Appeal Nos. 10-2701 and 10-2707
Appeal Nos. 10-2703 and 10-2708

In the United States Court of Appeals
for the Eighth Circuit

KENNETH BELL, *et al.* **Plaintiffs/Appellees/** **Cross-Appellants** **v.** **BAYER CROPSCIENCE LP, *et al.*** **Defendants/Appellants/** **Cross-Appellees**	**JIM PENN, *et al.*** **Plaintiffs/Appellees/** **Cross-Appellants** **v.** **BAYER CROPSCIENCE LP, *et al.*** **Defendants/Appellants/** **Cross-Appellees**

On Appeal from the United States District Court
for the Eastern District of Missouri
THE HONORABLE CATHERINE D. PERRY PRESIDING
MDL Case No. 06-MD-1811

BRIEF OF AMICUS CURIAE
BIOTECHNOLOGY INDUSTRY ORGANIZATION

IN SUPPORT OF APPELLANTS
AND IN SUPPORT OF REVERSAL

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BIOTECHNOLOGY INDUSTRY ORGANIZATION'S RULE 26.1 DISCLOSURE OF CORPORATE AFFILIATIONS AND FINANCIAL INTEREST

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1. Is said party a subsidiary or affiliate of a publicly owned corporation?

   No.

   If the answer is YES, list below the identity of the parent corporation or affiliate and the relationship between it and the named party: NA.

2. Is there a publicly owned corporation, not a party to the appeal, that has financial interest in the outcome?

   No.

   If the answer is YES, list the identity of such corporation and the nature of the financial interest: NA.

Dated: October 14, 2010

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

Amicus Biotechnology Industry Organization ("BIO") is the world's largest biotechnology association. It provides advocacy, business development, and communications services for more than 1,200 members, including corporate entities (from entrepreneurial start-ups to Fortune 500 multi-nationals), academic institutions, state biotechnology centers, and related organizations in all fifty U.S. states and thirty-three foreign nations.

BIO's members involved in food and agriculture are fully engaged in a broad range of innovative research and development projects advancing the use of biotechnology to improve agricultural practices and outcomes, as well as the environment. Indeed, this technology has already made significant contributions—with extraordinary future potential—to the betterment of the human condition and the environment. By 2009, for example, more than 13 million farmers around the world were growing biotechnology-based crops. More than 90% of these growers farm in developing countries where increased crop yield and income from biotechnology-derived crops contribute significantly to alleviating poverty and raising living standards. Indeed, people throughout the world benefit from the increased food supplies, lower prices, and healthier foods made possible by crops that are more resistant to pests and disease and which

increase production yields. At the same time, crops derived through biotechnology often require less pesticide use and less tilling of the soil, helping farmers to reduce the potential adverse impacts of agriculture on the environment.

As biotechnology's importance and impact on the world have increased, the industry's long-standing commitment to the responsible stewardship of this technology continues to become more focused and transparent. BIO members, for example, have worked to institutionalize and promote industry best practices—including, in many instances, independent third-party audits—to promote the technology's safe development and use.[1] BIO and its members have worked closely with USDA to develop this program in coordination with federal efforts to promote industry stewardship.[2] Both USDA and industry stewardship efforts benefit from a

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[1] In this regard, BIO and its leading agricultural biotechnology members — including Appellant Bayer CropScience, LP — created "Excellence Through Stewardship", which is now an independent corporation and is "the first biotechnology industry-coordinated initiative to promote the global adoption of stewardship programs and quality management systems for the full life cycle of biotechnology-derived plant products." *See* *http://www.excellencethroughstewardship.org* (last visited 10/13/2010).

[2] Transcript of conference call announcing USDA's Biotechnology Quality Management System and discussing Excellence Through Stewardship, Sept. 20, 2007, link available at http://aphisweb.aphis.usda.gov/newsroom/content/2007/09/content/printable/BQMS_transcript.pdf.

consistent application of the federal safety regulations that govern the development of agricultural biotechnology.

The district court's approach to the USDA regulations governing genetic engineering, however, appears to ignore the science-based standards mandated by the federal government. Instead, the court has allowed the jury to infer that federal regulations impose a strict outcome requirement rather than requiring the use of good agricultural practices. Notably, however, the district court simultaneously concluded that the regulations were not specific enough to inform what constitutes compliance with them.

As a result of these conflicting approaches by the district court, any expert testimony regarding USDA's understanding and application of its own regulations was excluded, but the regulations were still published to the jury to determine the standard of care. However, without evidence regarding how USDA developed and interprets the regulations, the jury had no way to understand the relevance of the expert testimony that was allowed regarding agricultural production and breeding practices on which the regulations were based. The court's rulings thus needlessly expose the biotechnology industry—as has happened to Appellants here—to unprecedented tort liability for the development and sale of biotechnology products that are ***undisputedly physically harmless*** and ***not subject to regulatory remediation***

or penalty. This directly conflicts with the federal government's express intent to encourage a science-based approach to the advancement of agricultural biotechnology. Unless the District Court's erroneous publication of the regulations to the jury without proper context is reversed, BIO's members will suffer real and substantial harm in their efforts to develop and promote more abundant agriculture and a healthier environment through the safe and science-based use of biotechnology.

BACKGROUND

The United States is the world leader in biotechnology due in many ways to the U.S. federal government's consistent commitment to developing and enforcing a sensible, science-based, and cautious approach to the regulation and development of products derived through biotechnology.[3] This approach allows the biotechnology industry's rich scientific knowledge and entrepreneurial creativity to flow to maximum benefit, consistently regulated by the federal government to address any potential for harm. These policies are manifest from the federal government's earliest activity in the biotechnology arena.

[3] Here, these products will also be referred to as "genetically engineered" or "GE."

