

GENETICALLY ENGINEERED CROPS: HOW THE COURTS DISMANTLED THE DOCTRINE OF SUBSTANTIAL EQUIVALENCE

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INTRODUCTION

Most Americans with a basic understanding of civics can tell you that the legislative branch creates the law, the executive branch implements the law, and the judicial branch interprets the law. Any lawyer can tell you that the lines between creating, implementing, and interpreting the law are not clear cut. Absent meaningful guidance from Congress, blurred lines and inconsistent interpretations are particularly apparent in the regulation of biotechnology in the United States. Because the laws governing biotechnology are based on laws that predate the advent of genetically engineered (“GE”) crops,¹ they are often inadequate to address the unique concerns presented by genetic engineering, such as compositional differences in food products, cross-pollination with non-genetically engineered crops, and what authority agencies have to regulate and monitor the use of GE products. As a result, Congress needs to provide meaningful authority for the regulation of biotechnology.

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1. Throughout this article, “genetically engineered,” “genetic engineering” and “biotechnology” refer to modern biotechnology, which are “new and controversial techniques which involve the transfer of genes between species in a manner and at a speed not previously possible.” Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J. L. & PUB. POL’Y 393, 398 n.21 (2007). More specifically, Article 3 of the Cartagena Protocol to the Convention on Biodiversity defines modern biotechnology as: “[T]he application of: (a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.” Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 3 Jan. 29, 2000, 39 I.L.M. 1027. The author recognizes that others may define biotechnology in much broader terms that include traditional plant breeding techniques, such as hybridization and cross-pollination, which have taken place for centuries.

From the outset, the regulation of biotechnology has largely occurred outside the halls of Congress. Currently, the executive branch of the United States relies on the Coordinated Framework for the Regulation of Biotechnology (“Coordinated Framework”), which is a legacy of the Reagan Administration. In drafting the Coordinated Framework, the Office of Science and Technology Policy in the Executive Office of the President interpreted existing laws to determine what authority government agencies had to regulate biotechnology. Lacking meaningful guidance from Congress, the executive and judicial branches have been at the front of setting governmental policy for regulating biotechnology today.

If the U.S. laws applicable to GE crops actually fit into the existing framework, as the drafters of the Coordinated Framework suggested, regulation outside the halls of Congress would not necessarily be a problem. But, as this article demonstrates, the use of GE technology in the United States has not fallen squarely within existing legal authority, courts have struggled to interpret Coordinated Framework principles, and gaps have emerged which do not adequately protect the interests of all Americans.

One example illustrates the Coordinated Framework’s inadequacy. After ten years of research, scientists in Australia’s national research organization, the Commonwealth Science and Industrial Research Organization, ended a project to bring GE peas to market.² The peas contained a natural protein gene from green beans that prevents weevils from digesting starch, thereby causing them to starve to death.³ The protein from the donor plant, the green bean, had no history of allergenicity.⁴ Just before the scientists were ready to release the GE pea onto the market, they completed an additional study that revealed the protein from the green bean plant, when expressed in the pea plant, demonstrated allergenic properties in mice.⁵ Not only was the GE pea allergenic, it caused the mice to react to other allergens.⁶ A heretofore non-allergenic protein became allergenic when transferred to a new plant. Had researchers not completed the additional study, which they were under no regulatory obligation to

2. Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U.J. SCI. & TECH. L. 220, 232 (2009).

3. *Id.*

4. *Id.* at 233.

5. *Id.*

6. *Id.*

complete, the potentially allergenic pea plant would have been commercially available on the market.

Although this specific example originates in Australia, a U.S. manufacturer of a similar GE pea plant would have been under no obligation to complete allergenic testing and could have released the product to the market.⁷ Alternatively, if Australia had not completed the additional study and instead commercialized the crop, growers and retailers in the United States could have easily imported the product and sold it to American consumers without them knowing of its allergenic properties.⁸ As this example makes clear, the Coordinated Framework fails to mandate safety testing accounting for potential allergenicity, among other things, in GE products.

This article first analyzes the Coordinated Framework and its origins. After examining the current regulatory structure, the article examines two different cases in each of three different areas impacted by GE products: food safety and composition, the environment, and intellectual property. A look at each of these cases highlights the judiciary's approach to the Coordinated Framework and the framework's underlying principle of substantial equivalence, and illuminates some of the challenges in applying existing law to new technology. Finally, the article analyzes the ways in which courts appear reluctant to perpetuate the doctrine of substantial equivalence but lack the authority necessary to provide meaningful results. Consequently, the article concludes that Congress should abandon the untenable Coordinated Framework and provide meaningful authority for the regulation of biotechnology.

I. THE COORDINATED FRAMEWORK

In 1986, the United States government determined that the existing regulatory framework was sufficient to regulate biotechnology, premising this idea on the notion that products of

7. See Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REFORM 403, 446–47 (2002) (discussing the regulatory process in the United States under an identical scenario and concluding that a manufacturer could determine that, “a plant with a previous history of safe use containing increased levels of a previously produced protein not ‘known’ to be toxic is substantially equivalent to the unmodified plant and is therefore [generally recognized as safe]”). *Id.* at 446.

8. Bratspies, *supra* note 1, at 413 (citing USDA ADVISORY COMMITTEE ON BIOTECHNOLOGY and 21ST CENTURY AGRICULTURE, OPPORTUNITIES AND CHALLENGES IN AGRICULTURAL BIOTECHNOLOGY: THE DECADE AHEAD (2006), http://www.usda.gov/documents/final_main_report-v6.pdf (acknowledging regulatory gaps, including the import of GE products from other countries)).

biotechnology are substantially equivalent to their natural counterparts. As a result, the government determined it did not need new laws or regulations to regulate biotechnology or to determine the safety of products derived from biotechnology. The United States presented this idea in the 1986 Coordinated Framework for Regulation of Biotechnology.⁹ The Coordinated Framework recognized the use of genetic engineering as an extension of traditional plant breeding techniques such as hybridization and selective breeding.¹⁰ The working group responsible for its drafting “sought 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.”¹¹ With the backdrop of increased technological innovation in Asia and under the leadership of a president known for deregulation, the government recognized that the biotechnology industry needed flexibility in order to remain competitive and that science could likely advance faster than the government could regulate.¹² As a result, U.S. policy toward biotechnology has been favorable to industry from the outset.¹³

Central to the Coordinated Framework is the notion that the final product, and not the process by which it was created, should be the focus of regulation.¹⁴ According to the drafters, existing laws regulated the safety of food and pesticide products created using traditional plant breeding techniques; because genetic engineering is an extension of traditional techniques, “[t]his approach provides the opportunity for similar products to be treated similarly by regulatory agencies.”¹⁵ By focusing on the product, regardless of the process by which it is created, regulatory authority covers genetically engineered products just as they would conventionally grown products.¹⁶ This authority includes the Federal Food, Drug, and Cosmetic Act (FDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Plant

9. The Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

10. *Id.* at 23,302.

11. *Id.* at 23,302–03.

12. *Id.* at 23,303.

13. Luis Acosta, *Restrictions on Genetically Modified Organisms: United States*, LIBRARY OF CONGRESS (July 9, 2015), <http://www.loc.gov/law/help/restrictions-on-gmos/usa.php> (“Compared to other countries, regulation of GMOs in the US is relatively favorable to their development.”).

14. Bratspies, *supra* note 1, at 406.

15. The Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,302.

16. McGarity, *supra* note 7, at 427.

Protection Act (PPA). The following briefly highlights the responsibilities of the three main agencies involved in the regulation of agricultural biotechnology.

A. The Food and Drug Administration

Consistent with the Coordinated Framework, the Food and Drug Administration (FDA) did not implement any regulations to govern biotechnology, but instead relied on existing laws and a non-binding policy statement. Under the FDCA, the FDA has the authority to regulate adulterated food, food labeling, and food additives, among other things.¹⁷ Adulterated food is food that “bears or contains any poisonous or deleterious substance which may render it injurious to health.”¹⁸ If the FDA ever determined that a GE food may be injurious to health, it would have the authority to regulate that food.

A food additive is “any 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.”¹⁹ If a substance is “generally recognized as safe” (“GRAS”) by experts in the field, it is not a food additive and may be added to food without approval by the FDA.²⁰ Based on the doctrine of substantial equivalence, the FDA concluded in its 1992 Statement of Policy: Foods Derived from New Plant Varieties (“Statement of Policy”), that in “most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food.”²¹ As a result, the FDA presumes that most GE foods are GRAS.²² The FDA also enforces EPA tolerance levels for pesticide residue on foods, but does not engage in any form of ongoing monitoring of GE foods.²³

B. Environmental Protection Agency

The Environmental Protection Agency (EPA) has authority under FIFRA to regulate a substance that prevents, destroys, repels,

17. *Id.*

18. 21 U.S.C. § 342(a)(1) (2012).

19. 21 U.S.C. § 321(s) (2012).

20. Bratspies, *supra* note 1, at 408.

21. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,985 (May 29, 1992).

