COEXISTENCE STRATEGIES, THE COMMON LAW OF BIOTECHNOLOGY AND ECONOMIC LIABILITY RISKS

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Trade disruptions, loss of confidence in the agricultural sector and institutional credibility are just a few of the issues of concern to governments when developing and implementing a biotechnology regulatory strategy. [1]

The International Service for the Acquisition of Agri-biotech Applications (ISAAA – publisher of the most relied upon data relating to the international adoption of agricultural genetic engineering technologies – noted in its latest report that the global area of biotech crops in 2006 totaled 102 million hectares, planted by 10.3 million farmers in twenty-two countries.[2] This amounted to a twelve million hectare increase over the previous year, equivalent to an annual growth rate of thirteen percent.[3] The five most aggressive countries in adopting this technology remained, in order of area, the United States (54.6 million hectares, 53 percent of the global biotech area), Argentina (18.0 million hectares), Brazil (11.5 million hectares), Canada (6.1 million hectares), India (3.8 million hectares) and China (3.5 million hectares).[4]

According to the USDA, domestic plantings in 2007 of genetically engineered varieties, as a percentage of total crop plantings, were 73 percent for corn (61 percent in 2006), 87 percent for cotton (83 percent in 2006), and 91 percent

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1. In the agricultural context, the United States Department of Agriculture (USDA) defines "biotechnology" as a broad "range of tools" to include genetic engineering technologies, as well as traditional breeding techniques, to alter living organisms for specific agricultural uses. USDA, Glossary of Agricultural Biotechnology Terms, http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&navid=AGRICULTURE&contentid=BiotechnologyGlossary.xml (last visited Feb. 19, 2008). "Genetic Engineering" is the process of manipulating "an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques." *Id.* For the purposes of this article, biotechnology refers exclusively to the process of genetic engineering. "The term *recombinant DNA* [rDNA] literally means the joining or recombining of two pieces of DNA from two different species." Biotechnology Indus. Org., The Technologies and Their Applications, http://bio.org/speeches/pubs/er/applications.asp (last visited Feb. 19, 2008). One type of organism resulting from the rDNA process is a transgenic—an organism containing genetic material from another organism. Biotechnology Indus. Org., Agricultural Production Applications, http://bio.org/speeches/pubs/er/agriculture.asp (last visited Feb. 19, 2007). "Bt crops" are one example of transgenic plants. These plants are genetically engineered to include a gene from the soil bacterium Bacillus thuringiensis (Bt). USDA, *supra*. The bacterium produces proteins toxic to some pests but not humans or other mammals. *Id.* Bt corn and Bt cotton are examples of commercially available crops containing the bacterium. *Id.*

2. Clive James, Int'l. Serv. For the Acquisition of Agri-Biotechnology Applications, Highlights of ISAAA Brief No. 35-2006, at 1, *available at* http://www.isaaa.org/resources/publications/briefs/35/highlights/pdf/Brief%2035%20-%20Highlights.pdf.

3. *Id.* The twenty-two countries with commercial biotech cultivation were split evenly between developing and industrial economies (eleven each).

4. *Id.*

for soybeans (89 percent in 2006).[5] As evidenced by the rates of adoption, farmers in the United States have embraced this technology since its commercial introduction in 1996. In marginal growing areas with variable weather and heavy pest pressures, such as in South Dakota, farmers have supported the technology with even greater vigor, with adoption rates for genetically engineered corn varieties reaching 93 percent (20 percentage points above the national average) and 97 percent for genetically engineered soybeans.[6]

Although certainly impressive statistics, especially considering that commercialization of genetically engineered crops began only in 1996, the technology is far from universal on a world scale. The 102 million hectares planted with genetically engineered crops amounts to only 7.6 percent of world cropland.[7] This is due, at least in part, to the serious debate regarding the cost-benefit calculus of agricultural biotechnology. Gordon Conway, President of the Rockefeller Foundation, outlined many of the issues surrounding this debate in an address to the Organisation for Economic Co-operation and Development (OECD), noting that the balancing of the benefits and risks of genetic engineering lies solely in the political arena.[8] Although scientists can provide evidence of the likely benefits and hazards and the probability of occurrence, "[i]n the end, politicians need to decide . . . what each country's policy should be."[9]

Many sectors of the global food/feed supply chain demand segregation of product into GM/GM-free pipelines. Success of these segregation efforts (also known as identity preservation) relies on coordinated operating procedures and marketing policies for all players in the supply chain. Failure at any stage could result in significant economic liability risks. A response to these risks is the development of a common law of agricultural biotechnology supplemented by regulatory and commercial strategies. This article examines developments in the regulatory arena and places them within the context of the common law of biotechnology.

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5. Margaret Rosso Grossman, Address at the 28th Annual Conference and Agricultural Law Symposium of the American Agricultural Law Association, *Anticipatory Nuisance and Genetically Modified Organisms* P-2-1 (Oct. 19-20, 2007); NAT'L. AGRIC. STATISTICS SERV., USDA, ACREAGE 24-25 (2007), *available at* http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0607.pdf.

6. NAT'L. AGRIC. STATISTICS SERV., *supra* note 5, at 24-25.

7. R. Lal & J.P. Bruce, *The Potential of World Cropland Soils to Sequester C and Mitigate the Greenhouse Effect*, 2 ENVTL. SCI. & POL'Y 177, 177 (1999) (noting total world cropland at 1338 million hectares).

8. Gordon Conway, President, Rockefeller Found., Crop Biotechnology: Benefits, Risks and Ownership (Mar. 28, 2000), *available at* http://www.agbioworld.org/biotech-info/articles/biotech-art/conwayspeech.html.

9. *Id.*

Part I of this article provides background on the regulatory structures in the United States to mitigate the health, safety and environmental risks of genetic engineering in the agricultural context. Part II explores segregation efforts and economic liability risks, with particular attention paid to a case study of byproducts from the corn-derived ethanol process. Part III examines the government's role in crop segregation and common law development. The article concludes with observations regarding future economic liability risks and biotechnology-related litigation.

I. BIOTECHNOLOGY REGULATORY STRUCTURES IN THE UNITED STATES

The biotechnology industry argues that biotechnology "[d]elivers significant and tangible benefits" from farm to fork.[10] Benefits from first generation genetic engineering technologies include lowering of production costs, primarily through better pest and weed control, and reduction in the toxicity of pesticides used with an accompanying environmental benefit.[11] Other agronomic advantages include yield increases for some crops due to less pest pressure.[12] Some of the human health benefits are a reduction in human poisoning among pesticide applicators and lower levels of mycotoxins caused by pest (corn borer) infestations.[13]

On the other hand, the capacity to move DNA between animals and plants "[m]ay give rise to unanticipated interactions within the genome with unknown effects."[14] One of the more important environmental risks is the transfer of genes to wild relatives.[15] This risk may be even higher in developing countries where wild relatives are more common and cultivated land is interspersed with wild.[16] Another environmental risk is the development of resistance (either to the toxin engineered into the plant or to the blanket herbicide applied as a broad

10. Biotechnology Indus. Org., Agricultural Biotechnology: Benefits Delivered, http://bio.org/foodag/background/AgBiotechBenefits.pdf (last visited Feb. 20, 2008). *See* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 1 (2004), *available at* http://www.pewtrusts.org/uploadedFiles /wwwpewtrustsorg/Reports/Food_and_Biotechnology/food_biotech_regulation_0404.pdf (listing some of the potential benefits of biotechnology).

11. Conway, *supra* note 8.

12. *See id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. *Id.*

spectrum weed control).[17] On a more human scale, risks include the development of antibiotic resistance or an increase in potential allergens.[18]

The task of balancing these benefits and risks[19] falls upon several federal agencies. As a foundation to a more in-depth discussion of economic liability implications, it is important to briefly describe the regulatory approval process for novel genetically engineered plant varieties in the United States.

A. *The Coordinated Framework*

The Coordinated Framework for Regulation of Biotechnology established a shared system of oversight between three primary federal regulatory

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17. *Id. See* Weed Resistance Risk Assessment, http://www.weedtool.com/index.html (providing an assessment to gauge the risk of developing glyphosate-resistant weeds) (last visited Feb. 20, 2008).

18. Conway, *supra* note 8.

19. For purposes of this article, discussion of risks and benefits will be confined to issues of concern to public health, safety, and the environment in the United States, rather than developing countries, where the risk-benefit calculus may be quite different. For example, the benefits for developing countries are less clear, as current investment in crops important to these populations lags despite significant NGO initiatives. Many developing countries lack the technical expertise to assess the risk-benefit calculus of novel genetically engineered varieties and subsistence farmers often are unable to afford improved seeds. *See id*. (discussing how developing countries have not yet benefited significantly from biotechnology). Ethical concerns of particular importance to the developing world include, *inter alia*, rights of the poor and excluded, and various arguments relating to sustainable versus "industrial" agriculture. Paul C. Jepson, *The Philosophical Perplexities and Ethical Enigmas of Biotechnology: An Examination of the Regulatory Process in the United States*, in BIOTECHNOLOGY: SCIENCE AND SOCIETY AT A CROSSROAD 197 (Nat'l Agric. Biotechnology Council, 2003). For example, a worst-case scenario for poor farmers caught in a biotechnology crossfire

> [w]ould be one in which technology fees were prohibitively expensive, yields were dramatically improved on farms of early adopters of new transgenic crops, and the poor were caught in a backwash of lower output prices because of increased yields on adopter-farms, but with no reduction in input costs or increases in yields on their own farms. Technical change in this scenario would accelerate agglomeration of ownership and the ruin of small farmers.

