



Unapproved Genetically Modified Wheat Discovered in Oregon and Montana: Status and Implications

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Summary

The U.S. Department of Agriculture (USDA) announced on May 31, 2013, that a variety of genetically engineered (GE) wheat had been discovered in a field in eastern Oregon. No varieties of genetically modified wheat have been approved, or deregulated, by the Animal Plant and Health Inspection Service (APHIS), the USDA agency responsible for regulating the release of GE plants into the environment. Release of GE plants into the natural environment is regulated by APHIS under the Plant Protection Act (PPA, 7 U.S.C. 7701 et seq.), as amended.

APHIS began a formal investigation in early May after notification by an Oregon State University scientist that preliminary tests of the wheat samples from the Oregon farm indicated the possible presence of GE glyphosate-tolerant wheat plants. Test results by APHIS indicated the presence of a variety tested by Monsanto Company under APHIS approval at approximately 100 field trials in 16 states between 1998 and 2005. The agency approved field testing of GE wheat in Oregon in 2001, but not on the field where the rogue GE wheat was discovered. In its September 2014 report on the investigation, APHIS stated that the incident was isolated to the one field, but they were unable to determine how the GE wheat came to grow in the field. A recent discovery of another variety of GE wheat in Montana was publicly reported in September 2014. A new APHIS investigation of this unauthorized wheat began in July.

The safety of GE organisms for food and feed is regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). A voluntary consultation on the safety of food derived from the Monsanto GE wheat variety was completed by FDA in 2004. FDA had determined that this GE wheat variety was as safe for food and feed as non-GE wheat, and that there were no public health concerns.

In its September report, APHIS stated that there was no evidence that GE wheat had entered commerce. Initial tests of wheat imported by Japan, South Korea, and the European Union in June 2013 found no evidence of the unapproved GE trait. APHIS sampled 100 businesses that sold or purchased certified seed planted in the Oregon field. APHIS also obtained samples of the producer's wheat harvests, including a sample of the producer's 2012 harvest. None of these samples of seed and grain tested positive for the presence of GE material.

The presence of GE wheat in the market could have had significant trade implications if the variety turned out to be widespread. That has not been the case, and the trade implications were minimal. The United States is a major wheat exporter, exporting about 50% of its wheat crop. About 90% of Oregon's wheat crop is exported. Many countries, including Japan, the European Union, and South Korea, have zero-tolerance policies regarding imports of unapproved GE varieties. Japan, the largest buyer of U.S. wheat, and South Korea temporarily suspended new purchases of U.S. soft white wheat grown in Oregon and the Pacific Northwest. Those purchases have resumed.

In November 2014, Monsanto reached a settlement with U.S. wheat farmers who had sued the company. While not admitting liability, Monsanto also agreed to pay \$250,000 to several wheat growers' associations. Monsanto also will pay \$2.1 million into a settlement fund for soft white wheat farmers in Washington, Oregon, and Idaho, and will reimburse plaintiff's attorneys for costs associated with the litigation. As part of the settlement, three pending class action suits will be dismissed.

The Oregon and Montana incidents are likely to continue fueling criticism of GE crops in general and the efficacy of APHIS regulatory oversight.

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Genetically Engineered Wheat: Background

Between 1998 and 2005, the Monsanto Company field-tested a variety of genetically engineered (GE) wheat that was tolerant of glyphosate, a widely used, broad-spectrum herbicide marketed by the Monsanto Company under its trade name, Roundup.¹ Many crop varieties, including soybeans, cotton, alfalfa, sugar beets, and canola, have been similarly engineered to be tolerant of glyphosate. These varieties constitute the largest acreage of GE plants globally. In 2005, Monsanto halted its field trials of GE wheat and withdrew its application for deregulated status. There was concern that the Canadian and Australian Wheat Boards might not approve the glyphosate-tolerant variety, leading Monsanto to reevaluate the marketability of the GE wheat variety at that time. With Monsanto's withdrawal of its application to deregulate and commercialize the GE wheat, no GE wheat varieties have been approved by the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS), the principal regulator of GE plants released into the environment.

