1-1-2012

The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply

Debra M. Strauss
Fairfield University, dstrauss@fairfield.edu

Peer Reviewed

Published Citation

Debra M. Strauss, "The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply". Idaho Law Review 48.2 (2012): 267-319.

THE ROLE OF COURTS, AGENCIES, AND CONGRESS IN GMOS: A MULTILATERAL APPROACH TO ENSURING THE SAFETY OF THE FOOD SUPPLY

DEBRA M. STRAUSS

FULL CITATION:

Debra M. Strauss, *The Role of Courts, Agencies, and Congress in GMOs: A Multilateral Approach to Ensuring the Safety of the Food Supply*, 48 IDAHO L. REV. 267 (2012).

THE ROLE OF COURTS, AGENCIES, AND CONGRESS IN GMOS: A MULTILATERAL APPROACH TO ENSURING THE SAFETY OF THE FOOD SUPPLY

DEBRA M. STRAUSS*

TABLE OF CONTENTS

* Associate Professor of Business Law, Charles F. Dolan School of Business, Fairfield University; B.A., Cornell University; J.D., Yale Law School. Professor Strauss, a former Food and Drug Law Institute Scholar, currently teaches the legal environment of business, international law, and law and ethics. She has also developed a new course on the international law and ethics of genetically modified food. This article was written under a research grant from the Charles F. Dolan School of Business.

I. INTRODUCTION

Food safety is occupying a place in the spotlight now more than ever, with a crescendo of recent food scares awakening the American consumer to the dangers from which they are not being adequately protected, and further resulting in new legislation like the FDA Food Safety Modernization Act (FSMA), a mandate from Congress and the President.[1] With this new focus on food safety comes an awareness that more change must soon follow, as law and policy struggle to catch up with years of regulatory neglect. The courts, other agencies, or Congress—who steps in when agencies fail to protect the U.S. food supply? Currently, food regulation is fractured, with authority split among a few agencies. While the courts are attempting to step in to fill the gaps, they are reaching the limits of their judicial review powers. Accordingly, the time is ripe to develop a new public policy approach for ensuring food safety in the United States.

These issues come most dramatically to the forefront in the area of genetically modified organisms (GMOs). Unlike traditional methods of selective breeding that have been used for centuries, genetically modified (GM) crops are created when the DNA of one organism is inserted into another, causing the target trait to be expressed in that non-related species at the cellular level throughout the plant, including the fruit or vegetable and the component ingredients that become part of a variety of food products. Most commonly, GM plants are engineered to withstand a weed-killing herbicide, Roundup, sold by Monsanto along with the herbicide-resistant varieties of soybeans, canola, cotton, corn, radicchio, rice, and sugar beet.[2] In addition, genes derived from a bacterium in the soil used as an insecticide, *Bacillus thuringiensis* (Bt), have been inserted into crops to induce the plant to produce a toxin against certain insects, producing Bt-corn, Bt-cotton, Bt-potatoes, Bt-rice, and Bt-tomatoes.[3] Meanwhile in the U.S., unlike in Europe, Japan, and most of the international community, these crops are not subject to special regulatory scrutiny in spite of their novel properties. Instead, they are

1. FDA Food Safety Modernization Act (FSMA), Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended at 21 U.S.C. § 2201 (2006)) (amending the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–99 (1938)). *See* Debra M. Strauss, *An Analysis of the FDA Food Safety Modernization Act: Protection for Consumers and Boon for Business*, 66 FOOD & DRUG L.J. 353 (2011) [hereinafter Strauss, *FSMA*] (analyzing the components and significance of the recently enacted FSMA and proposing a reassessment of GM regulation in view of this new proactive approach).

2. William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES, May 4, 2010, at B1.

3. *See* Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 167–68 (2006) [hereinafter Strauss, *Importing Caution*] (explaining this technology and examples of GM crops).

welcomed by the government for their touted benefits and are widely adopted by farmers.[4]

As a result, the most recent statistics show that 93% of soybeans,[5] 86% of corn,[6] and 93% of cotton[7] planted in 2010 were genetically modified; GM canola, squash, papaya, alfalfa, and sugar beet were also widely planted.[8] Seventy-nine GM crops were granted non-regulated status as of May 12, 2010, including fifteen species as well as smaller-volume crops such as beets, chicory, plums, and flax.[9] In fact, a vast majority of products on U.S. grocery shelves now contain GM ingredients.[10] Even Whole Foods Market, which attempts to stock natural foods, acknowledges that this proliferation makes stocking only non-GMO products difficult. "Until there's federal government mandated labeling of GMO ingredients, there's no way to tell if packaged products contain GMO ingredients," admits the quality standards coordinator for Whole Foods Market.[11] "Our approach is to work in the spirit of partnership with our suppliers . . . to encourage them to take active steps to avoid GMO ingredients."[12]

---

4. *Id.* at 174–76 (discussing the U.S. regulatory scheme in comparison to the international approach, which scrutinizes the human health and environmental risks as part of its precautionary approach).

5. USDA ECON. RESEARCH SERV., GENETICALLY ENGINEERED (GE) SOYBEAN VARIETIES BY STATE AND UNITED STATES (2010–2011), http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls (select "Soybeans" worksheet).

6. USDA ECON. RESEARCH SERV., GENETICALLY ENGINEERED (GE) CORN VARIETIES BY STATE AND UNITED STATES (2010–2011), http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls (select "Corn" worksheet).

7. USDA ECON. RESEARCH SERV., GENETICALLY ENGINEERED (GE) UPLAND COTTON VARIETIES BY STATE AND UNITED STATES (2010–2011), http://www.ers.usda.gov/Data/BiotechCrops/alltables.xls (select "Cotton" worksheet).

8. INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, *ISAAA Brief 41-2009: Executive Summary*, http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp (last visited Oct. 27, 2011) (documenting rise in GM plantings in the first fourteen years, from 1996 to 2009).

9. Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply – Past, Present, and Future*, 2011 WIS. L. REV. 399, 462 (2011). *See, e.g.*, *Petitions of Nonregulated Status Granted or Pending by APHIS as of October 12, 2011*, USDA ANIMAL & PLANT HEALTH INSPECTION SERV., http://www.aphis.usda.gov/biotechnology/not_reg.html (last visited Oct. 27, 2011) (listing eighty-seven crops that have been granted non-regulated status).

10. A conservative estimate by the Grocery Manufacturers Association estimated that 75% of all processed foods in the United States in 2005 contained a GM ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil. *See, e.g.*, *Americans Clueless About Gene-Altered Foods*, ASSOCIATED PRESS, Mar. 23, 2005, http://www.msnbc.msn.com/id/7277844/ns/health-genetics/t/americans-clueless-about-gene-altered-foods/ (statement of Stephanie Childs, Grocery Manufacturers of America). Considering the exponential increase in GM plantings since then, one would expect the number to be even higher today.

11. Monica Eng, *Debate Rages Over Labeling of Foods with Genetically Modified Ingredients*, LA TIMES, June 2, 2011, http://articles.latimes.com/2011/jun/02/business/la-fi-gmo-20110602.

12. *Id.*

The lack of required labeling for GMOs in the United States is particularly troubling to opponents as an ethical matter because consumers have no way of knowing what products contain GM ingredients and thus have been deprived of the rights of choice and informed consent.[13] Moreover, this policy conflicts with other U.S. labeling requirements such as nutrition and ingredients content. Increased consumer awareness of this fact has generated dissatisfaction with the lack of federal regulation. A recent poll by ABC News reported that 92% of the American public wants the federal government to require mandatory labeling on GM foods.[14] If it were labeled, 55% currently say they would avoid such foods, including 62% of women, who do most of the food shopping.[15] Nearly half of adults, 47%, also say they would try to avoid hormone- or antibiotic-treated food if it were labeled.[16]

Critics of this technology express concern about possible health risks and environmental hazards such as "soil and plant nutrient losses, contamination of non-[GM] crops, and increased pesticide use."[17] Already, incidents of contamination have led to numerous lawsuits by traditional and organic farmers for their economic loss and injury.[18] Yet instead of responding to the public, the FDA relies on the companies that have a financial interest in growing biotech crops to assess their safety. The FDA has stated that "[u]ltimately, it is the food producer who is responsible for assuring safety" of GM foods.[19] But this reliance on the industry for assessing risks is misplaced, as evidenced by a Monsanto statement:

---

13. *See* Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. FOOD L. & POL'Y 1, 7–19 (2007) [hereinafter Strauss, *Ethical Implications*] (discussing the failed promise of this technology and presenting an ethical framework in support of labeling and monitoring).

14. David Morris, *Poll: Modified Foods Give Consumers Pause*, ABC NEWS (July 15, 2011), http://abcnews.go.com/Business/story?id=86497&page=1.

15. *Id.*

16. *Id.* Consumers also favor voluntary labeling: 51% of the U.S. consumers surveyed indicate they are attracted to foods with labels saying they are not genetically modified and 46% say the same for food labeled as hormone- and antibiotic-free. *Id.*

17. Eng, *supra* note 11; *see, e.g.*, Strauss, *Importing Caution*, *supra* note 3, at 169–76 (discussing risks of GMOs).

18. *See* Debra M. Strauss, *We Reap What We Sow: The Legal Liability Risks of Genetically Modified Food*, 16 J. LEGAL STUD. BUS. 149, 155–68 (2010) [hereinafter Strauss, *Legal Liability Risks*] (analyzing through lawsuits arising from these incidents the legal liability risks of GMOs and concluding that the interests of seed companies, farmers, and consumers will converge in this area to mandate greater certainty and safety).

19. Eng, *supra* note 11 (quoting written statement by FDA to the *Chicago Tribune*); *see also* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992). FDA continued by stating, "FDA has long regarded it to be a prudent practice for producers of foods using new technologies to work cooperatively with the agency to ensure that the new products are safe and comply with applicable legal requirements. It has been the general practice of the food industry to seek informal consultation and cooperation, and this practice should continue with respect to foods produced using the newer techniques of genetic modification." *Id.*

> Experts in the field of food safety are satisfied that [the current] approach is sufficient and reliable to assure the genetically modified crops are as safe as their conventional counterparts. This expert community does not see a need and thus does not recommend long-term tests in humans or animals in order to establish food safety.[20]

Most troubling, the short- and long-term risks to human health and the environment are apparently not being studied in the United States, although some negative results are being discovered in other countries.[21]

Under the Obama administration, an "unprecedented number" of GM crops are being approved for deregulation, including ethanol corn, alfalfa, and sugar beets.[22] In the absence of regulatory restraint or even extensive study by the governmental agencies responsible, consumer and environmental groups have been increasingly turning to the courts to contain the spread of GMOs. However, this approach may not prove to be the most effective or efficient in the long run, as a closer examination of these cases and other developments reveals.

In studying the dilemma of food safety in the area of GMOs, Part II of this article first examines the evidence of agency inaction and criticisms, particularly of the U.S. Department of Agriculture (USDA) and the Animal and Plant Health Inspection Service (APHIS), in the regulatory process. In Part III, this article first analyzes the court cases that have been initiated by consumer and environmental groups against these agencies, and then addresses the limits of their judicial review. Part IV explores action from Congress, whose oversight is required, and legislative initiatives that could provide guidance as well as a shift in this area. Part V then discusses the roles of trade associations acting in their industries' best interests, suppliers standing up for non-GM components, and consumer-driven demands such as organics and non-GMO sales. With these broad constituencies in mind, Part VI presents proposals for a new multilateral, unified approach capitalizing on a broader involvement of these other branches of government and industry/academic partners with expertise to leverage knowledge and information. Accordingly, Part VII concludes that the time is ripe to establish a dedicated and specific statutory response for GM crops and GMOs in food. Doing so is the next logical step in building upon the progress al-

---

20. Eng, *supra* note 11 (alteration in original).

21. For example, a 2011 Canadian study reported that "the blood of 93% of pregnant women and 80% of their umbilical-cord blood samples contained a pesticide implanted in GMO corn by Monsanto, though digestion was supposed to remove it from the body." *Id.* The researchers concluded, "given the potential toxicity of these environmental pollutants and the fragility of the fetus, more studies are needed." Aris Aziz & Samuel Leblanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, 41 REPROD. TOXICOLOGY 528, 532 (2011).

22. Eng, *supra* note 11.

ready achieved by Congress through the FSMA in furthering the safety of the U.S food supply.

II. EVIDENCE OF AGENCY INACTION: USURPED BY INDUSTRY PARTNERSHIPS?

The regulatory scheme for GMOs originated in the Coordinated Framework for Regulation of Biotechnology, promulgated in 1986 before genetically engineered crops and food products were even developed.[23] By focusing simply on the physical attributes of the end products (i.e., whether they are "substantially equivalent" to non-GM products), the U.S. scheme fails to consider the biotechnology process itself or recognize that it may pose any inherent risks.[24] Regulatory authority is divided among three governmental agencies: the FDA, the Environmental Protection Agency (EPA), and the USDA (largely through APHIS), each with its narrow focus of inquiries and responsibilities.[25] As one commentator has observed, "The existing framework of power sharing between the USDA, EPA, and FDA yields an incomplete regulatory scheme. There is no strong central organization that is entrusted with overseeing GM crops from the issuance of permits through regulating what products ultimately reach store shelves."[26] As a consequence, with regard to GMOs, the U.S. system is "poorly regulated" and "largely dependent upon self-reporting."[27] In the absence of active agency oversight, this reliance on private industry has proved to be misplaced.

The Secretary of the USDA, Tom Vilsack, has repeatedly reached out to the biotech industry as well as nonconventional farmers, seeking a compromise position.[28] His position appears to reflect a lack of under-

---

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

24. *See* Strauss, *Importing Caution*, *supra* note 3, at 174–76.

25. *See* TADLOCK COWAN & GEOFFREY S. BECKER, CONG. RESEARCH SERV., RL 32809, AGRICULTURAL BIOTECHNOLOGY: BACKGROUND AND RECENT ISSUES 7 (2010), http://infousa.state.gov/economy/industry/docs/73949.pdf.

26. Blake Denton, Comment, *Regulating the Regulators: The Increased Role for the Federal Judiciary in Monitoring the Debate over Genetically Modified Crops*, 25 U.C.L.A. J. ENVTL. L. & POL'Y 333, 355 (2007) (highlighting the role of the courts in these lawsuits to allow private litigants to help shape public policy in the field, to provide a public forum to voice grievances about biotechnology, and to exert pressure on Congress to fix the current fragmented regulatory framework); *see also* Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulation*, 31 SETON HALL L. REV. 61, 65 (2000) (citing National Academy of Sciences committee recommendation that Congress should establish a unified and central framework for managing federal food safety programs headed by a single organization).

27. Denton, *supra* note 26, at 355.

28. *See, e.g.*, Charles Abbott, *USDA's Vilsack Seeks Compromise on Biotech Crops*, REUTERS (Jan. 10, 2011), http://www.reuters.com/article/2011/01/11/us-usa-agriculture-idUSTRE7083CA20110111 (Vilsack told the largest farm group that "farmers could see less government interference if they find a way for traditional and genetically modified crops to co-exist"). *See also* Strauss, *Importing Caution*, *supra* note 3, at 169–76 (citing potential dangers of GMOs to human health and the environment, including a precautionary report by the National Research Council). *But see* A. Bryan Endres, *Coexistence Strategies in a Bio-*

standing that coexistence may not be possible given the potential dangers of GMOs. His failure to acknowledge that GMOs could pose some risks is perhaps a function of his own biotech, farm state background.[29] Under his tenure, the USDA has continued to approve biotech products, including the world's first genetically engineered corn (known as Event 3272) designed specifically for biofuel production by Syngenta.[30] The Center for Food Safety (CFS) fears that this biofuel corn "will contaminate food-grade corn" and contends that it was approved without a comprehensive assessment of its "potential adverse effects on human health, the environment, or farmers' livelihoods."[31] Citing past incidents like the StarLink corn contamination caused by the same company,[32] the CFS charged the USDA with "once again put[ing] the special interests of the biotechnology and biofuels industries above the clear risks to our nation's food system."[33]

In a similar incident in 2006, the USDA deregulated LibertyLink rice after it contaminated the rice crop and wreaked havoc on the international export market.[34] The resulting severe economic loss for rice farmers across the country resulted in a series of lawsuits against the manufacturer, Bayer CropScience, with multimillion dollar jury verdicts last summer and a recent settlement with 11,000 farmers for $750 mil-

---

tech World: Exploring Statutory Grower Protections, 13 MO. ENVTL. L. & POL'Y REV. 206 (2006) (discussing statutory efforts by some states to implement coexistence strategies).

29. Agriculture Secretary Tom Vilsack's stand on GM crops and the biotech industry is not surprising. When he was appointed to the position by President Obama at the end of 2008 (confirmed by the Senate in January 2009), the Organic Consumers Association (OCA) opposed his nomination. *See Six Reasons Why Obama Appointing Monsanto's Buddy, Former Iowa Governor Vilsack, for USDA Head Would be a Terrible Idea,* ORGANIC CONSUMERS ASS'N (Nov. 12, 2008), http://www.organicconsumers.org/articles/article_15573.cfm. The OCA reported repeated events in which Vilsack demonstrated a preference for large industrial farms and GM crops. For example, as Iowa state governor in 2005, through a seed pre-emption bill, he blocked local communities from regulating where genetically engineered crops would be grown. *See id.* In addition, Vilsack was the founder and former chair of the Governor's Biotechnology Partnership, had often traveled in Monsanto's company jet, and was named Governor of the Year by the Biotechnology Industry Organization, an industry lobbying group. Mike Glover, *Vilsack, Gross Weigh in on Biotech Decision*, GENET-NEWS (Oct. 24, 2002), http://www.gene.ch/genet/2002/Oct/msg00057.html; Press Release, Biotechnology Indus. Org., Iowa's Vilsack Named BIO Governor of the Year, Sept. 20, 2001, http://www.bio.org/node/1084.

30. Press Release, Ctr. for Food Safety, World's First Genetically Engineered Biofuels Corn Threatens Contamination of Food-Grade Corn (Feb. 11, 2011), http://truefoodnow.org/2011/02/11/world%E2%80%99s-first-genetically-engineered-biofuels-corn-threatens-contamination-of-food-grade-corn/.

31. *Id.*

32. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 160–62 (discussing the StarLink corn contamination incident and its aftermath in terms of economic loss and liability).