Ronald J. Herring, *Disaggregating Biotechnology and Poverty: Finding Common International Goals* in AGRICULTURAL BIOTECHNOLOGY: FINDING COMMON INTERNATIONAL GOALS 273, 283 (Nat'l Agric. Biotechnology Council, 2004). Another concern is the imposition of intellectual property-based use restrictions on farmers' traditional practices of seed saving and exchange. Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 255 (2003) (discussing Monsanto's program which resulted in seeds capable of growing only one season); *see also* Monsanto Co. v. White, No. CV03-S-2804-NE, 2006 WL 2959458 (N.D. Ala. July 5, 2006) (entering consent decree and injunction in which seed processor admitted liability for growing, saving, processing, and selling Roundup Ready soybeans in violation of a utility patent and licensing agreement).

authorities – the Environmental Protection Agency, the Food and Drug Administration, and the Department of Agriculture.[20] With respect to agricultural applications of genetic engineering, a mosaic of federal law, including the Plant Protection Act ("PPA"),[21] Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"),[22] and the Federal Food, Drug, and Cosmetic Act ("FFDCA"),[23] and the accompanying regulations and administrative policies, seek to ensure innovations are safe for the environment, safe for food and feed, and do not adversely impact agricultural production.

1. *USDA Regulatory Responsibilities*

The Animal Plant Health Inspection Service (APHIS), under authority delegated by the USDA, has primary responsibility for implementation and enforcement of the PPA. The PPA seeks to prevent the spread of disease and invasive plants by controlling plant movement within interstate and international commerce and restricting release of plant material into the environment.[24] APHIS implementing regulations consider products of genetic engineering "potential plant pests," and thus subject to regulation under the PPA.[25]

As regulated articles, APHIS assesses the safety of any field trials of novel plant varieties modified by genetic engineering.[26] Field trials may proceed in accordance with either an annual permit or a simplified "notification" procedure. Regulated articles meeting certain performance standards may proceed to the field trial stage via notification.[27] Sponsors of all other field trials must receive annual, renewable permits.[28] "Nearly 99% of all field tests, importations,

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

21. Plant Protection Act, 7 U.S.C. §§ 7701-7786 (2006).

22. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y (2006).

23. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a (2006).

24. 7 U.S.C. §§ 7701, 7711-7712.

25. 7 C.F.R. §§ 340.0(a) n.1, 340.1 (2008).

26. 7 U.S.C. § 7711(a); 7 C.F.R. § 340.0(a)(2).

27. *See* 7 C.F.R. § 340.3(b), (c) (establishing performance criteria for notification procedure—a process generally limited to plants with introduced genetic material with which APHIS has had prior experience). *See also* BIOTECHNOLOGY REGULATORY SERV., ANIMAL & PLANT HEALTH INSPECTION SERV. (APHIS), USDA, USER'S GUIDE: NOTIFICATION 3 (2008), *available at* http://www.aphis.usda.gov/brs/pdf/Notification_Guidance.pdf (explaining in user-friendly terms the notification procedures in 7 C.F.R. § 340.3).

28. *See* 7 C.F.R. § 340.3(a)-(b) (field trials of plants genetically engineered for pharmaceutical or industrial purposes require permits); Glenda D. Webber, Office of Biotechnology, Iowa State Univ., *Biotechnology Information Series: How Does the USDA Regulate Genetically Engineered Food Plants?* (1995), http://www.biotech.iastate.edu/biotech_info_series/bio11.html.

and interstate movements of GE plants are performed under the notification process . . . ."[29]

After successful field trials, developers may petition APHIS to "deregulate" a variety based upon the agency's determination that the plant is not a potential plant pest.[30] In commodity-based agriculture, deregulation is a necessary precursor to commercializing a new variety. A deregulation decision allows the seed breeder to commercialize its product without further USDA/APHIS-imposed agronomic constraints[31] and to engage in unrestricted nationwide sale, distribution and post-harvest disposition of the new plant variety.

APHIS decisions to authorize a field test or deregulate a product implicate the National Environmental Policy Act (NEPA).[32] Proposed revisions to the APHIS decision-making process under NEPA, specifically the agency's draft environmental impact statement, and NEPA-based requirements imposed by the court in *Geertson Seed Farms v. Johanns*[33] will be discussed in part III, below.[34]

2. *EPA Regulatory Responsibilities*

As part of the Coordinated Framework, the EPA, via FIFRA, exercises jurisdiction over genetically engineered DNA incorporated into plants for pesticidal properties (plant-incorporated protectants, or PIPs). In accordance with FIFRA, the EPA may register pesticides that, "[w]hen used in accordance with widespread and commonly recognized practice, will not cause (or significantly increase the risk of) unreasonable adverse effects to humans or the environment."[35] As part of its pesticide registration process, the EPA may issue Experimental Use Permits (EUP) to allow applicants to accumulate the data necessary to complete pesticide registration.[36]

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29. PEW INITIATIVE, *supra* note 10, at 32.

30. *See* 7 C.F.R. § 340.6(a) (allowing persons to petition for determination of nonregulated status of an article.).

31. *See id*. § 340.3(c) (outlining agronomic conditions to field tests. The most important condition is that the field trial is conducted in a manner such that the tested item will not persist in the environment and no offspring of the regulated item could persist in the environment.). *See also* BIOTECHNOLOGY REGULATORY SERV., *supra* note 27, at 14 (noting that other restrains may include precautions to minimize pollen movement or eliminating synchrony of the flowering cycle with sexually compatible relatives).

32. *See* 7 C.F.R. § 372.5(b) (2008) (stating that certain actions of APHIS requires environmental assessments).

33. Geertson Seed Farms v. Johanns, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007).

34. *See infra* notes 146-161 and accompanying text.

35. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,319.

36. 7 U.S.C. § 136c(a).

In addition to its pesticide registration activities, the EPA, under the authority of the FFDCA, establishes tolerances for pesticide residues in food.[37] In the alternative, the EPA may issue a tolerance exemption if there is a reasonable certainty that no harm will result from exposure to the pesticide residue.[38] Similar to the deregulation process by APHIS, the establishment of a pesticide residue tolerance (or more likely, an exemption from a tolerance) is a necessary precursor to commercialization of a new genetically engineered plant variety.

The EPA has acknowledged the possibility of PIP dispersal during field trials.[39] Small scale field trials (<10 acres) may proceed without an EUP.[40] Moreover, because the entire harvest from the field testing is destroyed, held for further testing, or fed to experimental animals, residues generally should not enter the human food supply chain and the agency need not establish a pesticide tolerance or exemption.[41] Although the EPA assumes that field trials less than ten acres have sufficient physical and biological controls (if conducted in compliance with APHIS requirements), the agency may require additional control measures and/or the developer to petition for a temporary tolerance or EUP.[42] Food containing residues that have no tolerance or no tolerance exemption, even if the residue is at a low, intermittent level, is adulterated and prohibited from movement in interstate commerce.[43] This zero tolerance approach applies even within the context of small-scale field trials.[44]

An early example of the pesticide registration/tolerance process is the StarLink Cry9C protein incorporated into corn plants for protection from the European Corn Borer and other corn pests.[45] The EPA issued an EUP authorizing use of the StarLink variety on 3,305 acres for the 1997 growing season.[46] In

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37. 21 U.S.C. § 346a(a)(1)(A).

38. *Id.* § 346a(a)(1)(B). *See* 21 U.S.C. § 346a(l)(2)(D) (for factors used in determining whether a request for an exemption should be granted). *See* 40 C.F.R. §§ 174.500-.528 (listing tolerances and exemptions from the requirement of a tolerance for residue of plant incorporated protectants in or on food commodities).

39. *See* Pesticides; Draft Guidance for Pesticide Registrants on Small-Scale Field Testing and Low-level Intermittent Presence in Food of Plant-Incorporated Protectants (PIPs), 71 Fed. Reg. 57,509, 57,509–57,510 (Sept. 29, 2006).

40. 40 C.F.R. § 172.3(c)(1) (2008).

41. EPA, Pesticide Registration (PR) Notice 2007-2: Guidance on Small-Scale Field Testing and Low-level Presence in Food of Plant-Incorporated Protectants (PIPs).

42. *Id.*

43. *Id.*

44. *Id. Compare*, *infra* Section III (APHIS's proposed approach to adventitious presence of regulated material).

45. Plant Genetic Systems Inc.; Application to Register a Pesticide Product, 62 Fed. Reg. 42,784 (Aug. 8, 1997).

46. Issuance of an Experimental Use Permit, 62 Fed. Reg. 12,185 (Mar. 14, 1997).

August 1997, the EPA announced receipt of an application to register StarLink corn under FIFRA, and the agency approved a limited registration in May of 1998.[47] The limited registration authorized cultivation on 120,000 acres.[48] However, a corresponding request for an exemption from a pesticide residue tolerance (the Cry9c protein) was only granted in part.[49] The EPA granted an exemption from the tolerance for animal feed and the byproducts of the animals (i.e., meat, milk, poultry, eggs).[50] The EPA did not grant an exemption (or otherwise set a tolerance) for direct human consumption of food products containing the StarLink Cry9c protein.[51] This partial approval or "split registration" (i.e., pesticide tolerance exemption for feed, but not food) allowed the commercialization of the variety, but required the company to ensure the harvested product did not enter the human food supply. Subsequent limited pesticide registration permits under FIFRA for the 1999 and 2000 crop years incorporated the split registration limitations, specifically requiring a 660 foot buffer zone to minimize commingling with non-StarLink varieties and directing the harvest to be used only for animal feed/non-food uses.[52] Unfortunately, the harvested StarLink corn found its way into the food supply.

A review of the lessons learned from the *StarLink* case is important to current coexistence discussions. After its problems with the StarLink variety, the EPA announced that it would no longer endorse split authorizations – all tolerances or exemptions from tolerances would have to include both food and feed.[53] Whether this policy unduly restricts innovation is an important question. On the other hand, can society risk another StarLink crisis? Or more importantly, can the corn industry (or any other commodity group) risk another StarLink scenario with the conjoined drop in prices and loss of export markets? The EPA's current precautionary approach to forego split registrations recognizes the impossibility of complete segregation in the existing commodity production/distribution system – an approach unlikely to change until the food supply chain (from farm to fork) improves its segregation capabilities.

