An Agricultural Law Research Article

State Authority to Regulate Biotechnology under the Federal Coordinated Framework

by

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Originally published in DRAKE JOURNAL OF AGRICULTURAL LAW
12 DRAKE J. AGRIC. L. 439 (2007)

STATE AUTHORITY TO REGULATE BIOTECHNOLOGY UNDER THE FEDERAL COORDINATED FRAMEWORK

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I. INTRODUCTION

Agriculture in the United States has quietly evolved into a premier high technology industry. Biotechnology has created a worldwide agricultural system with tremendous capabilities.[1] As the use of biotechnology has grown in U.S. agriculture, the federal government has been the primary regulator. Like other agricultural products, a series of federal laws regulate biotechnology, authorized by the "Coordinated Framework," a policy statement written in 1986.[2] Although agricultural biotechnology has become widespread in the United States, it remains controversial, putting pressure on states to both increase its use and to regulate it.

To understand the areas left by the federal regulations for states to regulate biotechnology, this article first examines the history of biotechnology and biotechnology regulations. Next it explores the federal Coordinated Framework, before looking to areas that the states have attempted to regulate. This article then considers cases in which courts have applied the laws governing biotechnology to preempt state regulations, in cases of both biotech and conventional farming. With those cases in mind, this article concludes by looking at avenues open to states seeking to regulate the development and use of agricultural biotechnology within their jurisdictions.

II. HISTORY OF BIOTECHNOLOGY IN AGRICULTURE

Although a precise definition of biotechnology is still under debate, "[a]t its core . . . biotechnology applies scientific principles to living organisms and their components to produce new inventions or processes."[3] The modern bio-

1. For the purposes of this article, "biotechnology" refers to agricultural biotechnology, as opposed to medical biotechnology. The term biotechnology is used interchangeably with "biotech," "genetically-engineered," "transgenic," and "genetically-modified."

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

3. W. Christopher Matton & F. Scott Thomas, *The Continuing Balance: Federal Regulation of Biotechnology*, 44 JURIMETRICS J. 283, 284 (2004).

technology industry came to the forefront in the 1970s, with the development of recombinant DNA ("rDNA") techniques, which allow the modification of a species' genetic material, a process that has taken generations.[4] Additionally, rDNA techniques allowed scientists to introduce genetic traits from one species to another, a crossover that is impossible through conventional breeding techniques.[5] Fears of this new technology creating mutants released into the environment sparked public concerns and protests, including efforts to ban research into genetically-engineered plants and animals in some cities, counties, and even countries.[6] To counter growing public concern, a group of scientists chose to adopt self-regulation of rDNA research in 1975 at the Asilomar Conference where they agreed on interim guidelines to regulate the industry, until the federal government created guidelines.[7] The National Institutes of Health adopted these guidelines and, until 1984, remained the primary standard for federal monitoring and private research.[8]

In the 1980s, as agricultural products produced through biotechnology began to come onto the market, public concern again put pressure on the federal government for regulation of the industry.[9] However, with the United States becoming a leader in the biotechnology industry, the Reagan administration did not want to impede the industry's growth with burdensome regulations.[10] The Administration determined that agricultural biotechnology could be regulated with existing agricultural laws, and thus released a policy statement in 1986 entitled the "Coordinated Framework for the Regulation of Biotechnology" ("Coordinated Framework").[11] Under the Coordinated Framework, the Food and Drug Administration ("FDA") through the Federal Food, Drug, and Cosmetic Act ("FDCA"), [12] the Environmental Protection Agency ("EPA") through the Federal

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4. *Id.*
5. *Id.* at 285.
6. *See* Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture,* 44 B.C. L. REV. 733, 736 (2003) (The city of Cambridge, Mass. sought such a ban.). The counties of Marin, Trinity and Mendocino in California voted to ban genetically-engineered crops and animals. THE CENTER FOR FOOD SAFETY, GENETICALLY ENGINEERED CROPS AND FOODS: REGIONAL REGULATION AND PROHIBITION (2006), *available at* http://www.centerforfoodsafety.org/pubs/Regional_Regs_Charts_6-2006.pdf. Voters in Switzerland rejected a similar measure which would have banned the production and patenting of genetically-modified plants and animals. *Swiss Reject Genetic Ban,* BBC NEWS, June 7, 1998.
7. Marden, *supra* note 6, at 737.
8. *Id.*
9. *Id.*
10. *Id.* at 737-38.
11. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302.
12. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399 (2006).

Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[13] and the Toxic Substances Control Act ("TSCA"), [14] and the United States Department of Agriculture ("USDA") through the Plant Protection Act ("PPA")[15] and the Animal Health Protection Act ("AHPA"), each regulate different aspects of agricultural biotechnology, creating an overarching federal scheme that remains the primary regulation in force today.[16]

The proponents of using genetic engineering to enhance agricultural products argue that they are only shortening the time frame of efforts that nature and man have made through multiple growing seasons. Rather than waiting for generations, which in many species can last decades, centuries, or millennia for spontaneous mutation, scientists can instead create a desired mutation. Such mutations give biotechnology its potential to help increase production of agriculture, forestry, and fisheries in a world rapidly depleted of its resources and where many people starve to death.[17] This technology can develop strains of crops that produce higher yields on marginal lands, allowing countries to increase food production and crops to survive extreme weather such as prolonged droughts.[18] For example, scientists used biotechnology to create a strain of rice that has been modified to contain beta-carotene and iron, improving the nutritional value of the staple.[19] Scientists also use biotechnology to replicate and reproduce pharmaceuticals on a larger scale, increasing the quantity of drugs produced, while at the same time, decreasing the cost.[20]

However, biotechnology in agricultural also has its critics. The arguments against the use of genetic engineering focus on the unknown and the possible risks. Opponents question whether the augmentation of natural pesticides has the potential for increasing the natural evolution of insect pests, or have an adverse effect on other species of the environment. There are worries that genetically-engineered plants will have an evolutionary advantage, out-competing natural varieties, and leading to an overall decrease in genetic diversity.[21] The

13. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136–136y (2006).
14. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2692 (2006).
15. Plant Protection Act, 7 U.S.C. §§ 7701–7772 (2006).
16. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303.
17. U.N. Food & Agriculture Organization [U.N. FAO], FAO Statement on Biotechnology, http://www.fao.org/biotech/stat.asp (last visited Nov. 21, 2007).
18. *Id.*
19. *Id.*
20. *Pharming the Field: A Look at the Benefits and Risks of Bioengineering Plants to Produce Pharmaceuticals* 4 (Pew Initiative on Food and Biotechnology, 2002), http://pewagbiotech.org/events/0717/ConferenceReport.pdf [hereinafter *Pharming the Field*].
21. U.N. FAO, *supra* note 17; Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23, 302.

changes may be toxic to some who have unknown allergies.[22] Critics are concerned that pollen from genetically-engineered plants will cross-pollinate with other plants, introducing genes into the human food chain that regulators have not approved for human consumption.[23]

As this debate plays out on the state level, there has been pressure on state legislatures from both sides. States have already begun to take action, both encouraging the growth of the biotechnology industry within their borders, and controlling it through regulation.[24] Because federal biotechnology regulations are authorized via a series of federal laws, each law must be reviewed individually, and through the Coordinated Framework overall, to determine what room is provided for state law and which state regulations federal laws preempt.

III. PREEMPTION

When Congress acts in accordance with the Constitution, it preempts state laws in conflict with its actions.[25] The theory of preemption arises from Article VI, cl. 2 of the Constitution, which states that it, and all laws of the United States "shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby."[26]

Preemption is either express or implied.[27] In either case, courts look to congressional intent in determining whether federal action preempts a state law, using the purpose of Congress as "the ultimate touchstone."[28] When determining whether preemption exists, and its scope, the courts "'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"[29] In

22. U.N. FAO, *supra* note 17.

23. *See, e.g.,* Andrew Pollack, *Aventis Gives Up License to Sell Bioengineered Corn*, N.Y. TIMES, Oct. 13, 2000, at C5 (reporting that in 2000, StarLink corn, which contained a pesticide, was conditionally approved by the EPA for use in non-food products only. Traces of the genes were found in Kraft taco shells, eventually forcing a massive recall of taco shells by several brands, including Kraft and Mission Foods, and forcing Aventis, the company who created StarLink, to give up its permit from the EPA to sell StarLink seeds to farmers.).

24. *See generally,* National Conference of State Legislatures, Biotechnology Statutes Chart, July 7, 2007, http://www.ncsl.org/programs/agri/biotchlg.htm (providing a database for links to state biotechnology statutes).

25. Wis. Pub. Intervenor v. Mortier, 501 U.S. 597, 604 (1991).

26. U.S. CONST. art. VI, cl. 2.

27. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

28. Allis-Chalmers Corp. v. Lueck, 471 U.S. 202, 208 (1985) (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).

29. *Mortier*, 501 U.S. at 605 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

fields that are traditionally regulated by states, courts will presume that federal laws do not preempt local regulations.[30]

Express preemption occurs when Congress explicitly states, in the statute's language, the limits of state laws in the regulated field.[31] Although explicit in the law, courts must still interpret the scope of the language and its limits on states.[32]

In addition to express preemption, the Supreme Court has also recognized two types of implied preemption: field preemption and conflict preemption.[33] Field preemption occurs when federal regulation is:

> [s]o pervasive as to make reasonable the inference that Congress left no room for the States to supplement it . . . [o]r the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject.[34]

A federal law will also preempt a state law if the state law is in conflict with, or impedes, that federal law.[35] "The test of whether both federal and state regulations may operate, or the state regulation must give way, is whether both regulations can be enforced without impairing the federal superintendence of the field . . . ."[36] The Court need not even examine congressional intent "where compliance with both federal and state regulations is a physical impossibility, " as the federal law automatically preempts the state law in that circumstance.[37]

Additionally, conflict preemption may take the form of obstacle preemption, when a state law "stands as an obstacle to the accomplishment and execu-

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30. *See id.* at 604-05 (stating that in fields regulated by the federal government, federal laws do preempt local regulations).

