

Re: Docket No. 2004D-0369

Dear Commissioner Crawford,

I am writing to express my deep concern over the FDA's draft "Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use". I am also alarmed that the FDA is intending to use the FDA guidance as providing " *an international model to address the presence of low levels of bioengineered plant material in non-bioengineered crop fields.*" For the reasons outlined below, I urge you to reject these proposals.

The implications of these proposals are far-reaching. Not only will they legalise contamination of the US food chain with unapproved, untested GM traits, but food exported to any country in the world will also be at risk. Public worldwide has made it clear that we want to be able to choose food free of GM contamination - even if the GMOs are approved. But this attempt to legalise contamination from unapproved GM traits, with unknown consequences is reckless and totally unacceptable.

The stated purpose of this guidance document is to set up a voluntary mechanism for evaluating the potential health risks from contamination of the food supply with material from genetically engineered (GE) plants being field tested out-of-doors. However, the true purpose of this initiative has nothing to do with food safety. As stated by FDA Commissioner Lester Crawford in a recent speech, the goals are to "enhance public confidence" and "avoid product recalls" when such contamination occurs. This is also why the Biotechnology Industry Organization regards the initiative as "enormously important." It is unacceptable to protect biotechnology company interests at the expense of consumers.

In the event that these proposals were approved and US companies subsequently protected from legal liability, a significant questions over liability would emerge; who would be liable if contaminated food was exported into, and detected in other countries in the world? And who would be responsible if negative impacts on human health are discovered in the US or anywhere else in the world as a result of eating food contaminated with experimental traits?

The FDA presumes that any contamination that occurs will be at low levels, lessening concern. Yet "low level" is never defined. Permissible contaminant levels are in principle unlimited. Two considerations suggest that contamination may often be higher than anticipated. First, in some cases 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 be transferred back to food cultivars in the future. Secondly, by negating the existing de facto zero tolerance standard for experimental transgenic proteins in the food supply, GE crop field trial operators will have less incentive to strictly adhere to gene confinement protocols, resulting in more, not less, contamination.

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 tests to get the results they desire.

I urge you to reject this misconceived policy. The FDA should be devising rules and procedures to prevent contamination of the food supply with experimental transgenic proteins, not give rubber stamp approval to such contamination when it occurs.

Finally, I urge the FDA to replace its current non-rigorous "voluntary consultation" process with a mandatory, science-based review process designed to ensure food safety rather than, as at present, "enhance public confidence" in inadequately tested and potentially hazardous GE foods.

Yours sincerely,

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