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47. Certain Companies; Approval of Pesticide Product Registrations, 63 Fed. Reg. 43,936 (Aug. 17, 1998).

48. *Id.*

49. 40 C.F.R. § 174.517 (2007).

50. *Id.*

51. *Id.* (limiting the tolerance exemption to residues of the Cry9C protein resulting from feed use only).

52. D. L. Uchtmann, *StarLink™ – A Case Study of Agricultural Biotechnology Regulation*, 7 DRAKE J. AGRIC. L. 159, 185 (2002).

53. *Id.* at 205.

3. *FDA Regulatory Responsibilities*[54]

The FDA seeks to ensure the safe consumption of foods derived from genetically engineered crops.[55] As a baseline rule, the FFDCA prohibits the introduction of adulterated food into interstate commerce.[56] Under § 402(a)(1) of the FFDCA, a food is adulterated if it contains an added substance which may render it injurious to health.[57] Accordingly, a food produced though genetic engineering that contains a harmful or deleterious "added substance" would be adulterated and subject to enforcement actions by the FDA. This includes products with pesticide residues above the tolerance levels set by the EPA.

Similarly, section 409 of the FFDCA requires prior approval of food additives.[58] Food additives are defined as "[a]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts . . . to be safe under the conditions of its intended use."[59] At first glance, the insertion of foreign DNA into a food crop would be considered a food additive and thus subject the new biotech plant variety to the FDA's pre-market approval regimen.[60] A substance added to food, however, does not meet the legal definition of an "additive" if it is generally recognized among experts to be safe under the conditions of its intended use, also known as "GRAS."[61] The FDA's 1992 policy statement on food derived from genetically engineered plants, however, states that in most cases the substances added via genetic engineering are presumed GRAS and, thus, not subject to FDA pre-approval.[62] Although not required in light of the

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54. Because the purpose of this article is to examine the coexistence of genetically engineered plant varieties and possible economic liability risks, a complete discussion of FDA procedures for review of genetically engineered food and feed products is beyond the scope of this article. A brief outline follows, however, to complete a basic description of the Coordinated Framework. For greater insight regarding the FDA's role in the regulation of biotechnology, see Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992). *See also* FDA, GUIDANCE FOR INDUSTRY: RECOMMENDATIONS FOR THE EARLY FOOD SAFETY EVALUATION OF NEW NON-PESTICIDAL PROTEINS PRODUCED BY NEW PLANT VARIETIES INTENDED FOR FOOD USE (2006), *available at* http://www.cfsan.fda.gov/~dms/bioprgu2.html.

55. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302.

56. 21 U.S.C. § 331(a).

57. *Id.* § 342(a)(1).

58. *See id.* § 348(a) (establishing presumption that all new food additives are unsafe).

59. *Id.* § 321(s).

60. 21 C.F.R. § 170.3(e)(1), (g) (2008).

61. *See* 21 U.S.C. § 321(s) (Substances commonly used in food prior to January 1, 1958 are also presumed safe.).

62. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

1992 policy presumption of GRAS status, the FDA encourages novel plant developers to consult with the agency prior to introducing any new product to market.[63] The agency will not formally affirm the GRAS status or safety of the novel protein, but will simply issue a letter indicating that FDA has no further questions based on the data submitted by the petitioner.[64]

B. *State and Local Efforts at Biotechnology Regulations*

States play a relatively minor role in overseeing the introduction of genetically engineered plants. For several years, the Pew Initiative on Food and Biotechnology tracked proposed state legislation regarding plant genetic engineering.[65] Although legislators introduced a plethora of bills on a variety of biotech-related subjects, relatively few have passed. Of those bills actually enacted, the vast majority are preemptive in nature and designed to prohibit local regulation of biotechnology.[66]

Although preemptive legislation has been introduced repeatedly (and unsuccessfully) in California, the state remains the only jurisdiction to have county-level measures prohibiting the cultivation of genetically modified plants.[67] Minnesota does not prohibit the cultivation of genetically engineered plants, but has a unique requirement for plant developers to obtain a permit before initial introduction of novel varieties.[68] Two states, California and Arkansas, have established licensing boards to oversee the introduction of new rice varieties with potential "characteristics of commercial impact."[69] The most common "characteristic" with potential marketability concerns is genetic modification – as witnessed by the recent commingling of LibertyLink rice in export shipments.[70] Rice licensing boards established in California and Arkansas must approve the introduction of

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63. Guidance for Industry; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, 71 Fed. Reg. 35,688 (June 21, 200). *See* PEW INITIATIVE, *supra* note 10, at 89.

64. *See* Guidance for Industry, *supra* note 63.

65. *See* Pew Initiative on Food & Biotechnology, Legislative Tracker 2006, *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Legislative_Tracker.pdf (providing status update of proposed bills).

66. *See* A. Bryan Endres, *Coexistence Strategies in a Biotech World: Exploring Statutory Grower Protections*, 13 MO. ENVTL. L. & POL'Y REV. 206, 234-39 (2006) (providing a summary of state preemptive legislation).

67. *Id.* at 218-19.

68. MINN. STAT. § 18F.07(1) (2007).

69. CAL. FOOD & AGRIC. CODE § 55040(a) (2008); ARK. CODE ANN. § 2-15-204(b)(1) (2007).

70. *See* A. Bryan Endres & Justin G. Gardner, *Coexistence Failures and Damage Control: An Initial Look at Genetically Engineered Rice*, AGRIC. L. (Ill. Bar Ass'n), Nov. 2006, at 1.

new varieties before cultivation within their respective states and may impose restrictions on the growing, harvesting, transporting, processing or otherwise handling of the varieties.[71] Similar state commissions exist in Washington and Idaho to ensure segregation of rape seed (canola) varieties.[72]

A third, and thus far singular, approach to local biotechnology regulation is Missouri's enactment of voluntary grower districts.[73] The statute allows landowners to establish segregated districts for production of any agricultural crop raised for food, feed, industrial, or pharmaceutical uses, including organic, conventional, and genetically engineered varieties.[74] As of this writing, however, the author is not aware of landowners establishing a district for any purpose.

In 2006, the National Association of State Directors of Agriculture and the Pew Initiative on Food and Biotechnology co-hosted a discussion of possible regulatory measures states could take to facilitate peaceful coexistence between producers of genetically engineered, conventional, and organic crops.[75] In a separate workshop, the Pew Foundation explored the interactions between APHIS and state biotechnology regulatory authorities – specifically the consequences of APHIS's redaction of confidential business information from field trial permit requests.[76] Although states may have substantial flexibility under existing federal rules to regulate agricultural biotechnology,[77] limited resources, technical capacity, and politics have thus far and for the foreseeable future, foreclosed additional state regulatory activity in this field. Consequently, biotech regulation is almost exclusively a matter of federal oversight.

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71. *See* Endres, *supra* note 66, at 222-24, Appendix A (describing the duties and authority of rice licensing boards).

72. *See* WASH. ADMIN. CODE 16-570-020 (2008); IDAHO ADMIN. CODE r. 02.06.13.050 (2008); *see also* Endres, *supra* note 66 at 215-17, Appendix A (providing a more extensive discussion of rape seed grower districts).

73. MO. REV. STAT. §§ 261.256, 261.259 (2007).

74. *Id.* § 261.256.

75. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, PEACEFUL COEXISTENCE AMONG GROWERS OF GENETICALLY ENGINEERED, CONVENTIONAL AND ORGANIC CROPS (2006), *available at* http://www.pewtrusts.org/our_work_ektid18004.aspx.

76. *See* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, OPPORTUNITIES AND CHALLENGES: STATES AND THE FEDERAL COORDINATED FRAMEWORK GOVERNING AGRICULTURAL BIOTECHNOLOGY (2006), *available at* http://pewagbiotech.org/events/0524/WorkshopReport.pdf; *see supra* notes 24-34 and accompanying text.

77. *See* 7 U.S.C. § 7756 (2006) (preserving right of states to regulate plant health issues that are consistent with and not in excess of APHIS requirements).

II. THIRD GENERATION COEXISTENCE AND ECONOMIC LIABILITY RISKS

Initial concepts of coexistence referred to "[t]he ability of farmers to make a practical choice between conventional, organic and GM-crop production, in compliance with the legal obligations for labeling and/or purity standards."[78] Because farmers only cultivated varieties that had cleared all regulatory requirements for safety, the emphasis on crop segregation was a market-based response to downstream demand for GM-free food and feed, rather than a government mandate directed to crop purity. As genetic engineering technologies progressed into modification of plant varieties for industrial or pharmaceutical raw materials, health and safety concerns entered the coexistence debate, along with government imposed segregation practices – the second generation of coexistence.

The asynchronous[79] approval of new crop varieties creates a third iteration of coexistence – domestic-use-only segregation. Although used extensively in the United States, the rest of the world has not universally adopted genetic engineering technologies.[80] In addition to specific sectors of the food/feed supply chain that demand segregation into GM/GM-free pipelines, many nations with a history of GM acceptance/consumption often lag behind the United States in approving new varieties, creating a gap between U.S. commercialization and export market acceptance.

Unlike first- and second-generation coexistence, domestic-use-only segregation is not merely an issue of on-farm measures (e.g., seed testing, buffer zones, equipment cleaning, and transportation segregation). The value chain of many agricultural products extends beyond initial processing and requires segregation measures at each stage. Upon first inspection, this is similar to identity preservation measures employed for a multitude of agricultural products such as organic food or low linoleic soybeans (e.g., Vistive Low-Lin soy oil). Supply chain participants adopt identity preservation strategies to capture the price premiums associated with specialty products. It is on this point where domestic-use-only segregation diverges sharply from earlier coexistence concepts. Crops requiring domestic-use-only segregation do not possess the price premium found

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78. Commission Recommendation No. 556/03, O.J. L 189/36, 39 (2003).

