LLP Incidents

**It is important to note that the following incidents have involved GE organisms that were regulated at the time of the incident; therefore the incidents described here were in violation of Federal regulations.**

**The charge to the AC21 Committee is to investigate possible compensation mechanisms for economic losses due to the unintended presence of GE material that has been deregulated and is *not* in violation of Federal regulations.**

**Therefore, this information is provided as background only. It describes the results of incidents that have occurred in violation of regulations and actions that have been taken in response to them. U.S. regulatory agencies do not have legal authority or grounds to take similar actions in response to the unintended presence of deregulated GE material.**

**Starlink**® **Corn**

StarLink® refers to a variety of yellow corn genetically engineered to express the

protein Cry9C, which is toxic to various insect pests of corn and acts as a pesticide, therefore its sale and or distribution is subject to regulation by the U.S. Environmental Protection Agency (EPA or Agency) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). (More information at <http://www.epa.gov/pesticides/biopesticides/pips/starlink_corn.htm>)

Under FIFRA and FFDCA, a company seeking to sell or distribute a pesticide must

submit data demonstrating that it will not cause unreasonable adverse effects on the

environment and that any residues in food will be safe, i.e., that there is a reasonable

certainty that no harm will result from aggregate exposure to the chemical

residue, including all anticipated dietary exposures and all other exposures for which

there is reliable information.

Aventis Agroscience, Inc. (Aventis) submitted data on the safety of StarLink® and

applied for approvals under FIFRA and FFDCA. EPA concluded that the available data

did not provide enough information to support a conclusion that Cry9C was not a

potential human allergen, but that all other information indicated that it would not pose

any other types of risks to human health or the environment. Accordingly, in 1998 EPA

registered StarLink® for commercial use, provided that all grain derived from StarLink®

corn was directed to domestic animal feed or to industrial uses (e.g., biofuels). The intent of requiring all StarLink® to be segregated as either domestic animal feed or for industrial use was to preclude any occurrence of the potentially allergenic Cry9C in human food.

The registration contained several specific requirements designed to ensure that no

StarLink® grain entered the human food supply. Following registration, relatively small

quantities of StarLink® were planted in the United States: 9,018 acres in 1998, 247,694

acres in 1999, and 350,000 acres in 2000, with the largest planting representing less than half a percent of the total acreage planted to corn in the United States.

In September, 2000, residues from StarLink® were detected in taco shells.

In response to these detections, Aventis requested cancellation of the StarLink® registration. In addition, working with U.S. Department of Agriculture (USDA), Food and Drug Administration (FDA), EPA, and the food industry, Aventis undertook a program to remove all StarLink® from the food supply. Among other measures, FDA issued guidance “for sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues” that indicated that “manufacturers who detect Cry9C-containing corn in any lot should divert the lot to animal feed or industrial use.”

At the same time, Aventis requested that EPA reconsider its position that the

available data did not provide enough information to support a conclusion that Cry9C

was not a potential human allergen. Aventis provided additional data and analysis to

support its position that the allergenic risks of Cry9C were very small. Most of the

arguments advanced by Aventis involved the position that exposure to Cry9C was so

low, especially after the full implementation of the containment and removal program,

that there would be no threat to public health. EPA convened a meeting of its FIFRA

Scientific Advisory Panel (SAP or Panel) on November 28, 2000, to consider a series of

questions concerning the potential of Cry9C to cause a human allergic response.

After the discovery of StarLink® in food, 51 people reported adverse effects to the Food and Drug Administration. This information was provided to the Centers for Disease Control (CDC), which conducted an epidemiological investigation. Of the 51 cases reporting adverse effects, 28 met the case definition for the CDC investigation. Of these, 25 gave FDA permission to release identifying information to CDC. Seventeen allowed blood samples to be tested. The CDC released a report on June 13, 2001, concluding that although the claimants did appear to have had severe allergic reactions, blood tests demonstrated that StarLink® was not the cause. On July 19, 2001 the EPA’s scientific advisory panel (SAP) determined that although the CDC/FDA findings demonstrated that those individuals were not allergic to StarLink®, the findings should not be used to conclude that no one could be allergic to StarLink®. Following the advice of its SAP, the EPA indicated on July 27, 2001, that it would not accept the Aventis petition to allow traces of StarLink® to remain in the food supply.

