CITIZEN PETITION BEFORE THE
UNITED STATES DEPARTMENT OF AGRICULTURE

CENTER FOR FOOD SAFETY	)
Petitioner	) Docket No. ______________
Filed with:	)
UNITED STATES DEPARTMENT OF AGRICULTURE	)

PETITION TO REGULATE LIBERTYLINK RICE AS A PLANT PEST

The undersigned submit this petition under the Plant Protection Act §§ 7711(c)(2) to request that the United States Department of Agriculture ("USDA") regulate genetically engineered LibertyLink rice as plant pests, including varieties LLRICE06, LLRICE62, and LLRICE601. On August 18, 2006, USDA announced that LLRICE601 had contaminated commercial long-grain rice, even though it had not been approved for commercial sale.[1] This contamination event prompted Japan to suspend long-grain rice imports from the US and the European Union has imposed strict controls.[2] In light of this contamination event, the Secretary must act promptly. Specifically, petitioner requests that the Secretary take the following actions:

1. Determine that LibertyLink rice is a plant pest under the Plant Protection Act § 7711.
2. Add LibertyLink rice to the list of organisms that are plant pests.

[1] Press Release, USDA, *Statement by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice* (Aug. 18, 2006).
[2] *Japan Bans 'Contaminated' US Rice*, BBC News (Aug. 21, 2006); *EU to Keep Out GM Contaminated US Rice,* HOUSTON CHRONICLE (Aug. 23, 2006).

3. Determine that LibertyLink rice is a regulated article and restrict its introduction, dissemination, interstate movement, and conveyance under 7 C.F.R. §340.0.

The Secretary should take these actions to prevent injury to plants and plant products. Petitioner requests rulemaking and collateral relief under the Plant Protection Act, the Right to Petition Government Clause contained in the First Amendment of the US Constitution,[3] the Administrative Procedure Act,[4] and USDA's implementing regulations.[5]

Petitioner

Petitioner *Center for Food Safety* is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.

A. STATEMENT OF THE LAW

The Plant Protection Act specifies that a "plant pest" is any living organism "that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product."[6] A "plant product" includes any part of a plant or any manufactured or processed plant or plant part.[7] This definition emphasizes that there are a variety of harms that the agency aims to intercept through the regulation of plant pests. The Act seeks to

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[3] The right to petition for redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights. *United Mine Workers of America, Dist. 12 v. Illinois State Bar Ass'n*, 389 U.S. 217, 222, 88 S. Ct. 353, 356, 19 L. Ed. 2d 426 (1967). It shares the "preferred place" accorded in our system of government to the First Amendment freedoms, and has a sanctity and a sanction not permitting dubious intrusions. *Thomas v. Collins*, 323 U.S. 516, 530, 65 S. Ct. 315, 322, 89 L. Ed. 430 (1945)**.** "Any attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtful or remotely, but by clear and present danger." *Id*. The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. (2 Otto) 542, 552, 23 L. Ed. 588 (1875).

[4] 5 U.S.C. § 553(e) (2000).

[5] 21 C.F.R. §§ 10.20 & 10.30 (2000).

[6] 7 U.S.C. § 7702 (14). USDA regulations contain a similar definition at 7 C.F.R. § 340.1.

[7] 7 U.S.C. § 7702 (15).

prevent not only the spread of diseases and insect pests, but also to prevent economic harm.[8] USDA evaluates five criteria to determine if a genetically engineered plant is a plant pest:

1) Is the plant likely to increase the weediness of other cultivated or wild species with which it could interbreed?

2) Could the plant cause any damage to processed agricultural commodities?

3) Could the plant cause harm to threatened or endangered species or organisms that are beneficial to agriculture?

4) Is the plant more likely to become a weed than a non-genetically engineered variety?

5) Does the plant exhibit any plant pathogenic properties? That is, is the plant likely to cause diseases in other plants?[9]

A negative determination on any one of these five factors requires USDA to regulate LibertyLink rice as a plant pest. The Plant Protection Act prohibits unauthorized movement of plant pests and gives the Secretary authority to issue regulations that prevent the introduction and dissemination of plant pests in the US.[10] As a genetically engineered plant pest, LibertyLink rice should be regulated pursuant to 7 C.F.R. Part 340.

Further, the Plant Protection Act provides that any person may petition the Secretary to add a plant pest to the regulations issued by the Secretary.[11] The Secretary has a duty to act on the petition within a reasonable time and notify the petitioner of the final action the Secretary takes on the petition.[12]

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[8] Senate Report 189, Federal Plant Pest Act (Mar. 26, 1957) (noting that one of the harms that the Act sought to cure was the spread of witchweed, a plant that "greatly reduces the yield, making the crop uneconomic").
[9] *See* 7 C.F.R. §340.6(b).
[10] 7 U.S.C. § 7711 (a).
[11] *Id*. § 7711 (c)(2).
[12] *Id*. § 7711 (c)(3).

B. BACKGROUND

AgrEvo USA Company ("AgrEvo") developed herbicide-tolerant rice through genetic engineering. LibertyLink rice varieties are engineered with the *bar* gene from a soil bacterium and DNA sequences from cauliflower mosaic virus. The genetically engineered rice varieties produce an enzyme, PAT, that inactivates glufosinate-ammonium herbicides.

Initially, USDA regulated LibertyLink rice during field tests pursuant to the USDA's regulations at 7 C.F.R. Part 340. These regulations govern the introduction of genetically engineered organisms that are or are believed to be plant pests. As regulated articles, interstate movement and release of LibertyLink rice varieties into the environment without prior authorization from the USDA is prohibited.[13]

In response to a deregulation petition by AgrEvo,[14] USDA performed an Environmental Assessment ("EA") and made a Finding of No Significant Impact for its contemplated action of granting nonregulated status to LibertyLink rice events LLRICE06 and LLRICE 62. The EA included a determination that LibertyLink rice was not a plant pest.[15]

In 1999, USDA granted nonregulated status to LLRICE06 and LLRICE62.[16] This decision permits Bayer CropScience (formerly AgrEvo) to release LibertyLink rice into the environment and marketplace without further regulation or oversight. At this time,

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[13] 7 C.F.R. Part 340.
[14]APHIS Petition No. 98-329-01p [*hereinafter* "Petition"].
[15] 64 Fed. Reg. 22959 (Apr. 27 1999); USDA, Environmental Assessment (1999) [hereinafter "EA"].
[16] *Id.*

Bayer CropScience has not commercialized LibertyLink rice because the rice industry has objected to it.[17]

One variety of LibertyLink rice, LLRICE601, is still a regulated article. Although it was field tested between 1998 and 2001, Bayer CropScience dropped the project for unknown reasons and never sought deregulation by USDA.[18] In August, USDA reported that LLRICE601 had contaminated commercial US long-grain rice.[19] On August 22, 2006, Bayer CropScience petitioned USDA to grant nonregulated status to LLRICE601.[20]

USDA's plant pest determination was erroneous and new evidence based on sound science demonstrates that LibertyLink rice will injure and damage plants, crops, and the environment. Petitioner requests that USDA regulate all varieties of LibertyLink rice as plant pests. Given the evidence of the plant pest risk of LibertyLink rice and the immediate economic harm being caused to rice farmers and processors by the LLRICE601 contamination, USDA's "reasonable" time to respond to this petition should be 90 days *and* before any agency action or decision to allow Bayer CropScience to introduce LibertyLink rice commercially.

C. STATEMENT OF GROUNDS FOR REGULATING LIBERTYLINK RICE AS A PLANT PEST

USDA should regulate LibertyLink rice because its commercial release will injure plants and plant products. Most importantly, LibertyLink rice will create weedy glufosinate tolerant red rice, will promote herbicide resistant weeds, and it damages

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[17] David Bennett, *Arkansas Secretary of Agriculture Addresses GMO Rice Situation*, DELTA FARM PRESS (Aug. 29, 2006).
[18] Field trial data show that USDA has granted 48 permits to Bayer or predecessor companies authorizing over 4,000 acres of experimental genetically engineered rice, including many LibertyLink varieties, in California as well as the Southern rice belt, from 1996 to present. *See* Field Trial Spreadsheet in appendix.
[19] Press Release, USDA, *supra* note 1.
[20] Petitions of Nonregulated Status Granted or Pending by Aphis as of 23 August 2006, *available at* http://www.aphis.usda.gov/brs/not_reg.html (Sept. 5, 2006).

agricultural commodities through contamination. While a negative determination on any single plant pest risk should prompt USDA to regulate an organism, LibertyLink rice meets several of the risk criteria thus warranting its regulation. USDA must answer this petition promptly before Bayer CropScience introduces LibertyLink rice commercially.

(1) LibertyLink rice will increase weediness of red rice and other weeds.

USDA should regulate LibertyLink rice as a plant pest because it will increase the weediness of red rice and promote herbicide resistance in weeds. The Plant Protection Act aims to prevent injury to crops stemming from increased weediness.

i. LibertyLink rice genes will flow to red rice and increase its weediness.

Gene introgression into red rice is a plant pest risk posed by LibertyLink rice because it increases its weediness. Rice is generally self-pollinating, however it does cross-pollinate with closely related varieties of cultivated and wild rice under the right conditions.[21] Pollen from cultivated rice crops may travel up to 110 meters and outcrossing has been observed at a distance of 43 meters.[22] LibertyLink rice will outcross with red rice as a result of pollen dispersal.

