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PLANT BIOTECHNOLOGY LAW AFTER *GEERTSON SEED FARMS*: POTENTIAL IMPACTS ON REGULATION, LIABILITY, AND COEXISTENCE MEASURES*

by

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I. Introduction

In the 2007 decision *Geertson Seed Farms v. Johanns*¹ (“*Geertson*”), a district court held that the U.S. Department of Agriculture’s (“USDA”) Animal and Plant Health Inspection Service (“APHIS”) violated the National Environmental Policy Act (“NEPA”) by deregulating genetically engineered (“GE”) alfalfa without performing an environmental impact assessment. The harm alleged by the plaintiffs was the potential for contamination of conventional and organic alfalfa with the GE alfalfa, and the resulting economic loss that conventional and organic alfalfa farmers faced if they were unable to sell their crops to domestic and export markets.

By holding that the contamination of conventional and organic alfalfa by GE alfalfa constituted a “significant” effect on the human environment, the court signaled a challenge to a presumption that has characterized the U.S. regulatory regime for GE products: that those products are substantially equivalent to their non-GE counterparts. The court also signaled a potential sea change in the liability rules relating to contamination by GE material: the court rejected APHIS’s unsupported assumption that conventional and organic farmers could “fence out” the GE strains. The court’s holding suggests a shift toward a requirement that biotech growers “fence in” their crops, a duty that might give rise to liability for contamination by growers of GE crops and even producers of GE seed.

This article will review the *Geertson* decision and consider its actual and potential impact on the legal landscape related to plant biotechnology. After a summary of the decision, this article will briefly review the landscape of biotech regulation, liability rules, and coexistence strategies.

II. *Geertson*: Recognizing Economic Effects of Biotech Contamination as a “Significant” Effect on Human Environment

In *Geertson*, the court reviewed APHIS’s approval of a petition to deregulate Roundup-ready alfalfa, permitting the GE alfalfa variety to be sold without USDA regulation just like conventional alfalfa. Although APHIS had conducted an environmental assessment (“EA”) before granting the deregulation petition, the plaintiffs in *Geertson* claimed that an

* Any views, opinions, or any other information set forth in this article are derived solely from the author and do not reflect any views of the National Agricultural Law Center, or any other component of the United States Department of Agriculture.

¹ No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

environmental impact statement (“EIS”) was required because the deregulation of Roundup-ready alfalfa had the potential to “significantly affect[] the quality of the human environment.”² It was undisputed that alfalfa can be pollinated by insects traveling up to two miles.³ The plaintiffs, including farmers who wished to grow non-GE alfalfa, argued that the deregulation of Roundup-ready alfalfa would unavoidably lead to contamination of all alfalfa crops with the genetically modified variety, depriving plaintiffs of the opportunity to grow non-GE alfalfa for sale to organic and conventional markets, including import markets like Japan that prohibit GE varieties.⁴

APHIS made several arguments in support of its determination. First, APHIS concluded, based on the “buffer zones” required by the National Organic Program, that it was the responsibility of organic and conventional farmers, not the growers of GE varieties, to protect their crops and seed supplies from contamination. In effect, organic and conventional farmers had a duty to “fence out” contamination. The court rejected this reasoning, noting that APHIS had acknowledged the difficulty of guaranteeing that seeds or sprouts were free of contamination: “Neither the EA nor the [Finding of No Significant Impact] identify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby GE seed farm, even assuming the farmer maintains a ‘buffer zone.’”⁵

APHIS also based its determination on the fact that the National Organic Program (“NOP”) did not “necessarily” prohibit the unintentional presence of GE traits. In rejecting this argument, the court made a strong statement in favor of the right of farmers and consumers to have choice in the marketplace. The court noted that “many farmers and consumers have higher standards than what the federal government currently permits,” and that many importing countries, including Japan, have different regulations than the U.S.⁶ “[M]ost importantly, APHIS’s comment simply ignores that these farmers do not want to grow or feed to their livestock GE alfalfa, regardless of how such alfalfa can be marketed.”⁷

APHIS’s second major argument in support of its determination is that the National Environmental Policy Act (“NEPA”) only requires consideration of physical environmental impacts, not the economic impacts alleged by the plaintiffs. The court rejected this argument, citing cases holding that “economic effects are relevant ‘when they are ‘*interrelated*’ with ‘natural or physical environmental effects.’”⁸ The court held that the economic effects on conventional and organic farmers were a direct result of the effect of APHIS’s action on the physical environment, and thus should have been considered in an EIS.⁹

Finally, APHIS argued that its action was justified even if contamination was inevitable, because it had found that the glyphosate-resistant gene was not toxic or pathogenic to humans and livestock. In other words, the GE enzyme for glyphosate resistance was

² 2007 WL 518624 at *3 (quoting 42 U.S.C. § 433(2)(c)).

