

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE GENETICALLY MODIFIED
RICE LITIGATION

)
) 4:06 MD 1811 CDP
)
) TRIALS COMMENCING
) MAY AND JULY, 2011
)

**PLAINTIFFS’ REPLY TO THE BAYER DEFENDANTS’ RESPONSE
TO THE ARKANSAS PLAINTIFFS’ MOTION TO EXCLUDE
DESIGNATION, REPORT AND TESTIMONY OF ALAN MCHUGHEN**

In response to Plaintiffs’ motion to exclude designation, report and testimony of Alan McHughen, Bayer incorporates its responses to prior motions. *See* Bayer Defendants’ Response To The Arkansas Plaintiffs’ Motion To Exclude Designation, Report And Testimony of Alan McHughen (“Resp.”) at 1-2. Similarly, Plaintiffs incorporate the replies previously filed in the Missouri, Arkansas, Mississippi and Louisiana bellwether trials (D.I. 1566, 2008, 2876).

Bayer, however, does request the Court to reconsider its previous rulings that McHughen cannot disclose certain conversations he purportedly had with certain, and unidentified, agency employees, and a statement in the USDA Report that “adequate [confinement] . . . measures still might not prevent 100 percent of LP occurrences.” Resp. at 2. These arguments have been made, re-considered and rejected by this Court on multiple occasions. The Court’s rulings were correct and there is no basis to change them.

1. McHughen's Opinions Are Contrary To The Regulations And This Court's Order.

All of McHughen's proposed testimony goes to his efforts at interpreting the regulations in a manner contrary to their plain language, contrary to APHIS' own official statements, and contrary to this Court's order that they do not permit escape at any level. *See* Oct. 9, 2009 Mem. & Order (D.I. 1604) at 20. McHughen's reliance on the statement Bayer cites from the USDA Report, his unofficial discussions with Sally McCammon and Terry Medley, and his undisclosed discussions with unidentified "regulatory officers" all are found in the section of his Report entitled: "How Does APHIS Contemplate Confinement?" McHughen Report (Bayer Ex. C) at 23. The conclusion he draws from all these (and other) sources is: "Thus, escape of trace amounts of regulated material does not constitute a violation of the performance standards." McHughen Report at 25.¹ McHughen's opinion that the regulations permit escape is contrary to law and inadmissible.² The sources on which McHughen relies for that conclusion are as inadmissible as the conclusion itself.

1. Statements from USDA Report.

The hearsay statement Bayer cites is irrelevant and highly misleading. And Bayer misrepresents it. *See* Resp. at 2. The Report makes a generic observation that while APHIS' Biotechnology Regulatory Services ("BRS") "examines confinement measures . . . to ensure that they are adequate . . . these measures still might not prevent 100 percent of LLP occurrences."

¹ McHughen's opinions concerning Bayer's *negligence* are confined to rebuttal to plaintiffs' experts opinions, and McHughen's own opinions regarding industry practices. *See* McHughen Report at 58-66.

² It also is contrary to APHIS' own characterization of the LLRICE escape as a "major noncompliance incident." *See* Noncompliance History attached hereto as Exhibit 1. "Expert opinions that are contrary to law are inadmissible" as they "cannot be said to be scientific, to be reliable, or to be helpful to the trier of fact." *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp.2d 794; 806 (N.D. Ill. 2005). *See also United States v. Wintermute*, 443 F.3d 993, 1001 (8th Cir. 2006) (by misconstruing legal burden, expert's testimony was irrelevant and would "confuse rather than assist the jury"); *Southard v. United Regional Health Care System*, 2008 WL 4489692 at *2 (N.D. Tex. Aug. 5, 2008) (expert opinion based on erroneous legal premise excluded).

USDA Report (Bayer Ex.B) at 2. Whether such measures (whatever they are) prevent every escape from every field trial by every developer all the time says *nothing* about the measures that *Bayer* did—and did not—use for the particular LLRICE field trials at issue. And quite clearly, APHIS did *not* find Bayer’s containment measures adequate. To the contrary, records were unavailable or never made and hence, “all procedures employed at the [LSU] site to assure confinement could not be verified.” USDA Report at 5.