79. In the international context, some observers object to the term "asynchronous" as the term implies that the genetic engineering event in question would later be authorized by both the exporting and importing countries. Perhaps a more accurate term may be "asymmetric" authorizations. Codex Alimentarius Comm'n, *Report of the Sixth Session of the Codex* ad hoc *Intergovernmental Task Force on Foods Derived from Biotechnology*, ALINORM 07/30/34 (2006), at 9, *available at* http://www.codexalimentarius.net/download/report/653/al29_34e.pdf. Although technically incorrect, this paper will use the term "asynchronous" to indicate pending petitions that may or may not be actually approved.

80. *See supra* notes 7-9 and accompanying text.

with specialty products, but rather are "commodity" goods with attendant commodity-level prices. As such, there are no price premiums attached to asynchronously approved varieties to offset the necessary segregation costs – only potential liabilities.

A. *Third Generation Coexistence Liabilities – The DDGS Example*

Corn-derived ethanol is an excellent example of the 3rd generation, multi-stage coexistence efforts required under conditions of asynchronous novel variety approval. A seemingly simple solution to the problem of an unapproved-for-export corn variety (i.e., unapproved in major corn export markets) would be to direct the harvest to a domestic ethanol plant. This apparent solution, however, fails to consider the complete supply chain, specifically the by-products of ethanol production.

Distillers dried grains and solubles (DDGS) are one of the by-products of the ethanol conversion process and an important element in the profit potential of the refinery.[81] DDGS are exported worldwide as a feed product, with projected exports to reach three to four million tons in the next few years.[82]

> In ethanol production, the starch is fermented to obtain ethyl alcohol, but the remaining components of the grain kernel (endosperm, germ), preserve much of the original nutritional value of the grain, including energy, protein and phosphorous. Drymill [ethanol] plants recover and recombine these components into a variety of animal feed ingredients.[83]

As a corn-derived product, DDGS retains the DNA of the particular corn variety, and therefore must be "approved" for import by the receiving country. Accordingly, an unapproved export variety of corn initially directed to a domestic ethanol plant may, in its DDGS form, eventually work its way into the export market. A "positive" test for an unapproved variety at the export destination would send shockwaves through the commodity DDGS market, endanger future exports, and impact the profitability of drymill ethanol refining.

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81. Vijay Singh et al., *Comparison of Modified Dry-Grind Corn Processes for Fermentation Characteristics and DDGS Composition*, 82 CEREAL CHEM. 187, 187 (2005); U.S. GRAINS COUNCIL, DDGS USER HANDBOOK: ETHANOL PRODUCTION AND ITS CO-PRODUCTS 4, *available at* http://www.grains.org/page.ww?section=DDGS+User+Handbook&name=DDGS+ User+Handbook.

82. U.S. Grains Council, *DDGS Conference to Connect Buyers, Sellers*, GRAIN NEWS, July 2007, at 3.

83. U.S. GRAINS COUNCIL, DDGS USER HANDBOOK: A GUIDE TO DISTILLER'S DRIED GRAINS WITH SOLUBLES (DDGS) 1, *available at* http://www.grains.org/galleries/DDGS%20User%20Handbook/01%20-%20Introduction.ERE%20draft.pdf.

1. *Dodging the Agrisure Bullet*

In early 2007, Syngenta released for commercial cultivation its Agrisure RW MIR 604 genetically engineered corn designed to control corn rootworm pests.[84] Although approved (deregulated) for all domestic uses (food and feed),[85] Syngenta had not yet secured approval for the variety in Japan (the largest export market for DDGS).[86] In anticipation of the asynchronous approval, Syngenta required farmers to sign a "comprehensive grain use/marketing commitment" before purchasing its Agrisure seed.[87] Under the agreement, farmers pledged to deliver the harvested grain only to non-export locations.[88]

The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) condemned Syngenta's plan to commercialize the variety before full export market approval as "ill-conceived" as it put at risk the Nation's corn and corn product exports.[89] NGFA and NAEGA characterized Syngenta's belief that it could channel 100% of the Agrisure harvest away from export markets as "misguided and naïve," noting that it is "[i]mpossible to completely segregate this specific biotech variety from the rest of the commodity stream because of pollen drift, inadvertent commingling and human error."[90] To underscore the seriousness of liability concerns in the transport industry resulting from inadvertent admixture, BNSF announced that it would not transport any products containing the Agrisure variety, and that customers shipping a product containing Agrisure would be responsible for any resultant liability.[91]

Although farmers may have been aware of the marketing restrictions on their individual Agrisure harvests, a drymill ethanol plant would have other priorities. Plants would either incur a tremendous segregation burden to ensure Agri-

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84. Gill Gullickson, *Why Syngenta Marketed Agrisure RW Corn*, AGRIC. ONLINE, May 22, 2007, http://www.agriculture.com/ag/story.jhtml?storyid=/templatedata/ag/story/data/1179855939995.xml.

85. *See* APHIS, USDA, Petition for Non-regulated Status for Corn Line MIR604, Finding of No Significant Impact 1 (2007), *available at* http://www.aphis.usda.gov/brs/aphisdocs2/04_36201p_com.pdf (granting the petition as a whole upon finding the quality of human environment will not be significantly impacted).

86. Gullickson, *supra* note 84.

87. *Grain Industry Urges Sygenta to Reconsider Plan to Commercialize Biotech Corn Seed Not Approved in Export Markets*, GRAIN JOURNAL, April 4, 2007, *available at* http://www.grainnet.com/info/articles_print.html?ID=43164 (hereinafter *Grain Industry*).

88. *Id.*

89. *Id.*

90. *Id.*

91. USDA, *Grain Transportation Report* (May 3, 2007) 1, *available at* http://www.ams.usda.gov/tmdtsb/grain/2007/05-03-07.pdf.

sure-based DDGS remained out of export or, more likely, forego completely the export market and any potential added value. Failure to segregate while remaining active in the export market could have drastic results. Bob Dineen, president of the National Renewable Fuels Association, warned that "[d]iscovery of unapproved GMO content in DDGS could 'permanently damage the U.S. ethanol industry's relationship with these important markets.'"[92]

2. *Strategy Implications*

Although the Agrisure variety eventually received approval in many export markets,[93] thereby averting a potential trade disaster, the concerns raised in the discussion above will apply to each new genetically engineered commodity crop (cotton, soy, corn and rape seed) prior to approval in the major export markets. Moreover, genetically engineered transformations of heretofore traditionally-bred commodity crops such as alfalfa, rice and wheat – many of which are used directly as human food in their unprocessed form rather than as animal feed or processed into items such as soy sauce or high fructose corn syrup – present critical asynchronous approval concerns. Foreign government regulatory review and approval of these direct food products may be more difficult, politically charged and time consuming, and thus lead to larger gaps between domestic commercialization and export approval. Accordingly, participants in the domestic sector of the world food and feed supply chain, from the seed breeder to the processor (including co-product generators) to the export elevator, must acknowledge the legal situation and adjust their strategy to the account for the major world export markets. Moreover, most export markets require "ironclad guarantees" for unapproved biotech traits as most governments (including the United States) impose a zero-tolerance policy on unapproved genetically engineered events.[94]

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92. Martin Ross, *Growers Should Reconfirm Agrisure RW Buyers*, FARMWEEK, Aug. 1, 2007, *available at* http://farmweek.ilfb.org/viewdocument.asp?did=10584.

93. On August 23, 2007, at the start of the corn harvest, Japan approved the Argrisure variety for food and feed use, thus averting a potential disaster. *See Syngenta's Agrisure RW Corn Rootworm Trait Obtains Full Regulatory Approval in Japan*, GRAIN JOURNAL, Aug. 23, 2007, *available at* http://www.grainnet.com/info/articles_print.html?ID=47535 (In addition to Japan, Agrisure received approval for cultivation in Canada and for importation to Australia and New Zealand.).

94. *Grain Industry*, *supra* note 87.

B. *Industry Coexistence Initiatives*

Recognizing the negative implications of an unapproved-for-export variety on the agricultural industry, the Biotechnology Industry Organization (BIO) recently adopted an export stewardship policy for commercialization of new genetically engineered varieties.[95] In an attempt to avoid a realization of the risk presented by future Agrisure-type product launches arising from the various government stances on GM thresholds and asynchronous approvals of new genetic events, the non-binding policy requests companies to: (1) conduct a market and trade assessment to identify key product-specific import markets and (2) receive regulatory approval in those key markets prior to commercialization of a new biotechnology product.[96] Default essential markets for commercialization include the United States, Canada, Japan, and Mexico (once it develops over time a record of systematic authorizations with defined timelines and processes).[97] The policy states that developers should determine other key markets on a crop-by-crop basis.[98] As a voluntary program (due to antitrust issues), it remains to be seen whether pressures for immediate return on investment at the individual company level will override the potential commercialization delay of a growing season (or more) while waiting for total alignment of export market approvals. Failure to wait, however, may trigger litigation under the anticipatory nuisance doctrine.[99]

Any effective export approval policy depends on agronomic best practices on the domestic side to confront the vagaries of agricultural production. It is extremely difficult to segregate a specific genetically engineered variety from the rest of the commodity market at the 100% level due to seed impurity, pollen drift, inadvertent commingling during planting, harvest or transportation, and human error.[100] In 2003, James Riddle, a member of the National Organic Standards Board and holder of the Endowed Chair in Agricultural Systems at the University of Minnesota, outlined twelve best management practices for the coexistence of GM and non-GM crop production.[101] In July 2007, BIO an-

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95. Biotechnology Indus. Org., *Product Launch Stewardship Policy* (May 21, 2007), *available at* http://www.bio.org/foodag/stewardship/20070521.asp.

96. *Id.*

97. *Id.*

98. *Id.*

99. *See* Grossman, *supra* note 5, at P-2-6 to P-2-7 (stating that the anticipatory nuisance doctrine may be triggered to prevent future harm from a proposed activity).