Subsequent to the November 2000 SAP meeting, both Aventis and EPA

developed additional information. In July 2001, the SAP convened to review that information. Among the materials evaluated was a White Paper developed by EPA that described the corn wet milling process and documented that it removes virtually all of the protein present in corn grain from the various processed food forms produced by wet milling for human consumption - primarily corn syrup, corn oil, alcohol, and corn starch.

The SAP commented favorably on this White Paper in which EPA stated that “it is

reasonable to conclude that there is virtually no Cry9C protein in wet milled products and that there is no likely health concern for the public associated with the consumption of any food fraction produced by wet milling of corn…”

Following the cancellation of the StarLink® registration, Aventis established a

separate corporate entity, StarLink Logistics Inc. (SLLI), to oversee the StarLink® Enhanced Stewardship Program, through which SLLI and the U.S. corn millers continued efforts to contain and remove Cry9C from the human food supply. SLLI also maintained a monitoring database. By 2008 it contained the test results from more than 4 million tests from over 4 billion bushels of corn collected by dry milling facilities and other corn handling operations. These tests were carried out according to guidance developed by FDA and USDA’s Grain Inspection, Packers, and Stockyards Administration (GIPSA).

In 2005, SLLI commissioned Exponent, Inc., to prepare a new exposure

assessment of the levels of Cry9C present in the U.S. food supply for submission to EPA. SLLI provided supplemental information in 2006 that updated the 2005 exposure

assessment and that quantitatively characterized the impact of the monitoring and

diversion program on exposure to Cry9C. The USDA’s Agricultural Research Service

(ARS) provided the analytical data on Cry9C concentrations in corn grain used in

Exponent’s exposure analysis. In addition, the ARS provided results from testing corn

seeds from the 1970s and 1980s (that is, before Cry9C was ever bioengineered into corn) for the possible presence of naturally occurring Cry9C or other proteins that give a positive reaction in the Cry9C test. GIPSA conducted additional testing to verify the results of the ARS laboratory.

A careful review of this information showed that the cancellation of the StarLink®

registration and the program to contain and remove StarLink® from the corn supply

produced a dramatic decrease in the level of Cry9C estimated to be in the human food

supply.

EPA concluded that by 2006, the potential exposure of the U.S. population to Cry9C in the U.S. food supply was extremely low. In fact, exposure levels to Cry9C- a substance that occurs in nature- were below tolerance levels for approved chemical pesticides. Taken together, several lines of evidence supported a determination that testing corn grain for Cry9C at dry mills and masa operations was unnecessary since estimates of potential exposure were such that there was no likely health concern for the public associated with the consumption of corn-based food products, including food products from the dry milled process or masa operations. Therefore, EPA recommended that FDA withdraw its guidance for dry milling facilities and masa operations that had recommended sampling and testing yellow corn and dry-milled yellow corn shipments intended for human food use for Cry9C protein residues. FDA did withdraw its guidance in 2008.

In 2010, the Federal Grain Inspection Service, which had been providing testing services for the presence of StarLink® corn, announced that it saw no need to continue providing this service. There had been no positive test results for 5 years; the U.S. Food and Drug Administration no longer advised testing corn to be utilized for any purpose; no other country maintained testing requirements; and the number of service requests had dropped substantially.

Economic effects of StarLink® incident

A 2005 academic study (<http://onlinelibrary.wiley.com/doi/10.1002/agr.20054/pdf>)

concluded that while significant costs were incurred by the agricultural community because of the StarLink® incident, the federal Loan Deficiency Program (LDP) reduced the loss, since there were periods of time immediately following the discovery of StarLink® during which the market price dropped below the loan rate for corn. The study concluded that StarLink® caused U.S. producers to lose between $26 and $288 million over the 2000-2001 marketing year. Without the LDP program, losses would have been estimated at $298 million to $964 million.