³ *Id.* at *2.

⁴ *Id.*

⁵ *Id.* at *6.

⁶ *Id.* at *7.

⁷ *Id.*

⁸ *Id.*

⁹ *Id.* at *8.

“equivalent in all biological respects” to enzymes found in nature.¹⁰ Again, the court rejected this reasoning, stating that public health and safety was only one of the factors an agency was required to consider under NEPA. Returning to the argument of farmer and consumer choice, the court held that the potential elimination of an entire crop and market – non-GE alfalfa – was a “significant impact” on the environment even if public health and safety were not affected.¹¹

III. The Evolving Legal Landscape After *Geertson*

Geertson departs in significant respects from the legal regime that has been applied to plant biotechnology development so far. The decision immediately calls into question the continued legitimacy of APHIS’s regulatory assumptions; the distribution of liability risk among biotech and non-biotech farmers, as well as seed companies; and the types of coexistence measures, both voluntary and mandatory, that may be instituted.

The decision of at least one federal court to require APHIS to consider potential loss of non-GE varieties as a significant environmental effect under NEPA means, at a minimum, that APHIS will have to begin giving a harder look at permitting or deregulating the planting of GE varieties and their potential to contaminate conventional and organic crops. Whether other courts will follow *Geertson*, and whether its rulings will effect widespread change in the current biotech regulation and liability regimes remains to be seen.

Two other cases, *Center for Food Safety v. Johanns* (“CFS”),¹² and *International Center for Technology Assessment v. Johanns* (“ICTA”),¹³ suggest that *Geertson*’s challenge to the biotech regulatory regime may not be isolated to one California district court. Both *CFS* and *ICTA* involved challenges to APHIS permits for field testing of GE plants without an EA or an EIS under NEPA. In both cases, the courts held that APHIS could not justify its failure to conduct an EA or EIS by simply pointing to the categorical exemption for “confined field releases.” Instead, the courts held that APHIS must make a determination about whether GE varieties might be “new species or organisms or novel modifications that raise new issues”¹⁴ that “affect significantly the quality of the human environment,”¹⁵ for which the categorical exemption is not available.

Presumption of Equivalence Between GE and Non-GE Products in the U.S. Regulatory Scheme

The primary immediate impact of the *Geertson* decision is its challenge to the presumption of equivalence between biotech and non-biotech products. This presumption has animated APHIS’s determinations regarding field testing and deregulation of GE plant varieties. Those assumptions are derived from policy decisions made early in the commercial development of biotechnology.

¹⁰ *Id.*

¹¹ *Id.*

¹² 451 F. Supp. 2d 1165 (D. Hawaii 2006).

¹³ 473 F. Supp. 2d 9 (D.D.C. 2007).

¹⁴ *Id.* at 29 (quoting 7 C.F.R. § 372.5(d)(4)).

¹⁵ *Id.* at 29 (quoting 7 C.F.R. § 372.5(d)).

The Coordinated Framework and Assumptions Underlying APHIS Determinations

Since its early iteration in the 1980s, U.S. policy with regard to GMO regulation¹⁶ has been based on three tenets: First, regulation focuses on the characteristics of the end product of the genetic modification; the procedure of genetic modification is not viewed as being significant enough to justify regulatory scrutiny.¹⁷ Second, in contrast with the “precautionary principle” often incorporated in international agreements, the U.S. has taken the view that verifiable “scientific risk” is needed to bar a technology from being introduced and integrated.¹⁸ Third, the U.S. has viewed the risks associated with GE food as the same as risks associated with “traditionally” produced foods, such that the existing regulatory oversight is sufficient to safeguard the public.¹⁹

