

DEPARTMENT OF HEALTH & HUMAN SERVICES

HFF-300

Food and Drug Administration Rockville MD 20857

March 20, 1992

MEMORANDUM

TO:

The Secretary

Through: DS_

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AGC Otherwise A. Copp

FROM:

Commissioner of Food and Drugs

SUBJECT:

FDA Proposed Statement of Policy Clarifying the

Regulation of Food Derived From Genetically Modified

Plants -- DECISION

SUMMARY

We request your concurrence with FDA's publication of a "statement of policy" in the <u>Federal Register</u> clarifying how FDA will apply the Food, Drug, and Cosmetic Act (the Act) to foods (including animal feeds) derived from new plant varieties, including plants developed by recombinant DNA techniques. Our policy would utilize the identical approach that we apply to foods developed by traditional plant breeding.

BACKGROUND

Advances in biotechnology, including recombinant DNA techniques, mark an important evolutionary step in the development of new plant varieties. The new technologies give producers powerful, precise tools to introduce improved traits in food crops, opening the door to improvements in foods that will benefit food growers, processors, and consumers.

Companies are now ready to commercialize some of these improvements. To do so, however, they need to know how their products will be regulated. This is critical not only to provide them with a predictable guide to government oversight, but also to help them win public acceptance of these new products.

We have been monitoring the development of this new technology for several years and have had extensive contact with the food biotechnology industry, outside scientists, and other interested parties. One company, Calgene, has formally sought our advice on a particular tomato. Furthermore, the Biotechnology Working Group of the Council on Competitiveness wants us to issue a policy statement as soon as possible.

FDA'S POLICY STATEMENT

Under our proposed policy, most foods derived from genetically modified plants will be regulated under the post-market authority of section 402(a)(1) of the Act, which currently assures the safety of most of our food supply. This authority places a legal duty on companies to assure that the foods they market are safe and permits FDA to take enforcement action against foods that may be injurious to health.



Substances that are intentionally added to food as a result of genetic modification and that raise a safety question (e.g., because they are not substantially similar to substances commonly found in food, such as proteins, fats, and carbohydrates, and have no history of safe use in food) could be regulated as "food additives" under section 409 of the Act, requiring pre-market approval. This authority will be used on an exception basis but may be necessary in some cases to protect public health.

To further assure the safe introduction of this new technology into the marketplace, our policy statement includes a "guidance to industry" section to assist companies with their own internal safety reviews of these foods. The objective characteristics of the food that could trigger pre-market regulation under section 409 are described in this section. The guidance section outlines a "decision tree" approach to safety assessment, identifying scientific questions that raise sufficient concern to warrant consultation with FDA. This section is a critical part of the document, because the industry wants to have an agreed upon scientific basis for evaluating (and assuring the public about) the safety of these products.





The approach and provisions of the policy statement are consistent with the general biotechnology policy established by the Office of the President in the recently published "scope" document. It also responds to White House interest in assuring the safe, speedy development of the U.S. biotechnology industry. We have consulted extensively with USDA and EPA in the development of this policy, and we have briefed Dr. Young and Dr. Mason's staff. We would be pleased to brief you or your staff on what I believe is an important statement of policy.

We plan to publish simultaneously with the policy statement a notice announcing our ongoing review of the Calgene product. Calgene is anxious for this notice to be published as soon as possible.

POTENTIAL CONTROVERSY

A coalition of environmental groups -- the Environmental Defense Fund, the Natural Resources Defense Council and the National Wildlife Federation -- wrote FDA last year urging that we routinely require formal food additive premarket approval for foods from genetically modified plants and that we require that the fact that the food is from a genetically modified plant be disclosed in labeling. Although we believe our policy fully protects public health and will provide proper disclosure to consumers, we have not adopted the positions advanced by these groups. They may challenge our policy as leaving too much decisionmaking in the hands of industry and not adequately informing consumers. We also expect elements who fundamentally oppose any use of recombinant DNA techniques, such as Jeremy Rifkin's Foundation for Economic Trends, to oppose the policy generally, including the manner in which we propose to implement our duties under the National Environmental Policy Act.

RECOMMENDATION

We recommend you concur in publishing the attached statement of policy.

Concur _____ Date ______ David A. Kessler, M.D.

Attachment

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Drafted:JMaryanski:HFF:3/19/92

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