APHIS Factsheet
Biotechnology Regulatory Services May 2013

Questions and Answers: USDA Investigating Detection of Positive Genetically Engineered (GE) Glyphosate-Resistant Wheat in Oregon

Q: Why were the initial samples referred to the Oregon State University (OSU) scientist?
A: An Oregon farmer noticed some volunteers, or plants that had germinated and developed in a place where they were not intentionally planted, in his wheat field were resistant to glyphosate and sent the samples to the OSU scientist. She received the samples on April 30, 2013, and conducted tests on the samples. Based on her preliminary tests, the samples she received tested positive for the glyphosate trait and the farmer was informed of the testing results.

Q: What did USDA do after being notified by the Oregon State University scientist?
A: APHIS was contacted by the Oregon State University scientist on May 3, 2013, after her test results from an Oregon farm's volunteer plants indicated the possible presence of the transgene that conveys resistance to the commonly-used herbicide glyphosate. APHIS immediately began a formal investigation into this situation that included, among other things, dispatching investigators onsite to investigate how this situation occurred and collecting additional samples from the farm. This testing is extremely complicated and time consuming. APHIS made the public announcement about this detection as soon as USDA laboratories had absolute confirmation regarding the specific GE glyphosate-resistant wheat variety.

Q: Has APHIS ever authorized field testing of GE wheat in Oregon?
A: APHIS last approved field trials of glyphosate-resistant GE wheat in Oregon in 2001. There are no APHIS-authorized glyphosate-resistant GE wheat field trials being conducted in Oregon or any neighboring states at this time.

Q: Are there other states where APHIS has approved the field testing of this same glyphosate-resistant GE wheat variety detected in Oregon? Where and when?
A: Yes. APHIS authorized over 100 field tests with this specific glyphosate-resistant wheat variety in years spanning from 1998 through 2005. Field tests were conducted in Arizona, California, Colorado, Florida, Hawaii, Idaho, Illinois, Kansas, Minnesota, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wyoming.

Q. Has FDA completed an assessment to ensure the safety of Monsanto's GE glyphosate-resistant wheat?
A. Yes. The FDA completed a voluntary consultation on the safety of food and feed derived from this wheat variety in 2004. For the consultation, the developer provided information to FDA to support the safety of this wheat variety. FDA completed the voluntary consultation with no further questions concerning the safety of grain and forage derived from this wheat, meaning that this variety of wheat is as safe for food and feed use as non GE-wheat varieties now on the market.

FDA's consultation summary, which includes the developer's conclusion that "this wheat variety is not materially different in composition, safety, or any other relevant parameter from wheat now grown, marketed, and consumed," can be found here: http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm155777.htm

FDA's letter to the developer can be seen at: http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm155752.htm

Q. What is the status of GE wheat production by industry?
A: To our knowledge, GE wheat is not currently authorized for commercial sale or planting in any country. We understand that there have been, over the past decade or so, ongoing discussions

among wheat industry representatives, technology developers, and major users of wheat both in the United States and overseas about when GE wheat varieties might be commercially introduced into the worldwide marketplace.

Q: Does the U.S. export wheat from Oregon?
A: Yes. According to Oregon Wheat Commission, Oregon exports 90 percent of its wheat production.

Q: What type of wheat is exported from Oregon?
A: According to Oregon Wheat Commission, Oregon produces predominately soft white wheat and exports 90 percent of its wheat production.

Q: Is this GE wheat present in commerce?
A: At this time, we have no information that this GE glyphosate-resistant wheat variety has entered commerce. There is no public health concern. Our focus is on our ongoing investigation.

Q: What do you think the worldwide impact of this finding will be?
A: We don't wish to speculate on market reaction. As both a leading producer and consumer of wheat, the United States is directly aware of the concerns that an event like this could raise in the food/feed supply chain, from seed producers and farmers to retailers and consumers. We are working hard to reassure domestic and global wheat consumers that this development, although unwelcome, does not pose a risk to food safety.

Q: Might GE wheat be in U.S. food aid shipments?
A: Foods exported commercially or as food aid by the United States are the same foods consumed by Americans every day. This is the case with all commodities, including wheat. This development does not compromise our ability to provide recipients of U.S. food aid with healthy, wholesome, and nutritious foods. For the 2012/13 marketing year (June 2012-May2013), USDA and USAID have provided an estimated 498,000 tons of wheat as food aid with an estimated value between $180 -$200 million.

