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Noncompliance History

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The following is a summary of major incidents of noncompliance with APHIS biotechnology regulations from 1995 through present.

In each case, APHIS and the companies took remedial actions in order to protect agriculture, the food supply, and the environment and no adverse effects were reported. Investigative and Enforcement Services (IES) thoroughly investigated each incident. None of the incidents, except those by one company, included field tests of

plant-made pharmaceuticals or industrials.

Expand All

2016

Company/Institution: Monsanto Company and Montana State University's Southern Agricultural Research Center

On July 14, 2014, APHIS was notified that suspected GE wheat had been discovered growing at the Montana State University's Southern Agricultural Research Center (SARC) in Huntley, Montana, where Monsanto Company and researchers grew GE wheat as part of field trials between 2000 and 2003. These field tests were conducted under APHIS authorization.

APHIS conducted an investigation that confirmed that the wheat was genetically engineered to resist glyphosate. Monsanto and Montana State University/SARC were issued warning letters for failing to adhere to required performance standards for field trials.

2015

Company/Institution: Monsanto Company

On August 21, 2014, APHIS was informed by a Monsanto Company (Monsanto) seasonal employee of heavy rain storms that required the removal of regulated dicamba-tolerant soybean plants that had washed out from authorized field trials into neighboring fields and creek beds in Redwood and Renville counties, Minnesota. Based on its assessment of the situation and the origin of the allegations, APHIS inspected 41 dicamba-tolerant soybean field sites in these two counties and referred the incident to APHIS' Investigative and Enforcement Services (IES). IES initiated an investigation into the incident in August 2014.

APHIS alleges that Monsanto: Failed to apply appropriate safeguards to prevent escape and dissemination of regulated articles in eight locations in Redwood and

Renville counties, Minnesota, where Monsanto conducted field trials involving dicamba-tolerant soybeans under an APHIS-issued permit. Specifically, Monsanto allowed soybean plants in reproductive stages to grow within or outside of the required fallow zone surrounding the regulated material, thus failing to maintain the regulated articles separate from other organisms, in violation of the Permit Conditions.

Resolution: On September 21, 2015, under a settlement agreement, Monsanto paid a civil penalty of $81,200 to resolve alleged violations of the APHIS biotechnology regulations (7 CFR part 340). The investigation is now closed.

2014

Company/Institution/Permittee: Responsible Party

APHIS inspectors discovered that the responsible party of a regulated apple tree field trial in the state of Washington had failed to maintain appropriate isolation distances from the regulated apple trees to non-regulated trees.

Resolution: On November 12, 2013, the responsible party entered into a settlement agreement with APHIS. Under the settlement agreement, the responsible party agreed to pay a civil penalty.

2011

Company/Institution: Ventria Bioscience

On March 31, 2011, Ventria Bioscience (Ventria) entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR part 340). The incident involved the movement of dedicated equipment for the storage of regulated pharmaceutical/industrial rice that occurred in January 2010. Upon discovering this incident, APHIS requested an investigation and located the equipment. APHIS inspected the equipment and found that it

contained no regulated rice.

APHIS alleges that Ventria: Moved and sold a dedicated seed storage bin before APHIS could certify the bin had been properly cleaned prior to use in the storage of nonregulated materials.

Resolution: Under the settlement agreement, Ventria agreed to pay a civil penalty.

Company/Institution: Dow AgroSciences

On January 25, 2008, APHIS was informed by Dow AgroSciences (DAS) that the company detected extremely low levels of an unapproved event in commercial hybrid corn seed lines. The incident involved the presence of an unapproved genetically engineered (GE) plant-incorporated protectant (PIP), known as Event 32, in three of DAS' commercial GE hybrid corn seed lines that occurred in 2007. DAS immediately conducted an internal investigation to determine the causal factors and applied measures to track and secure all affected seed. APHIS initiated an investigation to validate DAS' findings in February 2008 and issued an Emergency Action Notice to formally secure and quarantine all potentially affected seed.

On May 30, 2011, DAS entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR part 340). Specifically, APHIS alleges that in 2007, DAS moved and sold small quantities of corn seed containing extremely low levels of the unapproved Event 32.

