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ARTICLES

JUSTICE KAGAN'S PRESIDENTIAL ADMINISTRATION AND BIOENGINEERED FOODS: MAKING THE CASE FOR CONGRESSIONAL GUIDANCE AS A CHECK TO PRESIDENTIAL POLICY SETTING

MICHÈLE ALEXANDRE*

INTRODUCTION

Imagine a system of government where the President is accorded a great deal of deference in matters of legislation. A combination of these two elements—"president and legislation"—immediately gives us cause for pause, considering our deliberate tripartite system of checks and balances. Imagine also the advancement of a completely new technology, like cloning. As the biotech industry works to perfect this new technology, the question remains as to who is best placed to regulate it. As we explore our options, should one of the options be for the Office of the President to set regulations? These are the questions that areas like biotechnology face or will currently face.

As biotechnology has evolved, the public has become increasingly concerned that processes for approving biotech foods are not transparent.[1] The power to approve biotech foods is delegated to administrative agencies, which receive considerable deference from the courts. Added to this judicial deference is the documented involvement of the President's office in setting policy in this area.

Justice Kagan labeled Presidential involvement in administrative agencies' decisions as "Presidential Administration."[2] "Presidential Administration," according to Justice Kagan, refers to the President directly setting policies by

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* Associate Professor of Law, University of Mississippi School of Law. B.A., 1996, Colgate University; J.D., 2000, Harvard Law School. The author thanks the University of Mississippi School of Law for its support as well as her colleagues on the faculty for their insight during faculty colloquia.

1. *See* Jennifer Kuzma et al., *Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms*, 37 J.L. MED. & ETHICS 546 (2009) (recognizing, through polling data, that "[c]onfidence in regulation [of genetically engineered organisms] is not high. . . . This is because the process is not transparent.").

2. Elena Kagan, *Presidential Administration*, 114 HARV. L. REV. 2245, 2325-26, 2246, 2250 (2001) (footnotes omitted).

providing directives to administrative agencies.[3] Tracing this practice from President Reagan to President Clinton, Justice Kagan explains that presidents have regularly used the administrative process to set policies as well as take ownership of administrative policies.[4] This remained the case until President Clinton refined the practice even more. According to then Professor Kagan:

> By the close of the Clinton Presidency, a distinctive form of administration and administrative control—call it "presidential administration"—had emerged, at the least augmenting, and in significant respects subordinating, other modes of bureaucratic governance. Triggered mainly by the re-emergence of divided government and built on the foundation of President Reagan's regulatory review process, President Clinton's articulation and use of directive authority over regulatory agencies, as well as his assertion of personal ownership over regulatory product, pervaded crucial areas of administration.[5]

This "directive authority" and personal ownership seem to stand in contradiction to the Chevron doctrine. An established administrative standard,[6] the Chevron doctrine contemplates a relationship between Congress and administrative agencies and illustrates the type of deference that should be accorded to agencies in the absence of a specific mandate from Congress.[7] The Chevron doctrine, however, does not contemplate the Executive as playing a role in carrying out

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3. *See generally id*. at 2331.

4. *Id*. at 2277-2315 (providing a history of Presidential Administration in both "[t]he Reagan Era" and "the Clinton Years").

5. *Id*. at 2250.

6. *Id*. at 2375 ("The courts, by contrast, have ignored the President's role in administration action in defining the scope of the Chevron doctrine. Although this consideration took pride of place in Chevron itself, the figure of the President has barely appeared in recent judicial discussions of deference. Courts grant (or decline to grant) step-two deference to administrative interpretations of law irrespective whether the President potentially could, or actually did, direct or otherwise participate in their promulgation."); *see* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837 (1984).

7. Kagan, *supra* note 2, at 2374 ("The Court noted at several points the special expertise and experience that agencies bring to the task of interpreting and administering their governing statutes. The Court quoted a prior statement that deference was appropriate when 'a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations'; the Court then added that in the instant case 'the regulatory scheme is technical and complex, the agency considered the matter in a detailed and reasoned fashion,' and 'judges are not experts in the field.' Still further augmenting the rationales for deference, the Court proposed that this approach comported with congressional intent. Gaps and ambiguities in legislation, the Court suggested, themselves could constitute explicit or implicit delegations to an agency to 'elucidate . . . the statute by regulation,' including through the 'accommodation of conflicting policies.'" (alterations in original) (footnotes omitted)); *Chevron*, 467 U.S. at 842-44.

legislative duties. In fact, the non-delegation doctrine stands for the opposite concept.[8] The non-delegation doctrine which prevents Congress from delegating its legislative power, though rarely invoked in our jurisprudence, has been judicially triggered only twice––both in the same year, 1935––to strike down legislation that granted too much legislative power to the President.[9]

In our system of government, balancing the duties, limits, and scope of our three branches is a delicate dance, but one which places certain limitations on the President. Specifically, the doctrine of separation of powers prohibits a branch from aggrandizing itself by usurping the powers of another branch.[10] Though the lines are a bit more blurred in administrative law, a branch's efforts to aggrandize its powers should not be taken lightly. Biotechnology is a context where such concerns are palpable.