100. James A. Riddle, A Plan for Co-Existence: Best Management Practices for Producers of GMO and Non-GMO Crops 1, *available at* http://www.wkkf.org/pubs/foodRur/Biotech BMPs03.final_00253_03862.pdf.

101. *Id.*

nounced the creation of a similar program for coexistence – "Excellence Through Stewardship."[102] The BIO initiative will attempt to ensure the smooth flow of goods in various supply chains by providing industry guidelines for the adoption of best quality management principles and management practices, as well as third-party audits of firm-level performance.[103] Whether the industry-derived "best practices" will give adequate consideration to non-GM growers/market concerns or "[i]s designed to make people feel good about the industry and not actually protect farmers and consumers" remains to be seen.[104] Achieving consensus, however, on coexistence best practices may be difficult. Brad Brummond from North Dakota State University, funded by a USDA-SARE grant, attempted to develop best management practices via a consensus process in 2003.[105] Unfortunately, the consensus process failed once the participants attempted to discuss some of the more decisive issues such as liability.[106]

C. *Economic Liability Risks*

"Risk is costless – liability is not."[107] "Risk is the probabilistic likelihood of an unplanned, undesired or unwanted event actually happening."[108] Once a risk is actualized, it is no longer a risk, but rather a liability.[109] "The biological conditions of plant breeding . . . are such that there is a potential for low levels of genes and gene products to occasionally move beyond confined research sites into commercial seeds and grain that enter commerce."[110] This risk of genetic movement engenders downstream economic risks. Who pays for the actualized risk (the liability) is at the heart of the ongoing coexistence debate.[111]

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102. Press Release, Excellence Through Stewardship, BIO Launches Excellence Through Stewardship[SM] Program (July 23, 2007), http://www.excellencethroughstewardship.org/press.

103. *Id.*

104. Carey Gillam, UPDATE 1-*Biotech Crop Sector Sets Standards, Seeks to Ease Fears*, REUTERS, July 25, 2007, http://www.reuters.com/article/governmentFilingsNews/idUSN2535513320070725.

105. N.D. State Univ. Extension, Suggested Best Management Practices for the Coexistence of Organic, Biotech and Conventional Crop Production Systems (Dec. 2003), *available at* http://www.ag.ndsu.edu/pubs/plantsci/crops/a1275w.htm.

106. *Id*.

107. STUART SMYTH ET AL., REGULATING THE LIABILITIES OF AGRICULTURAL BIOTECHNOLOGY 9 (2004).

108. *Id.*

109. *Id.*

110. APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials, 72 Fed. Reg. 14,649, 14,650 (Mar. 29, 2007) (to be codified at 7 C.F.R. pt. 340).

111. *Id.*

1. *Farmers' Assumption of Risk from Planting to Market*

The presence of unapproved varieties (whether unapproved in export markets or restricted in all jurisdictions in the case of an experimental crop) commingled within commercial grain shipments, presents an important and sometimes realized economic risk. To the extent possible, firms throughout the food/feed supply chain have adjusted their actions to shift potential liability arising from coexistence failures onto others, usually the entity with the least bargaining power. For example, in order to minimize risk, seed developers expressly disclaim responsibility for the adventitious presence of any genetically engineered seed.[112]

On the harvest end, the farmer must market the grain to an elevator that most likely will conduct some form of product testing and may hold the farmer responsible for products commingled with unapproved (or undisclosed) genetically engineered DNA. As noted above, adventitious presence results from a variety of circumstances beyond seed impurity – pollen drift, transport in containers with residue, etc. The farmer, therefore, assumes the risk of adventitious presence at both ends of the crop production cycle. The enforceability, however, of seed warranty disclaimer provisions is doubtful in those situations in which the seed company has a better understanding of potential purity problems but fails to disclose the risk. The ongoing litigation regarding the adventitious presence of LibertyLink LL601 genetically engineered rice is a current example.

2. *LibertyLink LL601 Rice Contamination*

> In December of 1998, Aventis CropScience (Aventis) began field testing the LLRice 601 variety at a University of Puerto Rico field station. Aventis conducted subsequent experiments in Louisiana, Mississippi, Arkansas and Texas. It did not seek regulatory approval for the commercial release of LLRice601, but did obtain approval from USDA/APHIS for two nearly-identical genetic modification events, LLRice06 and LLRice62.[113]

All three genetically modified rice varieties are resistant to Aventis' glufosinate ("Liberty") herbicide. As field trials concluded, Bayer purchased Aven-

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112. *See* Int'l Seed Fed'n, Model for Conditions of Sale Applicable to Seed Lots (2002), http://www.worldseed.org/en-us/international_seed/on_trade.html (click on "Model for Conditions of Sale Applicable to Seed Lots" under 2002) (model document disclaiming liability).

113. A. Bryan Endres & Justin G. Gardner, *Genetically Engineered Rice: A Summary of the LL Rice 601 Incident*, AGRIC. L. & TAXATION BRIEFS, Dec. 6, 2006, at 2, *available at* http://www.farmdoc.uiuc.edu/legal/articles/ALTBs/ALTB_06-04/ALTB_06-04.pdf.

tis CropScience, forming Bayer CropScience. Bayer did not petition USDA for deregulation of LLRice601.[114]

In January of 2006, Riceland, the Nation's largest rice cooperative, discovered trace amounts of genetically engineered DNA in the 2005 Midwest long-grain rice crop. According to Bill Reed, Riceland Vice President of Public Affairs, the company initially believed that the genetically engineered material was from "[r]esidual fragments of genetically engineered corn or soybeans resulting from use of common public transportation systems."[115] Because the genetically engineered material was present in such small quantities, a lab was unable to determine its origin. Riceland collected additional samples in May, and "[a] significant number tested positive for the Bayer trait."[116] Bayer confirmed that the genetically engineered material was LLRice601.[117] As of this writing, LLRice601 has not been found in California, which primarily grows short and medium-grain rice.

The USDA learned of the incident on July 31, 2006. On August 18, 2006, after conducting a safety review and approving a method to test for LLRice601, the Agency publicly announced the presence of genetically engineered rice in the food supply.[118] Based on Bayer's assertion of similarity to the previously deregulated LLRice06 and LLRice62, the USDA approved Bayer's petition for non-regulation of LLRice601.[119] Despite an extensive investigation, the USDA was unable to determine the source of the commingling and declined any regulatory enforcement action against Bayer.[120]

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114. *Id.*

115. Bill J. Reed, Vice President for Pub. Affairs, Riceland Foods, Inc., Statement Regarding Genetically Engineered Material in Rice (Aug. 18, 2006), *available at* http://www.riceland.com/about/ge_docs/Statement%20Regarding%20Material%20in%20Rice%20Updated.pdf.

116. *Id.*

117. *Id.*

118. Press Release, USDA, Fact Sheet: Genetically Engineered Rice (Aug. 2006), http://www.usda.gov/wps/portal/usdahome?contentidonly=tru&contentid=2006/08/0 306.xml.

119. *See* Bayer CropScience; Availability of an Environmental Assessment and a Preliminary Decision for an Extension of a Determination of Nonregulated Status for Rice Genetically Engineered for Glufosinate Herbicide Tolerance, 71 Fed. Reg. 53,076, 53,077 (Sept. 8, 2006) (concluding that a preliminary decision was reached that LLRice601 should be no longer be regulated).

120. USDA, REPORT OF LIBERTYLINK RICE INCIDENTS 1, 5-6 (2007), *available at* http://www.aphis.usda.gov/newsroom/content/2007/10/content/index.shtml (click on report dated Oct. 4, 2007) (noting that after discovery of the LLRice601 contamination, the USA Rice Federation commenced a seed-testing program for other GM contamination. The Arkansas State Plant Board notified USDA that up to thirty percent of the 2006 certified rice samples of CL131 – a long grain rice variety – tested positive for the same genetically engineered gene at the 601 rice. Subsequently identified as LLRice604, only three acres (by a single producer) were planted due to the early identification and response by APHIS. Although the crop was destroyed without incident, APHIS was unable to determine the cause of the contamination.).

Immediately following the USDA's August 2006 commingling announcement, Japan banned long-grain rice imports from the United States, and the European Union implemented a testing regime for all rice from the United States.[121] Within days, the first lawsuits by farmers were filed against Bayer and Riceland. On December 19, 2006, the Judicial Panel of Multi-District Litigation transferred thirteen of the pending LLRice601 actions to the Eastern District of Missouri in St. Louis.[122] The court noted the filing of twenty-one other "tag along" actions not consolidated with the original thirteen, which presumably seek recovery for the price impacts attributable to lost exports.[123] In addition, a German food processing firm, Rickmers, filed a breach of contract action against Riceland for the delivery of rice in 2005 and 2006 that contained GM material (an alleged non-conforming good).[124]

3. *LibertyLink in Light of the StarLink Precedent*

In re StarLink Corn Products Liability Litigation,[125] the underlying facts of which were discussed in section I.A.2., *supra*, provides potential precedent for tort causes of action applicable in the rice litigation. In ruling on the crop developer's (Aventis) motion to dismiss, the *StarLink* court held that the plaintiffs adequately alleged that Aventis had a duty to ensure the variety did not enter the human food supply (i.e., a regulatory duty to abide by EPA's permit restrictions) and that Aventis breached this duty, which caused contamination of plaintiffs' corn.[126]

Many of the complaints in the rice litigation allege a similar duty-breach-causation fact pattern. For example, plaintiffs in the now consolidated GeeRidge Farms suit allege that Bayer had a regulatory duty (Count I) as well a general duty (Count II) to test, grow, store, transport, and dispose of the LLRice601 variety in a manner that would not result in contamination of the rice market.[127]

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121. Rick Weiss, *Gene-Altered Profit-Killer*, WASH. POST, Sept. 21, 2006, at D01.