In addition, the incident resulted in class action lawsuits, including Mulholland et al. v. Aventis Crop Science USA Holding, Inc. in which the plaintiffs, who were non-StarLink® corn growers in seven Midwestern states, claimed property damage and corn loss claims. Property damage claimants were compensated for lost market value, transportation, and storage costs resulting from actual contamination of their crops, fields, equipment, and property. Corn loss claimants were compensated for the alleged reduction in the general price of corn due to the presence of StarLink® corn in the U.S. corn supply. A settlement for $110 million was reached in February 2003.

Trade with Japan

It was in September of 2000 that StarLink® residues were detected in human food. Outstanding sales of U.S. corn to Japan at the end of calendar year 2000 were down about 21 percent from a year earlier. By mid-April 2001, the gap had widened to 44 percent. Accumulated U.S. corn exports and outstanding sales to Japan together were down 2.2 million metric tons from a year earlier on April 12, 2001. While market forces (e.g., larger than anticipated corn crops and exports from Argentina and Brazil) probably accounted for a large portion of the decrease in U.S. corn exports to Japan (as well as South Korea), the StarLink® incident also appeared to be an important factor.

LibertyLink® Rice

Summary

Under a coordinated regulatory framework, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), the U.S. Food and Drug Administration (FDA), and the U.S. Environmental Protection Agency (EPA) share responsibility for regulating biotechnology products to ensure that the development, testing, and use of the products of biotechnology occur in a manner that is safe for plant and animal health, human health, and the environment. APHIS, through its Biotechnology Regulatory Service (BRS), enforces the Plant Protection Act (PPA) with respect to biotechnology, regulating the importation, interstate movement, and field testing of GE organisms that might pose a risk to plant health. APHIS is committed to ensuring that this technology moves forward safely through its rigorous regulatory system.

APHIS initiates an inquiry whenever regulated material is mixed with commercial seeds or grain to assess any risk, evaluate the circumstances surrounding the release, and determine whether remedial and/or enforcement actions may be appropriate.

An investigation was initiated on August 1, 2006, after Bayer CropScience reported that regulated LLRICE601 had been detected in the long-grain rice variety ‘Cheniere.’ The investigation was expanded on February 16, 2007 to include the discovery of regulated GE rice, later identified as LLRICE604, in the long-grain rice variety ‘Clearfield 131’ (‘CL131’).

Bayer CropScience developed LibertyLink® lines of rice to allow the company’s Liberty herbicide (glufosinate) to be sprayed on weeds without killing the rice plants. At the time these incidents were reported, USDA had approved—and FDA had completed its consultation process for—two LibertyLink® lines similar to LLRICE601, LLRICE06 and LLRICE62. Neither were in commercial production. Federal authorities concluded that LLRICE06 and LLRICE62 posed no food and feed safety concerns and that 601 and 604 posed no food or feed safety concerns at the expected low exposure levels. No rice food products were removed from the U.S. market as a result of these incidents.

These lines were produced by inserting the bar gene (35SBar), which encodes the enzyme phosphinothricin N-acetyltransferase (PAT). PAT provides resistance to the herbicide glufosinate, has a long history of safe use, and is present in many deregulated products. It has undergone repeated and thorough scientific evaluation and is used in food and feed, cultivation and breeding in the United States and many other countries. FDA has evaluated the PAT protein for safety on a number of occasions and has concluded that the presence of rice from the LLRICE600 series at low levels in food and feed would pose no safety concerns. APHIS has previously deregulated GE, herbicide-tolerant products such as corn, canola, and soybean that contain the PAT protein.

APHIS’ Investigative and Enforcement Services (IES), in coordination with USDA’s Office of the Inspector General (OIG), investigated the incidents. The investigation was a multi-agency effort at both the Federal and State level. APHIS’ Biotechnology Regulatory Services (BRS) program provided expertise in reviewing evidence, obtaining records, and assisting with subject interviews. USDA’s Grain Inspection, Packers and Stockyards Administration (GIPSA) and Agricultural Marketing Service (AMS) provided molecular services that validated molecular identification tests and also provided molecular identification tests on rice seed, flour, and tissue samples collected. APHIS’ Plant Protection and Quarantine program and GIPSA assisted in the collection of seed samples using standard techniques. USDA’s Economic Research Service provided information regarding rice production and trade in the United States. Several State departments of agriculture and public research centers were helpful in providing samples and information for the investigation.

