

GAO

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Agriculture, Nutrition, and Forestry,
U.S. Senate

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GENETICALLY ENGINEERED CROPS

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





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.

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.



United States Government Accountability Office
Washington, DC 20548

November 5, 2008

The Honorable Tom Harkin
Chairman
The Honorable Saxby Chambliss
Ranking Member
Committee on Agriculture, Nutrition,
and Forestry
United States Senate

The genetic engineering of agricultural crops is seen as both promising and controversial, with potentially significant implications for the United States' and other countries' food security and economic well-being, the environment, and international relations and trade. Proponents cite the potential for enhanced crop yields; more environmentally friendly food production; more nutritious foods; and the increased use of plants to inexpensively produce pharmaceutical compounds, such as human or veterinary drugs, or industrial compounds, such as substances used in paper production or detergent manufacturing. Opponents argue that not enough is known about the safety of genetically engineered (GE) crops and food, and that they should be more rigorously controlled than conventional alternatives. This debate has been exacerbated by several well-publicized cases of unauthorized release of GE crops into the food supply. For example, in August 2006, the U.S. Department of Agriculture (USDA) announced that trace amounts of a regulated variety of GE rice had been commingled with supplies of conventional rice. This announcement led several U.S. trading partners to refuse U.S. rice exports, potentially disrupting the \$1.3 billion U.S. rice export market and leading to financial losses for U.S. farmers and exporters. Furthermore, there also is concern that genetic traits could spread from crops into the environment with unintended consequences for plants and animals. This debate may intensify in the future as genetic modifications to crops become more complex, and as pressures build to increase agricultural yields to meet the growing demand for food and biofuel.

Currently, the United States accounts for about 50 percent of the GE crops planted globally. In 2008, GE varieties accounted for about 80 percent of the corn, 92 percent of the soybeans, and 86 percent of the cotton planted in the United States. In 2005, GE varieties accounted for about 93 percent of the canola. To date, the most common characteristics, or traits, engineered into these crops have been resistance to insect pests and the

ability to tolerate specific herbicides. The global value of GE seeds sold in 2007 was estimated at \$6.9 billion. Food industry sources indicate that over 70 percent of processed foods sold in the United States contain ingredients and oils from GE crops. Increasingly, some countries—including Argentina, Brazil, Canada, and India—have embraced GE crops and food to, among other things, increase yields. Other countries—including many in the European Union and some in Africa—have resisted GE crops and food, citing safety and economic concerns.

Three federal agencies have primary responsibility for regulating GE crops and food in the United States: USDA, the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). USDA is responsible for assessing whether GE crops pose a risk as “plant pests” that could directly or indirectly harm plants. To accomplish this, USDA regulates the importation, interstate movement, and release of GE crops into the environment, the latter of which could occur when a developer tests the crop in a field trial. USDA may, upon finding a GE crop does not pose a potential plant pest risk, grant a petition to extend “nonregulated” status to the crop, meaning that it can be moved or released without agency oversight. USDA also has the authority to regulate GE plants as noxious weeds; a noxious weed is any plant or plant product that can injure or cause damage to, among other things, crops, livestock, interests of agriculture, public health, or the environment. EPA is responsible for regulating all pesticides, including those produced by plants that have been genetically modified to protect themselves from insects, bacteria, and viruses. USDA and, to a lesser extent, EPA exercise oversight of the thousands of field trials in which developers have tested new varieties of GE plants since 1987. FDA has primary responsibility for ensuring the safety of most of the nation’s food supply and encourages companies to voluntarily submit safety data on a new food or feed derived from GE crops before it is marketed. The President’s Office of Science and Technology Policy (OSTP) published the final version of the *Coordinated Framework for Regulation of Biotechnology (Coordinated Framework)* in 1986. This document outlines the federal government’s policy for ensuring the safety of GE organisms, including relevant laws and definitions. It was developed in response to concerns that products resulting from genetic engineering might pose greater risks than those resulting from traditional breeding techniques.