Q: What does APHIS' investigative process entail?
A: APHIS may refer potential situations to its Investigative and Enforcement Services (IES) staff for further investigation. APHIS has done so in this instance and an onsite investigation has been initiated. APHIS also works closely with State Departments of Agriculture and other federal agencies, including the Food and Drug Administration, the Environmental Protection Agency and the Department of Justice, to ensure compliance with APHIS regulations. The Plant Protection Act provides for substantial penalties for serious infractions, including civil penalties up to $1,000,000 and the possibility of criminal prosecution. APHIS has a Memorandum of Understanding with USDA's Agricultural Marketing Service and Grain Inspection, Packers and Stockyards Administration for those agencies to provide technical sampling and testing expertise, when needed to support an APHIS investigation.

Q: What did USDA test as part of its investigation?
A: At this time, USDA has tested DNA extracted from tissue from wheat plants collected in the field by APHIS investigators; seeds or kernels of suspect wheat are not available at this time.

Q: Are there plans to expand the testing for this event?
A: USDA is conducting the investigation in a step-wise approach. Any additional testing for the investigation will depend on the outcome of tests currently underway.

Q: What tests are available to detect this event? Are these commercially available?
A: The polymerase chain reaction (PCR) test, which detects the DNA of the GE event, is used to detect it. The PCR test is a highly sensitive test that must be conducted by a competent laboratory with a validated method. Currently, there are no commercially available rapid tests validated for detecting the glyphosate-resistant trait in wheat. At APHIS' request, GIPSA is currently evaluating whether rapid tests validated for detecting the trait in other grains can do so in wheat.

Q: Will APHIS take any action against the Oregon farmer in this situation?
A: We have no reason to believe at this time that the farmer who reported the presence of glyphosate-resistant GE wheat volunteers in his field has committed any infraction.

Q: If APHIS were to detect GE glyphosate-resistant wheat in commercial seed and grain, what would APHIS' next steps be?
A: In instances when there are detections of low levels of regulated GE plant material in commercial seeds and grain, APHIS will initiate an inquiry to determine the circumstances surrounding the release, evaluate the risk, and determine what regulatory actions including remedial and enforcement actions, are required. This is the basis for APHIS' low level presence (LLP) policy, which APHIS clarified in March 2007. If APHIS determines that an incident involving regulated GE

plant material could pose a risk to plant health or the environment, APHIS will take appropriate remedial steps using its authority under the Plant Protection Act. In cases in which APHIS determines that remedial action is not necessary to mitigate LLP of regulated GE plant material to protect plant health and the environment, APHIS is not precluded from taking enforcement action against a company or individual for violations of APHIS regulations. Based on the FDA consultation that was completed on this particular variety of wheat in 2004, APHIS would not take remedial steps to remove LLP of this variety from the food supply, as FDA concluded that there is no food safety concern. More information about APHIS' LLP policy can be found at the following link http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/fs_llppolicy3-2007.pdf

Q: How does APHIS authorize the field testing of GE organisms?
A: APHIS has two methods that can be used: permit and notification.

- **Permits** - Permits can be used for any GE organism and are required for plants that do not meet the special requirements that would allow testing under the more-streamlined notification procedure. Permittees must follow permit conditions specified in the regulations plus additional conditions which are tailored specifically for their permit.

- **Notifications** - The notification procedure is an expedited authorization process that can be used only for GE plants which qualify based on criteria in APHIS' regulations. Review and acknowledgement of a notification takes 30 days after receipt. The responsible party who signs the notification letter agrees to meet performance standards specified in the regulations designed to prevent spread and establishment of potential plant pests.

Q: Has APHIS conducted verification tests?
A: Yes. APHIS collaborates with USDA's Agricultural Marketing Service (AMS) and Grain Inspection, Packers and Stockyards Administration (GIPSA) to test samples to detect specific genetic sequences or a protein expressed by the plant. AMS and GIPSA have nationally and internationally recognized technical expertise in commodity sampling, handling and testing.

Q. How are GE products regulated?
A. USDA, along with the FDA and EPA, is part of the Coordinated Framework for Regulation of Biotechnology which describes the Federal system for regulating the safe use of genetically engineered organisms.

FDA has primary responsibility for ensuring the safety of human food and animal feed, as well as safety of all plant-derived foods and feeds. EPA regulates pesticides, including plants with plant-incorporated protectants (pesticides intended to be produced and used in a living plant), to ensure public safety. That agency also regulates pesticide residue on food and animal feed. APHIS regulates the introduction of certain GE organisms that may pose a risk to plant health.

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