Bioengineering "is a term used to describe the process by which recombinant DNA ('rDNA') is placed into an organism. When scientists splice together pieces of DNA and then introduce the modified DNA into an organism, it is referred to as 'rDNA technology.'"[11] "A genetically engineered ('GE') plant or animal contains this rDNA[12] construct, thus changing the organism by giving it a new trait or characteristic."[13] This science is still under development and the health consequences of biotech products are not yet fully known. Still, even at the inception of biotechnology, Congress did not issue any regulations guiding the evaluation of biotech products.[14] Instead, the President issued directives to food agencies and set the now accepted policy: a presumption that bioengineered foods are the same as traditional foods.[15] In 1986,

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8. *See generally* Patrick M. Garry, *Accommodating the Administrative State: The Interrelationship between the Chevron and Nondelegation Doctrines*, 38 ARIZ. ST. L.J. 921 (2006).

9. Kagan, *supra* note 2, at 2364 ("In only two cases, both in 1935, has the Supreme Court struck down a federal statute on the ground that it delegated too much authority to the executive branch.").

10. *See generally* Gillian E. Metzger, *The Interdependent Relationship between Internal and External Separations of Powers*, 59 EMORY L.J. 423 (2009).

11. Madison Smith, Note, *Who Owns Your Dinner? A Discussion of America's Patented Genetically Engineered Food Sources, and Why Reform Is Necessary*, 23 LOY. CONSUMER L. REV. 182, 185-86 (2010) (footnotes omitted) [hereinafter Smith, *Who Owns Your Dinner?*]. For additional discussion on "[r]ecombinant DNA (rDNA) genetic engineering," see Michael Bennett Homer, *Frankenfish It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & SOC. PROBS. 83, 89 (2011).

12. Smith, *Who Owns Your Dinner?*, *supra* note 11, at 185-86.

13. *Id.*

14. *See generally* Matthew Rich, Note, *The Debate Over Genetically Modified Crops in the United States: Reassessment of Notions of Harm, Difference, and Choice*, 54 CASE W. RES. L. REV. 889, 904 (2004).

15. Jeffrey K. Francer, Note, *Frankenstein Foods or Flavor Savers?: Regulating Agricultural Biotechnology in the Untied States and European Union*, 7 VA. J. SOC. POL'Y & L. 257, 265-66 (2000).

> the White House Office of Science and Technology ("OST") established the federal government's "Coordinated Framework for Regulation of Biotechnology." This policy provided the foundation of current regulation for genetically modified foods. The thesis of the Coordinated Framework was the announcement that foods, drugs, medical devices, biologics, and pesticides developed through modern biotechnology would be regulated within the same statutory framework as comparable products using traditional techniques.[16]

This type of presidential policy setting in the administrative context is exactly what Justice Kagan describes in her 2001 article.[17] While Justice Kagan finds this practice beneficial and advocates for greater deference to the President in certain circumstances,[18] the case of biotechnology shows that Presidential Administration presents dangers.

When applied to biotechnology, which is still new and in need of expertise, deferring to the President for directives is alarming. Reliance on experts and vetting processes, provided by a notice-and-comment, should be a part of administrative rulemaking.[19] Allowing the President an ownership role in this process dilutes it, undermining the democratic process and creating extreme public dissatisfaction.[20] This risk is exacerbated by the deference exhibited by courts in reviewing agencies' actions in cases where congressional guidance is absent.[21] As a result, though new technologies have emerged, courts are still

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16. *Id.*

17. *See generally* Kagan, *supra* note 2.

18. *Id.* at 2369 ("[A]ll else equal, administrative action taken pursuant to a delegation to an agency official, but clothed with the imprimatur and authority of the President, should receive maximum protection against a nondelegation challenge. The President's involvement, at least if publicly disclosed, vests the action with an increased dose of accountability, which . . . renders the action less troublesome than solely bureaucratic measures from the standpoint of democratic values . . . . [T]his is not to say that presidential control of administration is the equivalent of congressional lawmaking. It is only to say that given the often urgent need for, and resulting omnipresence of, broad delegations, courts should understand and, by so doing, encourage this mechanism of control as mitigating the potential threat that administrative discretion poses.").