33. Press Release, Ctr. for Food Safety, *supra* note 30 (statement of Andrew Kimbrell, Executive Director for CFS).

34. News Release, USDA Animal Health & Plant Inspection Service, USDA Deregulates Line of Genetically Engineered Rice (Nov. 24, 2006), http://www.aphis.usda.gov/newsroom/content/2006/11/rice_deregulate.shtml.

lion.[35] Most astonishing, in that case the USDA approved the genetically engineered rice *after* it had caused all of that damage and without conducting or requiring safety tests, solely on the basis of its similarity to previously approved rice varieties.[36] In its press release, the USDA noted that "[d]eregulated items and their progeny are considered safe for the environment and can be grown without APHIS oversight."[37]

The agency responsible for plant regulation inspires little confidence with its track record of environmental and food contamination from escaped GMOs.[38] In an internal audit of APHIS in 2005, the USDA's inspector general disclosed that the agency charged with regulating field trials had no knowledge of the location of some field trials, did no independent testing of nearby crops, and failed to require biotech firms to submit protocols.[39] Citing multiple inadequacies, the report made the following observation:

> In fact, at various stages of the field test process—from approval of applications to inspection of fields—weaknesses in APHIS regulations and internal management controls increase the risk that regulated genetically engineered organisms (GEO) will inadvertently persist in the environment before they are deemed safe to grow without regulation.[40]

The audit concluded that "APHIS' current regulations, policies, and procedures do not go far enough to ensure the safe introduction of agricultural biotechnology."[41] Moreover, a 2004 report by the National Research Council urged the government to improve its management and supervision, but acknowledged that "there is no way to guarantee that field trialed crops will not pollute the environment."[42] Allowing the industry to monitor itself is essentially a tort waiting to happen.[43]

---

35. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 156–60 (extensively analyzing the massive LibertyLink rice litigation and predicting its ultimate settlement); Andrew Harris & David Beasley, *Bayer Agrees to Pay $750 Million to End Lawsuits Over Gene-Modified Rice*, BLOOMBERG (July 2, 2011), http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html.

36. *See* Press Release, Rachel Iadicicco & Jerry Redding, USDA Animal Health & Plant Inspection Service, USDA Deregulated Line of Genetically Engineered Rice, (Nov. 24, 2006), http://www.aphis.usda.gov/newsroom/content/2006/11/rice_deregulate.shtml; Jessica Fraser, *USDA Approves Genetically Engineered Rice that Contaminated U.S. Food Supply; Safety Tests Skipped*, NATURALNEWS.COM (Nov. 29, 2006), http://www.naturalnews.com/021203.html.

37. Press Release, Iadicicco & Redding, *supra* note 36.

38. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 167 (analyzing the legal liability risks of GMOs and concluding that the interests of seed companies, farmers, and consumers will converge in this area to mandate greater certainty and safety).

39. USDA, OFFICE OF INSPECTOR GENERAL: SW. REGION, AUDIT 50601-8-TE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE CONTROLS OVER ISSUANCE OF GENETICALLY ENGINEERED ORGANISM RELEASE PERMITS (2005), http://www.usda.gov/oig/webdocs/50601-08-TE.pdf.

40. *Id.* at i.

41. *Id.* at iv.

42. Jeffrey M. Smith, *Monsanto Whistleblower Says Genetically Engineered Crops May Cause Disease*, SPILLING THE BEANS, Aug. 2006, *available at* http://www.seedsofdecepti

Meanwhile, criticisms of current USDA inspection practices and calls for an improved system seek to strengthen the agency's oversight of food safety.[44] For example, Congresswoman Rosa DeLauro (D-CT) is urging the White House Office of Management and Budget to act on a proposal, submitted in January 2011 after four years of study, to allow the USDA to regulate additional strains of E. coli beyond the standard O157:H7.[45] Many food safety advocates claim the government has been stalling on expanding required beef testing to these deadly strains even as E. coli outbreaks spread throughout Europe.[46] Additional inspections in some areas have been ordered by the USDA's Food Safety and Inspection Service (FSIS).[47] Moreover, concern about the delay in addressing

---

on.com/Public/Newsletter/Aug2006MonsantoWhistleblowerSaysG/index.cfm [hereinafter Smith, *Whistleblower*] (quoting Justin Gillis, *Genetically Modified Organisms Not Easily Contained: National Research Council Panel Urges More Work to Protect Against Contamination of Food Supply*, WASH. POST (Jan. 20, 2004, 6:52 PM), http://www.washingtonpost.com/ac2/wp-dyn?pagename=article&node=&contentId=A32185-2004Jan20&notFound=true) (telling the story of a former Monsanto employee who reported that, in GM cotton, unknown proteins had been created during the gene insertion process—one of the many possible dangers that are not being evaluated by the biotech industry's superficial safety assessments).

43. Strauss, *Legal Liability Risks*, *supra* note 18, at 167. *See, e.g.*, Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337-01 (proposed Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340); Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed. Reg. 3271-01 (proposed Jan. 23, 2004) (to be codified at 7 C.F.R. pt. 340).

44. *See, e.g.*, Eileen Starbranch Pape, *A Flawed Inspection System: Improvements to Current USDA Inspection Practices Needed to Ensure Safer Beef Products*, 48 HOUS. L. REV. 421, 438–46 (2011) (discussing flaws and proposing changes to the regulatory scheme and inspection practices to reduce the number of foodborne illnesses and deaths caused by E. coli in meat).

45. Helena Bottemiller, *DeLauro Presses OMB on Non-O157 E. coli*, FOOD SAFETY NEWS (June 23, 2011), http://www.foodsafetynews.com/2011/06/rep-delauro-presses-omb-on-non-o157-e-coli/. Eventually, under pressure from food safety advocates, the ban on E. coli in ground beef was extended to six more strains. *See* William Newman, *Ban on E. Coli in Ground Beef is to Extend to 6 More Strains*, N.Y. TIMES, Sept. 12, 2011, at B1, http://www.nytimes.com/2011/09/13/business/federal-officials-extend-e-coli-ban.html.

46. Michele Simon, *A Decade of Inaction at USDA on Non-O157 E. Coli*, FOOD SAFETY NEWS (June 29, 2011), http://www.foodsafetynews.com/2011/06/usda-a-decade-of-inaction-on-non-o157-e-coli/; Deirdre Shesgreen, *Food Safety Advocates Say Administration is Stalling on E. Coli Rules*, THE CONN. MIRROR (June 27, 2011), http://www.ctmirror.org/story/13058/ecoli. The proposed rules purportedly address the "six dangerous strains of E. coli" in ground beef and are expected to require testing or even make it illegal to sell ground beef contaminated with these strains. William Neuman, *Outbreak in Europe May Revive Stalled U.S. Effort to Tighten Rules on Food Safety*, N.Y. TIMES, June 3, 2011, http://www.nytimes.com/2011/06/04/business/04prevent.html?_r=2.

47. *See, e.g.*, Dan Flynn, *More Ground Beef Testing Ordered by FSIS*, FOOD SAFETY NEWS (July 12, 2011), http://www.foodsafetynews.com/2011/07/more-ground-beef-testing-ordered-by-fsis/ (increase in sampling and testing slated for E. coli O157:H7 at mid- to large-sized ground beef processing plants for August and September 2011); News Desk, *FSIS Issues Notice on Program to Curb Salmonella*, FOOD SAFETY NEWS (July 11, 2011), http://www.foodsafetynews.com/2011/07/fsis-issues-notice-on-salmonella-initiative-program/ (FSIS posted notice on proposed policy changes to its voluntary, incentive-based Salmonella Initiative Program, SIP). *See also* News Release, USDA, USDA Takes New Steps to Fight E. Coli, Protect the Food Supply (Sept. 13, 2011), http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2011/09/0400.xml.

this gap in food safety is so heightened that, after earlier opposition from the industry, two U.S. companies have stepped in with their own plans to protect consumers. Costco Wholesale and Beef Products Inc. have begun testing programs for a broad range of toxic E. coli as a requirement for their suppliers of bagged produce and their own ground beef.[48]

The most important voices, those of consumers who the agencies are obligated to protect, add another dimension to the problem. A recent consumer survey reported that more than half of the shoppers who were asked where they believed that the food safety breaches occur pointed to food processing and manufacturing plants.[49] Responding to a question about who is responsible for ensuring food safety, more than half (58%) identified themselves, 35% named manufacturers and processors, followed by supermarkets and government agencies at 28% each.[50] It seems Americans recognize that ensuring food safety is not primarily the responsibility of government agencies. Equally significant, in spite of rising prices and budgetary pressures of a recession, interest in purchasing organic foods remains strong and is even on the rise.[51] The turn to organic foods may reflect another consumer message that they seek added food security and are willing to pay for it for as long as they can manage to do so.[52] However, these trends do not obviate the statutory responsibility of government agencies to protect the mainstream food supply for the average consumer in the United States.

III. COURT CASES AGAINST AGENCY INACTION: THE OUTER BOUNDS OF DEFERENCE

In the area of GMOs, the courts are now taking the role that was originally intended for the regulatory agencies, reasoning that those agencies have not been following their statutory mandates. The U.S. Supreme Court recently concluded that the lower courts had gone too far in blocking a deregulation by APHIS and ordering that the planting of GM alfalfa could not proceed. As the first Supreme Court case on GM foods, this case merits detailed analysis as to its future impact in this

48. William Neuman, *Food Companies Act to Protect Consumers from E. Coli Illness*, N.Y. TIMES, July 15, 2011, http://www.nytimes.com/2011/07/16/business/food-companies-act-to-protect-consumers-from-e-coli-illness.html ("Representative Rosa L. DeLauro, a Connecticut Democrat, on Friday sent a letter to Agriculture Secretary Tom Vilsack, decrying the delay and urging him to unilaterally declare any ground beef containing the six additional strains of toxic E. coli unfit for sale. Senator Kirsten E. Gillibrand, a New York Democrat, wrote last week to the Office of Management and Budget, asking it to act on the U.S.D.A. rules.").

49. News Release, Food Marketing Institute, FMI Grocery Shopper Trends 2011: Consumers More Confident in Safety of Food Supply (May 10, 2011), http://www.fmi.org/news_releases/index.cfm?fuseaction=mediatext&id=1236.

50. *Id.*

51. *Id.*

52. Among those who have decided not to continue purchasing organic, 85% stated cost is the main reason; another important reason cited by 38% is their preference to buy locally grown foods instead. *Id.*

area. Consumer and environmental organizations have instituted other litigation against government agencies, particularly under environmental statutes. An exploration of these key cases—involving GM alfalfa, GM sugar beets, GM creeping bentgrass, biopharming, GM eucalyptus, and others—demonstrates the limits of judicial review over agency inaction and the concurrent need to explore other solutions in order to improve the regulatory scheme for GM crops.

A. The Supreme Court and GM Alfalfa

Most significant in this area is the recent GM alfalfa case, *Monsanto Co. v. Geertson Seed Farms*.[53] As the U.S. Supreme Court's "first-ever ruling on genetically modified crops," this decision has been viewed as "a victory for Monsanto and others in the agricultural biotechnology industry, with potential implications for other cases."[54] Yet this impact may be overstated, at least with regards to the merits, because the ruling was—by its terms—narrow and limited.[55] "The Supreme Court did not go so far as to approve the GM alfalfa or address safety concerns; at most, it shifted some regulatory responsibility away from the courts and back on the regulatory agencies charged in the first instance with these oversight responsibilities."[56] As such, the case warrants a closer examination to determine precisely what the Court did hold and thus its implications both for potential appeals of cases that have been proceeding against agency inaction and for future cases that will continue to be filed in the effort to block the planting of GM crops.

Under authority delegated by the USDA, APHIS makes the determination of whether to grant nonregulated status to a GM plant if it does not present a "plant pest" risk and thus is not subject to the regulations promulgated under the Plant Protection Act (PPA).[57] In doing so, "APHIS must comply with NEPA [the National Environmental Protection Act], which requires federal agencies 'to the fullest extent possible' to prepare an environmental impact statement (EIS) for 'every recommendation or report on proposals for legislation and other major Federal action significantly affecting the quality of the human environment.'"[58] However, "[a]n agency need not complete an EIS for a particular pro-

---

53. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010).

54. *See* Andrew Pollack, *Justices Back Monsanto on Biotech Seed Planting*, N.Y. TIMES, June 21, 2010, http://www.nytimes.com/2010/06/22/business/22bizcourt.html?scp=1&sq=Justices%20Back%20Monsanto%20on%20Biotech%20Seed%20Planting&st=cse.

55. *See* Monsanto, 130 S. Ct. at 2756. The Court claimed that its opinion would address only the injunction prohibiting APHIS from deregulating RRA before the EIS was completed, and the nationwide injunction prohibiting almost all RRA planting while the EIS was pending. *Id.*

56. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 165.

57. The Plant Protection Act (PPA), 7 U.S.C. §§ 7701–11(c)(2) (2006); 7 C.F.R. § 340.6 (2012). APHIS may grant such a petition in whole or in part. 7 C.F.R. § 340.6(d)(3).

58. *Monsanto*, 130 S. Ct. at 2750 (citing The National Environmental Policy Act (NEPA), 42 U.S.C. § 4332(2)(C)).

posal if it finds, on the basis of a shorter 'environmental assessment' (EA), that the proposed action will not have a significant impact on the environment"[59] or if it produces a "convincing statement of reasons why potential effects are insignificant."[60]

In an action brought by conventional alfalfa growers and environmental groups against the developer of Roundup Ready Alfalfa (RRA) and APHIS, the district court concluded that APHIS had violated NEPA by failing to prepare an EIS before ordering a complete deregulation of RRA.[61] The district court held that an EIS was required because of the "potential significant environmental impact of gene transmission; specifically, the acknowledged risk that the genetically engineered gene will 'contaminate' organic and conventional alfalfa."[62] In addition, the district court found that the federal "defendants had failed to adequately consider the deregulation decision's impact on the development of Roundup-resistant weeds."[63] It then entered an injunction preventing the future planting of the engineered alfalfa until APHIS prepared an EIS.[64] The U.S. Court of Appeals for the Ninth Circuit upheld the district court's decision.[65] However, in a 7 to 1 decision on June 21, 2010, the U.S. Supreme Court reversed the lower courts, stating that the district court had abused its discretion in granting an injunction prohibiting partial deregulation of RRA.[66] The Supreme Court held that APHIS must still complete the EIS, but can decide to partially deregulate the alfalfa, thus allowing it to be planted before the EIS is finished.[67]

At the outset, it is significant to note that the Supreme Court recognized that the conventional alfalfa growers and environmental groups did have constitutional standing to seek injunctive relief from complete deregulation because they had established a reasonable probability that their conventional alfalfa crops would be infected with the engineered gene, and that this substantial risk of gene flow harm was sufficiently concrete to constitute injury-in-fact.[68] In doing so, the Supreme Court implicitly acknowledged that under NEPA the government must avoid

---

59. *Id.*

60. Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1175 (D. Haw. 2006) (citing Alaska Ctr. for the Env't v. U.S. Forest Serv., 189 F.3d 851, 859 (9th Cir. 1999)).

61. Geertson Farms Inc. v. Johanns, No. C06-01075CRB, U.S. Dist. LEXIS 21491 (N.D. Cal. Mar. 12, 2007) (order granting preliminary injunction). RRA is alfalfa genetically engineered to resist the herbicide Roundup. *Roundup Ready Alfalfa*, USDA ANIMAL & PLANT HEALTH INSPECTION SERV., http://www.aphis.usda.gov/biotechnology/alfalfa.shtml (last visited March 23, 2012)

62. Geertson Farms Inc. v. Johanns, U.S. Dist. LEXIS 21491, at *3.

63. *Id.*

64. Geertson Farms Inc. v. Johanns, No. C06-01075CRB, U.S. Dist. LEXIS 32701 (N.D. Cal. May 3, 2007).

65. Geertson Seed Farms v. Johanns, 570 F.3d 1130, 1141 (9th Cir. 2009), *cert. granted*, 130 S. Ct. 1133 (2010).

66. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

67. *Id.* at 2761.

68. *Id.* at 2755.

"contamination" in their regulation of GM crops.[69] Moreover, since the petitioners and the Government had not argued otherwise, the Supreme Court assumed without deciding that the district court acted lawfully in vacating the agency's decision to completely deregulate RRA.[70] As a result, the Court expressly limited its review to consideration of the injunction prohibiting APHIS from deregulating RRA pending completion of the EIS and the nationwide injunction prohibiting almost all RRA planting during this time.[71] Nor did the Court provide any view on the Government's contention that a limited deregulation would not require the preparation in advance of an EIS.[72] The Court merely observed that, when the preparation of an EIS is required, the NEPA regulations do permit the agency to take at least some action during the pendency of the EIS process. "Until APHIS actually seeks to effect a partial deregulation, any judicial review" of that approach's potential harm to an aggrieved party would be "premature."[73] If and when a partial deregulation should occur, plaintiffs could file another lawsuit challenging such action under NEPA and seeking appropriate preliminary relief.[74]

Instead, the essence of the Supreme Court's decision for which this case will be cited in the future is its reiteration of the standard for granting a permanent injunction.[75] Faced with the possibility that the district court had presumed that an injunction is the proper remedy for a NEPA violation except in unusual circumstances, the Supreme Court asserted that "[n]o such thumb on the scales is warranted."[76] The Court

---

69. *See* Thomas P. Redick, *Biotech Crops Encountering New "Economic Loss" Liability*, ENVTL. IMPACT ASSESSMENT COMMITTEE NEWSL. (Am. Bar Ass'n, Section of Envt., Energy, & Res., Envtl. Impact Assessment Comm., Chi., Ill.), Nov. 2010, at 7 (interpreting this ruling as the Supreme Court sending a message about economic loss that could impact common law nuisance and trespass cases in this area).

70. *Monsanto*, 130 S. Ct. at 2756.

71. *Id.*

72. *Id.*

73. *Id.* at 2758.

74. *Id.* at 2760; *see also* James A. Douglas & Patrick J. Hamill, *Injunction Pending Compliance*, *in* FED. ENVIR. REG. OF REAL EST. L. DIG. § 1:7 (2011).

75. *See, e.g.*, Animal Welfare Inst. v. Martin, 623 F.3d 19, 26 (1st Cir. 2010); Lands Council v. Cottrell, 731 F. Supp. 2d 1028, 1056 (D. Idaho 2010) ("Prior to the Supreme Court's decision in *Monsanto v. Geertson Seed Farms*, . . . there was a line of Ninth Circuit decisions suggesting that an injunction is the proper remedy for a NEPA violation absent unusual circumstances."). *But see* Idaho Watersheds Project v. Hahn, 307 F.3d 815 (9th Cir. 2002) (reasoning, before *Monsanto*, that an evidentiary hearing was not required before issuing a permanent injunction because it was a temporary measure until the Bureau of Land Management performed an environmental assessment); Daniel Mach, *Rules Without Reasons: The Diminishing Role of Statutory Policy and Equitable Discretion in the Law of NEPA Remedies*, 35 HARV. ENVTL. L.R. 205 (2011) (analyzing the Monsanto case and criticizing the Supreme Court's "development of rigid rules of equity for NEPA injunction decisions," proposing that "an effective law of NEPA remedies will require a workable balance of statutory interpretation, administrative law policy, and deference to trial courts' equitable discretion.").

76. *Monsanto*, 130 S. Ct. at 2757.

emphasized that an injunction should issue only if the traditional four-factor test is satisfied.[77] Accordingly, the plaintiff must demonstrate:

> (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.[78]

It was not clear whether the district court had applied this stringent standard in issuing a permanent injunction, and the Court expressed doubts that the conventional alfalfa growers and environmental groups could show that "they [would] suffer irreparable injury if APHIS [were] allowed to proceed with any partial deregulation."[79] Thus, the Supreme Court concluded, "[i]f a less drastic remedy (such as partial or complete vacatur of APHIS's deregulation decision) was sufficient to redress [their] injury, no recourse to the additional and extraordinary relief of an injunction was warranted."[80] Although the Supreme Court took care to limit the reach of courts in fashioning a remedy properly left to the agencies, its decision reflects a judicial readiness to require APHIS to prepare a formal EIS before complete deregulation of GM seeds.[81]

The GM alfalfa saga continues with the most recent developments arising in part as a consequence of the Supreme Court's decision lifting the ban but not obviating the need for an environmental review by the agency. In mid-December 2010, APHIS completed an EIS that concluded GM alfalfa would not harm organic or conventional crops.[82] APHIS offered two options—allowing the engineered alfalfa with no restrictions or with certain geographic and isolation restriction to protect non-engineered crops—and, after hearing objections by biotechnology companies and some members of Congress, chose complete deregulation.[83]

---

77. *Id.* (citing Winter v. Nat'l Res. Def. Council, Inc., 129 S. Ct. 365 (2008)).