122. Transfer Order, In re LLRice601 Contamination Litigation, No. 1811 (E.D. Mo. Dec. 19, 2006).

123. *Id.*

124. Complaint at 7, Rickmers Reismüehle GmbH v. Riceland Foods, Inc., No. 4-07-CV00000733-JMM (E.D. Ark. Aug. 21, 2007).

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

126. *Id.* at 843.

127. Complaint at 18-19, Geeridge Farms, Inc. v. Bayer CropScience L.P., No. 4-06-CV-01079GH (E.D. Ark. Aug. 28, 2006); *see also* Complaint at 68-69, 72, Bell v. Bayer CropScience L.P., No. 1:06-CV-00128-RWS (E.D. Mo. Sept. 13, 2006).

Plaintiffs allege that Bayer breached those duties by failing to adequately oversee or control its field test growers, directly resulting in damages to plaintiffs.[128]

In *StarLink*, the court identified four possible stages in which the variety could have entered the human food supply chain and caused harm: (1) farmers unknowingly purchased seed containing traces of the StarLink variety; (2) pollen drift; (3) post-harvest commingling during transportation or storage; and (4) commingling during food processing.[129] The economic loss doctrine, as generally understood in the law and economics literature, states that a plaintiff cannot recover damages for a pure financial loss; physical injury is a necessary prerequisite to maintaining an action in tort.[130] Accordingly, the economic loss doctrine foreclosed tort recovery for those farmers suffering a financial loss as a result of unknowingly purchasing seed contaminated with the StarLink variety.[131] In contrast to those farmers suffering a physical injury to crops via pollen drift or post-harvest commingling, farmers purchasing contaminated seed could have, but failed to negotiate, contractual protection from seed contamination from their suppliers.[132]

With respect to the rice litigation, the USDA investigation found LLRice601 contamination only in 2003 Cheniere rice variety foundation seeds. All seven of the samples tested positive, thereby possibly placing farmers who planted a variety derived from the 2003 Cheniere foundation seed within the first category of harms under the *StarLink* precedent and barring tort recovery under the economic loss doctrine.[133] On the other hand, farmers planting other varieties could recover if they alleged harm via pollen drift or post-harvest commingling. Of course, at this early stage in the litigation, without all of the facts, these conclusions are mere speculation. Moreover, those farmers seemingly barred for failing to negotiate a warranty for seed contamination may be able to defend their failure to negotiate under the doctrine of unconscionable adhesion contracts,[134] or assert other causes of action, especially if the seed seller had knowledge of the possible seed impurity and failed to disclose that material fact.

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128. Complaint at 1, Lonnie Parson v. Bayer CropScience US, No. 4-06-CV-01078JLH (E.D. Ark. Aug. 28, 2006).

129. In re StarLink, 212 F. Supp. 2d at 841-42.

130. Francesco Parisi et al., *The Comparative Law and Economics of Pure Economic Loss* 1 (Univ. of Minn. Law School, Legal Studies Research Paper No. 07-18), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=742104.

131. *In re StarLink*, 212 F. Supp. 2d at 842.

132. *Id.*

133. USDA, *supra* note 120, at 4.

134. *See* U.C.C. § 2-302 (2003); *see also* Monsanto Co. v. McFarling, 302 F.3d 1291, 1300-01 (5th Cir. 2002) (Clevenger, J., dissenting) (noting adhesion aspects of Roundup Ready soybean licensing/purchase agreements).

4. *Federal Lessons Learned from LibertyLink*

The USDA's investigation of GM rice contamination revealed several gaps in the regulatory process, especially with respect to the government's ability to audit compliance with field testing protocols. As a result, APHIS compiled a list of lessons learned and considerations to enhance the regulatory framework.[135] First, the agency noted the need to improve the quality and completeness of field testing records.[136] Current regulations do not require record retention, making tracking of field tests, especially field trials proceeding via streamlined notification procedures as opposed to permits, exceedingly difficult.[137] Requiring preservation of seed samples would also facilitate investigations. APHIS, however, lacks authority to subpoena items other than documents, and the voluntary submission of seed samples results in unacceptable delays to the investigation.[138] The deficiencies indicate a broader problem of maintaining identity, control, and responsibility for corrective actions in the event of an unauthorized release.[139] Furthermore, many researchers or developers were unclear about responsibilities in the event of an unauthorized release.[140] To correct this problem, APHIS is considering the following requirements: (1) contingency plans as a part of all permit applications; (2) gene-specific testing procedures to identify regulated articles in the event of unauthorized releases; (3) maintenance of samples for use as positive control for a designated time; and (4) comprehensive, written corrective action plans with all applications.[141]

Other issues under APHIS review include contractual relationships and the use of the latest science in field testing.[142] APHIS found its investigation into the rice incident hindered by incomplete access to agreements among researchers – some of which were oral, had expired, or did not contain adequate information to conduct an investigation.[143] In the future, APHIS may require certain agreements among genetic engineering researchers or developers to be in writing and

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135. USDA, LESSONS LEARNED AND REVISIONS UNDER CONSIDERATION FOR APHIS'S BIOTECHNOLOGY FRAMEWORK 1 (2007), http://www.aphis.usda.gov/newsroom/content/2007/10/index.shtml (follow lessons learned link under Oct. 4, 2007).

136. *Id.*

137. *Id.*

138. *Id.*

139. *Id.* at 2.

140. *Id.*

141. *Id.*

142. *Id.* at 3.

143. *Id.*

retained.[144] In addition, APHIS pledged to monitor peer reviewed scientific information to ensure the latest science is incorporated into isolation distances.[145]

The Agrisure and LibertyLink controversies demonstrate lingering post-Starlink coexistence concerns. APHIS proposals to strengthen field testing controls is an important first step, but falls far short of eliminating the substantial risk of coexistence failures. Two non-exclusive options remain – further regulatory revision and common law gap filing – both of which will challenge the commodity agricultural community's current coexistence methods.

III. THE FUTURE OF COEXISTENCE: AN EXPANDED GOVERNMENT ROLE OR COMMON LAW DEVELOPMENT TO FILL THE VOID?

In contrast to European Union member states' direct (and mandatory) role in facilitating coexistence,[146] early efforts in the U.S. relegated coexistence concerns to individual market-based transactions rather than a concerted government policy. This laissez faire approach to coexistence can be traced as far back as the underlying assumptions found in the 1986 Coordinated Framework for the Regulation of Biotechnology.[147] By conceptualizing the products of genetic engineering as "substantially equivalent" to conventional counterparts,[148] the government could not justify (or simply was not interested in) a simultaneous initiative to encourage, much less require, the segregation of these novel products. Rather, the market-based assumptions so characteristic of the Reagan administration would determine coexistence efforts.[149]

Even after the StarLink debacle, federal abstinence from the coexistence debate persists. APHIS continues to advocate its position that coexistence is a matter best left for the market to resolve. For example, in its Response to Comments on Petition 04-110-01p for the Determination of Non-regulated Status for

144. *Id.* at 2-3.

145. *Id.* at 3.

146. Commission Recommendation, *supra* note 78, at 40.

147. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–23,303.

148. *See* COUNCIL FOR BIOTECHNOLOGY INFO., SUBSTANTIAL EQUIVALENCE IN FOOD SAFETY ASSESSMENT 1 (2001), *available at* http://www.whybiotech.com/html/pdf/Substantial_Equivalence.pdf.

149. *See* David L. Pelletier, *FDA's Regulation of Genetically Engineered Foods: Scientific, Legal and Political Dimensions*, 31 FOOD POL'Y 570, 575-79 (2006) (discussing the development of biotechnology regulation within the context of the Reagan administration's movement toward reduced regulation of industry).

Roundup Ready® Alfalfa Events J101 and J163,[150] APHIS reiterated its position that the role of the agency is

> [t]o provide regulatory oversight that allows for the safe development and use of genetically engineered organisms. Once a new biotech variety has been granted non-regulated status by APHIS, any decisions to produce or market that product are made by the technology providers and producers and are driven by market demand.[151]

With respect to the potential impact of pollen drift, APHIS acknowledged evidence of alfalfa pollen presence as far as two miles from the source.[152] Despite this documentation, the agency stated that "[i]solation distances are not required for genetically engineered 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."[153]

Safety is clearly the sole consideration of the regulatory agencies. In its finding of no significant impact in the Agrisure case, APHIS stated that its

> [b]iotechnology regulations are pursuant to the Plant Protection Act (PPA), which is a safety statute intended to protect plant health in the U.S. As long as [the variety] is a regulated article under APHIS regulations (7 CFR Part 340), it is subject to the provisions of the regulation under the PPA, which is not a marketing statute . . . . 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.[154]

It is the responsibility of the individual desiring a GM-free crop (or a crop free of unapproved-for-export varieties) to independently develop and maintain production systems to avoid cross pollination from neighboring operations.[155] Moreover, procedures to avoid economic or liability concerns arising from cross pollination are the sole responsibility of the individual operators, without government assistance or oversight.[156]

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150. APHIS, USDA, RETURN TO REGULATED STATUS OF ALFALFA GENETICALLY ENGINEERED FOR TOLERANCE TO THE HERBICIDE GLYPHOSPHATE 1 (2005), *available at* http://www.aphis.usda.gov/brs/aphisdocs2/04_11001p_com.pdf.

151. *Id.*

152. *Id.* at 2.

153. *Id.*

154. 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_36201p_com.pdf.

155. APHIS, *supra* note 150, at 2.

156. *Id.* at 5.