Moreover, recognition that escapes sometimes happen does not change the regulations, which unambiguously make no exception for “low-level,” adventitious, or any other presence of regulated material outside the authorized field-testing site. Oct. 9, 2009 Mem. & Order (D.I. 1604) at 20. As previously discussed during the Louisiana bellwether trial, McHughen has, despite this Court’s ruling, volunteered testimony in previous trials that the performance standards seek only to “minimize” escape. *See* Tr. June 16, 2010 Pretrial Conference Transcript at 72-75, attached hereto as Exhibit 2, at 72:2-20. Of course, McHughen’s opinion is that the regulations *do* permit escape. While this Court has permitted McHughen to testify about his own belief that it is not possible to guarantee no escapes, it recognized the misleading and improper nature of testimony that regulators believe that confinement is impossible and escape is permissible:

I am telling you that Mr. McHughen may not testify that the regulations or that everybody believes or that other people know or that, oh, we are just friends here and everybody knows that all we can do is minimize the opportunities, we are not really trying to do it and people know we are really not trying to do it and that is okay. He can't say that because that conflicts with the regulations.

Ex. 2 at 74:20-75:2. Testimony from a scientific or statistical viewpoint regarding guarantees is “very different from [McHughen] saying everybody knows, the regulators know, we can't guarantee it, the regulators know we are not really going to comply with these regulations, they don't really intend for us to.” McHughen did sort of try to say that last [trial], so I think it is

important that he not do that.” Ex. 2 at 75:5-19. This ruling is correct and should not be reconsidered.

2. Hearsay Conversations with Regulatory Employees

McHughen’s proposed testimony regarding conversations with regulatory employees is inadmissible for the same reasons and other independent reasons as well.

McHughen cites to discussions with current and former APHIS employees Sally McCammon and Terry Medley. McHughen Report at 24. *See also* Deposition of Alan McHughen (DI 1440 Ex.2), incorporated herein, at 106:22-107:1.³ The purported statements he recounts are unofficial *personal opinions* as opposed to official APHIS position. *Id.* at 109:2-13, 111:5-14; 312:8-13, 313:4-13.⁴ The personal opinions of agency employees have no weight. *Sidell v. C.I.R.*, 225 F.3d 103, 111 (1st Cir. 2000); *see also Mola Devel Corp. v. United States*, 516 F.3d 1370, 1379 n.6 (Fed. Cir. 2008) (affidavit of former government official “should not be received, much less considered.”). And the “isolated opinion of an agency official” does not permit reading a regulation “inconsistently with its language.” *Environmental Defense v. Duke Energy*, 549 U.S. 561, 580 (2007).

McHughen also states that “[b]eginning in the 1980s, I have had many discussions with regulatory officials, including those at APHIS, about the concept of confinement and what it entails.” McHughen Report at 23. The “general understanding” McHughen drew from these undisclosed discussions with unnamed “regulatory officials” was “that biological systems growing outdoors cannot be absolutely confined, [and] that there will always be some degree of

³ There is no recorded or written confirmation of McCammon’s purported statements, made during a telephone conversation with McHughen. *Id.* at 110:10-24, 311:-312:2. The email from Medley (Report at 23) is not attached to his report. *Id.* at 113:2-114:1. Bayer eventually produced Medley’s e-mail (only after McHughen’s deposition) in which all text other than Medley’s statement was redacted.

⁴ McHughen agrees that people in any organization may disagree with its official view. *Id.* at 109:14-19.

escape, however small” and accordingly, the regulations are not “interpreted as absolute.” *Id.* When asked at his deposition, McHughen did not identify any of these discussions, who they were with, or what time period they relate to. *See* Depo. (D.I. 1440 Ex. 2) at 107:2-109:1. Undisclosed statements from undisclosed people is even less reliable, less relevant, and more prejudicial than personal opinions from disclosed declarants not purporting to state official agency position. Barren of content or context, McHughen’s conglomerate representation about whatever discussions he had with unidentified “regulatory officers” is contrary to the basic gatekeeping function under *Daubert*, which requires more than simply taking an expert’s word for it. Fed. R. Civ. P. 702 Committee Comments (citing *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995)).⁵ McHughen also should not be permitted to bolster his opinions with undisclosed opinions from unidentified persons, implicating phantom experts that Plaintiffs had no opportunity to cross examine.

