

*From the Center for Food Safety*

## THE FAILURE OF THE U.S. GOVERNMENT TO REGULATE GENETICALLY ENGINEERED FOODS

ALTHOUGH THE U.S. GOVERNMENT maintains that genetically engineered (GE) foods are tightly regulated and thoroughly tested, a closer look at the U.S. regulatory framework reveals a system that is full of loopholes and inadequate to protect human health and the environment from the potential hazards of these novel foods.

In the U.S., regulatory jurisdiction of GE foods resides mainly in the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the Department of Agriculture (USDA). The policies and laws that guide these agencies' oversight of GE foods were originally designed to regulate other products and were put in place before GE products were developed. As a result, these laws have been adapted to a purpose for which they were not intended. The result is a weak regulatory framework that does not require pre-market review or labeling of GE products; grants corporations broad privileges to withhold data and health and safety information from the public; and lacks protocols for adequate monitoring of GE products.

### U.S. FOOD AND DRUG ADMINISTRATION

#### *Current FDA Policy and Regulation on GE Foods*

The FDA is responsible for enforcing pesticide tolerances set by the EPA for all agricultural commodities and for product labeling in general. Although the FDA has the authority to regulate all GE foods, under its current policy the agency essentially has no regulations for GE foods.

On May 29, 1992, the FDA issued a policy for foods derived from new plant varieties (i.e., GE foods). Without scientific basis, the policy determined that all transferred genetic material and the resulting food products derived from GE plant varieties were to be "generally recognized as safe" (except those containing genes from the ten most allergenic species). As a result, the agency determined that it would not subject GE foods to any mandatory pre-market safety testing. In 1996, the FDA issued guidelines (revised in 1997) consistent with the 1992 policy. These guidelines were designed to aid companies through a voluntary consulting process for GE foods. In addition, under current FDA policy GE foods do not have to be labeled.

#### *Regulatory Failures*

The FDA's regulatory position is contrary to assessments by its own scientific authorities. Numerous documents have been released showing scientists within FDA have significant concerns that "the processes of genetic engineering and traditional breeding are different, and . . . lead to different risks." These unique food safety risks include creating new toxins and allergens in food, undermining the effectiveness of therapeutic antibiotics and lowering nutritional value. Dozens of GE foods derived from new plant varieties have been approved. None of these products have been safety tested, and none are labeled as genetically modified.

In March 2000, a legal petition was filed by 55 non-governmental organizations (NGOs) demanding that the FDA revoke its 1992 policy and establish significant pre-market safety testing and environmental review safeguards prior to the release of GE food into the marketplace. To date, the FDA has not responded to this legal petition, and further legal actions are currently in development.

## U. S. ENVIRONMENTAL PROTECTION AGENCY

### *Jurisdiction over Genetically Engineered Crops*

The EPA oversees pesticides, both chemical pesticides and those produced by plants, such as GE *Bacillus thuringiensis* (Bt) plants which are regulated as “plant incorporated protectants” (PIPs). The EPA determines the risk plant-pesticides pose to both people and the environment, including the maximum allowable levels of pesticide residues in or on foods—known as “food tolerances.” The agency may grant an exemption from the food tolerance requirement if it finds that there is a “reasonable certainty” that aggregate exposures to the residue will not cause harm. To date, the EPA has registered a number of Bt crops—including corn, cotton, and potatoes—under its PIP process.

### *Regulatory Failures*

The EPA approved a GE corn called Starlink™, which is classified as a PIP and only allowed for use as animal feed. The corn was deemed not fit for human consumption because of the presence of a protein (Cry9C) that exhibits characteristics of known allergens. Despite these restrictions, the EPA had no mandatory monitoring or testing policy in place to ensure the proper segregation of Starlink™ corn to keep it from entering the food supply.

In 2000, Starlink™ corn was found in dozens of corn-based food products, triggering a massive food recall in the U.S. Since that time, Starlink™ corn contaminated much of the country’s corn supply and hundreds of food products. Clearly the EPA and other government agencies weak regulatory systems have failed to protect the public from potential human health risks posed by GE foods.

## U. S. DEPARTMENT OF AGRICULTURE

### *Jurisdiction over Genetically Engineered Crops*

The USDA issues and oversees permits for GE field tests, and is also charged with monitoring GE pharmaceutical crops, GE grasses, and GE insects. The USDA is required to conduct environmental reviews of such products under the National Environmental Policy Act (NEPA); however, to date the USDA has never completed a full environmental impact statement for any GE crop despite their use on millions of acres.

### *Regulatory Failures*

The USDA has been permitting open-ai red field tests of GE pharmaceutical-producing plant varieties (GEPPVs) without conducting proper environmental assessments of these novel plants. Clearly GEPPVs containing such compounds as pig vaccines are new organisms with novel modifications that raise new issues. On November 17, 2002 the USDA announced that there were two biocontamination incidents where GE corn developed by Prodigene, Inc. polluted conventional soybeans and neighboring cornfields. While ordering the quarantine and/or destruction of the polluted conventional plants, the USDA refused to divulge the identity of the biopharm contaminants or details of either contamination episode. The USDA has refused repeated requests for a detailed account of the biocontamination.

Legal actions have been taken demanding an immediate moratorium on all planting of food crops genetically engineered with pharmaceuticals and industrial chemicals, as well as strong mandatory regulations and environmental impact statements of all biopharm crops. To date, the USDA has not responded to these legal actions.

The recent Bush Administration challenge of the EU five-year moratorium of GMO foods at the World Trade Organization (WTO) does not bode well for U.S. citizens who hope to achieve similar health and safety protections here. ▲