Resolution: Under the settlement agreement, Dow AgroSciences agreed to pay a civil penalty.

2010

Company/Institution: Monsanto Company

On February 17, 2010, Monsanto Company entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR part 340). The incident involved regulated cotton that occurred in November, 2008. Specifically, APHIS alleges that Monsanto:

- Allowed regulated cotton to be harvested with non-regulated cotton.
- Failed to notify APHIS of an accidental/unauthorized release within the required time period.

Resolution: Under the settlement agreement, Monsanto agrees to pay a civil penalty of $18,690.

2008

Company/Institution: Syngenta Seeds, Inc.

On April 2, 2008, Syngenta Seeds, Inc. entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR part 340). The incident involved regulated corn seed and it occurred in December, 2006. Specifically, APHIS alleges that Syngenta:

- Failed to notify APHIS of an accidental/unauthorized release within the required time period.
- Failed to contain or devitalize 29 pounds of regulated corn seed when it was no longer in use. This corn seed was subsequently misidentified and disseminated in transit.
- Was responsible for an unauthorized introduction that occurred when corn seed was accidentally released into the environment while in transit.

The regulated parental line was granted non-regulated status in March, 2007.

Resolution: Under the settlement agreement, Syngenta Seeds, Inc. agrees to pay a civil penalty of $13,125.

2007

Company/Institution: The Scotts Company LLC

On November 26, 2007, in response to an administrative complaint filed against it, The Scotts Company, LLC entered into a settlement agreement with APHIS to resolve alleged violations of APHIS biotechnology regulations (7 CFR part 340). Specifically, APHIS alleges that Scotts:

- Failed to comply with performance standards for field trials of glyphosate-tolerant creeping bentgrass (GTCB) conducted under notifications from 1999 to 2005 at multiple test sites located in 19 states,
- Violated supplemental permit conditions for a 2005 Idaho field trial of GTCB by failing to remove immature seed heads, and
- Failed to conduct a 2003 Oregon field trial in a manner that ensured the GTCB and/or its offspring would not persist in the environment.
- In a related incident, APHIS also alleges that Scotts improperly moved GE Kentucky bluegrass seed heads.

Resolution: Under the settlement agreement, Scotts agrees to pay a civil penalty of $500,000. In addition, Scotts agrees to conduct three public workshops within 1 year to present best management practices and technical guidance for other potential developers of GE plants and all interested parties on the identification and prompt resolution of biotechnology incidents. The workshops will take place:

- In Oregon, to address current and ongoing efforts to monitor and destroy GTCB in and around the Oregon Control District,
- At a national conference of seed producers or turfgrass specialists, and
- At a location selected by Scotts, with APHIS approval.

Scotts has already implemented measures to comply with performance standards and permit conditions related to these allegations. In addition, Scotts is carrying out monitoring and mitigation actions in Oregon to locate and remove the regulated GE material that was accidentally released during the 2003 field trial. These actions were required by APHIS beginning in 2004 to address past allegations that Scotts failed to notify APHIS of the accidental release of the GTCB in 2003. The current allegations address the ongoing persistence in the environment related to the accidental release.

Company/Institution: Bayer CropScience

APHIS' Investigative and Enforcement Services (IES), in coordination with USDA's Office of the Inspector General (OIG), conducted an investigation into the release of regulated genetically engineered (GE) material detected in 2 varieties of commercial long-grain rice. APHIS initiated the investigation in August 2006 after Bayer CropScience reported that regulated GE LLRICE601 had been detected in the long-grain rice variety Cheniere. This investigation was expanded in February 2007 to include the discovery of regulated GE material, later identified as LLRICE604, in the long-grain rice variety Clearfield 131 (CL131). Both GE rice lines have the same added protein which has been safely used in other deregulated products for more than 10 years.

Resolution: 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. However, direct cross-pollination was probably not a factor for LLRICE604's entry point into CL131.

Based on the findings of the investigation, APHIS is not taking any enforcement action against Bayer. Given the lack of available information and evidence, APHIS was unable to make any definitive determinations that could have resulted in enforcement action. LLRICE601 was deregulated in November 2006, and as such no longer falls under APHIS oversight. In March 2007, APHIS issued emergency action notifications to stop the further distribution and planting of CL131 rice seed to minimize the spread of LLRICE604. The investigation is now closed.