The Coordinated Framework

In December 1984, the President's Office of Science and Technology Policy ("OSTP") issued a notice for public comment extolling the "[e]xciting research . . . underway in agricultural applications to enhance plant and animal productivity to help feed the world's people[,] . . . alleviate many problems of disease and pollution and increase the supply of food, energy, and raw materials." 49 Fed. Reg. 50,856, 50,856 (Dec. 31, 1984). The OSTP noted that the United States was then "the world leader in biotechnology" and that this leadership "derived from a strong science base, a vigorous entrepreneurial spirit and availability of venture capital." *Id.* Nevertheless, the OSTP expressed concern regarding the "intense domestic and international competition" triggered by new uses of biotechnology and actions by other nations to "elevate[] the development of biotechnology to a national priority." This made it "imperative that progress in biotechnology be encouraged" throughout the United States. *Id.*

In this spirit, the OSTP proposed a "Coordinated Framework for Regulation of Biotechnology" through which the U.S. Department of Agriculture ("USDA")[4], the U.S. Environmental Protection Agency

[4] USDA primarily regulates plants derived using biotechnology through its Animal and Plant Health Inspection Service ("APHIS"). For simplicity, USDA and APHIS are referred to jointly throughout this brief as USDA.

("EPA"), and the U.S. Food and Drug Administration ("FDA")—the agencies that would "be involved most extensively in oversight of research and industr[y]"—would work together to promote biotechnology, while at the same time balancing "legitimate concerns about safety" raised as "additional products of biotechnology move from contained research laboratories into full contact with the public and the environment." *Id.* The fundamental purpose of this agency working group was to "insure that the regulatory process adequately considers health and environmental safety," while "minimiz[ing] the uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of U.S. industry." *Id.* at 50,857.

Thus, the OSTP directed "not only [that] approaches be consistent from agency to agency and within each agency from application to application, but also that regulatory decisions . . . be based upon the best available science." *Id.* Finally, the OSTP committed that "[a]ttention will be paid also to international harmonization," with the United States "seeking to promote scientific cooperation, mutual understanding of regulatory approaches and international agreement on a range of common technical problems such as the development of consistent test guidelines, laboratory practices and principles for assessing potential risks." *Id.* The Executive Office also "committed to reducing barriers to trade in biotechnology." *Id.*

These steps, the OSTP concluded, would "allow[] U.S. producers to remain competitive and, most importantly, assur[e] that everyone will reap the benefits of this exciting biological revolution." *Id.*

In coordination with OSTP's proposal of the Coordinated Framework, the federal agencies involved proposed their own policies for implementing its purposes. USDA, which has primary oversight for the use of biotechnology in agriculture and forestry, announced that its regulatory actions would take place within its "existing regulatory framework." 49 Fed. Reg. 50,880, 50,898 (Dec. 31, 1984). The agency noted that "scientists have long been able to create new gene combinations within single organisms—even creating new species—through mutagenesis, cross-hybridization, and other breeding techniques." *Id.* Although "modern biotechnology" added "sophistication" and accuracy to these processes, *id.* at 50,897, USDA noted that the "products" of biotechnology "are not fundamentally different from products obtained by conventional technology, *id.* at 50,898. USDA further stated that it already had "vast amounts of expertise and scientific data relevant to the evaluation of safety and efficacy of organisms or other products derived from modern biotechnology procedures." *Id.* Thus, USDA concluded that the "existing framework" of laws and regulations would allow it to adequately promote biotechnology,

while ensuring its safe and effective use. Among other laws forming this "existing framework," USDA specifically identified "various plant quarantine and related laws," including the Federal Seed Act, 7 U.S.C. § 1551, *et seq.*, which governs the "levels" of seed adulteration (*i.e.*, mixtures with other seed varieties, or other foreign material) that are "allowed by the Secretary of Agriculture." *Id.* at 50,898, 50,903. Finally, USDA committed—consistent with the purposes of the OSTP's Coordinated Framework—to "achieving consistency in national regulation and international harmonization," so that "regulatory decisions can be made in a socially responsible manner, protecting human health and the environment, while allowing U.S. producers to remain competitive." *Id.* at 50,904.

Part 340 and the Permitting Process

Within the next two years, USDA proposed new regulations specific to GE organisms and reiterated its "perspective" that "agriculture and forestry products developed by modern biotechnology will not differ fundamentally from conventional products." 51 Fed. Reg. 23,352 (June 26, 1986). Nevertheless, USDA expressed concern that the "growing domestic and international trade in genetically engineered organisms" could "introduce exotic plant diseases and pests into the United States and pose a threat to U.S. agriculture" if not regulated. *Id.* Specifically, in addition to

"[c]ertain organisms themselves," there was concern that the "packaging" and "cultures" in which organisms are transported could be "contaminated with plant pests." *Id.* USDA thus proposed a new set of regulations specific to genetically engineered organisms "to prevent the introduction, spread, or establishment of plant pests that are new to or not known to be widely prevalent or distributed within and throughout the United States." *Id.* at 23,353. "Plant pests" were defined in accordance with the Federal Plant Pest Act as organisms that "can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof." *Id.* at 23,361; *see* 7 U.S.C. § 150aa(c) (repealed 2000).[5] The regulations, codified at 7 C.F.R. Part 340 ("Part 340"), imposed a permitting process for any "regulated article," *i.e.*, anything the Administrator "determines [to be] a plant pest or has reason to believe is a plant pest." *Id.* at 23,361; *see also* 52 Fed. Reg. 22,892, 22,896 (June 16, 1987). Permits thus became necessary for the release into the environment, or importation or interstate transportation of, any regulated article. 51 Fed. Reg. at 23,363-64; 52 Fed. Reg. at 22,896-97. In practice, USDA has treated all genetically engineered crops tested in outdoor field tests as regulated articles based on their plant pest potential.

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[5] The old Federal Plant Pest Act was consolidated with other plant protection statutes into the Plant Protection Act of 2000.

Based upon the results of years of USDA-regulated field trials, a developer may petition USDA for a determination of non-regulated status. If USDA—after providing an opportunity for public comments—determines that the GE crop is unlikely to pose a plant pest risk, that crop will be "de-regulated," and USDA will treat it like every other traditionally-bred crop. GE crops have been commercialized only following a USDA de-regulation decision.

