



# BEYOND PESTICIDES

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

RE: **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FDA's Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by Bioengineered Plants Intended for Food Use; Availability

Thank you for the opportunity to comment on FDA's Draft Guidance.

Beyond Pesticides is a national, non-profit grassroots organization that advocates for strong policy to protect human health and the environment from hazardous pesticides and the adoption of alternative pest management strategies that reduce or eliminate a dependency on toxic chemicals.

We are extremely alarmed that FDA is proposing to weaken, rather than fortify, the oversight of genetically engineered crops. The potential dangers of genetic engineering are immeasurable. The consequences of contamination of the food supply can be deadly and irreversible. It is incumbent on FDA to ensure that consumers, farmers, and the environment are absolutely protected from contamination by experimental genetically engineered crops.

However, FDA's proposed Guidance does little to protect consumers, farmers, or the environment. The Guidelines are inadequate for the following very basic reasons:

- The Guidance is merely voluntary. Industry developing a new product is not even required to notify FDA.
- The recommended "safety tests" neither provide, nor comply with, any set of standards for testing.
- Widely accepted International Standards for performing safety tests are ignored.

- The Guidance not only fails to require oversight, it actually discourages it. For example, "It is not necessary to have a meeting with [FDA] to communicate about your early food safety evaluation of your new protein."
- The Guidance is apathetic at best, suggesting that an early food safety evaluation be encouraged "prior to the time you have concerns that the new protein could enter the food supply, for example via pollen flow or commingling."
- The Guidance provides dangerous recommendations: For example, "If a protein has been evaluated in an early food safety evaluation and no safety concerns are identified, we would not expect an additional early food safety evaluation to be submitted if the same protein is introduced into another plant species."
- Ultimately, the Guidance provides no safety evaluation, merely the statement that "we have no questions at this time regarding your view that the new protein raises no food safety concerns."
- The Guidance appears to serve no other purpose than to provide legal protection to the bio-tech industry, since it provides no assurances of safety to the public.

## **RECOMMENDATIONS:**

We recommend that FDA's proposed Guidance be scrapped and that FDA draft new regulations that provide meaningful protection to consumers, farmers, and the environment. At a minimum, FDA needs to:

1. Require independent, mandatory pre-market approval of GE crops for human health and environmental safety. The food safety assessment should be 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. Maintain and enforce 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. Require that all experiments involving crops genetically engineered to produce pharmaceuticals and/or industrial compounds be conducted in greenhouses or similarly controlled environments.
4. Require labeling of all foods that contain genetically engineered material.

Thank you for your consideration.

Sincerely,

Shawnee Hoover  
Special Projects Director  
Beyond Pesticides/NCAMP