Company/Institution: ProdiGene

On July 26, 2007, ProdiGene, Inc., and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR part 340.4(f), which states that a person who is issued a permit must comply with those permit conditions. Specifically, APHIS alleged that ProdiGene failed to monitor for volunteers associated with a 2004 GE field test of a corn variety modified to produce pharmaceutical compounds. APHIS also alleged that the company did not manage the fallow zone properly and allowed oats being grown in the fallow zone to be harvested and baled for use as on-farm

animal feed. These alleged violations arose from APHIS inspections of the field test, in which the inspector found volunteer corn growing and flowering within the fallow zone surrounding the field trial and in a nearby sorghum field planted within a 1-mile isolation distance. An APHIS inspector and compliance officer also discovered that oats growing in the border rows immediately surrounding the regulated article had been cut and baled.

Resolution: ProdiGene destroyed all volunteers in the 1-mile isolation zone, and plowed under the sorghum field. All suspect oat bales were quarantined and later destroyed. An APHIS inspector supervised the destruction of the regulated plant material. The case was referred to IES for investigation. In addition to paying a civil penalty, ProdiGene, Inc., has agreed that it and its successors in interest will never again apply to BRS for a notification or permit to introduce GE organisms.

2006

Company/Institution: BASF

On June 15, 2006, BASF, Research Triangle Park, NC and APHIS entered into a stipulation to settle alleged violations of 7 CFR part 340.4(f)(4). APHIS alleged that BASF failed to maintain the regulated article only in areas and premises specified in the permit. These alleged violations arose from an APHIS inspection of the field test, in which the inspector noted that the corn was planted in a different location from what was approved in the permit.

Resolution: The case was referred to IES. BASF paid a civil penalty.

Company/Institution: ArborGen, LLC

On July 17, 2006, ArborGen, LLC, Summerville, SC, and APHIS entered into a settlement agreement regarding alleged violations of 7 CFR part 340.3(c)(3) and 340.3(d)(2)(ii)(b). APHIS alleged that ArborGen, LLC failed to maintain the identity of trees of a genetic construct introduced in field trials and failed to follow procedural requirements for notifying APHIS of identification of a regulated article in the notification. These alleged violations arose from a self disclosure by the company

that several trees were of a genetic construct not listed on their notification.

Resolution: The trees have been cut and removed from the location. The stumps are being monitored for re-sprouting and will be treated as appropriate. The case was referred to IES. In addition to paying a civil penalty, ArborGen, LLC employed a third-party consultant to review quality control measures for the management of product identity and inventory. Based on this consultation, ArborGen, LLC presented a written plan to BRS describing how ArborGen, LLC will improve and implement quality control measures. The measures will enhance the genotypic and phenotypic identification of all products that are, will, or may, be regulated articles subject to 7 CFR part 340 regulations, including those received from outside contractors.

2005

Company/Institution: Syngenta Seeds, Inc.

On March 24, 2005, Syngenta Seeds, Inc., Research Triangle, NC, and the Animal and Plant Health Inspection Service (APHIS) entered into a Stipulation Agreement to settle alleged violations of 7 CFR part 340.4 (b) (c). APHIS alleged that Syngenta planted and moved interstate genetically engineered corn seed without obtaining USDA APHIS permits. These alleged violations arose from a disclosure made by the company to APHIS. Specifically, Syngenta mistakenly produced and distributed a limited amount of its genetically engineered Bt 10 corn, which had not complete the Federal government's full regulatory review.

Resolution: EPA and USDA reviewed the scientific information and concluded that there are no human or animal health or environmental concerns with Bt10 corn due to the limited amount in the environment, the results of the review of product characterization information, and the close similarity of the Bt10 corn line and another Bt corn line which had cleared regulatory review. EPA and USDA coordinated their investigative efforts. All plants of Bt10 corn were destroyed, seed stocks were quarantined, and their disposal was then overseen by USDA. In addition to paying a civil penalty, the Stipulation Agreement required Syngenta to sponsor a training conference for other members of the regulated community that focused on compliance with APHIS rules regulating biotechnology crops (7 CFR Part 340). The

conference goals were:

1. Develop best management practices or technical guidelines for insuring no contamination or cross contamination of biotech genes in the seed development and breeding program; and
2. Develop best management practices or technical guidelines to identify, promptly address, and implement corrective measures to resolve unintended biotech releases.