The Notification Process

The original permitting process for regulated articles that USDA established in Part 340 proved cumbersome, but over the next five years, USDA "issued over 300 permits for field tests and over 1000 permits for [interstate] movement." 57 Fed. Reg. 53,036, 53,037 (Nov. 6, 1992). As a result of this experience, USDA determined that "introductions [*i.e.*, interstate movement or field testing] of many regulated articles can be conducted with little or no plant pest or environmental risk, provided that certain criteria and performance standards are met." *Id.* USDA thus proposed that the six species with which it had the most experience (corn, cotton, potato, soybean, tobacco, and tomato) be regulated and field tested under a less onerous "notification" process rather than the more detailed "permitting" process. Based upon its broad experience, USDA recognized

that any plant pest or environmental risk posed by GE varieties of these six species was "likely to be comparable to the risks posed by plants developed through more traditional plant breeding techniques." *Id.* at 53,038.

Having made this determination, USDA's performance standards articulate practices consistent with the traditional high standards of seed purity the USDA has historically required for seed breeding. Those seed purity standards, like Part 340's performance standards, recognize the realities of agricultural production. Thus, rather than the detailed field test requirements imposed by individual permits, USDA concluded that standard "good agricultural practices" for breeding plants would be sufficient to address any potential plant pest or environmental risk under the notification process:

> Over the years, plant breeders have developed standard agricultural practices to address these risks, and the Agency believes that such practices will be adequate to address any risk from plants introduced under this rule. . . . [T]he Agency has sought to enumerate them in this rule as performance standards.

Id. at 53,038-39.

USDA's experience with good agricultural practices necessary for the flow of commercial goods in commerce is well-established. For example, USDA promulgated the standards associated with seed purity under the Federal Seed Act. 7 C.F.R. Part 201. These standards allow for up to 0.2%

of certified rice seed, up to 0.1% of breeder seed, and up to 0.05% of foundation seed to be off-types or varieties other than those labeled. *Id.* at § 201.76 (table 5). Similarly, USDA's standards for rice grain purity allow for up to 1.0% of other types of rice in U.S. No. 1 grade long-grain milled rice. *Id.* at § 868.310.

In their current form, the performance standards enacted under 7 C.F.R. § 340 ("Part 340") provide as follows:

> (1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is ***unlikely to be disseminated*** while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.
>
> (2) When the introduction is an environmental release, the regulated article must be ***planted in such a way*** that they are not inadvertently mixed with non-regulated plant materials of any species which are not part of the environmental release.
>
> (3) The plants and plant parts must be ***maintained in such a way*** that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.
>
> (4) There must be no viable vector agent associated with the regulated article.
>
> (5) The field trial must be ***conducted such that***:
>
> > (i) The regulated article ***will not persist*** in the environment, and
> >
> > (ii) No offspring can be produced that could ***persist*** in the environment.
>
> (6) Upon termination of the field test:

(i) No viable material shall remain which is ***likely*** to volunteer in subsequent seasons, or
(ii) Volunteers shall be managed to prevent persistence in the environment.

7 C.F.R. § 340.3(c) (emphases added). The emphasized portions of these Part 340 performance standards demonstrate the regulations' emphasis on adherence to good agricultural practices and procedures, not to an absolute end result.

For example, Performance Standard 1 requires that plants or plant materials be shipped in such a way that the viable plant material is "***unlikely***" to be disseminated. Since some risk of dissemination is inherent in the term "***unlikely*** to be disseminated," this provision—on its face—does not categorically prohibit a release.[6] Similarly, Performance Standard 6—on its face—likewise recognizes that some volunteers (*i.e.*, unwanted plants that may sprout from seed left in a field following grain harvest) may appear in "subsequent seasons," and requires practices that make this not "likely" to happen.

Likewise, phrases in Performance Standard 1 ("***maintained*** . . . in such a way that"; Performance Standard 2 ("***planted*** in such a way that"); Performance Standard 3 ("***maintained*** in such a way that") and Performance

[6] A separate regulation, 7 C.F.R. § 340.8(b), provides more specific requirements for shipping plants, plant parts, seeds, and other regulated articles.

Standard 5 ("***conducted*** such that") emphasize the ***manner*** in which containment methods are designed and carried out, not the end results. So long as the practices are followed, any potential plant pest and environmental risks are minimized or eliminated.

The performance standards highlight USDA's focus in regulating the plant pest risk of GE field trials—*i.e.*, potential physical harm to plants and the environment, not seed purity. For example, Performance Standard 5's instruction that field trials be conducted so that regulated articles will "not persist in the environment" should be understood in the context of USDA's authority. USDA has defined "persist" as meaning "producing ***feral*** or sustained populations of the regulated article or its offspring that can persist in agricultural or nonagricultural habitats ***without human intervention***." 58 Fed. Reg. 17,044, 17,049 (Mar. 31, 1993). The focus on preventing the occurrence of new weeds is consistent with good agricultural practices and USDA's mandate.

The Expanded Notification Process

The Part 340 regulations were again modified in 1997 to make the less-cumbersome notification process available to "***most*** genetically engineered plants," including rice. 62 Fed. Reg. 23,945, 23,945 (May 2, 1997) (emphasis added). The specific eligibility requirements for plants to

be field tested under the notification process are set out at 7 C.F.R. § 340.3(b). The plant must not be a noxious weed, and must not have other characteristics likely to pose a threat to plants, human health, or the environment. USDA expanded the notification procedure because its experience under the permit process had shown that the safety profile observed with the original six species approved for notification should not be so limited, but that "introductions of many different regulated articles can be conducted with little or no plant pest or environmental risk, provided that certain criteria and performance standards are met." 60 Fed. Reg. 43,567, 43,568 (Aug. 22, 1995); *see also id.* at 43,568-69 ("The Agency's experience with interstate movement, importation, and release [field testing] permits indicates that crop plants can be released into the environment under notification procedures with little or no plant pest risk or potential for significant impact on the environment, if the applicant meets the performance standards given in the regulations.").

Several commenters to this new proposal expressed the view that it was "too broad" and that "permitting procedures should remain in force for a regulated article that has wild relatives in the United States with which the plant can interbreed." 62 Fed. Reg. at 23,947. USDA disagreed that this was a significant concern. It conceded that there are "important differences

in the biology of different crop species that will affect the ***ability*** of confinement procedures to achieve the required performance standard." *Id.* (emphasis added). However, USDA firmly rejected the notion that the mere fact of genetic engineering posed an unacceptable risk, noting that any risk of legitimate plant, health, or environmental harm was low, and would be evaluated on a case-by-case basis:

> [T]hese commenters appear to presume that all gene transfers pose risks, even those that . . . do not persist in the environment (in accordance with the requirements of performance standards in §§ 340.3(c)(5) and 340.3(c)(6)). ***We believe that this is not the case***. Indeed, it would be inaccurate to assert that any trait that is transferred from a transgenic plant to a wild relative, ***even with the potential of persisting in a population of that wild relative,*** will necessarily pose a risk per se. The environmental analysis to address the effect of a particular trait on a recipient population . . . would likely involve [a] case-by-case analysis . . .