22. Bratspies, *supra* note 1, at 408.

23. *Id.* at 410.

or mitigates a pest.²⁴ This includes the authority to regulate transgenic mutations such as *Bacillus thuringiensis* (Bt), a bacteria endogenously produced in some GE crops to prevent pests.²⁵ The EPA also has authority under FDCA to set tolerance levels for pesticide residue on foods and can exempt entire classes of pesticides from having a tolerance level.²⁶ The EPA does not have authority to regulate GE plants that do not produce pesticides.²⁷ Although the EPA can regulate the amount of pesticide use on herbicide resistant GE crops, such as glyphosate resistant corn and soybeans, it does not have regulatory authority over the crops themselves.²⁸

C. United States Department of Agriculture

Under the Federal Plant Pest Act of 1957 later combined with other authority to create the Plant Pest Act of 2000 (PPA), the United States Department of Agriculture (USDA) through the Animal and Plant Health Inspection Service (APHIS) has authority to regulate products of biotechnology that rely on bacteria or viral vectors.²⁹ This authority extends only to GE crops that use known plant pests and does not require the USDA to examine GE crops that do not use known plant pests.³⁰

Like other government agencies, APHIS begins its analysis of GE crops under the assumption that GE crops are substantially equivalent to their natural counterparts.³¹ In general, APHIS does not require a permit before a biotech company begins field trials of a GE crop.³² Rather, APHIS utilizes a less stringent notification procedure.³³ After field testing, the biotech company can petition for deregulation and

24. 7 U.S.C. § 136(u) (2012).

25. EPA's Regulation of *Bacillus thuringiensis* (Bt) Crops, ENVIRONMENTAL PROTECTION AGENCY, <http://www.epa.gov/pesticides/biopesticides/pips/regofbt crops.htm> (last updated May 2015).

26. Linda Beebe, *In re Starlink Corn: The Link Between Genetically Damaged Crops and an Inadequate Regulatory Framework for Biotechnology*, 28 WM. & MARY ENVTL. L. & POL'Y REV. 511, 519 (2004).

27. Bratspies, *supra* note 1, at 411.

28. *Id.*

29. Alison Peck, *The Case of GMOs*, 46 CREIGHTON L. REV. 653, 660 (2013).

30. Beebe, *supra* note 26, at 518.

31. Bratspies, *supra* note 1, at 412.

32. *Id.*

33. 7 C.F.R. § 340.3 (2016).

subsequently, commercial sale of the product.³⁴ Once deregulated, APHIS no longer has authority over a GE crop.³⁵

II. THE DOCTRINE OF SUBSTANTIAL EQUIVALENCE

The underlying assumption of the Coordinated Framework, made with little explanation, is that GE seeds create a product substantially equivalent to seeds created by traditional breeding techniques.³⁶ To the extent the Coordinated Framework substantiates this underlying assumption of substantial equivalence, it highlights that genetic engineering “enable[s] more precise genetic modifications, and therefore hold[s] the promise for exciting innovation and new areas of commercial opportunity.”³⁷ Because it is more precise, it seems, there should be little concern about anything other than its ability to drive new markets.

While the Coordinated Framework demonstrates the government’s reliance on the doctrine of substantial equivalence, the 100+ page document only uses the phrase “substantially equivalent” three times, all in reference to medical devices.³⁸ The phrase “substantial equivalence” first came into popular parlance in a document published by the Organization for Economic Cooperation and Development—the Safety Evaluation of Foods Derived by Modern Biotechnology, Concepts and Principles (“OECD Safety Evaluation”)—in 1992.³⁹ The report focuses exclusively on the safety of food for human health, and does not consider the safety of genetically engineered crops on animals or the environment.⁴⁰

When the OECD used substantial equivalence, it examined the process for evaluating the safety of new foods, and not the presumption that foods created by biotechnology are substantially equivalent to their natural counterparts.⁴¹ The safety evaluation, however, largely appears as an attempt to demonstrate that biotech products are

34. Bratspies, *supra* note 1, at 412.

35. *Id.*

36. McGarity, *supra* note 7, at 431.

37. The Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. at 23,302.

38. *See generally id.*

39. McGarity, *supra* note 7, at 428.

40. *See generally* ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY: CONCEPTS AND PRINCIPLES (1993) [hereinafter “OECD Safety Evaluation”].

41. *See generally id.*

substantially equivalent to their natural counterparts, thereby obviating the need for further analysis.⁴²

In order to show substantial equivalence, a regulator should look at any processing the food may undergo, the use of the food in the human diet, the exposure of the food to humans, the pattern of consumption, and the attributes of consumers.⁴³ The OECD also recommends looking at the traits, composition, and characteristics of the traditional or parental organism; potential secondary effects of the modification; and any knowledge of the new product and its new traits.⁴⁴ When a regulator determines a product is not substantially equivalent to its natural counterpart or it has no natural counterpart, additional testing is necessary.⁴⁵

Although the OECD report appears to suggest regulators have to prove substantial equivalence by examining the genetically engineered product and considering a number of factors, the process it outlines seems woefully inadequate given that scientists are creating new food through processes not exhibited in nature.⁴⁶ Instead, according to the OECD, “the most practical approach to the determination of [the] safety [of GE foods] is to consider whether they are substantially equivalent to analogous conventional products.”⁴⁷ Thus, the first step in determining safety is to determine whether the GE product is substantially equivalent to its natural counterpart. Once completed, safety appears to be a foregone conclusion.⁴⁸

The case studies included in the OECD Safety Evaluation provide more guidance than the main text of the document.⁴⁹ Case study one, completed by the FDA, explains the process for determining the safety of genetically engineered microbial chymosin, as compared to that of its natural counterpart, animal rennet.⁵⁰ In the case study, the FDA determined that, although functionally identical, the processes used by

42. *Id.* at 16.

43. *Id.* at 15.

44. *Id.*

45. *Id.* at 14–15.

46. See McGarity, *supra* note 7, at 430 (“Employing the substantial equivalence doctrine [will not] take into account all of the subtle changes in delicately balanced biochemical pathways within genetically engineered plants.”).

47. OECD Safety Evaluation, *supra* note 40, at 14 (emphasis omitted).

48. See McGarity, *supra* note 7, at 430–31 (“[T]he substantial equivalence doctrine is not so much a ‘scientific’ risk assessment tool as it is an excuse for regulatory agencies to avoid their responsibilities.”).

49. See *id.* at 430–31 (noting the great amount of discretion and flexibility in determining substantial equivalence).

50. OECD Safety Evaluation, *supra* note 40, at 21–22.

manufacturers to create chymosin and rennet are different enough to warrant a formal review “in order to determine whether the new preparation was substantially equivalent to the traditional one.”⁵¹

Thus, the FDA did not start from the position of substantial equivalence even though the two enzymes are functionally identical. Instead, it examined the production process, which used procedures substantially equivalent to those it would use for other, non-genetically engineered enzymes, to determine that chymosin’s use as an enzyme in food is safe.⁵² Thus, unlike the Coordinated Framework, the FDA appears to have examined the process to determine safety for purposes of the OECD Safety Evaluation.

Therefore, the doctrine of substantial equivalence in the United States appears to be of mixed origin. The underlying principles are rooted in the Coordinated Framework, which acknowledged that the laws governing naturally occurring counterparts were sufficient to regulate products of biotechnology. The actual phrase “substantial equivalence” as it relates to food originates in the OECD Safety Evaluation, although apparently in a slightly different context than the proposition for which it stands today in the United States. For purposes of this article, the relevant point is that the approach of the executive and legislative branches of government remains relatively unchanged since the 1986 Coordinated Framework.⁵³ For producers of agricultural biotech products in the United States, this means they continue to operate in a framework where the underlying presumption—one which they need not independently prove in the

51. *Id.*

52. *Id.*

53. Just prior to publication, the Obama Administration released its proposed updates to the Coordinated Framework. On January 4, 2017, days before the end of President Obama’s Administration, the White House released the “2017 Update to the Coordinated Framework for the Regulation of Biotechnology” and the “National Strategy for Modernizing the Regulatory System for Biotechnology Products.” Along with the announcement, the FDA and the USDA released proposed rules to update how they regulate biotechnology. Because of uncertainty surrounding the Trump Administration’s approach to new regulations—and the likelihood such proposed regulations will be implemented in their current form—it would be premature to include an analysis of the proposed regulations in this article. See Robbie Barbero, James Kim, Ted Boling, & Julia Doherty, *Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System*, WHITE HOUSE (Jan. 4, 2017), <https://obamawhitehouse.archives.gov/blog/2017/01/04/increasing-transparency-coordination-and-predictability-biotechnology-regulatory>; Regulation of Intentionally Altered Genomic DNA in Animals; Draft Guidance for Industry; Availability, 82 Fed. Reg. 6,561 (Jan. 19, 2017), <https://www.federalregister.gov/documents/2017/01/19/2017-00839/regulation-of-intentionally-altered-genomic-dna-in-animals-draft-guidance-for-industry-availability>; U.S. Dept. of Agric, *2017 Proposed Biotechnology Regulations* (Feb. 13, 2017), <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/2016-340-rule/2016-340-home>.

regulatory process—is that products of biotechnology are substantially equivalent to their natural counterparts.⁵⁴

III. BIOTECHNOLOGY IN THE COURTS

This section examines the judicial branch's approach to biotechnology by examining two cases in three different areas impacted by biotechnology: food safety and composition, the environment, and intellectual property.