2004

Company/Institution: Seminis Vegetable Seeds, Inc.

On September 30, 2004, Seminis Vegetable Seeds, Inc., Oxnard, CA, and APHIS entered into a stipulation to settle alleged violations of 7 CFR part 340.3 (c) (1). APHIS alleged that Seminis shipped small amounts of genetically engineered tomato seeds to the University of California (UC), Davis, without proper identification. APHIS also alleged that UC inadvertently shipped these seeds to multiple US and international investigators. Seminis retrieved seeds and documented seed locations. In addition to paying a civil penalty, the company was required to implement training and procedures to prevent future violations.

Company/Institution: The Scotts Company

On August 3, 2004, the Scotts Company of Marysville, OH, and APHIS entered into a stipulation to settle alleged violations of permit conditions requiring the immediate notification upon discovery of accidental or unauthorized releases of regulated articles. [7 CFR part 340.4 (f)(10)(i)]. APHIS alleged that, on two occasions, Scotts failed to notify APHIS about the accidental release of glyphosate-tolerant, or Roundup Ready, Creeping Bentgrass (GTCB), which resulted from unanticipated wind events at a field test site in Jefferson County, OR that carried dried GTCB seed heads beyond the field test location.

Resolution: Scotts provided a mitigation plan and committed to additional control measures outlined in a Compliance Agreement with BRS. In addition to paying a civil penalty, Scotts was required to implement training and procedures to prevent future

violations.

2003

Company/Institution: Pioneer Hi-Bred International, Inc.

IES initiated an investigation in May of 2003 after tests required by the Environmental Protection Agency indicated a small amount of genetically engineered corn had cross contaminated surrounding genetically engineered corn being grown at the research nursery. Of the 337,000 leaf and seed samples collected from the surrounding research fields, 12 leaf samples indicated cross contamination had occurred. All of the corn planted at the Pioneer nursery was for use in research breeding trials and was not to be used for food or feed.

Resolution: The cross-contaminated research corn was destroyed immediately upon discovery. Following a thorough investigation into Pioneer Hi-Bred International, Inc.'s adherence to BRS-imposed confinement conditions, IES determined that no conditions of the APHIS permit were violated. In addition, no unapproved corn plants entered the food or feed supply. The investigation is now closed.

2002

Company/Institution: ProdiGene

Location 1: APHIS inspectors found volunteer corn growing within a soybean field that had been a field test site for a pharmaceutical-producing plant in the previous season. Commercial corn surrounded the site within the appropriate isolation distance. ProdiGene failed to notify APHIS of volunteers with tassels within 24 hours of discovery.

Remedial measures: ProdiGene destroyed all corn seed and plant material within 1320 feet of the previous year's test plot. APHIS inspectors supervised the destruction of the regulated corn seed and plant material.

Location 2: At a second location, APHIS inspectors found volunteer corn from the previous year's test sites with tassels growing in a soybean field. APHIS required the company to remove all the volunteer corn to prevent its harvesting, along with the soybeans. Despite APHIS notification of appropriate volunteer corn removal, the soybean field was harvested with volunteer corn plants standing in the field. The soybeans were sent to a grain elevator where they were mixed with 500,000 bushels of soybeans.

Remedial measures: APHIS and the company stopped movement of all the soybeans at the elevator. USDA destroyed the 500,000 bushels of soybeans.

Joint Resolution: IES investigated both incidents and through a formal administrative proceeding, ProdiGene is paying a $250,000 penalty to resolve the allegations. ProdiGene also entered into a consent decision with USDA. ProdiGene agreed to reimburse USDA for the cost of moving and destroying 500,000 bushels of soybeans and provided proof of financial responsibility of $1 million trust fund. In addition, the company agreed to develop a new compliance implementation program and engage in an audit by a third party; ProdiGene must comply with the auditor's requirements.

2001

Company/Institution: North Carolina State University

USDA's Office of the Inspector General (OIG) inspected field test sites of transgenic tobacco engineered for virus resistance and determined that the N.C. State researcher did not have a current permit. The field test was near completion when OIG discovered the infraction.