Beyond all this, McHughen cannot repeat hearsay statements to the jury. October 9, 2009 Mem & Order (D.I. 1604) at 30 (experts not “allowed to recite hearsay statements”). *See also* *Loeffel Steel Prods., Inc. v. Delta Brands, Inc.*, 387 F. Supp.2d 794, 808 (N.D. Ill. 2005) (while an expert may rely on hearsay in forming his opinions, he may not repeat it as the mouthpiece of another under Rule 703); *U.S. v. Rubi-Gonzalez*, 2009 WL 464208 at *3-4 (2d Cir. Feb. 25, 2009) (expert may not transmit hearsay to jury).

This Court’s prior rulings in regard to McHughen’s proposed testimony regarding hearsay statements in the USDA Report and other regulatory declarants were correct and Bayer provides no basis upon which they should be revisited or reversed.

Dated: March 4, 2011

⁵ Neither does it provide any basis for compliance with Rule 703. *Zotta v. NationsCredit Financial Servs.*, 297 F. Supp.2d 1196, 1204-05 (E.D. Mo. 2003).
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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify that I have this 4th day of March, 2011, electronically filed a copy of the foregoing with the Clerk of the Court to be served by operation of the Court's electronic filing system upon the parties of record.

/s/ Don M. Downing_____

EXHIBIT 1

This is Google's cache of http://www.aphis.usda.gov/biotechnology/compliance_history.shtml. It is a snapshot of the page as it appeared on Aug 9, 2009 23:17:59 GMT. The [current page](#) could have changed in the meantime. [Learn more](#)

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Animal and Plant Health Inspection Service



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Biotechnology

Noncompliance History

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.

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 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 340). Specifically, APHIS alleges that Scotts:

- Overview
- Introducing Genetically Engineered Organisms that may be Plant Pests
- About BRS
- About Permits, Notifications, and Petitions
- Status of Permits, Notifications, and Petitions
- Compliance and Inspection
- Biotechnology Regulations and Statutes
- BRS Library
- News and Information
- Biotechnology Site Map

- Apply for a Permit, Notification, or Petition
- Check the Status of a Permit, Notification, or Petition
- Report a Compliance Issue
- Register as a BRS Stakeholder
- Learn about BRS
- Find Biotechnology Environmental Documents
- Submit a Public Comment
- Learn about BRS Job Opportunities
- Learn about Roundup Ready Alfalfa
- Ask a Question



- 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 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 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 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 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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EXHIBIT 2

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

IN RE GENETICALLY MODIFIED RICE
LITIGATION

)
) No. 4:06-MD-1811-CDP
)
)

PRETRIAL CONFERENCE

BEFORE THE HONORABLE CATHERINE D. PERRY
UNITED STATES DISTRICT JUDGE

JUNE 16, 2010

APPEARANCES:

For Plaintiffs:

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For SLLI: Pamela R. Mascari, Esq.
KEAN MILLER

REPORTED BY: Angela K. Daley, CSR, RMR, CRR
United States District Court
111 South Tenth Street, Third Floor
St. Louis, MO 63102 (314) 244-7978

1 THE COURT: Okay.

2 MS. GARRISON: And we added a sentence to simply --
3 down where it says "despite the Court's ruling, McHughen has
4 testified that the performance standards seek only to
5 minimize," and we simply brought that up because that was
6 something we were concerned about. The defendants have
7 indicated that they understand the Court's ruling in terms of
8 excluding any testimony contrary to the order interpreting 7
9 CFR Part 340, so I am not sure this is a substantive
10 difference given the defendants' concession on that point.

11 THE COURT: What is it you are asking me to do?

12 MS. GARRISON: Well, Dr. McHughen has several times
13 volunteered his belief that we are talking about minimizing
14 escape. He does it often, and, you know, this was something
15 that I thought we should bring up and talk about.

16 THE COURT: Yeah, he did do that. He sort of was one
17 of those experts, and I have them from time to time, who say I
18 know what the judge ruled, but I am going to say it anyway,
19 just do it a little different and see if that works. So what
20 do we do about that?

