



Highlights of [GAO-09-60](#), a report to the Committee on Agriculture, Nutrition, and Forestry, U.S. Senate

## Why GAO Did This Study

Genetically engineered (GE) crops—including crops engineered to resist pests or tolerate herbicides—are widespread in the United States and around the world. Taking direction from the 1986 *Coordinated Framework for Regulation of Biotechnology*, the U.S. Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA) regulate GE crops to ensure that they are safe. The unauthorized mixing of some GE crops with non-GE crops has caused controversy and financial harm. GAO examined (1) unauthorized releases of GE crops, (2) coordination among the three agencies, and (3) additional actions they have proposed to improve oversight. GAO gathered data from agencies and stakeholders; used criteria from prior GAO work to assess coordination; and reviewed agency proposals.

## What GAO Recommends

GAO recommends that (1) FDA make public the results of its early food safety assessments of GE crops; (2) USDA and FDA develop an agreement to share information on GE crops with traits that, if released into the food or feed supply, could cause health concerns; and (3) USDA, EPA, and FDA develop a risk-based strategy for monitoring the widespread use of marketed GE crops. FDA agreed with the first recommendation, and, with USDA, agreed in part with the second. The agencies agreed in part with the third recommendation. We stand by the recommendations.

To view the full product, including the scope and methodology, click on [GAO-09-60](#). For more information, contact Lisa Shames at (202) 512-3841, or [shamesl@gao.gov](mailto:shamesl@gao.gov).

# GENETICALLY ENGINEERED CROPS

## Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring

### What GAO Found

Unauthorized releases of GE crops into food, animal feed, or the environment beyond farm fields have occurred, and it is likely that such incidents will occur again. While there is no evidence that the six known releases into the food or feed supply or into crops meant for the food or feed supply affected human or animal health, some resulted in lost trade opportunities. Moreover, the total number of unauthorized releases into the environment is unknown. USDA and EPA have the authority to inspect fields in which GE crops are tested, but crop developers have detected most violations. USDA and EPA have taken enforcement actions in response to violations, ranging from warning letters to significant penalties. The agencies have used lessons learned from unauthorized releases to make regulatory and policy changes. For example, USDA increased inspections of field trial sites for GE crops producing pharmaceutical compounds; EPA discontinued a policy under which a GE crop containing a pesticidal agent could be approved for animal feed, but not for food; and FDA established a voluntary early food safety evaluation program for certain GE crops intended for food use to help mitigate the impact should unauthorized releases occur during field trials, although it has not made these evaluations available to the public.

USDA, EPA, and FDA routinely coordinate their oversight and regulation of GE crops in many respects, but could improve their efforts. Specifically, USDA and FDA do not have a formal method for sharing information that could enhance FDA's voluntary early food safety review for certain GE crops in the field trial stage and support USDA's oversight. Also, the three agencies do not have a coordinated program for monitoring the use of marketed GE crops to determine whether the spread of genetic traits is causing undesirable effects on the environment, non-GE segments of agriculture, or food safety, as recommended by the National Research Council and others.

USDA, EPA, and FDA have proposed regulatory changes intended to improve their oversight of GE crops. In 2007, USDA assessed a wide array of regulatory alternatives that could redefine, on the basis of risk, which GE crops it regulates and how it will respond to unauthorized releases. USDA's fiscal year 2009 budget request also seeks funding for a voluntary system to help GE crop developers employ best management practices to reduce the risk of unauthorized releases. Furthermore, the 2008 Farm Bill required USDA to take actions on lessons learned from its investigation of an unauthorized release of GE rice. EPA has proposed several changes to its regulations for GE crops that produce pesticides, including one change that would distinguish between pesticidal agents produced in GE crops and those applied topically to crops. In 2001, FDA proposed to require that GE food developers notify the agency before marketing their products. However, as of July 2008, FDA had not taken action to finalize the proposed rule, believing its current approach calling for voluntary notice is sufficient.