Red rice plants that acquire the glufosinate tolerance gene, and their progeny, will have a competitive advantage compared to other rice weeds that are controlled by glufosinate. This is because weeds compete against each other for space and resources. For example, weeds shifts are often noted in agriculture, where weed species that are naturally more tolerant to an herbicide become more predominant at the expense of weed

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[21] AgBios, GM Database. *LLRICE06, LLRICE62* (Aug 20, 2001), *available at* http://www.agbios.com/dbase.php

[22] Song, Z.P., *et al. Gene Flow from Cultivated Rice to the Wild Species Oryza rufipogon under Experimental Field Conditions*, 157 NEW PHYTOLOGIST 657 (2003); Song, Z.P., et al. *Pollen Flow of Cultivated Rice Measured under Experimental Conditions.* 13 BIODIVERSITY & CONSERVATION 579 (2004).

species that are well controlled. Therefore, by killing competing weeds, glufosinate use will allow glufosinate-tolerant red rice to grow and spread even faster than it would in the absence of LibertyLink rice. Therefore, glufosinate-tolerant red rice is likely to become weedier when glufosinate is applied.

Recent studies reveal variable rates of outcrossing in rice. A 2004 study to assess gene flow from genetically engineered varieties of LibertyLink and Roundup Ready rice revealed outcrossing rates ranging from 0.01 to 0.415%.[23] In 2003, a study of glufosinate-tolerant rice showed outcrossing to red rice at 0.33%.[24] A 2004 study by Chen *et al*. showed transgenic rice with the *bar* gene outcrossing to red rice at a rate of 0.011 to 0.046% and a cultivated rice variety (non-transgenic) outcrossing to wild rice at 1.21 to 2.19%.[25] This study concluded that, "gene flow occurs with a noticeable frequency from cultivated rice to its weedy and wild relatives and this might cause potential ecological consequences."[26]

Although rice is self-fertilizing, a gene that confers a fitness advantage "could spread quickly through wild or weedy rice populations, even with very low rates of cross-pollination from the crop."[27] Since herbicide tolerance is a dominant genetic trait it can

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[23] Fischer, A.J., Cheetham, D.P, et al., *Outcrossing Study Between Transgenic Herbicide-Resistant Rice and Non-Transgenic Rice in California* [abstract], in Ferrero, A., Vidooto, F., eds., PROCEEDINGS OF THE CONFERENCE CHALLENGES AND OPPORTUNITIES FOR SUSTAINABLE RICE-BASED PRODUCTION SYSTEMS 407-408 (2004) (finding natural outcrossing up to 1.8 meters from the transgenic source).

[24] Nengyi Zhang, et al., *Out-crossing Frequency and Genetic Analysis of Hybrids Between Transgenic Glufosinate Herbicide-Resistant Rice and the Weed, Red Rice,* 130 EUPHYTICA 35, 40 (2003) (measuring outcrossing from a plot seeded with a mixture of red rice and transgenic rice seeds).

[25] Li J. Chen, Dong s. Lee, et al. *Gene Flow from Cultivated Rice (Oryza sativa) to its Weedy and Wild Relatives*, 93 ANNALS OF BOTANY 67(2004) (finding that, in the transgenic to red rice outcrossing experiment, the two types of seeds were mixed together and in another part of the study, cultivated rice and wild rice were grown in alternating rows which were 50 cm apart).

[26] *Id.* at Abstract.

[27] Bao-rong Lu & Allison A. Snow, *Gene Flow from Genetically Modified Rice and Its Environmental Consequences*, 55 BIOSCIENCE 669, 674 (2005).

spread easily to weedy rice.[28] Even with outcrossing at less than one percent, herbicide-tolerant weeds can become common because each plant produces hundreds of seeds and use of glufosinate will select for the survival of herbicide-tolerant weeds.[29] Once hybrids form, they will proliferate within only a few generations when herbicide-tolerant crops and their accompanying herbicide select for the tolerant red rice varieties.[30] A 2002 study modeling commercial production of glufosinate-tolerant rice predicted that herbicide-tolerant weedy rice populations would develop within three to eight years.[31]

Although USDA acknowledged the *bar* gene will introgress into red rice, USDA assessed that gene introgression would be low because of different flowering times and height.[32] However, under selection of glufosinate herbicide outcrossing will likely result in higher numbers of progeny, and after introgression of *bar* into red rice for several generations the phenology of these tolerant plants will likely be similar to wild type red rice, allowing rapid spread afterward. In addition, because rice and red rice are highly selfing, glufosinate-tolerant red rice hybrids may self at high rates, producing a large number of offspring selected by glufosinate herbicide applications. The EA incorrectly estimated the plant pest risk because, at that time, USDA knew little about the fitness of red rice with introgressed glufosinate-tolerance. The EA was based on experiments using hybrids which cannot accurately determine how traits will express when the gene introgresses into red rice. Hybrid properties such as heterosis (hybrid vigor), epistasis (altering effect of one gene on other genes), and transgressive traits (traits that exceed the

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[28] *Id*. at 675.
[29] *Id*.
[30] Gealy, D., et al. *Gene Flow between Red Rice (Oryza sativa) and Herbicide-resistant Rice (O. sativa): Implications for weed management*. 17 WEED TECHNOLOGY 627, 643 (2003).
[31] Madsen, et al., *Risk Assessment of Herbicide-Resistant Crops: A Latin American Perspective Using Rice* (Oryza sativa) *as a Model*, 16 WEED 215 (2002).
[32] EA, *supra* note 15, at 17.

range in either parent) are common. It is also common for hybrids to have lower fertility than either parent compared to the introgressed trait. As acknowledged by USDA and AgrEvo, the fitness of red rice does not appear to be reduced by the presence of the *bar* gene.[33] Therefore, once the glufosinate-tolerance gene crosses into red rice it will not be readily eliminated and instead it will increase in prevalence.

Red rice is already one of the most troublesome weeds of rice in the South; it competes with crops for nutrients, water, and space.[34] The common rice weed known as red rice is the same species as cultivated rice (*O. sativa*) and is highly sexually compatible with cultivated rice.[35] A number of studies have shown that cultivated rice will outcross with red rice[36] and that genetically engineered, herbicide-tolerant genes can be transferred to red rice.[37] This gene flow will make glufosinate ineffective for controlling red rice that acquires the tolerance gene, giving red rice a fitness advantage in agricultural settings where glufosinate is used, thus increasing the weediness potential of red rice.

Outcrossing of Clearfield rice demonstrates the plant pest risks posed by gene flow from LibertyLink rice. In 2004, non-genetically engineered, herbicide-tolerant rice cross-pollinated with red rice to produce herbicide-tolerant red rice.[38] Clearfield rice, bred to be tolerant to imadazolinone herbicides, outcrossed with red rice in an Arkansas

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[33] Petition, *supra* note 14, at 54.
[34] Gealy, D., et al., *supra* note 30.
[35] Lu, Bao-Rong, *Gene Flow from Cultivated Rice: Ecological Consequences* (May 2004), *available at:* http://www.isb.vt.edu/articles/may0402.htm.
[36] Chen, L.J. et al., *supra* note 25, at 67; Langevin, S.A., et al. *The Incidence and Effects of Hybridization between Cultivated Rice and Its Related Weed Rice* (Oryza sativa L.), 44 EVOLUTION 1000 (1990).
[37] *See* Bao-rong Lu & Allison A. Snow, *supra* note 27; Gealy, D., et al. *supra* note 30; Zhang, N., et al. *supra* note 24.
[38] Bob Scott & Nilda Burgos, *Clearfield/Red Rice Outcross Confirmed in Arkansas Field*, DELTA FARM PRESS (Nov. 12, 2004).

field and passed herbicide-tolerance to red rice.[39] Researchers predicted that the second generation of hybrids will not only have the herbicide-tolerant trait, but it will also vary in flowering times and plant height.[40] These outcrosses will be more difficult to detect after the first generation and tolerant red rice seeds could easily spread between fields on harvesting equipment.[41] Another recent report suggests that even some initial hybrids may be difficult to detect because varieties of red rice have been adapting by mimicking the form of cultivated rice.[42] This is important because it will make it easier for red rice to escape resistance management. Not only does Clearfield rice demonstrate the plant pest problem of herbicide-tolerant red rice, but it also amplifies the injury created by LibertyLink rice. Introduction of LibertyLink rice is likely to promote the additional trait of tolerance to glufosinate in red rice, thus conferring on red rice the fitness advantage of resistance to multiple herbicides when they are used to control resistant plants.

The effects of LibertyLink rice outcrossing to red rice are especially concerning because of the persistence of weedy rice varieties. Red rice has stronger seed dormancy than cultivated rice and persists longer in the environment.[43] Red rice that is contaminated by LibertyLink rice can be extremely durable in the environment. Herbicide-tolerant red rice may act as a reservoir for the genetically engineered genes, which could accumulate and spread in populations of red rice, resulting in a risk of contamination of future non-genetically engineered crops and further weed control

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[39] *Id*.
[40] *Id*.
[41] *Id*.
[42] Mississippi State University Extension Service, IS930, RICE – RED RICE CONTROL, *available at* http://msucares.com/pubs/infosheets/is0930.htm (last visited Nov. 14, 2005).
[43] Nengyi Zhang, *et al., supra* note 24; *see also* Doreen Stabinsky & Janet Cotter, RICE AT RISK: WILL THERE BE A CHOICE WITH GENETICALLY ENGINEERED RICE? 4 (Sept. 2004).

problems.[44] As one researcher stated, "Although the gene flow values are relatively low, the shattering and dormancy of the red rice seeds, which ensure their persistence in the field, lead into an undesirable effect of durability of the transferred genes."[45] Any gene flow of *bar* into red rice will not be eliminated by natural selection against such plants, even in the absence of glufosinate applications. Therefore, once *bar* enters the red rice population, it will likely remain indefinitely exacerbating weediness.