31. *Id.*

32. *See, e.g.*, Bates v. Dow Agrosciences, L.L.C., 544 U.S. 431 (2005) (in which, in order to resolve a split in the Circuit Courts of Appeal, the Supreme Court held that the FIFRA provision that prohibited states from requiring labeling different from, or in addition to, the EPA approved labels preempted common law claims premised on defective labeling. The Court ruled that common law tort liability was a requirement beyond the EPA label, but that common law claims that used the EPA labels as the standard of care were permitted, as this did not require anything in addition to, or different from federal requirements.).

33. *Gade*, 505 U.S. at 98.

34. *Rice*, 331 U.S. at 230 (examining the federal Warehouse Act's language and legislative history to determine that Congress intended to be the sole regulator in the field when it eliminated a provision from the Act that allowed states to license warehousemen). *See also* Hines v. Davidowitz, 312 U.S. 52, 68 (1941) (holding that Congress preempted the field of immigration and alien registration with the Federal Alien Registration Act, as immigration is a field traditionally reserved to the federal government).

35. *Hines*, 312 U.S. at 67-68.

36. Fla. Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142 (1963).

37. *Id.* at 142-43.

tion of the full purposes and objectives of Congress."[38] A clear example of obstacle preemption occurred in *Nash v. Florida Industrial Commission*, in which the court found that federal unfair labor practice laws preempted a state law denying unemployment benefits to employees that filed an unfair labor practice charge with the National Labor Relations Board, as the state law stood as an obstacle to federal laws discouraging unfair labor practices.[39]

Because the starting point for any preemption discussion is the federal law, as well as its Congressional intent, any discussion of the states' role in biotechnology regulation must begin with the Coordinated Framework.

IV. COORDINATED FRAMEWORK

In 1986, the White House's Office of Science and Technology Policy published the Coordinated Framework, as an attempt to create a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."[40] Rather than recommend the creation of a new, unitary authority, the office determined that existing statutes provided the basic network of agency jurisdiction necessary to assure reasonable safeguards on new technology.[41] The network of agency jurisdiction was already in place, regulating products created through traditional genetic modification techniques, such as crossbreeding and selective breeding.[42] The working group chose to regulate biotechnology by product (rather than the process used to create the product) in order to maintain sufficient regulatory flexibility while providing immediate regulatory protection with laws which the industry was familiar.[43] Additionally, a coordinated approach allowed agencies to operate their programs in an integrated fashion, cov-

38. *Hines*, 312 U.S. at 67.

39. *See* Nash v. Fla. Industrial Comm'n, 389 U.S. 235, 240 (1967). However, obstacle preemption is not always this clear. *See* ERWIN CHEMERINSKY, CONSTITUTIONAL LAW: PRINCIPLES AND POLICIES, 414 (Aspen Publishers 3d ed., 2006), for a discussion of Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n, 461 U.S. 190 (1983), in which the court found that California's moratorium on new nuclear power plants was not an obstacle to the federal goal of promoting nuclear power as California's moratorium was based on economic concerns, rather than safety concerns, and the Court characterized the federal objective as encouraging nuclear power only to the extent it was economically feasible. Chemerinsky argues that in characterizing the federal and state objectives as it did, the Court avoided finding preemption; however, had the Court viewed either objective more broadly, it would have likely found obstacle preemption.

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

41. *Id.*

42. *Id.* at 23,303. For an index of the applicable U.S. laws, *see* Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee, 50 Fed. Reg. 47,174, 47,177-95 (Nov. 14, 1985).

43. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-23,303.

ering "the full range of plants, animals and microorganisms derived by the new genetic engineering techniques."[44] The EPA, FDA, and USDA would review genetically-engineered products with the same standards they reviewed conventional products, meaning that once a product reached the marketplace, it would generally fit within the agencies' standards of safety.[45] The Working Group recognized that a fast changing field would evolve, and at times present new regulatory challenges, and stayed in place in order to be alert to the implications of the evolving field, and make appropriate recommendations.[46]

A. *U.S. Department of Agriculture*

1. *Development of new plant varieties*

The USDA has several roles in agricultural biotechnology. The USDA has broad statutory power to regulate agricultural research and agricultural products, and its guidelines control everything from genetically-modified plants to animal vaccines.[47] USDA's Office of Agricultural Biotechnology ("OAB") coordinates all the department's biotechnology activities, but ten of its various agencies participate in some aspect of its work.[48]

Perhaps the single most important of these agencies is the Animal and Plant Health Inspection Service ("APHIS"), which manages and enforces all USDA biotechnology-related regulations.[49] APHIS also reviews and approves field research projects involving the genetic modification of plants via plant pests through the EPA.[50]

When a developer files an application to test a new genetically-engineered plant, the agency reviews the genetic background of the material to be tested and the plans for the test.[51] If APHIS approves, it then establishes the rules under which the researchers must conduct the test.[52] Next, it grants the necessary permits if the genetically-modified material is to be transported interstate, before finally giving final approval for the test.[53]

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44. *Id.* at 23,303.
45. *Id.* at 23,304.
46. *Id.* at 23,306.
47. *See generally* U.S. Dep't of Agric., Biotechnology Agency Descriptions (Oct. 6, 2005), http://www.usda.gov/wps/portal/!ut/p/_s.7_0_A/7_0_1OB?contentidonly=true&navid=AGRICULTURE&contentid=BiotechnologyAgencyDesc.xml.
48. *Id.*
49. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304.
50. *Id.*
51. *See* 7 C.F.R. § 340.4 (2007).
52. *Id.*
53. *Id.*

In March 1993 APHIS announced an amendment to its rules that excludes six crops with a history of safe genetic modification from the prior approval requirement.[54] The amendment allows genetically-modified crops (such as corn, cotton, potato, soybean, tobacco, or tomato) that meet the following criteria to undergo field tests with only thirty days advance notification to APHIS:

- The introduced genetic material is "stably integrated" into the plant genome;
- The function of the introduced genetic material is known and . . . does not result in a plant disease;
- The genetic material does not cause infection, produce toxins, or produce products intended for pharmaceutical or industrial use;
- If the genetic material is derived from a virus, it must not pose a risk of creating a new plant virus; and
- The plant has not been modified to contain genetic material from a known animal or human pathogen.[55]

Field test permits granted for these crops before 1993 accounted for eighty-five percent of total APHIS test permits.[56] Considering the extensive data obtained from these field tests, APHIS determined that the tests of these crops do not result in any substance persisting in the environment or the introduction and dissemination of a plant pest.[57] The amendment allows APHIS to focus on less familiar crops while still providing oversight for crops that have shown themselves not to be a risk.[58]

2. *Development of plant made pharmaceuticals*

With the advent of biotechnology, plant scientists have been developing genetically-modified crops capable of producing human pharmaceuticals, known as plant made pharmaceuticals ("PMPs"), or pharmacrops.[59] Many pharmaceuticals require living systems for production. Currently, manufacturers synthesize those drugs in mammalian cell cultures.[60] Others believe that pharmacrops will

54. *See id.* at 340.3.
55. *Id.*
56. NAT'L ASS'N OF STATE DEP'TS OF AGRIC., A BRIEF LOOK AT FEDERAL REGULATIONS, *in* AG IN PERSPECTIVE: A CONTINUING SERIES ON ISSUES AFFECTING RURAL AMERICA (June 1994), http://www.nasdahq.org/nasda/nasda/News_Publications/News/aginper/jun94dum.pdf.
57. *Id.*
58. *Id.*
59. *Pharming the Field*, *supra* note 20, at 1.
60. *Id.* at 4.

allow the production of larger numbers, and thus more affordable drugs.[61] Like other biotechnological crops, the USDA and FDA regulate PMPs.[62]

As with other crops, the USDA, through APHIS, is responsible for determining whether pharmacrops are safe to plant or cultivate. However, unlike other crops, APHIS requires a permit for each new pharmacrop, and will not declare one "unregulated."[63]

Once APHIS receives a request for a permit, its scientists review the request and identify any deficiencies.[64] If APHIS scientists are satisfied with the request, APHIS will issue a permit with certain conditions, tailored on a case-by-case basis.[65] APHIS requires manufactures to grow PMPs under "extremely strict management protocols, " confining the plants in a release area with additional precautions to prevent escape of seeds, pollen, or other plant parts.[66] Once the manufacturer has conducted extensive field tests, the developer may request the deregulation of the organism if he or she can show that the organism does not pose a plant pest risk.[67]