Id.[7]

Enhancing Transparency

Over the next several years, the OSTP and USDA took several steps to clarify their policy of balancing the risk of unintentional releases of regulated articles from field trials with the actual risk of harm posed by such

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[7] *See* National Academy of Sciences, 1987, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues,* Washington D.C. ("[T]he risks associated with the introduction of rDNA-engineered organism are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.")

a release. First, this risk-based approach was expressly condoned by the OSTP in August 2002, in what has become known as the U.S. government's "low-level presence" or "LLP" policy. *See* 67 Fed. Reg. 50,578 (Aug. 2, 2002).[8] The OSTP recognized that "[a]s the number and diversity of field tests increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced under field tests with commercial seeds or grain may also increase." *Id.* "This could result in intermittent, low-levels of biotechnology-derived genes and gene products occurring in commerce that have not gone through all applicable regulatory reviews." *Id.* Thus, OSTP outlined the following three principles to be adopted by USDA, EPA, and FDA for "***further reducing***" the already small likelihood of LLP from field tests being found in commercial products. Each of these principles recognizes that the level of confinement is not absolute, but that it should be driven by the level of environmental, human, and animal health risk:

(1) ***The level of confinement for biotechnology-derived plants "should be consistent with the level of environmental, human, and animal health risk"***;

(2) If the risk is unacceptable or cannot adequately be determined, confinement requirements must be "rigorous" and "any level of biotechnology-derived

[8] "Low-level presence" is also known as "adventitious presence."

genes and gene products" would be "prohibited" from commercial products;

(3) Even if the risk is not unacceptable, confinement requirements "should still ***minimize***" the occurrence of out-crossing and comingling, but ***"low levels of biotechnology-derived genes and gene products . . . could be found acceptable*** . . . ."

67 Fed. Reg. at 50,579 (emphases added).

Although USDA had already recognized these basic principles in its 1993 introduction and 1997 expansion of the notification process, "[f]or purposes of transparency" it reiterated them in its own 2007 "Policy Responding to the Low-Level Presence of Regulatd [Genetically Engineered] Plant Materials" (the "USDA LLP Policy") "for the public." 72 Fed. Reg. 14,649, 14,650 (Mar. 29, 2007). The 2007 USDA LLP Policy expressly acknowledged that "[t]he biological conditions of plant breeding, whether with conventional or GE plants, ***are such*** that there is a potential for low levels of genes and gene products to occasionally move beyond confined research sites into commercial seeds and grain that enter commerce." *Id.* at 14,650 (emphasis added). USDA noted that OSTP's three principles for "strengthening the controls for preventing low levels of regulated materials" demonstrated recognition of this inevitable "fact." *Id.*

USDA explained that it had already "developed a policy ***based on current regulations*** for responding to the low-level presence" that would

"***minimize the likelihood***" of such occurrences. *Id.* (emphases added). More specifically, USDA stated that it would "respond to occurrences of regulated materials in commercial seeds and grain with remedial action that is appropriate to the level of risk and warranted by the facts in each case." *Id.* Finally, USDA confirmed that it was considering amending its regulations to make these policies even more explicit. *Id.*

The Current Proposed Amended Regulations

A few months later, in July 2007, USDA issued for notice and comment a draft environmental impact statement ("DEIS") regarding the proposed amendments to Part 340 under consideration. The DEIS emphasized that USDA "has ***always*** used a risk-based approach in regulating genetically engineered organisms." 72 Fed. Reg. 39,021, 39,023 (July 17, 2007) (emphasis added). Nevertheless, due to "public interest in biotechnology regulation," the Agency was proposing revisions "to make the Agency's use of risk-based categories . . . more refined, more explicit and more transparent to the industry and the public." *Id.* The DEIS indicated that the proposed regulations would combine the permit and notification procedures into a tiered permitting system. "For well characterized low-risk genetically engineered organisms, [USDA] would continue to use a process similar to the current notification process . . .; however, the term notification

would no longer be used. Such a process would become the lowest risk 'permit.'" *Id.* The tiered permitting system would "increase transparency . . . [and] regulatory flexibility such that the Agency could move genetically engineered organisms among the tiers as new information becomes available." *Id.*

The proposed regulations themselves were published on October 9, 2008. 73 Fed. Reg. 60,008 (Oct. 9, 2008). There, USDA explained that, although the notification procedure was more "streamlined" than the permitting process, the performance standards were sufficiently vague that it was difficult for USDA "inspectors to determine if a notification holder ***is in compliance***." *Id.* at 60,016 (emphasis added). Thus, the proposed regulations are intended to make the performance standards more specific. *Id.* The proposal also notes that the amended regulations would "***explicitly incorporate*** [USDA's] low level presence policy." *Id.* at 60,025 (emphasis added).

International Enforcement

For decades, the federal government has consistently promoted its science-based approach to generic engineering both at home and abroad. In addition to the legal challenge that the United States brought against Europe before the World Trade Organization, *Report of WTO, European*

Communities—Measures Affecting the Approval and Marketing of Biotech Products (Sept. 29, 2006), the United States has argued for a science-and-risk-based approach to these crops in multiple other international fora.

For example, in an October 22, 2009 presentation before the North American Plant Protection Organization (NAPPO),[9] a USDA Deputy Administrator described the harmonization among the United States, Canada and Mexico in those countries' regulation of genetically engineered crops. Regarding the field testing phase of regulation, the presentation refers to "Conditions imposed to ***minimize gene flow*** and the likelihood of establishment and spread of the regulated organism."[10]

The United States government has also urged international standard-setting organizations to address LLP from a science-and-risk-based approach in instances where a crop has completed the regulatory process in its country of origin, but not in an importing country. For example, the United States

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[9] NAPPO is a Regional Plant Protection Organization created under the authority of the International Plant Protection Convention (IPPC) of the Food and Agriculture Organization (FAO) of the United Nations. NAPPO encourages cooperative efforts among the member countries to prevent the entry, establishment and spread of quarantine pests and to limit the economic impact of regulated non-quarantine pests while facilitating international trade in plants, plant products and other regulated articles.