A. *Food Safety and Composition*

One of the first challenges to the Coordinated Framework took place in *Alliance for Bio-Integrity v. Shalala*.⁵⁵ The plaintiffs included scientists, religious leaders, and other individuals concerned about GE foods.⁵⁶ They challenged the FDA's Statement of Policy in which it announced that foods created through biotechnology were generally recognized as safe under the FDCA, and therefore not subject to regulation as food additives.⁵⁷ The FDA made the Statement of Policy without notice and comment, and did not provide an environmental assessment or an environmental impact statement.⁵⁸

The Statement of Policy reaffirmed the FDA's commitments made under the Coordinated Framework that the product, and not the process, should be the focal point for determining safety.⁵⁹ The FDA also acknowledged that its position was consistent with the "concepts of substantial equivalence of new foods discussed in a document under development" by the OECD,⁶⁰ confirmed that products made with GE foods need not be labeled,⁶¹ and stated that "substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food."⁶²

54. McGarity, *supra* note 7, at 431.

55. 116 F. Supp. 2d 166 (2000).

56. *Id.* at 170.

57. *Id.*

58. *Id.*

59. Statement of Policy: Foods Derived From New Plant Materials, 57 Fed. Reg. at 22,948–85.

60. *Id.* at 22,992.

61. *Id.* at 22,991.

62. *Id.* at 22,985.

Plaintiffs challenged a variety of aspects of the Statement of Policy, alleging that the FDA failed to comply with applicable notice and comment procedures, failed to comply with the National Environmental Policy Act (NEPA) when it did not complete an environmental assessment or environmental impact statement, acted arbitrarily and capriciously when it presumed GRAS status for GE foods, and violated the Free Exercise Clause and the Religious Freedom Restoration Act (RFRA) when it decided to not require labeling.⁶³

On the claim that FDA violated the Administrative Procedure Act's rulemaking requirements, the court held that the Policy Statement was in fact a policy statement, not a rule, because it did not bind the agency and only created a presumption of GRAS.⁶⁴ Because it is a policy statement and not a binding rule, notice and comment rulemaking was not required.⁶⁵ The Court also found that the FDA did not violate NEPA when it failed to complete an environmental assessment or environmental impact statement because the agency did not take an agency action, but merely preserved the status quo.⁶⁶

Moreover, the agency's GRAS presumption was subject to *Chevron* deference and therefore not arbitrary and capricious.⁶⁷ The court based its decision about arbitrary and capricious action on the record at the time the agency created the Policy Statement in 1992, so information about the safety of GE technology provided by Plaintiffs after that point could not be used to demonstrate that the FDA acted arbitrarily and capriciously.⁶⁸

The Plaintiffs also failed on their labeling claim. The court viewed the FDA's conclusion—that the use of GE technology in foods is not a “material difference” from the use of their naturally occurring counterparts—as a finding entitled to deference.⁶⁹ Therefore, the FDA did not have to label GE foods, and in fact could not, as the FDA does not have authority to mandate labeling based solely on consumer opinion.⁷⁰

63. *All. for Bio-Integrity*, 116 F. Supp. 2d at 170.

64. *Id.* at 173.

65. *Id.*

66. *Id.* at 174–75.

67. *Id.* at 176–77.

68. *Id.* at 177.

69. *Id.* at 179.

70. *Id.* Also on the labeling claims, the court denied the First Amendment free exercise claim because the policy statement is neutral and generally applicable. *Id.* at 179–80. The court denied the RFRA claim because labeling food for purposes of religion would come “precariously close

Although plaintiffs failed on all their claims, *Alliance for Bio-Integrity v. Shalala* is notable for several reasons. First, it was the earliest major challenge to the government's Coordinated Framework and the FDA's Statement of Policy. Second, it highlights the great amount of deference the judicial system initially gave to the government without actually analyzing the science underlying the agency's action.⁷¹ Third, the case acknowledges that even scientists at the FDA questioned the government's approach to regulating biotechnology at the time of the policy statement.⁷²

As science has progressed, so too have the courts. While *Alliance for Bio-Integrity* was a case decided in 2000, using a record created in or before 1992, more recent cases appear to be less deferential to the government. In *International Dairy Foods Association v. Boggs*,⁷³ the United States Court of Appeals for the Sixth Circuit examined Ohio's labeling requirements for milk produced using recombinant bovine somatotropin (rBST), a genetically engineered growth hormone used in dairy cows to increase milk production.⁷⁴

In 1992, the FDA approved the use of rBST for milk production after finding, consistent with its reliance on substantial equivalence, that "there was no significant difference between milk from treated and untreated cows."⁷⁵ In its guidance document addressing rBST, the FDA issued guidance for labeling claims.⁷⁶ The Ohio Department of Agriculture (ODA) acted on this guidance and implemented the labeling requirements at issue in the case.⁷⁷ The International Dairy Foods Association (IDFA) and other plaintiffs challenged the labeling requirements as unconstitutional.⁷⁸ One aspect of the challenged statute prohibited composition claims on milk labels.⁷⁹ The Sixth Circuit disagreed with the FDA's finding that there "was no

to violating the First Amendment's Establishment Clause." *Id.* at 180.

71. See McGarity, *supra* note 7, at 440 (noting the court's "brief three-paragraph analysis").

72. *All. for Bio-Integrity*, 116 F. Supp. 2d at 177.

73. 622 F.3d 628, 632 (6th Cir. 2010).

74. *Id.*

75. *Id.* (quoting Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6,279, 6,280 (Feb. 10, 1994)).

76. *Id.* at 632–33.

77. *Id.* at 633–34.

78. *Id.* at 634.

79. *Id.* at 636.

measurable compositional difference between the two.”⁸⁰ Disagreeing with the FDA’s position of substantial equivalence, the court stated:

[The FDA] conclusion is belied by the record, however, which shows that, contrary to the district court’s assertion, a compositional difference does exist between milk from untreated cows and conventional milk (. . . cows treated with rBST). As detailed by the amici parties seeking to strike down the Rule, the use of rBST in milk production has been shown to elevate the levels of insulin-like growth factor 1 (IGF-1), a naturally-occurring hormone that in high levels is linked to several types of cancers, among other things.⁸¹

The court then acknowledged other differences in the milk from cows treated with rBST, including increased fat and lower protein content during certain phases, and increased somatic cell counts that cause milk to sour more quickly.⁸² These factors, the court stated, prevented it from agreeing with the FDA that there are no compositional differences in the two types of milk.⁸³

Because the court found that there is a compositional difference, a claim such as “rbST free” is not misleading.⁸⁴ The court then completed the *Central Hudson* test for commercial speech and determined that the ODA’s prohibition on compositional claims like “rbST free” was unconstitutional.⁸⁵ In doing so, the court noted that the state’s interest in preventing deception was weak because the state did not demonstrate that consumer deception occurred and concluded that the state’s reliance on the FDA’s guidance document as evidence that consumers may be misled is not sufficient.⁸⁶ The court also found that ODA’s rule did not directly advance the state’s interest and it was more extensive than necessary.⁸⁷

This case is significant because, after examining the scientific data, the court acknowledged that compositional differences may exist between the products of biotechnology and their naturally occurring counterparts. Cows treated with GE hormones create a different product, and milk created from cows treated with rBST is not substantially equivalent to milk from cows not treated with rBST.⁸⁸ As the court suggested, it is misleading to say the two products, created by

80. *Id.*

81. *Id.*

82. *Id.* at 636–37.

83. *Id.* at 637.

84. *Id.*

85. *Id.* at 638–40.

86. *Id.* at 638.

87. *Id.* at 639.

88. *Id.* at 637 (“Taken collectively, this evidence points to two distinct types of milk.”).

different processes, are equivalent. The case is also significant because the court pointedly disagreed with the FDA's reliance on substantial equivalence.

B. Environment

Whereas the previous section dealt primarily with the FDA's regulation of foods produced using biotechnology and state reliance on FDA guidance, many individuals and organizations also challenge biotechnology on environmental grounds. As the Coordinated Framework indicates, both the EPA and the USDA have limited authority to regulate the environmental impact of GE crops. In addition, NEPA requires that federal agencies complete an environmental assessment or environmental impact statement before beginning major federal actions.⁸⁹ A number of environmental challenges have taken place in response to APHIS attempts to deregulate specific biotech crops. Because deregulation is a major federal action, APHIS must complete an environmental impact statement or an environmental assessment when it chooses to deregulate a crop.⁹⁰

In February 2007, the United States District Court for the District of Columbia issued its opinion in *International Center for Technology Assessment v. Johanns*,⁹¹ which supports the idea that biotechnology raises new issues and demonstrates one way in which biotechnology may harm society. The case involved two types of grass, creeping bentgrass and Kentucky bluegrass, both of which are listed as invasive weeds by ten federal organizations and 145 non-federal cooperators.⁹² Scott developed GE versions of the grasses resistant to glyphosate, which would allow those who plant the GE varieties, like golf courses, to spray the grass with Round Up and only kill weeds.⁹³ The use of the GE seed presented a number of concerns, including: gene flow which could allow the genetically engineered mutation to appear in wild relatives and persist outside of its intended use, enhanced weediness since the plant is already considered a pest and would not be able to be killed with Round Up, and a subsequent increase in the use of more

89. 42 U.S.C. § 4332(C) (2012). *All. for Bio-Integrity* included a NEPA claim but the court determined the agency did not undertake a major federal action; it only preserved the status quo. See *supra* note 66, and accompanying text.

90. 7 C.F.R. § 372.5 (2016).