3. *Regulation of genetically-engineered animals*

In addition to genetically-engineered plants, scientists have been developing genetically-engineered animals for use in agriculture. Transgenic animals may prove useful in the development of organs for human transplant and proteins for pharmaceutical and industrial production.[68] Additionally, in agriculture, they may limit the environmental harm created by feedlots and other farming operations while increasing the productivity of the operations.[69] For example the Enviropig™, developed by scientists at the University of Guelph in Ontario, Canada, can digest ninety to 100 percent of the phosphorous in its diet, compared to fifty percent in non-transgenic pigs.[70] This decreases the amount of phosphorous in the pig's manure. Phosphorous in the runoff from fields fertilized with pig ma-

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61. *Id.*
62. *Id.* at 19.
63. 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).
64. *Id.*
65. *Id.*
66. *Id.*
67. *Id.*
68. *Biotech in the Barnyard: Implications of Genetically Engineered Animals* 6 (Pew Initiative on Food and Biotechnology, 2002), http://pewagbiotech.org/events/0924/proceedings1.pdf[hereinafter *Biotech in the Barnyard*].
69. *Id.*
70. *Id.* at 19.

nure causes algal blooms, which kills off other aquatic life.[71] Reducing the phosphorous in pig manure reduces the number and severity of these blooms.[72]

However, there are potential drawbacks as well. The two primary environmental risks to the development of transgenic animals are invasion and extinction.[73] These risks are similar to those posed by exotic species, and occur when genetic modifications increase a transgenic animal's ability to adapt and reproduce.[74] Escaped transgenetic animals may out-compete natural animals by consuming limited resources and having more offspring, which, with the modified genes, survive.[75] Factors that make these risks more likely are if the animals "are highly mobile, able to escape captivity and . . . can easily return to a wild state."[76] A related concern is the Trojan gene – a genetic modification that increases an animal's reproduction rate, but also contains a maladaptive trait that lowers the net fitness of the animal.[77] The fitness of the species suffers, as this animal's offspring are more prevalent, but less fit than their natural counterparts.[78] Risks to human health include the introduction of "new food allergens, toxins, or bioactive compounds such as hormones, " either directly "through the transgene itself, or by activating other genes in the host animal."[79]

Under the Animal Health Protection Act, the USDA has the authority to restrict movement, including through quarantine, of anything that may spread disease in livestock.[80] Passed in 2002, this law consolidated a number of quarantine laws, and is modeled after the Plant Protection Act.[81] Under this law, the Secretary of Agriculture may quarantine transgenic animals if researchers or manufacturers alter their genetics with a livestock disease or pest, or if the alterations make them more susceptible or resistant to a livestock pest, making them a vector that can more easily spread the pest.[82]

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71. *Id.*
72. *Id.*
73. *Id.* at 13.
74. *Id.*
75. *Id.*
76. *Id.* at 14.
77. *Id.* at 13.
78. *Id.*
79. *Id.* at 15.
80. Animal Health Protection Act, 7 U.S.C. § 8305 (2006).
81. Thomas Bundy, *Statutory Authorities of the U.S. Department of Agriculture and Their Potential Relevance to GE Animals* in *Exploring the Regulatory and Commercialization Issues Related to Genetically Engineered Animals* 15 (Pew Initiative on Food and Biotechnology, 2005), *available at* http://pewagbiotech.org/events/0321/proceedings.pdf.
82. *Id.* at 15, 19; Animal Health Protection Act, 7 U.S.C. § 8305.

B. *U.S. Food and Drug Administration*

1. *Food Content and Safety*

The FDA is the primary agency responsible for ensuring the safety of food and feed products.[83] In May 1992, the FDA published a policy statement regarding its role in the regulation of new plant varieties.[84] This document stated that the characteristics of a food, not the method used to produce the food, form the basis of the FDA's role in ensuring the safety of foods from new plant varieties.[85]

Consistent with the FDA's "product, not process" position, it judges foods developed through plant biotechnology to determine whether they are equivalent to foods developed through traditional plant breeding.[86] In this context, "equivalent" means that there is no meaningful change in nutritional value or composition of the food and that the new variety is as safe as the existing varieties already in commerce.[87]

Included in the FDA's May 1992 statement are guidelines to assist developers of new plant varieties to ensure this equivalence.[88] These guidelines, or "decision trees, " pose safety questions and make recommendations as to when a manufacturer may need to consult with the FDA on questions ranging from natural plant toxicants to nutrient content and possible allergenicity.[89]

FDA's role in the development of crops through plant biotechnology is one of consultant in all stages of crop development.[90] In most instances, FDA

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83. Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,304.

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

85. *Id.*

86. *See id.* When determining whether a genetically-modified food is substantially equivalent, the FDA focuses on the following conditions:

> 1. Toxicants known to be characteristic of the host and donor species;
> 2. The potential that food allergens will be transferred from one food source to another;
> 3. The concentration and bioavailability of important nutrients for which a food crop is ordinarily consumed;
> 4. The safety and nutritional value of newly introduced proteins; and
> 5. The identity, composition and nutritional value of modified carbohydrates, or fats and oils. *Id.* at 22,992.

87. *Id.* at 22,984.

88. *Id.* at 22,992.

89. *Id.* at 22,985.

90. *Id.* at 22,992; *see also* Larry Thompson, *Are Bioengineered Foods Safe?*, FDA CONSUMER, Jan.-Feb. 2000, http://www. fda.gov/fdac/features/2000/100_bio.html.

approval of new plant varieties – as with traditionally bred plant varieties – is not required because the plants are equivalent to those already in commerce.[91] Based on the questions and issues posed by the FDA decision trees, the plant developer seeks agency consultation as indicated.[92] Factors that a developer must consider include:

- Has the concentration of naturally occurring toxicants or allergens in the product changed?
- Have the levels of important nutrients changed?
- Could any alterations affect the product's digestibility?
- Have accepted, established scientific procedures been followed in the product's development?
- What are the environmental effects of the product's growth and production?
- Does the genetically-modified plant have a history of safe use in food?
- Has the maker introduced into the product any substances that do not have a history of safe use in food?[93]

The decision trees have three possible results: "(1) no concerns; (2) new variety not acceptable, and (3) consult FDA."[94] For example, if the new plant contains a known allergen that it previously did not contain, the FDA requires product approval before it reaches consumers.[95] In addition, if the new plant contains a food additive not "generally recognized as safe" (GRAS), FDA approval of the plant is required.[96] Additionally, the FDA can ban the product from commercial sale at any time if it determines that a material added to a product renders it injurious to health.[97] If questions arise after a product is on the market, the FDA can remove it from stores until it answers these questions.[98]

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91. *See* Thompson, *supra* note 90.
92. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,992.
93. *See id.* at 22,984-23, 005 (setting forth an entire sample decision tree).
94. *Id.* at 22,992.
95. *See id.* at 22,998.
96. *See id.* at 22,985, 22,990.
97. 21 U.S.C. § 334 (2006) (allowing the FDA to seize food in interstate commerce that has been adulterated); *see also* 21 U.S.C. § 342 (2006) (defining adulterated food).
98. 21 U.S.C.A. § 334(h) (West 1998 & Supp. 2007).

2. *Labeling of Foods Obtained Using Biotechnology*

No discussion of biotechnology, and its application in agriculture, generates more interest and apparent divergence of opinion than the topic of labeling. Proponents for labeling argue that all biotech products should have labels to facilitate the consumers' right to know what is in their food.[99] Yet the FDA contends that genetic modification is not a material fact that requires labeling under the FDCA.[100]

The central purposes of food labeling are to inform and educate consumers to enable them to wisely choose food and improve their health.[101] The issue thus becomes not whether a developer employed a particular technique in the production of a food, but instead, whether nutritional or compositional issues arise in light of that technology, and whether those issues should be brought to the attention of the consumer through labeling.[102] The FDA's labeling policy requires that manufacturers label any issue related to safety, including known allergens.[103] The policy also requires that manufacturers present the consumer with information when they alter properties of a food or its preparation.[104] If the nutritional content or potential allergens are the same, FDA will not require a label.[105] Under existing law, consumer demand is not a sufficient justification to require labeling without an underlying nutritional or safety concern.[106]

However, consumer demand and developers' desire for clarification have driven the FDA to release draft guidance on voluntary labeling, indicating whether or not foods have been modified using biotechnology.[107] The FDA stated that, although it did not consider modification using biotechnology a material difference requiring special labeling, it did recognize that some companies and consumers desired more information.[108] The agency reiterated its view that statements such as "GMO free" and "biotech free" were potentially misleading

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99. *See, e.g.*, Katelyn Lord, Editorial, *Should Oregonians Require Labeling of Genetically Engineered Food? Yes: Measure 27 Would Let Consumers Make Informed Choices*, OREGONIAN, Oct. 9, 2002, at C7.

100. CTR. FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: VOLUNTARY LABELING INDICATING WHETHER FOODS HAVE OR HAVE NOT BEEN DEVELOPED USING BIOENGINEERING (DRAFT) 6 (2001), *available at* http://www.fda.gov/cvm/Guidance/001598gd.pdf [hereinafter CTR. FOR FOOD SAFETY].

101. *Id.* at 3.

102. *Id.* at 4.

103. *Id.*

104. *Id.*

105. *Id.*

106. Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000).