Resolution: APHIS required the researcher to monitor the site in the following year. IES investigated the case and North Carolina State University paid a stipulated penalty of $1,250.

Company/Institution: Monsanto

Monsanto failed to monitor for corn volunteers in the year following a GE crop field test on an insect-resistant corn variety. The company allowed the volunteers to release pollen within commercial corn planted over the field test site. Consultants and other field workers reported the issue of corn planted on the previous test site to Monsanto, but the company failed to take immediate action or report the situation to APHIS.

Resolution: Monsanto destroyed all the corn planted on the site of the previous years' test crop. Monsanto also purchased and destroyed all the corn growing within the isolation distance. IES investigated and Monsanto paid stipulated penalty of $12,500. Patriot Seed, their cooperator, paid a stipulated penalty of $3,750.

Company/Institution: Monsanto

Monsanto did not follow APHIS' permit conditions for border rows of cotton. The border rows on this field test were too small.

Resolution: Once the infraction was detected, Monsanto destroyed all of the cotton. IES investigated and Monsanto paid a stipulated penalty of $25,000. Monsanto's cooperators paid the following stipulated penalties: University of Tennessee $3,750; Delta and Pine Land $15,000; University of Georgia $3,750.

1998

Company/Institution: University of Hawaii

Contrary to assigned permit conditions, 15 papaya plants genetically engineered for virus resistance were allowed to grow on an experimental plot. APHIS was notified after the plants had been present for 3 to 5 months. Pollen from these 15 plants would have been able to fertilize nontransgenic trees. An APHIS inspector was sent to the site to investigate and determined that the nearest papaya trees were one-quarter of a mile away, which is an adequate isolation distance to prevent fertilizing nontransgenic plants. The inspector also took immediate steps to cut down the 15 plants and remove all flowering parts containing pollen.

Resolution: IES investigated the case and the University of Hawaii paid a stipulated penalty of $500. A written warning had already been sent to the permit holder for infractions at another test site.

Company/Institution: Monsanto

Monsanto planted three GE crop field tests in Puerto Rico and one GE crop field test in Illinois without notifying APHIS. Several field tests included plants engineered with insect resistance. Other field tests included plants engineered with glyphosate resistance. The company also moved regulated GE material without notifying APHIS.

Resolution: Monsanto accounted for all the GE corn seed. All the GE corn seed was either in storage or planted as a regulated article under a new APHIS permit. Monsanto destroyed any regulated articles in the field not under an APHIS permit. Monsanto improved their experimental tracking database and provided training for the relevant field personnel. IES investigated and Monsanto paid a stipulated penalty of $2,500.

1997

Company/Institution: Monsanto

Monsanto failed to monitor for canola volunteers in the year following a GE crop field test that modified the corn's oil profiles at numerous locations. The company also failed to notify APHIS within 24 hours once the lapse in monitoring was detected.

Resolution: Monsanto removed the canola using herbicides. At one location, the volunteers were located within the isolation distance of a commercial birdseed canola crop. APHIS required the company to purchase and destroy the crop that could have been pollinated by the volunteers. APHIS also required Monsanto to monitor the sites for one year and destroy any additional volunteers. IES investigated the case and Monsanto paid a stipulated penalty of $3,300.

1995

Company/Institution: Harvey Campbell and Associates, Inc.

The company planted cotton seed with genetically engineered herbicide resistance in California without obtaining a permit or requesting permission to release the cotton into the environment. In addition, the company had received APHIS permission to move the cotton, but provided inaccurate information about the name and address of the person receiving the GE cotton seed. The 40-foot border rows of nontransgenic cotton surrounding the field test were harvested and pressed for oil, which was used in animal feed.

Resolution: An APHIS officer visited the site to verify that all of the GE cotton plants were destroyed. All of the cotton seed and lint that was harvested from the GE crop was also ordered to be seized and destroyed. As a result of cross pollination, the 40-foot border rows of nontransgenic cotton could have contained some GE material, however, the cotton seed oil would have been free of all GE proteins. The case was referred to IES, and Harvey Campbell and Associates paid a stipulated penalty of $500.

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