91. 473 F. Supp. 2d 9, 13–14 (D.C.C. 2007).

92. *Id.* at 13.

93. *Id.*

toxic pesticides.⁹⁴ The International Center for Technology Assessment (CTA) and other individual plaintiffs sued the USDA for declaratory judgment and injunctive relief, challenging the USDA's denial of CTA's petition to have the GE grasses labeled as noxious weeds under the Plant Protection Act.⁹⁵ The plaintiffs also included claims for violations of NEPA and the Administrative Procedure Act when the USDA allowed The Scotts Company ("Scotts") to grow certain varieties of genetically engineered grass in field trials without (1) identifying whether GE creeping bentgrass was a plant pest under PPA or (2) preparing an environmental impact statement or an environmental assessment as required by NEPA.⁹⁶ Scotts, who petitioned the USDA to deregulate the GE seed at issue, intervened as a defendant.⁹⁷

Scotts challenged plaintiff's standing, arguing that plaintiffs had not incurred an injury in fact.⁹⁸ In addressing the argument, the Court acknowledged that "for injury to plaintiffs' aesthetic interests to occur, it is not essential that plaintiffs actually encounter a [glyphosate-tolerant creeping bentgrass] plant. To the contrary, the mere *desire* to use or observe a plant species, even for purely esthetic purposes, is undeniably a cognizable interest for purposes of standing."⁹⁹ In other words, in order to show that they are harmed by defendants' deregulation of genetically engineered grass, plaintiffs only have to show that it is likely that GE seed will establish itself in the wild or hybridize with naturally occurring grass.¹⁰⁰ This later occurred, when GE seed escaped the field trial area and contaminated the Crooked River National Grassland 13 miles away from the field trial.¹⁰¹

Where the harm is only an increased risk of natural grass being contaminated with GE grass, courts must find that the likelihood is "nontrivial."¹⁰² Following an extensive quantitative analysis, the court determined the increased risk in this case to be somewhere between .7% and 8.9%, which it found to be non-trivial.¹⁰³

94. *Id.* at 14.

95. *Id.* at 12.

96. *Id.*

97. *Id.* at 12–13.

98. *Id.* at 14.

99. *Id.* at 16 (emphasis in original) (internal citations and quotations omitted).

100. *Id.*

101. Holly Gill, *Study reports spread of GMO*, PORTLAND TRIB. (Aug. 20, 2006, 6:00 PM), <http://portlandtribune.com/msp/129-news/138539-study-reports-spread-of-gmo>.

102. *Int'l Ctr. for Tech.*, 473 F. Supp. 2d at 16.

103. *Id.* at 20–21. The court also cited case law that found an increased risk of 1 in 10,000 is

Following the substantially equivalent line of reasoning, Scotts argued that even if plaintiffs encountered glyphosate-tolerant creeping bentgrass in their areas of interest, there would be no harm because they would not be able to tell the difference, unless they sprayed it with glyphosate.¹⁰⁴ In an apparent rejection of the doctrine of substantial equivalence, the court stated: “Plaintiffs’ alleged interest is in viewing native fauna, and the relevant inquiry is whether injury to *that* interest is probable or has occurred, regardless of whether the injury is visible.”¹⁰⁵ The fact that plaintiffs could not visually distinguish between the GE and non-GE plants was irrelevant. Harm to the mere interest of viewing non-GE plants is sufficient.

Following its finding that the plaintiffs had standing, the court went on to determine that APHIS improperly denied the plaintiffs’ petition to have the grasses listed as noxious weeds, and acted arbitrarily and capriciously by not completing an environmental assessment or environmental impact statement when it chose to allow field trials of glyphosate-tolerant creeping bentgrass.¹⁰⁶ The court remanded the noxious weed petition to APHIS, and noted that APHIS had wide discretion under the PPA to determine which weeds to classify as noxious, so long as it based its decision on sound science.¹⁰⁷

On the NEPA claim, the court found that APHIS must conduct an environmental assessment or environmental impact statement “[w]hen a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.”¹⁰⁸ Because APHIS failed to present evidence that it had made proper findings to exclude itself from producing an environmental assessment or environmental impact statement for the field trials, it acted in an arbitrary and capricious manner.¹⁰⁹ According to the court, the record contained “substantial evidence” that field tests could significantly affect the “quality of the human environment” and the “tests may have involved, at the least, novel modifications (if not “new organisms”) that raised new environmental issues.”¹¹⁰ Because

non-trivial, suggesting an extremely low bar to show harm. *Id.* at 21.

104. *Id.* at 22.

105. *Id.*

106. *Id.* at 29.

107. *Id.* at 26–27. APHIS appears to have utilized its wide discretion when it determined GE Kentucky Bluegrass was not a noxious weed and therefore not subject to APHIS regulation. *See id.* at 22.

108. *Id.* at 20 (citing 7 C.F.R. § 372.5(d)(4)).

109. *Id.* at 29.

110. *Id.* at 30.

of these new environmental issues, the government could not rely on the notion that the end product is substantially equivalent to its non-GE counterpart.

The case demonstrates two important factors: (1) the non-trivial possibility that people will encounter genetically engineered grass in a natural environment is a legally cognizable harm and (2) the release of genetically engineered organisms “raise[s] new issues,”¹¹¹ a proposition the Coordinated Framework seems to overlook. If the GE grass seed truly were substantially equivalent, it would not harm plaintiff’s aesthetic interests and would not raise new issues.

Four years after the case, the USDA determined it would not regulate Kentucky bluegrass.¹¹² The USDA based its decision on two factors. First, when Scotts genetically engineered the grass it did not include a plant pest, a fact that exempted it from the PPA.¹¹³ Second, the USDA determined that the grass is not a noxious weed because it is the same as naturally occurring bluegrass, which people can find nearly anywhere.¹¹⁴ Consequently, Scotts is now free to market the product commercially, and plans to introduce it to the market in 2015.¹¹⁵

While parties who oppose the widespread release of genetically engineered products have been successful in challenging agency action to demand environmental assessments or environmental impact statements, the end result may be of limited significance. Scotts proved this when it chose to engineer the plant so it did not include a plant pest, thereby removing it from the USDA’s jurisdiction. Once the USDA determined it was not a noxious weed, the USDA then had no authority to regulate the crop. Just as the USDA did when it determined GE grass was not a noxious weed, agencies may exercise their discretion after an environmental assessment or environmental

111. *Id.*

112. *USDA Responds to Regulation Requests Regarding Kentucky Bluegrass*, APHIS (July 1, 2011), https://www.aphis.usda.gov/aphis/newsroom/news!/ut/p/z0/fYzLDoIwEEW_hqWZgfhYg1EjIWBiTkcCbZiANVLCftqD8vegHuDsn9wEMcmCKJlmTk1pRt3jB9jzJtkc_umNyOd9OGD6yOLqmGGC6gxjY_8LyIJ_DwEJglVZOfBzk1DfS8lWV450sDZnZQ0tcibc1Wr88_NGGTNXISdg1C9D3V8CDh5Xj7Tleq3bmZTeK2pC10Les-AJXUuPE/.

113. *Id.*

114. *Id.* The USDA’s finding that GE and non-GE Kentucky Bluegrass are the same seems to ignore the court’s acknowledgment that GE Kentucky Bluegrass is different because it cannot be killed with Round Up, in addition to the court’s finding that the mere presence of GE plants harms the aesthetic value the public has in viewing native flora.

115. Mary Vanac, *Scotts tests genetically modified grass seed at homes*, THE COLUMBUS DISPATCH (Jan. 31, 2014, 8:10 AM), <http://www.dispatch.com/content/stories/business/2014/01/31/scotts-tests-modified-grass-seed-at-homes.html>.

impact statement to still allow the widespread use of GE products. In some cases, the existing laws provide an inadequate framework for addressing the challenges associated with the widespread use of GE seeds, as the court highlighted in *Center for Food Safety v. Vilsack*.¹¹⁶

In *Center for Food Safety*, the plaintiffs challenged APHIS's unconditional deregulation of GE alfalfa.¹¹⁷ They argued that APHIS violated the PPA when it concluded that GE alfalfa was not a plant pest or noxious weed.¹¹⁸ To support their claim that APHIS should regulate GE alfalfa as a plant pest, the plaintiffs put forth two primary arguments: (1) GE alfalfa is a plant pest because it will cross-pollinate with non-GE alfalfa and (2) widespread commercialization of GE alfalfa will cause increased glyphosate use and a subsequent increase in superweeds.¹¹⁹

After reviewing the PPA and applicable regulations, the court noted that APHIS correctly determined that GE alfalfa was not a plant pest and that, once it made that decision, it no longer had discretion to do anything other than deregulate GE alfalfa.¹²⁰ The definition of plant pest and the agency's longstanding interpretation of plant pests did not include any consideration of the potential for cross-pollination and increased glyphosate resistance among weeds.¹²¹ The court also found that the agency was not required to review GE alfalfa as a noxious weed once it determined it was not a plant pest.¹²² Because no party petitioned APHIS to make such a determination, APHIS did not err when it did not evaluate GE alfalfa as a noxious weed.¹²³

Interestingly, APHIS noted in its environmental impact statement that the environmentally preferred outcome is continued regulation of GE alfalfa.¹²⁴ APHIS acknowledged that the possible harms from deregulation include cross-pollination that might harm organic and non-GE farmers, cross-pollination that could limit exports to foreign markets that do not allow GE products, and potential increased costs

116. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 843 (9th Cir. 2013).