Additionally, a resistance management plan will be insufficient to prevent herbicide-tolerance in red rice. As noted in the Hybrid Fitness Report of Appendix III of the AgrEvo petition, Linscomb *et al*. write that: "An important management practice is to never allow red rice to flower in a field of herbicide-tolerant rice. Two applications of glufosinate ammonium herbicide may be advised to control any late germinating red rice in a field of glufosinate-tolerant rice."[46] This is an unrealistic standard for farmer compliance. A study of *Bt* resistance management requirements for corn showed that farmer compliance with such mandatory measures ranged between 72-76%.[47] The resistance management plan for LibertyLink rice is merely voluntary, so compliance rates will be even lower. Moreover, if the amount of late-germinating red rice is low, farmers may be reluctant to incur the expense and time involved in a second herbicide application when potential value of yield loss from the remaining red rice may be less than the cost of the second herbicide application. Additionally, since red rice is adapting to mimic the

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[44] Lu, *supra* note 27.
[45] Messeguer, J. et al. *A Field Study of Pollen-mediated Gene Flow from Mediterranean GM Rice to Conventional Rice and Red Rice Weed*. 13 MOLECULAR BREEDING 103 (2004).
[46] Petition, *supra* note 14, at Appendix 3, page 12.
[47] Goldberger, J., Merrill, J., & Hurley, T., *Bt Corn Farmer Compliance with Insect Resistance Management Requirements in Minnesota and Wisconsin,* 8 AGBIOFORUM 151-160 (2005), a*vailable at*: http://www.agbioforum.org/v8n23/v8n23a12-hurley.htm.

appearance of cultivated rice, it is difficult to distinguish.[48] This will make recognition of small numbers of these adapted plants difficult to recognize in a large rice field, and therefore allow them to escape detection and treatment.

Gene introgression from LibertyLink rice into red rice will be permanent and will increase its weediness by giving red rice a fitness advantage in an agricultural setting. Since red rice is already a serious weed, USDA should regulate LibertyLink rice to prevent escalation of the injury caused by red rice.

ii. LibertyLink rice promotes herbicide resistant weeds.

In the previous section, this petition considered the increased weediness of red rice resulting from introgression of the glufosinate-tolerance gene into red rice. Additionally, LibertyLink rice promotes the development of other herbicide resistant weeds through other mechanisms, thus increasing their weediness and injuring crops. In a plant pest analysis, USDA must consider this type of injury as an indirect injury to plants and plant products created by LibertyLink rice. The Plant Protection Act aims to protect the US agricultural economy and herbicide resistant weeds compete with crops and are difficult for farmers to control.

Since the 1970s there has been a growing awareness that many weeds are becoming resistant to the herbicides used to control them. The use of a single primary herbicide, such as glufosinate, in fields planted with herbicide-tolerant crops provides a strong selection pressure to dramatically increase the populations of weeds, initially quite small, that are naturally resistant to the herbicide.[49] Consider, for example, that since the

[48] Mississippi State University Extension Service, *supra* note 42.
[49] Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Eight Years,* BIOTECH INFONET TECHNICAL PAPER NUMBER 6 (Nov. 2003), *available at:*

introduction of genetically engineered, herbicide-tolerant "Roundup Ready" crops many weeds have developed resistance to the herbicide glyphosate, the active ingredient in Roundup.[50] Resistance problems have contributed to the need to increase glyphosate application rates and apply additional herbicides to Roundup Ready crops.[51]

At least four species of weeds in the US alone have developed resistance to glyphosate due, in part, to greatly increased use of this herbicide.[52] In particular, resistant horsetail (*Conyza canadensis*) developed in only about three years under the heavy selection pressure in glyphosate-tolerant soybeans.[53] Since its first discovery in Delaware in 2000, it has now spread to at least 13 states.[54] This has lead to dramatic weed control problems for farmers and increased herbicide use. Glufosinate shows several similarities to glyphosate as both are non-selective, broad-spectrum herbicides, and it is likely that the commercialization of glufosinate-tolerant rice will result in similar problems with weed resistance. As with glyphosate prior to glyphosate-tolerant crops, glufosinate is not widely used; but LibertyLink rice will increase use of the herbicide thus selecting for resistant weeds. In particular, California rice crops are rarely rotated, thus increasing the likelihood of resistance due to continuous use.

It has been argued that that glufosinate resistance is unlikely to develop in weeds based in part on unsuccessful attempts to produce resistance through mutagenesis of the

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http://www.biotech-info.net/Technical_Paper_6.pdf; *see also* Topsy Jewell, *Glufosinate and Genetic Engineering* (Nov. 1996).

50 Charles Benbrook, *Evidence of the Magnitude and Consequences of the Round-up Ready Soybean Yield Drag from University Based Varietal Trials in 1998*, AGBIO TECH INFONET TECHNICAL PAPER NUMBER 1 (July 13, 1999), *available at*: http://www.biotech-info.net/Rr_yield_drag_98.pdf (last visited Oct. 12, 2005).

51 *Id*.

52 International Survey of Herbicide Resistant Weeds, *available at*: http://www.weedscience.org (last visited Aug. 21, 2006).

53 VanGessel, *Glyphosate Resistant Horseweed from Delaware*, 49 WEED SCI. 703 (2001).

54 Herbicide Resistant Weeds Database, *available at* http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12&FmHRACGroup=Go (last visited Sept. 5, 2006).

crop. Attempts to make crops resistant through mutagenesis are not equivalent to resistance in weeds because of the different genetic makeup of crops and weeds, and hence different potential for resistance. Glufosinate resistance may not develop in the herbicide target gene, which is the usual object of mutagenesis. Other mechanisms such as reduced herbicide uptake or translocation may ultimately be the mechanism to cause resistance. This has apparently been the case with glyphosate resistant weeds. It is also possible that a mechanism for glufosinate resistance could be non-specific, and make such weeds resistant to multiple herbicides. There is a large variation in the level of sensitivity to glufosinate among plants and some weeds. Fat hen or lambsquarters (*Chenopodium album*) and common milkweed (*Asclepias syriaca*) are more resistant to glufosinate use than others.[55] Therefore it is highly likely that continual use of glufosinate will lead to resistant weed populations, or weed shifts to naturally more tolerant weeds species that will require additional herbicide use. In particular, USDA needs to look at the potential for glufosinate resistance to develop in major rice weeds, including red rice, barnyard grass, smallflower umbrellaplant, redstem, ducksalad, watergrass, and other rice weeds.[56]

Reliance entirely upon the availability of herbicides other than glufosinate to control resistant weeds is misplaced because grass herbicides are limited and plants can develop resistance to an entire class of herbicides. Grass herbicides are limited in

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[55] Wendy Pline, *Effect of Temperature and Chemical Additives on the Efficacy of the Herbicides Glufosinate and Glyphosate in Weed Management of Liberty-Link and Roundup-Ready Soybeans*, Thesis submitted to the faculty of Virginia Polytechnic Institute (Mar. 25, 1999), *available at:* http://scholar.lib.vt.edu/theses/available/etd-041299-151856/; Steckel, G.J., Wax, L.M., Simmons, F.W., and W.H. Phillips, *Glufosinate Efficacy on Annual Weeds Is Influenced by Rate and Growth Stage,*. 11 WEED TECHNOLOGY 484 (1997).

[56] J. F. Williams, S. R. Roberts, J. E. Hill, S. C. Scardaci, G. Tibbits, *Managing Water for Weed Control in Rice,* 44 CALIFORNIA AGRICULTURE 7 (1990), *available at*: http://www.agronomy.ucdavis.edu/uccerice/WATER/wtrmgt01.htm.

California, and recently Syngenta asked EPA to cancel the registration for molinate, one of the most widely used rice herbicides.[57] Furthermore, partly due to the dominance of herbicide-tolerant crops, new herbicide modes of action have not been registered.[58] Although some new herbicides are registered, they are versions of existing classes, especially acetolactosynthase ("ALS") inhibitors. Unfortunately, resistance to one of these herbicides by a weed often results in resistance to others in the class, and ALS resistance is common.

Weed resistance to glufosinate herbicide is a serious risk posed by the farming system associated with LibertyLink rice. The dissemination of LibertyLink rice will increase glufosinate use on rice crops, in turn promoting herbicide resistant weeds that are a serious pest problem and injure plants. This scientific evidence strongly supports the conclusion that LibertyLink rice is likely to increase the weediness of red rice and other weeds.

(2) LibertyLink rice will cause damage to agricultural commodities

LibertyLink rice will contaminate rice commodities with adverse economic impacts thus damaging agricultural commodities. By including protection of plant products, Congress intended to avoid harm to the US agricultural economy by preventing injury to agricultural commodities.[59] Congress also sought to prevent harm to export markets.[60] LibertyLink rice will contaminate rice crops via outcrossing and seed commingling.

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[57] Environmental Protection Agency, *Notice: Molinate; Cancellation Order*, 69 Fed. Reg. 18368 (April 7, 2004).
[58] SB Powles, Preston , Bryan , Jutsum, *Herbicide Resistance: Impact and Management*, 58 ADV. AGRON. 57 (1997).
[59] *See* 7 U.S.C. § 7701 (Congressional findings).
[60] *Id.*

In August 2006, USDA reported that an unapproved variety of LibertyLink rice, LLRICE601, was found in commercial long-grain rice.[61] Bayer CropScience field tested LLRICE601 from 1998-2001 but dropped the project before seeking deregulation.[62] Japan subsequently suspended its US long grain rice imports.[63] The European Union implemented strict rules requiring certification that US rice imports be free from unauthorized LLRICE601.[64] Nearly all of commercial long-grain rice supplies are contaminated with the LLRICE601.[65] At least two federal class action lawsuits have been filed by rice farmers against Bayer CropScience alleging damage to rice commodities.[66] This contamination event demonstrates the likelihood of unwanted genetically engineered rice contaminating rice supplies and its damage to agricultural commodities. Further, this rice was not even deregulated for commercial production or sale, yet it still contaminated conventional rice crops.

