

Office of the Assistant Secretary for Health Washington DC 20201

MAR 27 1932

NOTE TO JOHN GALLIVAN

Subject:

Food Biotechnology Policy Statement

Dr. Hudson and I have both reviewed FDA's food biotech document. As you know, we have received a full briefing from FDA that was enormously helpful in laying out the general issues. We have also spoken with Dr. Young to help coordinate our comments and concerns, and we understand Dr. Young will be providing his own written comments.

Dr. Hudson and I are both most impressed with the document and the general approach it maps out, and we congratulate FDA on both the content of the document and the speed with which FDA staff prepared it. We are also pleased that FDA elected to solicit OASH feedback at this stage. Accordingly, we concur in the overall document, with the exception of the NEPA section where we must non-concur as explained below, and in a few passages where we offer technical comments on language for the sake of accuracy or clarity.

1. Environmental Concerns under NEPA. The extensive twelve page discussion seems to be a dangerously detailed and drawn-out method for meeting the requirements of the statute. The extensive discussion seems largely unnecessary, gives disproportionate attention to environmental concerns, and may even provide a possible basis for later legal challenges. While it is clearly important to include a discussion of environmental considerations in the policy statement, FDA's responsibilities and obligations under NEPA could be adequately addressed in a more abbreviated form.

In contrast to the sections on food safety, which properly imply that biotechnology is a fundamentally innocuous tool of food production and that the fruits of biotechnology will be substantially equivalent to those with which we are already familiar, the NEPA section gives an incorrect impression that biotechnology raises significant new agricultural and environmental concerns.

The extensive discussion in this section seems unwarranted given that most, if not all, of the environmental concerns raised by new plant varieties developed with biotechnology are addressed by the EAs conducted by USDA before they issue permits under the authority of the Plant Pest Act. The only impacts that USDA might not consider are those that might be associated with consuming the plant. For example, what is the impact on species that may feed on the plant variety (i.e. birds, rodents, insects, etc.). Other questions relating to the impact of potential changes in the composition of animal wastes as the result of consuming new varieties should also be considered. With this

possible exception, it seems that the entire range of concerns for an EA would be addressed in USDA's prior EA evaluation and should be part of the tiering process discussed in the document.

We recommend that the language from paragraph 2, page 75 to the end of page 83 be deleted. This would preserve the general guidance on the types of issues that might demand attention in the (hopefully unlikely) event that FDA requires EA data from the sponsor beyond that which is available from other Federal agencies in the tiering process. If FDA feels compelled to provide detailed guidance on NEPA to sponsors, we recommend that such guidance be provided in the form of a "points to consider" document or other informal communication.

- Technical comments. We offer a few technical comments where language changes could improve accuracy or clarity.
- o The use of "host" in the document conjures up images of host-pathogen or host-parasite interactions. Perhaps "variety" or "recipient" could be used. See page 12, para. 1, page 40 (1).
- o Page 24, para. 3, 2nd sentence, may render standard is "more stringent". Unclear reference, more stringent that what?
- o Page 71, para. 2. This section should say that nucleic acids or the RNA products do not raise safety concerns. Rather it is the effect of the RNA or the protein product and its effects. This paragraph focuses too exclusively on anti sense RNA.
- o Page 72, paragraph 2. Is it really essential that consensus be reached? Is this possible?
- 3. Coordination with Calgene petition. As a final point, let us note that we agree with FDA on the importance of coordinating this document with the specific request from Calgene for an advisory opinion. We intend to write separately to discuss strategy options and policy considerations on this point, and those comments may have an impact on this general policy document as well as on the specific response to the Calgene petition.

En Katz