78. *Id.* at 2756 (quoting eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006)).

79. *Id.* at 2759.

80. *Id.* at 2761.

81. *See* Aoki, *supra* note 9, at 468–69; Thomas P. Redick, *Biotech Liability's Watershed Year*, TRENDS (Am. Bar Ass'n, Section of Envt., Energy, & Res., Chi., Ill.), Sept.–Oct. 2010, at 1, 14 (interpreting *Monsanto* to say that "the district court should have remanded the matter 'to the [USDA] so that it could determine whether to pursue a partial deregulation during the pendency of the EIS process.'" (quoting *Monsanto*, 130 S. Ct. at 2754)).

82. ANDREA HUBERTY ET AL., U.S. DEP'T OF AGRIC., GLYPHOSATE-TOLERANT ALFALFA EVENTS J101 AND J163: REQUEST FOR NONREGULATED STATUS – FINAL ENVIRONMENTAL IMPACT STATEMENT (2010), http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

83. *Id.*; *see* News Release, USDA, USDA Announces Final Environmental Impact Statement for Genetically Engineered Alfalfa (Dec. 16, 2010), http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2010/12/0667.xml. Note that the agency did not set forth as a third option maintaining the GM alfalfa's regulated status. *See also* Helena Bottemiller, *USDA Fully Deregulates Roundup Ready Alfalfa*, FOOD SAFETY NEWS

Agriculture Secretary Vilsack had favored partial deregulation, predicting that complete deregulation would end up back in court:

> The rapid adoption of GE [genetically engineered] crops has clashed with the rapid expansion of the demand for organic and other non-GE products. This clash led to litigation and uncertainty. Such litigation will potentially lead to the courts' deciding who gets to farm their way and who will be prevented from doing so.[84]

Vilsack attempted to strike a placatory note towards coexistence between biotechnology and the non-genetically engineered sectors in agriculture, stating that the USDA is willing to work with all the stakeholders in the debate.[85] However, in what was considered "an unexpected move," Secretary Vilsack later announced that rather than implement partial deregulation, the USDA would allow Roundup Ready alfalfa to be planted without restriction, purportedly under pressure from the Obama administration, which sought to appear friendly to big business.[86]

In response, CFS and Earthjustice filed a new lawsuit against APHIS for unlawfully permitting GM alfalfa to be grown without restriction.[87] The plaintiffs included a diverse coalition of conventional and organic farmers, dairies and agricultural associations, and environmental and consumer groups: CFS, Beyond Pesticides, Cornucopia Institute, California Farmers Union, Dakota Resources Council, Geertson Seed Farms, National Family Farm Coalition, Northeast Organic Dairy Producers Alliance, Sierra Club, Trask Family Seeds, and the Western Organization of Resource Councils.[88] The executive director of CFS complained that the "USDA has once again failed to provide adequate oversight of a biotech crop,"[89] further asserting that:

(Jan. 28, 2011), http://www.foodsafetynews.com/2011/01/usda-fully-deregulates-ge-roundup-ready-alfalfa/.

84. Mary Rothschild, *New Lawsuit Challenges USDA Approval of GE Alfalfa*, FOOD SAFETY NEWS (Mar. 19, 2011), http://www.foodsafetynews.com/2011/03/new-lawsuit-challenges-usda-approval-of-ge-alfalfa/; *see also* Helena Bottemiller, *Vilsack Calls for a Truce in GE Crops Fight*, FOOD SAFETY NEWS (Dec. 31, 2010), http://www.foodsafetynews.com/2010/12/vilsavk-calls-for-coexistance-cooperation-in-ge-debate/.

85. Rothschild, *supra* note 84; *see also* Bottemiller, *supra* note 84. In an open letter to stakeholders, USDA Secretary Vilsack called for "a new paradigm of coexistence and cooperation" among GM and non-GM sectors. Letter from Thomas J. Vilsack, Secretary, USDA, to Stakeholders (December 2010), http://www.usda.gov/documents/GE_Alfalfa-to_stakeholders-2010Dec.pdf. However, actions speak louder than words, as the subsequent one-sided approval may make such coexistence impossible.

86. Bottemiller, *supra* note 83.

87. Ctr. for Food Safety v. Vilsack, No. CV11-1310 (N.D. Cal. Mar. 18, 2011).

88. *Id.*

89. Press Release, Ctr. for Food Safety, Farmers and Consumer Groups File Lawsuit Challenging Genetically Engineered Alfalfa Approval (Mar. 18, 2011), http://www.centerforfoodsafety.org/2011/03/18/farmers-and-consumer-groups-file-lawsuit-challenging-genetical

> USDA has become a rogue agency in its regulation of biotech crops and its decision to appease the few companies who seek to benefit from this technology comes despite increasing evidence that GE alfalfa will threaten the rights of farmers and consumers, as well as damage the environment.[90]

One plaintiff, farmer Phil Geertson, argued that the "USDA's review is inaccurate and completely failed to consider critical issues. The decision to deregulate Roundup Ready alfalfa opens the door to widespread transgenic contamination, costing farmers their markets, reputation and ability to grow natural varieties."[91] The Northeast Alliance of Organic Dairy Products added,

> Approving the unrestricted planting of GE alfalfa is a blatant case of the USDA serving one form of agriculture at the expense of all others. If this decision is not remedied, the result will be lost livelihoods for organic dairy farmers, loss of choice for farmers and consumers, and no transparency about GE contamination of our foods.[92]

Genetic contamination of organic alfalfa, which also serves as a source of organic feed, could cause economic loss for the $20 billion-dollar organic milk industry.[93] In addition to causing contamination of conventional and organic farms through pollen-drift and cross-pollination by bees, it is estimated that with the full deregulation of GM alfalfa, up to 23 million more pounds of toxic herbicides will be released into the environment each year.[94] In the last ten years, the proliferation of other Roundup Ready crops, such as soy, cotton, and corn, have resulted in a 382 million pound overall increase in herbicide usage.[95] The increased use of the herbicide will lead to the development of more glyphosate-resistant weeds. Such "superweeds" have increased four-fold to infest over 10 million acres since 2008, and it is projected that 38 million acres will be infested by 2013.[96] Alfalfa is the fourth most prevalent crop in the United States, which covers more than 20 million acres and

---

ly-engineered-alfalfa-approval/ ("USDA failures guarantee transgenic contamination, creation of more superweeds.").

90. Bottemiller, *supra* note 83 (statement of Andrew Kimbrell, Executive Director of CFS).

91. Press Release, Ctr. for Food Safety, *supra* note 89.

92. Rothschild, *supra* note 84 (statement of executive director Ed Maltby); *see also GM Alfalfa Decision Prompts New Lawsuit*, FOODNAVIGATOR-USA.COM (Mar. 21, 2011), http://www.foodnavigator-usa.com/Regulation/GM-alfalfa-decision-prompts-new-lawsuit.

93. Rothschild, *supra* note 84.

94. Press Release, Ctr. for Food Safety, *supra* note 89.

95. Press Release, Ctr. for Food Safety, Farmers and Conservationists Challenge Latest Federal Approval of Genetically Engineered Sugar Beets (Feb. 4, 2011), *available at* http://www.centerforfoodsafety.org/2011/02/04/farmers-and-conservationists-challenge-latest-federal-approval-of-genetically-engineered-sugar-beets/.

96. Press Release, Ctr. for Food Safety, *supra* note 89.

spans every state.[97] Thus the potential results of this complete deregulation could be both negative and far-reaching.

B. The Epic Case of GM Sugar Beets

In another epic, ongoing action initiated in 2008, plaintiff farmers, the Sierra Club, and other consumer organizations challenged the USDA's decision to deregulate Monsanto's glyphosate-resistant sugar beets despite considerable questions about potential environmental degradation and alleged violations of NEPA.[98] In the spring of 2008 as the planting of Roundup Ready sugar beets was beginning in the western United States, the agriculture manager for Amalgamated Sugar announced that 95% of Idaho's sugar beet production would be Roundup Ready.[99] With the previous year's production of 167,000 acres of sugar beets, Idaho farmers would plant 150,000 acres of GM sugar beets that year.[100] In total, farmers grow approximately 1.3 million acres of sugar beets in 12 states, largely in western Minnesota, eastern North Dakota, the Pacific Northwest, Great Plains, and Great Lakes regions.[101]

Since Roundup Ready sugar beets are wind pollinated and the crops are grown in close proximity, there is a strong possibility that pollen from GM sugar beets could contaminate non-GM sugar beets and other major related crops such as chard and red and yellow beets ("table beets").[102] As a result, the economic impact for conventional and organic farmers could be catastrophic. In addition, the fact that the planting of GM sugar beets can exacerbate the problem of herbicide-resistant weeds has already been well documented.[103] Despite initial promises to the contrary, scientific studies show that the use of Roundup herbicide has increased with the planting of Roundup Ready crops which, in turn, has led to the rapid spread of "superweeds" (e.g., marestail, common and giant ragweed, waterhemp, Palmer pigweed, cocklebur, lambsquarters, morning glory, and velvetleaf) that did not exhibit this resistance prior

97. *Id.*

98. Ctr. for Food Safety v. Vilsack (*Sugar Beets I*), No. 08-00484 (N.D. Cal. Sep. 21, 2009) (order regarding cross-motions for summary judgment); Alex McNally, *Lawsuit Filed Over Monsantos GM Sugar Beet*, FOODNAVIGATOR-USA.COM (Jan. 24, 2008), http://www.foodnavigator-usa.com/Regulation/Lawsuit-filed-over-Monsantos-GM-sugar-beet; *see also* Strauss, *Legal Liability Risks*, *supra* note 18, at 164 (discussing sugar beet and other GM cases).

99. *Battle Lines Drawn Over GM Sugar Beets*, ENVTL. NEWS NETWORK (Mar. 6, 2008), http://www.enn.com/agriculture/article/32414 (statement of John Schorr, agriculture manager for Amalgamated Sugar).

100. *Id.*

101. *Id.*

102. *Id.*

103. *Id.* The National Research Council has also issued its own warning about the emergence of resistant weeds and other risks as limiting the potential benefits of GM crops. NAT'L RESEARCH COUNCIL, THE IMPACT OF GENETICALLY ENGINEERED CROPS ON FARM SUSTAINABILITY IN THE UNITED STATES (2010), http://www.nationalacademies.org/includes/genengcrops.pdf.

to the introduction of Roundup Ready and are now increasingly threatening farmers' crops.[104]

Trade organizations and environmental groups have questioned whether the government has fulfilled its oversight responsibilities. As the President of High Mowing Organic Seeds commented, "the issue of releasing GMO crops without serious research or oversight risks the security of our food supply and the economic viability of our nation's non-GMO and organic farmers."[105] Earthjustice added,

> The law requires the government to take a hard look at the impact that deregulating Roundup Ready sugar beets will have on human health, agriculture and the environment. The government cannot simply ignore the fact that deregulation will harm organic farmers and consumers, and exacerbate the growing epidemic of herbicide-resistant weeds.[106]

In the GM sugar beet case, District Judge Jeffrey S. White ruled in September 2009 that the USDA failed to adequately assess the environmental impact of Monsanto's Roundup Ready sugar beets before introducing them into the food supply,[107] but in a later decision denied plaintiffs' motion for a preliminary injunction.[108] On August 13, 2010, the judge declined to grant a permanent injunction as unnecessary due to his vacatur of the USDA approval.[109] Explaining that the vacatur applied to all future plantings but not previous ones, he ordered the crop harvested and processed or stored, but did not require it to be destroyed.[110] In his decision, Judge White cited the *Monsanto* GM alfalfa

---

104. *Battle Lines Drawn Over GM Sugar Beets*, *supra* note 99. According to an independent analysis of USDA data by Dr. Charles Benbrook, former Board of Agriculture Chair of the National Academy of Sciences, GM crops increased U.S. herbicide use by 15 times—122 million pounds—between 1994, when planting of herbicide resistant crops began, and 2004. *Id.* As a consequence, Roundup-resistant weeds have been reported on 2.4 million acres of cropland in the United States. *Id.*; *see also* Strauss, *Ethical Implications*, *supra* note 13, at 7–19 (debunking the myths that this technology would reduce world hunger, decrease pesticide usage, improve nutritional content, and increase farmers' income and contrasting these claims of potential benefits with the risks).

105. *Battle Lines Drawn Over GM Sugar Beets*, *supra* note 99 (statement of Tom Stearns, President of High Mowing Organic Seeds).

106. *Id.* (statement of Greg Loarie of Earthjustice).

107. Ctr. for Food Safety v. Vilsack, No. C 08-00484 JSW, 2009 WL 3047227, at 13-14 (N.D. Cal. Sept. 21, 2009) (APHIS required to prepare EIS for GM sugar beets); *see also* Caroline Scott-Thomas, *Judge Rules Against Monsanto's GM Sugar Beets*, FOODNAVIGATOR-USA.COM (Sept. 23, 2009), http://www.foodnavigator-usa.com/Regulation/Judge-rules-agains t-Monsanto-s-GM-sugar-beets [hereinafter Scott-Thomas, *Judge Rules Against Sugar Beets*]; *Battle Lines Drawn Over GM Sugar Beets*, *supra* note 99.

108. Ctr. for Food Safety v. Schafer, No. C 08-00484 JSW, 2010 WL 964017, at *4–5 (N.D. Cal. Mar. 16, 2010) (expressing serious reservations in weighing the equities of the parties and denying the injunction)."In light of Plaintiffs' showing of irreparable harm to the environment, the Court is troubled by maintaining the status quo that consists of ninety-five percent of sugar beets being genetically engineered while APHIS conducts the environmental review that should have occurred before the sugar beets were deregulated." *Id.*

109. Ctr. for Food Safety v. Vilsack, 734 F. Supp. 2d 948, 955 (N.D. Cal. 2010).

110. *Id.*

case and considered his ruling to be in keeping with the Supreme Court's admonition against overly broad remedies and premature review of potential agency action.[111] Although he concluded that "the 'additional and extraordinary relief of an injunction' was not warranted if a less drastic remedy, such as vacatur of APHIS's deregulation decision, was sufficient to redress the plaintiff's injury," Judge White made it clear that further redress would be available to plaintiffs in the future if defendants or other third parties actually violated the vacatur.[112] Most importantly, the court expressed concern that the government defendants were "not taking this process seriously," but instead viewed the "requisite comprehensive review [as] a mere formality."[113] Denying defendants' request to delay its vacatur and provide APHIS with time to implement interim measures, the court noted there had been ample time since its previous ruling and banned the deregulation of the crop until USDA fully analyzed the impacts of the GE plant on the environment, farmers and the public with an EIS.[114]

Three weeks later, despite the court's ruling and with only a less-than-comprehensive EA, the USDA issued permits to seed growers to plant the genetically modified sugar beets.[115] The groups again sued the USDA (the court labeled the case "*Sugar Beets II*").[116] On November 30, 2010, the court granted the plaintiffs' motion for a preliminary injunction and ordered the seed crop destroyed.[117] That order was stayed pending appeal.[118]

On February 25, 2011, the U.S. Court of Appeals for the Ninth Circuit overturned the preliminary injunction in *Sugar Beets II*, citing the

---

111. *Id.* at 954.

112. *Id.* (quoting Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2761 (2010)).

113. *Id.* at 953.

114. *Id.*

115. *See* Press Release, Ctr. for Food Safety, Farmers and Consumer Groups File Lawsuit Challenging Genetically Engineered Alfalfa Approval, *supra* note 89. *But see* Sugar Indus. Biotech Council, Statement by the Sugar Industry Biotech Council on USDA's APHIS Announcement for Partial Deregulation of Roundup Ready Sugar Beets (Feb. 8, 2011), http://www.sugarindustrybiotechcouncil.org/sugar-beet-news/statement-by-the-sugar-industry-biotech-council-on-usdas-aphis-announcement-for-partial-deregulation-of-roundup-ready-sugar-beets (stating that the sugar beet industry "appreciates the Secretary's leadership" and that there has been no evidence of harm, as the commercial crop grown for sugar production does not produce seed).

116. Ctr. for Food Safety v. Vilsack (*Sugar Beets II*), No. 10-4038 JSW (N.D. Cal. Nov. 30, 2010) (order granting preliminary injunction).

117. Ctr. for Food Safety v. Vilsack, 753 F. Supp. 2d 1051, 1062 (N.D. Cal. 2010).

118. Ctr. for Food Safety v. Vilsack, 636 F.3d 1166, 1171 (9th Cir. 2011). *See* Press Release, Farmers and Conservationists Challenge Federal Approval of GE Sugar Beets, *supra* note 95; Press Release, Ctr. for Food Safety, Organic Industry Supports CFS in GE Sugar Beets Appeal (Jan. 31, 2011), *available at* http://www.centerforfoodsafety.org/2011/01/31/organic-industry-supports-cfs-in-ge-sugar-beets-appeal/ (leading organic businesses and trade groups file joint brief to Court of Appeals in support of CFS and in opposition to Monsanto on behalf of $25 billion a year organic industry warning of imminent threat to their businesses from biotech contamination).

Supreme Court's holding in *Monsanto* as a warning "against premature review of APHIS's regulatory actions."[119] With a similar analysis, the Court of Appeals found that the plaintiffs had failed to meet the burdens of demonstrating a substantial likelihood of irreparable injury and showing a "reason not to defer to APHIS's technical expertise and judgments."[120] In the limited deregulation at issue, which was geographically restricted and prohibited flowering or pollination, the court determined that the immature sugar beet plants ("stecklings") posed a negligible risk of genetic contamination.[121] The juvenile plants were biologically incapable of flowering or cross-pollinating before February 28, 2011, when the permits would expire and the stecklings, under the APHIS order, were required to be destroyed.[122] Thus, the court concluded that these plaintiffs were "unlikely to face irreparable substantive harm from the stecklings, and if a subsequent APHIS decision aggrieves them, they may challenge it and seek appropriate preliminary relief."[123] The Court of Appeals was careful to note that it made this ruling "without expressing any views on the merits of the ultimate issues in this case or other pending related litigation."[124] However, this caveat did not stop the sugar industry from declaring victory in broader terms, saying it was pleased that the Ninth Circuit, "after considering relevant legal precedents and evidence, concluded that the planting of these permitted stecklings was unlikely to cause harm and that deference should be given to APHIS' 'technical expertise and judgments on this score.'"[125]

Again, on February 4, 2011, APHIS issued a new decision to allow plantings of GM sugar beets with only a limited EA to support the partial deregulation.[126] In response, the CFS issued a statement:

> There is clear evidence of harm to the environment from GE sugar beets. . . . Because USDA continues to bow to industry pressure and permits further commercial production of Roundup Ready sugar beets, without first preparing an EIS or protecting the public, the Center for Food Safety will once again seek to halt the planting in court.[127]

---

119. Ctr. for Food Safety v. Vilsack, 636 F.3d 1166, 1174 (9th Cir. 2011).

120. *Id.* at 1173.