Numerous episodes of contamination of non-genetically engineered crops have also occurred as a result of cross-pollination from, or seed dispersal of, genetically engineered corn, soy, and oil-seed rape (canola).[67] Likewise, gene introgression from LibertyLink rice into cultivated rice is possible. And once contamination occurs, it will persist indefinitely.

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[61] Press Release, USDA, *Statement by Agriculture Secretary Mike Johanns Regarding Genetically Engineered Rice* (Aug. 18, 2006).
[62] *Id.*
[63] *Japan Bans "Contaminated" U.S. Rice*, BBC NEWS (Aug. 21, 2006).
[64] *EU to Keep Out GM Contaminated US Rice, supra* note 2.
[65] David Bennett, *supra* note 17.
[66] *Geeridge Farm, Inc. et al*. v. *Bayer CropScience L.P.*, 4-06-CV-01079-GH (Filed Aug. 28, 2006); *Lonnie & Linda Parson v. Bayer CropScience*, 4-06-CV-01078-JLH (Filed Aug. 28, 2006).
[67] GeneWatch UK and Greenpeace International, GM CONTAMINATION REGISTER, *available at:* http://www.gmcontaminationregister.org/; GeneWatch & Greenpeace, *GM Contamination Report 2005* (2005); David Quist & Ignacio Chapela, *Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico*, 414 NATURE 541 (Nov. 29, 2001).

Contamination may also occur by accidental mixing of LibertyLink rice with other rice seed. LibertyLink rice can commingle with other rice varieties in a number of ways. Volunteer plants may emerge in fields planted with other varieties of rice, and animals and birds may transport LibertyLink rice from one field to another. Additionally, transportation, farm machinery, and processing equipment will commingle LibertyLink rice with other rice varieties unless it is separated and meticulously cleaned.

Non-genetically engineered crops contaminated by LibertyLink rice are damaged commodities because they lose value. Additionally, rice producers who wish to sell to markets that restrict genetically engineered materials will incur additional costs to test rice and certify that it is free from transgenes. Contamination events lead to extensive costs to both farmers and the food production industry when contaminated crops must be destroyed, food products are rejected, export markets are lost, and farmers are fined or forced to pay licensing fees for growing genetically engineered crops. USDA should act to prevent further injury to plant products by LibertyLink rice.

i. LibertyLink rice will damage US rice commodities for export.

The commercial introduction of LibertyLink rice will have a dramatic economic impact on the viability of US rice exports. Rice is an important US commodity. The US exports more than 40 percent of its rice and ranks as the world's fourth largest exporter of rice.[68] In 2005, the US harvested 1.35 million hectares of rice.[69] Of a total supply of 8.77 million metric tons, 3.77 million metric tons were exported.[70] Although the US accounts

[68] David R. Gealy, *et al.*, *supra* note 30, at 627.
[69] Source: Foreign Agricultural Service, Official USDA Estimates, *available at* http://www.fas.usda.gov/psd (last visited Oct. 17, 2005).
[70] *Id.*

for only 1.5-2 percent of global rice production, it is a major exporter.[71] US rice accounts for 12 percent of the global rice trade.[72] In 2004, rice generated about $1-$1.5 billion a year in farming income.[73] Estimates of the 2006 crop value are $1.9 billion.[74]

The dissemination of LibertyLink rice threatens to result in lost US rice exports to countries that refuse to import genetically engineered crops or require labeling and segregation. Market losses have already arisen for growers of genetically engineered crops.[75] Unapproved genetically engineered crops found in US agricultural commodities results in severe losses. When the US corn supply was contaminated with unapproved genetically engineered StarLink corn, exports suffered. For example, US corn sales to Japan decreased up to 44% the following year as Japan turned to other sources.[76] More losses are expected due to the LLRICE601 contamination of long-grain rice supplies.[77]

Importantly, losses result even from genetically engineered crops that have been deregulated in the US. The market for US products softens because certain markets have not approved a crop or is not accepted by consumers. For example, the European Union's concern about genetically engineered corn has caused US exporters to lose about $300 million per year.[78] Thus, losses in rice commodities can be expected for all varieties of LibertyLink rice. The US rice industry is currently unable to segregate, label, or prevent contamination by LibertyLink rice. Since export markets are extremely

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[71] USDA Economic Research Service, *Rice Briefing*, *available at* http://www.ers.usda.gov/Briefing/Rice/ (last visited Oct. 17, 2005).
[72] USDA Economic Research Service, *Briefing Room: Rice Background* (June 28, 2001), *available at:* http://www.ers.usda.gov/briefing/rice/background.htm (last visited Oct 24, 2005).
[73] USDA Economic Research Service, 2004 RICE YEARBOOK (2004).
[74] Andrew Pollack, *Unapproved Rice Strain Found in Wide Area*, NEW YORK TIMES C-2 (Aug. 22, 2006).
[75] Pew Initiative on Food and Biotechnology, US V. EU: AN EXAMINATION OF THE TRADE ISSUES SURROUNDING GENETICALLY MODIFIED FOOD 3-5 (August 2003).
[76] Hur, *US Corn Exports to Japan Hit Hard by StarLink,* Reuters (Aug. 31, 2001).
[77] Estimates suggest that farmers lost about $150 million on Aug. 21 and Aug. 22 alone due to the LLRICE601 contamination. David Bennett, *Questions Abound as Rice Industry Faces GMO Concerns*, DELTA FARM PRESS (Aug. 30, 2006).
[78] Pew Initiative on Food & Biotechnology*, supra* note 75 at 4.

sensitive to genetic contamination, LibertyLink rice will damage US rice commodities for export. Additionally, consumer rejection of genetically engineered rice will exacerbate economic harms. Although genetically engineered corn and soy have a limited market in Europe as animal feed, rice is used exclusively for human food. Even if LibertyLink rice varieties are approved by the European Union, US rice commodities are likely to be rejected by consumers and retailers.

Several major importing countries of US rice have current regulations that would either prevent them from importing genetically engineered rice or would require strict labeling and segregation. In either case, these important export markets for rice commodities will be jeopardized from genetic contamination. Between 2000 and 2004 Mexico and Japan were the two largest importers of US grown rice, in terms of the value of rice imported.[79] Japan currently requires mandatory labeling of products containing genetically engineered ingredients and has a zero-tolerance policy for unapproved genetically engineered varieties in food.[80] In Mexico, labeling requirements have been under development for several years and the Mexican Senate has passed mandatory labeling legislation which may take effect in the near future.[81] Some other major importers of US rice include Taiwan, Korea, Saudi Arabia, the United Kingdom, and the Netherlands, all of which currently require mandatory labeling of genetically engineered products.[82] Several other countries have plans to label or limit genetically engineered

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[79] Derived from USDA, ERS, FATUS EXPORT AGGREGATIONS (Oct 24, 2005), *available at:* http://www.fas.usda.gov/ustrdscripts/USReport.exe.
[80] Greenpeace, *Governments Worldwide Require Regulation and Labeling of GMOs*. (July 2003) available at: http://www.greenpeace.org/raw/content/international/press/reports/governments-worldwide-require.pdf (last visited Oct 24, 2005).
[81] Heiki Baumuller, Draft: *Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rules, Some Key Issues*. Prepared for the Trade Knowledge Network, (July 2003), *available at* http://www.ictsd.org/pubs/respaper/TKN2003.pdf .
[82] Greenpeace, *supra* note 80.

crops. For World Food Day 2005, sponsored by the United Nations Food and Agriculture Organization, a coalition of organizations from across Asia issued a statement calling for a global ban on the introduction of genetically engineered rice.[83] Signatory organizations represented some key countries for US exports of rice including Japan.[84]

Accordingly, if LibertyLink rice is introduced commercially in the US, it will contaminate and damage rice commodities, creating lost market viability and the loss of important export markets.

ii. LibertyLink rice will damage organic products.

Organic commodities will also be harmed from contamination by LibertyLink rice. In the 1990's, organic agriculture was one of the fastest growing segments of US agriculture with total organic cropland production doubling between 1992 and 1997 to approximately 850,000 acres.[85] It doubled again between 1997 and 2001.[86] Organic product sales through all outlets in the US have increased 20-25 percent annually between 1990 and 2000, and reached $7.8 billion in 2000.[87] Organic food sales generally account for 1 to 2 percent of total food sales in the US and other major markets for organic products.[88] Annual growth rates for the organic market are forecast at 20 percent or more for the next five to ten years.[89]

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[83] Greenpeace Press Release, *UN World Food Day - Asians Call for Ban on Genetically Engineered Rice* (Oct. 14, 2005); *available at* http://www.greenpeace.org/international/press/releases/worldfoodday1410.
[84] *Id.*
[85] Catherine Greene & Thomas Dobbs, *Organic Wheat Production in the United States: Expanding Markets and Supplies*, WHEAT YEARBOOK 31 (2001).
[86] USDA, *Data Organic Production*, *available* at http://www.ers.usda.gov/Data/Organic/ (last visited Oct. 18, 2005).
[87] Catherine Greene and Thomas Dobbs, *supra* note 85, at 31-32.
[88] *Id.*
[89] *Id.*

Organic rice production continues to be part of this trend and has seen a steady increase in demand.[90] Organic rice production increased 163% between 1997 and 2001 and remains on the rise.[91] And organic commodities such as rice continue to carry significant price premiums. Organic rice can sell for two to three times more than conventional rice.[92] The demand for US organic grain exports is expected to rise, with a 15 percent growth rate projected for the export of organic rice to Europe.[93] The introduction of LibertyLink rice severely threatens to damage organic rice commodities.