This policy developed from the initial regulatory policy regarding the emerging technology of genetic modification in the 1980s and early 1990s. Early in the process of commercialization of biotech products, the Reagan Administration charged the White House Office of Science and Technology Policy (“OSTP”) with drafting a federal framework for food biotechnology. The OSTP, in its 1984 Coordinated Framework for Regulation of Biotechnology (“Coordinated Framework”), announced a policy that products created by biotechnology were no different than other products, and that existing statutes were sufficient to regulate biotechnology.²⁰ The Coordinated Framework also generally outlined that biotechnology regulation would be divided among existing federal agencies. The FDA would be responsible for regulating food, feed, food additives, and veterinary drugs, the USDA would be responsible for plant pests, plants, and veterinary biologic, and the EPA for microbial/plant-pesticides, new uses of existing pesticides, novel microorganisms.²¹

U.S. biotech policy was developed with the goal of promoting the biotech industry. After publication of the Coordinated Framework, the White House initially convened the Biotechnology Science Coordinating Committee (“BSCC”), an inter-agency committee responsible for coordination of science policy. However, when the BSCC was unable to come to agreement, its working materials were forwarded to the President’s Council on Competitiveness, a council formed under the first Bush Administration. The Council on Competitiveness established an Ad Hoc Committee on Scope, which, together with the OSTP, established the scope of agency jurisdiction over biotechnology.²²

¹⁶ For an excellent and thorough description and analysis of the tenets of U.S. GMO regulatory policy, see Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733 (2003).

¹⁷ See Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 6753 (proposed Feb. 27, 1992).

¹⁸ See FDA, A Description of the U.S. Food Safety System (2000), available at <http://www.fsis.usda.gov/OA/codex/system.htm>.

¹⁹ See generally Marsh Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525 (1998).

²⁰ Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23, 302 (proposed June 26, 1986).

²¹ *Id.*

²² Principles for Federal Oversight of Biotechnology: Planned Introduction Into the Environment of Organisms With Modified Hereditary Traits, 55 Fed. Reg. 31, 118 (proposed July 31, 1990). See also Marden, *supra* note 16, at 739-40; SHELDON KRIMSKY, BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS 197, 204 (1991).

During its deliberation process the OSTP proposed draft policy statements that indicated a goal to “minimize regulatory burden while assuring protection of public health and welfare,” and to “accommodate the rapid advances in biotechnology.”²³ These goals were facilitated by the OSTP’s perspective on risk: “Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics of use of the individual products.”²⁴

The OSTP published its Final Statement of Scope in 1992. The Final Statement of Scope includes five policy principles underlying the Administration’s tenets regarding GE foods:

1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods;
2. Information about the process used to produce a GM organism is ... not a useful criterion for determining whether the product requires less or more oversight;
3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques ...;
4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits...; and
5. In many respects, molecular methods resemble the classical methods for modifying particular strains for microorganisms, but [are even more useful than the classical methods.]²⁵

APHIS has authority to regulate plant biotechnology as “potential plant pests” under the Plant Protection Act (“PPA”).²⁶ Parties testing novel plant varieties modified by genetic engineering may proceed by an annual permit (for pharmaceutical and industrial biotechnology)²⁷ or through a simplified notification procedure.²⁸ After successful field tests, a developer may petition APHIS to “deregulate” the plant variety, permitting commercialization of the product without further regulatory constraints by APHIS.²⁹ APHIS’s decision to permit field testing or to deregulate a plant variety constitutes agency action triggering evaluation of environmental impacts under NEPA.

APHIS’s permitting determinations under the PPA have reflected the assumptions underlying the Coordinated Framework. For example, in its Response to Comments on Petition 04-110-01p for the Determination of Non-regulated Status for Roundup Ready®

²³ Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753 (proposed Feb. 27, 1992), at 6760 [hereinafter “Final Statement of Scope”].

²⁴ *Id.*

²⁵ *Id.* at 6755. For additional statements of the first Bush Administration’s view of risk and tenets of oversight, see President’s Council on Competitiveness, Report on National Biotechnology Policy (1991).

²⁶ Plant Protection Act, 7 U.S.C. §§ 7701-7786 (2006); 7 C.F.R. §§ 340.0(a) note 1, 340.1 (2008).

²⁷ 7 C.F.R. § 340.3(a)-(b).

²⁸ See 7 C.F.R. § 340.3(b), (c).

²⁹ See 7 C.F.R. § 340.6(a).