In this context, you asked us to examine (1) unauthorized releases of GE crops into the food or feed supply, or the environment; (2) the degree of coordination among the three key agencies that regulate GE crops under the 1986 *Coordinated Framework*—USDA, EPA, and FDA; and

(3) additional actions these agencies have proposed to improve the oversight of GE crops and reduce the potential for unauthorized releases.

In conducting this work, we spoke with and reviewed documents provided by officials at USDA, EPA, and FDA as well as OSTP, which is charged with coordinating federal government policy on biotechnology. We also reviewed scientific and technical studies and other literature and spoke with officials in academia, private industry, and consumer groups. We reviewed applicable laws and regulations as well as available public comments on several agency-proposed GE regulations or initiatives as of October 2008. In addition, we reviewed information on all known unauthorized releases of GE crops into the food or feed supply as of September 2008, and on potentially unauthorized releases of GE crops into the environment for the period of January 2003 through August 2007. We assessed the agencies' coordination efforts, using criteria that we have developed in prior work on agency collaboration and coordination.¹ We did not assess the federal regulation of GE animals. Furthermore, we did not assess U.S. efforts to reduce barriers to international trade in GE agricultural commodities. A more detailed description of our objectives, scope and methodology is presented in appendix I. We conducted this performance audit from July 2007 to November 2008 in accordance with generally accepted government auditing standards. These standards require that we plan and perform our audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides this reasonable basis.

Results in Brief

Federal agencies have documented six unauthorized releases of GE crops into the food and feed supply or into crops meant for the food or feed supply and additional releases into the environment, as of September 2008, and the ease with which genetic material from crops can be spread makes future releases likely. While the agencies maintain that there is no evidence that any of the known releases have adversely affected human or animal health or the environment, several releases resulted in food recalls or lost trade opportunities that caused financial losses. Moreover, the actual number of unauthorized releases is unknown. Specifically, while USDA and EPA regulations subject crop developers to periodic

¹GAO, *Results-Oriented Government: Practices That Can Help Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

inspections by federal or state personnel to ensure that developers have taken adequate measures to isolate regulated GE crops from other crops, USDA does not have the resources to inspect all sites, and EPA and the states have not made inspections a priority. In most cases, crop developers have self-reported known unauthorized releases and other violations of regulations. USDA and EPA have taken enforcement actions—ranging from issuing warning letters to assessing significant financial penalties—against GE crop developers who violated regulations. USDA, EPA, and FDA have also taken steps in response to these incidents to reduce the potential for future unauthorized releases and to mitigate the impact of any releases. For example, USDA has increased the frequency of inspections of field trial sites for GE crops producing pharmaceutical and industrial compounds; EPA has discontinued a policy under which a GE crop containing a pesticidal agent could be approved for animal feed, but not for food; and FDA has established a voluntary early food safety evaluation of GE crops that might pose a new risk to help mitigate the impact of unauthorized releases, although FDA has not yet fulfilled a commitment to publish the results of those evaluations.

As called for by the *Coordinated Framework* and measured against other established criteria, the three federal agencies routinely work together to regulate GE crops. For example, the agencies have agreed on their respective roles and responsibilities and developed mechanisms for making policy decisions, sharing information, and responding to incidents. However, the agencies could enhance their coordination by leveraging resources and developing mechanisms to monitor and evaluate results. For example, USDA and FDA do not have a formal method for sharing information that could enhance FDA's voluntary early food safety evaluation of certain GE crops in the field trial stage and USDA's oversight of those field trials. Sharing such information could better leverage resources to address food safety issues for GE crops at the field trial stage. In addition, USDA, EPA, and FDA do not have a coordinated program for monitoring and evaluating the use of marketed GE crops to determine whether they are causing (1) undesirable effects to the environment or economic harm to non-GE segments of agriculture through the unintentional spread of GE traits or (2) food safety concerns, such as the unintentional introduction of pharmaceutical or industrial compounds into the food supply. Several organizations, such as the National Research Council, have made such recommendations regarding the monitoring of GE crops.