121. *Id.*

122. *Id.*

123. *Id.* at 1174.

124. *Id.*

125. Sugar Indus. Biotech Council, Statement by the Sugar Industry Biotech Council on Appellate Court Activity (Feb. 28, 2011), http://www.sugarindustrybiotechcouncil.org/sugar-beet-news/statement-by-the-sugar-industry-biotech-council-on-appellate-court-activity.

126. Press Release, USDA, USDA Announces Partial Deregulation for Roundup Ready Sugar Beets (Feb. 4, 2011), http://www.aphis.usda.gov/newsroom/2011/02/rr_sugar_beets.shtml.

127. Press Release, Farmers and Conservationists Challenge Latest Federal Approval of Genetically Engineered Sugar Beets, *supra* note 95 (statement of Paige Tomaselli, Staff Attorney for the CFS).

Then, on February 7, 2011, in a related action that the original plaintiffs called a "race to the courthouse," a group of sugar beet growers, processors, seed producers and trade associations, including three intervenor-defendants in the *Sugar Beets II* case, filed a declaratory relief action in the District Court for the District of Columbia, *Grant v. Vilsack*.[128] The *Grant* action challenges the conditions APHIS's February 4, 2011 decision imposed on Roundup Ready sugar beet root and seed crop production activities and, in the alternative, seeks a declaratory judgment that the EA and Finding of No Significant Impact (FONSI: an explanation of why the selected action will have no significant effects on the human environment) comply with NEPA.[129] *Grant* named CFS and Sierra Club as non-governmental defendants because their "past actions and threats of further [legal] action" allegedly present "a significant threat to our nation's sugar supply in the 2011 crop year."[130] Upon a motion of the Federal Defendants (APHIS and USDA) in the original action (*Sugar Beets II*), Judge White transferred his case to the District of Columbia to be heard with the *Grant* case for efficiency and consistency in rulings and, in part, "because the APHIS's administrative process occurred in the District of Columbia and Federal Defendants reside there, the District of Columbia has a stronger local interest than this district in adjudicating this action challenging the interim agency decision."[131]

In a subsequent development, the Court of Appeals on May 20, 2011, issued a summary order dismissing the appeal of Monsanto and other biotech industry intervenors and affirming the lower court's rulings in *Sugar Beets I*, effectively concluding the long-standing lawsuit.[132] The attorney for CFS praised the decision:

> Today's order cements a critical legal benchmark in the battle for meaningful oversight of biotech crops and food. Because of this case, there will be public disclosure and debate on the harmful impacts of these pesticide-promoting crops, as well as legal protections for farmers threatened by contamination.[133]

However, the biotech sugar industry portrayed a different spin, stating on its website that the intervenor group had voluntarily asked that the appeal be dismissed:

---

128. Complaint, Grant v. Vilsack, No. 11-308 JDB (D.D.C. filed Feb. 7, 2011), *available at* http://www.courthousenews.com/2011/02/08/RoboSugar.pdf.

129. *Id.* at 22.

130. *Id.* at 19.

131. Ctr. for Food Safety v. Vilsack, No. C11-00831JSW, 2011 U.S. Dist. LEXIS 31688, at *7 (N.D. Cal. Mar. 17, 2011).

132. This decision concerned case No. 10-17335 (*Sugar Beets I*). *See* Press Release, Ctr. for Food Safety, Court of Appeals Dismisses Monsanto's Appeal of Biotech Beets Case, Preserves Victory for Farmers, Environment (May 20, 2011), http://www.centerforfoodsafety.org/2011/05/20/court-of-appeals-dismisses-monsantos-appeal-of-biotech-beets-case-preserves-victory-for-farmers-environment/ [hereinafter *Dismissal of Monsanto's Appeal*].

133. *Dismissal of Monsanto's Appeal*, *supra* note 132 (statement of CFS attorney George Kimbrell).

> As a result of subsequent court decisions and the U.S. Department of Agriculture (USDA) actions, continuation of the appeals had little consequence for Roundup Ready sugar beet growers or seed companies. The USDA's Animal and Plant Health Inspection Service (APHIS) has issued interim measures to allow the planting of Roundup Ready sugar beets and farmers are planting Roundup Ready sugar beet crops.[134]

Although the partial deregulation scheme for the 2011–2012 season is the subject of a second case proceeding through the courts (*Sugar Beets II*), the dismissal of this appeal has the effect of requiring the USDA to prepare a thorough review of the GM sugar beets before it can make a decision on whether to allow a reentry into commercial production.[135] The EIS should be completed in 2012, around mid-year.[136]

Astonishingly, this is only the second EIS "the USDA has undertaken for any GE crop in over 15 years of approving such crops for human consumption," and both assessments "were court ordered."[137] In his remarks to the press in connection with this litigation, Agriculture Secretary Tom Vilsack again displayed his pro-industry, biotech bent, criticizing "a circumstance where a single judge can essentially decide whether someone gets to farm or doesn't get to farm."[138] He continues to insist that, "We need to figure out ways in which those who wish to do biotech and those who wish to do organic can live together in the same universe and be able to do what they think is best for their operation."[139] His conciliatory approach clearly favors a coexistence that may not be possible without a more thorough examination of the genuine risks.[140] Meanwhile, in spite of the claims that Monsanto's Roundup Ready crops have led to the greater use of herbicides and the spread of herbicide resistant weeds, as well as contamination of conventional and organic

---

134. Sugar Indus. Biotech Council, Statement by the Sugar Industry Biotech Council on Appellate Court Activity (May 26, 2011), http://www.sugarindustrybiotechcouncil.org/sugar-beet-news/.

135. Caroline Scott-Thomas, *Sugar Beet Appeal Dismissed: Plaintiffs Hail Dismissal of Appeal in GM Sugar Beet Case*, FOODNAVIGATOR-USA.COM (May 26, 2011), http://www.saynotogmos.org/ud2011/index.php/2011/05/26/sugar-beet-appeal-dismissed/ [hereinafter Scott-Thomas, *Sugar Beet Appeal Dismissed*].

136. *Id.*; *see also* USDA, *supra* note 126.

137. *Dismissal of Monsanto's Appeal*, *supra* note 132.

138. Andrew Pollack, *Duel Over Sugar Beet Seeds Could Create Shortage*, N.Y. TIMES, Dec. 2, 2010, at B7.

139. *Id.*

140. If the USDA and APHIS continue to view this dispute as a mere "philosophical" difference in values and preferences of organic consumers and producers, as indicated in their EIS for GM alfalfa, their failure to recognize the economic and environmental harms will require a change at the policy-making level rather than enforcement of existing law through litigation in federal courts. *See* Alex Platt, *Center for Food Safety v. Vilsak: Roundup Ready Regulations*, 37 ECOLOGY L.Q. 773, 779–80 (2010) (analyzing GM sugar beets case prior to the Supreme Court GM alfalfa decision and questioning capacity of federal courts to bring about the desired substantive regulatory changes).

crops costly to U.S. farmers, this proliferation of the GM sugar beet has continued.[141]

First harvested in the fall of 2008, GM sugar beets now "account for 95 percent of those being grown in the United States, according to USDA figures."[142] "Beets supply about half" of the total U.S. sugar supply, "with the rest coming from sugar cane."[143] As a result, some have argued that this litigation could create a shortage of sugar production and "possible price increases for consumers and food processors."[144] Americans consume about ten million tons of refined sugar each year and about twelve million tons of corn sweeteners such as high fructose corn syrup.[145] Yet, as with other GM products, the source of these two leading sweeteners—GM corn and sugar beets—need not be indicated to consumers through labeling.[146] Moreover, the implications for international trade are significant because, under current European law, any U.S. export that contains sugar would not be accepted unless the manufacturer can verify through a costly traceability program that it was not derived from GM sugar beets.[147] Meanwhile, due to increased demand for organic sugar, the USDA has just taken action to elevate imports of organic raw cane and specialty sugar into the United States.[148]

---

141. *Dismissal of Monsanto's Appeal*, *supra* note 132 (discussing the fact that GM crops have led to an increase in herbicides and herbicide resistant weeds); *see also Battle Lines Drawn Over GM Sugar Beets*, *supra* note 99.

142. Scott-Thomas, *Sugar Beet Appeal Dismissed*, *supra* note 135; *see also* Sugar Indus. Biotech Council, *supra* note 115 (noting that sugar beets are planted on 1.2 million acres in the United States annually, supplying half of U.S. sugar, and that Roundup Ready sugar beets are planted on 95% of all sugar beet acreage).

143. Andrew Pollack, *Judge Revokes Approval of Modified Sugar Beets*, N.Y. TIMES, Aug. 13, 2010, at B1.

144. Andrew Pollack, *supra* note 138. *But see* Scott-Thomas, *Judge Rules Against GM Sugar Beets*, *supra* note 107 (over 100 food companies have signed a non-GM beet sugar registry pledging not to knowingly use GM sugar in their products).

145. *Benefits of Current Policy*, AM. SUGARBEET GROWERS ASS'N, http://www.americansugarbeet.org/us-sugar-policy/benefits-of-current-policy.html (last visited Nov. 11, 2011).

146. *Id.*; *see generally* Strauss, *Importing Caution, supra* note 3 (analyzing the U.S. and EU regulatory treatment of GMOs and, in view of the health and environmental risks, proposing that the United States adopt a more cautious model of labeling and monitoring).

147. *Battle Lines Drawn Over GM Sugar Beets*, *supra* note 99. For more on issues of international trade involving GM foods, see Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of GM Foods*, 45 AM. BUS. L.J. 775 (2008) [hereinafter Strauss, *Impact of the WTO*]. *See also* Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT'L LAW. 95 (2006) [hereinafter Strauss, *A Model of Labeling*] (analyzing the differing regulatory approaches of the United States and the EU as a reflection of the cultural views of risk and scientific uncertainty with an impact on international trade).

148. Caroline Scott-Thomas, *USDA Allows Extra Specialty Sugar Imports to Meet Organic Sugar Demand*, FOODNAVIGATOR-USA.COM (Aug. 2, 2011), http://www.foodnavigator-usa.com/Product-Categories/Carbohydrates-and-fibers-sugar-starches/USDA-allows-extra-specialty-sugar-imports-to-meet-organic-sugar-demand. A recent report from Packaged Facts found that U.S. sales of organic foods and beverages continued to outpace conventional grocery sales in 2010, with the market growing 8.5% to reach $23.2 billion retail. *Natural and Organic Foods and Beverages in the U.S., 3rd Edition*, PACKAGED FACTS (July 1, 2011),

C. Other Cases of Courts Policing the Agencies

In the area of GM crops, there have been other cases of the courts responding to challenges to agency action or inaction, both prior to and after the *Monsanto* Supreme Court case. In the case of the creeping bentgrass, plaintiffs sued APHIS and officials of the USDA, including the Agriculture Secretary, for allowing field tests that later had damaged the environment.[149] Plaintiff organizations International Center for Technology Assessment, CFS, and Klamath Siskiyou Wildlands Center, along with five individual plaintiffs who resided or recreated outside of test plots, alleged that by permitting the field tests, APHIS had violated the PPA, the Administrative Procedure Act (APA), and NEPA.[150] They claimed that APHIS had failed to consider whether this crop is a plant pest under the PPA, to evaluate the environmental impact under NEPA, and to follow its own regulations.[151] In the summer of 2006, the creeping bentgrass, under development by the Scotts Miracle-Gro Company and Monsanto, was discovered to have escaped into the wild from Oregon test sites that had been used a few years earlier.[152] The genetically engineered grass (GTCB), intended for use on golf courses and not yet approved by the USDA, contained a bacterial gene that made it resistant to the herbicide glyphosate, sold commercially as Roundup. Apparently the wind had dispersed the seeds and the pollen had crossed with other varieties. Scientists have expressed concern that the variety will cross pollinate with other grass varieties and may contaminate the commercial grass seed supply—70% of which is grown in Oregon.[153] Another danger is the creation of "superweeds," which are harder to control with glyphosate (a widely used herbicide), thus leading to the use of more toxic herbicides.[154] In the litigation that ensued, the court held that the

---

http://www.packagedfacts.com/Natural-Organic-Foods-6057035/. According to the USDA, the United States is the world's largest consumer of sweeteners, including sugar and high fructose corn syrup, and is one of the biggest sweetener importers. *Id. Sugar and Sweeteners*, USDA, http://www.ers.usda.gov/Briefing/Sugar/ (last updated Aug. 3, 2009).

149. Int'l Ctr. For Tech. Assessment v. Johanns, 473 F. Supp. 2d 9, 12–13 (D.D.C. 2007). The Scotts Company intervened in the case as a defendant. *Id.*

150. Plant Protection Act, 7 U.S.C. §§ 7701–58 (2006); Administrative Procedure Act, 5 U.S.C. §§ 500–706 (2010); National Environmental Policy Act, 42 U.S.C. §§ 4321–70f (2009).

151. Int'l Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d at 12–13.

152. Andrew Pollack, *Grass Created in Lab is Found in the Wild*, N.Y. TIMES, Aug. 16, 2006, http://www.nytimes.com/2006/08/16/science/16grass.html [hereinafter Pollack, *Grass*], *cited in* Rachel Durkee Walker & Jill Doerfler, *Wild Rice: The Minnesota Legislature, a Distinctive Crop, GMOs, and OJIBWE Perspectives*, 32 HAMLINE L. REV. 499, 518 (2009) (statement to Minnesota legislature citing examples of the dangers of GMOs and evidence that the regulators are not regulating).

153. Smith, *Whistleblower*, *supra* note 42.

154. Pollack, *Grass*, *supra* note 152; *see also* Neuman & Pollack, *supra* note 2. Roundup-resistant weeds like horseweed and giant ragweed are forcing farmers to spray fields with more toxic herbicides and to use more expensive techniques previously abandoned—more labor-intensive methods like pulling weeds and regular plowing. Margaret Rosso Grossman, *Anticipatory Nuisance and the Prevention of Environmental Harm and Economic Loss from GMOs in the United States*, 18 J. ENVTL. L. & PRAC. 107, 147–49 (2008)

denial of plaintiffs' petition to list GTCB as a noxious weed was arbitrary and capricious, as was its failure to require an environmental impact assessment.[155]

In the first federal case to address biopharming, in August 2006, a district court judge ruled that drug-producing GM crops grown in Hawaii violated both the Endangered Species Act (ESA) and NEPA.[156] Between 2001 and 2003, several companies had run field tests of corn and sugarcane genetically engineered to produce experimental vaccines, hormones, and cancer-fighting agents.[157] In view of concerns for Hawaii's fragile ecosystem, the court held that APHIS violated the ESA by failing to obtain information about endangered and threatened species in the permit area and violated NEPA by failing to prepare an environmental assessment or impact statement.[158] However, by the time the court issued its decision, the field tests had already been completed and the potential damage done; thus, a declaratory judgment was the only available relief requested. As further evidence of this type of harm, in September 2004, citizen groups revealed that tests of nearly 20,000 papaya seeds on the Big Island of Hawaii determined that half were genetically modified; to make matters worse, 80% were from organic farms, while 20% were from home gardens and wild papaya trees.[159]

In the long line of post-*Monsanto* cases, the courts continue to find unlawful agency action but generally limit the appropriate remedy for these violations to remand and vacatur rather than direct injunctive relief.[160] For example, in *Sierra Club v. Van Antwerp*, the District Court for the District of Columbia held that remand with partial vacatur of a Clean Water Act (CWA) permit was warranted to prevent significant harm.[161] In that case, environmental groups sued federal agency officials for alleged violation of the Clean Water Act (CWA), ESA, NEPA, and APA as a result of the Army Corps of Engineers' (COE) issuance of a

---

(discussing this case and others as illustrating the type of environmental damage feared from GM crops).

155. Int'l Ctr. For Tech. Assessment v. Johanns, 473 F. Supp. 2d at 29–30; *see also* Strauss, *Legal Liability Risks*, *supra* note 18, at 163.

156. Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d 1165, 1182–83 (D. Haw. 2006). *See also* Bernadette Tansey, *Hawaii Judge Rules 'Biopharming' Illegal*, S.F. CHRONICLE (Aug. 16, 2006), http://articles.sfgate.com/2006-08-15/business/17306113_1_ruling-endangered-species-act-earthjustice-legal-defense-fund; Denton, *supra* note 26, at 361–67 (discussing significance of the Hawaii biopharming case).

157. Ctr. for Food Safety v. Johanns, 451 F. Supp. 2d at 1170.

158. *Id.* at 1183. *See also* Grossman, *supra* note 154, at 149–51.

159. Jeffrey M. Smith, *The Myth and Necessity of GM Free Zones*, SPILLING THE BEANS (Inst. for Responsible Tech., Fairfield, Iowa), Oct 1, 2004, http://www.nofamass.org/programs/social/pdfs/11myths.pdf; *see also* Strauss, *Legal Liability Risks*, *supra* note 18, at 163–64.

160. *See, e.g.*, Animal Welfare Inst. v. Martin, 623 F.3d 19 (1st Cir. 2010) (denying a permanent injunction to preclude the State of Maine from authorizing trapping of the Canada lynx, a threatened species under the Endangered Species Act).

161. Sierra Club v. Van Antwerp (*Sierra Club II*), 719 F. Supp. 2d 77, 78–79 (D.D.C. 2010).

CWA permit for developers of a shopping mall to discharge dredged and fill material into wetlands.[162] Specifically, the plaintiffs alleged that the COE violated the CWA by issuing the permit and failing to prepare an EIS as required by NEPA, and by the Fish and Wildlife Service (FWS) in its concurrence letter stating that development would not adversely impact four endangered species.[163] After granting summary judgment on the CWA and NEPA claims, the court emphasized that the APA provides that "the reviewing court shall set aside any agency action that is arbitrary and capricious."[164] In determining an appropriate remedy, the court concluded that

> While the U.S. Supreme Court made clear in *Monsanto* that there is no presumption to other injunctive relief, both the Supreme Court and the D.C. Circuit Court have held that remand, along with vacatur, is the presumptively appropriate remedy for a violation of the APA. Indeed, the Court in *Monsanto* assumed that a remand and vacatur of the agency's decision was lawful.[165]

Citing the four-part test set forth in the *Monsanto* case, and finding that plaintiffs had failed to demonstrate any of these requirements, the court concluded that injunctive relief would be inappropriate.[166] However, an injunction may still be warranted under this more stringent test, depending on the factual record, as has been found in other cases.[167]

Consumer and environmental groups continue to file cases against agencies for their inaction. In *Center for Biological Diversity v. Animal & Plant Health Inspection Service & U.S. Department of Agriculture*, an alliance of conservation organizations challenged the USDA's approval of ArborGen's biotech eucalyptus for field testing on twenty-eight secret

---

162. Sierra Club v. Van Antwerp (*Sierra Club I*), 719 F. Supp. 2d 58, 60 (D.D.C. 2010), *aff'd in part, rev'd in part*, 661 F.3d 1147 (D.C. Cir. 2011).

163. *Id.*

164. *Sierra Club II*, 719 F. Supp. 2d at 78 (citing 5 U.S.C. § 706 (2006)).

165. *Id.* at 79 (citations omitted).