Alfalfa Events J101 and J163,³⁰ APHIS acknowledged that alfalfa pollen had been detected as far as two miles from the source.³¹ Nevertheless, APHIS stated that “[i]solation distances are not required for GE products that have been approved by EPA, FDA, and USDA for general release into the environment because the safety of these products has been thoroughly evaluated by the involved agencies.”³²

APHIS has also indicated its view that its review is limited to any unique health and safety issues related to novel GE plant varieties, not to other environmental or related economic effects of changes to the ecosystem as a result of GE plant varieties. In its Finding of No Significant Impact for the deregulation of Syngenta’s Agrisure RW MIR 604, a variety of corn genetically engineered to control rootworm pests, APHIS determined that lack of approval of the variety by regulators in Japan – Agrisure’s largest import market – did not affect APHIS’s consideration of the petition under the PPA. “Biotechnology regulations are pursuant to the [PPA], which is a safety statute intended to protect plant health in the U.S. ... Any future marketability of [the variety to] countries outside the U.S. is the responsibility of those who wish to market it in those countries.”³³

Impact of *Geertson* on the Presumption of Equivalence

Geertson requires only that APHIS consider the potential for contamination of non-biotech crops when granting field permits or petitions for deregulation. APHIS might, in many cases, satisfy this test by concluding that contamination is unlikely. That determination, however, would have to be backed by enough evidence and reasoning to survive review under the “arbitrary and capricious” standard of the Administrative Procedure Act (APA).

In *Geertson*, the court expressly rejected APHIS’s argument that “the engineered enzyme is equivalent in all biological respects to those that are common and harmless in nature and therefore the introduction of that engineered gene into conventional or organic alfalfa is not a significant environmental impact as a matter of law.”³⁴ The court pointed out that Congress intended for NEPA to protect against “[environmental] degradation, risk to health and safety, or other undesirable and unintended consequences.”³⁵ Although the court ostensibly deferred to APHIS’s determination that Roundup-ready alfalfa does not pose health risks for humans or livestock,³⁶ its holding that loss of conventional or organic alfalfa is a significant impact under NEPA has far-reaching implications. APHIS’s determination that RoundupReady alfalfa is safe was based on its presumption of equivalence between GE and non-GE plants.³⁷ By rejecting

³⁰ APHIS, USDA, Return to Regulated Status of Alfalfa GE for Tolerance to the Herbicide Glyphosphate (2005), available at http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf.

³¹ *Id.* at 2.

³² *Id.*

³³ APHIS, USDA, Finding of No Significant Impact: Animal and Plant Health Inspection Service Petition for Non-Regulated Status for Corn Line MIR604 (APHS 04-362-01p) 8-9 (2007), available at http://www.aphis.usda.gov/brs/aphisdocs2/04_35201p_com.pdf.

³⁴ *Geertson*, 2007 WL 518624 at *8.

³⁵ *Id.*, quoting NEPA, 42 U.S.C. § 4331(b)(3) (emphasis supplied by court in *Geertson*).

³⁶ *Id.*

³⁷ *Geertson*, 2007 WL 518624, at *8 (“APHIS has determined that the introduction of that gene to alfalfa is harmless to humans and livestock APHIS’s position is based on its finding that the engineered gene is similar to another gene already present in non-engineered alfalfa and is the equivalent to a natural enzyme found in both green plants and microorganisms that are common in nature.”).

this presumption of equivalence, the court's holding tacitly calls into question APHIS's determination that the Roundup Ready alfalfa is, in fact, safe.

The Final Statement of Scope took the position that “[p]roducts developed through biotechnology processes do not *per se* pose risks to human health and the environment; risk depends instead on the characteristics of use of the individual products.”³⁸ The *Geertson* decision challenges this presumption as well, by broadening the scope of “risks to ... the environment”, at least under NEPA, to include the loss of choice by farmers to grow, and by consumers to purchase, non-GE plant varieties.³⁹

While the practical effect of *Geertson* remains to be seen, the most immediate impact of the decision is to create federal court precedent for a finding that agency reliance on the presumption of equivalence between GE and non-GE products may in some cases be arbitrary and capricious. At a minimum, this will require APHIS to review GE plant varieties based on different criteria from non-GE varieties. Any altered regulatory presumptions for GE and non-GE plants will be a reversal of the position in the Final Statement of Scope that “[i]nformation about the process used to produce a GM organism is ... not a useful criterion for determining whether the product requires less or more oversight.”⁴⁰