Many observers believe that current gene containment strategies will not work in the field.[94] As stated in a recent *Nature Biotechnology* editorial on genetically engineered pharmaceutical-producing crops:

> Current gene-containment strategies cannot work reliably in the field. Seed companies will continue to mix varieties. Although "buffer zones" may theoretically control pollen dispersal (and gene spread), in practice, farmers will be unable (or unwilling) to follow planting rules. Can we reasonably expect farmers to [clean] (sic) their agricultural equipment meticulously enough to remove all [genetically engineered] seed?[95]

The European Union recently finished an analysis stating that even if very low *de facto* threshold limits (such as lowest detection limits) are set for genetically engineered crops

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[90] Holly Born, *Marketing Organic Grains,* NATIONAL SUSTAINABLE AGRICULTURE INFORMATION SERVICE (January 2005), *available at* http://attra.ncat.org/attra-pub/marketingorganicgrains.html#marketSituation (last visited Oct. 24, 2005).
[91] USDA, *supra* note 86, at data tables.
[92] Preston Sullivan, *Organic Rice Production* NATIONAL SUSTAINABLE AGRICULTURE INFORMATION SERVICE, (April 2003), *available at* http://attra.ncat.org/attra-pub/rice.html (last visited Oct. 24, 2005).
[93] Dr. Winfried H. Fuchshofen & Silke Fuchshofen*,* ORGANIC TRADE ASSOCIATION' EXPORT STUDY FOR ORGANIC PRODUCTS TO ASIA AND EUROPE (December 2000), *available at* http://www.ota.com/organic/mt/export_form.html (last visited Oct. 24, 2005).
[94] Editorial, *Going with the Flow*, 20 NATURE BIOTECHNOLOGY 527 (2002), *available at:* http://www.nature.com/nbt/index.html (last visited Oct 25, 2004).
[95] *Id.*

in organic production, organic crops would not be feasible in a region with genetically engineered crops.[96]

USDA needs to assess the injury to organic rice commodities caused by LibertyLink rice. USDA itself stated:

> Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. *This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label*.[97]

Therefore, USDA said that the organic standards must meet consumer expectations and consumers expect organic products to be free from genetically engineered materials. Contamination of organic rice with LibertyLink rice will injure organic rice commodities.

iii. LibertyLink rice will damage the purity of seed stocks.

The introduction of LibertyLink rice will make seed stocks vulnerable to genetic contamination thus damaging rice seed. The seed industry places strict requirements on genetic purity for seed. Contamination of germplasm by LibertyLink transgenes will constrain the seed industry. Seed certification programs are well-established in most states and their objective is to maintain genetic purity and quality.[98] Among other characteristics, certified seeds are tested for purity and viability.[99]

Maintaining breeder and foundation seed stocks free from genetically engineered traits is critical to ensure that farmers may still obtain non-genetically engineered rice

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[96] Anne Katrin Block, et al., SCENARIOS FOR CO-EXISTENCE OF GENETICALLY MODIFIED CONVENTIONAL AND ORGANIC CROPS IN EUROPEAN AGRICULTURE 2 (Jan 2002), *available at* http://www.jrc.cec.eu.int/download/GMCrops_coexistence.pdf (last visited Oct. 25, 2005).
[97] 65 Fed. Reg. 13534-35 (March 13, 2000) (emphasis added).
[98] K.J. Bradford, SEED PRODUCTION AND QUALITY 70 (2004).
[99] *Id.*

varieties. Of particular importance is a recent report showing that major non-genetically engineered commodity crop seed supplies have become contaminated by their genetically engineered counterparts.[100] Especially relevant is that conventional soybean seed, a self-fertilizing crop like rice, is contaminated at similar levels as outcrossing crops like corn or canola.[101] Contamination levels were high enough to trigger rejection by several export partners. LibertyLink rice is a plant pest because it can contaminate rice seed and damage the genetic purity of breeder and foundation stocks. In fact, LLRICE601 was recently discovered in foundation rice seed maintained by Louisiana State University.[102] Genetic contamination of seed stock by LLRICE601 has already caused damage to long-grain rice and all varieties of LibertyLink rice threaten to damage to seed stock. Seed producers experience increased costs of testing seeds to ensure they do not contain genetically engineered materials.

The commercial introduction of LibertyLink rice will injure rice commodities because gene introgression and commingling of LibertyLink rice will contaminate rice commodities. Rice commodities have already been injured by the LLRICE601 contamination. Contamination of rice products make them undesirable for exports, organic sales, and seed supply. These injuries to rice commodities therefore warrant USDA regulation of LibertyLink rice as a plant pest according to USDA's own criteria.[103]

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[100] M. Mellon and J. Rissler, Union of Concerned Scientists, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEED SUPPLY (2004).

[101] *Id.*

[102] Bruce Schultz, *LibertyLink 601Found in LSU AgCenter Foundation Seed Rice*, DELTA FARM PRESS (Aug. 31, 2006).

[103] *See* 7 C.F.R. § 340.6(b).

(3) LibertyLink rice will harm endangered plants and may harm other threatened or endangered species or beneficial organisms.

USDA must regulate LibertyLink rice to prevent injury to endangered plants and organisms beneficial to agriculture. Most importantly, LibertyLink rice will injure non-target organisms because its dissemination will drastically increase the amount of herbicide used in rice growing areas. Harm arising from increased herbicide use is an injury that cannot be separated from LibertyLink rice's use because it was expressly designed to withstand more herbicide use. Harm to beneficial organisms and other species from this herbicide-tolerant system must be prevented under the Plant Protection Act. USDA also has a duty to prevent adverse impacts on endangered and threatened species and migratory birds under the Endangered Species Act and Migratory Bird Treaty Act.[104] Moreover, USDA cannot rely on EPA's pesticide registration to prevent injury because it is the farming system associated with LibertyLink rice itself that will increase the overall amount of glufosinate use.

Increased use of the herbicide glufosinate is expected with the adoption of LibertyLink rice. For example, development of genetically engineered crops that are tolerant to glyphosate, the active ingredient in Roundup, has markedly increased the use of glyphosate in the US. A 1998 study of over 8,200 soybean trials demonstrated that farmers use 2 to 5 times more herbicide on Roundup Ready soybeans when compared to non-Roundup Ready soybeans.[105] A 2004 review of USDA data on genetically engineered crop production reports that herbicide-tolerant crops caused an increase in

[104] *See* Endangered Species Act, 16 U.S.C. § 1531 *et seq.*; Executive Order 13186; Migratory Bird Treaty Act, 16 U.S.C. § 701, *et seq.*
[105] Charles Benbrook, *supra* note 50.

pesticide use of 138 million pounds over nine years.[106] The increased herbicide use associated with the commercialization of herbicide tolerant, genetically engineered crops occurred, in part, because of resistance and changes in weed communities that decrease the effectiveness of an herbicide.[107] Similar to these other herbicide-tolerant crops, LibertyLink rice will result in a significant increase in glufosinate use in fields where rice is grown. It is expected that farmers will adopt LibertyLink rice on a massive scale, thus markedly increasing the use of glufosinate. For example, herbicide-tolerant soybeans made up 87% of the total US soybean acreage in 2005, a rapid increase from 68% in 2001 and 17% in 1997.[108] This rapid adoption is especially likely for rice because, except for the recent introduction of Clearfield rice, there have been no effective herbicides to control red rice, a problematic weed of rice in the South. Increased herbicide use coupled with a rapid dissemination of LibertyLink rice will drastically increase the exposure of non-target organisms to glufosinate.

Glufosinate is a broad-spectrum herbicide that inhibits the production of the glutamine enzyme. In plants, this causes reduced glutamine and increased ammonia levels thus causing photosynthesis to cease and the plant to die. Glufosinate kills a wide range of plants, including many non-weed species, found in and around rice fields.[109] The herbicide is extremely hazardous to endangered plants, which will be killed or damaged by exposure to glufosinate. For example, several newly listed vernal pool species in

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[106] Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Nine Years,* BIOTECH INFONET TECHNICAL PAPER NUMBER 7 (Oct. 2004), *available at*: http://www.biotech-info.net/Full_version_first_nine.pdf.

[107] Charles Benbrook, *supra* note 49; *see also* Topsy Jewell and David Buffin, *Health and Environmental Impacts of Glufosinate Ammonium* (May 2001).

[108] USDA, Economic Research Service, ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S. (July 13, 2005), *available at* http://www.ers.usda.gov/Data/BiotechCrops/adoption.htm (last visited Dec. 8, 2005).

[109] Ricarda Steinbrecher, *Ecological Consequences of Genetic Engineering*, in REDESIGNING LIFE (2001).

California have habitat in proximity to rice cultivation. Since 95% of California's rice cultivation takes place in the Sacramento Valley,[110] the vernal pool species that inhabit that area may be affected by the deregulation and cultivation of LibertyLink rice.[111] Among the listed vernal pool species are several endangered and threatened plants such as Burke's Goldfields (*Lasthenia burkei*), Colusa Grass (*Neostapfia colusana*), Contra Costa Goldfields (*Lasthenia conjugens*), Greene's Tuctoria (*Tuctoria greenei*), and Solano Grass (*Tuctoria mucronata*).[112] Texas Bitterweed (*Hymenoxys texana*), [113] Many-Flowered Navarretia (*Navarretia leucocephala ssp. Plieantha*),[114] and Sensitive Jointvetch, (*Aeschynomene virginica*)[115] are also found in and around rice fields. These and other plants that grown in or around rice fields are will be damaged by herbicide use associated with LibertyLink rice.

