Unapproved Genetically Modified Wheat Discovered in Oregon: 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 glyphosate-tolerant variety field-tested by Monsanto Company, a major corporate presence in agricultural biotechnology, 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. At this time, APHIS does not know how the presence of the unapproved wheat variety occurred, how the wheat could have gotten into the field after so many years, whether violations under the PPA occurred, or whether the growth of the wheat is more widespread. Answers to these questions are among the objectives of the APHIS investigation.

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 GE wheat variety was completed by FDA in 2004. FDA determined that the GE wheat variety was as safe for food and feed as non-GE wheat, and that there were no public health concerns.

As of early June 2013, APHIS has stated that there is no evidence that GE wheat has entered commerce. Initial tests of wheat imported by Japan, South Korea, and European Union have found no evidence of the unapproved GE trait. The presence of GE wheat in the market could have significant trade implications if the variety turns out to be widespread. 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 have temporarily halted imports of U.S. soft white wheat grown in Oregon and the Pacific Northwest.

Monsanto Company, the variety's developer, provided a validated testing method for the presence of the GE trait to APHIS and to government regulators in Japan, South Korea, Taiwan, and the European Union. If APHIS's investigation shows that the GE wheat is isolated to the one field and a few unintended volunteer wheat plants, the trade implications are likely to be minimal. Should the investigation show that the contamination is from commingled seed, or that the GE wheat is widely dispersed, the trade implications could be more significant.

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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. A letter from USDA's Grain Inspection, Packers, and Stockyards Administration (GIPSA) stated further that "there are no transgenic wheat varieties for sale or in commercial production in the United States at this time."[2]

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.[3] 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.[4] Subsequent test results by APHIS indicated the presence of a glyphosate-tolerant wheat variety field-tested by Monsanto 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. As of early June, APHIS does not yet know how the presence of the unapproved wheat variety occurred, how the GE wheat appeared in the field after so many years, whether regulatory violations occurred, or whether the growth of the wheat is more widespread than a single field in Oregon. Answering these questions is among the primary objectives of the APHIS investigation.

[1] Monsanto Company is the world's largest seed owner 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 is planted in 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] See May 31, 2013, letter from John B. Pitchford, Director, Departmental Initiatives and International Affairs, USDA, Grain Inspection, Packers and Stockyards Administration, at http://www.agri-pulse.com/uploaded/GIPSA-no-transgenic-wheat.pdf.

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

[4] 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).[5] 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, such as corn borer.[6] 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 CFR 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.[7]

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[5] *51 Federal Register, 23302*.

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

[7] 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 has concluded that there are no health or safety concerns from consuming food or feed derived from the GE wheat (see below), APHIS has stated that it would not take steps to remove low-level presence (LLP) of this variety from the food supply.[8] 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.[9]

Safety of GE Wheat for Food and Feed

While the glyphosate-tolerant GE wheat was never deregulated by APHIS, Monsanto 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."[10] 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.

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

[8] 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.

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

[10] 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

APHIS has stated that, as of early June 2013, there is no evidence that GE wheat has entered commerce. Initial tests of wheat imported by Japan, Korea, and the European Union have found no evidence of the unapproved GE trait.

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.[11] 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.

Many countries have zero-tolerance policies regarding imports of unapproved GE varieties. Japan, the largest buyer of U.S. wheat, and South Korea have temporarily halted imports of U.S. soft white wheat grown in Oregon and the Pacific Northwest. Japan has continued to purchase U.S. hard red spring wheat and hard red winter wheat. Monsanto Company, the variety's developer, provided a validated testing method for the presence of the GE trait to APHIS and to government regulators in Japan, Korea, Taiwan, and the European Union.[12] According to a Monsanto spokesman, the test would allow governments to test for the original GE trait—named the MON71800 genetic event—while distinguishing it from similar traits approved and used in other crops. Secretary of Agriculture Tom Vilsack stated that APHIS will use an independent test to reassure wheat importers that their wheat shipments are free of any GE trait.

Policy Implications

Incidents of regulatory noncompliance have continued to raise concerns about the adequacy of biotechnology regulatory structures. 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.[13]

[11] The United States' top wheat export markets are Japan, Mexico, Nigeria, the Philippines, Egypt, South Korea, and Taiwan.

[12] A Monsanto spokesman told CRS that the test the company provided to APHIS and other governments was an "event-specific assay" that can determine the specific glyphosate-tolerant trait of the GE wheat variety (MON71800), but avoids "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.

[13] On June 4, a Kansas wheat farmer filed suit in federal court against Monsanto for gross negligence over the GE wheat discovery. The suit is seeking unspecified damages for lower wheat prices triggered by the export limits. See http://www.newssentinel.com/apps/pbcs.dll/article?AID=/20130604/AP01/306049947.

At this time, APHIS does not know whether the GE wheat incident has similar characteristics to these earlier cases. If APHIS's investigation shows that the GE wheat is isolated to the one field and a few volunteer wheat plants, the trade implications are likely to be minimal. Should the investigation show that the contamination is from commingled seed, and not just the few volunteer plants in an Oregon field, and that the GE wheat or seed is widely dispersed, the trade implications could be more significant. The incident is also likely to continue fueling criticism of those opposed to GE crops in general, and those who question the strength and reliability of APHIS's regulatory oversight of GE plants.

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