117. *Id.* at 832.

118. *Id.*

119. *Id.* In earlier litigation, Plaintiffs established that bees pollinate alfalfa and GE alfalfa may be cross-pollinated at a distance of up to 2 miles from the field where it is planted. *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *2 (N.D. Cal. Feb. 13, 2007) (memorandum).

120. *Ctr. for Food Safety*, 718 F.3d at 841.

121. *Id.* at 840-41.

122. *Id.* at 843.

123. *Id.* at 833.

124. *Id.* at 838.

for non-GE farmers who have to test their crops for the presence of GE alfalfa.¹²⁵ But APHIS cannot consider these economic harms in its determination of what constitutes a plant pest.¹²⁶ Similarly, the Court and APHIS acknowledged that deregulation of GE alfalfa will increase glyphosate use by an estimated 4800 percent, but the PPA does not concern itself with such possibilities.¹²⁷

Center for Food Safety highlights the need for congressional action. In a comment directed at the challenges of regulating GE technology under the Coordinated Framework, the court said, “The job of updating the [Plant Protection Act] to address the potential harms caused by genetic modification (including transgenic contamination and increased herbicide use) is a job for the Congress, not this court, to undertake.”¹²⁸

The earlier stages of litigation in this case also demonstrated that courts are unwilling to accept the underlying premise of the Coordinated Framework in claims alleging violations of NEPA. In *Geertson Seed Farms v. Monsanto*, the precursor to *Center for Food Safety*, the district court ruled that APHIS’s finding of no significant impact under its environmental assessment failed to take the “hard look” required by NEPA.¹²⁹ Unlike the statutes used to regulate under the Coordinated Framework, NEPA aims to prevent “other undesirable and unattended consequences” in addition to protecting health, safety, and the environment.¹³⁰ Because of its wide scope, the “hard look” required by NEPA allows, and requires, agencies to consider a multitude of factors, including increased glyphosate use and the potential for transgenic pollination.¹³¹ Because bees pollinate alfalfa and can travel up to two miles, non-GE farmers in a 2-mile radius are at risk for cross-pollination.¹³² The court acknowledged that it is an undesirable consequence to eliminate “a farmer’s choice to grow non-genetically engineered crops, or a consumer’s choice to eat

125. *Id.* at 841.

126. *Id.* at 838. *See also* 7 U.S.C. § 7702(14) (2012) (limiting plant pests to agents at any *living* stage).

127. *Ctr. for Food Safety*, 718 F.3d at 836, 841.

128. *Id.* at 841.

129. *Geertson Seed Farms v. Johanns*, No. C 06–01075 CRB, 2007 WL 518624, at *10 (N.D. Cal. Feb. 13, 2007) (memorandum).

130. *Id.* at 9–10.

131. *Id.* at 10.

132. *Id.* at 2.

non-genetically engineered food.”¹³³ Rejecting the doctrine of substantial equivalence, the court stated:

For those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop. The government’s apparent belief that farmers’ and consumers’ choice is irrational because the engineered gene is similar in all biological respects to a gene found in nature (although never in alfalfa) is beside the point.¹³⁴

Both *Geertson* and *Center for Food Safety* are important for several reasons. First, both cases acknowledge the severe limitations of the Coordinated Framework and highlight that there are both economic and environmental consequences that the government has not adequately addressed with existing law. Second, they further demonstrate that at least some courts are unwilling to accept the artificial distinction between process and product as drawn by the Coordinated Framework. Third, each case’s complex procedural history and arguments demonstrate the need for clearer guidance on biotechnology.¹³⁵

C. Intellectual Property

As it did with laws that regulate biotechnology in food and the environment, Congress did not specifically authorize intellectual property protection for products of biotechnology. Rather, inventors protect genetically engineered seeds and seed parts using statutes that predate the advent of biotechnology.¹³⁶ Although seed producers have three different means to protect their inventions, a utility patent provides the greatest amount of protection from infringing uses and

133. *Id.* at 8.

134. *Id.* at 9.

135. The case originated as *Geertson Seed Farms v. Johanns* in the district court. *See id.* at *1. Monsanto, who intervened as a Defendant, appealed the scope of the district court’s injunction to the Ninth Circuit, which affirmed the lower court’s decision. *Geertson Seed Farms v. Johanns*, 570 F.3d 1130 at 1133 (9th Cir. 2009). Monsanto appealed to the Supreme Court, which reversed the judgment of the Ninth Circuit. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 at 166 (2010). APHIS released its environmental impact statement, as ordered by the district court, in December 2010. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829 at 838 (9th Cir. 2013). The Center for Food Safety then filed suit against APHIS and appealed the district court’s decision to uphold the agency’s decision to deregulate. *Id.* at 831–32. The dispute culminated in *Ctr. for Food Safety v. Vilsack*, where the Ninth Circuit affirmed the district court’s decision. *Id.* at 843.

136. *See* Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 151 (2005) (discussing the history of seed-specific legislation during the early 20th century).

allows GE seed producers to patent individual components of a seed.¹³⁷ As a result, manufacturers of genetically engineered seeds primarily rely on utility patents to protect their product.

The Supreme Court's application of agricultural biotechnology to patent law demonstrates that (1) unlike the Coordinated Framework, process matters and (2) the fact that something is human-made makes it different enough from its natural counterpart to be patentable subject matter.

Two cases demonstrate how utility patent protection came about for GE seeds, even though neither case deals directly with them. *Diamond v. Chakrabarty* involves a genetically engineered bacterium¹³⁸ and *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* involves a traditionally bred hybrid seed.¹³⁹ *Chakrabarty* and *J.E.M. Ag Supply, Inc.*, when read together, demonstrate that genetically engineered seeds are patentable subject matter for which a biotech company can obtain a utility patent.

In *Chakrabarty*, the Supreme Court addressed the patentable subject matter requirement for obtaining a utility patent. *Chakrabarty*, a microbiologist, sought a patent on human-made, genetically engineered bacteria that could break down components of crude oil.¹⁴⁰ Congress identified the scope of patentable subject matter in 35 U.S.C. § 101, which states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.¹⁴¹

The court focused on “manufacture” and “composition of matter.”¹⁴² Citing a dictionary definition and prior case law, the court defined manufacture as: “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by

137. *Id.* at 166. The other two forms of protection are a Plant Patent and a Plant Variety Protection Certificate. Although the court in both *Chakrabarty* and *J.E.M. Ag Supply* discusses both, this article focuses on utility patents. For additional information about Plant Variety Protection Certificates and Plant Patents, see David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J. L. & TECH. 7, 14–22 (2003).

138. 447 U.S. 303 (1980).

139. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001).

140. *Chakrabarty*, 447 U.S. at 305.

141. 35 U.S.C. § 101 (2012).

142. *Chakrabarty*, 447 U.S. at 308.

machinery.”¹⁴³ Referring to “common usage” and again citing case law, the Court defined composition of matter to include “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.”¹⁴⁴ After examining legislative history, the Court concluded that “Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”¹⁴⁵

Following its broad interpretation of patentable subject matter, the Court acknowledged the limits of § 101. Citing a series of cases dating back to 1853, the Court stated, “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable.”¹⁴⁶ For instance, Einstein could not patent “his celebrated law that $E=mc^2$,” Newton could not patent the law of gravity, and nobody could patent “a new mineral discovered in the earth or a new plant found in the wild.”¹⁴⁷ These latter examples explicitly recognize that products of nature, like naturally occurring seeds, are not patentable subject matter.

Distinguishing Chakrabarty’s bacteria from “a hitherto unknown natural phenomenon,” the court found that man-made bacteria are patentable subject matter because they are “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity having a distinct name, character [and] use.”¹⁴⁸ Moreover, “the patentee has produced a new bacterium with markedly different characteristics from any found in nature . . . [the] discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”¹⁴⁹

Thus, *Chakrabarty* stands for the proposition that living things are patentable subject matter under § 101, and the relevant distinction is not between living and non-living, but between human-made and naturally occurring. Nobody disputed the fact that the bacteria in *Chakrabarty* were a product of human invention, nor could they. The bacteria, as patented, do not exist in nature.

143. *Id.* (internal citations omitted).

144. *Id.* (internal citations omitted).

145. *Id.* at 309 (internal citations omitted).

146. *Id.* (citing *Parker v. Flook*, 437 U.S. 584 (1978); *Gottschlalk v. Benson*, 409 U.S. 63, 67 (1972); *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *O’Reilly v. Morse*, 15 How. 62, 112–21 (1854); *Le Roy v. Tatham*, 14 How. 156, 175 (1853)).

147. *Id.*

148. *Id.* at 309–10 (internal citations omitted).

149. *Id.* at 310.

Although the Court in *Chakrabarty* referred to the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 (PVPA), it did so in the context of determining the scope of patentable subject matter, and more specifically, to determine whether § 101 included living things. It did not examine whether those acts are the sole means for patenting plants, a matter which it decided in *J.E.M. Ag Supply*.