19. *See* Elizabeth V. Foote, *Statutory Interpretation or Public Administration: How Chevron Misconceives the Function of Agencies and Why It Matters*, 59 ADMIN. L. REV. 673, 700 (2007).

20. Michael Richard Dimino, *D.C. Circuit Revives Nondelegation Doctrine . . . or Does It?:* American Trucking Associations, Inc. v. EPA*, 175 F.3d 1027 (D.C. Cir. 1999),* Modified*, 195 F.3d 4 (D.C. Cir. 1999)*, 23 HARV. J.L. & PUB. POL'Y 581, 597 n.98 (2000) ("If agencies are independent of Congress but dependent on the President, then the President gains an upper hand in negotiations vis-a-vis Congress, and vice versa. This Comment treats departments and agencies as part of the presidential administration, but agency independence from the President is an area of considerable controversy with potential impacts on the nondelegation doctrine. Delegating power to an independent agency allows for decisions to be made on a non-political basis, which may or may not be beneficial from the country's or Congress's perspective.").

21. *See* Meredith Abernathy, Note, *Running on Empty: Will Exxon Mobil Cause a Breakdown*

applying old approaches to novel contexts.

Courts' deference has, in fact, already served as a tacit judicial endorsement of Presidential Administration [22] while failing to adequately balance the interests of the public and concerns for branch aggrandizement.[23] This approach has caused a great deal of unrest, especially since an increasing portion of the American public has turned to the organic food market.[24] In addition, it stands in contrast to Europe's precautionary approach. In Europe, where the public has voiced similar unease and disapproval regarding automatic approval of genetically altered foods, the dissemination of genetically altered foods in the market has been curtailed.[25]

The European approach, however, only serves as a comparative tool and will not be the central focus of this Article. Instead, this Article focuses on the use of Presidential Administration to promote the introduction of genetically altered foods in the market and argues that such efforts deserve great scrutiny. Throughout the world, biotech companies have pushed for the use of genetically engineered crops, like soy and corn.[26] In the United States, food agencies have already approved the use of a number of genetically engineered foods despite protests from a large number of Americans.[27] The approval of these products by federal agencies has triggered various lawsuits from food watch groups and concerned citizens.[28] In addition, the Food and Drug Administration (the FDA)

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for Chevron and the Administrative State?, 64 WASH. & LEE L. REV. 583, 589-93 (2007).

22. *See, e.g.*, Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 250-252 (2010) (discussing the regulatory framework for biotechnology implemented during the Reagan and (first) Bush administrations).

23. *See* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2766 (2010) (explaining the court's role in making a determination of unlawful agency action as being based in equity, and, thus, the court must weigh "the public interest, private needs, and competing private claims . . . against the background of the court's own limitations and its particular familiarity with the case" (internal quotation marks omitted) (quoting Hecht Co. v. Bowles, 321 U.S. 321, 329-30 (1944))).

24. *See Tabs Group Survey: Organic Food Sales Hit Record in 2011; Sales Jump 15-20 Percent*, PR NEWSWIRE (Feb. 15, 2012), http://www.prnewswire.com/news-releases-test/tabs-group-survey--organic-food-sales-hit-record-in-2011-sales-jump-15-20-percent-139384123.html.

25. Francer, *supra* note 15, at 297 ("[A] 1997 poll of 5,000 Europeans conducted by Greenpeace and Market & Opinion Research International indicated that 59 percent of Danes, Dutch, French, British, Italians, and Swedes do not support the development of genetically modified foods." (footnotes omitted)).

26. *World's Farmers Flock to Biotech Crop Varieties*, WESTERN FARM PRESS (Feb. 23, 2011), http://westernfarmpress.com/management/world-s-farmers-flock-biotech-crop-varieties.