166. *Id. But cf.* Alliance for the Wild Rockies v. Cottrell, 622 F.3d 1045 (9th Cir. 2010). There, in an attempt to avoid the Supreme Court's more stringent standard altogether, the Ninth Circuit concluded that preliminary injunctive relief is available as long as the balance of hardships "tips sharply" toward the plaintiffs. *Id.* at 1055. Further, it found that salvage logging of burnt trees would result in the "irreparabl[e]" loss of work and recreational opportunities on the logged land. *Id.*

167. *See, e.g.*, Lands Council v. Cottrell, 731 F. Supp. 2d 1028 (D. Idaho 2010). After finding that the Forest Service had acted arbitrarily and capriciously, and that money damages could not compensate for the threat to species viability, the court issued an injunction prohibiting all commercial logging until the agency complied with NEPA and the National Forest Management Act. *Id. See also* Oregon Natural Desert Ass'n v. Tidwell, 07-1871, 2010 U.S. Dist. LEXIS 137612 (D. Or. Dec. 29, 2010) (holding that the possibility of irreparable harm, the inadequacy of other remedies, and the public interest warranted a permanent injunction barring grazing cattle in Malheur National Forest that had been allowed by the Forest Service and National Marine Fisheries Service in violation of the ESA and NFMA). *See also* Steve Jones, *Some Ninth Circuit Panels Adhere to Own Test for NEPA Injunctions, Despite Supreme Court Mandate*, 271 ENVTL. COUNS. 2 (2011) (analyzing cases decided after *Monsanto*).

sites (located in Alabama, Florida, Georgia, Louisiana, Mississippi, South Carolina, and Texas) with only minimal environmental review.[168] In approving the GM eucalyptus permits, the USDA failed to heed the concerns of numerous agencies and scientists, including other federal and state governmental entities, who fear the uncontrollable spread of these experimental engineered trees because "eucalyptus trees are not native to the United States and are known to become invasive, displacing native wildlife and plants in various areas around the country and increasing wildfire risk."[169]

Nor are such lawsuits limited to environmental agency defendants. A lawsuit filed by Center for Science in the Public Interest (CSPI), Food Animal Concerns Trust (FACT), Public Citizen, the Union of Concerned Scientists (UCS), and the Natural Resources Defense Council (NRDC) challenges the FDA for its failure to take action on the groups' petitions asking the FDA to withdraw approvals for subtherapeutic uses of penicillin and tetracyclines in animal feed.[170] The groups charge that "the misuse and overuse of antibiotics has given rise to a growing and dangerous trend of antibiotic resistance" and through their lawsuit seek to push the FDA to issue final responses to their petitions by a court-ordered deadline.[171] Among the outcomes of this lawsuit, one expert observes, "in its making public the history of non-action on agricultural antibiotic overuse, it establishes that this isn't a scientific question anymore, but a political one."[172] The only microbiologist in Congress, Representative Louise Slaughter (D-N.Y.), who has unsuccessfully sponsored legislation to limit the use of antibiotics in animal agriculture, commented:

> Today's lawsuit is an indication of the growing concern about the overuse of antibiotics in agriculture. We should be able to buy our food without worrying that eating it will expose our

168. Plaintiffs' Amended Complaint for Declaratory and Injunctive Relief at 10, Ctr. for Biological Diversity v. Animal & Plant Health Inspection Serv. & USDA, No. 10-14175-CV (S.D. Fl. filed Aug. 10, 2010), http://www.globaljusticeecology.org/files/Amended%20Complaint%20(filed).pdf.

169. Press Release, Ctr. for Biological Diversity, Lawsuit Filed to Halt Release of Genetically Engineered Eucalyptus Trees Across the American South (July 1, 2010), http://www.biologicaldiversity.org/news/press_releases/2010/eucalyptus-07-01-2010.html.

170. Complaint for Declaratory and Injunctive Relief at 2–3, Natural Resources Defense Council, Inc., et al. v. U.S. Food and Drug Administration, et al., No. 11 CV 3562 (S.D.N.Y. filed May 25, 2011).

171. Dan Flynn, *Groups Sue Over Ag Antibiotic Use*, FOOD SAFETY NEWS (May 26, 2011), http://www.foodsafetynews.com/2011/05/big-apple-court-asked-to-take-bite-out-of-ag-antibiotic-use/; Press Release, Natural Resources Defense Council (NRDC), Superbug Suit: Groups Sue FDA Over Risky Use of Human Antibiotics in Animal Feed (May 25, 2011), http://www.nrdc.org/media/2011/110525.asp.

172. Flynn, *supra* note 171 (statement of Maryn McKenna, food policy journalist and author). *See also* Maryn McKenna, *FDA Sued over Growth-Promoting Antibiotic Use on the Farm*, ARS TECHNICA (Oct. 31, 2011, 6:45 PM), *available at* http://arstechnica.com/science/news/2011/05/fda-sued-over-growth-promoting-antibiotic-use-on-the-farm.ars.

> families to bacteria no longer responsive to medical treatments. The FDA needs to take common sense steps to reduce the needless use of antibiotics in healthy animals, and protect human beings.[173]

As these lawsuits against regulatory inaction proceed through the courts, it becomes even more evident that nothing in the *Monsanto* case precluded such judicial review. Although not calling into question the merits of these challenges, the courts' application of the *Monsanto* non-presumptive four-part test makes it more difficult to block agency approvals that have been made without environmental analysis, even when the courts have ruled that such approvals violated NEPA, ESA, and other statutory mandates. This is particularly true in the area of GM crops, which by their nature are scientifically uncertain and cannot always be shown to engender irreparable harm. However, this higher hurdle is not insurmountable. As discussed above, some courts have found this stringent standard to be met, and issued injunctive relief if the factual predicate was established and balance of factors so warranted.

D. Reaching the Limits of Judicial Oversight

Regulating by litigation is not the most efficient method of protecting consumers and the environment. Often the outcome takes years of procedural delays and appeals through the court system. In allowing planting of a GM crop through partial deregulation before an EIS is completed and its potential effects are fully evaluated, cases like *Monsanto* have shown that NEPA's requirements are "essentially procedural" and thus "insufficient to address all concerns relating to GMOs."[174] In view of their requisite deference, there are limits to the courts' jurisdiction to review agencies' actions and to provide injunctive remedies. In addition, issuing injunctions on a case-by-case basis may become more expensive and ineffective with the growth of problems associated with the rise of GM crops. Moreover, since the remedies available—money damages or declaratory judgment—are backward-looking, the relief at times seems woefully inadequate in view of the irreparable harm that has been done. By far the preferable approach would be for the agencies to do the job they were given by the regulatory scheme in the first instance, since they are the entities purported to possess the necessary scientific expertise. If that cannot be accomplished under the current structure, perhaps Congress can provide oversight as to the deficiencies

---

173. Flynn, *supra* note 171.

174. *See* Claire Althouse, *"Farming Out" Regulatory Responsibility: Private Parties in the Biotechnology Age*, 23 GEO. INT'L ENVTL. L. REV. 421, 432 (2011) (arguing that GMO regulation is fractured both horizontally and vertically, relying on private parties to fill in the holes in the regulatory net, and that the GMO regulatory regime should be revised to reflect and optimize the role that private parties play in this public governance system).

and enact more specific and stringent standards and responsibilities.[175] As a last resort, the courts must continue in their role as a forum for the grievances of private litigants, as well as a backup in the event of regulatory default and the abdication of statutory responsibility.[176]

As with most federal statutes, Congress included in all environmental statutes judicial review provisions that allow nongovernmental organizations, citizens, and private entities to increase compliance with environmental laws through litigation.[177] The regulatory scheme thus recognized the need for oversight of agency implementation of environmental legislation, despite delegating powers in the agencies with broad statutory language and specific directives.[178] Yet there are inherent limits to judicial review under the general principles of administrative law.[179] In turn, there are also limits to the power of agencies, particularly in the implementation of their statutory mandates and in matters of creating policy.[180] However, these limitations do not apply to Congress, whose oversight is necessary in order to retain the legitimacy of its grant of authority to these agencies.[181] Moreover, the constrained role of agencies is another reason they need a clear signal from Congress about the seriousness of this area and the necessity for strict monitoring and control—along with consideration of environmental and human im-

175. *See, e.g.*, Allison M. Straka, *Geertson Seed Farms v. Johanns: Why Alfalfa is Not the Only Little Rascal for Bio-Agriculture Law*, 21 VILL. ENVTL. L.J. 383, 405 (2010) ("New laws specifically devoted to the regulation of GM agriculture must be developed, and the division of regulatory authority over GM agriculture must shift from APHIS to an agency with the scientific knowledge, experience and resources to properly assess the environmental effects of this technology.").

176. *See* Denton, *supra* note 26, at 367–69.

177. *See* Robert L. Glicksman, *The Constitution, the Environment, and the Prospect of Enhanced Executive Power*, 40 ENVTL. L. REP. NEWS & ANALYSIS 11002, 11003 (2010) (citing 33 U.S.C. §§ 1365(a), 1369(b) (2006); 42 U.S.C. §§ 7607(b), 7604(a)) (discussing separation of powers as well as Constitutional limits of judicial review and agency power in the context of environmental law).

178. *Id.* at 11002–03.

179. *See generally* O. LEE REED ET AL., THE LEGAL AND REGULATORY ENVIRONMENT OF BUSINESS 187 (15th ed. 2010) ("[C]ourts cannot interfere with the discretion given to the agency and cannot substitute their judgment for that of the agency. In essence, there is a policy of deference by the judges to the decision of the administrators.").

180. *See, e.g.*, Debra M. Strauss, *Reaffirming the Delaney Anticancer Clause: The Legal and Policy Implications of an Administratively Created De Minimis Exception*, 42 FOOD DRUG COSM. L. J. 393–94 (1987) (analyzing the role of agencies and courts in applying the Delaney Clause of the FDCA, which prohibits the use of carcinogenic food and color additives in the food supply, and concluding that only Congress can amend its zero risk policy); Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375, 392 (D.C. Cir. 1973) (remanding to the EPA for further review after finding critical defects in the agency's decision-making process due to its failure to make available to manufacturers in timely fashion test results and procedures used on existing plants, which formed partial basis for the emission control level adopted; failure to clearly identify the basis for the standards promulgated; and failure to respond adequately to the comments and technical objections of the cement manufacturers).

181. *See* REED ET AL., *supra* note 179, at 187 (noting that, in determining a valid delegation of authority, "unlimited authority cannot be passed from Congress to an agency or official of the executive branch").

pacts—and broad policy goals that should be followed. Congress can and must set clear and more definite standards, and the time is ripe to do so.

IV. ACTION FROM CONGRESS: STEPPING UP TO THE PLATE

There are signs that Congress may be willing to step in to assume its role as the architect of public policy. Beginning with the new FSMA, Congress has begun to set the priority of food safety and the foundation for a proactive policy in this area. The beams of a congressional mandate can be observed through an examination of the FSMA, a ban on the approval of GE salmon, other emerging food safety laws, potential GMO legislation, and state initiatives that have taken hold and turned federal.

A. Food Safety Modernization Act (FSMA)

The importance of these issues has been amplified by the passage of new legislation in this area in January 2011. Prompted by recently increasing incidents of contamination, the FSMA will strengthen food law by enlarging the powers of the FDA to inspect plants and order recalls. It will also require food producers to develop food safety plans, including identifying potential risks of contamination or other hazards and identifying the mechanisms through which those risks would be controlled. The legislation establishes a food tracing system through which consumers can be rapidly identified and deaths and illnesses minimized in the event of a contamination outbreak. The tracing system requires farms and processors to keep records to help the government trace recalled foods.[182] Strengthening restrictions on imported foods, the FSMA empowers the FDA to prevent foods that do not comply with U.S. food safety requirements from being imported, and to request inspections of overseas facilities.[183] Most notably, the FSMA signifies a shift in U.S. regulatory policy from reactive to proactive.[184]

However, the FDA is only one of the regulatory agencies in this area. While it is responsible for overseeing 80% of the nation's food supply the USDA is responsible for handling meat and poultry, products not covered by the new law.[185] And, the EPA is the third "partner," given a particularly prominent role in the regulation of GM crops.[186] In addition, the FSMA relies upon partnerships with other constituencies, including local, state, and foreign governmental entities.[187] Will this new law be effective in protecting our food supply? The answer hinges on the need

182. Strauss, *FSMA*, *supra* note 1, at 354.

183. *Id.* at 358.

184. *Id.* at 358 (providing a detailed analysis of the components of the FSMA, including history of its passage and limitations it may face in the future).

185. *Id.* at 354.

186. *Id.* at 368.

187. *Id.* at 358, 368–69; *see also* Background on the FDA Food Safety Modernization Act (FSMA), FDA, http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm (last visited Nov. 10, 2011).

for an integrated approach to implementation by U.S. regulatory agencies and continued oversight and funding by Congress.[188]

The FSMA represents only a first, but significant, step in improving food safety, as it is the first time in seventy years that food law has been changed substantially. With bipartisan support from both houses of Congress and the President, this new legislation represents a mandate that food safety is at this moment becoming a priority.[189] In light of this considerable movement in the right direction towards enhancing food safety, now is the ideal time to reexamine other food laws. Specifically, the regulation of GM foods and the use of milk and meat from cloned animals and their progeny—which are also allowed under current U.S. law without labeling, preapprovals, or post-market monitoring, unlike foreign countries—should be reexamined.[190] In addition to causing agricultural trade problems,[191] these areas warrant special regulation because they raise concerns for consumers about the safety of the national and global food supply.[192]

Thus, Congress has begun to speak in this area with a mandate for food safety, initiating a new proactive policy on food safety—embodied in the FSMA—with more precautionary regulation potentially to follow.[193]

B. GE Salmon Ban from Congress

In addition, the House of Representatives even more recently passed legislation to prohibit the FDA from approving GE salmon.[194] The FDA had been on the brink of approving GE salmon, which would

188. Strauss, *FSMA*, *supra* note 1, at 375.

189. *Id.* at 370–72 (exploring the significance and breadth of this mandate from the perspectives of Congress, the President, agencies such as the FDA, food safety and consumer groups, and the food industry).

190. *See* Strauss, *Importing Caution*, *supra* note 3, at 182–89 (discussing the U.S. laissez-faire regulatory treatment of GMOs).

191. *See* Strauss, *Impact of the WTO*, *supra* note 147 (characterizing the EC-Biotech dispute as a disruption in trade between the United States and EU caused by their different regulatory approaches toward GMOs, which are in turn a reflection of the differing views and levels of concern about genetically modified food in the face of scientific uncertainty); Debra M. Strauss & Melanie C. Strauss, *Globalization and National Sovereignty: Controlling the International Food Supply in the Age of Biotechnology*, 15 J. LEGAL STUD. BUS. 75 (2009) (analyzing the implications of the WTO's food trade dispute decision on nation-state control in the regulation of its food supply, and multilateral environmental and trade agreements; concluding that the WTO has exceeded its scope of international trade and that perhaps another supranational organization should be formed to regulate the world's food supply as a scientific and policy-making entity that would take into account public health, safety, and sustainability).

192. *See* Strauss, *A Model of Labeling*, *supra* note 147, at 96.

193. *See* Strauss, *FSMA*, *supra* note 1.

194. Press Release, Ctr. for Food Safety, U.S. House of Representatives Passes Amendment to Prohibit Genetically Engineered Salmon Approval (June 16, 2011), http://www.centerforfoodsafety.org/2011/06/16/u-s-house-of-representatives-passes-amendment-to-prohibit-genetically-engineered-salmon-approval/.

have been the first GE food animal to be approved for human consumption.[195] Developed by AquaBounty Technologies, the AquaAdvantage salmon are engineered by inserting into an Atlantic salmon a growth gene from a Chinook salmon and an antifreeze gene from an ocean pout.[196] They grow twice as fast as typical ocean pout with 10% less feed.[197] The company is also developing advanced-hybrid trout and tilapia.[198] Consumers submitted nearly 400,000 public comments to the FDA demanding the agency deny its approval or, at the very least, require mandatory labeling of this transgenic salmon. Recent polls indicate that 95% of the public want labeling of genetically-modified foods, and that nearly 50% of the public would not eat seafood that has been genetically engineered.[199]

In response to signs the FDA would approve the GE salmon for human consumption, the Senate reintroduced a bill to ban GE salmon and a bill to require labeling if GE fish are approved.[200] More than sixty-seven consumer, worker, religious, and environmental groups endorsed the bill, along with commercial, recreational, and subsistence fisheries associations, and food businesses and retailers; earlier in the fall of 2010, more than 300 organizations had signed joint letters to the FDA opposing the approval.[201] In addition, more than forty members of Congress sent letters requesting the FDA halt the approval. One of them, Representative Peter DeFazio (D-Ore.), stated:

> The FDA's hastily completed approval process puts American consumers and the environment at risk. GE salmon could be devastating to fishing and coastal communities, our food source, and already depleted wild salmon populations. The FDA should

195. *See id.*

196. ARCADIS U.S., INC., ENVIRONMENTAL ASSESSMENT FOR AQUADVANTAGE SALMON 12 (2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf.

197. *See id.* at 36.

198. *See* Helena Bottemiller, *Senators Introduce Bill to Ban GE Salmon*, FOOD SAFETY NEWS (Feb. 2, 2011), http://www.foodsafetynews.com/2011/02/senators-introduce-bill-to-ban-genetically-engineered-salmon/.

199. Press Release, Ctr. for Food Safety, California Assembly Health Committee Passes Bill to Require Labels on Genetically Engineered Salmon (May 4, 2011), http://www.centerforfoodsafety.org/2011/05/04/assembly-health-committee-passes-bill-to-require-labels-on-genetically-engineered-salmon/.

200. S. 230, 112th Cong. (2011) (referred to the Committee on Health, Education, Labor, and Pensions) (preventing approval of genetically engineered fish); S. 229, 112th Cong. (2011) (referred to the Committee on Health, Education, Labor, and Pensions) (requiring labeling of genetically engineered fish).

201. Press Release, Ctr. for Food Safety, U.S. House of Representatives Passes Amendment to Prohibit Genetically Engineered Salmon Approval, *supra* note 194 (listing several of the groups that supported the Senate bill). *But see* Andrew Seidman, *Trade Groups Tell Congress: Stay out of FDA Salmon Probe*, LA TIMES, Aug. 2, 2011, http://www.latimes.com/news/politics/la-pn-salmon-fda-20110802,0,7205500.story?track=rss. A coalition of animal agriculture industry organizations sent a letter to heads of the House and Senate asking lawmakers not to intervene with FDA authority for "science-based regulation." *Id.*

> put the interests and safety of American families and our ocean resources above special interests.[202]

Citing the lack of consideration of the potential health and safety issues, a group of senators (supported by environmental groups such as Food & Water Watch) urged the FDA to shift the approval process to the FDA's Center for Food Safety and Applied Nutrition to study the potential consequences to human health.[203] On June 15, 2011, the House passed an amendment to the Fiscal Year 2012 Agriculture and FDA appropriations bill, proposed by Representative Don Young (R-Ark.), to prohibit the use of FDA funds to grant any application for approval of GE salmon.[204]

Congress has begun to intervene, and the precedent for a more stringent oversight has now been set. This action further supports the notion of a multilateral approach to food safety, consistent with a new strong, proactive federal policy. Through these signals, in addition to the courts, Congress will be more vigilant over agency action or inaction, and the Constitution's principle of checks and balances can strengthen our resolve for a unified approach toward food safety.