The Evolution of Coexistence Measures

“Coexistence” is the term used to describe efforts, whether mandatory or voluntary, to preserve the identity of conventional and organic crops while permitting the development, growing and marketing of GE varieties.⁴¹ Coexistence measures are sought by growers of both GE and non-GE varieties: the latter to preserve the identity of (and premium paid for) their non-GE crops, the former to provide assurances of crop segregation for ease in receiving testing and commercial development permits, and, increasingly, to establish an industry standard for growers of GE varieties to rely on in defending against liability for contamination. With APHIS now directed by the court in *Geertson* to take a harder look at the practicality and effectiveness of coexistence measures, those measures will become increasingly important at the permitting/deregulation stage, and potentially at the liability stage (which will be discussed in Section C).

Coexistence Requirements and Proposals

Coexistence measures vary in many respects, including the mandatory (legally-imposed) or voluntary (privately-developed) nature of the rules, the amount of responsibility placed on the GE variety developer and farmer or the conventional and organic farmer, whether any low-level tolerance of adventitious presence of GE traits in non-biotech crops is assumed.

Coexistence can be approached by segregating particular fields, or by segregating entire regions or counties. The NOP,⁴² for example, requires that organic producers have

³⁸ Final Statement of Scope, *supra* note 23, at 6760.

³⁹ *Geertson*, 2007 WL 518624

⁴⁰ Final Statement of Scope, *supra* note 23, at 6755.

⁴¹ See A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 Mo. ENV'T. L. & POL'Y REV. 206, 214 (2006).

⁴² See Organic Foods Production Act, 7 U.S.C. §§ 6501-6522, and 7 C.F.R. Part 205.

defined boundaries and “buffer zones” separating organic cropland from land that is not in organic production. The size of the buffer zones is left to the organic producer and the certifying agent.⁴³ The NOP also requires organic producers to prepare an organic production system plan that details measures taken to prevent cross-pollination and other commingling with non-organic products.⁴⁴

On the other side of the fence, the biotechnology industry recently published a “Quality Management Program Guide” to encourage plant biotechnology developers and growers to establish internal policies to prevent commingling at all stages of product development, including confined field tests and commercialization and marketing.⁴⁵ The guide contains sample forms for tracking segregation of GE plant materials and sample policies for obtaining approval from key import markets prior to domestic commercialization.

Attempts to segregate entire regions or political entities have met with mixed success. Some local governments have exercised their police power to create GE-free zones, sometimes viewed as mandatory “grower districts” that consolidate production of GE crops within a geographic region to minimize the risk of commingling.⁴⁶ However, a number of states have also passed legislation pre-empting such local actions.⁴⁷ In some states, regulation of GE varieties, especially rules for co-existence of GE and non-GE crops, has been attempted through legislation permitting voluntary grower districts or crop-specific licensing commissions that limit the production of crops with “characteristics of commercial impact,” which may include GE traits.⁴⁸

The success of coexistence measures also depends on regulations, and consumer attitudes, toward legally-mandated tolerance levels, which require that trace amounts of GE product be tolerated in crops or seed designated as non-GE without affecting price, marketing, or, in the case of international tolerance standards, import regulations. Although the U.S. currently does not recognize a mandatory tolerance level, APHIS recently proposed, in a draft environmental impact statement, establishing safety criteria under which low levels of adventitious presence of GE traits would be non-actionable, or allowed, in otherwise non-GE seed stocks and crops.⁴⁹ On the international level, the Codex Alimentarius ad hoc Task Force on Foods Derived from Biotechnology recently published a proposed annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.⁵⁰ The annex deals with the low-level presence of GE material in non-GM food imports that have passed safety assessments in at least one country, but not the country of import. Codex concluded

⁴³ 7 C.F.R. § 205.202(c).

⁴⁴ 7 C.F.R. § 205.201(a)(5).

⁴⁵ Excellence Through Stewardship, Quality Management Program Guide to Maintaining Plant Product Integrity of Biotechnology-Derived Plants, *available at* http://excellencethroughstewardship.org/images/pdfs/Final_Bio_Finished_Book.pdf.