USDA, EPA, and FDA have proposed several regulatory changes intended to improve the oversight of GE crops and reduce the potential for

unauthorized release. For example, in July 2007, USDA released a draft programmatic environmental impact statement (DEIS) that assessed proposals to modify many aspects of how the agency regulates GE crops, such as how it will respond to the unauthorized release of low levels of GE crops and how it will address the food safety risks posed by GE crops that produce pharmaceutical or industrial compounds when setting requirements for field trials. In October 2008, USDA released for public comment its proposed amendments to those regulations. In addition, USDA's fiscal year 2009 budget request seeks funding to establish a voluntary system to encourage GE crop developers to employ best management practices for field trials and the handling of regulated materials, including third-party audits of their field trial plans and records. The Food, Conservation, and Energy Act of 2008 (2008 Farm Bill) directs USDA to consider regulatory and procedural changes based on the agency's *Lessons Learned and Revisions Under Consideration for APHIS' Biotechnology Framework*, a document resulting from lessons learned from its investigation of the unauthorized release of GE rice into the food supply in 2006, as well as from its years of regulatory experience, and to take action to, among other things, enhance the availability of genetic samples from developers and the quality and completeness of records by developers. For its part, EPA is working on three proposed changes to regulations, including one that would make a distinction between pesticidal agents produced in GE crops and pesticides made from chemicals that are applied topically to crops, noting that currently approved GE-based pesticides are less toxic and, therefore, generally present less risk. FDA proposed in 2001 to require—rather than to encourage, as it does now—developers of GE food products to consult with the agency about the safety of the food before it is marketed. However, as of July 2008, FDA had not taken action to finalize the proposed rule. FDA officials told us that such a rule may no longer be needed because the voluntary consultation process is working well and fully protects the public health.

To ensure that the federal government addresses emerging risks associated with new developments in GE crops, we are recommending that FDA post on its Web site the results of its early food safety evaluations, and that USDA and FDA develop a formal agreement to share information concerning GE crops with novel genetic traits that could cause, or are likely to cause, health concerns if unintentionally released into the food or feed supply. We are also recommending that USDA, EPA, and FDA develop a coordinated strategy for monitoring the marketed use of GE crops for unintended consequences to the environment, non-GE segments of agriculture, or food safety.

In commenting on a draft of this report, USDA, EPA, and FDA generally agreed with the report's findings. On the first recommendation, FDA said it intends to make every effort to fulfill its commitment to post to its Web site the results of completed and future early food safety evaluations. However, FDA also said that activities of greater public health priority have been the focus of its limited resources. Nevertheless, we believe that posting the results of these evaluations would be a low-cost way to increase public transparency and mitigate the impact of unintended releases of GE crops. Regarding the second recommendation, USDA and FDA agreed, in part, saying that they would explore the development of a formal agreement for sharing information on GE crops with novel genetic traits. However, they also said that they should focus their resources on issues that present or are likely to present public health concerns, rather than perceived concerns. We modified this recommendation to remove the reference to "perceived health concerns" and instead emphasize that the agreement would cover GE crops that present or are likely to present public health concerns. Concerning the third recommendation, USDA, EPA, and FDA agreed, in part, to the development of a coordinated strategy to do risk-based monitoring of marketed GE crops for unintended consequences. However, USDA emphasized that its current regulations limit it to monitoring only regulated crops that pose a potential plant pest risk; EPA stated that GE crops that produce pesticides do not require any further post-market monitoring; and FDA said post-market monitoring of food and feed derived from GE crops is not necessary and random sampling to detect GE crops producing pharmaceutical or industrial substances in food and feed would present significant technical challenges and greatly affect resources. Nevertheless, the agencies agreed to enter into discussions to develop a coordinated strategy should such monitoring be necessary in the future. Given that in the United States (1) GE crop varieties are grown extensively, (2) most processed foods contain ingredients from GE crops, (3) it is inherently difficult to prevent the spread of plant genetic material in the environment, (4) there may be an increasing use of GE crops to produce an even wider array of pharmaceutical and industrial compounds in the future, and (5) genetic modifications are becoming increasingly complex in response to pressures to increase yields for food and biofuel, we continue to believe the agencies should develop a coordinated strategy for risk-based monitoring of marketed GE crops.

USDA's and FDA's comments are presented in appendixes II and III, respectively. EPA provided its comments orally. EPA and FDA also provided technical comments that we have incorporated as appropriate.