After the Supreme Court's decision in *Chakrabarty*, the Patent and Trademark Office Board of Patent Appeals and Interferences determined plants were included in the meaning of "manufacture" and "composition of matter," which made them patentable subject matter under 35 U.S.C. § 101.¹⁵⁰ At the time of *J.E.M. Ag Supply*, the United States Patent and Trademark Office had issued more than 1,800 utility patents for plants, plant parts, and seeds under 35 U.S.C. § 101.¹⁵¹ Pioneer Hi-Bred owned such patents on 17 different plants and plant parts, and sold such varieties subject to a "limited label license" that restricted seed use "solely to produce grain and/or forage."¹⁵² J.E.M. Ag Supply, who was not an authorized dealer, purchased patented hybrid seeds which bore the license agreement, and resold them.¹⁵³

Pioneer Hi-Bred subsequently brought a patent infringement suit.¹⁵⁴ J.E.M. Ag Supply denied infringement and filed a counterclaim for patent invalidity, arguing that the Plant Patent Act of 1930 (creating plant patents) and the PVPA (creating Plant Variety Protection certificates) are the exclusive means for protecting plant life, which makes utility patents obtained on plants under 35 U.S.C. § 101 invalid.¹⁵⁵

The Court examined the Plant Patent Act and the PVPA, and relied heavily on their finding in *Chakrabarty* that Congress intended for 35 U.S.C. § 101 to be broad in scope and applicability.¹⁵⁶ Consequently, the Court found that "plants have always had the *potential* to fall within the general subject matter of 35 U.S.C. § 101," even though the written description requirement previously made it difficult to get a utility patent.¹⁵⁷ The Court concluded that the 1930 Plant Patent Act recognized that a plant breeder's work was patentable

150. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* 534 U.S. 124, 131 (2001).

151. *Id.* at 127.

152. *Id.* at 127–28.

153. *Id.* at 128.

154. *Id.* at 128–29.

155. *Id.* at 129.

156. *Id.* at 130–31.

157. *Id.* at 135 (emphasis in original).

and relaxed the written description requirement, which made it easier for plant breeders to obtain patent protection under a separate plant patent.¹⁵⁸

According to the Court, denying breeders a utility patent simply because it was difficult to obtain in 1930, however, “would be inconsistent with the forward-looking perspective of the utility patent statute.”¹⁵⁹ In that regard, the 1930 Plant Patent Act did not broaden the scope of patentable subject matter, it just made it easier for plant breeders to obtain patent protection on new products.¹⁶⁰

The Court also examined the Plant Variety Protection Act (PVPA), and reached a similar conclusion. The Plant Patent Act only provided intellectual property protection to asexually reproduced plants (reproduced by grafts) and not to sexually reproduced plants (reproduced by seeds).¹⁶¹ The Plant Variety Protection Act extended intellectual property protection to certain sexually reproduced plants.¹⁶² As the court noted, the PVPA does not state that Congress intended for PVPA certificates to be the exclusive means of intellectual property protection for sexually reproduced plants.¹⁶³

Because PVPA protection is easier to obtain and protects less, it can “easily be reconciled” with allowing plants protection under a utility patent.¹⁶⁴ In order to obtain a certificate under PVPA, a breeder must only demonstrate that the variety is new, distinct, uniform, and stable.¹⁶⁵ To get a utility patent, a breeder must show that the plant is useful and nonobvious.¹⁶⁶ In addition, varieties protected by certificates under PVPA are subject to more exemptions that weaken the holder’s rights when compared to a utility patent, including exemptions for research and saving seed to plant the next year’s crop.¹⁶⁷ A utility patent has no such exceptions.¹⁶⁸ Because the two different forms of protection have different requirements, and varying levels of protection, they can coexist and those that do not meet the stringent

158. *Id.* at 134.

159. *Id.* at 135.

160. *See id.* at 134 (noting the PPA “gave patent protection to breeders who were previously unable to overcome the obstacles described in *Chakrabarty*”).

161. *Id.* at 132.

162. *Id.* at 138.

163. *Id.* at 141.

164. *Id.* at 138.

165. 7 U.S.C. § 2402(a) (2012).

166. 35 U.S.C. §§ 101–03 (2012).

167. *J.E.M. Ag Supply*, 534 U.S. at 140.

168. *Id.* at 143.

requirements for utility patent protection may still qualify for protection under a PVPA certificate.¹⁶⁹

Justice Breyer, in a dissent joined by Justice Stevens, considered the Court's heavy reliance on *Chakrabarty* misplaced.¹⁷⁰ He argued that the Court in *Chakrabarty* examined two statutes that did not deal specifically with bacteria, in order to determine whether bacteria were patentable subject matter.¹⁷¹ Here, the Court had been asked to determine the scope of the same two statutes, which specifically deal with the subject matter in dispute—plants.¹⁷² Justice Breyer interpreted the Plant Patent Act, noting that it applies to all plants, not just those asexually reproduced, so long as they are distinct, new, and on one or more occasion have been asexually reproduced.¹⁷³ He correctly noted that “virtually any plant” can reproduce both sexually and asexually, and that the coverage provided by the act gave the breeder a monopoly over asexual reproduction.¹⁷⁴ By excluding sexual reproduction, or reproduction through seeds, Congress allowed farmers to continue the long-standing practice of saving seed.¹⁷⁵ Despite Justice Breyer's compelling dissent, the law today allows plant breeders to obtain a utility patent on their inventions.

Although the seeds in dispute were a patented hybrid line and not genetically engineered, *Chakrabarty* and *J.E.M. Ag Supply* read together demonstrate that genetically engineered seeds are patentable subject matter for which a biotech company can obtain a utility patent. Similar to the Coordinated Framework, the Supreme Court is also unwilling to stand in the way of innovation. However, the Supreme Court has acknowledged that, unlike the Coordinated Framework, it understands that process matters.

IV. ANALYSIS

The previous cases demonstrate why Congress must enact meaningful legislation to regulate biotechnology. Today, scientists know more about the science underlying agricultural biotechnology

169. *Id.* at 144.

170. *See id.* at 147 (Breyer, J. dissenting) (arguing that *Chakrabarty* did not consider the relevant question of “whether the words ‘manufacture’ or ‘compositions of matter’ . . . cover plants that also fall within the scope of” the PPA and PVPA).

171. *Id.* at 148–49.

172. *Id.* at 149.

173. *Id.* at 150.

174. *Id.* at 150–51.

175. *Id.* at 151.

and that science shows that the assumptions made in creating the Coordinated Framework are outdated. As recent cases demonstrate, the Coordinated Framework also fails to account for the interests of those affected by biotechnology. Moreover, current law, which focuses on process in granting intellectual property protection and final product in food safety and environmental regulation, is inconsistent. Lastly, courts cannot currently provide a satisfactory remedy to those harmed by biotechnology. As a result, Congress is the only branch of government that can create a meaningful framework to regulate biotechnology.

A. The underlying assumptions of the Coordinated Framework are outdated

Science has progressed significantly since the promulgation of the Coordinated Framework. At the time of its drafting, the framework reflected the scientific belief that one gene sequence was traited for one specific protein.¹⁷⁶ When scientists injected that one sequence into a new organism, they believed they were only entering one trait.¹⁷⁷ This now-rudimentary understanding is demonstrably false, as biologists have confirmed that gene sequences are networks that overlap and interact in a way such that the insertion of a gene sequence in a new plant will alter the way these sequences operate and communicate with one another.¹⁷⁸ As early as 2000, other countries began to question their reliance on the doctrine of substantial equivalence, including major U.S. trade partners the European Union and Canada.¹⁷⁹

The GE pea plant example at the beginning of this article demonstrates just how unsophisticated our understanding of biotechnology is. This alone should give consumers and Congress some pause. While GE plants currently on the market may not have these allergenic properties (or such allergenic properties have not yet presented themselves), the mere possibility that the Coordinated Framework created a pathway for the possibility of such characteristics

176. See Maria R. Lee-Muramoto, *Reforming the “Uncoordinated” Framework for Regulation of Biotechnology*, 17 *DRAKE J. OF AGRIC. L.* 311, 339 (2013) (noting that the Coordinated Framework’s doctrine of substantial equivalence is based on the “one gene-one protein” model); Van Tassel, *supra* note 2, at 221–22.

177. See Lee-Muramoto, *supra* note 175, at 339–40 (noting the tenant of the “Central Dogma”); Van Tassel, *supra* note 2, at 221–22.

178. Lee-Muramoto, *supra* note 175, at 341; Van Tassel, *supra* note 2, at 221.

179. See McGarity, *supra* note 7, at 489–90 (“With the impending demise of the substantial equivalence doctrine as a credible theoretical underpinning, the fragile veneer that has protected the regulatory process in the United States from overwhelming criticism is cracking.”).

in our food is alarming. The Coordinated Framework operates under the assumption that products of biotechnology are the same as their natural counterparts, but the GE pea plant demonstrates otherwise.

The troubles resulting from these outdated assumptions are compounded in the courts. When the court heard *Alliance for Bio-Integrity* in 2000, it reviewed an FDA record developed in the lead-up to the FDA's 1992 Statement of Policy. Eight years passed from the time the FDA created the record and the time the court heard the challenge. While the plaintiffs had contemporary scientific evidence that demonstrated fallacies in the Statement of Policy, the court could not consider them in determining whether the agency acted arbitrarily and capriciously in 1992. Today, scientists know even more about genetic engineering, or at the very least, have a greater understanding of how much we do not know. But challenging agency action—be it that of the FDA, the EPA, or the USDA—is exceedingly difficult when these agencies are operating under the Coordinated Framework, a policy developed based on an understanding of science in 1986.