APHIS's filings in the *Geertson* case, discussed below, support the conclusion that the federal government is not interested in playing a major role in coexistence. The agency argued in *Geertson* that:

> [e]ven if the deregulation of Roundup Ready alfalfa could result in the elimination of all non-genetically engineered alfalfa—in other words, there would be no alfalfa grown in the United States that does not contain the engineered gene . . .such a result would still not constitute a significant environmental impact because [the agency] has determined that the introduction of that gene to alfalfa is harmless to humans and livestock . . . In sum, . . . 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.[157]

Perhaps the exception that proves the rule regarding coexistence is the EPA's decision to end split authorizations for food-versus-feed uses for new genetically engineered varieties. EPA originally approved a pesticide residue tolerance for StarLink corn for animal feed and the animal's byproducts, but not for direct consumption as food.[158] In light of the extreme difficulty of achieving complete segregation in the commodity corn market, EPA announced that it would no longer endorse split authorizations – all pesticide residue tolerances (or exemptions) would have to cover both food and feed.[159] Of course, the rationale for the elimination of split pesticide approvals is based on human safety considerations rather than coexistence standards.[160] Even the EPA's refuge requirements for certain plant-incorporated protectants are designed for pest resistance measures to enhance the long-term efficacy of the genetic technology, not coexistence.[161]

In the global world of agricultural trade, characterized by asynchronous product approvals and economic liability risks, governments, however, are often in the best position to endorse some low-cost measures to facilitate supply chain segregation—an action the federal government in the near future will be forced to consider as a result of the *Geertson* litigation, discussed below.

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157. *Geertson Seed Farms*, 2007 WL 518624, at *8.

158. 40 C.F.R. § 174.517 (2007).

159. *See generally* APHIS, USDA, DRAFT GUIDANCE FOR APHIS PERMITS FOR FIELD TESTING OR MOVEMENT OF ORGANISMS WITH PHARMACEUTICAL OR INDUSTRIAL INTENT 24 (2007), *available at* http://www.aphis.usda.gov/brs/pdf/Pharma_Guidance.pdf.

160. *Id.* at 19, 22, 25 (noting that segregation and isolation measures are mandated for industrial and pharmaceutical crops grown under permits. This is in accord with the government's concern for health and safety, rather than coexistence and economic liability avoidance.).

161. *See* EPA, Insect Resistance Management Fact Sheet for Bacillus thuringiensis (Bt) Corn Products, http://www.epa.gov/oppbppd1/biopesticides/pips/bt_corn_refuge_2006.htm; EPA, Insect Resistance Management Fact Sheet for *Bacillus thuringiensis (Bt)* Cotton Products, http://www.epa.gov/oppbppd1/biopesticides/pips/bt_cotton_refuge_2006.htm.

A. *The Geertson Litigation: A New Coexistence Role for the Federal Government*[162]

In April 2004, Monsanto Co. and Forage Genetics International submitted a petition requesting the deregulation of glyphosate-tolerant alfalfa.[163] As required by the NEPA, APHIS prepared an Environmental Assessment (EA) and solicited public comment on the assessment and deregulation petition.[164] Many commenters' primary concern was the possible "contamination" of organic or conventionally grown alfalfa with genetically modified varieties during pollination.[165] Alfalfa, unlike many commodity crops, is pollinated mainly by bees, and these winged insects have the ability to transport genetically engineered pollen relatively long distances.[166]

Farmers wishing to sell conventional or organic alfalfa feared that they would be unable to meet the domestic market's contractual requirements for genetic purity.[167] In 2005, alfalfa dry hay produced in the United States was valued at over $ 7.3 billion, mostly used on farm or sold within the United States for animal feed.[168] Export markets, specifically exports to Japan, magnified these concerns. Five percent of the alfalfa grown in the United States is exported, of which seventy-five percent is shipped to Japan ($500 million annually).[169] Complicating matters, Japan did not permit the import of glyphosate-tolerant alfalfa.[170] Despite these concerns, APHIS issued a determination of nonregulated status for the herbicide tolerant alfalfa.[171]

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162. This subsection is adapted from A. Bryan Endres, *Genetically Engineered Alfalfa, Export Markets, and the Common Law of Biotechnology*, AGRIC. MGMT. COMM. NEWSL., (ABA Sec. of Env't Energy and Resources), Sept. 2007, at 7-10.

163. Petition for Determination of Nonregulated Status for Roundup Ready® Alfalfa (*Medicago sativa L.*) Events J101 and J163, at 3 (2004), *available at* http://www.aphis.usda.gov/brs/aphisdocs/04_11001p.pdf.

164. APHIS, USDA, ENVIRONMENTAL ASSESSMENT: MONSANTO COMPANY AND FORAGE GENETICS INTERNATIONAL PETITION 04-110-01P FOR DETERMINATION OF NON-REGULATED STATUS FOR ROUNDUP READY® ALFALFA EVENTS J101 AND J163, at 1 (2004), *available at* http://www.aphis.usda.gov/brs/aphisdocs/04_11001p_pea.pdf; *Geertson Seed Farms*, 2007 WL 518624, at *2.

165. *Geertson Seed Farms*, 2007 WL 518624, at *2.

166. APHIS, *supra* note 164, at 20; *Geertson Seed Farms*, 2007 WL 518624, at *2.

167. *Geertson Seed Farms*, 2007 WL 518624, at *2.

168. Nat'l Agric. Statistics Serv., USDA, Statistics by Subject: Hay Alfalfa (Dry), http://www.nass.usda.gov/QuickStats/index2.jsp.

169. APHIS, supra note 150, at 1.

170. *Id.*

171. Monsanto Co. and Forage Genetics International; Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg. 36,917 (June 27, 2005).

In 2006, farmers planted an estimated 200,000 acres of RR Alfalfa for forage and another 20,000 acres for seed.[172] In early 2006, a group of alfalfa farmers, seed producers, and environmental advocates challenged APHIS's deregulation decision in federal district court.[173] In pleadings before the court, APHIS acknowledged the potential export problems of alfalfa planting. It reasoned, however, that stewardship efforts on the part of farmers growing conventional alfalfa could keep any commingling below the one percent threshold for unapproved genetic events in Japan.[174] With respect to contamination of organic alfalfa production, APHIS concluded that because organic operators already had to implement a production system that would avoid cross-pollination with neighboring, non-organic farmers, the deregulation decision would be unlikely to have a significant environmental impact.[175]

The government, in similar agency actions, has repeatedly resolved the question of who should be responsible for preserving the integrity of a non-genetically modified (conventional or organic) harvest in favor of the farmer adopting the new, genetically engineered technology, regardless of the amount of disruption it may cause on established farming practices.

The court in *Geertson* challenged this approach. It noted that while APHIS based its "no significant impact" decision on its conclusion that it is the organic and conventional farmers who should ensure that contamination does not occur, APHIS failed to "[i]dentify a single method that an organic farmer can employ to protect his crop from being pollinated by a bee that travels from a nearby genetically engineered seed farm, even assuming the [organic] farmer maintains a 'buffer zone.'"[176] In addition, the court found that the potential eco-

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172. Geertson Farms Inc. v. Johanns, No. C 06-0175, 2007 WL 1302981, at *2 (N.D. Cal. May 3, 2007). *See* 2006 Monsanto Technology/Stewardship Agreement, *available at* http://www.farmsource.com/images/pdf/2006%20EMTA%20Rev3.pdf (subjecting growers to a grower agreement with Monsanto containing the following provisions limiting its use: (1) "If growing Roundup Ready alfalfa: to comply with the Seed and Feed Use Agreement, which is incorporated and part of this Agreement, to direct any product produced from a Roundup Ready alfalfa crop or seed, including hay and hay products, only to those countries where regulatory approvals have been granted, and not to plant Roundup Ready alfalfa for the production of sprouts. Refer to the Technology Use Guide for additional information." (2) "Grower acknowledges that Grower has received a copy of Monsanto's Technology Use Guide (TUG). To obtain additional copies of the TUG, contact Monsanto at 1-800-768-6387 or go to Farmsource.com." (3) "Crop Stewardship & Specialty Crops: Refer to the section on Coexistence and Identity Preservation in the TUG for information on crop stewardship and considerations for production of identity preserved crops.").

173. Complaint at 2, Geertson Seed Farms v. Johanns, 2006 WL 521847 (N.D. Cal. Feb. 16, 2006).

174. APHIS, *supra* note 150, at 2.

175. *Id.*; APHIS, *supra* note 164, at 13.

176. *Geertson Seed Farms*, 2007 WL 518624, at *6.

nomic or financial impacts suffered by conventional and organic farmers directly result from the deregulation of genetically engineered alfalfa and APHIS's conclusion of "no significant impact" simply was not convincing.[177] Accordingly, the court granted plaintiffs' motion for summary judgment on the NEPA claim and ordered APHIS to prepare a full Environmental Impact Statement (EIS).[178]

On May 3, 2007, the court permanently enjoined future planting of Roundup Ready (RR) Alfalfa pending completion of the EIS and a decision on the deregulation petition, but declined to enjoin the harvesting of already-planted seed and hay.[179] While the court initially ordered the online disclosure of all the production sites for RR Alfalfa, a subsequent order backed away from full disclosure, limiting it only to those counties where RR Alfalfa was planted.[180] On August 13, Monsanto filed a notice of appeal to the planting injunction.[181]

Decided just a few days after a ruling on another case challenging APHIS's approval of field trials of genetically engineered grass,[182] *Geertson*'s legal significance, if upheld on appeal, lies in its challenge to the express regulatory assumption that organic and conventional producers must bear the full burden of segregation to avoid undesirable commingling prior to delivery – an abrupt departure from almost twenty years of regulatory history.

B. *APHIS's Draft EIS for Biotechnology Regulation*

In January 2004, APHIS announced its intent to prepare a programmatic environmental impact statement within the context of revising its biotechnology regulations.[183] The purpose of any revisions "[w]ould be to address current and future technological trends resulting in [genetically engineered] plants with which the agency is less familiar."[184] On July 17, 2007, the USDA released its

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177. *Id.* at *12.

178. *Id.*

179. Geertson Farms Inc. v. Johanns, No. C 06-001075, 2007 WL 1302981, at *9 (N.D. Cal. May 3, 2007).

180. Geertson Farms Inc. v. Johanns, No. C 06-01075, 2007 WL 1839894, at *3-*4 (N.D. Cal. June 26, 2007).

181. *Monsanto Appeals Biotech Alfalfa Ruling*, FEEDSTUFFS, Aug. 14, 2007.