21 MR. FERGUSON: Your Honor, this actually bears on
22 something that came up in briefing on the APHIS report, and as
23 you may recall, one of the things that the USDA has concluded
24 and stated in the APHIS report is that even adequate
25 containment measures may not prevent a hundred percent of

1 releases, and I think at a certain point, Your Honor ruled
2 that Dr. McHughen could testify his belief to that effect, but
3 he couldn't cite the USDA report or I think you said the
4 National Academy of Sciences or something like that, that you
5 didn't want him doing that. That is his belief. It actually
6 happens to be the belief of the USDA as well, which Your Honor
7 has excluded and which we have asked Your Honor to reconsider.
8 But I think what he did testify to was consistent with the
9 ruling that I have just suggested took place in connection
10 with this other issue.

11 MS. GARRISON: Your Honor, if I may, all of this
12 is -- all of this is terribly misleading to the jury, and, you
13 know, from our perspective, what do I do about that. You
14 know, what do I say about this when you say, well, minimize.
15 And it doesn't matter whether he is talking about the USDA
16 report or not. I mean, certainly in regard to the USDA
17 report, the statement that Mr. Ferguson is talking about, you
18 know, that has to do with the, you know, the low level policy,
19 and all those things Your Honor has already ruled on. But
20 when he says "minimizing", he does it often. It is very
21 misleading, and, you know, from our perspective, what do we do
22 at that point.

23 THE COURT: So what is it you are asking me to tell
24 him? Tell me what you want me to say to him.

25 MS. GARRISON: Don't use the words "minimized". Just

1 don't say it. Just don't go there. That is what we are
2 asking.

3 THE COURT: Don't you think -- well, I previously
4 said he can testify to his belief that it is not possible to
5 comply with the regulations. Did I say that or not?

6 MS. GARRISON: No. I think what you said was he can
7 testify about it is not possible to a hundred percent confine
8 pollen.

9 THE COURT: Well, I think what I was trying to say is
10 that he can testify that it is not possible to guarantee with
11 a hundred percent certainty that nothing will happen, that it
12 will not escape, and I believe that that is simply a fact that
13 is indisputable, that nobody in advance can guarantee a
14 hundred percent that something will not happen. Certainly in
15 this case even if they had complied, they cannot guarantee to
16 a hundred percent that nothing will happen, but they didn't
17 comply in lots of ways is the plaintiffs' evidence. And so I
18 don't think -- I mean, I think -- I am not changing my ruling
19 on the APHIS report. I do not agree with the defendants'
20 characterization of it, and I am telling you that Mr. McHughen
21 may not testify that the regulations or that everybody
22 believes or that other people know or that, oh, we are just
23 friends here and everybody knows that all we can do is
24 minimize the opportunities, we are not really trying to do it
25 and people know we are really not trying to do it and that is

1 okay. He can't say that because that conflicts with the
2 regulations. So that is my ruling to the extent it makes
3 sense; otherwise, the plaintiffs are going to just have to
4 object if he starts doing that, okay?

5 MR. FERGUSON: Your Honor, I just want to raise the
6 issue with scientists here is that the scientists understand
7 that there is a statistical issue here, and it is that very
8 thing that you can't guarantee a hundred percent.

9 THE COURT: And that is very different from saying
10 that the regulations allow us, therefore, to have a certain
11 amount spill over.

12 MR. FERGUSON: And I don't expect him to say that.

13 THE COURT: And it is very different from him saying
14 everybody knows, the regulators know, we can't guarantee it,
15 the regulators know we are not really going to comply with
16 these regulations, they don't really intend for us to.

17 MR. FERGUSON: And that is not the expectation.

18 THE COURT: He did sort of try to say that last time,
19 so I think it is important that he not do that.

20 MR. FERGUSON: We will avoid that. The reason I am
21 raising it the way I have is because people say things that
22 sound -- they run across a spectrum that has this hundred
23 percent concept in it, and it's sometimes hard to tell whether
24 they are doing what Your Honor was suggesting he may have been
25 doing or something that is much more down the line, and I