In spring 2013, an eastern Oregon farmer, spraying glyphosate in preparation for planting, discovered volunteer wheat plants in part of the 80-acre field that were not killed by the herbicide.² On April 30, 2013, the grower took samples of the plants to be tested at Oregon State University. Preliminary tests by a scientist at the university indicated the possible presence of GE glyphosate-tolerant wheat plants. On May 3, the scientist notified APHIS of the preliminary test results, and APHIS began a formal investigation.³ Subsequent test results by APHIS indicated the presence of a glyphosate-tolerant wheat variety tested by Monsanto under APHIS approval at approximately 100 field trials in 16 states between 1998 and 2005. The agency had approved field testing of GE wheat in Oregon in 2001, but not on the site where the rogue GE wheat was discovered.

APHIS stated at the time that there was no evidence that GE wheat had entered commerce. The agency's investigation report confirmed that early finding. Initial tests of wheat imported by Japan, South Korea, and European Union also found no evidence of the unapproved GE trait. APHIS has concluded that the incident is a single isolated incident in a single field on a single farm, although they were unable to determine exactly how the GE wheat came to be in that field. APHIS also interviewed wheat seed suppliers to the producer, and obtained samples of the wheat seed sold to the producer and other growers. APHIS also obtained samples of the producer's wheat harvests, including a sample of the producer's 2012 harvest. None of these samples of seed and grain tested positive for the presence of GE material.

¹ Monsanto Company is the world's largest producer of agricultural seed and a major corporate presence in global agricultural biotechnology. While there are no commercialized GE wheat varieties, most of the world's acreage planted to GE crops are glyphosate-tolerant varieties developed and licensed by Monsanto (e.g., soybean, canola, cotton). For more information on the seed industry and biotechnology, see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, by Tadlock Cowan.

² "Volunteers" are plants that have germinated and grown in a place where they were not intentionally planted.

³ APHIS has referred the investigation to its Investigative and Enforcement Services, in addition to its onsite investigation. APHIS also has a memorandum of understanding with USDA's Agricultural Marketing Service and Grain Inspection, Packers, and Stockyards Administration to provide technical sampling and testing expertise when needed.

Federal Regulation of Genetically Engineered Plants

The basic federal guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology published in 1986 by the White House Office of Science and Technology Policy (OSTP).⁴ A key regulatory principle in the U.S. biotechnology regulatory structure is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method—that is, whether or not they were created through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products using existing statutory authority and previous agency experience with traditional breeding techniques.

Three lead federal agencies regulate genetically modified organisms:

- USDA’s Animal and Plant Health Inspection Service (APHIS);
- the Department of Health and Human Services, Food and Drug Administration (FDA); and
- the Environmental Protection Agency (EPA).

APHIS regulates plants engineered to be herbicide-tolerant. EPA, with APHIS, regulates plants that contain pesticides, such as the many corn varieties that are engineered with *Bacillus thuringiensis* to be resistant to certain pests (e.g., corn borer).⁵ FDA has regulatory authority under the Federal Food, Drug, and Cosmetic Act for the safety and nutritional quality of GE foods and feeds.

APHIS regulates the importation, interstate movement, and field testing of GE plants and organisms that are or might be plant pests under the Plant Protection Act (PPA; 7 U.S.C. 7701 et seq.). APHIS also regulates animal biologics (i.e., viruses, serums, toxins for animal vaccines) under the Virus, Serum, and Toxins Act (21 U.S.C. 151 et seq.). Specifically, GE plants that are or might be plant pests are considered “regulated articles” under APHIS regulations (7 C.F.R. 340-340.9). APHIS authorization must be obtained prior to import, interstate movement, or environmental release, including field testing.