Plants also provide essential habitats and food for insects, which in turn are an important food source for many bird species.[116] LibertyLink rice may also have direct impacts on the habitat of many migratory birds, and the Migratory Bird Treaty Act

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[110] California Rice Commission, *California's Rice Growing Region*, About California Rice, *available at* http://www.calrice.org/e7b_cas_rice_growing_region.htm (last visited Oct. 20, 2005).
[111] California Dept. of Fish & Game, Department of Fish and Game Issues Natomas Basin Habitat Conservation Plan Incidental Take Permits, Press Release (July 11, 2003), available at http://www.dfg.ca.gov/news/news03/03065.html (In 2003, an incidental take permit was issued in California for several species that were threatened by rice cultivation plus other development in the Natomas Basin).
[112] Proximate to rice farming activities that may affect listed plant in the Natomas basin. Fish & Wildlife Serv., *Notice of Intent To Prepare an Environmental Impact Statement for Issuance of Permits, to Incidentally Take Threatened and Endangered Species, to the City of Sacramento and Sutter County in Association with a revised Natomas Basin Habitat Conservation Plan, Sacramento and Sutter Counties, California*, 65 Fed. Reg. 79115 (Dec. 18, 2000).
[113] Center for plant Conservation, Hymenoxys texana, available at http://centerforplantconservation.org/ASP/CPC_ViewProfile.asp?CPCNum=2296 (last visited Oct. 19, 2005).
[114] 62 Fed. Reg. 33029, (Jun. 18, 1997).
[115] Smith, R. J., Jr. *Biological control of northern jointvetch (Aeschynomene virginica) in rice (Oryza sativa) and soybeans (Glycine max)--a researcher's view.* 34 WEED SCIENCE 17 (1986).
[116] *Id*.

requires agencies to conserve migratory birds.[117] Rice paddies are important habitat for a number of migrating birds because they provide wetland habitat that is becoming increasingly rare. An increased use of glufosinate on rice fields and surrounding habitat will alter the ecology of treated areas. For example, a study comparing conventional to genetically engineered, glufosinate-tolerant canola concluded that the genetically engineered crop would negatively impact farm birds because decreased weed, insect, and seed diversity would limit food supply.[118] Therefore, LibertyLink rice will cause the plant species' diversity to decrease, and along with it, the numbers of insects and birds utilizing these areas of habitat. Additionally, many sensitive species may feed upon or inhabit fields of LibertyLink rice.

Glufosinate is toxic to some species. In mammals, low doses of glufosinate have been shown to alter nervous system development in baby rats and cause neuroepithelial cell death in mouse embryos.[119] In addition, studies have shown toxic effects of glufosinate-containing products on clam and oyster larvae, shrimp, water fleas, some freshwater fish, and reproductive effects on mallard ducks.[120] These results suggest that glufosinate poses a risk to a wide range of nontarget species, especially when heavily applied.

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[117] Executive Order 13186; Migratory Bird Treaty Act, 16 U.S.C. § 701, *et seq.*

[118] Farmscale Evaluations Research Consortium, MANAGING GM CROPS WITH HERBICIDES: EFFECTS ON FARMLAND & WILDLIFE 5-8 (2003). Bohan, David A., et al., *Effects on Weed and Invertebrate Abundance and Diversity of Herbicide Management in Genetically Modified Herbicide-tolerant Winter-sown Oilseed Rape*, 272 PROC. OF THE ROYAL SOCIETY B: BIOLOGICAL SCIENCES 463-474 (2005) *available at:* http://www.pubs.royalsoc.ac.uk/proc_bio_content/pdf/rspb20043049.pdf.

[119] Fuji, T., T. Ohata, M. Horinaka, *Alternations in the Response to Kainic Acid in Rats Exposed to Glufosinate-Ammonium, a Herbicide, During Infantile Period*, 72 PROC. OF THE JAPAN. ACAD. SERIES B-PHYSICAL AND BIOLOGICAL SCIENCES 7 (1996); Watanabe, T, *Apoptosis Induced by Glufosinate Ammonium in the Neuroepithelium of Developing Mouse Embryos in Culture,* 222 NEUROSCIENCE LETTERS 17-20 (1992).

[120] Caroline Cox, *Herbicide Factsheet: Glufosinate*, 16 JOURNAL OF PESTICIDE REFORM 15 (1996). Adverse effects were noted at the following concentrations: clams at ½ ppm; oysters at 8ppm, oyster larvae at ½ ppm; shrimp at 7.5 ppm; water fleas at 15 ppm; sheepshead minnows at 13 ppm; rainbow trout at 27 ppm; and mallard ducks at 60 mg/kg of bodyweight laid 20 percent fewer eggs than untreated birds.

Recent studies on glufosinate suggest that LibertyLink rice may cause injury to insects, including some that are beneficial to agriculture. These studies demonstrate mortality of insects due to glufosinate exposure. In 2001, researchers found that glufosinate had lethal neurotoxic impacts on the skipper butterfly at levels of herbicide experienced in field use.[121] Before caterpillars died they showed symptoms of loss of rectal control, tremors, body convulsions, and paralysis.[122] The cuticle of larvae also became very thin caused by the depletion of glutamine in the caterpillar.[123] Another study, shows toxicity at levels applied in the field to some predatory arthropods.[124] These studies have implications for beneficial organisms that need assessment.

Genetically engineered crops also process glufosinate differently than non-genetically engineered varieties, increasing glufosinate residue in seeds, and thus increasing herbicide exposure. A 2001 study of glufosinate compared impacts on cell cultures of various genetically engineered versus non-genetically engineered plants.[125] The study found that the genetically engineered varieties contained higher levels of glufosinate and acetyl glufosinate.[126] This suggests that genetically engineered sugar beet, carrot, purple foxglove, and thorn apple processed glufosinate differently, leading to higher residues in food.[127] Additionally, glufosinate is highly mobile in herbicide-tolerant

[121] Nicole Kutlesa & Stanley Caveney, *Insecticidal Activity of Glufosinate through Glutamine Depletion in a Caterpillar,* 57 PEST MANAG. SCI. 25, 31 (2001).
[122] *Id.*
[123] *Id.*
[124] Young-Joon Ahn, Young-joon Kim, & Jai-Ki Yoo, *Toxicity of the Herbicide Glufosinate-Ammonium to Predatory Insects and Mites of Tetranychus urticae (Acari:tetranychidae) Under Laboratory Conditions,* 94 J. OF ECONOMIC ENTOMOLOGY 157, 160 (2001).
[125] Boris Müller, et al., *Metabolism of the Herbicide Glufosinate-ammonium in Plant Cell Cultures of Transgenic and Non-transgenic Sugarbeet, Carrot, Purple Foxglove, and Thorn Apple,* 57 PEST MANAG. SCI. 46 (2001).
[126] *Id.*
[127] *Id.*

plant varieties,[128] and it is more easily transported in phloem of herbicide-tolerant canola.[129] Acetyl glufosinate gathered in the flowers and buds of the plant.[130] These findings suggest increased accumulation of glufosinate residues in genetically engineered rice, which will increase the exposure of insects, wildlife, and humans that feed on rice. In fact, Bayer CropScience found it necessary to petition the U.S. Environmental Protection Agency ("EPA") to obtain approval of residues of glufosinate on transgenic rice. EPA approved these tolerances in September 2003.[131] This demonstrates that commercial production of LibertyLink rice will result in consumer exposure to glufosinate residues.

Additionally, surfactants found in herbicides may be more harmful to non-target organisms than previously believed. Liberty herbicide contains the surfactant called alkyl hydroxyl-poly (oxyethylene) sulfate. This was exempted from food tolerance levels in 1996 and was subject to reassessment in 2005. A study of glufosinate indicated that herbicide formulas with alkyl hydroxyl-poly(oxyethylene) sulfate were more toxic to aquatic organisms than glufosinate alone.[132] The toxicity of the surfactant used in Liberty should be tested for amphibian mortality, especially because of the irrigation practices used with rice, such as field flooding.

LibertyLink rice also injures plants by changing soil ecology. Specifically, the cultivation of a transgenic glufosinate-tolerant crop and the application of glufosinate,

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[128] Jennifer Bariault, Geoff Horsman, & Malcolm Devine, *Phloem Transport of Glufosinate and Acetyl Glufosinate in Glufosinate Resistant and Susceptible Brassica Napus*, 121 PLANT PHYSIOLOGY 619 (1999).
[129] *Id.*
[130] *Id.*
[131] 68 Fed. Reg. 55833 (Sept. 29, 2003.)
[132] Caroline Cox, *Herbicide Factsheet: Glufosinate*, 16 J. OF PESTICIDE REFORM 16, 18 (Winter 1996).

alter the activity of microorganisms in the rhizosphere.[133] A comparison of glufosinate-tolerant and wild type oilseed rape showed that the abundance and activities of rhizosphere bacteria populations (bacteria that live in close proximity to the root) were altered by both genetic modification and the use of glufosinate.[134]

A recent two year study assessing the effects of a genetically engineered, herbicide-tolerant canola variety on the rhizosphere found that the root interior and rhizosphere bacterial communities associated with the use of the genetically engineered variety differed from that of conventional varieties, indicating that the composition, functional diversity, and microbial community in soil were influenced by the use of the genetically engineered plant variety.[135] Similar studies have found that use of genetically engineered plant varieties have had different spatial and temporal effects on the structural composition of the bacterial communities when compared to conventional varieties.[136] Other studies have found that transgenic plant genotype may affect rhizosphere microorganisms.[137] Studies of 227 soil and water bacteria found that in 37 percent of the bacterial strains growth was inhibited by low concentrations (less than 1mM) of glufosinate, 17 percent of the strains were resistant to glufosinate at concentrations of up

