetic engineering.

On May 29, 1992, almost eight months prior to Calgene's FAP, the FDA issued its preliminary proposed Statement of Policy for Foods Derived From New Plant Varieties on May 1992 (Statement of Policy) (Docket No. 92N-0139). The proposed Statement of Policy attempts to establish the regulatory status of foods derived from new plant varieties, including plants developed by newer methods of genetic modification.³

Upon the initial publication of the proposed Statement of Policy, the FDA sought public comments from May 29, 1992 until August 27, 1992.⁴ On April 28, 1993, the FDA sought additional comments on the proposed Statement of Policy.⁵ This comment period remained open until July 27, 1993.⁶ To date, the FDA continues to review all comments received during the two notice and comment periods and has not yet issued a final Statement of Policy.

STATEMENT OF LAW

I. 21 U.S.C. Section 348. Food additives - Unsafe food additives; exception for conformity with exemption or regulation states:

(c)(1) The Secretary shall--

(a) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additives may be safely used (including, but not limited to, specifications as to particular food or classes of food in or which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may added to or used in or such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action. (emphasis added).

³ 57 Fed. Reg. 22984 (Friday, May 29, 1992).

⁴ 57 Fed. Reg. 23005 (May 29, 1992).

⁵ 58 Fed. Reg. 25837 (April 28, 1993).

⁶ 58 Fed. Reg. 25837, 25841 (April 28, 1993).

II. 21 C.F.R. Section 171.100 Regulation based on petition.

(a) The Commissioner will forward for publication in the Federal Register, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 409(c)(2) of the Act), a regulation prescribing the conditions under which the food additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity that may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure safety of such use), and prior to the forwarding of the order to the Federal Register for publication shall notify the petitioner of such order and the reasons for such action; or by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

III. Administrative Procedure Act, 5 U.S.C. Section 706, Scope of Review.

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning and applicability of the terms of an agency action. The reviewing court shall --

(2) hold unlawful and set aside agency action, findings and conclusions found to be -- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

A. Action Requested

Petitions request the FDA to postpone the issuance of any regulations or any and all rulings concerning the FAP for Calgene's Aminoglycoside 3'-Phosphotransferase II (APH(3')II) in Tomatoes, Cotton and Oilseed Rape until final issuance of the agency's Statement of Policy: Foods Derived From New Plant Varieties.

B. Statement of Grounds

The FDA's proposed Statement of Policy was developed to address a wide range of questions pertaining to the introduction of genetically altered foods into the marketplace. Among the issues

to be addressed in the Statement of Policy are: whether the agency will conduct premarket review of these new foods, whether such foods introduced into interstate commerce would be challenged by FDA on legal grounds, which new plant varieties might come under the jurisdiction of FDA, what scientific information may be necessary to satisfy FDA that such foods are safe and comply with law, whether petitions would be required by the agency, and whether special labeling would be required.⁷

In addition, in April of this year the FDA sought additional comments on its Statement of Policy. Among the issues addressed in this notice for comment were: whether all foods derived from new plant varieties developed using genetic engineering techniques be required to be labeled, should labeling the source of introduced DNA be required, under what circumstances is ingredient labeling appropriate, how can required labeling for food allergy be accomplished, what are the practical difficulties and economic impact of labeling genetically engineered foods, and consideration of voluntary labeling.⁸

Currently, the FDA is considering the comments received during these two notice and comment periods and will be developing a final Statement of Policy which will regulate the introduction of genetically engineered foods into the marketplace.

On January 4, 1993 Calgene submitted a food additive petition (FAP) seeks a ruling on APH(3')II, a processing aid in the production of transgenic plants such as tomatoes, cotton and rapeseed. The proposed food additive has been used to develop such Calgene products as the FLAVR SAVR (TM), a tomato that contains the genetically engineered kanamycin resistance gene and a mirror image of a tomato gene inhibiting rot.

The process of genetic alteration used in products such as the FLAVR SAVR (TM) does not always result in predictable modifications. The interactions between the host organism and the synthetic genetic material can be dynamic and complex, and it will not always be possible to predict the toxic or nutritional consequences of the insertion of a particular gene.

There has already been one case of a genetically engineered foodstuff that has produced deadly results. The amino acid L-tryptophan, manufactured using genetically engineered bacteria, has been linked with the deaths of least 31 Americans and with more

⁷ 57 Fed. Reg. 22984 (May 29, 1992).