More specifically, a “regulated” plant cannot be introduced into the environment, or even field tested, unless its developer obtains APHIS authorization through (1) the permit process or (2) the notification process. Permits impose restrictions on movement and planting to prevent escape of plant material that may pose a pest risk. Sponsors follow APHIS guidance on testing and movements to ensure that the plant will not damage agriculture, human health, or the environment. Most GE crops have been developed under the notification option, an expedited procedure that is less rigorous than permitting. Notification can be used in lieu of permitting when the plant species is not considered a noxious weed (or weed in the release area), and other APHIS standards are met.⁶

⁴ 51 *Federal Register*, 23302.

⁵ EPA regulates pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C 121 et seq.), as amended.

⁶ The notification procedure is the streamlined authorization process used only for GE plants that qualify based on APHIS regulatory criteria. Permits may be used for any GE plant, but are required for plants that do not meet APHIS’s criteria for the expedited notification procedure. In addition to following conditions required by regulations under the (continued...)

Regardless of the process chosen, after testing is completed, a developer next seeks “non-regulated status” from APHIS, the typical route to full commercialization and no further formal oversight. The developer must provide APHIS with extensive information on plant biology and genetics, and potential environmental and plant pest impacts that may result from the modification. APHIS conducts a formal environmental assessment (EA) under the National Environmental Protection Act and has public comment periods before deciding whether to approve the developer’s request for “non-regulated status.” Once the GE plant is deregulated, it is no longer subject to APHIS regulation under 7 C.F.R. Part 340.

While a plant remains under APHIS regulatory control (i.e., it remains a “regulated article”), APHIS imposes conditions on field testing, harvesting, and transporting GE materials. APHIS could also impose penalties up to \$1 million for violations under the PPA. Should tests show the presence of an unapproved GE trait in shipments of grains or in commercial seed, APHIS would determine whether remedial action was necessary to protect plant health or the environment under the authority of the PPA. Given that FDA concluded that there were no health or safety concerns from consuming food or feed derived from the GE wheat (see below), APHIS stated at the time that it would not take steps to remove low-level presence (LLP) of this variety from the food supply.⁷ Low-level presence is the commingling of genes and gene products from unintended plant sources, whether conventionally bred plants or those derived from biotechnology. APHIS’s LLP policy was clarified in March 2007 and considers six safety-related criteria when determining a GE plant material’s potential to pose a risk to plant health or to the environment.⁸

Safety of GE Wheat for Food and Feed

While the glyphosate-tolerant GE wheat was never deregulated by APHIS, Monsanto had submitted materials to FDA on the biological characteristics of the GE variety for a determination of the variety’s safety. FDA completed a voluntary consultation on the safety of food and feed derived from the glyphosate-tolerant GE wheat in 2004, and agreed with Monsanto that the GE wheat was not “materially different in composition, safety, or any other relevant parameter from wheat now grown, marketed, and consumed.”⁹ In other words, FDA concluded that food and feed derived from GE wheat was as safe as and nutritionally equivalent to food and feed derived from non-GE wheat. Once a determination is made by FDA on the substantial equivalence of a GE variety compared to a non-GE variety, FDA’s role in the regulatory process typically ends.

(...continued)

Plant Protection Act, permits impose additional conditions specific to the application.

⁷ APHIS. Biotechnology Regulatory Services. *Questions and Answers: USDA Investigating Detection of Positive Genetically Engineered Glyphosate-Resistant Wheat in Oregon*, May 2013, http://www.aphis.usda.gov/publications/biotechnology/2013/faq_brs_ge_wheat_detection.pdf.

⁸ APHIS. Biotechnology Regulatory Services. *Low-Level Presence*, March 2007, http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_llppolicy3-2007.pdf.

⁹ FDA’s summary of their consultative process can be found at the following FDA site: <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm155577752.htm>.

United States Wheat Export Markets

Although the United States produces only about 10% of the world's wheat, it is consistently the world's largest wheat exporter. The United States exports about 50% of its wheat crop, and Oregon exports nearly 90% of its wheat crop. In its March 2013 National Agricultural Statistical Service (NASS) Prospective Plantings report, USDA projected U.S. winter wheat seedings in fall 2012 for harvest in 2013 of 56.44 million acres, up 1.3% (or 704,000 acres) from 55.74 million acres in 2012, and also up from 54.409 million acres in 2011.