107. Marden, *supra* note 6, at 761.

108. CTR. FOR FOOD SAFETY, *supra* note 100, at 6.

because there are no established threshold levels of foods or ingredients modified with biotechnology, and such a statement may imply that bioengineered foods are inferior to traditionally modified foods.[109] Companies that choose to label their products which are developed using biotechnology, were encouraged to include specific information, such as the ingredient modified, and the purpose of the modification.[110]

3. *Development of PMPs*

The FDA becomes involved in the pharmacrop process when the developer requests permission to perform clinical trials on humans.[111] It derives its authority from its regulations that require pharmaceutical facilities to follow "good manufacturing practices."[112] The FDA views the farm as a facility and regulates it as such.[113] The FDA also has the authority to track the amount of a crop planted compared to the amount of the drug produced to ensure that seeds are not mislabeled or misplaced.[114] Finally, the FDA has the authority to regulate the disposal of waste from a facility.[115]

Once developed, the FDA will regulate the safety and efficacy of drugs produced through pharmacrops in the same way it regulates the safety and efficacy of drugs produced through conventional methods.[116]

4. *Genetically-engineered animals*

The FDA regulates transgenic animals through the Center for Veterinary Medicine ("CVM").[117] The CVM has the authority to regulate transgenic animals under the New Animal Drug Application ("NADA") provision of the FDCA.[118]

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109. *Id.* at 11-12. However, the FDA did identify examples of voluntary statements that companies could use, such as: "'This product contains cornmeal that was produced using biotechnology;'" "'This product contains high oleic acid soybean oil from soybeans developed using biotechnology to decrease the amount of saturated fat;'" and "'These tomatoes were genetically engineered to improve texture.'" *Id.* at 7-8.

110. *See id.* at 7-10.

111. *Pharming the Field, supra* note 20, at 19.

112. 21 U.S.C. § 351(a)(1) (2006).

113. *Pharming the Field, supra* note 20, at 19.

114. *Id.* at 20.

115. *Id.*

116. *Id.*

117. *See* Fred Degnan, *The FDCA's "New Animal Drug" Rubric* in *Exploring the Regulatory and Commercialization Issues Related To Genetically Engineered Animals* 21 (2005), *available at* http://pewagbiotech.org/events/0321/proceedings.pdf.

118. *See id.* at 22.

Under the FDCA, an animal drug is a substance intended to cure, mitigate, treat, or prevent disease in an animal or a substance that is not a food, and is intended to affect the structure or function of an animal's body.[119] The FDA must approve all new animal drugs.[120] Manufacturers must demonstrate to the FDA that the drug is effective, safe for the animal, and if humans will consume the animal, the resulting food must be safe for humans.[121] The FDA considers introduced genetic material a drug, as it is not food and it is intended to affect the structure or function of the animal's body.[122] Therefore, it is under this authority that the CVM regulates the use of biotechnology on animals.[123]

C. *The Environmental Protection Agency*

The EPA administers two laws that apply to biotechnology: FIFRA[124] and TSCA.[125]

1. *Federal Insecticide, Fungicide, and Rodenticide Act*

FIFRA regulates the registration, manufacture, and use of all pesticides in the United States.[126] Under this law, the EPA must review and approve applications for genetically-modified pesticides or crop plants that contain pesticidal properties, which the EPA has termed "plant-incorporated protectants, " ("PIP"), before any field tests can be conducted.[127] A PIP is "a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance."[128] Examples of plants that would fall under this regulation are insect-resistant potatoes or viral-resistant cantaloupes.

Before the EPA approves a field test, it must issue an experimental use permit ("EUP").[129] To obtain a permit, the recipient – usually a company or university – must supply the EPA with documentation describing in detail:

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119. 21 U.S.C. § 321(g)(1) (2006).
120. 21 U.S.C. § 360b (2006).
121. *Id.* at § 360b(6) (manufacturers must demonstrate that the new drug is safe); *See* 21 U.S.C. § 342(a)(1) (food containing an unsafe new animal drug is adulterated).
122. *See* Degnan, *supra* note 117, at 23.
123. *Id.*
124. 7 U.S.C. §§ 136–136y.
125. 15 U.S.C. §§ 2601–2692.
126. 7 U.S.C. § 136a. No person may distribute or sell a pesticide that is not registered with the EPA. *Id.* § 136a(a).
127. 40 C.F.R. §§ 152.3, 152.42 (2007).
128. 40 C.F.R. § 152.3.
129. 7 U.S.C. § 136c (2006).

- The genetic makeup of both the host and donor organisms;
- The genetic modification that took place on those organisms;
- The stability of the newly modified material;
- The proposed field test's design and monitoring;
- All available health and environmental information on the host and donor organisms; and
- Results of tests performed in the laboratory and growth chambers.[130]

After studying the proposed test's potential exposure and possible hazards, the EPA has five options: (1) require additional information; (2) approve the proposed test; (3) approve the proposed test with some required modifications; (4) require an experimental use permit for the test; or (5) disapprove the test due to the potential for unreasonable adverse effects.[131]

2. *Toxic Substances Control Act*

Regulation of genetically-modified chemical products is equally strenuous under the TSCA.[132] The EPA must review and approve every new chemical product that falls under TSCA jurisdiction before developers may manufacture or distribute the product for commercial use.[133] EPA regulations define any new microbe developed with biotechnology as a new chemical product.[134] Any manufacturer, importer, or processor of a microorganism must file a Microbial Commercial Activity notice with the EPA.[135] This pre-manufacture notification process is required even if the product is to remain in a laboratory, fermenting vat, or other type of closed system.[136]

130. 40 C.F.R. § 172.4 (2007); *see* Charles W. Schmidt, *Natural Born Killers*, 106 ENVTL. HEALTH PERSP. A432, A436 (1998).

131. 40 C.F.R. § 172.1–172.5 (2007).

132. *See* Microbial Products of Biotechnology; Final Regulation Under the Toxic Substances Control Act, 62 Fed. Reg. 17,910 (Apr. 11, 1997) (to be codified at 40 C.F.R. pts. 700, 720, 721, 723 and 725).

133. 15 U.S.C. § 2604.

134. Microbial Products of Biotechnology, 62 Fed. Reg. at 17,910.

135. *Id.* at 17,911-17,912.

136. *See generally* 15 U.S.C. § 2604.

3. *Regulation of PMPs*

The EPA regulates pharmacrops through the TSCA, which regulates new chemical production.[137] To be subject to this rule, plants must contain new or intergenic microorganisms, as microorganisms that are not intergenic or new, would not be subject to reporting under the TSCA.

If the EPA identifies a microorganism as new, such as a pharmacrop, the EPA must evaluate certain factors before approving commercial production of the new microorganism. These factors include: (1) the projected volume of manufacturing and processing of a chemical substance; (2) if a use changes the type or form of exposure to the microorganism to humans or the environment; (3) the extent to which a use increases the magnitude and duration of human or environmental exposure; and (4) the anticipated method of production, processing, distribution and disposal.[138]

Once the EPA receives this information, it has ninety days to review the risks perceived by this product through a review of known chemicals.[139] If the review indicates no cause for concern, then the crop may go into production.[140] If the agency does find areas of concern, it may negotiate with the manufacturer to ensure the manufacturer addresses these concerns, or limit the production to ensure the chemical poses no threats.[141]

The EPA may also choose to test the modified crop, under TSCA Section 4, if the agency believes that the crop poses an unreasonable risk to human health, or that it will be produced in such volumes that currently cannot account for the impact it poses on the environment or human health.[142]

D. *Oversight by Multiple Agencies*

Most products of biotechnology have regulatory oversight by at least two, and often three, federal agencies. For example, for plant technology, the USDA will regulate a potato developed to contain a higher-solids content for field testing safety. In addition, the potato developer must complete a consultation process with the FDA. If the potato contains a known allergen, or other additive that is not GRAS, the FDA must approve that food additive. Additionally,

137. *Id.*
138. *Id.* § 2604(a)(2).
139. *Id.* § 2604(a)(1).
140. *Id.*
141. *See* 15 U.S.C. § 2604.
142. *Id.* § 2603(2).

if a potato has an insect protection, the EPA will be involved in the regulatory process, along with the USDA and the FDA.

V. CRITICISM OF THE COORDINATED FRAMEWORK

Although proponents argue that the Coordinated Framework allows federal agencies to oversee aspects of biotechnology they are specialists in, it has its critics as well. One of the primary criticisms is that Congress wrote many of the laws used to govern biotechnology before scientists even knew that rDNA modifications were possible, and the laws are not keeping pace with new technological developments. Critics point to the GloFish™ as an example. The GloFish™ is the nation's first officially sanctioned genetically-engineered pet, a zebra fish whose genome includes a coral gene, causing it to be a bright color and glow under a black light.[143] Yet no federal agency is regulating this new pet.[144] Because the fish is a pet, and not livestock, APHIS does not have the authority to regulate it. It contains no pesticides, which means that the EPA has no statutory power over it. The GloFish™ is not intended to be eaten or released into the environment, meaning that the FDA's authority over it is limited to the NADA. The FDA released a statement that, because the fish will not enter the food chain, and because the fish poses no "more threat to the environment than their unmodified counterparts," which pet stores have already sold as pets in the United States, the FDA would not regulate the sale of the GloFish™.[145] Although there is little concern that the GloFish™ poses a risk to human health or the environment, critics contend that this decision creates a precedent for light regulations of transgenic pets currently anticipated, including flea-resistant dogs and cats with non-allergenic fur.[146] It also serves as an example of a loophole in current federal regulation.

VI. CURRENT STATE ACTION

Although the federal government is the primary regulator of biotechnology, states have a role as well. In December 2004, the Pew Foundation pub-

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143. Griff Witte, *Shining Under Scrutiny: New Biotech Pets Make Some Uneasy*, WASH. POST, Mar. 13, 2004, at A1.

144. Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation,* 6 MINN. J. L. SCI. & TECH. 457, 458-59 (2005).

145. FDA Statement Regarding GloFish (Dec. 9, 2003), *available at* http://www.fda.gov/bbs/topics/NEWS/2003/NEW00994.html.

146. Gregory M. Lamb, *GloFish Zoom to Market*, CHRISTIAN SCI. MONITOR, Jan. 22, 2004, at 14.

lished a survey of biotechnology stakeholders at the state level.[147] According to the survey, state officials see their role in biotechnology as addressing local concerns, including economic concerns such as the welfare of local farmers and access to domestic and foreign markets.[148] They feel that the primary responsibility for health and safety of biotechnology should remain with the federal government.[149] States do not have the resources or expertise to replicate federal studies, and as one response stated, there is no need for states "to reinvent the wheel."[150]

Pew's survey also found that states, especially those trying to promote their biotech economies, feel two competing pressures: first, that adequate safety and health regulations assure the public that biotech is safe, encouraging consumers to trust biotech crops. Second, states also worry that regulations that are too rigorous may hinder development, and drive biotech developers elsewhere.[151] Additionally, agricultural states also have an interest in insuring that their farmers have access to foreign markets, such as Japan and Europe, where consumers and governments are more skeptical of genetically-engineered foods.[152]

The Framers of the Constitution designed the United States' federalist system to allow states to experiment with policies and adopt laws that reflect local concerns. For example, Alaska,[153] California,[154] Maryland,[155] Michigan,[156] and Mississippi[157] each have state statutes relating specifically to genetically-modified fish species, reflecting the large fish industries in those states. California, whose wild fisheries netted over $100 million in 2001,[158] and Maryland, whose wild fisheries netted over $60 million in 2005,[159] have the strictest laws.

147. *See* Michael R. Taylor et al., *Tending the Fields: State & Federal Roles in the Oversight of Genetically Modified Crops* (Pew Initiative on Food and Biotechnology, 2004), http://pewagbiotech.org/research/fields/report.pdf.

148. *Id.* at 22.

149. *Id.*

150. *Id.* n.11.

151. *Id.* at 25-26.

152. *See id.* at 28 (stating "Japanese and European markets might be closed to U.S. wheat growers if biotech varieties were introduced in the northern plains states").

153. ALASKA STAT. § 16.40.100(d) (2007).

154. CAL. FISH & GAME CODE § 15007 (West 2007).

155. MD. CODE ANN., NAT. RES. § 4-11A-02 (West 2007).

156. MICH. COMP. LAWS § 324.48735(5) (2007); *see also* MICH. COMP. LAWS § 287.712(5) (2007).

157. MISS. CODE ANN. § 79-22-9(1)(d) (2007).

158. CAL. DEP'T OF FISH & GAME, TABLE G-34 – POUNDAGE AND VALUE OF LANDINGS OF COMMERCIAL FISH INTO CALIFORNIA (2001), *available at* http://countingcalifornia.cdlib.org/pdfdata/csa02/G34.

159. Office of Sci. & Tech., Nat'l. Oceanic & Atmospheric Admin., Annual Commercial Landing Statistics (2005), http://www.st.nmfs.gov/st1/commerical/landings/annual_landings.html

California makes it illegal to spawn, cultivate, or incubate any transgenic fish in the state waters of the Pacific Ocean,[160] and Maryland will only issue an aquaculture permit for genetically-modified fish if the operator can assure state regulators that the stock cannot co-mingle with wild fish, or be released in any other way.[161] Alaska, which has banned the aquaculture of all Atlantic salmon, whether bioengineered or not,[162] requires the labeling of genetically-modified fish and fish products sold in the state.[163]

States have chosen to tackle biotechnology issues in different ways. Nine states have either mandatory or voluntary labeling guidelines for both agricultural or food products.[164] Twenty-two states provide either funding, tax credits, or other support for biotechnology development in their state.[165] California is the only state to have an outright ban on a biotechnology product,[166] but twenty-nine bills have been introduced seeking to ban some aspect of biotechnology,[167] and nine states require a permit either for the importation or release of genetically-modified products.[168]

Biotechnology issues are surfacing at the state level, which is reflected by many of the bills that state legislatures are proposing.[169] Since 2002, close to 350 bills have been introduced by state legislatures relating to biotechnology in

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(select "2005" to "2006" under "year range" box; then "Atlantic by State" drop down box for geographical area).

160. CAL. FISH & GAME CODE § 15007.

161. MD. CODE ANN., NAT. RES. §§ 4-11A-02.

162. ALASKA STAT. § 16.40.100(d).

163. *Id.* at § 17.20.040(a)(12)(A), (a)(14).

164. These states are Alaska, Maine, Michigan, Minnesota, Mississippi, Pennsylvania, Vermont, Virginia and Wisconsin. National Conference of State Legislatures, *supra* note 24. For example, Alaska requires the labeling of all genetically-modified fish and fish products. ALASKA STAT. § 17.20.040(a)(12)(A), (2)(14). Maine provides voluntary guidelines for labeling foods that contain one percent or less genetically engineered ingredients, ME. REV. STAT. ANN. tit. 7 § 530-A (2007). Virginia requires all transgenic seeds to be labeled as such, VA. CODE ANN. § 3.1-275.4 (2007).

165. These states are Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Iowa, Kansas, Louisiana, Maine, Massachusetts, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, New Mexico, North Carolina, Oklahoma, and Texas. National Conference of State Legislatures, *supra* note 24.

166. *See* CAL. FISH & GAME CODE § 15007(a) (making it "unlawful to spawn, incubate, or cultivate" any transgenic fish in state controlled waters of the Pacific Ocean).

167. *See* Nat'l Conference of State Legislatures, *supra* note 164.

168. These states are Florida, Idaho, Maryland, Michigan, Minnesota, Mississippi, Nebraska, Oklahoma, and Washington. *Id.*

169. *See, e.g.*, CAL. FISH & GAME CODE § 15007.

thirty-six states, ranging in form from economic incentives to prohibitions.[170] Nineteen states have enacted these laws.[171]

While it is impossible to survey every proposed bill since scientists developed rDNA transfer technology in the 1970s, examining a few samples from the past ten years shines light onto some of the debates going on in states. Some bills focus on the public's right to know, such as the 2005 house bill in Hawaii that sought to require life science companies that produce crops to make public disclosures to inform the public of the location of test sites of genetically-modified crops and to specify the tests conducted.[172] A 1999 Senate bill in California would have required the Superintendent of Public Instruction to explore ways of informing parents about the basic nutritional value of all foods served in public schools, including genetically-modified foods.[173]

A West Virginia bill would have taken concern for schoolchildren one step further by banning genetically-modified foods and components in public schools.[174] Maine,[175] Minnesota,[176] and New York[177] have all had bills introduced that would have put a moratorium on the planting and cultivation of genetically modified plants; while Maryland[178] and New York[179] have proposed bans on genetically-engineered terminator seeds, which are seeds that are engineered to be unable to reproduce.

In perhaps one the most interesting measures proposed, in 2001 North Dakota lawmakers proposed banning genetically-modified wheat in their state.[180] Wheat production is North Dakota's primary industry, and legislators were under pressure from consumers, particularly the Japanese, who import the majority of North Dakota's wheat.[181] North Dakota would have used the ban in marketing to assure consumers that GM crops had not contaminated the wheat.[182] Although the legislature amended the bill to study the effect of genetically-modified foods

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170. *See* Pew Initiative on Food and Biotechnology, *Resources: Factsheets – Legislation Tracker 2006* (Feb. 2007), http://pewagbiotech.org/resources/factsheets/legislation/index.php.

171. *See* National Conference of State Legislatures, *supra* note 24 (California has adopted the most with five.).

172. H.B. 1024, 23d Leg., Reg. Sess. (Haw. 2005).

173. S.B. 1514, 1999-2000 Leg., Reg. Sess. (Cal. 1999).

174. S.B. 605, 72d Leg., Reg. Sess. (W. Va. 2000).

175. L.D. 893, 121st Leg., Reg. Sess. (Me. 2003).

176. H.F. 3654, 81st Leg., Reg. Sess. (Minn. 1999).

177. A.B. 9871, 223d Leg., Reg. Sess. (N.Y. 1999).

178. H.B. 257, 414th Gen. Assem., Reg. Sess. (Md. 2000).

179. A.B. 10129, 223d Leg., Reg. Sess. (N.Y. 1999).

180. H.B. 1338, 57th Leg. Assem. (N.D. 2001).

181. *See* Taylor, *supra* note 147, at 209-10.

182. Matt Gouras, *Biotech Wheat Ban Fails*, GRAND FORKS HERALD, Apr. 3, 2001, at A1.

on human health, the environment, and the food supply,[183] this and the other bills previously discussed illustrate a growing concern at the state level of the impact of biotechnology on our health, environment, and food supply. As the public demand grows, it is important for those states to have a firm understanding of actions which are and are not preempted by the Federal Coordinated Framework.