When the drafters of the Coordinated Framework created the policy, they failed to account for the ways in which GE technology would alter biology and ecology. In their minds, GE technology created a product substantially equivalent to its natural counterpart. So, in theory, the use of recombinant bovine somatotropin as a growth hormone in dairy cows caused those cows to produce milk substantially equivalent to milk from cows not treated with rBST.

Thankfully, not all court actions are limited to older agency records that rely on outdated science. In *International Dairy*, the court found that the two milk products were in fact compositionally different.¹⁸⁰ Milk produced from cows with rBST had higher levels of insulin-like growth factor 1, higher somatic cell counts, and, during certain phases of milk production, increased fat and decreased protein content.¹⁸¹ Thus, at least one court opinion uses quantifiable science to highlight a fallacy in the Coordinated Framework's underlying assumption of substantial equivalence.

Similarly, scientists continue to learn more about DNA. We now know that genes overlap with each other and operate in a network instead of segmented parts that scientists can remove from one plant and expect to perform the same function in another.¹⁸² The growing

180. *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 636 (6th Cir. 2010).

181. *Id.* at 636–37.

182. *See* Van Tassel, *supra* note 2, at 231–32 (noting that “sections of previously characterized junk DNA modulate a labyrinthine of silencing, switching and splicing operations”).

field of epigenetics is helping scientists understand how and when genes express themselves, and the possibility that certain factors may silence genetic expression in one instance, and unleash its expression in later iterations.¹⁸³ Just like individuals in a community, genes interact with one another and are a product of their environment.¹⁸⁴ When removed, they can and do act differently. Because society does not have the benefit of centuries of knowledge and real world trials with these new plants as they do with naturally occurring plants, assuming that our bodies and the environment will interact with them in the exact same way is shortsighted.

B. The Coordinated Framework does not account for all interests affected by biotechnology

The Coordinated Framework's focus on products of biotechnology unnecessarily limits the scope of factors impacted by GE technology. This is particularly noticeable in three different areas: the environment, international trade, and the non-GE growing industry.

Both *Center for Food Safety* and *Geertson Seed Farms* highlight the disconnect created by the Coordinated Framework's silence on the environmental effects of biotechnology. The court in *Center for Food Safety* acknowledged that annual glyphosate use would increase from a half-million pounds to more than 24 million pounds,¹⁸⁵ which undeniably creates additional stress on the environment. The court explicitly acknowledged its inability to address the known increase in herbicide use that will result from the deregulation of alfalfa. While the district court in *Geertson Seed Farms* found that increased glyphosate use was a factor showing that the USDA failed to take the hard look required by NEPA, this finding only helped establish that the USDA needed to complete an environmental impact statement.¹⁸⁶ After completing the environmental impact statement, the USDA did

183. *See id.* at 236–37 (noting that epigenetic mechanisms “turn genes on and off during the course of an organism’s life” according to environmental factors).

184. *See id.* at 236 (“Epigenetics concentrates on the multiple influences on DNA . . . that determine whether genes are turned on and off”); *see also id.* at 237 (describing epigenetic inheritance in genetically modified food).

185. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 836 (9th Cir. 2013).

186. *See Geertson Farms Inc. v. Johanns*, No. C 06-01075, 2007 WL 1302981 at *1 (N.D. Cal. May 3, 2007) (memorandum) (“[G]ene transmission could and had occurred . . . [and] failure to analyze the likely extent of gene flow . . . did not demonstrate the ‘hard look’ required by NEPA.”); *see also Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2,743, 2,759 (noting that under some circumstances it could be “hard to see why the limited planting and harvesting . . . did not also require the preparation of an EIS).

not have the authority to stop deregulation of alfalfa.¹⁸⁷ As a result, one of the few accomplishments of existing laws and regulations is that they confirm that the deregulation of alfalfa would cause growers to use more glyphosate.¹⁸⁸ Although the EPA has the authority to regulate the amount of glyphosate used on crops, that decision making process is not included with or tied into the decision to deregulate a GE crop. Because the alfalfa in question was not modified to include a pesticide, the EPA had no role in the GE approval process even though deregulation of the GE seed will have a significant impact on the environment and the amount of glyphosate used. The Coordinated Framework fails to consider environmental concerns, thereby drawing a completely artificial line between food production and the environment.

Another interest identified in *Center for Food Safety*, throughout the opinion, was the potential impact of adventitious presence, or unauthorized cross-pollination.¹⁸⁹ The possibility of cross-pollination is particularly relevant for GE alfalfa because alfalfa is pollinated by bees which can travel up to two miles, thereby creating risks for non-GE alfalfa growers up to two miles away from a GE alfalfa field.¹⁹⁰

Cross-pollination has the potential to impact a number of different areas, including international trade, organic production, and non-GE production. Because some foreign countries will not import genetically engineered products,¹⁹¹ farmers whose non-GE crops are cross-contaminated with GE crops will suffer losses. In some instances, a country will ban all imports of a specific crop from a country based merely on a fear that imported crops may contain GE products, which can impact an entire industry. For example, when an Oregon farmer discovered rogue GE wheat in his field, Japan halted all imports of Oregon wheat.¹⁹² Wheat growers throughout the United States sued

187. See *Ctr. For Food Safety*, 718 F.3d at 842 (“[O]nce APHIS concluded that RRA was not a plant pest . . . the agency had no jurisdiction to continue regulating the crop.”).

188. *Id.* at 841.

189. See *id.* at 832 (noting the plaintiff’s concern over RRA cross-pollinating with conventional alfalfa plants).

190. UNITED STATES DEP’T OF AGRIC., GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J103: REQUEST OF NONREGULATED STATUS 25–26 (2010), https://www.aphis.usda.gov/bio-technology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

191. Sarah Shemkus, *Is China’s GMO Corn Ban Protecting Consumers or Protecting Markets?*, THE GUARDIAN, (Nov. 20, 2014), <http://www.theguardian.com/sustainable-business/2014/nov/20/china-gmo-corn-boycott-markets>.

192. Aya Takada, *Japan Halts Some U.S. Wheat Imports on Gene-Altered Crops*, BLOOMBERG BUSINESS (May 30, 2013), <http://www.bloomberg.com/news/articles/2013-05-30/japan-halts-some-u-s-wheat-imports-on-gene-altered-crops>; Dan Charles, *In Oregon, the*

Monsanto, the producer of the GE seeds, for economic losses incurred as a result of Japan's ban.¹⁹³ As this example makes clear, both possible and actual cross-contamination of non-GE crops with GE crops can lead to economic losses for growers of non-GE seed. With a crop such as alfalfa that is easily subject to cross-pollination, nothing in the current GE regulatory process forces any government agency to consider the potential economic impacts of cross-pollination before a GE product enters the market.

The possibility of cross-pollination for organic and non-GE producers can have even greater economic impacts. If these types of growers want to export their products, they will run into the same problems noted above. Even in domestic markets, however, they will likely incur additional costs. Organic farmers cannot sell their crops as organic if they are contaminated with GE product. As a result, the organic farmer typically must pay for additional testing to ensure the absence of GE crops. If organic crops are contaminated, the farmer loses the benefit of an organic crop price premium. Also, an organic farmer may buy seeds that allow her to save seed to plant the next year, like most farmers used to do. If GE seeds contaminate the farmer's fields they not only lose their organic status, but the farmer also incurs additional costs in buying more seeds the following year. Because there is now a price premium associated with some non-GE crops, these same realities apply to growers who choose to raise non-GE crops, even if not certified organic.¹⁹⁴

C. Focus on product, and not process is artificial and inconsistent

Although prescient observers likely knew it in 1986, the distinction between product and process in the Coordinated Framework is artificial and inconsistent. Thankfully, the courts seem less willing than the executive branch to accept this artificial distinction. The court in *International Center* acknowledged that process alone can cause harm. There, residents of Central Oregon had an interest in viewing native flora and the small possibility that GE grass could replace native grass, even though it looked the same, was sufficient to cause an injury.

GMO Wheat Mystery Deepens, NPR: THE SALT (July 17, 2013), <http://www.npr.org/blogs/thesalt/2013/07/17/202684064/in-oregon-the-gmo-wheat-mystery-deepens>.

193. Elizabeth Barber, *Monsanto Reaches \$2.4M Settlement with U.S. Wheat Farmers*, TIME (Nov. 13, 2014), <http://time.com/3582953/monsanto-wheat-farming-genetically-modified-settlement/>.

194. Jacob Bunge, *Fields of Gold: GMO-Free Crops Prove Lucrative for Farmers*, WALL STREET JOURNAL (Feb. 2, 2015), <http://www.wsj.com/articles/fields-of-gold-gmo-free-crops-prove-lucrative-for-farmers-1422909700>.

Visually, the two products—GE grass and non-GE grass—appeared the same. However, the fact that Scotts genetically engineered one of the grasses was enough to harm the plaintiff’s interest in viewing native flora.

Center for Food Safety and *Geertson* also highlight the fact that process matters. If the GE alfalfa truly was substantially equivalent to its natural counterpart, the parties would not have pursued the case up to the Supreme Court and then back to the Ninth Circuit. Food is the unique result of many interdependent factors in the production process, and the alteration of any single factor can have a butterfly effect on the entire chain, including a different end product. To regulate food without regard to these factors, and the important steps each of them play, is indefensibly shortsighted.

