

Quotes from FDA Scientists

Key documents revealing the hazards of Genetically Modified foods and flaws with how the agency made its policy.

[Courtesy of Alliance for Bio-Integrity](#)

About the Documents

You will see scanned reproductions (exact copies) of some of the Food & Drug Administration's (FDA) internal memoranda about the hazards of genetically engineered foods. These documents became available through the Alliance for Bio-Integrity's lawsuit (Alliance for Bio-Integrity et al., vs. Shalala, et al.) to gain mandatory safety testing and labeling of these foods. The large numbers on the bottom of each page (i.e. 18952) are the Administrative Record (A.R.) numbers affixed by the FDA.

To print the PDF files you will need Adobe Acrobat Reader. If you don't already have Adobe Acrobat Reader, you can download it [here](#)

FDA Scientists Discuss Various Safety Concerns

- Comments from Dr. Linda Kahl, FDA compliance officer, to Dr. James Maryanski, FDA Biotechnology Coordinator, about the Federal Register document "Statement of Policy: Foods from Genetically Modified Plants." Dated January 8, 1992. (3 pages) [View PDF](#)
- Memorandum from Dr. Edwin J. Mathews to the Toxicology Section of the Biotechnology Working Group. Subject: "Analysis of the Major Plant Toxicants." Dated October 28, 1991. (2 pages) [View PDF](#)
- Memorandum from Dr. Samuel I. Shibko to Dr. James Maryanski, FDA Biotechnology Coordinator. Subject: "Revision of Toxicology Section of the Statement of Policy: Foods Derived from Genetically Modified Plants." Dated January 31, 1992. (3 pages) [View PDF](#)
- Comments from Dr. Louis J. Pribyl re: the "Biotechnology Draft Document, 2/27/92." Dated March 6, 1992. (5 pages) [View PDF](#)

- Comments from Dr. Louis J. Pribyl re: "... the March 18, 1992 Version of the Biotechnology Document." Dated March 18, 1992. (1 page) [View PDF](#)
- Comments from Division of Food Chemistry and Technology and Division of Contaminants Chemistry. Subject: "Points to Consider for Safety Evaluation of Genetically Modified Foods. Supplemental Information." Dated November 1, 1991. (3 pages) [View PDF](#)
- Memorandum from Dr. Mitchell Smith, Head, Biological and Organic Chemistry Section, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Comments on Draft Federal Register Notice on Food Biotechnology, Dec. 12, 1991 draft." Dated January 8, 1992. (2 pages) [View PDF](#)
- Letter from Dr. James Maryanski, Biotechnology Coordinator, to Dr. Bill Murray, Chairman of the Food Directorate, Canada. Subject: the safety assessment of foods and food ingredients developed through new biotechnology. Dated October 23, 1991. (2 pages) [View PDF](#)
- Comments from Dr. Carl B. Johnson on the "draft statement of policy 12/12/91." Dated January 8, 1992. (2 pages) [View PDF](#)
- Memorandum from Dr. Gerald B. Guest, Director of the Center for Veterinary Medicine, to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Regulation of Transgenic Plants—FDA Draft Federal Register Notice on Food Biotechnology." Dated February 5, 1992. (4 pages) [View PDF](#)

Specific Objections to the Use of Antibiotic-Resistant Marker Genes

- Memorandum from Dr. James Maryanski, Biotechnology Coordinator, to Dr. Murray Lumpkin. Subject: "Use of Kanamycin Resistance Marker Gene in Tomatoes." (1 page) [View PDF](#)
- Memorandum from Dr. Murray Lumpkin to Dr. Bruce Burlington. Subject: "The tomatoes that will eat Akron." Dated December 17, 1992. (7 pages) [View PDF](#)

- Memorandum from Dr. Albert Sheldon to Dr. James Maryanski, Biotechnology Coordinator. Subject: "Use of Kanamycin Resistance Markers in Tomatoes." Dated March 30, 1993. (3 pages) [View PDF](#)

Safety Questions Raised by Tests on the Flavr Savr Tomato™—the First Bioengineered Plant that Came to Market

- Memorandum from Dr. Fred Hines to Dr. Linda Kahl. Subject: "FLAVR SAVR Tomato:" ... "Pathology Branch's Evaluation of Rats with Stomach Lesions From Three Four-Week Oral (Gavage) Toxicity Studies" ... "and an Expert Panel's Report." Dated June 16, 1993. (3 pages) [View PDF](#)
- Memorandum from Robert J. Scheuplein, Ph.D. to the FDA Biotechnology Coordinator and others. Subject: "Response to Calgene Amended Petition." Dated October 27, 1993. (3 pages) [View PDF](#)
- Memorandum from Dr. Carl B. Johnson to Dr. Linda Kahl & Others. Subject: "Flavr Savr(TM) tomato; significance of pending DHEE question." Dated Dec 7, 1993. (1 page) [View PDF](#)
- Memorandum from Dr. Fred Hines to Dr. Linda Kahl. Subject: "FLAVR SAVR Tomato" ... "Pathology Branch's Remarks to Calgene Inc.'s Response to FDA Letter of June 29, 1993." Dated December 10, 1993. (3 pages) [View PDF](#)

Evidence of Improprieties In The Formation Of FDA Policy On Bioengineered Foods

- Note from Dr. James Maryanski, Biotechnology Coordinator, to Mr. Michael Taylor. Subject: "Food Biotechnology Policy Development." Dated October 7, 1993. (1 page) [View PDF](#)
- Document titled "FDA REGULATION OF FOOD PRODUCTS DERIVED FROM GENETICALLY ALTERED PLANTS: POINTS TO CONSIDER" Not dated. (3 pages) [View PDF](#)
- Memorandum from Dr. James Maryanski, Biotechnology Coordinator, to the Director of the Center for Applied Nutrition. Subject: "FDA Task Group

on Food Biotechnology: Progress Report 2.” Dated August 15, 1991. (1 page) [View PDF](#)

- Memorandum from David Kessler, Commissioner of Food & Drugs. Subject: “FDA Proposed Statement of Policy Clarifying the Regulation of Food Derived from Genetically Modified Plants–DECISION.” Dated March 20, 1992. (4 pages) [View PDF](#)
- Letter from Terry Medley, J.D. (of USDA’s Animal and Plant Health Inspection Service), to Dr. James Maryanski, Biotechnology Coordinator. Subject: “Comments on FDA Draft Statement of Policy on foods derived from new plant varieties, including plants derived by recombinant DNA techniques. Dated April 2, 1992. (5 pages) [View PDF](#)
- Note from Eric Katz (Dept. of Health & Human Services) to John Gallivan. Subject: “Food Biotechnology Policy Statement.” Dated March 27, 1992. (2 pages) [View PDF](#)
- Memorandum from James B. MacRae, Jr. (of the Office of Management and Budget), for C. Boyden Gray (President Bush’s White House counsel). Subject: “FDA Food Biotechnology Policy.” Dated March 21, 1992. (2 pages) [View PDF](#)