USDA devoted considerable resources to the investigations of LLRICE 601 and LLRICE 604 to ensure that they were conducted in a thorough and extensive manner. The investigations involved more than 8,500 staff hours gathering information across 11 States and Puerto Rico and site visits to more than 45 locations in 25 counties in 6 States. USDA officials tested 396 samples from 57 rice varieties that had been harvested between 2002 and 2006. Investigators were able to determine that the presence of LLRICE601 was limited to the long-grain rice variety of Cheniere and that the presence of LLRICE604 was limited to the long-grain variety CL131. No short- or medium-grain rice varieties tested positive for either LLRICE601 or LLRICE604. Investigators had hoped to identify how each GE rice line entered the commercial rice supply, but the exact mechanism for introduction could not be determined in either instance, as described below. However, direct cross-pollination probably was not a factor for LLRICE604’s entry point into CL131.

After thorough safety evaluations, APHIS extended deregulation to include LLRICE601 in November 2006. The presence of LLRICE 604 was detected at a point at which only three acres of CL131 had been planted, and the rice seed industry has been successful in effectively removing it from the seed supply.

LLRICE601 Investigation

On August 1, 2006, IES initiated an investigation, and on August 21, 2006, USDA expanded the investigation to include OIG. The objective of the investigation was to determine the specific identity of the gene, the manner in which the LLRICE601 made its way into commercial rice, and whether any USDA regulations were violated.

IES invested 2,090 hours of investigative work in the first phase of this effort, which involved 15 IES investigators, 1 IES enforcement specialist, 1 IES field supervisor, and 3 IES intelligence analysts. In addition, three OIG agents were assigned to this effort. In 11 States—Arkansas, Colorado, Iowa, Louisiana, Mississippi, Missouri, North Carolina, Pennsylvania, Tennessee, Texas, and Virginia—as well as Puerto Rico, investigators conducted interviews and reviewed documents to determine if all parties involved had provided information to USDA within required timeframes of discovery. Evidence was provided showing that parties had notified USDA as soon as they had verified the presence of LLRICE601 in rice.

USDA cast a broad net to determine which varieties of rice in the United States may have contained LLRICE601. Seed materials representing 90 percent of rice seed from breeding facilities in the United States were selected using recent seed certification production records. Initially, small-, medium-, and long-grain varieties were all sampled for testing. From these sources, 233 samples were taken of 57 varieties of rice from the main breeding centers in Arkansas (65), California (44), Louisiana (82), Missouri (12), Mississippi (5), and Texas (25). Because rice seed is not normally held for more than 2 years, the oldest samples that could be obtained were from 2002.

By investigating where LLRICE 601 was field tested, USDA was able to determine that it was grown in proximity to Cheniere at only one site. At that site, the two lines were grown in the years 1999, 2000, 2001, and the isolation distances in those three instances was 240, 3000, and 165 feet respectively. These distances exceed separation distances for production of foundation seed recommended by the Association of Official Seed Certifying Agencies (AOSCA). Planting records indicate that Cheniere was never planted on a site that was previously used for LLRICE 601, so volunteers from a prior crop are unlikely to be the source of the commingling. Volunteers are plants that grow spontaneously from seed left by a previous crop. Affidavits obtained verified that equipment cleaning had been performed by the parties involved for all planting, harvesting, and cleaning operations during this period. Because Cheniere rice samples from 1999-2002 could not be obtained, molecular forensics could not be applied to distinguish between gene flow and seed commingling as a source of the presence of LLRICE 601. As a result of all these factors, USDA was unable to determine how LLRICE 601 became commingled in the Cheniere variety.

LLRICE604 Investigation

In response to the LLRICE601 incident, the USA Rice Federation implemented an action plan to ensure that U.S. rice was free of GE material. The plan established a standard seed-testing protocol for the detection of the presence of the LibertyLink® trait. In addition, the Arkansas State Plant Board notified BRS that up to 30 percent of the samples of CL131—a long-grain variety of rice developed by LSU that was to be sold as certified rice seed in the spring of 2006—had tested positive for LibertyLink®. Based on this discovery, BRS subsequently initiated a second phase of the investigation on February 16, 2007.