⁴⁶ See Endres, *supra* note 41, at 218 (counties of Mendocino, Marin, and Trinity, California).

⁴⁷ See *id.* at 218-20 & 234-40, Appendix A (Arizona, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Texas, West Virginia, and “arguably” Illinois). Regional bans on growing GE crops are common among EU Member State plans for implementing Commission recommendations to develop coexistence rules. *Id.* at 210-12.

⁴⁸ See *id.* at 221-28.

⁴⁹ USDA, Introduction of GE Organisms: Draft Programmatic Environmental Impact Statement—July 2007 at 152-55 (2007) [hereinafter APHIS Draft EIS].

⁵⁰ See Codex Alimentarius Comm’n, Report of the Seventh Session of the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, ALINORM 07/31/34 (2006), *available at* http://www.codexalimentarius.net/download/report/693/al31_34e.pdf.

that the safety risks from such material are low, and therefore only certain aspects of the Codex Plant Guideline for food safety assessments would apply.⁵¹

The Impact of *Geertson* on Coexistence Measures

Geertson will undoubtedly impact the ongoing development of coexistence measures by calling into question APHIS's assumptions that conventional and organic farmers can effectively "fence out" GE traits, at least with respect to crops like alfalfa that can be pollinated across wide geographic areas. The decision opens the door for reconsideration of coexistence measures, both mandatory and voluntary, that place greater responsibility on seed developers and biotech growers.

In *Geertson*, APHIS ignored evidence that pollination by bees was possible within two miles of the planting site and determined, without support, that conventional and organic farmers could "fence out" GE alfalfa. *Geertson* does not expressly require APHIS to move to a "fence in" standard, which would place the burden of segregation (and, potentially, liability for contamination) on growers or developers of GE products. *Geertson* does, however, require that APHIS make determinations supporting the reasonableness of whatever coexistence standard it relies upon – whether it be a "fence out" rule placing the burden on growers of non-GE crops, a "fence in" rule placing the burden on growers or developers of GE varieties, or some combination. Whether the coexistence measures are reasonable and effective depends, in turn, on whether low tolerance levels for contamination are established by APHIS, and whether the Codex standards (which have no binding force) are widely recognized internationally.

Liability for GMO Contamination: Fence-Out or Fence-In?

Liability Before *Geertson*: The "Fence-Out" Rule

In the pre-*Geertson* legal landscape, farmers who wished to grow and sell non-GE crops bore (and still bear) most of the liability risk for economic loss due to contamination. On the front end, seed developers expressly disclaim liability for commingling, leaving farmers to bear any economic losses associated with loss of markets or lower prices due to GE contamination in the seed.⁵² Conventional and organic growers may even be liable to seed developers for intellectual property violations if their crops are unintentionally contaminated with GE varieties of the crops, at least if the farmer knowingly takes any action to cultivate the GE seed once it has been found in his seed or crop.⁵³ After harvest, buyers will often reject or pay a lower price for products contaminated with unapproved GE traits, placing economic liability again on the farmer.⁵⁴

⁵¹ *Id.*

⁵² See Int'l Seed Fed'n, Model for Conditions of Sale Applicable to Seed Lots (2002), available at http://www.worldseed.org/en-us/international_seed/on_trade.html.

⁵³ In Canada, farmer Percy Schmeiser was held liable for knowingly cultivating Monsanto's Roundup-ready seed after it had inadvertently spread to his field, but the Supreme Court of Canada reversed an award of damages against Schmeiser. See *Schmeiser v. Monsanto Canada Inc.*, No. 29437, 2004 SCC 34 (Can. Jan. 20, 2004), available at <http://www.lexum.umontreal.ca/lcsd-scc/en/rec/html/2004scc034.wpd.html>. But see *SmithKline Beecham Co. v. Apotex Co.*, 365 F.2d 1306, 1330-31 (Fed. Cir. 2004) (Gajarsa, J., concurring) (stating that farmers would not be liable for patent infringement just because GE seed blew onto their property).

⁵⁴ See R. David Moeller & Michael Sligh, *Farmer's Guide to GMOs* (November 2004), at 21 and notes 126-27, available at http://www.rafiusa.org/pubs/Farmers_Guide_to_GMOs.pdf.

