



MAY 17 1994

- Mr. Donald L. Emlay
Director, Regulatory Affairs
Calgene, Inc.
1920 Fifth Street
Davis, CA 95616

Re: FMF 526 and Docket No. 91A-0330

Dear Mr. Emlay:

This is in response to your request, dated August 12, 1991, for consultation with the Food and Drug Administration (FDA) concerning FLAVR SAVR™ tomatoes. You requested that FDA issue an advisory opinion under 21 CFR 10.85 concerning whether FLAVR SAVR™ tomatoes are food and, therefore, subject to the same regulation as other tomato varieties. This request is separate from your request for the evaluation of safety of the aminoglycoside-3'-phosphotransferase II (APH(3')II) protein used for selection of plant cells that incorporated the new genetic trait. Because the question concerning APH(3')II is addressed in a separate rulemaking, this letter addresses only aspects of FLAVR SAVR™ tomatoes other than APH(3')II.

In the *Federal Register* of May 29, 1992 (57 FR 22984), FDA issued a "Statement of Policy: Foods Derived from New Plant Varieties", in which FDA advised that requests for consultation with the agency should be made consistent with the principles outlined in the policy. Therefore, we are treating your request as a consultation in accordance with the May 1992 policy statement.

As noted in that statement (57 FR 22984 at 22990), FDA has rarely had the occasion to review the regulatory status of foods derived from new plant varieties because these foods have been widely accepted as safe. FDA regulations in 21 CFR 170.30(f) do, however, provide for review of the regulatory status of certain substances of natural biological origin in certain circumstances. Specifically, 21 CFR 170.30(f)(2) provides for the review of the regulatory status of any substance of natural biological origin with a history of safe use that has had "significant alteration of composition by breeding or selection." Based on the information that Calgene has submitted concerning the FLAVR SAVR™ tomato, we believe that this new variety has not been significantly altered within the meaning of 21 CFR 170.30(f)(2), when compared to varieties of tomatoes with a history of safe use.

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Although the agency has concluded that the FLAVR SAVR™ tomato has not been significantly altered, we emphasize that under the Federal Food, Drug, and Cosmetic Act (the Act), it is Calgene's responsibility to ensure that foods that the firm markets are safe, wholesome, and in compliance with all provisions of the Act.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Alan M. Rulis", with a long horizontal flourish extending to the right.

Alan M. Rulis, Ph.D.
Acting Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition