



January 10, 2005

Division of Dockets Management (HFA-305),  
Food and Drug Administration,  
5630 Fishers Lane, Room 1061  
Rockville, MD20852, USA

re: Docket No. 2004D-0369

To FDA Commissioner Ken Salizar,  
These comments are written on behalf of the Sierra Club, the oldest and largest grassroots conservation organization in the U.S.

We strongly believe that the proposed FDA draft proposal permits the continued contamination of our food and seed supply with genetic material from thousands of biotech crop experiments.

The transgenes responsible for novel proteins can cross over to related weed species or compatible cultivars, which can act as a genetic reservoir for the persistence and amplification of the transgene, which could then be transferred back to food cultivars in the future.

Furthermore, the proposed "safety evaluation" is totally inadequate. First, it applies only to experimental GE crop varieties that generate non-pesticidal proteins, by definition excluding the growing number of trials involving metabolic manipulations rather than novel proteins. Secondly, it excludes standard toxicological testing procedures and proposes absolutely no assay to detect unintended effects of the genetic engineering process. Third, experts agree that the digestive stability and amino acid homology tests proposed in the guidance cannot exclude a novel protein's toxicity or allergenicity, particularly since test conditions are not specified, giving applicants ample leeway to devise their own tests to get the results they desire.

The FDA's policy for regulating genetically engineered crops needs a major overhaul. Your band-aid approach in this Draft Guidance is unacceptable to protect public health and safety.

The FDA needs to develop an entirely new policy for regulating crops produced through agricultural biotechnology.

- \* There must be mandatory labeling of all genetically engineered foods.
- \* There must be mandatory safety testing of plants that contain or are produced from genetically engineered organisms. The requirements must be similar to those for a new drug or food additive.
- \* The public must have full disclosure regarding what genes are being spliced into these experimental GE crops. No more trade secrets!
- \* All crop experiments using transgenetic engineering technology must be conducted in indoor controlled environments, not outdoors where genetic engineered traits can "escape" field test plots and enter the food supply.
- \* Replace your current non-rigorous "voluntary consultation" process with a mandatory, science-based review process designed to ensure food safety.

Taking into account the potential threat of serious damage derived from the unknown consequences of introducing untested GE material not intended for human consumption into the food chain, FDA's proposal to legalize contamination from GE experimental crops is a clear breach of the precautionary approach anchored in the United Nations agreement dealing with GE crops, the Biosafety Protocol.

Most sincerely,

Laurel Hopwood, Chair, Sierra Club Genetic Engineering Committee

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