[10] *See* http://www.nappo.org/annualmtg/2009/AnnualMtg.PPT2009/RBech-NAPPO-Symposium09.pdf (Oct. 22, 2009) (emphasis added).

played a major role in the adoption of a risk-based *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, along with an LLP-specific annex to that guideline, *Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food.*[11] The U.S. government's risk-based approach outlined in the OSTP LLP policy is consistent with Codex's international LLP guideline.

Similarly, the U.S. government is also leading an effort within the Organization for Economic Cooperation and Development (OECD)[12] regarding a risk-based approach to LLP. A U.S. government representative is currently chairing the OECD's *Working Group on Harmonization of Regulatory Oversight of Biotechnology*, and among that group's activities is

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[11] The guideline and annex were adopted by The Codex Alimentarius Commission, which was created in 1963 by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex, which comprises about 165 countries worldwide, is a scientific body that develops the international standards for food safety aimed at protecting public health and promoting fair trade practices.

[12] The OECD is the main worldwide reference for the certification and standardization of certain agricultural commodities and inputs, including seed. OECD certification provides official worldwide recognition of "quality-guaranteed" seed, facilitating international trade and contributing to removal of technical trade barriers. More than fifty-five countries participate in the OECD Seed Schemes.

the consideration of the consequences of low level presence of genetically engineered grains in conventional seeds or commodities.[13]

ARGUMENT

The Part 340 regulations were before the district court on several motions for summary judgment. Most significantly, Defendant-Appellants (collectively "Bayer") had moved for summary judgment on Plaintiff-Appellees' (hereafter "Plaintiffs") claims for negligence *per se*, which sought to impose liability based strictly on the fact that Bayer's GE rice had been found in commercial rice crops. In addition, Plaintiffs had filed their own motion for summary judgment on Bayer's affirmative defenses that it had "complied fully with all applicable statutes and regulations." Finally, each party's *Daubert* motions also touched on the Part 340 regulations to the extent the opposing side sought to introduce expert testimony regarding the regulations. *See In re Genetically Modified Rice Litig.*, 666 F. Supp. 2d 1004, 1019 n.6 (E.D. Mo. 2009).

The court's ultimate reading of the performance standards was that "they . . . are not sufficiently precise about what a person must do to comply" and do "not dictate what a reasonable person would do" to prevent an unauthorized release. *Id.* at 1022. The court thus concluded that the

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[13] *See* http://www.oecd.org/dataoecd/13/7/45604987.pdf (emphasis added).

Plaintiffs could not sustain a claim for "negligence *per se* " or "strict liability." *Id.* at 1022, 1023. Rather, the jury would have to resolve the "factual disputes" that "remain about the standard of care and whether Bayer met it." *Id.* at 1023. The court emphasized that both "[i]ndustry practices" and the "regulatory scheme" would be "relevant to a determination of the standard of care and whether Bayer met it." *Id.* at 1024. However, neither party could "rely on compliance or noncompliance with the regulations as evidence for or against liability, because the regulations do not provide a standard of care." *Id.*

BIO does not take issue with the district court's ruling to this extent. The court erred, however, in barring evidence regarding USDA's own development and interpretation of the performance standards, particularly the performance standards' grounding in existing good agricultural practices. This decision by the district court wrongly deprived the jury of critical context in which to base their determination of the standard of care.

This error appears to have arisen from the district court's determination that expert testimony was "neither helpful nor proper" to interpret the meaning of the regulations. Relying strictly on its own reading of the performance standards, the court concluded that they unambiguously precluded any allowance for low-level presence. 666 F. Supp. 2d at 1022.

In fact, the performance standards are sufficiently ambiguous to confirm the need for expert testimony regarding the USDA's interpretation of them.

I. The District Court Erred by Excluding Expert Testimony and Other Evidence Regarding USDA's Application of the Performance Standards

The district court acknowledged that the Part 340 regulations "are not sufficiently precise about what a person must do to comply" and that it would be up to the jury to determine the appropriate standard of care. *Id.* at 1022. Under such circumstances, it was error for the court to nonetheless allow the regulations to be published to the jury and argued by the parties without allowing evidence of how APHIS developed and interprets its own regulations.

In determining a standard of care, proper consideration "is not limited to a particular regulation of a specific area; it expands to encompass the issue of whether the overall operation or conduct in question was careless or reckless." *Abdullah v. Am. Airlines, Inc.*, 181 F.3d 363, 371 (3d Cir. 1999). In such circumstances, "expert testimony on various aspects of . . . safety may be helpful to the jury." *Id.* Thus, as a general rule, in allowing a factfinder to consider relevant regulations, "to the extent those regulations are unclear or nonexistent, expert testimony of common industry practices" should be admitted "as relevant evidence of reasonable care under the

circumstances." *Martin ex rel. Heckman v. Midwest Express Holdings, Inc.*, 555 F.3d 806, 815 (9th Cir. 2009) (Bea, J., concurring); *see also McNeil Pharm. v. Hawkins*, 686 A.2d 567, 583 (D.C. 1996) ("[T]his jurisdiction has required expert testimony to explain the applicability of statutes where the statute is relied upon as establishing the standard of care.").

Here, the court did allow expert testimony regarding standard industry rice breeding and production practices. However, the value and importance of that testimony was lost on the jury, which was never allowed to hear that those good breeding practices were the basis of Part 340's performance standards.

II. The Jury Could Not Have Derived a Legitimate Standard of Care from the Regulations Without Understanding USDA's Interpretation of Its Regulations

The district court's reading of the performance standards as unambiguously precluding the existence of low-level presence is illustrative of how the jury likely read them unaided by evidence of their origins and interpretation by USDA. However, the regulations alone cannot provide a clear roadmap for a jury to determine the actual standard of care. While the performance standards are intended to ***minimize*** the risk that test plants will persist outside the test field, as demonstrated in the Background section of this brief, there is ample evidence in the regulatory history that USDA has

consistently recognized the natural limits of confinement in agricultural systems. Without an understanding of USDA's development and interpretation of the performance standards, a jury would not fully appreciate the relevance of expert testimony regarding the good agricultural practices on which they were based. Simply stated, the jury was not adequately equipped with information sufficient to establish the standard of care. Several examples illustrate the context which the jurors missed.

