

Dr. Bill Murray
Chairman, Food Directorate
Working Group on Biotechnology
Bureau of Chemical Safety
Food Directorate
Sir Frederick Banting Bldg.
Ottawa, Ontario
Canada, K1A 0L2

10/23/91

Dear Dr. Murray:

This replies to your letter of June 14, 1991, that requested my comments on a set of guidelines and case studies for the safety assessment of foods and food ingredients developed through new biotechnology. I appreciate the opportunity to review and comment on the document, and I have also asked several scientists in our Center to review the document. Several individuals provided comments, and their comments are attached. I understand that you have also asked Dr. Flamm and Dr. Shibko to comment, and they will do so separately.

I have reviewed the document, and I think that you are to be commended on its contents. You have identified the important considerations and the case studies provide useful examples of products that are likely to be developed. The document is thorough and well-balanced. As I know you are aware, there are a number of specific issues addressed in the document for which a scientific consensus does not exist currently, especially the need for specific toxicology tests. Also, the quantity and quality of data that would be required is not addressed and is difficult to specify at this time. I think the question of the potential for some substances to cause allergic reactions is particularly difficult to predict. I have enclosed a publication that deals with this issue for food additives that may be useful to you.

We are currently developing a document that will address scientific and regulatory issues that pertain to whole foods developed by new biotechnology. The agency has given this effort high priority, and we plan to complete the document by the end of this year. I will be glad to share the document with you when it is available. I also believe it would be useful to arrange for our scientists to get together at some future time to discuss these issues once we have completed our current task.

Thank you again for sharing your document with us, and I hope we will have an opportunity to continue to discuss these issues. I have also enclosed a copy of the comments we received on the notice of filing of Calgene, Inc.'s request on the use of the marker gene and a document submitted to us by the Environmental Defense Fund for your information.

Sincerely yours,

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James H. Maryanski, Ph.D.
Biotechnology Coordinator
Center for Food Safety
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Enclosures

cc:

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