The alternative, an emphasis on process rather than product, would be consistent with other aspects of food regulation. Foods labeled organic are organic because of the process by which farmers and food manufacturers created them.¹⁹⁵ Fish markets can label fish as “wild caught” because of how the fish are raised and harvested.¹⁹⁶ Juice created from concentrate is labeled “from concentrate” because of the process by which it is created.¹⁹⁷ Olive oil can be labeled extra virgin because of the way it is pressed.¹⁹⁸ These examples demonstrate that an emphasis on process is not new in the regulation of food.

Perhaps nowhere is the distinction between process and product more relevant than in intellectual property protection. In order to obtain a utility patent, which is the primary means for protecting biotech products, the inventor must show, among other things, that the product is man-made. In that regard, intellectual property protection completely flips the analysis and focuses exclusively on process. While neither the Coordinated Framework nor the 1992 Policy Statement purported to address intellectual property, the case law is relevant for two reasons. First, like the Coordinated Framework, Congress created the laws that govern intellectual property rights in biotech products prior to the advent of agricultural biotechnology.¹⁹⁹ As a result, courts had to apply then-existing law to new technology. Second, the grant of

195. See 7 C.F.R. § 205.1 (2016) (defining “organic”).

196. Cf. 7 C.F.R. § 60.300 (2016) (stating that product sold as a combination of farm-raised and wild fish may be labeled “wild caught”).

197. 21 C.F.R. § 102.33(g)(1) (2016).

198. See United States Standards for Grades of Olive Oil and Olive-Pomace Oil, 74 Fed. Reg. 22,363 (Oct. 25, 2010) (noting that extra virgin olive oil is unprocessed).

199. See generally *supra* note 1.

intellectual property rights has fueled the rapid increase in the use of GE technology.²⁰⁰ Absent Congressional action, courts have taken on the responsibility of expanding the scope of protection for agricultural biotech companies and have allowed them to extend their monopolies.

When determining the scope of patentable subject matter, the court acknowledged the economic incentive provided by patent protection: the grant or denial of a patent determines whether research is “accelerated by the hope of reward or slowed by want of incentives.”²⁰¹ Thus, when the Supreme Court determined the relevant distinction is whether the product is created by man or nature, it “accelerated the hope of reward” for man-made products of biotechnology. Moreover, the court based its expansion of this right entirely on how manufacturers created the product. It is inconsistent to base the grant of a monopoly on process, and to then limit the regulation of that monopoly based on product.

D. Courts have taken it as far as they can, now Congress must act

Despite a patchwork of laws and regulations, courts have dutifully examined the facts surrounding the rapid increase in agricultural biotechnology. From *Alliance for Bio-Integrity* in 2000 to *Center for Food Safety* in 2013, courts have increased their scrutiny when examining the government’s reliance on the doctrine of substantial equivalence. Recent cases highlight not only the unwillingness of courts to accept the doctrine, but also their limitations in demanding greater agency action.

In *Alliance for Bio-Integrity*, where the court sided with the government on every claim challenging the FDA’s 1992 Policy Statement, the dispute was largely procedural and the court did not have an opportunity to examine the most recent scientific data. The court’s analysis was short and demonstrated the limitations of relying on an agency’s interpretation of existing statutes. It is difficult to show arbitrary and capricious behavior, particularly when relying on dated science. Even though some scientists at the FDA disagreed when the agency created the Policy Statement, this disagreement was insufficient to find the agency’s actions arbitrary and capricious. Because the court’s review of agency action is limited to the agency’s record at the time the agency acted, new science, even if contrary to previously accepted science, is not relevant. Lastly, because the government’s

200. Brian D. Wright, *Plant Genetic Engineering and Intellectual Property Protection*, AGRICULTURAL BIOTECHNOLOGY IN CALIFORNIA SERIES, PUBLICATION 8,186, at 4.

201. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

policy directing agency regulation of biotechnology is based not on law, but on an executive branch notice (Coordinated Framework) and policy statements (Statement of Policy), it is difficult to challenge the underlying approach or influence the creation of policy as one would in the traditional democratic process through legislation in Congress or rulemaking in administrative agencies.²⁰²

In *International Dairy*, the court offered little deference to the FDA and the State of Ohio's reliance on FDA guidance. There, the court could, and did, consider more recent science when it found that milk from cows treated with GE hormones created milk compositionally different from cows treated without GE hormones. Unlike *Alliance for Bio-Integrity*, the challenge to agency regulation occurred closer to the time of the regulation, and the record more accurately reflected the state of science. The court found the State of Ohio's reliance on FDA guidance and the doctrine of substantial equivalence misplaced. The process mattered, and the process created a different product. As a result, the government could not prevent dairy producers from identifying their milk as being from cows not treated with rBST. Despite the favorable outcome for dairy farmers who did not use rBST, the case involved a state regulation that relied on FDA guidance. While the Ohio regulation was unconstitutional, questionable guidance still exists at the federal level.

In *International Center*, the court again analyzed quantitative scientific data and came to the conclusion that GE crops are not substantially equivalent to their natural counterparts.²⁰³ There, the court concluded that a member of the public is harmed even when the possibility of them seeing GE grass in the natural environment is less than 10% (or even as small as less than 1%).²⁰⁴ The fact that GE and non-GE grasses look the same is irrelevant. The mere fact that one is genetically engineered to be glyphosate resistant is enough to harm the public's interest in seeing native flora. Moreover, because of the risk to the environment from cross-pollination and the inability to control pollen flow, the government must complete an environmental impact statement.²⁰⁵ This highlights the court's belief that genetically

202. See Peck, *supra* note 29.

203. See *supra* notes 90–110 and accompanying text (summarizing the case).

204. See Int'l. Ctr. for Tech. Assessment v. Johanns, 473 F.Supp 2d 9, 20–21 (D.D.C. 2007) (noting that Crooked River National Grassland's "extremely close" proximity to area where "near-term GTCB establishment risk may fall somewhere between 0.7 and 8.9 percent" means that "the risk is certainly non-trivial" that GTCB could establish itself in the Grassland).

205. See *id.* at 29–30.

engineered plants present unique issues and are not equivalent to naturally occurring counterparts.

But the court's authority is limited. As Scotts later demonstrated, scientists can circumvent existing regulations by using different techniques for genetic engineering. After the case, the USDA determined that it did not have the authority to regulate a variety of glyphosate resistant Kentucky bluegrass created by Scotts because it was not a plant pest or noxious weed. While some believe the USDA's reasoning is questionable, it may be difficult to prove it is arbitrary and capricious. The new product presents the same concerns raised by the court in *International Center*, but the USDA's interpretation of laws that predate biotechnology have limited the scope of the court's power.

The limitations of the judicial system are highlighted and expressly acknowledged in *Center for Food Safety*. There, following several rounds of appellate litigation, the court found that after completing an environmental impact statement the USDA completed its statutory mandate.²⁰⁶ Although new harms were likely to occur, including potential economic losses and environmental damage, the court had no authority to require the USDA to consider those impacts in deciding to deregulate alfalfa.²⁰⁷ The district court in *Geertson* undertook a rigorous analysis of scientific data and found that the USDA acted arbitrarily and capriciously when it found no significant impact to the environment by the deregulation of GE alfalfa. Rather, unlike its natural counterpart, GE alfalfa presented a number of potential environmental and economic harms that the USDA had to consider. But, after a circuitous path through the courts, the Ninth Circuit found in *Center for Food Safety* that there is no other remedy within the existing framework. After requiring an environmental impact statement, the judicial system could do nothing more to address the environmental and economic harms caused by the deregulation of alfalfa.²⁰⁸

Consequently, the impetus is on Congress. Consumer groups and non-GE farmers can continue to challenge the government and biotechnology companies in court, but the remedies available to them do little more than delay the inevitable. Because there are valuable interests not currently accounted for, including the future health and

206. *Ctr. for Food Safety v. Vilsack*, 718 F. 3d 829 (9th Cir. 2013).

207. *See id.* at 842 (holding that the USDA "was not required to look at alternatives to the unconditional deregulation of RRA" because it lacked jurisdiction to adopt the alternatives).

208. *See id.* (holding that the USDA was not required to consider the alternatives to deregulation).

wellbeing of society and the environment, Congress needs to act. Like technological advances in other areas, including drones, information technology, and energy, citizens have a right to participate in the democratic process on issues that impact their lives. When the government deliberately conceals those avenues by governing from notices and policy statements, it fails to represent the people.

CONCLUSION

In the nearly thirty years since the Coordinated Framework, many things have changed. While it might have been a difficult task thirty years ago even for the most prudent observer forecasting these changes and trying to predict the ways in which agricultural biotechnology might impact our lives, we now have the experience necessary to identify at least some of these impacts. Most notably, we know that food safety for GE products is not as simple as we thought, we know that GE products impact the environment through increased pesticide use and cross-pollination with non-GE crops, and we know that the use of GE crops can cause negative economic consequences. The Coordinated Framework accounts for none of these impacts. While a growing number of cases in the judicial system question the doctrine of substantial equivalence and highlight gaps in the Coordinated Framework, courts are increasingly limited in the remedies they can provide. As a result, it is time for government to operate in the way our founders intended. Congress needs to create and pass laws that meaningfully address the interests unaccounted for by a patchwork of legislative shortcomings.