The 2007 USDA LLP Policy is foremost in illustrating the longstanding existence of USDA's LLP policy. In it, USDA expressly acknowledged that "[t]he biological conditions of plant breeding, whether with conventional or GE plants, ***are such*** that there is a potential for low levels of genes and gene products to occasionally move beyond confined research sites . . . ." 72 Fed. Reg. at 14,650. Thus, USDA characterized both the permitting and notification processes as "***minimiz[ing]*** the likelihood that regulated GE plant materials will occur in commercial seeds and grain." *Id* (emphasis added).

This policy was not "new" in 2007, but previously had been implemented based upon the underlying LLP policy statement issued by OSTP in 2002. The OSTP LLP policy also recognized the biological impossibility of fully eliminating LLP. The OSTP instead sought to "further

reduce" and "minimize" low-level presence of regulated articles in commercial food and feed crops. 67 Fed. Reg. at 50,578, 50,579. In addition, when USDA issued the 2007 USDA LLP Policy , it explained that it would consider amending its regulations to "establish[] new criteria" governing LLP, but that it already had "a policy ***based on current regulations*** for responding to the low-level presence of regulated materials in commercial seeds and grain." 72 Fed. Reg. at 14,650 (emphasis added). USDA's determination to take no action against Bayer following its investigation of the LLRice release is illustrative of this longstanding policy. There, USDA acknowledged that even the required "confinement measures . . . still might not prevent 100 percent of LLP occurrences." Add. at 2.[14] However, there was no way for the jury to know this without expert and other evidence showing the "practices in fact generally followed" by USDA. *See Nat'l Tel. Coop. Ass'n. v. Exxon Mobil Corp.*, 244 F.3d 153, 157 (D.C. Cir. 2001).

USDA's longstanding LLP policy is manifest in many other ways. For example, as discussed in the Background section above, in originally proposing the notification procedures, USDA emphasized that the Part 340 performance standards were intended to implement "***standard good***

[14] "Add." refers to the Addendum to this brief.

agricultural practice as might be implemented by researchers and plant breeders in field trials involving the introduction of new plant material." 60 Fed. Reg. 43,567, 43,569 (Aug. 22, 1995) (emphasis added). USDA recognized that "[a]ny risk posed by the introduction into the environment of a regulated article under the notification procedures [was] ***likely to be comparable*** to the risks posed by plants developed through more traditional plant breeding techniques." 57 Fed. Reg. at 53,038 (emphasis added). Since absolute biological containment has never been an element of "standard good agricultural practice"—it is clear that USDA, even at this early stage, construed its regulations as articulating an existing, achievable standard of care.

Another indication of USDA's intent to ground Part 340's performance standards in a standard of care based on "good agricultural practices" is found in its explanation of Performance Standard 5, where USDA required that Part 340 isolation distances be maintained to Federal Seed Act standards:

> When the regulated article is male fertile and allowed to flower, it must be separated from any foundation or breeder seed production of non-regulated plant material of the same species, by at least the isolation distances for foundation seed production ***given in 7 CFR 201.76.***

58 Fed. Reg. 17,044, 17,049 (Mar. 31, 1993) (emphasis added). The standards "given in 7 CFR 201.76" were promulgated under the Federal Seed Act to establish standards for production of certified seed. ***These standards do not guarantee 100% varietal purity***. Importantly, 7 C.F.R. § 201.76's standards for rice seed allow for up to 0.05% of "other [rice seed] varieties or off-types," and breeder seed may contain up to 0.1%, each with a 10-foot isolation distance. 7 C.F.R. § 201.76. USDA's implementation of the same isolation standard as part of Part 340's performance standards shows it recognized the limitations of even the highest seed purity standards required by the federal government.

The foregoing examples demonstrate that the district court erred by allowing the jury to read the Part 340 performance standards in isolation without providing the context of how they were developed and are actually interpreted by USDA.

III. The District Court Erred by Construing Part 340 As Unambiguous

The evidentiary error described above was based in the district court's reading of the Part 340 performance standards as unambiguous on their face. However, as set forth in the Background section above, Part 340's performance standards ***are*** ambiguous and must be interpreted in the context of USDA's interpretation and application of them. The record is replete

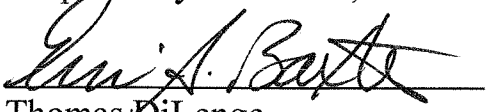
with evidence that USDA construes the Part 340 performance standards as allowing for the possibility of low-level presence, despite the best efforts of a field researcher to contain it. As set forth more fully in Bayer's appellate brief, the court erred in its interpretation of Part 340's performance standards.

CONCLUSION

For the foregoing reasons, *amicus* respectfully urges that the judgment of the district court be reversed.

Dated: October 14, 2010

Respectfully submitted,



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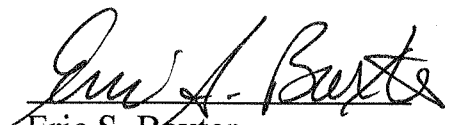
RULE 32(A)(7) CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C)(i), I certify that the foregoing *Brief of Amicus Curiae Biotechnology Industry Organization* was prepared using Microsoft® Office Word 2007, that it uses a proportionately-spaced typeface of 14 point or more, and that it contains 5,971words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).



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CERTIFICATION OF DIGITAL SUBMISSION

I certify that:

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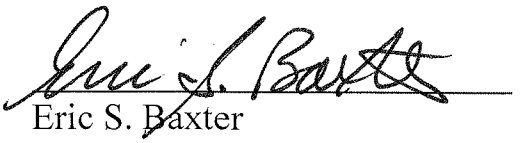

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ADDENDUM

USDA

Report of LibertyLink Rice Incidents

Introduction

This report summarizes the U.S. Department of Agriculture's (USDA) response to the low-level presence of two regulated lines of genetically engineered (GE) rice—LLRICE601 and LLRICE604—found in U.S. commercial rice. It is important to note that both GE rice lines have the same protein, which has been safely used in other deregulated products for more than 10 years. USDA's Animal and Plant Health Inspection Service (APHIS) initiated an investigation on August 1, 2006, after Bayer CropScience reported that regulated genetic material 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 genetic material, later identified as LLRICE604, in the long-grain rice variety Clearfield 131 (CL131). APHIS has now completed the investigation.