Some states have introduced legislation modeled after laws in countries such as Germany and Denmark that shift liability for GE contamination to parties other than the injured growers.⁵⁵ The German law provides for strict liability for economic injuries, which includes inability to place a crop on the market, ability to market the crop only with a label referencing genetic modification, or inability to label a product as “organic.”⁵⁶ The Danish law provides that injured farmers be paid the difference between the market prices of non-GE and GE crops, drawing from a compensation fund financed by a tax per hectare planted with GE crops. Civil and criminal liability under other Danish law is also available to injured parties, and the government may seek recovery for monies paid from the compensation fund.⁵⁷ No state (nor the federal government) in the U.S. has yet to pass such a liability-shifting initiative.⁵⁸

Farmers injured by GE contamination have also found limited recourse under tort law. In *In re StarLink Corn Products Liability Litigation*,⁵⁹ farmers who suffered losses due to contaminated seed were denied recovery under tort law. The court in *StarLink* held that where contamination occurred at the seed level, there was no physical injury accompanying the economic loss, and thus recovery was barred under the economic loss doctrine,⁶⁰ although farmers injured during growing or processing were permitted to pursue claims.

StarLink, and the pending litigation *In re LLRice 601 Contamination Litigation*, however, provide support for the notion that evolving restrictions in APHIS’s field testing permits or other determinations may provide a foundation for liability in tort against growers of GE products. In *StarLink*, the EPA, acting pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), had granted an exemption for a pest-resistant GM corn variety from the pesticide tolerance for animal feed (and consumption of the animals’ by-products).⁶¹ The EPA’s “split registration” permit, however, did not grant an exemption for direct human consumption of the *StarLink* corn.⁶² The *StarLink* permits required a 660-foot buffer zone to prevent the variety from commingling with crops intended for human consumption and directed that the *StarLink* variety be used only for animal feed and non-food uses.⁶³ Nevertheless, *StarLink* corn entered the human food supply.

The court in *StarLink* denied the defendant’s motion to dismiss, holding that the plaintiffs adequately alleged that the EPA permit created a duty that defendants not allow the genetically modified corn to enter the human food supply, and that the defendants breached that duty.⁶⁴ The EPA eliminated the practice of allowing split registrations for

⁵⁵ See Endres, *supra* note 41, at 212-13.

⁵⁶ *Id.*

⁵⁷ *Id.* at 213.

⁵⁸ See Pew Initiative on Food & Biotechnology, Legislative Activity 2001-2006 Related to Agricultural Biotechnology, available at

http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PI_FB_Legislative_Tracker.pdf.

⁵⁹ 212 F. Supp. 2d 828 (N.D. Ill. 2002).

⁶⁰ *Id.* at 842.

⁶¹ 40 C.F.R. § 174.517 (2007).

⁶² *Id.*

⁶³ See D.L. Uchtmann, *StarLink™ – A Case Study of Agricultural Biotechnology Regulation*, 7 Drake J. Agric. L. 159, 185 (2002).

⁶⁴ *In re StarLink Corn Prods. Liabl. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

feed/non-food uses,⁶⁵ but the *StarLink* case stands as a precedent that restrictions in planting permits for GE crops can create a regulatory duty, the violation of which may give rise to liability in tort.

Similarly, in the *LibertyLink* rice litigation, some of the plaintiffs have alleged that the regulatory permitting by APHIS created a duty that was breached by defendants. In December 1998, the developers of LibertyLink (Aventis CropScience, later purchased by Bayer to form Bayer CropScience) began field trials of three varieties of rice, LLRice06, LLRice62, and LLRice601.⁶⁶ Following the trials, APHIS approved Aventis' petition to deregulate the first two varieties. Aventis did not seek regulatory approval for commercial release of LLRice601.⁶⁷ Nevertheless, in January 2006, Riceland, the nation's largest rice cooperative, discovered LLRice601 contamination in the 2005 Midwest long-grain rice crop.⁶⁸ After the USDA announced the commingling in August 2006, Japan banned long-grain rice imports from the U.S., and the European Union began testing all U.S. rice imports.⁶⁹ Following the precedent in *StarLink*, some plaintiffs in the consolidated *LibertyLink* litigation have alleged that Aventis breached a regulatory duty to keep LLRice601 from entering the human food supply.⁷⁰

Liability Implications of *Geertson*: Move to a "Fence-In" Rule?

