

March 14,2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: F.R. 66:4706-4738.2000
Docket No. 00N-1396

To whom it may concern:

The American Phytopathological Society (APS), founded in 1909, is the premier educational, professional and scientific society dedicated to the promotion of the plant health and plant disease control for the common good. The Society represents more than 5,000 microbiologists, including scientists and science administrators in academic, industrial and government institutions working in a variety of areas, including applied and environmental plant pathology, food, horticultural and forestry science, and biotechnology, including basic and applied research on producing transgenic plants resistant to pathogens and abiotic stresses.

The APS appreciates the opportunity to comment on the FDA proposed rule that would require food and feed developers to notify the FDA at least 120 days in advance of their intent to market a food produced through biotechnology and provide information to demonstrate that the product is at least as safe as its conventional counterpart.

We remind FDA that at its November 30, 1999 public meeting in Washington, D.C., the APS supported the FDA's previous position on voluntary consultation, because it was de facto, a mandatory consultation. However, the public did not perceive this to be the case, thus the APS supports the proposed rule to make premarket notification and consultation for bioengineered foods and feeds obligatory. Due to the long time period of development of such products, it does not appear to be an onerous requirement. The APS also supports the position that the FDA notification requirement should include the status of consultations with other agencies that have jurisdiction of other aspects of food and feed, particularly EPA and USDA. We would encourage processes of communication and deliberation so that agreements on such issues as allergenicity are in concordance before public announcements.

The APS concurs with the suggested exclusions from notification, that the notification process should not extend to bioengineered food from plant varieties derived from a specific transformation event, provided that both the transformation process and the use of the bioengineered food were addressed appropriately in a consultation completed under the FDA 1996 voluntary program. Consultations in progress should be completed under existing 1996 procedures, but pending consultations should be administered under the January 18,2001 rule change as and when enacted.

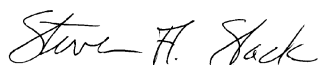
The APS also agrees that exclusions from the notification requirement include uses and applications of bioengineered food identical to those already addressed by the agency in previously submitted applications that were complete and judged to be in compliance.

The scope of the proposed notification (192.25.Part II, Section 5) is generally comprehensive, however deletions are not mentioned. Such manipulations are hypothesized as possibly resulting in unanticipated change(s) in the plant. Further, it is not clear that supplements would be included. An example relevant to our profession is rose hips, used in some vitamin C supplements. Would such a supplement be covered if the parent plant were engineered for disease resistance, such as for black spot of roses? If the above comment is considered relevant, then the definition of bioengineered food may need clarification. We agree that 'transformation event' appears appropriately defined.

With respect to inclusion of detection methods in the notification, the APS believes that this should be optional. The scientific community and the marketplace are developing methods, which are in a state of flux. As FDA is aware, at present, there are no agreed upon standards, and there are disparities in detection, depending on the degree of processing. If the methods do not present a safety or nutritional issue, we do not recommend obligatory inclusion.

The APS supports the FDA efforts to safeguard public health as recombinant DNA technology continues to evolve and provide new and/or enhanced foods and feed. We are concerned that additional requirements and costs will potentially preclude the development of so-called minor crops, namely the fruits and vegetables that are considered desirable elements of everyday diets. The FDA should thus consider how it might support such applications.

Sincerely,

A handwritten signature in cursive script that reads "Steve A. Slack".

Steven A. Slack
President, APS