182. Int'l Ctr. for Techn. Assessment v. Johanns, 473 F. Supp. 2d 9, 12, 30 (D.D.C. Feb. 5, 2007) (vacating APHIS's denial of a noxious weed petition for genetically engineered grass and granting summary judgment on plaintiffs' NEPA claims alleging that APHIS failed to properly assess potential impacts of the field trials).

183. Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271 (Jan. 23, 2004) (to be codified at 7 C.F.R. pt. 340).

184. USDA, INTRODUCTION OF GENETICALLY ENGINEERED ORGANISMS: DRAFT PROGRAMMATIC ENVIRONMENTAL IMPACT STATEMENT—JULY 2007, at ii (2007).

draft EIS, requesting comment on ten issues.[185] Although a full discussion is beyond the scope of this article, at least two proposals warrant mentioning as they may signal a change in APHIS's coexistence policy.

1. *Low-level Occurrence of Regulated Articles?*

APHIS asserted that the low level presence of unapproved genetically engineered DNA in commercial commodities and seeds is an inevitable result of large scale field tests of genetically engineered crops.[186] Current domestic regulations (as well as rules in most other countries) set a zero tolerance.[187] APHIS proposed the establishment of safety criteria under which such occurrences would be non-actionable – in other words, allowed.[188] Although in the majority of cases such low-level presence (LLP) of regulated articles may be of minimal risk to health and safety,[189] the economic liability implications of this policy are severe. In essence, the agency is abdicating responsibility for the purity of the most fundamental element of a successful coexistence policy – the seed.[190] As justification, APHIS merely notes that "[t]here are ongoing research efforts to investigate successful methods for minimizing [commingling and gene flow]."[191] The current proposed policy leaves farmers with even less coexistence protection available from a government already reluctant to address the needs of non-GM production.

2. *Non-Regulated Status and Retained Jurisdiction*

The second proposed change, depending on its implementation, could decrease coexistence risk. Under the current system, once the agency deregulates a genetically engineered variety, APHIS lacks authority to place further restrictions or requirements on its use (unless the agency re-regulates the article).[192] Under its proposed approach, APHIS could retain oversight, when appropriate, of some genetically engineered organisms that it otherwise might have approved for

185. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering, 72 Fed. Reg. 39,021, 39,022 (July 17, 2007) (to be codified at 7 C.F.R. pt. 340).

186. USDA, *supra* note 184, at 152-53.

187. *Id.* at 152 ("regulations do not expressly allow for any such occurrence").

188. *Id.* at 155.

189. *Id.* at 171.

190. *See* A. Bryan Endres, *Revising Seed Purity Laws to Account for the Adventitious Presence of Genetically Modified Varieties: A First Step Towards Coexistence*, 1 J. FOOD L. & POL'Y 131, 133 (2005) (stating that "the undisputed starting point for a successful identity preservation system is ensuring seed purity").

191. USDA, *supra* note 184, at 159-60.

192. *Id.* at 141. *See supra* Section I.A.1.

unconfined release.[193] This "deregulation-in-part" mechanism would provide needed flexibility for the agency to manage the conditions of release to facilitate coexistence efforts. In light of APHIS's unwavering concentration on safety, however, whether it would exercise the proposed partial deregulation for purely economic (coexistence) reasons is unlikely.

C. *A Developing Common Law of Biotechnology: The Impact of Geertson and BIO's Coexistence Initiatives*

As of this writing, it is too early to determine whether the *Geertson* decision will impact common law tort or contract litigation. Although the common law plaintiffs' victory in *StarLink* did not alter the government's assumption that conventional and organic growers have a duty to "fence out" contamination from genetically engineered varieties, from a NEPA regulatory perspective, the issue, closed since the 1986 Coordinated Framework, is now post-*Geertson*, opened for discussion.

Moving forward, the government, in deregulation petitions, must consider at least some alternatives to protect the economic interests of organic and conventional farmers.[194] The *Geertson* court explicitly found fault with the administrative record in the genetically engineered alfalfa deregulation, stating:

> [n]either the EA nor the FONSI contain any reference to any material in support of APHIS's conclusion that gene transmission is 'highly unlikely' to occur with 'reasonable quality control.' APHIS does not identify any 'quality control' that will prevent gene transmission between neighboring seed farms. It similarly does not identify any material to support its EA statement that non-genetically engineered alfalfa will 'likely still be sold and available to those who wish to plant it.'[195]

Simply placing the burden on the individual non-GM grower to institute procedures to assure their crops will not include any genetically engineered varieties, with no assessment of the possibility for success, is not sufficient.[196] Perhaps APHIS will apply its deregulation-in-part proposition to address these concerns. On the other hand, creative plaintiffs could translate this new regulatory requirement into common law tort claims. In either case, change in the legal landscape is forthcoming.

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193. USDA, *supra* note 184, at 142.

194. *Geertson Seed Farms*, 2007 WL 518624, at *8.

195. *Id.*, at *7. *Cf.* APHIS, *supra* note 154, at 9 (noting domestic corn growers "cooperative and coordinated approach" to account for regulatory approvals and online market access information sharing with respect to concerns regarding marketability of the Agrisure variety).

196. *See Geertson Seed Farms*, 2007 WL 518624, at *7.

The *Geertson* litigation also corresponds with BIO's policy initiatives regarding commercialization decisions and coexistence measures outlined in section II.C. above. BIO's new policy may establish a standard of care from which to evaluate the reasonableness of a biotechnology company's commercialization decision for common law negligence purposes. Custom is one approach to determine the reasonableness of a defendant's action. Widespread and longstanding practices typically, but not necessarily, are reasonable. If the industry custom is not updated adequately, compliance will not preclude liability for unreasonable behavior. Moreover, custom is normally viewed as evidence of a reasonableness determination rather than a substitute for the appropriate standard of care. Section 295A of the Restatement (Second) of Torts notes that "[i]n determining whether conduct is negligent, the customs of the community, or of others under like circumstances, are factors to be taken into account."[197]

As comment c to the Restatement notes:

> [n]o industry or trade can be permitted, by adopting careless and slipshod methods to save time, effort, or money, to set its own uncontrolled standard at the expense of the rest of the community. If the only test is to be what has always been done, no one will ever have any great incentive to make any progress in the direction of safety.[198]

In the biotechnology context, the trade group is promoting a higher standard, rather than the slipshod methods referred to in the Restatement comments. The mere adoption of a resolution, however, may not yet give rise to a custom until it is a "generally followed practice." Even then, the policy may be supererogatory. For example, in *Gilson v. Metropolitan Opera*, plaintiff sought to use the Met's internal policy regarding escorting patrons to their seats as evidence of negligence in a slip-and-fall case.[199] The court disagreed, finding that "[t]hese internal guidelines go beyond the standard of ordinary care and cannot serve as a basis for imposing liability."[200]

This discussion, however, presumes that the BIO policy initiatives actually raise the standard of care. The two cases discussed above, *StarLink* and *Geertson*, however, may have already established a standard the BIO policy merely seeks to equate. *Geertson* requires the government to consider the trade and marketability actions of any deregulation position – similar to the BIO policy of securing major export market approval prior to commercialization. *StarLink* validated several common law causes of action related to pollen drift and post-

197. RESTATEMENT (SECOND) OF TORTS § 295A (1965).
198. *Id.*, cmt. c.
199. Gilson v. Metro. Opera, 841 N.E.2d 747, 749 (N.Y. 2005).
200. *Id.*

harvest commingling – certainly issues BIO will address in its forthcoming stewardship quality management guidelines. Therefore, the BIO policy may not be out in front of the standard of ordinary care, but simply an industry restatement of baseline behavior.

Although the government's "customary" mode of dealing with coexistence may be changing in the post-*Geertson* environment, along with industry trade group promotion of new coexistence initiatives, evolving international mechanisms may alleviate some economic liability concerns resulting from trade disruptions. The Codex ad hoc Task Force on Foods Derived from Biotechnology recently completed work on a proposed annex to the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.[201] The proposed annex describes the food safety assessment approach for the low-level presence of rDNA plant material that has passed a food safety assessment according to the Codex Guidelines in at least one country, but not the country of import.[202] The task force concluded that because the dietary exposure from the adventitious presence is likely to be very low, only certain aspects of the Codex Plant Guideline for food safety assessments would apply.[203] This uniform, WTO compliant method of conducting safety assessments, if adopted by the Codex Commission, could provide consistency for novel product approvals and eliminate at least some risk in the international commodity markets.

IV. CONCLUSION

Although not without serious underlying tensions, the international supply chain for some non-GM commodity crops (e.g., corn, soy, cotton and canola) has learned to coexist in an increasingly biotech world. With the introduction of each new genetically engineered product, however, new issues will surface. The pending LibertyLink rice class action may prove to be another *StarLink*-type case with significant consequences for the domestic biotech industry and the common law of biotechnology. Rulings in *Geertson*, along with the genetically engineered grass case, *International Center for Technology Assessment v. Johanns*,[204] combined with a critical inspector general audit,[205] may force

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201. *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.

202. *See id.* at 6.

203. *Id.* at 6-7.

204. Int'l. Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d 9 (D.C. Cir. 2007).

205. *See* USDA, AUDIT REPORT: ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS 1 (2005), *available at* http://www.usda.gov/oig/webdocs/50601-08-TE.pdf. (finding that the "USDA agency

a transformation in the federal government's coexistence policy. The final disposition of the alfalfa deregulation petition, and the agency's response to the draft EIS comments, may also signal significant policy change. With respect to private law issues, industry-developed stewardship standards are a step in the right direction toward risk prevention, but must seriously consider the markets of non-GM and export-oriented growers. Unfortunately, in the near term, resolution of private tort and contract law duties and responsibilities may only occur via continued litigation, rather than a peaceful coexistence.

that oversees biotechnology regulatory functions for the Department . . . needs to strengthen its accountability for field tests of GE crops").