APHIS' Investigative and Enforcement Services (IES), in coordination with USDA's Office of the Inspector General (OIG), investigated the events described in this report. 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 investigation to ensure that it was conducted in a thorough and extensive manner. The investigation 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. However, direct cross-pollination probably was not a factor for LLRICE604's entry point into CL131.

Based on the findings of the investigation, APHIS will not be pursuing enforcement action against Bayer CropScience, the company that developed and field tested LLRICE601 and LLRICE604. Given the lack of available information and evidence,

APHIS was unable to make any definitive determinations that could have resulted in enforcement action. APHIS recognized at the start of the investigation that it faced a difficult task given that the field tests for these GE lines were conducted between 1998 and 2001. In addition, during the investigation, it was discovered that some records that might have been pertinent had not been maintained and were not available. Nevertheless, APHIS officials made every effort to learn as much as they could about the events that resulted in the unauthorized release of LLRICE601 and LLRICE604.

To protect the integrity of an investigation, it is APHIS' policy not to disclose information regarding an investigation until it is complete. However, as part of APHIS' commitment to transparency, certain information was released during this investigation to help farmers make decisions for upcoming planting seasons and to keep trading partners informed.

APHIS' Role in the Regulation of Biotechnology

Under a coordinated regulatory framework, 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 BRS program, 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.

On March 27, 2007, APHIS clarified its existing policy regarding the low-level presence (LLP) of regulated GE plant material in commercial seeds and grain. LLP is the mixing—at extremely low levels—of genes and gene products from unintended plant sources. This can occur with both conventionally bred plants as well as biotechnology-derived plants. These occurrences can result from natural processes such as the movement of seeds or pollen or human-mediated processes associated with field testing, plant breeding, or seed production. BRS continually examines confinement measures, including isolation distances, to ensure that they are adequate; however, these measures still might not prevent 100 percent of LLP occurrences.

When LLP incidents occur, APHIS' policy is to respond with actions appropriate to the level of risk, as determined by a scientific assessment and warranted by the facts in each case. APHIS' course of action when it announced that trace amounts of regulated GE rice had been found in commercial rice was consistent with its LLP policy. APHIS' first priority was to assess the safety of the GE rice. APHIS reviewed scientific data and information about the GE rice and determined that the GE rice poses no identifiable concerns related to agriculture or the environment.

APHIS will initiate 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.

Background on LibertyLink Rice

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. USDA has approved—and FDA has completed its consultation process for—two LibertyLink lines similar to LLRICE601, LLRICE06 and LLRICE62. However, they are not in commercial production. Federal authorities have concluded that LibertyLink rice poses no threat to food safety, human health, or the environment, and after thorough safety evaluations, APHIS extended deregulation to include LLRICE601 in November 2006.

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.

To facilitate the investigation, GIPSA verified two analytical methods that Bayer CropScience provided to detect LLRICE. Both tests are real-time polymerase chain reaction (PCR) methods. One detects the 35SBar DNA sequence found in LLRICE, and the other detects the DNA sequence specific to the LLRICE601 trait.

Initial Discoveries Pertaining to LLRICE601

On July 31, 2006, Bayer CropScience orally informed BRS and FDA of the possible LLP of regulated GE rice in U.S. commodity rice. Preliminary information provided to USDA indicated that one long-grain rice variety, Cheniere, may have contained the 35SBar construct, although it was unknown at that time whether other varieties also could have contained the gene.

APHIS participated in discussions with FDA and EPA to consider food safety issues. BRS began to examine the possible source of the LLRICE601 by gathering information from Bayer CropScience on the exact identity of the genetic material. BRS also reviewed testing protocols provided by Bayer CropScience and reviewed all documents on rice field trials conducted by the company and its two predecessors, AgrEvo and Aventis. At the same time, BRS began to examine the planting history of the rice variety Cheniere.

Investigation of LLRICE601

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 top 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.

It is important to note that, in rice breeding, typical seed development begins with the planting of the "head row," which produces seed for the breeder rice. Breeder seed is then used to produce foundation seed, which is grown by licensed plant breeders. Foundation seed can be used to produce either registered or certified seed, and it is typically a 6- to 7-year process from the harvest of the "head row" to the availability of certified seed for commercial use.

Of the seed material that was sampled, only 2003 Cheniere foundation rice seed samples tested positive for LLRICE601. All seven of the 2003 Cheniere rice seed samples tested positive, and all of these were derived or originated from Louisiana State University (LSU). None of the Cheniere rice seed samples for 2004, 2005, or 2006 tested positive for LLRICE601. Lineage was confirmed between the 2003 Cheniere foundation rice seed and both the 2005 Cheniere certified seed lots and 2006 commodity seed that originally tested positive for 35SBar.

Because the LLRICE601 trait was originally inserted in the variety Cocodrie, it was important to determine how the Cocodrie variety rice may have mixed with the variety Cheniere during its development. Investigators looked at all locations where LLRICE601 had been grown, visiting 44 locations in 25 counties in 6 States. They also interviewed 22 cooperators to determine the locations at which any rice seed production, particularly Cheniere variety development, coincided with Cocodrie LLRICE601 research.

Investigators determined that Cocodrie LLRICE601 and Cheniere were grown at the same location and at the same time at the Rice Research Center North Farm in Crowley, Louisiana, in 1999, 2000, and 2001 under a Bayer CropScience contract. The varieties were separated during those three years by distances of 210 feet, 3,000 feet, and 165 feet respectively. Cheniere was never planted on a location that had been previously occupied by Cocodrie containing LLRICE601, according to the records provided. Affidavits obtained verified that equipment cleaning had been accomplished by the parties involved at the Rice Research Center North Farm in Crowley, Louisiana, for all planting, harvesting, and cleaning operations during this period. Detailed maps were reconstructed from breeding records because maps had not been developed for each planting season at these sites. In addition, some records at LSU were not available while others records were never taken. As a result, all procedures employed at the site to assure confinement could not be verified.