C. Other Legislation to Improve Food Safety

Improvements in meat safety, which fall under the purview of the USDA, are also needed.[205] New provisions to enhance the authority of the USDA, akin to those provided in the new FSMA for the FDA, would follow logically from the new mandate for food safety.[206] Such powers should include stringent safety standards, mandatory recall authority, increased ability for inspections, the availability of more effective penalties such as fines, and whistleblower provisions for employees throughout the supply chain of the meatpacking industry.[207] In the process of

---

202. Press Release, Ctr. for Food Safety, U.S. House of Representatives Passes Amendment to Prohibit Genetically Engineered Salmon Approval, *supra* note 194 (listing several of the groups that supported the Senate bill).

203. *Id.* (arguing that the FDA has not studied the environmental effects on Alaska's wild salmon fisheries or the economic impacts on the seafood market).

204. Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2012, H. Amdt. 449 to H.R. 2112, 112th Cong. (2011).

205. *See* Pape, *supra* note 44, at 438–46.

206. *See* Strauss, *FSMA*, *supra* note 1 (discussing provisions of the FSMA, demonstrating that this legislation represents a new mandate for food safety, and proposing additional proactive legislation in furtherance of food safety).

207. Pape, *supra* note 44, at 446–55. *See, e.g.*, E. Coli Eradication Act of 2009, S. 2792, 111th Cong. (2009) (proposing testing of boneless beef manufacturing trimmings and ground beef) (referred to the Committee on Agriculture, Nutrition, and Forestry); E. coli Traceability and Eradication Act, H.R. 6024, 111th Cong. (2010) (referred to the Subcommittee on Livestock, Dairy, and Poultry). *See also* Bill Tomson, *Government Knew About Bacteria in Turkey*, WALL ST. J., Aug. 10, 2011, http://online.wsj.com/article/SB10001424053111904140604576498590579065416.html (reporting that USDA knew of salmonella contamination of ground turkey, but was unable to order recalls under its rules until the contamination was linked to injury or death).

ensuring these powers become a reality, the need for adequate funding should not be overlooked.[208]

However, despite its statutorily defined role in protecting the safety of the food supply, "the predominant view by many in the agency remains that production is the agency's primary, and perhaps sole, mission."[209] For instance, the stated mission of its Agricultural Marketing Service (AMS) is "to facilitate the competitive and efficient marketing of agricultural products";[210] and the Administrator of AMS in testimony to Congress insisted that "AMS is not a food safety agency."[211] Yet these agency statements contradict "its responsibility for grading and labeling eggs, quarterly plant inspections, developing sanitation and good manufacturing practices, and implementing industry-developed safety programs—clear examples of food safety responsibilities."[212]

Moreover, there are signs that the USDA may be resisting any increase in its authority. The USDA's decision to grant nationwide approval of GM alfalfa was based upon its "limited authority" which confines its scope to "plant pest" risks.[213] In the GM eucalyptus trees action, the CFS has urged the USDA to use the 2008 Farm Bill, which has not been fully implemented by the USDA, to expand its regulatory oversight to include consideration of "other effects" of "noxious weeds."[214] Congressional reaction has been divergent. Regarding the GM sugar beets decision, Senator Patrick Leahy (D-Vt.) and Representative Peter DeFazio (D-Or.) wrote to Agriculture Secretary Tom Vilsack expressing "serious concern" over the proposed EIS which supported the deregulation of RRA, stating that "[w]e have concluded that [the] USDA's preliminary

---

208. Funding is a problem anticipated potentially to hamper the FDA, even with its enhanced role under the FSMA. Strauss, *FSMA*, *supra* note 1, at 365–66; *see also* Molly Peterson & Alan Bierga, *FDA Seeks $1.4 Billion for Food-Safety Law as Budget Faces Cuts*, BLOOMBERG (July 6, 2011), http://www.bloomberg.com/news/2011-07-06/fda-seeks-1-4-billion-for-food-safety-law-as-budget-faces-cuts.html; *Deficit Focus Coming at Expense of Food Safety?*, CBS NEWS (July 5, 2011), http://www.cbsnews.com/stories/2011/06/30/earlyshow/main20075715.shtml.

209. A. Bryan Endres & Nicholas R. Johnson, *Integrating Stakeholder Roles in Food Production, Marketing, and Safety Systems: An Evolving Multi-Jurisdictional Approach*, 26 J. ENVTL. L. & LITIG. 29, 44 (2011) (discussing safety regulations for leafy greens).

210. *Agency Mission Statement*, USDA AGRIC. MKTG. SERV., http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&navID=AMSMissionStatement&rightNav1=AMSMissionStatement&topNav=AboutAMS&leftNav=&page=AboutAMSMissionStatement&resultType=&acct=AMSPW (last visited Nov. 1 2011).

211. Rayne Pegg, Adm'r., Agric. Mktg. Serv., Ready to Eat or Not? Examining the Impact of Leafy Green Marketing Agreements, Hearing Before the Subcomm. on Domestic Policy of the H. Comm. of Oversight and Gov't Reform (July 29, 2009), http://republicans.oversight.house.gov/images/stories/Hearings/pdfs/20090729Pegg.pdf.

212. Endres & Johnson, *supra* note 209, at 44.

213. Jillian Hishaw & Thomas P. Redick, *Case Law Update: Biotech Crops, RBST, Farmland Preservation, and the CAFO Rule*, ABA AGRIC. MGMT. COMMITTEE NEWSL. (Am. Bar Ass'n, Section of Envt., Energy, & Res., Agric. Mgmt. Committee, Chi., Ill.), May 2011, at 3, 5.

214. *Id.*; *see* Food, Conservation, and Energy Act of 2008, Pub. L. No. 110-246, Tit. X § 10204, 122 Stat. 1651, 2105 ("2008 Farm Bill").

finding of 'No Significant Impact' cannot be justified."[215] Citing "new authority under the 2008 Farm Bill to bolster regulation of GM plant products[, the letter] complains that the Department of Agriculture has failed to adopt regulations appropriately implementing that authority."[216] In contrast, Senators Blanche Lincoln (D-Ark.), chair of the Senate Committee on Agriculture, Nutrition and Forestry, and Saxby Chambliss (R-Ga.), the committee's ranking member, wrote to Secretary Vilsack that "[d]espite countless findings and studies confirming the safety of genetically engineered crops, recent wrongly-decided court decisions threaten to thrust the U.S. regulatory system for agricultural biotechnology into a non-functioning regulatory system."[217] Referencing the *Geertson Seed Farms* decision, the senators encouraged the USDA and the U.S. Department of Justice "to continue to mount vigorous defenses against lawsuits that seek to upend science-based regulatory decisions."[218] This split in Congress, along with mounting pressures on the USDA from the industry, necessitates hearings and debate in a public forum with the goal of promulgating clear and specific statutory guidance for these agencies.

It is increasingly apparent that the agencies are not policing food safety adequately because they are following the vague standards that apply to the agricultural industry generally. This observation presents another reason for federal legislation that is more stringent and specific. Perhaps in no area is the need more pressing than for GMOs (particularly GM crops), which warrant separate and tailored statutory directives and regulations. As evidenced by these incidents and lawsuits, which have established the dangers of pollen drift, the EIS mechanism does not provide adequate protection.

D. Federal Legislation on GMOs

During the most recent five-year period reported by the Pew Initiative on Food and Biotechnology (PIFB) (2001–2006), the only bills passed at the federal level that have concerned GMOs have supported biotechnology.[219] None of the GM-restrictive legislation in this area was

---

215. Letter from Patrick Leahy, Senator, and Peter Defazio, Representative, to Tom Vilsack, Sec'y, U.S. Dep't of Agric. (June 23, 2010), http://www.defazio.house.gov/index.php?option=com_content&task=view&id=590.

216. *Id.*

217. *Id.* at 5–6.

218. *Id.* at 6.

219. Pew Initiative on Food and Biotechnology, Legislative Activity 2001-2006 Related to Agricultural Biotechnology (Feb. 2007), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Legislative_Tracker.pdf [hereinafter PIFB Legislative Tracker]. It should be noted that this data is the most recent that is available at this comprehensive level because the grant for the Pew Initiative ended in March 2006. In its final report, the organization stated, "The nonprofit Pew Initiative on Food and Biotechnology is closing, but the need for an independent and neutral body to facilitate dialogue on U.S. biotech policy has never been greater." The PEW Charitable Trusts,

enacted, but several bills were introduced.[220] In May 2002, H.R. 4814 was one of five bills introduced by Representative Dennis Kucinich (D-Ohio) that sought to expand the regulation of agricultural biotechnology.[221] H.R. 4812, the Genetically Engineered Crop and Animal Farmer Protection Act, would "provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals," establishing a Farmer's Bill of Rights "to ensure fairness for farmers and ranchers in their dealings with biotech companies that sell genetically engineered seeds, plants, or animals."[222] Among these protections, the bill would require biotechnology companies to disclose the legal and environmental risks that the use of the genetically engineered seeds, plants, or animals may pose to the consumer; prevent noncompetitive practices involving technology fees; preclude biotechnology companies from limiting liability for harm that may result from the release of genetically engineered material into the environment; and prohibit the sale of certain nonfertile plant seeds (a seed that is genetically engineered to produce a plant whose seeds are not capable of reproduction). Finally, H.R. 4816, the Genetically Engineered Organism Liability Act, would hold biotechnology companies liable to any party for injuries caused by the release of a genetically engineered organism into the environment.[223] The potential injuries include crop failures suffered by farmers, cross pollination of neighboring farms, and increased insect resistance, as well as health and environmental impacts on consumers.[224] All of these proposals died in subcommittees.[225]

Nevertheless, Rep. Kucinich again introduced similar bills in the 111th Congress.[226] The purpose of one of these bills was:

> To provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals, to ensure fairness for farmers and ranchers in their dealings with biotech companies that sell genetically engineered seeds, plants, or animals, to assign liability for inju-

---

Lessons Learned: Food for Thought and Discussion, TRUST MAGAZINE, Fall 2007, *available at* http://www.pewtrusts.org/our_work_report_detail.aspx?id=32992.

220. PIFB Legislative Tracker, *supra* note 219.

221. Genetically Engineered Food Right to Know Act, H.R. 4814, 107th Cong. (2002).

222. Genetically Engineered Crop and Animal Farmer Protection Act of 2002, H.R. 4812, 107th Cong. (2002).

223. Genetically Engineered Organism Liability Act of 2002, H.R. 4816, 107th Cong. (2002).

224. *Id.*

225. Strauss, *Legal Liability Risks*, *supra* note 18, at 171.

226. Genetically Engineered Technology Farmer Protection Act, H.R. 5579, 111th Cong. (2010) (referred to the Committee on Agriculture and the Committees on Energy and Commerce); Genetically Engineered Food Right to Know Act, H.R. 5577, 111th Cong. (2010) (referred to the Subcommittee on Livestock, Dairy, and Poultry); Genetically Engineered Safety Act-Genetically Engineered Pharmaceutical and Industrial Crop Safety Act of 2010, H.R. 5578, 111th Cong. (2010) (referred to the Subcommittee on Rural Development, Biotechnology, Specialty Crops, and Foreign Agriculture).

ry caused by genetically engineered organisms, and for other purposes.[227]

The Genetically Engineered Organism Liability Act of 2010 further states that: (1) "A biotech company [shall be] liable to any party injured by the release of a genetically engineered organism into the environment if the injury results from such genetic engineering;" and (2) "liability may not be waived or otherwise avoided by contract."[228] No further action has been taken since the end of 2010, when the bills were submitted to the appropriate House committees.

There are some signs that the recent climate of food safety may translate into further changes in the law. Currently, Congress is considering such issues as "food safety initiatives covering meat, poultry, and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of certain plastic components commonly used in food containers; food labeling; and the use of plant and animal biotechnology."[229]

"In the area of [GM] food, although supporters of this technology from agricultural states have previously prevailed, the new focus on safety issues may turn the tide to scrutinize the adequacy of a U.S. regulatory framework that predates the advent of agricultural biotechnology."[230] Ongoing issues associated with the widespread use of GM crops include concerns about increased herbicide resistant weeds as well as the cross-contamination of other traditional and organically grown crops.[231] As discussed above, the predominant GM legislation introduced in the current Congress recently resulted in passage of a bill against FDA approval of GE salmon.[232] Meanwhile Congress can be expected to continue to deliberate on other bills involving GMOs.[233]

E. State Initiatives Effectively Turn Federal

State legislatures have been more active than Congress in developing GM regulation, and at times these initiatives have taken hold and effectively spurred a federal response. For example, in the GE salmon

---

227. Genetically Engineered Technology Farmer Protection Act, H.R. 5579, 111th Cong. (2010).

228. Genetically Engineered Organism Liability Act of 2010, H.R. 5579, 111th Cong. (2010).

229. RENÉE JOHNSON, CRS REPORT FOR CONGRESS, FOOD SAFETY ISSUES FOR THE 112TH CONGRESS, R41629, at 6 (Feb. 10, 2011), http://assets.opencrs.com/rpts/R41629_20110210.pdf [hereinafter JOHNSON, CRS REPORT R41629].

230. Strauss, *FSMA*, *supra* note 1, at 375.

231. JOHNSON, CRS REPORT R41629, *supra* note 229, at 12.

232. *See supra* Section IV.B.

233. *See, e.g.*, Dallas Duncan, *Genetically Engineered Food Sparks 'Vigorous Debate'*, REDANDBLACK.COM (Jan. 25, 2011), http://www.redandblack.com/2011/01/25/geneticall y-engineered-food-sparks-%E2%80%98vigorous-debate%E2%80%99/ (discussing research into genetically modified organisms at the University of Georgia and the contentious debate this technology has generated both in the university community and in Congress).

legislation, federal action followed passage of a bill in the California Assembly Health Committee.[234] Prompted by the FDA's imminent approval of the proposed commercialization of GE salmon, the California Assembly Health Committee bill (AB 88) would require that all GE fish sold in California contain clear and prominent labeling.[235] The CFS, cosponsor of the bill, explained its importance:

> The FDA has indicated that it will not require these GE fish to be labeled once they are approved. . . . As such, it is incumbent on the California State legislature, starting with the Health Committee, to let the people of California make informed choices about the food they eat by requiring the labeling of GE fish sold in California.[236]

In the midst of public outcry for mandatory labeling of the untested transgenic salmon—the first genetically engineered animal intended for human consumption—the CFS cited California as a leader in environmental and food safety laws to protect the public from potentially harmful food technology and to employ labeling as a means to give consumers a choice in the marketplace.[237] In a subsequent development, the California Assembly decided to hold the bill after it did not garner enough votes to pass in the Appropriations Committee.[238] The Committee noted, however, the widespread support for the bill, particularly from consumer letters, and expressed optimism that it would become law the next year.[239] Soon after, the parallel federal bill passed in the House of Representatives.[240]

Another state-initiated standard originated in California with lettuce and spinach producers who seek to unify farm safety standards nationwide.[241] The USDA formally proposed a "leafy greens marketing agreement" that would essentially extend California's leafy greens regulatory system across the United States.[242] The California Leafy Green Marketing Agreement, launched after a widespread E. coli outbreak in 2006, encompasses almost all of the lettuce and spinach produced in the state.[243] The federal version, although voluntary, would set binding standards on everyone who joined, covering "recordkeeping, soil testing,

---

234. Press Release, Ctr. for Food Safety, California Assembly Health Committee Passes Bill to Require Labels on Genetically Engineered Salmon, *supra* note 199.

235. *Id.*

236. *Id.* (statement of Rebecca Spector, West Coast Director of the CFS).

237. *Id.*

238. Press Release, Ctr. for Food Safety, CA GE Fish Labeling Bill Held (May 24, 2011), *available at* http://www.centerforfoodsafety.org/2011/05/24/ca-ge-fish-labeling-bill-held/.

239. *Id.*

240. *See supra* Section IV.B.

241. Michael Doyle, *Feds Finally Catching up with California Farmers' Food Safety Standards*, THE SACRAMENTO BEE (Apr. 30, 2011), http://www.ongo.com/v/841376/-1/D00166308A71C3B1/feds-finally-catching-up-with-california-farmers-food-safety-standards.

242. *Id.*

243. *Id.*

and field sanitation requirements."[244] The marketing agreement would be "[g]overned by a 26-member board, including as many as seven handlers and producers from California."[245] In a formal statement, the Western Growers Association and other farm groups reacted positively to the development: "It is encouraging to know the USDA has come to this point."[246] A local agricultural economist testified during hearings conducted by the Agriculture Department, identifying a "labyrinth" of competing safety rules and stating: "In the absence of one universally accepted set of standards, producers and food providers are often faced with having to comply with a different set of standards for different customers."[247]

The most recent PIFB report on state legislative activity indicates that initiatives grew exponentially at the state and local levels.[248] Michael Fernandez, executive director of the Pew Initiative on Food and Biotechnology, explained: "As agricultural biotechnology progresses, and farmers, the food industry and consumers continue to adapt to it, state legislatures are at the forefront. States sometimes have little choice but to address new policy issues, even before they emerge at the federal level."[249] State legislatures increasingly introduced bills that attempted to preempt local and county initiatives to limit or prohibit GM seeds and crops, prompted by concerns that local regulations could be inconsistent with, and more restrictive than, statewide policies.[250]

In addition, states sought to balance the competing interests of different stakeholders. While many of the bills supported agricultural biotechnology as a means of promoting economic growth, others aimed to manage the potential economic conflicts between farmers who use GM crops and those using conventional or organic techniques. This category of "liability and contracts" encompassed 15% of the bills introduced in 2005–2006 and 11% of adopted legislation in 2005–2006, compared to

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.* (statement of Mechel Paggi, director of the Center for Agricultural Business at California State University, Fresno).

248. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 172–73 (exploring state legislation on GMOs and biotechnology).

249. *Report: State Legislatures Continue to Be Active in Addressing Challenges Associated with Agricultural Biotechnology*, PEW TRUSTS (June 22, 2006), http://www.pewtrusts.org/our_work_report_detail.aspx?id=20040&category=442 [hereinafter PEW Report]; *see also* Michael R. Taylor, Jody S. Tick & Diane M. Sherman, *Tending the Fields: State & Federal Roles in the Oversight of Genetically Modified Crops*, PEW TRUSTS (Dec. 2004), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/Tending_Fields_Biotech1204.pdf (examining the role of state governments in the regulatory oversight of crops and foods produced using the tools of modern biotechnology).

250. Pew Initiative on Food and Biotechnology (PIFB), *Factsheet: State Legislative Activity Related to Agricultural Biotechnology in 2005-2006*, PEW TRUSTS (Feb. 2007), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/PIFB_State_Legislature_2005-2006Session.pdf [hereinafter PEW Legislative Activities].