VII. STATE ACTIONS PREEMPTED BY THE COORDINATED FRAMEWORK

A. *USDA Laws*

1. *Plant Protection Act*

Although the PPA has a preemption clause,[184] state regulations generally run parallel to APHIS regulations, so no one has challenged state laws under the Act.[185] For the most part, APHIS relies on states to control conventional pests because APHIS views those as local or regional problems that require local or regional solutions.[186] However, APHIS must approve all test permits for genetically-engineered plants.[187] APHIS provides state officials with information about the planned test, and works with states to address any concerns, by altering test requirements or adding permit conditions.[188] APHIS has not yet approved a permit without addressing a state's concerns or objections.[189]

However, were a conflict to arise, PPA has an express preemption clause.[190] Under it, no state may regulate "any article, means of conveyance, plant, biological control organism, plant pest, noxious weed, or plant product in order to control," eradicate, or prevent the introduction of a plant pest, noxious weed, or biological control agent.[191] Additionally, if the Department of Agriculture "has issued a regulation or order to prevent the dissemination of the biological control organism, plant pest, or noxious weed within the United States," no state can issue a regulation pertaining to the same plant.[192]

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183. *Id.*
184. 7 U.S.C. § 7756.
185. Taylor, *supra* note 147, at 21.
186. *Id.* at 36.
187. *See* 7 C.F.R. § 340.4.
188. National Conference of State Legislatures, *USDA's Role in Federal Regulation of Biotechnology*, Jan. 10, 2006, http://www.ncsl.org/programs/agri/biotechfinal.htm.
189. *Id.*
190. 7 U.S.C. § 7756.
191. *Id.* § 7756(b)(1).
192. *Id.*

The exceptions provided in this clause include a state's ability to impose restrictions on the interstate movement of federally regulated articles if those restrictions "are consistent with and do not exceed the regulations or orders issued by the Secretary."[193] A state may also impose additional restrictions on a regulated article if it can demonstrate to the Department of Agriculture, and the Department is in agreement, that there is a special need for those additional restrictions based on "sound scientific data or a thorough risk assessment."[194]

It is clear based on the PPA preemption clause, if APHIS approves field-testing in a state, or once the researchers complete field-testing and APHIS approves a crop for deregulation, a state cannot go against that decision by preventing exotic species or plant pests. Because APHIS must approve all field-testing and deregulations, it is difficult to imagine a situation in which the preemption clause would not include a genetically-engineered plant, as APHIS must act in each situation. Therefore, PPA leaves states little room to prohibit genetically-engineered crops on the grounds that they may be plant pests or noxious weeds. However, due to APHIS's consultation with states for field tests, and the "special need" exemption from the preemption clause, states still have a role in protecting their crops from pests and weeds. They just may not do it independently of USDA.

2. *Animal Health Protection Act*

Although the Secretary of Agriculture has the authority to quarantine animals viewed as being a danger to the health of livestock under AHPA, the Act has no explicit preemption clause, like the PPA.[195] Additionally, the Supreme Court has a long history of upholding livestock quarantines, including quarantining animals from out of state, as a valid exercise of a state's police powers.[196] A state livestock quarantine is only an invalid obstruction to interstate commerce if the police power goes beyond "*what is necessary for any proper quarantine*," without discrimination between "the good and the bad [or] the healthy and the diseased."[197] If an order is appropriate and a good faith effort to prevent the further spread of a disease and to safeguard public health, it is not an unconstitutional impediment to interstate commerce.[198] Because such a quarantine is not

193. *Id.* § 7756(b)(2)(A).
194. *Id.* § 7756(b)(2)(B).
195. *See* 7 U.S.C. § 8305 (2006).
196. *See, e.g.*, Smith v. St. Louis & Sw. Ry. Co., 181 U.S. 248, 256 (1901).
197. *Id.* at 255.
198. Mintz v. Baldwin, 289 U.S. 346, 349-50 (1933). The Supreme Court has inferred from the power to regulate commerce, granted to Congress in Article I, § 8 of the Constitution, that states cannot regulate interstate commerce; that is, they cannot impede interstate commerce by

unconstitutional, states have the power to make and enforce a quarantine order unless the order contradicts federal law, or federal law limits the states' power.[199]

If a state acts in a field traditionally seen as authorized under its police power, the Supreme Court will start with the presumption that federal law does not preempt the state's action.[200] Although not yet tested in the courts, because AHPA does not have an express preemption clause, it is likely that the courts will not find that it preempts the states' attempts to quarantine animals, both conventional and genetically-engineered, to protect individual state's livestock. However, state quarantines of genetically-engineered animals will be subject to the same restrictions as state quarantines of conventionally bred animals – states cannot issue blanket quarantines; rather, they must attempt to discriminate between animals that pose a risk to their livestock and animals that do not.[201] Additionally, courts are likely to give deference to the USDA if the Secretary does determine that a genetically-engineered animal does not pose a disease risk.[202] In order to ban genetically-engineered animals, states must show that those animals pose a risk to the health or safety of the states' animals or people.

B. *EPA Laws*

1. *Federal Insecticide, Fungicide, and Rodenticide Act*

Under FIFRA, states have significantly more room to regulate than under PPA. FIFRA expressly allows states to regulate the use of pesticides, so long as the state regulation does not allow a use that EPA regulations prohibit.[203] Additionally, states cannot impose any labeling or packaging requirements that are different from, or in addition to, federal labeling and packaging requirements.[204]

The only case to deal with preemption for a biotechnology product, *In re StarLink Corn Products Liability Litigation*, treated claims against StarLink producers in the same way that claims against conventional pesticide producers are

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discriminating against out of state products unless there is a compelling state interest to do so, and no less discriminatory manner in which to achieve the state interest. *See* ERWIN CHEMERINSKY, *supra* note 39 at 428-30.

199. *Mintz*, 289 U.S. at 349-50.

200. *See Mortier*, 501 U.S. at 605.

201. *See Smith*, 181 U.S. at 256-57.

202. *See* City of New York v. F.C.C., 486 U.S. 57, 63-64 (1988) (holding that federal regulations made in accordance with federal laws have the same preemptive effect as the laws themselves).

203. 7 U.S.C. § 136v (2006).

204. *Id.*

treated.[205] Defendants had manufactured StarLink corn, a type of corn genetically-engineered to produce a toxin poisonous to some corn pests.[206] During the approval process, however, the EPA determined that the product was not fit for human consumption, and approved it only for animal feed.[207] As a condition on the approval of StarLink, the EPA imposed several growing restrictions to ensure that StarLink corn, and conventional corn intended for human consumption, did not cross pollinate and were kept apart during storage and transport.[208] The manufacturer was required to inform growers of these restrictions, instruct farmers on how to safely plant StarLink following the EPA's regulations, and require growers to sign a contract agreeing to abide by the EPA restrictions.[209] Allegedly the manufacturer, believing that StarLink would soon be approved for human consumption, did not include the Grower's Guidelines in shipments, did not require growers to sign a contract and advised them that StarLink was safe for human consumption.[210] The result was widespread contamination of the U.S. corn supply – thereby increasing costs to all corn growers while depressing corn prices – as much of the corn in the United States was unfit for human consumption.[211] Farmers whose crops had been contaminated by StarLink sued the manufacturer for negligence, strict liability, private nuisance, public nuisance, and conversion.[212] The court ruled that FIFRA does not preempt private actions so long as they would not require any additional or different labeling or warnings than the EPA already requires.[213] Additionally states, through either statute or common law, can require that either manufacturers or growers relay EPA warnings to those that may not have access to the labels on the seeds, such as grain elevator operators, transport providers, and the general public.[214]

It is clear from the *StarLink* case that in order to understand preemption of plant incorporated pesticides one must understand general FIFRA preemption and its relation to state law. Prior to 1910, the states were the primary regulators of poisonous substances, including pesticides.[215] In 1947, Congress adopted FIFRA, primarily as a means to register pesticides sold in interstate commerce.[216]

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205. *In re* StarLink Corn Prod. Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill. 2002).
206. *Id.* at 833-34.
207. *Id.* at 834.
208. *Id.*
209. *Id.*
210. *Id.* at 835.
211. *Id.* at 834-35.
212. *Id.* at 833.
213. *Id.* at 836.
214. *Id.* at 837.
215. *Bates*, 544 U.S. at 437.
216. *Id.*

However, since the 1970s, amendments "transformed FIFRA from a labeling law to a comprehensive regulatory statute".[217] Despite this transformation, Congress did not intend FIFRA to preempt the entire field of pesticide regulation – only the labeling and packaging portion.[218] Its preemption clause, § 136v(a), explicitly leaves room for states and localities to "supplement federal efforts" in controlling pesticides.[219]

These supplements may take the form of state and local permitting or notification. For example, the local ordinance at issue in *Wisconsin Public Intervener v. Mortier* required a permit for the application of any pesticide on public and private land subject to public use, and for all aerial spraying.[220] The town could "'deny the permit, grant the permit, or grant the permit . . . with reasonable conditions.'"[221] The Court held that this exercise of power was valid under § 136v(a), supplementing the federal restrictions on the pesticide.[222] Additionally, the Court ruled that, in addition to states, local government regulation of pesticides were not preempted, so long as they were within the grounds carved out by § 136v.[223]

States may require warnings designed to notify the general public of a pesticide's use.[224] For the purposes of FIFRA, labeling "comprises those materials designed to accompany the product through the stream of commerce to the end user, but not those designed to notify . . . the general public."[225] The required warnings, however, cannot be greater than those imposed by the EPA-approved label.[226]