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[133] Sessitsch, A., Gyamfi, S., Tscherko, D., Gerzabek, M., and E. Kandeler, *Activity of Microorganisms in the Rhizosphere of Herbicide Treated and Untreated Transgenic Glufosinate-tolerant and Wildtype Oilseed Rape Grown in Containment*. 266 PLANT & SOIL 105 (2004).
[134] *Id*.
[135] Dunfield, K.E., and Germida, J.J., *Diversity of Bacterial Communities in the Rhizosphere and Root Interior of Field Grown Genetically Modified Brassica Nupus,* 38 FEMS MICROBIOLOGY ECOLOGY 1 (2001).
[136] Lukow, T., et al., *Use of the T-RFLP to Assess Spatial and Temporal Changes in the Bacterial Community Structure within an Agricultural Soil Planted with Transgenic and Non-transgenic Potato Plants*. 32 FEMS MICROBIOLOGY ECOLOGY 241 (2000).
[137] DiGiovanni, G.D., et al. *Comparison of Parental and Transgenic Alfalfa Rhizosphere Bacterial Communities Using Biology GN Metabolic Fingerprinting and Enterobacterial Repetitive Intergenic Consensus Sequence-PCR(ERIC-PCR),* 37 MICROBIAL ECOLOGY 129 (1999).

to 3mM.[138] A study of agricultural and forest soils found that the use of glufosinate reduced the number of fungi by 20 percent and the number of bacteria by 40 percent in agricultural soils.[139] In forest soils glufosinate reduced the number of bacteria by 20 percent. Follow-up studies showed that the species most resistant to glufosinate were fungi known to cause plant diseases, while some of the most sensitive species were beneficial *Trichoderma* species, which parasitize disease-causing fungi.[140] This finding indicates a possibility of increasing the occurrence of certain plant diseases due to changes in soil ecology which may occur as a result of the use of glufosinate in genetically engineered rice crops.

The community of soil microorganisms is extremely important to soil fertility, the decomposition of organic matter, nitrogen availability, water retention, and the prevalence of soil-borne diseases, all factors which can significantly impact agricultural productivity.[141]

LibertyLink rice and its associated farming system will cause an increase in the use of glufosinate. Increased glufosinate use will injure endangered plants, is toxic to beneficial organisms, and will alter soil ecology. These impacts indirectly damage plants and plant products, thus further supporting the conclusion that USDA must regulate LibertyLink rice as a plant pest.

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[138] Quinn, J.P., J.K. Heron, and G. McMullan, *Glufosinate Tolerance and Utilization by Soil and Aquatic Bacteria. Biol. & Environ.*, 39B(3) PROCEEDINGS OF THE ROYAL IRISH ACADEMY 181 (1993).
[139] Ahmed, I., and D. Malloch, *Interaction of Soil Microflora with the Bioherbicide Phosphinothricin*. 54 AGRIC. ECOSYSTEMS AND ENVIRON. 54 165 (1995).
[140] *Id.*; *see also* Cox, *supra* note 132.
[141] Physicians and Scientists for Responsible Application of Science and Technology. *Genetically Engineered Crops: A Threat to Soil Fertility* (Mar. 21, 2001), *available at*: http://www.mindfully.org/genetically engineered/Soil-Fertility-Threat-PSRAST.htm.

(4) LibertyLink rice varieties are more likely to become weeds than rice varieties developed by traditional plant breeding.

LibertyLink rice injures plants and plant products because it is more likely to become a weed in rotation crops than non-genetically engineered rice. Glufosinate tolerance enhances the fitness of LibertyLink rice in the presence of glufosinate, thus making LibertyLink rice more difficult to control. As described below, unintended characteristics of LibertyLink rice may also bear upon its weediness. For example, the height variation could result in weedy traits. Herbicide tolerance traits confer weediness on a plant if it becomes established in another crop. If LibertyLink rice is, by its nature, weedier than other rice varieties and thus should be regulated.

(5) LibertyLink rice may exhibit unpredicted properties that could bear on its plant pest traits including pathogenic properties.

LibertyLink rice also has some unexpected traits that could be due to unpredicted effects of genetic engineering. These unanticipated traits may confer plant pest qualities. For example, if metabolic pathways controlling natural disease or insect resistance in LibertyLink rice are inadvertently impeded, the rice could become more susceptible to certain diseases or insects. Subsequent increases in the pests on LibertyLink rice could then increase disease on other rice plants because, as is well known in both plant pathology and entomology, higher levels of a pest typically facilitate its spread. Thus, the plant could act as an incubator for plant pathogens and diseases. Other crops could also be harmed if the pathogen or insect was a pest on those crops in addition to rice. Many pathogens and insects can attack several species of crops, so this scenario is feasible. In fact, the substantial unintended reduction in lectin in LLRICE62 may result in increased insect damage because lectins often contribute to the control of insect pests in crops. Accordingly, USDA should regulate LibertyLink rice until a thorough evaluation assuages all plant pest concerns.

E. UNINTENDED CHARACTERISTICS OF LIBERTYLINK RICE WARRANT ITS REGULATION

The unintended effects of genetic engineering have not been adequately assessed for LibertyLink rice and regulation of LibertyLink rice is warranted. Petitioner believes that, in 1999, USDA performed an inadequate assessment of the plant pest risks arising from the unintended effects of the genetic engineering process used to develop LibertyLink rice. When AgrEvo submitted data to the USDA on LibertyLink rice, little was known about the unintended effects of genetic engineering; therefore the data submitted by AgrEvo was inadequate for USDA's conclusion that: "Other than production of the PAT enzyme [produced by the *bar* gene], these plants [LLRICE06 and LLRICE62] are the same as the commercial rice varieties from which they were produced."[142] New science about the unintended effects of genetic engineering bears on the plant pest status of LibertyLink rice. Unintended characteristics of LibertyLink rice may influence its fitness, weediness, and disease susceptibility.

Recent studies show that unintended characteristics may arise from genetic engineering because genes and proteins change and produce unexpected adverse effects. Insertion of DNA sequences can modify, interrupt, or silence existing genes or it can activate silent genes.[143] Unintended effects can include increased production of harmful substances such as toxicants, anti-nutrients, or allergens that may result in harm to

[142] EA, *supra* note 15, at 9.
[143] Alexander G. Haslberger, *Codex Guidelines for GM Foods Include the Analysis of Unintended Effects,* 21 NATURE BIOTECHNOLOGY 739 (2003).

nontarget organisms or weediness.[144] Other unintended effects can cause changes in substances that the crop uses to defend itself against insects and diseases.[145]

Several recent experiments show that genetic engineering produces unintended effects in various crops (see Table below derived from Cellini 2004 and Haselberger 2003).

Transgenic Crop	Unanticipated Effect	Year
Barley	Transgenic barley lines containing the bar gene, the uidA gene and the gene for heat-stable β-glucanase exhibited unchanged levels of β-glucanase but were inferior to conventional barley in a number of genetic backgrounds and environmental conditions.	2001
Canola	Oilseed rape plants containing the bialaphos tolerance gene (bar) regulated by the cauliflower mosaic virus (CaMV) 35S promoter became sensitive to the herbicide after infection with CaMV.	2000
	Herbicide-tolerant rape expressed unexpected physiological changes that affected biotic soil communities.	2004
	Seed –specific overexpression of phytoene synthase resulted in up to a 500-fold increase in levels of α- and β-carotene, but not of lutein, the predominant carotenoid in control seeds.	1999
Maize	The stems of Bt maize contain more lignin than controls with complex effects on degradation and consumption in the food chain.	2001
Potato	Transgenic potato lines from three cultivars expressing a kanamycin resistance marker showed unexpected changes in phenotypic and yield performance. Changes attributed to epigenetic/genetic events occurring during tissue culture phase of transformation	1994
	Potato plants transformed with lectin genes to enhance insect resistance exhibited lower levels of leaf-glycoalkaloids with potential consequences for nontarget insects and food or feed uses.	2001
	Potato with bacterial levansucrase developed adverse tuber tissue perturbations	1999
	Potato plants with soybean glycinin had increased glycoalkaloid content. Glycoalkaloids are poisons expressed in the nightshade family of plants.	1999
	Transgenic potato with yeast invertase had reduced glycoalkaloid content.	1998
Rice	Transgenic rice containing soybean glycinin gene exhibited 20% increase in protein content and a 50% increase in vitamin B6.	1999
	Transgenic rice containing expression of carotenoid biosynthetic pathway formed unexpected carotenoid derivatives (β-carotene, lutein, zeaxanthin).	2000
	Herbicide-tolerant Btt cryIIIA and bar transgenes in rice were unexpectedly silent and genetically engineered rice plants were herbicide-sensitive and identical to parent varieties.	1997
Soybean	Glyphosate-tolerant soybean had unexpected detrimental effects under certain environmental conditions. Splitting stems and yield reduction (up to 40%) at high soil temperatures.	1999
Wheat	Transgenic wheat intended to express phosphatidyl serine synthease developed necrotic lesions.	1999
	Wheat intended to express glucose oxidase unexpectedly had phytotoxicity.	1999

Several previous cases of unintended effects, both from traditional breeding and transgenic crops, have attributes with plant pest implications. For example, the worst

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[144] H.A. Kuiper et al., *Assessment of the Food Safety Issues Related to Genetically Modified Goods,* 27 THE PLANT JOURNAL 503 (2001); Doug Gurian-Sherman, Center for Science in the Public Interest, HOLES IN THE BIOTECH SAFETY NET: FDA POLICY DOES NOT ASSURE THE SAFETY OF GENETICALLY ENGINEERED FOODS (2003).

