

January 24, 2005

TO: fdadockets@oc.fda.gov
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FDA's Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by Bioengineered Plants Intended for Food Use;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

To Whom It Concerns:

Thank you for the opportunity to comment on FDA's *Draft Guidance for Industry*, as referenced above. The California Sustainable Agriculture Working Group (CA SAWG) is a coalition of organizations working together to create a food system that is economically sound, environmentally safe and socially just. Our diverse membership allows us to craft policy positions that are broad in scope and reflective of a wide range of opinion. The issue of "GMOs" is one that we discuss carefully, due to the nature of our coalition. So it is with careful consideration that we send our comments on the *Draft Guidance for Industry*.

CA SAWG is 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 by any organism, genetically engineered or not, 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 nothing to protect consumers, farmers, or the environment. The Guidelines are completely 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 for manufacturers to have a meeting with FDA or any other agency to communicate about their early food safety evaluation of any newly developed protein.

The *Guidance* is apathetic at best, suggesting that an early food safety evaluation be encouraged prior to the time the manufacturer has 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, FDA would not expect the manufacturer to submit an additional early food safety evaluation if the same protein is introduced into another plant species.

Ultimately, the *Guidance* provides no safety evaluation, merely the statement that FDA has no questions at this time regarding the manufacturer's 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.

CA SAWG RECOMMENDATIONS:

CA SAWG recommends that FDA's proposed *Guidance* be completely rewritten with **new draft** 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 been 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,

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