APHIS stated in June 2013 that there was no evidence that GE wheat had entered commerce. Initial tests of wheat imported by Japan, Korea, and the European Union found no evidence of the unapproved GE trait. APHIS's final report on its investigation confirmed these early findings.

Many countries have zero-tolerance policies regarding imports of unapproved GE varieties. After the announcement of the GE wheat discovery, Japan (the largest buyer of U.S. wheat) and South Korea temporarily suspended new purchases of U.S. soft white wheat grown in Oregon and the Pacific Northwest. Those purchases resumed within several months.

In June 2013, APHIS validated an event-specific assay PCR (DNA-based) method for detecting MON71800, the variety of GE wheat discovered in Oregon. The APHIS validation process included a specificity study and a sensitivity study. USDA determined that the method could reliably detect the specific genetic trait—named the MON71800 genetic event—when it is present at a frequency of 1 in 200 kernels. Additionally, APHIS provided this validated DNA test method to detect this specific GE variety to U.S. trading partners that requested it. According to a Monsanto spokesman, the test allows governments to test for the original GE trait while distinguishing it from similar traits approved and used in other crops.¹⁰

APHIS Final Report on the GE Wheat Discovery and a New Investigation of GE Wheat Discovered in Montana

In September 2014, APHIS announced that its investigation of the Oregon incident was closed, and the agency released its findings.¹¹ The investigation indicated that the incident appeared to be an isolated occurrence, limited to the single field. No GE wheat was detected in commerce. APHIS concluded that the genetic characteristics of the GE wheat volunteers suggested that it was a variety representative of a wheat breeding program. However, APHIS stated that it was unable to determine precisely how the GE wheat came to be growing in the single Oregon field.

¹⁰ A Monsanto spokesman told CRS that the event-specific assay the company provided to APHIS and other governments can determine the specific glyphosate-tolerant trait of the GE wheat variety (MON71800), but avoid “false positives.” False positives can result from less accurate “strip tests” and “dip-stick” tests that might not differentiate the presence of a glyphosate-tolerance trait in other approved crop varieties (e.g., soybeans) from the specific genetic MON71800 event of the glyphosate-tolerant wheat.

¹¹ The report is available on the APHIS website at <http://www.aphis.usda.gov/foia/efoia.php>.

In July 2014, APHIS launched a new investigation into the discovery of GE wheat volunteers growing at the Montana State University Southern Agricultural Research Center in Huntley, where Monsanto grew GE wheat in field trials between 2000 and 2003. The variety discovered in Montana is different from that of Oregon, although both are glyphosate-tolerant varieties. APHIS has determined that the GE wheat in Montana was not the source of the GE wheat contamination in Oregon, or vice versa. None of the Montana GE wheat grown in the field trials entered commerce, and none was sold as seed.

Monsanto Settlement Agreement Regarding the Oregon GE Wheat

In November 2014, Monsanto reached a settlement with U.S. wheat farmers who had sued the company. While not admitting liability, Monsanto agreed to pay a total of \$250,000 to several wheat growers' associations. Monsanto also will pay \$2.1 million into a settlement fund for soft white wheat farmers in Washington, Oregon, and Idaho who sold wheat between May 30, 2013, and November 30, 2013. The settlement also reimburses plaintiff's attorneys for costs associated with the litigation.¹² As part of the settlement, three pending class action suits will be dismissed.¹³

Implications

The Oregon and Montana incidents are not unique in APHIS's GE regulatory history. Commingling of unauthorized GE crops in exports, contamination of food products with unauthorized GE material, and plant residue from GE field trials have been continuing issues. In December 2008, a small amount of unapproved GE cotton was harvested along with commercially available GE cotton. The unapproved GE cotton variety produces a pesticide that is a plant-incorporated protectant (PIP). In August 2006, traces of an unapproved variety of GE rice—Liberty Link—were reported in commercial rice samples from parts of the southern United States. APHIS subsequently retroactively approved the variety, but not before rice prices fell and the European Union and Japan refused to buy from the United States. In 2001, a variety of GE corn known as StarLink was discovered in taco shells made by Kraft Foods. The GE corn had been approved by APHIS, but only as an animal feed and not for human consumption. In that case, hundreds of corn products were recalled, and Aventis, the developer of the GE corn, paid over \$120 million to settle various lawsuits. Such incidents of regulatory noncompliance continue to raise concerns about the limitations of APHIS's biotechnology regulatory structure.