Representative samples of the variety Cheniere from 1999-2002 could not be obtained because the breeder seed for the variety had not been maintained from this early stage of development. Because rice seed for the period 1999-2002 was no longer available, the exact mechanism for incursion of the LLRICE601 gene into the Cheniere variety, such as gene flow or mechanical mixture, was not determined.

Description of the LLRICE604 Incident

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 the 35SBar gene. 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.

On March 26, 2007, after USDA conducted testing to identify the genetic material, AMS and GIPSA confirmed that the unidentified genetic material was LLRICE604. Investigators then initiated an effort to identify and trace back those lots of CL131 that were positive for LLRICE604. Determining the circumstances by which the genetic material LLRICE604, originally inserted into the variety Cocodrie, was introduced in CL131 required an analysis of the planting history of field trials containing both rice varieties, as well as sampling and testing CL131 seed lots from all phases in the seed development process.

Based on the fact that the identified material was LLRICE604, and based on FDA's previous food safety evaluations of the PAT protein, the possible presence of minute levels of LLRICE604 in CL131 posed no concern, and the rice was safe to process. Since LLRICE604 remained a regulated article, producers were not permitted to plant any CL131 that was being held under the EAN. APHIS did not prevent the movement of CL131 rice or seed from previous years, although that seed may not be planted.

In February 2007, the samples of varieties collected from LSU during the original LLRICE601 investigation were retested by USDA for 35SBar and LLRICE62. USDA collected additional samples of CL131 in Arkansas, Louisiana, and Texas beginning on March 3, 2007; testing for the LLRICE604 gene started at the end of March. Of the CL131 seed sampled, ultimately only one lot of seed tested positive for both 35SBar and LLRICE604. The seed lot of CL131, numbered EGF5G90, grown and distributed by Garrett Farms of Danbury, Texas, is the lot that has tested positive for LLRICE604 as both registered seed (2005) and certified seed (2006). Evidence acquired during the investigation did not indicate that the variety Cocodrie containing LLRICE604 was ever grown at the Danbury, Texas location, and other samples of rice collected by USDA at the location did not test positive for LLRICE604.

The foundation seed lot (2004, LSU) that was the parent to this registered seed did not test positive for LLRICE604; however, the LSU head row CL131 seed sample from 2004 tested positive for 35SBar and LLRICE62. Although material derived directly from LSU was testing negative for LLRICE604, it tested positive for the LLRICE62 trait. Investigators recognized that there was a chance that the levels of the LLRICE604 gene in these samples were so low that they may not be detectable from the samples that were obtained.

Based on the above results, investigators analyzed the history of all field trials containing both rice lines. Investigators determined that CL131 was developed at the LSU Rice Research Station between 1998 and 2001 and was subsequently released for commercial sale. The variety Cocodrie containing LLRICE604 was developed by Bayer CropScience (formerly AgroEvo) and was tested at various locations, including the LSU Rice Research Station North Farm in Crowley, Louisiana, between 1998 and 2000.

Records and affidavits obtained during the investigation showed that the development of these two varieties did not overlap in location at any time. Records provided also showed that CL131 was never planted on the same field plot as Cocodrie containing the

LLRICE604 line, so that volunteers were not likely a cause of mixture. Volunteers are plants that grow spontaneously from seed left by a previous crop. 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.

The prevalence of LLRICE62 in samples tested by HorizonAg and Producers Rice Mill corroborated observations made by the Arkansas State Plant Board. Based on that finding, as well as the occurrence in LSU samples tested by USDA, the investigation examined the possibility that a variety containing LLRICE62 and LLRICE604 may have mixed with CL131.

Because LLRICE604 was not detected in representative samples of breeding lines at LSU, the exact time period and means of incursion of the LLRICE604 gene into the CL131 variety was not determined.

Additional Information from the Investigation

During the course of the investigation, IES discovered seven instances in which field trials were planted or not terminated during the period specified by APHIS requirements. However, these instances occurred between 2000 and 2002 and are no longer within the 5-year statute of limitations. More importantly, however, these infractions did not contribute to the LLP of LLRICE601 and LLRICE604 in U.S. commercial rice.

USDA's Continuing Commitment to the Safe Development of GE Organisms

APHIS remains dedicated to fulfilling its role as part of the Federal framework for the regulation of biotechnology. Since 1987, when the first field trial for GE plants under APHIS regulations was approved, the Agency has effectively overseen approximately 13,500 field tests and has issued more than 70 determinations of nonregulated status for GE crops in the United States. These field tests were conducted at more than 79,000 sites. None of the products that have been deregulated have been reported to significantly impact the environment in a negative way. Rare occurrences involving the LLP of GE material in commercial seed or grain must be considered in light of USDA's long record of success in biotechnology regulation. USDA remains confident that its regulation of biotechnology is effective.

Nevertheless, biotechnology is a rapidly advancing science, and USDA understands that it must keep pace with this new technology by continually enhancing its biotechnology regulations. One of USDA's most significant biotechnology initiatives is a programmatic review of its regulatory framework. On July 12, 2007, USDA published a draft environmental impact statement (EIS) that evaluates potential revisions to its existing regulations regarding the importation, interstate movement, and environmental release of GE organisms. APHIS published a notice in the *Federal Register* on July 17, 2007, to announce the availability of the draft EIS and to seek public comments until September 11, 2007.

The draft EIS outlines several key areas APHIS is evaluating, including expanding its regulatory scope through additional provisions in the PPA, using a tiered permitting system based on potential environmental risk, and implementing a process for continued oversight of crops that do not meet the criteria for deregulation. USDA will consider possible future changes to the regulations based on the information in the draft EIS, public comments received, and the latest scientific information available.

CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2010, the original and ten (10) copies of the foregoing *Brief of Amicus Curiae Biotechnology Industry Organization* was sent via Federal Express to the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit. I further certify that on October 14, 2010, I served copies of the foregoing *Brief of Amicus Curiae* on the following individuals via Federal Express:

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