APHIS Factsheet

Biotechnology Regulatory Services

February 2008

Question and Answers: Genetically Engineered Corn "Event 32"

Q. How did the Federal Government find out about the presence of unregistered genetically engineered (GE) plant-incorporated protectant (PIP) in 3 of Dow AgroSciences' commercial GE hybrid corn seed lines?
A. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration (FDA) were notified by Dow AgroSciences that the company detected extremely low levels of an unregistered GE corn PIP in 3 of its commercial GE hybrid corn seed lines.

Q. Are there any safety concerns associated with this unregistered GE corn PIP?
A. APHIS, EPA and FDA have concluded that there are no public health, food or feed safety concerns. Additionally APHIS and EPA have determined that that the unregistered GE corn PIP poses no plant pest or environmental concerns.

Q. What is a PIP?
A. PIPs are pesticidal substances produced and used by the living plant to protect it against pests, such as insects, viruses and fungi. PIPs can occur naturally in plants or can be introduced into plants through either conventional breeding or biotechnology.

Q. Have other PIPS been approved by APHIS and EPA that resemble Event 32?
A. EPA and APHIS previously approved Herculex® Rootworm Protection products containing a closely related PIP, Event 22 (DAS-59122-7). Corn containing Event 22 is also the subject of a completed consultation with FDA. Through careful analysis, EPA determined that the proteins produced by Event 32 are identical to those approved for Event 22, and therefore they are covered by an existing tolerance exemption (EPA food safety clearance). In addition, APHIS' scientific analysis concluded that Event 32 poses no plant pest or environmental concerns.

Q. What is the difference between Event 32 and Event 22?
A. Event 32 and 22 are considered "sister" lines. The difference is that corn Event 32 is regulated, which means that it falls under APHIS biotechnology regulatory authority and can only be field tested with Agency approval. Dow is still reviewing whether they plan to apply for an extension of the deregulation for Event 22 to include Event 32.

Q. What are Herculex corn seed products?
A. Herculex® products are a family of varieties that confer tolerance to the herbicide glufosinate and resistance to several varieties of corn rootworm. Herculex® XTRA is also resistant to the European corn borer. Dow developed multiple Herculex® hybrids for planting and 3 of the hybrid lines were affected by Event 32. Companies typically develop multiple hybrids of a product for purposes such as size, flowering, color, and taste.

Q. How many of the Herculex lines were affected by Event 32?
A. The unregistered GE corn PIP, known as Event 32, was found in 3 of Dow's commercial GE hybrid corn seed lines marketed under the names Herculex® RW and Herculex® XTRA Rootworm Protection products.

Q. Has any affected Event 32 seed been planted during the 2008 season?
A. APHIS took steps to ensure the company recalled all affected seed that was shipped to dealers for the 2008 planting season. The 2008 U.S. corn crop will not be affected.

Q. Was seed containing Event 32 sold in previous planting seasons?
A. Seed containing low levels of the unregistered Event 32 was inadvertently sold to farmers by Dow's affiliate Mycogen Seeds and planted in 2006 and 2007.

Q. How much of Corn Event 32 was found in Herculex seed products?
A. Corn Event 32 was found at extremely low levels—approximately 3 seeds per 1,000—in affected Herculex® seed products. Dow reported that in 2007 approximately 53,000 acres of the affected products were planted in the United States. Total U.S. corn

acreage in 2007 was more than 93 million acres. Taking into account the low levels of Event 32 in the Herculex seed products, as well as the very small proportion of these seeds that were planted, any amount of Event 32 in harvested corn would be negligible. It is estimated that no more than 0.0002 percent (two ten–thousandths of one percent) of the 2007 corn crop may have contained Event 32.

Q. How many acres of the two affected lines were planted in 2006 and 2007?
A. Approximately 19,000 acres were planted in the United States in 2006 and approximately 53,000 acres were planted in 2007.

Q. What next steps will APHIS and EPA take regarding Event 32?
A. APHIS, EPA and FDA have concluded that there are no public health, food or feed safety concerns. Additionally, APHIS and EPA have determined that the unregistered GE corn PIP poses no plant pest or environmental concerns. APHIS took steps to ensure the company recalled all affected seed that was shipped to dealers for the 2008 planting season. No affected lines of Herculex® RW and Herculex® XTRA have been planted in 2008. Because the line of GE corn in question was not registered, APHIS and EPA are coordinating to investigate the circumstances surrounding the release and whether any violations of federal regulations occurred.

