

**Addendum to Briefing Report:  
Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops**

— Brian Tokar, Institute for Social Ecology Biotechnology Project, June 29, 2006

In June 2006, the Food and Drug Administration released a new set of guidelines for the evaluation of experimental genetically engineered (GE) crop varieties. This was a response to widespread public concern that the food supply could become contaminated with pharmaceutical ingredients engineered into food crops undergoing field trials, along with other experimental GE proteins that have not yet been evaluated in any regulatory proceeding.

This new FDA document, “Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use,” merely extends the process of “voluntary consultation” that is already applied to new GE food varieties, and allows companies to apply for an “early evaluation” of experimental proteins that could become part of the food supply. It does not provide the additional protections that various public interest organizations requested to prevent the contamination of our food with pharmaceuticals and other experimental substances.

The FDA guidance states right at the outset what many critics of the agency have been pointing out for several years, “FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities.” “Early evaluation” of experimental GE crop varieties is “suggested or recommended, but not required.” Ignoring the basic biochemical fact that even small modifications in the structure of a protein can drastically alter its biological activity, the guidance states, “In most cases, the [new] proteins ... will be the same or quite similar to proteins commonly found in food.”

As with conventional consultations with the FDA for new GE food ingredients, the FDA only requests “a synopsis of the safety data” on these new proteins and a report on the company’s own conclusions as to their safety. The agency requests that the application focus on potential allergenicity or toxicity, and lists some of the specific information it would like to receive. The FDA allows itself 120 days to respond to these submissions.

It is clear that these guidelines offer no new substantive protections to those who may be exposed to experimental genetically engineered substances. They simply allow companies to continue submitting cursory data, and receive a rubber stamp from the agency saying that their data has been evaluated and found to raise no new concerns. This policy only reinforces the need for local jurisdictions to retain the right to address the potential hazards of GE crops grown in their regions.