3% in 2003–2004.[251] Most notable was legislation proposed in Vermont ("the Farmer Protection Act") that was vetoed by the Governor. Prompted by concerns about the "unintended presence of GM crops in conventional and organic crops," this bill (SB 18) would have held manufacturers strictly liable for damage caused by GM material, while an alternate House version (H.B. 309) "would have required that manufacturers be negligent to be held responsible."[252] Some of the proposed legislation aimed to "impose moratoria on GM crops and animals" (16%, as compared to 6% in 2003–2004); "8% proposed to impose labeling requirements (compared to 7%); 9% involved studies and taskforces (compared to 19%); and 1% concerned crop destruction (compared to a similarly small number in 2003–2004)."[253] Through these conflicting bills, the states attempted to implement coexistence strategies.[254]

Of the total bills and resolutions introduced in state legislatures in 2005–2006, twenty-seven (20%) passed.[255] Most of the new state laws supported biotechnology, disallowed local and county initiatives, or criminalized the destruction of crops.[256] Only a few of the many labeling bills introduced were adopted: Alaska enacted a labeling statute (SB 25), which requires that GM fish be conspicuously labeled before being sold for human consumption;[257] Maine provided for voluntary labeling of foods designated as GM free (LD 1733);[258] and Vermont mandated labeling of seed as GM (HB 777).[259] In addition, one bill on the subject of liability and agricultural contracts previously became law in Illinois.[260]

---

251. *Id.* At the same time, state legislators proposed contrasting legislation "in support of agricultural biotechnology, the second most prominent category of bills in 2005-2006, both in terms of introduced bills (22%) and adopted bills (33%)." *Id.* By comparison, in 2003-2004, 34% of introduced bills and 57% of adopted bills supported biotechnology. . . ." *Id.* Proposed support "provided favorable tax treatment for investment, approved bond issues for laboratories and infrastructure, and created high-level commissions to promote the industry, among other things." *Id.* "Bills supportive of biotechnology combined with preemption bills" comprised "two-thirds of adopted bills in 2005-2006, indicating that adopted legislation in 2005-2006 was largely supportive of agricultural biotechnology." *Id.*

252. *Id.*

253. *Id.*

254. *See generally* Endres, *supra* note 28.

255. PEW Legislative Activities, *supra* note 250.

256. *Id.*

257. ALASKA STAT. § 17.20.040 (2011).

258. ME. REV. STAT. ANN. tit. 7, § 530-A (2012).

259. VT. STAT. ANN. tit. 6, § 644 (West 2011); *see also* LB 114, 102d Leg., 1st Sess. (Neb. 2011) (providing a standard and labeling restrictions for honey in Nebraska and directing the state's department of agriculture to develop rules and regulations for a honey standard consistent with that of the U.N. Food and Agriculture Organization and the World Health Organization). There are hopes that, as more states adopt similar labeling statutes, these initiatives will attain a critical mass and spark federal legislation. *See Bill Would Require Ag Department to Develop Honey Standard*, UNICAMERAL UPDATE (Jan. 26, 2011), http://update.legislature.ne.gov/?p=2927 (listing Florida, California, and Wisconsin honey standards in absence of FDA's).

260. 2003 Ill. Laws 3410 (outlining requirements for contracts between producers and purchasers of grain and suggesting that any requirements pertaining to GMO content should be considered for inclusion in an accompanying materials sheet). *See* PIFB Legislative Tracker, *supra* note 219.

Calls have been renewed for a greater statutory response, particularly at the state level.[261] Some experts prefer these decisions be made by the legislatures rather than the courts: "An appropriate statutory and regulatory regime enacted with the purpose of establishing standards of care for growers of GE crops would place the important policy questions presented by gene flow squarely in the hands of the political branches of government."[262] Grassroots local efforts carry great potential to take hold and expand further into a federal regulatory scheme. As the voice of consumers grows stronger, and as word of contamination and potentially other incidents spreads, so do the prospects that the United States may react to a changing political climate with the passage of new federal and state legislation that restricts the continued proliferation of GM crops, requires labeling of GM ingredients, and clearly defines liability for the future harms caused by GMOs in food.[263]

V. OTHER CONSTITUENCIES PROVIDE A DRIVING FORCE

As governmental agencies appear to take an ever more passive role in the regulation of genetically engineered foods, other stakeholders increasingly attempt to fill the void. Most recently, these constituents have included trade associations acting in their industries' best interests with suppliers demanding non-GM ingredients, the organics industry proactively pressing for protection through preemptive litigation against Monsanto, and consumer-driven demands expressed through organic and non-GMO sales.

A. The Impact of Trade Associations and Suppliers

Trade associations and suppliers have increasingly provided a voice that has shaped the actions of government agencies and industry players in this area. As seen in the grassroots push against GE salmon, fishing associations, food companies, restaurants, and organizations promoting environmental protection, consumer interests, health, and ani-

261. *See, e.g.*, Stephanie E. Cox, Note, *Genetically Modified Organisms: Who Should Pay the Price for Pollen Drift Contamination?*, 13 DRAKE J. AGRIC. L. 401, 406 (2008) (proposing state legislation); Walker & Doerfler, *supra* note 152, at 519 (addressing statutory action in Minnesota); DREW L. KERSHEN, PROPOSED LIABILITY FOR TRANSGENIC CROPS 3 (2005), http://ucbiotech.org/issues_pgl/ARTICLES/Proposed%20Liability%20for%20Transgenic%20Crops.rtf.

262. Joshua B. Cannon, *Statutory Stones and Regulatory Mortar: Using Negligence Per Se to Mend the Wall Between Farmers Growing Genetically Engineered Crops and their Neighbors*, 67 WASH. & LEE L. REV. 653, 679 (2010) (preferring legislative and administrative statements on standards of care to the courts' in private tort actions); *see also* Kanchana Kariyawasam, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, 19 PAC. RIM L. & POL'Y J. 459, 483 (2010) (analyzing the level of protection provided by Australia's Gene Technology Act of 2000 and arguing that it should be strengthened by following the liability legislation of Germany, which "allocate[s] liability for the financial risk arising from the cultivation of GMOs, with a general focus on responsible parties meeting the costs and a clear intent to protect non-GM farmers").

263. Strauss, *Legal Liability Risks*, *supra* note 18, at 173.

mal welfare, all played a role in activating legislation at both the state and federal level.[264] In addition, an industry registry for non-GM sugar sources has been established and joined by over seventy food companies and retailers: the Non-GM Sugar Beet Registry notifies consumers of its members' intention to avoid GM beet sugar.[265] Through consumer petitions, organizations such as CFS solicit the assurances of additional companies that they will commit to avoiding GM sugar.[266] With a similar approach, CFS has organized a consumer boycott—targeting the dairy industry—of dairy products derived from cows that are fed GM alfalfa; through petitions they seek to obtain industry pledges to use only non-GM alfalfa.[267] Another organizational initiative promotes non-GM lunches in local schools.[268]

In the absence of government regulation, the market has also intervened through measures such as a voluntary non-GMO certification.[269] Suppliers and manufacturers who seek to assure their buyers and consumers that their products do not contain GMOs are increasingly utilizing third-party certification programs.[270] A new "Non-GMO Project Verified" seal offers third-party testing and certification that less than 0.9% of the product ingredients came from GMOs. More than 2000 products have been verified in the program and another 2000 are in process.[271] These industry initiatives do indeed speak volumes.[272]

---

264. These diverse groups included the CFS, Ocean Conservancy, Bristol Bay Regional Seafood Development, the Alaska Trollers Association, Food and Water Watch, the National Cooperative Grocers Association, Trout Unlimited, and the Pacific Coast Federation of Fisherman's Associations. *See* Press Release, Ctr. for Food Safety, U.S. House of Representatives Passes Amendment to Prohibit Genetically Engineered Salmon Approval, *supra* note 194; *supra* Section IV.B.

265. *Non-GM Beet Sugar Registry*, SEEDS OF DECEPTION, http://www.seedsofdeception.com/includes/services/nongm_sugar_beet_registry_display.cfm (last visited Nov. 1, 2011).

266. *See, e.g.*, Petition, Ctr. for Food Safety, Tell Mars and Hershey's to Sign the Non-GM Beet Sugar Registry, https://secure3.convio.net/cfs/site/Advocacy?cmd=display&page=UserAction&id=299 (last visited Nov. 1, 2011).

267. Petition, Ctr. for Food Safety, Tell U.S. Dairies You Don't Want GE Alfalfa, https://secure3.convio.net/cfs/site/Advocacy?cmd=display&page=UserAction&id=357 (last visited Nov. 1, 2011).

268. *GM Free Schools, IRT Support for Your Local GM-Free Schools Effort*, INST. FOR RESPONSIBLE TECHN., http://responsibletechnology.org/take-action/gm-free-schools (last visited July 29, 2011).

269. *See, e.g.*, Ken Roseboro, *Certification Seen as a Key to Success in Non-GMO Markets*, NETWORK OF CONCERNED FARMERS (Jan. 5, 2004), http://www.non-gm-farmers.com/news_details.asp?ID=960; NON-GMO PROJECT, http://www.nongmoproject.org/product-verification/ (last visited Nov. 1, 2011) (The Non-GMO Project "offers North America's *only* independent verification for products made according to best practices for GMO avoidance."); *Non-GMO Certification*, CERT ID, http://www.cert-id.eu/Certification-Programmes/Non-GMO-Certification (last visited Nov. 1, 2011) (international independent certification company based in Europe).

270. Roseboro, *supra* note 269 (noting that large supermarket chains such as Whole Foods Markets and Wild Oats Markets, along with manufacturers including Gerber, H.J. Heinz, Seagram, and Frito-Lay, have announced they will eliminate GMO ingredients from their products).

271. Eng, *supra* note 11 (statement of Megan Westgate, executive director of the Non-GMO Project).

B. Organics Industry Litigation for Changing Tide

In a novel case filed recently, the organics industry is going on the offensive against Monsanto as a preemptive strike on future damages and the validity of its patents.[273] Against a legal landscape in which Monsanto has aggressively pursued farmers for patent infringement in incidents of "unintentional seed drift into their fields (a scenario that could more appropriately be viewed as contamination warranting a countersuit by the farmer)," a group of farmers is challenging the company's patents for GM seeds.[274] The farmers contend that wind-blown pollen from gene-altered crops can contaminate organic plants; as a result, organic canola is "virtually extinct," and there are concerns that corn, soybeans, cotton, sugar beets, and alfalfa will also suffer this fate.[275]

In *Organic Seed Growers & Trade Association v. Monsanto Co.*, these plaintiffs, who represent a "broad array of the organic and conventional agriculture community," in total 36 agriculture and food safety membership organizations, 14 seed businesses, and 33 farms and farmers, are challenging the validity of Monsanto's GM patents, claiming that the patents fail to meet the constitutional and patent law requirement of utility or usefulness.[276] The plaintiffs, represented by Daniel Ravicher of the Public Patent Foundation (PUBPAT), are seeking a declaratory judgment that Monsanto's transgenic seed patents are invalid and cannot be enforced. Under the Patent Act, "an invention is 'useful' if it is capable of providing some identifiable benefit," and this standard

---

272. *See, e.g.*, Inst. for Responsible Tech., NON-GMO SHOPPING GUIDE (2011), http://www.nongmoshoppingguide.com/Non-GMO-Shopping-Guide.pdf (listing products and brands participating in the Non-GMO Project, a non-profit organization committed to providing consumers with clearly labeled and independently verified non-GMO choices including testing of at-risk ingredients).

273. *See* David Bario, *Seeds of Discontent*, SAVE OUR SEEDS (Apr. 11, 2011), http://saveourseeds.com/?p=56; Ethan A. Huff, *Organic Groups, Farmers File Preemptive Lawsuit Against Monsanto to Protect Themselves from Inevitable Destruction by GMOs*, NATURALNEWS.COM (Apr. 1, 2011), http://www.naturalnews.com/031922_Monsanto_lawsuit.html.

274. *See* Debra M. Strauss, *The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT'L L. 287, 299 (2009) [hereinafter Strauss, *International Intellectual Property Rights*] (parentheses added) (discussing the inappropriate use of patent protection for GM seeds as in the case of Percy Schmeiser). *But see* Strauss, *Legal Liability Risks*, *supra* note 18, at 156–60 (analyzing the LibertyLink rice litigation where farmers successfully sued for contamination of the national rice crop).

275. Susan Decker & Jack Kaskey, *Monsanto Sued by Organic Farmers Over Modified-Seed Patents*, BLOOMBERG (Mar. 29, 2011), http://www.bloomberg.com/news/2011-03-29/monsanto-sued-by-organic-farmers-over-modified-seed-patents-1-.html.

276. First Amended Complaint at ¶ 11, Organic Seed Growers & Trade Ass'n et al. v. Monsanto Co., No. 11-CV-02163-NRB (S.D.N.Y. June 1, 2011); Press Release, Ctr. for Food Safety, Family Farmers Amplify Complaint Against Monsanto's GMOs, Reinforcing Their Arguments with Two Dozen Additional Plaintiffs (June 1, 2011), *available at* http://www.centerforfoodsafety.org/2011/06/01/family-farmers-amplify-complaint-against-monsanto%E2%80%99s-gmos-reinforcing-their-arguments-with-two-dozen-additional-plaintiffs/.

for utility cannot be met until a "specific benefit exists in currently available form."[277] Citing a historic case that defined the patent utility doctrine as rejecting inventions that "poison people" or are "injurious to the wellbeing, good policy, or sound morals of society," the plaintiffs claim that the GM seeds do not produce the alleged benefits.[278] Additionally, plaintiffs assert that the GM seeds fail to increase crop yield and, instead of reducing herbicide and pesticide use, actually promote pesticide use and plant tolerance to chemicals, causing farmers to spray their crops more heavily.[279] According to the complaint, "since the harm of transgenic seed is known, and the promises of transgenic seed's benefits are false, transgenic seed is not useful for society."[280]

It remains to be seen whether this innovative argument will be able to turn back the clock on the proliferation of patents for genetically engineered plants, but the lawsuit documents many of the hazards and represents a new offensive against Monsanto's aggressive enforcement tactics. The plaintiffs also allege that the transgenic seed patents are unenforceable because Monsanto misuses its intellectual property through "abusive litigation practices and anticompetitive licensing agreements."[281] If the plaintiffs prevail, they will be able to pursue further cases against the company for contamination without the threat of reprisals for having the unwanted presence of the patented seed in their fields.[282] As courts give increased scrutiny to actions taken by govern-

---

277. First Amended Complaint, *supra* note 276, ¶ 144 (citing Brenner v. Manson, 383 U.S. 519, 534 (1966)). The Complaint also recites, "[t]he Patent Act provides that '[w]hoever 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 on the invention or discovery." *Id.* (quoting 35 U.S.C. § 101 (2006)) (emphasis in original).

278. First Amended Complaint, *supra* note 276, ¶ 144 (citing Lowell v. Lewis, 15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8568) (Story, J.)).

279. Bario, *supra* note 273; Neuman & Pollack, *supra* note 2; *see also* Strauss, *Ethical Implications*, *supra* note 13, at 7–19 (contrasting the false promise that this technology would reduce world hunger, decrease pesticide usage, improve nutritional content, and increase farmers' income with the actual and potential risks).

280. First Amended Complaint, *supra* note 276, ¶ 125; *see also* Strauss, *International Intellectual Property Rights*, *supra* note 241, at 316–20 (proposing an approach for patents in the area of GM plants and seeds that would reward socially responsible technology with the goal of promoting not only trade but innovation for the public benefit).

281. Bario, *supra* note 273; First Amended Complaint, *supra* note 276, ¶¶ 151–56.

282. Huff, *supra* note 273. *But see* Monsanto, *PUBPAT Allegations are False, Misleading and Deceptive*, BEYOND THE ROWS (Mar. 29, 2011), http://www.monsantoblog.com/2011/03/29/pubpat-allegations-are-false-misleading-and-deceptive/ (claiming that "[i]t has never been, nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seed or traits are present in farmer's fields as a result of inadvertent means"). Plaintiffs interpret the ambiguity of the phrase "trace amounts" as further evidence of an veiled threat that Monsanto will continue to pursue actions against "certified organic and nontransgenic seed farmers who come to possess more than 'trace amounts' of Monsanto's transgenic seed, even if it is not their fault." First Amended Complaint, *supra* note 276, ¶¶ 158–59. *See also* Ctr. for Food Safety, Family Farmers Amplify Complaint Against Monsanto's GMOs, *supra* note 276 (citing correspondence from Monsanto's attorneys, attached to Amended Complaint, refusing plaintiffs' request to make its promise legally binding). In subsequent developments, on February 27, 2012, District Judge Naomi Reice Buchwald dismissed this lawsuit for lack of standing, and on March 28, 2012, the plaintiffs filed an appeal

ment agencies, in this case the U.S. Patent and Trademark Office, they are uniquely positioned to account for public policy considerations that may reverse the government's pro-biotechnology stance.[283]

C. Consumer Driven Demands

Ultimately, it may be the consumer through the marketplace that determines the boundaries in this area. However, such an approach precariously relies on the education of the consumer and access to accurate information, most of which is held exclusively by the biotechnology industry.

Nevertheless, the purchase power of consumers in choosing organics and non-GMO is speaking effectively with increasing sales. For example, "[p]olls taken by the Pew Center, Consumers Union, Harris Interactive and ABC over the last decade have consistently found that the vast majority of Americans would like to see GM foods better regulated and labeled."[284] Moreover, "'non-GMO' was the fastest-growing health and wellness claim on store-brand foods in 2009, up by 67% from the previous year and representing $60.2 million in sales."[285] Significantly, the organic industry, currently generating $25 billion a year, has been the fastest growing sector of U.S. agriculture for more than a decade.[286]

These trends should highlight to the government the mandate of the American public, whose health and safety it is duty-bound to protect. In the past, the FDA has pointed to organic food as the solution for those who are concerned about such issues. However, this attitude is inappropriate, because organic food is not readily available to all con-

---

with the U.S. Court of Appeals for the Federal Circuit. *See Farmers Determined to Defend Right to Grow Food—File Appeal in OSGATA v. Monsanto*, ORGANIC SEED GROWERS & TRADE ASS'N (March 28, 2012), http://www.osgata.org/farmers-determined-to-defend-right-to-grow-food-file-appeal-in-osgata-vs-monsanto.

283. *See Assoc. for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010) (invalidating two gene patents by Myriad Genetics, BRCA1 and BRCA2, both associated with hereditary breast and ovarian cancer, on the grounds that the public would be better served by sharing information to lead to further research and innovation), *aff'd in part, rev'd in part*, No. 2010-1406, slip op. (Fed. Cir. July 29, 2011) (affirming portion that held Myriad's method claims directed to "comparing" or "analyzing" DNA sequences are patent ineligible), *available at* http://www.cafc.uscourts.gov/images/stories/opinions-orders/10-1406.pdf; Sharon Begley, *In Surprise Ruling, Court Declares Two Gene Patents Invalid*, THE DAILY BEAST (Mar. 29, 2010, 7:27 PM), http://www.thedailybeast.com/newsweek/blogs/the-human-condition/2010/03/29/in-surprise-ruling-court-declares-two-gene-patents-invalid.html; *Divided Appeals Court Rules That Companies May Patent Breast Cancer Genes, but Invalidates Patents on Comparing the Genes*, ACLU (July 29, 2011), http://www.aclu.org/print/womens-rights/divided-appeals-court-rules-companies-may-patent-breast-cancer-genes-invalidates.