Q. Is this considered a low-level release?
A. Yes, and APHIS' recently published Policy on the Low-Level Presence of Regulated GE Plant Materials will apply. The policy describes how the Agency responds to such occurrences in commercial seeds and grain. If APHIS determines that an incident involving a GE plant would result in the introduction of material that could pose a risk to plant health or the environment, the Agency will use its authority under the Plant Protection Act (PPA) to mitigate that risk. In cases in which the occurrence of a GE plant material poses no risk to plant health and the environment, APHIS may not take remedial action under the PPA. This could include occurrences involving a plant that qualifies for APHIS' notification process, which is used for those plants that present minimal risk, as well as if the GE plant is similar to another GE plant that has already been deregulated, or shown to not pose a plant pest risk. Even if APHIS determines that no remedial action is necessary to mitigate the low-level presence of a regulated GE material, the Agency can still take legal action for violations of the Agency's biotechnology regulations.

Q. Was any of the affected seed sold outside the U.S.?
A. According to Dow, as of July 2007, Herculex® RW and Herculex® XTRA are approved for cultivation in the United States and Canada, however, no seed or affected seed containing Event 32 was sold outside the United States. Herculex® RW is approved for import of grain in the European Union, Japan, Korea, Mexico, Philippines, Australia, New Zealand and Taiwan. Herculex® XTRA is approved for import of grain in Japan, Australia, New Zealand, Mexico and Korea.

Q. Will trading partners stop corn trade with the United States?
A. We encourage our trading partners to use regulatory flexibility and to take steps appropriate to the level of risk identified. As we've said, there are no food or feed safety concerns associated with Event 32. In addition, we hope that our quick action to bring this unregistered event to the attention of our partners will help assuage concerns. We will continue to work with partners in the best interest of maintaining supplies for food and feed.

Q. What countries represent our top corn markets?
A. Overall, exports of US corn in 2007 were $9.75 billion. Our top five export markets in Calendar Year 2007, in order, were:

1. Japan, with $2.61 billion
2. Mexico, with $1.49 billion
3. South Korea, with $824 million
4. Taiwan, with $753 million
5. Egypt, with $612 million

The European Union, comprising 27 nations, represents a small portion of the corn export market, with $7.6 million.

Q. Is a test available to detect Event 32?
A. Dow AgroSciences used its own test to detect Event 32. USDA's Grain Inspection, Packers and Stockyards Administration (GIPSA) is in the process of verifying the results of Dow AgroSciences test for Event 32. Once verified, the test would be able to identify Event 32 at the 0.1 percent level of detection. Based on the information provided by Dow, the estimated level of Event 32 in the U.S. corn supply suggests it would not likely be detected.

Q. Will USDA provide testing services for the commercial market?
A. USDA does not plan to provide testing services for Event 32 since APHIS, EPA and FDA have concluded that there are no public health, food or feed safety concerns. However, commercial testing laboratories are available to provide testing services to meet market needs.

Q. Why are APHIS, EPA, and FDA all involved in the investigation of Event 32?

A. APHIS, EPA and FDA share responsibility for regulating biotechnology in the United States under the Coordinated Framework for the Regulation of Biotechnology. APHIS and EPA are the agencies responsible for ensuring the safety of agriculture and the environment while FDA has primary responsibility for ensuring the safety of food and any food ingredient derived from genetic engineering.

Q. What is the Coordinated Framework for the Regulation of Biotechnology?

A. The Coordinated Framework for the Regulation of Biotechnology describes the Government's system for evaluating products developed using modern biotechnology.

Q. Will APHIS' Biotechnology Quality Management System help to prevent incidents like this from occurring in the future?

A. No system comes with a 100 percent guarantee. The mixing of one crop with another at very low levels can occur with both conventional crop breeding as well GE crop development. To prevent this from occurring during field testing, we require confinement measures and other restrictions in order to minimize the likelihood of what is known as low level presence. And we take compliance with our requirements very seriously.

In September 2007, APHIS announced plans for a new Biotechnology Quality Management System to help industry establish best management practices to enhance compliance with regulatory requirements for field trials and movements of GE organisms. The voluntary compliance program is scheduled for initial implementation this spring and APHIS will encourage universities, small businesses and large companies to participate. The goal of the voluntary program is to help developers establish policies and quality control practices that proactively address potential issues before they materialize.