Critics of GE crops have pointed to these incidents as evidence of APHIS's lax oversight and inadequate field trial protocols, although the industry would like to see the regulatory process

¹² The \$250,000 payment includes \$100,000 to the National Wheat Foundation, and \$50,000 each to the Washington Association of Wheat Growers, the Oregon Wheat Growers' League, and the Idaho Grain Producers' Association.

¹³ In June 2013, a Kansas wheat farmer filed suit in federal court against Monsanto for gross negligence over the GE wheat discovery. The suit sought unspecified damages for lower wheat prices triggered by the export limits. See <http://www.newssentinel.com/apps/pbcs.dll/article?AID=/20130604/AP01/306049947>. On June 6, several wheat farms in Washington were seeking a class action lawsuit against the Monsanto Co., accusing the biotech developer of negligence for the unauthorized release of transgenic wheat. Two other Washington wheat farms, Dreger Enterprises and Wahl Ranch, also filed a legal complaint seeking compensation for diminished wheat prices, loss of export markets, and "contamination of the entire wheat farming and production chain."

more streamlined.¹⁴ The trade impacts that occurred with the Oregon wheat incident, as well as earlier trade impacts from unauthorized GE rice and corn noted above, suggest that these incidents are perhaps inherent to the introduction of GE materials into the environment. With the global food and commodity supply chains so integrated, comingling of non-approved GE varieties is almost certain to occur from time to time. The implications of the Oregon wheat and Liberty rice incidents for international trade demonstrate that these events can be disruptive and costly. APHIS is currently evaluating its regulations for the introduction of GE plants into the environment, but has yet to publish a final rule on its proposed revisions.¹⁵ The proposed revisions are the first since the regulations were established in 1987.¹⁶

APHIS stated in their investigative report that they do not know how the GE wheat appeared in the Oregon field. That field was not the site of any authorized field trials of the wheat. In September 2014, a different variety of Monsanto's GE wheat was also discovered growing in a Montana field. The Montana discovery calls into question APHIS's original statement that they found nothing to indicate that the Oregon incident was more than a single isolated incident. If APHIS's ongoing investigations show that the GE wheat is isolated to these two fields and a few volunteer plants, trade implications are likely to remain minimal. Should subsequent analysis show that the contamination came from commingled seed, and that GE wheat or seed could be more widely dispersed, the trade implications are likely to be more significant. Until APHIS completes its investigation of the Montana wheat and issues a final report, wheat growers will remain concerned. The incidents are also likely to continue fueling criticism of those opposed to GE crops in general, and who question the strength and reliability of APHIS's regulatory oversight of the introduction of GE plants into the environment.

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¹⁴ Brian Tokar, *Deficiencies in Federal Regulatory Oversight of Genetically Engineered Crops*, Institute for Social Ecology Biotechnology Report, June 2006, at <http://gmo-journal.com/2010/01/05/doubts-about-usdas-ability-to-effectively-regulate-second-generation-gmos/#sthash.jTvQ5wkN.dpuf>.

¹⁵ See Government Accountability Office, *Genetically Engineered Crops: Agencies are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, GAO-09-60, November 2008, at <http://www.gao.gov/assets/290/283060.pdf>.

¹⁶ 73 *Federal Register* 60009 (October 9, 2008), at <http://frwebgate1.access.gpo.gov/cgi-bin/PDFgate.cgi?WAISdocID=DZom2U/2/2/0&WAIAction=retrieve>.