Preempted state actions include not only positive enactments such as statutes and regulations, but also common law.[227] State courts may not impose liability upon a pesticide manufacturer if that liability is premised on an inadequate label, as the manufacturer would be required to change the label in order to avoid liability.[228] However, the scope of FIFRA's preemption limits this rule: first, the

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217. *Id.* (quoting Ruckelshaus v. Monsanto Co., 467 U.S. 986, 991 (1984)).
218. *Mortier*, 501 U.S. at 606-07.
219. *Id.* at 607, 613.
220. *Id.* at 602-03.
221. *Id.* at 603.
222. *Id.* at 607.
223. *Id.* at 612.
224. *See* N.Y. State Pesticide Coal., Inc. v. Jorling, 874 F.2d. 115, 120 (2d Cir. 1989); *see also* Coparr, Ltd. v. City of Boulder, 942 F.2d 724 (10th Cir. 1991).
225. *N.Y. State Pesticide Coal., Inc.*, 874 F.2d. at 120.
226. *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d at 836-37.
227. *See Bates*, 544 U.S. at 444.
228. *See id.*

claim must be based on labeling and packaging; next, it must impose requirements that are different from, or in addition to, EPA requirements.[229]

However, "[r]ules that require manufacturers to design reasonably safe products, to use due care in conducting appropriate testing of their products, to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not qualify as requirements for 'labeling and packaging.'"[230] Additionally, states can create a cause of action to enforce a federal requirement if it is not different from nor in addition to the federal requirements.[231] Therefore, states may use FIFRA's labeling requirements as a standard of care in civil actions, but may not impose a standard of care greater than FIFRA's.[232]

If federal courts continue to follow the *StarLink* court's lead, and treat PIPs in the same manner as conventional pesticides under preemption, it is clear that states do have some options under FIFRA. They may require permits, notifications, and even put limits on the use of PIPs. They may require manufacturers and growers to notify both the general public and those handling the seeds of the EPA's warnings. The only thing that states may not do under FIFRA is require any relayed warning to be substantively different, or impose liability with regards to the labels or warnings if the standard of care differs from the federal standard.

2. *Toxic Substances Control Act*

Like FIFRA, TSCA has an express preemption clause.[233] If the EPA has not acted with regards to a chemical substance or mixture, the courts shall not construe TSCA to limit the states' powers to regulate that substance or mixture.[234] If the EPA has promulgated a rule for the testing of a chemical substance or mixture, states may not issue a rule or regulation requiring testing for the same purpose.[235] If the EPA issues a rule applicable to a chemical substance or mixture in order to protect health and safety, no state may issue a requirement to protect against that same risk, unless: (1) the state's requirement is the same; (2) the state's requirement is adopted through its authority under the Clean Air Act or another federal law; or (3) the regulation prohibits the use of a substance or mixture, other than its use in manufacturing or processing other substances or mix-

229. *Id.*
230. *Id.*
231. *Id.* at 447-48.
232. *Id.*
233. 15 U.S.C. § 2617.
234. *Id.* § 2617(a)(1).
235. *Id.* § 2617(a)(2)(A).

tures.[236] The exception to this preemption clause is if a state's regulation does not conflict with the EPA's regulations and the state's requirement provides "a significantly higher degree of protection" without unduly burdening interstate commerce.[237]

Two cases that shine light onto preemption under the TSCA both have to do with toxic waste disposal.[238] In response to a proposed PCB disposal site within Warren County, North Carolina, the county passed an ordinance banning the disposal of PCBs within its borders.[239] The court found that, although through the TSCA, Congress intended to give states and localities some leeway in imposing more stringent standards, a total disposal ban frustrated Congress's purpose to safely dispose of chemicals.[240] Not only would a local ban possibly prevent use of the most suitable site for disposal, it would push the waste to other counties and states, which would likely also ban disposal, leaving nowhere to dispose the toxic chemicals.[241]

In 1985, the Fifth Circuit Court of Appeals expanded this line of reasoning by finding that Congress intended the TSCA to be a "comprehensive, national scheme to protect humans and the environment from the dangers of toxic substances."[242] *Rollins Environmental Services* dealt with a similar question – a Louisiana parish had banned "commercial solvent cleaning, " which in effect banned a proposed PCB disposal site.[243] The court examined the legislative history, and ruled that if, as in this case, the intent and effect of a local ordinance was a result that the TSCA would have preempted, the TSCA preempts the ordinance.[244] States do have some room to regulate toxic substances – they are free to act if the EPA has not regulated a substance.[245] If the EPA has acted, states may request an exemption from the EPA in order to regulate a substance.[246] However, the courts have found that the TSCA reflects an understanding that although no state or locality wants a toxic waste dump in its backyard, the national goal of promoting human health and the environment will be frustrated if states and localities can prohibit toxic waste or limit its disposal.[247]

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236. *Id.* § 2617(a)(2)(B).
237. *Id.* § 2617(b)(2).
238. Rollins Envtl. Servs. (FS), Inc. v. Parish of St. James, 775 F.2d 627 (5th Cir. 1985); Warren County v. North Carolina, 528 F. Supp. 276, 288 (E.D.N.C. 1981).
239. *Warren County*, 528 F. Supp. at 288.
240. *Id.* at 289.
241. *Id.* at 290.
242. *Rollins Envtl. Servs. (FS), Inc.*, 775 F.2d. at 632.
243. *Id.* at 634-35.
244. *Id.* at 635-36.
245. *Id.* at 633.
246. *Id.*
247. *Id.* at 637.

Because EPA regulates all genetically-engineered microorganisms as "new chemical substances," all of these microorganisms will fall into the category of chemicals that the EPA has taken action on.[248] Therefore, the TSCA preempts state regulation of these microorganisms, unless the regulation falls into the exemption categories approved by EPA. It is unlikely that courts will uphold an outright ban on genetically-engineered microorganisms, as seen from the two waste disposal cases. However, states and localities will have the opportunity to work with the EPA to tailor regulations to fit the needs of individual communities, so long as those needs do not impose an undue burden on interstate commerce.[249]

C. *Food and Drug Administration*

1. *Food Safety*

The Supreme Court views food safety, and readying food for the market, to be traditionally a local concern.[250] Although Congress has the authority to regulate food in interstate commerce, for food solely sold within the state, states may regulate the selling in retail establishments.[251] The FDCA reflects this – although a preemption section follows the federal standards for mislabeled products,[252] no such section follows the FDCA standards for adulterated foods.

Because food safety is generally a local concern, courts require either explicit preemption or conflict preemption in order to preempt a state or local regulation.[253] No state may completely exclude federally licensed commerce, either explicitly or through conflicting regulations, but it may put limits on that commerce unless preempted by federal legislation.[254] If both regulations may be enforced without impairing the federal regulation, and it is possible to comply with both regulations, then the state regulation may stand.[255]

In addition to ensuring that its regulations do not conflict with any federal regulations, a state must also ensure that its laws do not impose an unreasonable burden on interstate commerce.[256] A law regulating food standards cannot

248. Microbial Products of Biotechnology; Final Regulation under Toxic Substances Control Act, 62 Fed. Reg. 17,910, 17,910-17,911 (Apr. 11, 1997).
249. 15 U.S.C. § 2617(b)(2).
250. *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 144.
251. Weigle v. Curtice Bros. Co., 248 U.S. 285, 288 (1919).
252. 21 U.S.C. § 343(w)(4).
253. *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 144.
254. *Id.* at 142.
255. *Id.*
256. *Id.* at 154.

have a discriminatory objective; that is, it cannot be passed to give in-state producers an advantage in the market.[257] Additionally, it cannot be overly burdensome on out of state producers by having the effect of favoring in-state producers.[258]

The definition of adulterated food in the FDCA[259] is considered a floor for food safety regulations, not a ceiling. Therefore, under the FDCA, states may place additional restrictions on food products produced using biotechnology. However, it is unlikely courts would sustain a full ban, as they are a federally-regulated product – any ban would likely be preempted, as *Florida Lime & Avocado Growers* explains.[260] Additionally, the *StarLink* corn controversy illustrates how difficult it is to segregate certain crops.[261] Requiring farmers and food producers all over the country to separate GM crops from non-GM crops for a single state would likely be an undue burden on commerce, and again, not sustained. However, short of a ban, states may regulate food safety so long as those regulations do not contradict federal regulations, and food producers can comply with both sets of rules.