The second phase focused on determining the specific identity of the genetic material, which was subsequently identified as LLRICE604, and how it was introduced into CL131. IES invested more than 500 hours in investigative work in this second phase of the investigation. APHIS officials involved in this phase included six IES investigators, one IES enforcement specialist, one IES field supervisor, and one IES intelligence analyst. In six States—Arkansas, Colorado, Louisiana, North Carolina, Tennessee, and Texas—as well as Puerto Rico, investigators conducted interviews and reviewed documentation.

On March 5, 2007, APHIS issued emergency action notifications (EANs) to alert processors and farmers that they should not further distribute or plant CL131 rice seed until the unidentified genetic material could be identified. As a result of early action by APHIS, only three acres of CL131 were planted, and APHIS provided the single affected producer with crop destruction information.

In attempting to determine how LLRICE601 was introduced into CL131, APHIS conducted an exhaustive analysis. It determined that only one lot of CL131 registered seed - grown on a single farm in Texas - tested positive for the LibertyLink trait, which was subsequently determined to be derived from LLRICE604. This location was the sole source of the registered seed used to produce certified seed later tested in Arkansas and showing LibertyLink traits. The USDA investigation determined that LLRICE 604 was never field-tested in proximity to CL131. Because the development of these two varieties did not overlap in location and time, the most likely entry point for LLRICE604 into CL131 was through a means other than direct cross-pollination.

Economic Effects of LibertyLink® Incident

When they were discovered in commercial rice, LLRICE604 and LLRICE601 had not been deregulated and had not been reviewed by FDA for food use under FDA’s voluntary consultation process. Rice futures plunged, and Japan and European countries banned the import of U.S. rice. This caused significant hardship and financial loss in the rice growing industry. Numerous lawsuits ensued.

In the largest of these, in July of 2011Bayer CropScience agreed to pay up to $750 million to farmers in Missouri, Arkansas, Texas, Louisiana and Mississippi to settle lawsuits.

According to news accounts, the settlement was broken down into three categories. The first offered $310 an acre to compensate farmers for market losses and is available to those who had long grain rice planted in 2006-10, with lesser amounts for farmers who only planted in some of those years. The second is for farmers who planted either of two rice varieties in 2006, ‘Clearfield 131’ or ‘Cheniere’, that were most affected. Many of those farmers had to leave fields fallow, plant lower-value crops or spend money cleaning equipment of contaminated rice, according to plaintiffs’ lawyers. The third category is for those who feel that they lost more, and requires additional documentation.

Read more:

<http://www.stltoday.com/news/local/metro/article_38270243-c82f-5682-ba3b-8f8e24b85a92.html#ixzz1bbWHSch7>

Other Incidents

Bt10 corn- (Bt refers to Bacillus thurengensis, a bacterium whose gene is inserted into a plant, enabling the plant to resist insects.) In December, 2004, Syngenta notified APHIS that they had produced and distributed corn which contained very low levels of a small amount of regulated Bt10 corn. APHIS determined there was no plant pest risk due to low levels and also due to similarity to deregulated Bt11. Bt10 seed stocks were quarantined with disposal overseen by USDA. Syngenta paid a civil penalty.

Event 32 Corn- In 2008, Dow AgroSciences (DAS) reported finding regulated Event 32 in its corn breeding and seed material. APHIS investigated and issued an Emergency Action Notice (EAN) to secure and quarantine all potentially affected seed. In a settlement agreement, DAS agreed to pay a civil penalty.

Bt Cotton- In 2008 Monsanto notified BRS that it had mistakenly harvested 0.5 acres of experimental cotton with 54 acres of non-regulated cotton. The cotton was a Bt cotton variety. The same protein had also been produced in a corn variety which was fully approved and had a tolerance exemption from EPA for corn. APHIS used an EAN to hold viable seed at the facility until the tolerance exemption for cotton was established at which time the EAN was lifted. In a settlement agreement, Monsanto agreed to pay a civil penalty.