

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

IN RE GENETICALLY MODIFIED RICE)	
LITIGATION)	4:06 MD 1811 CDP
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**PLAINTIFFS’ RESPONSE TO DEFENDANTS’ STATEMENT OF UNDISPUTED
FACTS AND PLAINTIFFS’ STATEMENT OF UNDISPUTED FACTS**

Pursuant to Federal Rule of Civil Procedure 56 and Local Rule 7-4.01(E), Plaintiffs submit the following response to Defendants’ Statement of Undisputed Facts in support of its pending Motion for Partial Summary Judgment Based on Express Federal Preemption (“Motion”) (D.I. 1053). Plaintiffs provide an additional statement of undisputed facts in opposition to Defendants’ motion.

RESPONSE TO DEFENDANTS’ STATEMENT OF FACTS

Bayer’s Statement No. 1. On August 1, 2006, the U.S. Department of Agriculture’s (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) initiated an investigation concerning the facts and circumstances of the presence of LLRICE601 in commercially available rice.

Plaintiffs’ Response: Plaintiffs admit that the USDA/APHIS initiated such an investigation, but as explained below in response to Bayer’s Statement No. 3, Plaintiffs object to consideration of the USDA’s investigation and report, and also deny any assertion or implication that APHIS found no violation.

Bayer's Statement No. 2. On February 16, 2007, APHIS expanded its investigation to include the facts and circumstances of the presence of LLRICE604 in commercially available rice.

Plaintiffs' Response: Plaintiffs admit that the USDA expanded its investigation as described, but as explained below in response to Bayer's Statement No. 3, Plaintiffs object to consideration of the USDA's investigation and report, and also deny any assertion or implication that APHIS found no violation.

Bayer Statement No. 3. On October 5, 2007, the USDA issued a report entitled "Report of LibertyLink Rice Incidents" ("USDA Report") summarizing the USDA's investigation and response to the presence of LLRICE601 and LLRICE604 in commercially available rice. The USDA Report is attached as Exhibit 1 to the Affidavit of John M. Hughes.

Plaintiffs' Response: Plaintiffs admit that the USDA issued a report entitled "Report of LibertyLink Rice Incidents," and admit that the document attached as Exhibit 1 to the Affidavit of John M. Hughes purports to be a copy of that Report, which speaks for itself. Plaintiffs object, however, in that the Report is irrelevant and immaterial to the issues raised in Bayer CropScience, LP's Motion for Partial Summary Judgment (for the reasons stated in Plaintiffs' Response thereto). Therefore, Plaintiffs respectfully request that the Court strike the Report for purposes of consideration of Bayer's Motion for Partial Summary Judgment.

Although not expressly discussed in the Bayer's Statement of Undisputed Facts, Plaintiffs also deny any assertion or implication that APHIS found no violation. In the Report, APHIS stated that one of the objectives of its investigation was to determine

“whether any USDA regulations were violated.” *See* Defs Ex. B-1 at 4. APHIS did not expressly state an answer to that question, but did characterize the entry of LLRICE 601 and LLRICE 604 into the commercial rice supply as an “unauthorized release.” *Id.* at 2. The USDA did not pursue enforcement action against Bayer CropScience due to the “lack of available information and evidence.” *Id.* APHIS stated: “Given the lack of available information and evidence, APHIS was unable to make any *definitive* determinations that could have resulted in enforcement action . . . during the investigation, it was discovered that some records that might have been pertinent had not been maintained and were not available. Defs Ex. B-1 at 2-3 (emphasis added).

Though not expressly discussed in the Bayer’s Statement of Undisputed Facts, Plaintiffs also object to Exhibit 2 attached to the Affidavit of John M. Hughes on the grounds that Exhibit 2 is irrelevant and immaterial to the issues raised in Bayer’s motion, constitutes hearsay, and is not properly authenticated. For these reasons, Exhibit 2 is inadmissible and not properly considered in connection with a motion for summary judgment. Therefore, Plaintiffs respectfully request that the Court strike Exhibit 2 to the Affidavit of John M. Hughes.

**PLAINTIFFS’ STATEMENT OF UNDISPUTED FACTS IN OPPOSITION
TO BAYER’S MOTION FOR PARTIAL SUMMARY JUDGMENT**

1. At least as of May 2006 and thereafter, LLRICE 601 was found in the U.S. commercial rice supply. *See* Complaint, ¶¶ 103-106; Answer, ¶¶ 103-106;¹ Affidavit of Gretchen Garrison, attached hereto as Exhibit A, and Ex. A-2 thereto (Statement dated August 18, 2006 by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice).

¹ “Complaint” refers to the Amended Class Action Consolidated Complaint (D.I. 1010) and the Answer of Bayer Bayer CropScience LP thereto (D.I. 1034).

2. On August 18, 2006, U.S. Secretary of Agriculture publicly announced that unapproved genetically modified rice had been found in the U.S. commercial rice supply. Specifically, the USDA announced that Bayer had notified the USDA and the FDA that LLRICE 601 had been detected in samples taken from commercial long-grain rice. *See* Ex. A-2 (August 18, 2006 USDA Announcement).