2. *Food Labeling*

Unlike food safety, Congress has expressed a desire to preempt state labeling requirements through the National Uniform Nutritional Labeling clause of the FDCA.[262] After describing what a misbranded food is in Section 343, Section 343-1 asserts that state regulations of food labels must be identical to FDA regulations – if the FDA has acted to require a certain label, states cannot require anything but that same label.[263] States may petition the FDA for an exception, if they can show that the regulation: (1) will not cause the food to be in violation of federal labeling laws; (2) will not unduly burden interstate commerce; and (3) is designed to address a particular need for the information.[264] The FDA has acted, spelling out what needs to be labeled on genetically-modified food, and what labeling is voluntary.[265] Because the FDA has determined that information about biotechnology used in the production of food is not necessary nutritional or safety information, it is unlikely it will find that the general public of a state has a

257. *Id.*
258. *Id.*
259. 21 U.S.C. § 342.
260. *Fla. Lime & Avocado Growers, Inc.*, 373 U.S. at 142.
261. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 834.
262. 21 U.S.C. § 343-1(a).
263. *Id.* at § 343-1(a)(1).
264. *Id.* at § 343-1(b)(1)-(3).
265. CTR. FOR FOOD SAFETY, *supra* note 100, at 7.

particular need for the information; and thus, it is unlikely that the FDA will grant an exemption for mandatory labeling.[266]

Even if the FDA were to grant an exemption, a state may not be able to require labeling of biotechnology products, as such a requirement could violate the commercial free speech rights of manufacturers. Required labeling has been considered by the courts as a limitation on the commercial speech of the producer.[267] There is a four-pronged test for whether a limitation is constitutional: (1) whether the expression limited is misleading; (2) if there is a substantial government interest being regulated; (3) if the required label directly serves that interest; and (4) if the law is no more extensive than necessary to serve that interest.[268] In 1994, the state of Vermont passed a law requiring that milk produced with artificial growth hormones (often used on the dairy herds) be labeled as such.[269] The Second Circuit Court of Appeals determined that Vermont failed the second prong of the test.[270] Because the FDA found that there was no significant difference in the safety or nutritional value of milk with or without the hormones, Vermont could only claim a state interest in its citizens' "'right to know.'"[271] The court added that, in light of the FDA's findings, even if Vermont had claimed a safety or health interest, it would likely have failed as a government interest as well.[272] Therefore, because the consumer's right to know is not a substantial state interest, Vermont could not require labeling of artificial growth hormones.[273]

Like bovine growth hormones, the FDA has found little nutritional or safety differences between conventional and biotech crops; it would require labeling where there is a difference.[274] Because of this finding, it is unlikely that a state could prevail claiming a substantial interest in the health or safety of the food; rather, a court would find that any required labeling is based on a consumer's desire to know. As the court found above, that is not a substantial enough interest to require labeling. Therefore, absent any study by the FDA, requiring

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266. *Id.*

267. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 72 (2d Cir. 1996).

268. *Id.*

269. *Id.* at 69.

270. *Id.* at 73.

271. *Id.* (quoting Int'l Dairy Foods Ass'n v. Amestoy, 898 F.Supp. 246, 249 (D. Vt. 1995)).

272. *Id.*

273. *See id.* Interestingly, the Second Circuit chose to decide this case not based on the "National Uniform Nutritional Labeling" section of the FDCA, but rather as a constitutional free speech question. Although not dealing with the FDCA directly, this case provides an outer limit to what states can regulate, regardless of what is and is not preempted by the FDCA, as a federal agency cannot authorize states to violate the U.S. Constitution.

274. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22,991.

labeling of genetically-modified foods would be an unconstitutional restriction of commercial speech.

States have found a way around this restriction by setting up standards for voluntary labeling.[275] While not requiring manufacturers to provide information on genetically-modified ingredients, voluntary labeling guidelines give both producers and consumers a uniform guide for the use of certain terms, such as "GMO-free."[276] Other states have chosen to incorporate the use of genetically-modified ingredients into their definitions of "organic," requiring that organic products be produced with minimal or no biotechnology.[277]

D. *Oversight by Multiple Agencies*

A question that the courts have not addressed is how the Coordinated Framework interacts to affect preemption. *In re StarLink Corn Products Liability Litigation* treated StarLink corn as a pesticide, only regulated under FIFRA.[278] It is unknown whether other courts will follow that trend.

There are two possibilities when the preemption issue arises in light of the Coordinated Framework: first, that a state law must not be preempted under any of the statutes making up the Coordinated Framework; or second, that a law must only be an authorized exercise of state power under one of the statutes. The answer likely lies somewhere in the middle. Each of the four preemption clauses discussed in this article specify that they preempt state actions in that field. The PPA states that no state or political subdivision may regulate the movement of any plant or means of conveyance "in order to control a plant pest or noxious weed, eradicate a plant pest or noxious weed, or prevent the introduction or dissemination of a biological control organism, plant pest, or noxious weed" if the Secretary has also acted for those purposes.[279] FIFRA only preempts states from issuing requirements that are in addition to or different from federal labeling and packaging requirements, specifically granting that states are free to impose sale and use restrictions on federally registered pesticides.[280] Rules issued under the TSCA preempt state requirements intended to protect against the same risk as the federal rules.[281] Finally, the FDCA preempts state labeling requirements, but

275. Nat'l Conference of State Legislatures, Biotechnology Legislation (July 2007), http://www.ncsl.org/programs/agri/biotchlg.htm.

276. *See, e.g.*, ME. REV. STAT. ANN. tit. 7, § 530-A.

277. *See, e.g.*, MICH. COMP. LAWS §§ 286.905-.907 (2007).

278. *In re StarLink Corn Prod. Liab. Litig.*, 212 F. Supp. 2d at 828.

279. 7 U.S.C. § 7756(b)(1).

280. 7 U.S.C. § 136v.

281. 15 U.S.C. § 2617(a)(2)(A)-(B).

allows states to continue to regulate food safety.[282] It is likely that, because each of these preemptions are specific to the types of regulations they permit, in assessing whether a state statute is preempted, the court will first evaluate the risk addressed by the state statute. Due to the presumption against preemption, a court will likely only find preemption where federal and state regulations purport to address the same risk, not merely the same product.

One final factor to consider is the purpose of the Coordinated Framework. The framework seeks to "achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[283] It is likely that any state law seeking to impede the biotechnology field would stand as an obstacle to that purpose. State law may not prevent the accomplishment of federal objectives, and a ban on biotechnology prevents the balance between safety and industry being achieved.[284]

E. *Coordinated Framework Preemption in Action*

Taking the proposed North Dakota GM wheat ban as an example,[285] the concept of multiple agencies and preemption plays out. North Dakota sought to ban the sale of genetically-modified wheat seed within the state. Although the bill did not specify a purpose, there is evidence that it arose from pressures by international markets, which were not willing to purchase genetically-modified food.[286] The PPA would only preempt the North Dakota ban if the federal government could show that North Dakota was enacting the ban to control a plant pest or noxious weed.[287] If, once passed, there was floor debate or evidence that a factor in the decision was that genetically-modified corn is difficult to contain, this may be a valid argument. However, if the only evidence is that North Dakota wanted to use its GM-free status to market all wheat overseas, then PPA preemption likely does not stand. Likewise, FIFRA would not preempt such a ban, even if the GM wheat contained PIPs. FIFRA's preemption language allows states to regulate the sale and use of pesticides; North Dakota simply cannot modify the labels.[288] Finally, because North Dakota's ban focuses on crops, not food, it would not involve the FDA.

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282. *See* 21 U.S.C. § 343-1.
283. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302.
284. *Hines*, 312 U.S. at 67.
285. H.B. 1338, 57th Leg. Assem. (N.D. 2001).
286. *See* Gouras, *supra* note 182 (interviewing bill supporters).
287. 7 U.S.C. § 7756.
288. 7 U.S.C. § 136v(a)-(b).

Despite seemingly not being preempted by the Coordinated Framework, the language in the federal register itself would likely be the downfall of a GM-wheat ban. The Coordinated Framework seeks not only to protect human health and environmental safety, but also to achieve a balance so as not to unduly burden the industry.[289] An outright ban of a GM crop would burden the industry, without a health and safety justification.

Once again though, it may turn on how a court characterizes the goals of the state regulations. In *Pacific Gas & Electric v. State Energy Resources Conservation & Development Commission,* the U.S. Supreme Court found that California's moratorium on new nuclear plants did not stand as an obstacle to the federal goal of promoting nuclear power.[290] This was because California based its moratorium on economic concerns, while the federal objective was encouraging nuclear power where economically feasible.[291] It is likely that, had the court viewed California's objectives as regulating the safety of nuclear plants, the moratorium would have been recognized as an obstacle to federal policy.[292] Because North Dakota would base its policy on economic concerns not on health or safety concerns, courts may rule that the Coordinated Framework does not preempt a ban of this type, since the federal objective is to avoid health and safety regulations that burden the industry, not economic regulations.[293] Like *Pacific Gas & Electric Company,* the result centers on how broadly or narrowly the court chooses to read both state and federal objectives.

VIII. CONCLUSION

Because Congress has chosen not to act with regard to biotechnology, and rather, allow the executive branch to interpret existing laws, there is no Congressional intent specific to biotechnology to reference when determining whether a state statute is preempted; nor is there any evidence that Congress wishes biotechnology products to be treated differently than a conventional product. Although rDNA transfers are a relatively new technology, regulation of food, agriculture, and agricultural chemicals is not. Also, that regulation is traditionally within the realm of state powers, leading courts to presume against preemption. This presumption, combined with Congress's inaction on the subject, will lead courts to treat biotechnology products in the same manner they treat conven-

289. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-23,303.

290. *See Pac. Gas & Elec. Co.*, 461 U.S. at 199.

291. *See id.* at 199-200.

292. *See* CHEMERINSKY, *supra* note 39, at 428-30.

293. Coordinated Framework for Regulation of Biotechnolgy, 51 Fed. Reg. at 23,302-23,303.

tional products when a question of preemption arises. The only situation when the regulation of a genetically-modified crop or food may be subject to greater preemption would be when it conflicts with the Coordinated Framework's stated goal of balancing safety with industry growth. If Congress wishes to treat biotechnology differently from conventional crops, and either grant states greater or lesser power to regulate the field, it must act and specify that desire. Until then, courts will likely view the inaction as satisfaction with the currently regulatory scheme, including that scheme's preemption.