[145] *Id.*

disease epidemic in corn in the US was caused by the unintended effect of a traditionally bred male sterile gene causing susceptibility to a previously minor pathogen that caused Southern corn leaf blight. Genetically engineered *Bt* corn stalks have elevated levels of lignin, a woody tissue that resists degradation in the environment and the guts of animals that consume *Bt* corn and fodder.[146] In another example, transgenic potato had reduced alkaloid levels, which might increase susceptibility to some pests.[147] And in an example of an herbicide-tolerant crop, Arabidopsis transformed with an ALS resistance gene unexpectedly had a ten-fold higher outcrossing rate, a trait that could affect fitness or gene flow to, and between, a wild relative.[148]

AgrEvo's data on LibertyLink rice contained evidence of unintended effects with possible plant pest implications. One LibertyLink rice variety had multiple rearranged insertions and different height properties than its parent. Another LibertyLink variety had less lectin and more phytic-acid than the parent variety, which might increase insect susceptibility and reduce nutritional quality of LibertyLink rice, respectively. These changes indicate unintended effects in LibertyLink rice.[149] These unintended changes suggest that other, undetected, unintended changes may also have occurred, since AgrEvo assayed only a few of the thousands of properties of rice. Evidence of unintended characteristics of LibertyLink rice is troubling because unpredicted changes in other crops have been associated with possible plant pest status.

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[146] D. Saxena and G. Stotzky, *Bt Corn Has a Higher Lignin Content than Non-Bt Corn*, 88 AMERICAN J. BOT. 1704 (2001); Poerschmann et al., *Molecular Composition of Leaves and Stems of Genetically Modified Bt and Near-isogenic Non-Bt Maize – Characterization of Lignin Patterns*, 34 J. ENVIRON. QUAL. 1508 (2005).

[147] A.N.E. Birch et al. *The Effect of Genetic Transformation for Pest Resistance on Foliar Solanidine-based Glycoalkaloids of Potato (Solanum tuberosum),* 140 ANNALS OF APPLIED BIOLOGY 143 (2002).

[148] Bergelson et al., *Promiscuity in Transgenic Plants*, 395 NATURE 25 (1998).

[149] Petition, *supra* note 14, at 60.

Of particular concern is that LLRICE06, to be used in Southern rice growing areas,[150] contains multiple rearranged insertions, probably spanning at least 20-30 kb (20,000-30,000 bases).[151] Recent studies show that such rearranged genes are typically interspersed with gene or gene fragments that might affect the expression of crop genes, possibly inducing harmful properties.[152] A 20-30 kb region is large enough to contain tens of genes or many more gene fragments.

Data from the AgrEvo petition also showed that crop properties differed between the parent rice and the genetically engineered rice; such variation may reveal unintended effects. Several properties differed between the parent rice, M202, and the genetically engineered LLRICE06. First, M202 required no dry afterripening, while about 60% of LLRICE06 required one week or more of dry afterripening.[153] Second, some LLRICE06 lines apparently differed from M202 in panicle and rice kernel characteristics.[154] Third, data showed a variation in plant height between M202 and LLRICE06. AgrEvo attributed the height difference to somaclonal variation without providing any support.[155] USDA improperly accepted this explanation without experimental evidence. It is possible that height variation is due to the transgene or position effects from insertion location rather than somaclonal variation. Even if due to somaclonal variation, such changes can indicate

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[150] The 06 transformant is in rice variety Bengal, a popular variety in southern states. In addition, the transgene may be moved by traditional breeding methods into other varieties. In the latter case, the rearranged region will very likely remain as it is in 06.
[151] Petition, *supra* note 14, at 27-29.
[152] W.P. Pawlowski & D.A. Somers, *Transgenic DNA Integrated into the Oat Genome is Frequently Interspersed by Host DNA,* 95 PROCEEDINGS OF THE NATIONAL ACADEMIES OF SCIENCE USA 12106 (1998); S.K. Svitashev and D.A. Somers, *Genomic Interspersions Determine the Size and Complexity of Transgene Loci in Transgenic Plants Produced by Microprojectile Bombardment*, 44 GENOME 691 (2001).
[153] Petition, *supra* note 14, at 46.
[154] Petition, *supra* note 14, at 43. Unfortunately, AgrEvo only says that six lines conformed to the M202 type, but disclosed neither the number that differed, nor the magnitude of the difference, both important data. For other parameters in the same table, AgrEvo conducted measurements on either 20 or 34 lines. USDA should have demanded fuller data reporting on all tested lines prior to considering deregulation.
[155] *Id.*

mutation or epigenetic changes (heritable changes in gene function not due to changes in gene sequence) that may also have plant pest consequences. These differences between parent and transformant do not of themselves indicate plant pest properties, but do indicate that LLRICE06 may be significantly changed compared to M202, very possibly including other changes in some of the thousands of unmeasured traits of LLRICE06. Any altered traits undetected in USDA's defective review could have plant pest implications.

Additionally, changes in nutrient properties indicate that LibertyLink rice has unexpected traits. Both LibertyLink rice varieties had a 33-40% more phytic acid than their parent lines.[156] Phytic acid is a recognized anti-nutrient. Phytate binds several important mineral nutrients, such as zinc, thus making them unavailable to the body. For organisms that consume rice as a significant portion of their diet, anti-nutrients can be tied to nutritional deficiencies. LLRICE62 also had four-fold less lectin than parent Bengal.[157] Another known rice anti-nutrient, trypsin inhibitor, was conspicuously absent in samples of both LibertyLink rice varieties and their unmodified parents.[158] According to AgrEvo, trypsin inhibitor was "not detected" in any sample, suggesting that either the rice lacked trypsin inhibitor or AgrEvo used insensitive methods to detect it. In any case, more sensitive methods should have been used, positive controls should have been included, and the sensitivity of the method used should have been reported. Additionally, contrary to acceptable scientific standards, only one replication (measurement) was performed for these important parameters, making statistical analyses of their significance impossible.

[156] Petition, *supra* note 14, at 49.
[157] *Id.*
[158] *Id.*

These data are troubling because lectins and trypsin inhibitors are insecticidal compounds known to play important roles in defending plants against herbivorous insects. Therefore, the noted reduction in lectin might have implications for insect susceptibility for LLRICE62. If reduced lectin increased susceptibility to insect pests, and if LibertyLink rice is widely adopted (as other herbicide-tolerant crops have been), the use of harmful chemical insecticides could increase. Neither AgrEvo nor USDA analyzed potential changes in insect susceptibility. AgrEvo's two-paragraph section on "Disease and Pest Characteristics" was based purely on casual observation of field trials, not controlled experiments, and thus provides no usable data on a potential increase in the susceptibility of LLRICE62 to insect damage due to reduced lectin levels or other unintended effects.

Although reporting of nutritional composition was not mandatory, USDA rightly noted that it was not accompanied by proper statistical analysis.[159] AgrEvo responded that only a single sample was analyzed to look for possible "gross changes."[160] However, this admission by AgrEvo suggests that the detection of a substantial change in the expression of lectin is in fact a "gross change." A four hundred percent change in expression is substantial, and therefore warrants further study.

USDA should assess the unintended effects of genetic engineering on LibertyLink rice. Since it is impossible to predict the fate and site of the integration of a transgene into the plant, new methods of assessing the safety and environmental consequence of

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[159] Petition, *supra* note 14, Amendment at 8.
[160] *Id.*

genetically engineered crops are recommended.[161] For example, adequate molecular characterization is now considered by international standards to include sequencing of the transgenes in the plant and characterization of surrounding genomic DNA to determine possible rearrangements that might have adverse effects.[162] AgrEvo performed restriction mapping and southern blot tests,[163] methods that only determine the size of the inserted DNA not its sequence. In addition, complex genetic engineering that consists of multiple inserts and truncated or rearranged genes increases the possibility of unintended adverse changes in the crop. Because rice varieties M202 and Bengal were transformed by undisclosed direct gene transfer methods (claimed as confidential business information),[164] gene sequencing is vital to determine whether alterations have occurred that may have plant pest and other environmental effects. A thorough risk assessment should take into account unintended effects, environmental signals, and the genetic background of the parent plant.[165] It is important to note that some unintended effects of a genetically engineered crop may only be expressed under certain environmental conditions thus field trial data may be deficient.[166]

LibertyLink rice exhibits unintended characteristics that require consideration for LibertyLink rice's status as a plant pest. Once LibertyLink rice is introduced commercially it will be difficult, if not impossible to contain. USDA should act promptly to regulate genetically engineered rice as to prevent injury and damage to plants and plant products.

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[161] *Id.*; *see also* Keith Atherton, ed., *Strategies for Analyzing Unintended Effects in Transgenic Food Crops*, GENETICALLY MODIFIED CROPS: ASSESSING SAFETY 74, 78 (2002).
[162] *See* Paragraphs 30-33 of: Codex Alimentarius, *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants*, CAC/GL 45-2003 (2003)
[163] Petition, *supra* note 14, at 26-31.
[164] Petition, *supra* note 14, Amendment at 4.
[165] Alexander Haselberger, *supra* note 143, at 740.
[166] *Id.*

E. CONCLUSION

USDA must regulate LibertyLink rice as a plant pest because it meets several of the criteria that USDA uses to evaluate plant pest risk. This petition demonstrates that LibertyLink rice increases weediness in red rice, increases herbicide resistant weeds, injures rice commodities due to contamination, causes harm to endangered plants and potential adverse impacts on other non-target species. Additionally, this petition shows that unintended effects of genetic engineering trigger plant pest concerns. Any one of these finding should warrant regulating the LibertyLink rice as a plant pest.

In summary, petitioner requests that USDA:

1. Determine that all varieties of LibertyLink rice, including LLRICE06, LLRICE62, and LLRICE601, are plant pests under the Plant Protection Act § 7711.

2. Add LibertyLink rice varieties to the list of organisms that are plant pests.

3. Determine that LibertyLink rice is a regulated article and restrict its introduction, dissemination, interstate movement, and conveyance under 7 C.F.R. §340.0.

Respectfully submitted on behalf of the petitioner,

______________________ on September 14, 2006.

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