By requiring that APHIS give a harder look at segregation of GE and non-GE crops before granting field testing permits or deregulation petitions, *Geertson* has begun to shift the issue of liability for contamination away from the automatic "fence out" rule that places all the burden of loss on growers of non-GE varieties. The opinion does not go so far as to indicate a new "fence in" standard that would place all responsibility for segregation on the grower of GE varieties, but it does leave open the question whether APHIS will, in some cases, shift some of the burden of segregation for coexistence – and potentially more liability for contamination – onto those growers of GE varieties.

Geertson's requirement that APHIS take a harder look at coexistence measures, and its holding that loss of non-GE product markets due to contamination concerns is a significant environmental impact under NEPA and may lead to new regulatory requirements placed on developers and growers of GE products in granting field testing permits or deregulation. For example, in the July 2007 draft EIS, APHIS proposed a mechanism to retain limited oversight over plant varieties that might otherwise have been granted deregulated status.⁷¹ One mechanism available to APHIS in the post-*Geertson* world would be to use this proposed "deregulation-in-part" authority to grant deregulation only in certain grower districts, or only a certain prescribed distance from any existing alfalfa plantings, or other duties or restrictions.

⁶⁵ See Uchtmann, *supra* note 63, at 205.

⁶⁶ See A. Bryan Endres & Justin G. Gardner, *Genetically Engineered Rice: A Summary of the LL Rice 601 Incident*, AGRIC. L. & TAX'N BRIEFS, December 6, 2006, at 2.

⁶⁷ *Id.* See also USDA, REPORT OF LIBERTLINK RICE INCIDENTS, at 3, available at <http://www.aphis.usda.gov/newsroom/content/2007/10/content/printable/RiceReport10-2007.pdf>.

⁶⁸ Endres & Gardner, *supra* note 66, at 2.

⁶⁹ Harry Cline, *California Disappointed at New Japanese Rice Testing*, WESTERN FARM PRESS, Sep. 29, 2006, available at <http://westernfarmpress.com/news/09296-ricetesting/>.

⁷⁰ See, e.g., *Geeridge Farms, Inc. v. Bayer CropScience L.P.*, No. 4-06-CV-01079GH (E.D. Ark. Aug. 28, 2006), Complaint at 18-19; *Bell v. Bayer CropScience L.P.*, No. 1:06-CV-00128RWS (E.D. Mo. Sept. 13, 2006), Complaint at 68-69.

⁷¹ APHIS Draft EIS, *supra* note 49, at 142.

Following the precedent of *StarLink*, and possibly the pending claims in *LibertyLink*, any regulatory duties placed on the developers or growers of GE varieties, either in field testing permits or in decisions to grant deregulation-in-part for a particular GE plant variety, could give rise to tort liability for breach of those duties. As alleged in *LibertyLink*, the tort could be based on breach of a direct regulatory duty, or breach of a general duty arising from failure to observe the standard of care evidenced by the regulatory requirements. Numerous issues, such as the nature of the tort, defenses relating to causation and mitigation, division of liability where multiple defendants are in breach, and any limits on liability, would have to be worked out in litigation.

The hard look at coexistence measures required by the court in *Geertson* is more likely to lead to effective and practicable coexistence of GE and non-GE products. Farmers who plant and harvest GE varieties are in a better position to know that contamination may occur, and to take steps to prevent it, than farmers who may not even be aware (if a crop has been deregulated by APHIS) that plantings of the GE variety are occurring in the same area. While the most effective coexistence rules will vary according to the crop and its means and likelihood of unintended spread, *Geertson's* elimination of the presumption in favor of the "fence out" rule supplies the opportunity for arrival at a more effective coexistence scheme on a case-by-case basis.

As long as the possibility, raised by *Geertson*, exists for more liability to be shifted to developers and growers of GE varieties, it is likely that the biotech industry will continue to develop and support voluntary coexistence schemes that place some limited responsibilities on biotech growers, the observance of which would create some defense against liability if contamination does occur. In conjunction, the industry may be expected to support tolerance levels, since price and market protections ensured by mandatory tolerance levels would leave many conventional or organic farmers unable to show harm in the event of low levels of adventitious presence of GE traits. As discussed above, such a rule would be questionable with regard to consumer freedom of choice, but it would simplify marketing and eliminate many potential liability issues arising from contamination.