



**Proposed Guidance Insufficient:  
Comment of the Organic Trade Association on Docket No. 2004D-0369,  
FDA's Draft Guidance for Industry:  
Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins  
Produced by Bioengineered Plants Intended for Food Use**

*Submitted by:  
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January 24, 2005*

The Organic Trade Association requests FDA to consider the following points and recommendations:

- 1) The proposed guidance is voluntary, which is insufficient due to the lack of knowledge regarding the ecological consequences of the use of this product, and therefore ultimately human health.
- 2) Companies developing new products would not be required to notify, much less gain the approval of, FDA.
- 3) The safety tests recommended in the guidance neither provide, nor comply with, any existing set of standards for testing. OTA requests that FDA outline its rationale for such tests, and address their variance from existing international standards.
- 4) The proposed guidance fails to require federal oversight of what amounts to highly experimental use.
- 5) Early food safety evaluation should be required, rather than simply encouraged: the prevention of problems is universally more cost effective than their mitigation, though it seems FDA is willing to assume the political costs of an ecological failure that leads to human problems.
- 6) Each instance of a gene being introduced into a plant variety—let alone specie—is a separate event, and calls for an early food safety evaluation and the identification of possible safety concerns.

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Single proteins are less of a safety concern than the effect of transgenes on the organism as a whole. If there were a one-to-one correspondence between genes and traits, this might be arguable, but there is not, so the whole organism should be evaluated.

To address these deficiencies, OTA recommends that FDA's withdraw its proposed guidance and that FDA draft new regulations that provide meaningful protection and information to itself, consumers, farmers, and the environment. OTA believes FDA's role includes:

- 1) requiring independent, mandatory pre-market approval of GE crops for human health and environmental safety, with a food safety assessment at least as stringent as the range of tests laid out in the internationally accepted Codex Alimentarius "Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants";
- 2) maintaining and enforcing zero tolerance for any contamination of the food supply with any genetic material or gene product from a transgenic crop that is undergoing field testing and for which a full food safety assessment has not be completed;
- 3) requiring that all experiments involving crops genetically engineered to produce pharmaceuticals and/or industrial compounds be conducted in greenhouses or similarly controlled environments;
- 4) requiring labeling of all foods that contain genetically engineered material.

Thank you for your consideration.

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