⁸ 58 Fed. Reg. 25837 (April 28, 1993).

than 1500 serious illnesses.⁹ Millions of Americans had consumed L-tryptophan as a dietary supplement for over 30 years, but only with the advent of genetic engineering has the ingestion of the product had fatal results. To date, the source of the L-tryptophan contaminant that caused the deaths and illnesses has not been determined. The FDA has not been able to rule out the possibility that it was the genetic engineering process itself that caused the deadly contamination of L-tryptophan. In a recent radio interview, the FDA Commissioner admitted that the FDA had not yet been able to determine the exact cause of the contamination of L-tryptophan.¹⁰

The Calgene APH(3')II FAP seeks an agency ruling on proposed additive that will be utilized on genetically engineered foods such as the FLAVR SAVR tomato. Under the FFDCa, the Secretary's consideration of this FAP will address a number of issues such as safety and labeling and usage guidelines, that have yet to be fully addressed by the agency's Statement of Policy on New Plant Varieties.

Under Section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) the Secretary of FDA has the statutory discretion to promulgate regulations pursuant to "food additive" applications.¹¹ Among the issues that may be contained in the Secretary's regulatory response to a FAP are the conditions under which such an additive may be safely used including, inter alia, the maximum quantity of the additive in question, the manner in which such an additive may be used, and other packaging or labeling requirements.¹² The resolution of these issues are the goal of the FDA's attempt to develop a regulatory policy for addressing genetically engineered foods and related proposed additives such as APH(3')II.

Should FDA rule upon the APH(3')II FAP it would be making a policy determination on genetically engineered foods prior to the issuance of its final statement of policy. Given the FDA's mandate to protect the health and safety of the American consumer from incidents such as the L-tryptophan case, it is imperative that the agency establish a comprehensive regulatory framework to protect the public from the risks of food substances that have had no history of human consumption. For the FDA to rule on Calgene's FAP prior to the finalizing of the Statement of Policy would not only contradict FDA's mandate, it would be an abandonment of the

⁹ See e.g., Raphals, P., "Does Medical Mystery Threaten Biotech?," *Science* 619 (2 Nov. 1990); "FDA's Regulation of the Dietary Supplement L-tryptophan," 1991: Hearing Before the Human Resources and Intergovernmental Relations Subcomm., 102d Cong., 1st Sess. 54 (statement of Esther Sternberg, M.D., National Institutes of Mental Health).

¹⁰ Remarks of Dr. Kessler, Diane Rehm Show, WAMU Radio 88.5 FM (6 May 1992).

¹¹ 21 U.S.C.A. 348 (1988 & supp. 1992).

¹² 21 U.S.C.A. Section 348(c)(1)(A) (1988 & Supp. 1992).

agency's year long mission to establish a new regulatory policy on genetically engineered foods. Such an action can only be describe as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

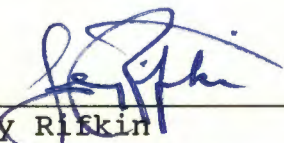
C. Environmental Impact

The enforcement actions here requested will not cause the release of any substance into the environment. They are categorically excluded from the requirement of environmental documentation under 21 C.F.R. 25.24 (a)(c)(d).

D. Certification

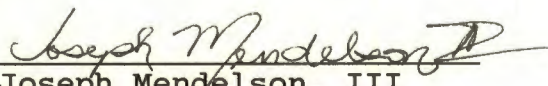
We are requesting a response to this petition within (20) calendar days. A denial of the requests in this petition will compel the Foundation to consider litigation in order to achieve the full and complete action required to address this arbitrary and capricious violation of federal law that threatens the public health and safety.

The undersigned certify, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to petition.



Jeremy Rifkin
President
Foundation on Economic Trends
1130 17th Street, N.W. #630
Washington, D.C. 20036
202-466-2823

Andrew Kimbrell
Policy Director
Foundation on Economic Trends
1130 17th Street, N.W. #630
Washington, D.C. 20036
202-466-2823



Joseph Mendelson, III
Staff Attorney
Foundation on Economic Trends
1130 17th Street, N.W. #630
Washington, D.C. 20036
202-466-2823

The Foundation on Economic Trends

1130 Seventeenth Street, N.W., Suite #630

Washington, DC 20036 — (202) 466-2823

Lyle Jaffe
Docket Management Branch
F.D.A.
Room 1-23
12120 Parklawn Drive
Rockville, MD 20857