3. LLRICE 604 also was found in the U.S. commercial rice supply. *See* Complaint ¶¶ 126-129 and paragraphs 4-8 below.

4. On March 5, 2007, the USDA issued a statement that its Animal and Plant Health Inspection Service (“APHIS”) was taking action to prevent the planting and distribution of a long-grain rice seed known as Clearfield CL 131 because testing revealed the possible presence of genetic material not approved for commercialization. *See* USDA Statement By Dr. Ron DeHaven Regarding APHIS Hold On Clearfield CL 131 Long-Grain Rice Seed dated March 5, 2007, attached hereto as Exhibit A-3.

5. APHIS issuance of Emergency Action Notifications advising distributors and producers not to plant 2005, 2006 and 2007 registered or certified Clearfield CL 131 rice seed. Exhibit A-3.

6. On March 9, 2007, APHIS prohibited further distribution or planting of 2005, 2006 and 2007 registered or certified Clearfield CL 131 rice seed. Complaint, ¶ 131; Answer, ¶ 131; USDA “Update For Rice Industry Regarding Clearfield 131 Long-Grain Rice Seed,” dated March 9, 2007, attached hereto as Exhibit A-4.

7. APHIS also advised producers who already planted Clearfield CL 131 seed for the 2007 season that their options included destroying the plant by herbicide application or mechanical means. *Id.*

8. On March 22, 2007, APHIS announced that the unapproved genetic material found in Clearfield CL 131 was LLRICE 604. Complaint, ¶¶ 132, 133; March 22, 2007 APHIS News Release, attached hereto as Exhibit A-5. APHIS stated: “Because LLRICE 604 remains a regulated article, producers will not be permitted to plant any CL131 seed that is currently on hold. The [Emergency Action Notices] that have been issued will remain in place . . . until APHIS can ensure the untreated rice seed has gone through a process that eliminates the possibility it can be germinated or grown.” *Id.*

9. In December 2006, the Arkansas State Plant Board passed emergency regulations that banned the planting of Cheniere rice in the state in 2007 and 2008, and required testing of all seed for the LLRICE trait at the 0.01% level (*i.e.*, one grain out of every 10,000). *See* Arkansas State Plant Board, Circular 11 (Emergency Rule), Part VIII at 42-44 (December, 2006); Arkansas Register, Vol. XXX, Nos. 7 & 8 (January, February 2007) at 8 (Emergency Rule: Circular 11 – Rule Regulating Planting of Cheniere Rice in Arkansas in 2007 and 2008), attached hereto as Exhibit A-6. *See also* Code Ark. R. 209 02 011 Part VIII (stating that: a) “Rice of the varieties Cheniere, that was produced from seed tracing back to the 2003 Foundation Class from Louisiana State University and Clearfield 131 tracing back to registered or certified classes produced in 2005, 2006 or 2007, shall not be offered for sale, sold, planted, produced, harvested, stored, distributed, transported, subjected to conditioning processes or handled in any manner for grain production in 2007 and 2008;” b) “Any other rice variety or lot of seed that may be identified as having a transgenic trait, either a variant of the traits known as ‘LL Rice’ or other traits not currently known, will also be subject to these regulations.”).

10. Attached hereto as Exhibit A-7 is a BRS Factsheet (February 2006) stating that introduction of genetically engineered material must be in accordance with performance standards “to ensure confinement of the regulated material.”

11. Attached hereto as Exhibit A-8 is an APHIS Factsheet (March 2005) stating that genetically engineered material must be introduced in accordance with specified performance standards “to ensure confinement of the regulated material.”

12. Attached hereto as Exhibit A-9 is a publication by APHIS entitled “Policy on Responding to the Low-Level Presence of Genetically Engineered Plant Materials” stating: (“The mixing of low levels of GE plant materials may result in unauthorized introductions of regulated materials in, for example, commercial seeds and grain. . . . [T]he developer must adhere to APHIS regulations and requirements to ensure, through appropriate measures, confinement of the regulated material.”

13. Attached hereto as Exhibit A-10 is an APHIS Factsheet (March 2007) stating: (“Developers must adhere to certain performance standards or conditions to ensure that the regulated GE organisms do not persist in the environment or enter the food or feed supply.”

14. Attached hereto as Exhibit A-11 is an APHIS News Release (March 27, 2007) regarding APHIS’ policy on low-level presence stating: “Developers must [still] comply with all APHIS regulations and permit conditions *to* prevent the release of regulated GE material.”

15. On July 17, 2007, APHIS published a Draft Programmatic Environmental Impact Statement (“DEIS”), attached hereto as Exhibit A-12, evaluating various regulatory alternatives under consideration, including whether to broaden its “regulatory

scope beyond genetically engineered organisms that may pose a plant pest risk to include genetically engineered plants that may pose a noxious weed risk and . . . that may be used as biological control agents.”

16. The DEIS also discusses consideration of options regarding low-level presence of genetically engineered material. Exhibit A-12 at vii-viii. APHIS stated that it was considering revision to make low-level incidents “non actionable,” meaning that “agency action to restrict movement or otherwise prevent environmental introduction is not necessary” but that “such materials are still regulated and any introductions not in accordance with the regulations or permit conditions are unlawful.” DEIS at 152-153.

17. APHIS published a report describing the release of LLRICE into the U.S. commercial rice supply as a “noncompliance event.” 2008 APHIS Newsroom Publication (last modified May 29, 2008), attached hereto as Exhibit A-13.

19. APHIS does not regulate the non-interstate movement of genetically modified material from the United States into foreign countries. See APHIS “Biotechnology Questions and Answers on Permits, attached hereto as Exhibit A-1.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify that I have this 10th day of March 2009, 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