284. Eng, *supra* note 11.

285. *Id.*

286. Press Release, Ctr. for Food Safety, Organic Industry Supports CFS in GE Sugar Beets Appeal, *supra* note 118; *see also* Press Release, Ctr. for Food Safety, Farmers and Consumer Groups File Lawsuit Challenging Genetically Engineered Alfalfa Approval, *supra* note 89 (organic sector growing 20% annually).

sumers due to geographical limitations and higher prices. In addition, as discussed above, genetic contamination increasingly threatens the integrity and economic viability of the organic food supply. Most of all, such statements fail to recognize—and indeed neglect—the responsibility of the government to protect the mainstream food supply for the average citizen.[287]

VI. SUGGESTIONS FOR A NEW MULTILATERAL, UNIFIED APPROACH

Perhaps some of the weakness of the current food legal regime can be transformed into its strength. A fractionated treatment could evolve into a multilateral, unified approach accompanied by a new strong federal statutory policy mandate. In exploring this potential shift, policymakers should include consideration of non-governmental partners who could bring valuable expertise and varied perspectives to the table.

A. Broader Involvement of Other Governmental Branches

Wide participation of all branches of government along with agencies, at both the state and federal level, would tap into the wisdom of the founders of this country to distribute responsibility vertically, through federalism, and horizontally, through separation of powers, thereby ensuring numerous eyes are "watching the soup" and contributing to the common good of food safety.

Critics have observed that food policy and its implementation are too fractionated,[288] and that "[t]his fragmented federal system makes communication, efficiency and uniformity almost impossible during an

287. *See* Strauss, *Ethical Implications*, *supra* note 13, at 28.

288. Strauss, *FSMA*, *supra* note 1, at 368–69. In the United States, food safety is regulated by 30 federal statutes, 15 federal agencies, and 400 state agencies. *Hearing to Review Current Food Safety Systems Before the H. Comm. on Agriculture*, 111th Cong. 50–57 (2009) (statement of Carol L. Tucker-Foreman, Distinguished Fellow, The Food Policy Institute at Consumer Federation of America), *cited in* Sara M. Benson, *Guidance for Improving the Federal Response to Foodborne Illness Outbreaks Associated with Fresh Produce*, 65 FOOD & DRUG L.J. 503, 504 (2010) (providing guidelines and suggestions for improving the way the FDA and CDC respond to foodborne illness outbreaks caused by fresh produce); *see also* Caroline Scott-Thomas, *Food Safety Fragmentation Still a Problem Says GAO*, FOODNAVIGATOR-USA.COM (Mar. 21, 2011), http://www.foodnavigator-usa.com/Legislation/Food-safety-fragmentation-still-a-problem-says-GAO; Sandra Hoffmann, *Food Safety Policy and Economics: A Review of the Literature* 14 (Research for the Future, Discussion Paper 1036, 2010), http://indiaenvironmentportal.org.in/files/Food%20Safety%20Policy.pdf; Nathan M. Trexler, Note, *"Market" Regulation: Confronting Industrial Agriculture's Food Safety Failures*, 17 WIDENER L. REV. 311, 314 (2011) (proposing a framework for reform of U.S. food safety by prioritizing prevention, strengthening surveillance and enforcement, improving response and recovery, and increasing support of local food systems).

emergency."[289] As a consequence, the need for better coordination is paramount.[290]

In every Congress since the 105th, the idea of a single federal food agency has been debated.[291] According to the CFS, a separate and effective government agency dedicated to food safety must be established, such that "[w]e need to separate out the 'Food' part of the Food and Drug Administration and consolidate all authority under a new Food Safety Agency."[292] Others question the limits of the FDA in terms of its scientific expertise.[293] However, in an area of such complexity with overlapping and intersecting spheres of expertise (e.g., food and components, plants, environmental hazards), perhaps the effort would be better spent on improving coordination, communication, and management under a common mandate rather than creating yet another administrative agency. At the very least, in keeping with the new directive on food safety, the regulations and authority of these agencies should be reexamined.

Bringing together these agencies in a coordinated effort is a goal of President Obama in establishing the Food Safety Working Group (FSWG), which was created in March 2009 to advise the president on modernizing food safety laws in the United States.[294] Chaired by the Secretary of HHS and the Secretary of Agriculture, the FSWG is "rec-

---

289. Benson, *supra* note 288, at 504; *see also* Note, *Reforming the Food Safety System: What If Consolidation Isn't Enough?*, 120 HARV. L. REV. 1345, 1345–47 (2007).

290. *See, e.g.*, Michael R. Taylor, *Lead or React? A Game Plan for Modernizing the Food Safety System in the United States*, 59 FOOD & DRUG L.J. 399, 402 (2004) ("Experts widely recognize that prevention of foodborne illness and management of such problems as mad cow disease and bioterrorism require an integrated, systems approach from farm to table and should harness the tools of research, regulation, and education in a coherent strategy. This is made impossible by the current organizational fragmentation of the system, which divides food safety leadership and defeats accountability for the system's successes and failures.").

291. JOHNSON, CRS REPORT R41629, *supra* note 229, at 13 (explaining that while some continue to push for this level of consolidation on the grounds that it would improve the efficiency and effectiveness of food safety regulation, others worry that it could "unnecessarily compromise day-to-day food safety efforts."). *See, e.g.*, Single Food Safety Agency Act of 2010, H.R. 6552, 111th Cong. (2010); Richard J. Durbin, *Food Safety Oversight for the 21st Century: The Creation of a Single, Independent Federal Food Safety Agency*, 59 FOOD & DRUG L. J. 383, 383 (2004).

292. *Food Safety Modernization Bill Q & A*, Ctr. for Food Safety, http://truefoodnow.org/campaigns/food-safety/food-safety-modernization-bill-qa/ (last visited Nov. 1, 2011) (listing amendments added to support small farmers and processors who sell directly to consumers and end users); *see also* Sandra B. Eskin, *Putting All Your Eggs in One Basket: Egg Safety and the Case for a Single Food Safety Agency*, 59 FOOD & DRUG L. J. 441 (2004); Merrill & Francer, *supra* note 26, at 115–36 (discussing the historical origins of the federal food safety bureaucracy and proposing a plan for consolidation).

293. Erik Stokstad, *Food Safety Law Will Likely Strain FDA Science*, 331 SCIENCE 270 (2011). *See generally* ENHANCING FOOD SAFETY: THE ROLE OF THE FOOD AND DRUG ADMINISTRATION (Robert B. Wallace & Maria Oria, eds., 2010).

294. Scott-Thomas, *Food Safety Fragmentation Still a Problem Says GAO*, *supra* note 288; PRESIDENT'S FOOD SAFETY WORKING GRP., http://www.foodsafetyworkinggroup.gov/ (last visited Nov. 1, 2011).

ommending a new, public health-focused approach to food safety based on three core principles: prioritizing prevention; strengthening surveillance and enforcement; and improving response and recovery."[295]

A recent report by the Government Accountability Office (GAO) concluded that more work needs to be done to address fragmented oversight of U.S. food safety:[296]

> Through the FSWG, federal agencies have taken steps designed to increase collaboration in some areas that cross regulatory jurisdictions—in particular, improving produce safety, reducing *Salmonella* contamination, and developing food safety performance measures. However, the FSWG has not developed a governmentwide performance plan for food safety that provides a comprehensive picture of the federal government's food safety efforts.[297]

Regarding the new FSMA, the GAO observed that it "strengthens a major part of the food safety system; however, it does not apply to the federal food safety system as a whole or create a new risk-based food safety structure."[298]

As a consequence of this substantial action for securing food safety, the moment has come for a reassessment of other areas of food laws, as well as the roles these agencies will play together in implementing their charge.[299] This coalition could include state enforcement actions, for which there has been some precedent in other areas where agency inaction has expanded avenues of judicial review.[300] In order for this multilateral approach to succeed, policymakers will need to set the same clear

---

295. *About the President's Food Safety Working Group (FSWG)*, PRESIDENT'S FOOD SAFETY WORKING GRP., http://www.foodsafetyworkinggroup.gov/ContentAboutFSWG/HomeAbout.htm (last visited Nov. 1, 2011).

296. Scott-Thomas, *Food Safety Fragmentation Still a Problem Says GAO, supra* note 288 (citing U.S. Gov't Accountability Office (GAO), Report to Congressional Committees, Federal Food Safety Oversight: Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation GAO-11-289 (2011), http://www.gao.gov/new.items/d11289.pdf [hereinafter GAO Report]); *see also* Teddi Dineley Johnson, *2012 Budget Proposal Would Mean Cuts for Public Health: CDC Programs Slated for Reduction*, 41 THE NATION'S HEALTH 1 (Apr. 2011), http://thenationshealth.aphapublications.org/content/41/3/1.4.full (President's proposed budget seeks to strengthen the President's Food Safety Working Group as well as to fund key provisions of the FSMA). *See generally* GAO, Federal Food Safety and Security System: Fundamental Restructuring is Needed to Address Fragmentation and Overlap, GAO-04-588T, at 7 (2004), http://www.gao.gov/new.items/d04588t.pdf.

297. GAO, HIGHLIGHTS (Mar. 2011), http://www.gao.gov/highlights/d11289high.pdf.

298. *Id.*; *see also* GAO, Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food, GAO-09-873 (2009), http://www.gao.gov/new.items/d09873.pdf.

299. Strauss, *FSMA*, *supra* note 1, at 370.

300. *See* Amy Widman, *Advancing Federalism Concerns in Administrative Law Through a Revitalization of State Enforcement Powers: A Case Study of the Consumer Product Safety and Improvement Act of 2008*, 29 YALE L. & POL'Y REV. 165, 208 (2010) (strengthening consumer protection through Congressional delegation to state enforcement power under the Consumer Product Safety and Improvement Act of 2008).

goals for all, along with an effective mechanism of coordination and budgetary support.

In light of the FSMA and FSWG, as mandates from both the President and Congress prioritizing food safety, along with the possibility of new laws concerning GM crops and ingredients, these goals should embody a precautionary approach, which would be more aligned with the new proactive policy. Rather than waiting to see if GMOs are proven to be unsafe—at which point it would be exceedingly difficult, if not impossible, to turn back the clock, due to the lack of labeling or traceability to enable withdrawal of these substances—it would make more sense to require labeling and segregation from non-GM foods at the outset. Moreover, a strict regulatory structure that would order additional studies and pre-screening for approval, as well as post-market monitoring, would be most prudent. Doing so would also signal to our overseas counterparts that the United States is serious about the recent emphasis on food safety and expects foreign suppliers to comply with the inspection and certification requirements imposed on them under the new U.S. law. By enacting regulations more in harmony with international law in the area of GMOs, the government would be opening foreign markets to U.S. agricultural products, thereby strengthening international trade as well as the FSMA. Thus, U.S. policy would appear consistent and reciprocal with the international community.[301]

B. Industry/Academic Partners with Expertise to Leverage Knowledge and Information

Are agencies being co-opted by the companies they are charged to regulate?[302] Or are they simply not asking the right questions? Given the conflicts of interest in university research and the fact that agencies rely on the research data provided by companies who have a disincentive to truly investigate and seek out potential problems, is anyone studying the long-term effects of GMOs?

These troubling questions stem in large part from a systemic problem. The FDA and other agencies in this area do not do their own research, but rely instead on information provided by the companies they regulate who are seeking approval of the drugs and food products they produce or seek to bring to market.[303] Each agency focuses only on its

---

301. Strauss, *FSMA*, *supra* note 1, at 373–75. For example, major U.S. grain companies recently rejected genetically modified grains not yet approved by foreign markets, announcing they would only accept grain approved for commercial use in the European Union, as they fear any trace of the biotech grain in shipments could shut off export markets. *See* Christine Stebbins & Karl Plume, *Update 3—US Grain Cos Tighten GMO Policy, Eye Syngenta Corn*, REUTERS (Sept. 2, 2011), *available at* http://af.reuters.com/article/energyOilNews/idAFN1E78017Q20110902?sp=true.

302. *See* Widman, *supra* note 300, at 179–90 (studying Consumer Product Safety Commission as an example of agency capture by industry or an industry-sympathetic executive branch, the agency's weakened enforcement, and Congress' statutory response).

303. *See* Aoki, *supra* note 9, at 465.

own narrow charge without viewing the broader scope of food safety, and they lack the scientific expertise to comprehend the real potential impact of GM crops on the environment or even raise the most relevant concerns.[304] In the GM industry, an added problem arises from the type of patent protection granted to companies such as Monsanto, Pioneer, and Syngenta. This protection enables these firms to require that all users of their products sign end-user agreements that, in addition to protecting intellectual property, also forbid the use of any seed for independent research; as a result, the company controls all research on GM seeds, including which information gets published.[305]

This situation is particularly challenging in view of the obvious conflicts of interest. Moreover, even assuming honest and complete reporting despite the self-interest, there is another more subtle and hidden hindrance. Monsanto and other companies only answer the questions asked by the government, construed as narrowly as possible while still technically in compliance, and do not investigate any more comprehensively or through their own independent queries because any answers or findings would be information they would have to disclose to the government.[306] For this reason, the questions that are asked by the government to which the company must respond become critical. Yet the FDA and other government agencies (including the Securities and Exchange Commission in the securities industry) often cannot attract the best and brightest scientists and lawyers to ask these important and complex questions, given the fact that professionals in the biotech companies are more highly paid than those in the FDA and are generally given more intellectually stimulating work. Thus, for the research being used to support government approvals, these studies and investigations into some of the most crucial and fundamental issues are in essence not being done.

How can government agencies attract top talent and expertise given the tremendous salary differential between government and private industry that is unlikely to be bridged, although often partially offset by a more favorable lifestyle and benefits?

A possible solution might be reached from creatively leveraging outside talent. When the FDA or another government agency is investigating a problem or issue, it could convene an advisory panel of several outside experts—scientists or academics, as well as organizational and industry members who do not have a conflict of interest as a competitor or other financial stake. This type of advisory panel would differ from those chartered by the USDA in the past, and recently announced for

---

304. *See id.* at 469 (arguing for a renewed regulatory focus on genetically engineered crops).

305. *Id.* at 470; *see also* Strauss, *International Intellectual Property Rights*, *supra* note 274, at 302–03.

306. *See, e.g.*, Aoki, *supra* note 9, at 469 (noting that "the voluntary nature of participation in some of the regulation creates absolutely no incentive for companies to do additional research or have consistent reporting mechanisms because of the potential for unfavorable data to emerge").

renewal, which have been comprised only of industry representatives rather than scientific or academic experts.[307] In addition, the government and panel should focus on encouraging individuals to ask a broader range of appropriate questions under the circumstances. This approach may not prompt the company to be more forthright in its answers, but by making the right inquiries a more relevant and comprehensive picture may emerge. Particularly in this climate of budget cuts and financial stringency, an increase in salaries for FDA and USDA scientists is not a realistic option. However, through the creation of advisory boards, the government may be able to invite eminent scientists to ask the questions critical to obtaining essential information. Such boards could be impaneled on a permanent basis with rotating membership, or for a finite period in order to focus on a particular issue, investigation, or food/drug approval. Attracting experts to participate in these panels should not be difficult, as participation would constitute a prestigious honor, without committing the government to expend further limited financial resources. This is likely even more true if the government taps faculty and experts from land grant universities, at which it is part of the institutional mission to help the public and contribute to the common good, and panel service might fulfill contractual responsibilities or otherwise be rewarded through tenure and promotion.

In view of the conflict of interest in university research, due in large part to the fact that the academic community involved in research is predominantly tied to funding by the industries and the patents they seek to develop, great care must be given to the choice of academic panel members.[308] On a broader level, are universities being usurped by corporations in a myriad of other ways? If so, including members of these universities on an advisory panel would not help and might even compound the problem. Thus, the government must be very careful in the selection process to thoroughly ascertain any ties to private industry so as to ensure that the individual does not double count as an industry representative. The success of these panels hinges on vigilant and transparent investigation as to who is taking each seat, full disclosure of

---

307. For example, the USDA recently announced a committee to examine "the full spectrum of issues faced by the fruit and vegetable industry. The committee also advises the Secretary on how USDA's Agricultural Marketing Service (AMS) can tailor its programs to better meet the needs of the fruit and vegetable industry." News Release, USDA, USDA Calls for Nominations to Recharter Fruit and Vegetable Industry Advisory Committee (June 27, 2011), http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateDta.do?template=TemplateU&navID=&page=Newsroom&resultType=Details&dDocName=STELPRDC5091735&dID=151352&wf=false&description=USDA+Calls+for+Nominations+to+Recharter+Fruit+and+Vegeble+Industry+Advisory+Committee&topNav=Newsroom&leftNav=&rightNav1=&rightNav2=. It will be comprised of "up to 25 representatives from the nation's fruit and vegetable industry to serve two-three-year terms." *Id.*; *see also* Bottemiller, *supra* note 83 (reporting that Secretary of Agriculture Vilsack will reestablish advisory committees "to review tools and options available to farmers on all sides of the issue"). Presumably these representatives would also be exclusively from the industry, as has been USDA's model in the past.

308. *See* Strauss, *Ethical Implications*, *supra* note 13, at 32–33.

which constituencies are represented, and proper apportionment of representation.

VII. CONCLUSION

In the area of GM foods, the courts have stepped in to fill the void left by regulatory agencies and, in doing so, have assumed part of the role that was originally intended for these agencies. As demonstrated by the Supreme Court opinion in *Monsanto*, involving GM alfalfa, the courts may be reaching the inherent limits of judicial review. An exploration of these cases provides another reason for further, though more stringent and specific, federal legislation: Agencies following the vague standards that apply to the agricultural industry generally are not adequately policing GMOs. This analysis demonstrates the need for a separate and specific statute and regulations that pertain to GM crops, given the already established dangers of pollen drift shown by these incidents and lawsuits. Ultimately, piecemeal lawsuits are not the way to regulate our food supply, especially given the reactive, rather than proactive, nature of most tort suits.[309]

Moreover, now that Congress has effectively spoken through the FSMA—the first substantial change in food law in 70 years—the effect of this law on the role of the courts and federal agencies in this area must be consistent. As a first significant step toward improving food safety, the time is ripe for a reassessment of other areas of food regulation. A precautionary approach towards GMOs would be more in keeping with the new mandate for the FDA to prioritize prevention in the area of food safety. "[A] strict regulatory structure that would mandate additional studies and pre-screening for approval, as well as post-market monitoring," would fit harmoniously with the new proactive policy.[310]

Until Congress exercises its oversight and provides clear statutory guidance, the courts in appropriate cases will need to scrutinize agency action and give their full consideration to the public policy issues engendered by GMOs. Other stakeholders, particularly trade associations and suppliers, organic and conventional farmers, and consumers, will also need to remain vigilant in their demands for a proactive regulatory regime, and avoid becoming complacent. In an area of such increasing scientific and socioeconomic complexity, a unified multilateral approach is clearly warranted. Governmental units and experts must work together to study the long-term human health and environmental effects of GMOs and prevent further contamination and extinction of non-GM crops. Until these effects are known, mandatory labeling, monitoring, and segregation of crops would be the most prudent approach to protect the integrity and security of the food supply.

---

309. *See* Strauss, *Legal Liability Risks*, *supra* note 18, at 174–77 (offering proposals for industry and the stakeholders that would limit of the risk of regulation by litigation).

310. *See* Strauss, *FSMA*, *supra* note 1, at 374; *see supra* note 301 and accompanying text.

With the new focus on preventative measures, this is an opportune time to make meaningful change in the area of biotechnology and food safety standards. Policymakers should capitalize on momentum sparked by the congruent interests of a broad range of government bodies, including agencies, the courts, and Congress, as well as industry and academic experts, to work toward the best public policy approach for ensuring food safety in the United States.