

Regulation of Genetically Engineered Crops and Foods in the United States

Executive Summary

This report is intended to be a briefing paper for newly appointed administrators. It outlines and details the significant outstanding regulatory issues facing the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the United States Department of Agriculture (USDA). As background, it describes each of the three agency's intended roles and responsibilities and analyzes the shortcomings of the existing framework. It then summarizes some current legal actions against the agencies, and concludes with recommendations to best protect human health and the environment.

Scientists have raised a host of questions regarding the safety of genetically engineered (GE) crops and foods, including their impact on human health and the environment. Yet no major legislation has ever been passed with respect to GE foods and crops; FDA, EPA, and USDA, the three agencies with major regulatory responsibilities for GE foods and crops, simply extended existing regulations to cover this radical new technology. The result is that the public's health and safety are being compromised every day by lax or nonexistent regulatory oversight.

Specifically, some of the major points made in the report about the current regulatory structure are:

FDA

- **Inadequate scientific safety review** - FDA admits that they have not conducted a comprehensive scientific review of data on GE foods
- **No public right to know** - The agency has refused to give the public the right to know about the food they are eating despite a substantial majority of the public requesting such information
- **Poor track record** - The mishandling of recombinant Bovine Growth Hormone portends problems for FDA's recently announced proposed rule and proposed guidance on GE foods

EPA

- **Faulty data** - EPA has accepted inappropriate and scientifically questionable studies in approving GE crops
- **No enforcement** - Resistance management plans, designed to delay the onset of insect resistance to certain GE crops, are not monitored through an effective compliance program
- **Lack of testing** - EPA's own Scientific Advisory Panel has concluded that current requirements for testing the impacts of GE crops on non-target insects and soil organisms are not adequate

USDA

- **Too little data** - Independent analyses have criticized that data upon which USDA has made decisions as critically flawed or in some cases nonexistent
- **Potential conflict of interest** - USDA is financially invested in GE technology as a co-owner of several patents on Terminator technology, rendering seed progeny sterile
- **Rubber stamp** - USDA has never rejected an application for deregulation it has received

The report concludes that GE crops have been introduced before adequate safety testing has been conducted and appropriate regulations put in place. In light of these circumstances, a more appropriate policy would be to implement a basic principle of precaution. A logical course of action would be a moratorium on the commercialization of these products until three basic conditions have been met.

- **First**, GE crops must be demonstrated to be safe for human health and the environment.
- **Second**, liability for any damage posed by these crops must be clearly established as lying with the seed manufacturers.
- **Third**, the consumer's right to know about what he or she is buying must be respected through clear product labeling for all GE products.