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

28. Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 113-14 (2001) (stating that a number of lawsuits have been filed challenging the use or approval of biotech products. The courts often

is currently considering the approval of biologically engineered salmon.[29] This has caused great public outrage,[30] as seen in social media and the blogosphere.[31] In response, some members of Congress introduced three bills designed to ban or regulate bioengineered salmon in areas that would be most affected by its introduction.[32] Still, under the entrenched presumption that treats bioengineered foods like traditional foods––a policy set by the White House Office of Science and Technology ("OST") under President Bush––cases often are decided in favor of biotech companies.[33]

This is problematic because inherent in our governmental structure is a process of checks and balances,[34] which, while far from perfect, provides interconnected synergy between congressional legislative powers, agencies' administrative powers to execute legislation, public involvement through comments and questions, and judicial review of administrative decisions. The Constitution establishes the President's duties, which have not traditionally included lawmaking.[35] This concern for separation of powers is even more relevant when exploring regulations related to genetically modified foods. As such, exercises of Presidential Administration warrant greater, not lesser, scrutiny. Though explicit deference to the President's assessment of agencies' decisions would be more efficient in certain ways, judicial evaluations of these decisions must reflect concerns for separation of powers. These concerns are all the more present in the context of genetically modified crops and foods. The

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rule in favor of biotech companies, even in relation to claims against the FDA challenging its approval of GMO products without testing).

29. *See* Homer, *supra* note 11, at 85-86.

30. *See* Naomi Starkman, *Just Label It: We Have a Right to Know What's in Our Food*, HUNTINGTON POST (Oct. 5, 2011, 3:01 PM), http://www.huffingtonpost.com/naomi-Starkman/just-label-it-we-have-a-r_b_994488.html ("'Polls show that consumers demand transparency in the foods they buy and overwhelmingly support labeling of [genetically engineered] food,' said Dr. Michael Hansen, senior scientist at Consumers Union, the public policy division of Consumer Reports.").

31. *See, e.g.*, Jeannie Moulton, *Understand Why Genetically Engineered Salmon is Scary*, EAT DRINK BETTER (Apr. 8, 2011), http://eatdrinkbetter.com/2011/04/08/12784; Becky Striepe, *Truth in Labeling: Tell Congress You Want Labels on GE Salmon*, EAT DRINK BETTER (Apr. 19, 2011), http://eatdrinkbetter.com/2011/04/19/truth-in-labeling-tell-congress-you-want-labels-on-ge-salmon.

32. S. 229, 112th Congress (2011) (proposing amendment of "the Federal Food, Drug, and Cosmetic Act to require labeling of genetically engineered fish"); S. 230, 112th Congress (2011) (proposing amendment of "the Federal Food, Drug, and Cosmetic Act to prevent the approval of genetically-engineered fish"); S. 1717, 112th Congress (2011) (setting forth a Bill "[t]o prevent the escapement of genetically altered salmon in the United States, and for other purposes").

33. *See* Heather N. Ellison, *Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?*, 10 PENN ST. ENVTL. L. REV. 345, 353-60 (2002).

34. *See generally* Paul E. McGreal, *Ambition's Playground*, 68 FORDHAM L. REV. 1107 (2000).

35. *See* U.S. CONST. art. 11, §§ 1, 2.

dangers of Presidential Administration are stark when considering the involvement of the President's office in setting the regulatory framework for bioengineered foods.

This Article explores the issues inherent in presidential control of administrative regulatory processes related to genetically modified foods. In that context, especially, congressional silence is unsatisfactory because it unevenly shifts the balance of power to influential interest groups and to the President's office. This awkward balancing has been made all the more evident by *Monsanto Co. v. Geertson Seeds Farms*,[36] the Supreme Court's first decision regarding genetically altered crops.[37] *Monsanto* and other cases illustrate the legal and ethical complexities of balancing the public's interest with that of biotech companies and monitoring federal agencies.[38] Thus far, the balancing of interests has erred in favor of biotech companies. The standards applied by the courts[39] for evaluating biotech foods are insufficient and vague.[40] What is more, the procedures in place for overseeing and regulating biotech products are needlessly complex and inefficient.[41]

This Article points out deficiencies in the regulation of bioengineered foods and demonstrates that regulating agencies have sponsored a policy that fails to concentrate on the potential harm to human health; rather, the policy focuses on market aggrandizement.[42] The "substantial equivalence" doctrine applied by regulating agencies when evaluating bioengineered products is under particular scrutiny in this Article.[43] Under the substantial equivalence test, bioengineered products have been assumed to be safe by virtue of the initial presidential

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36. 130 S. Ct. 2743 (2010).

37. *Id.* at 2749.

38. Emily Robertson, Note, *Finding a Compromise in the Debate Over Genetically Modified Food: An Introduction to a Model State Consumer Right-To-Know Act*, 9 B.U. J. SCI. & TECH. L. 156, 159-60 (2003).

39. Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 734 (2003) (stating the United States's "focus is . . . on the end product of GM technology, rather than on the fact that the process of genetic modification is used").

40. Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J.L. REFORM 403, 430-31 (2002).

41. Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL'Y 393, 413 (2007).

42. Nathan W. Eckley, Comment, *Reaping the Benefits of Agricultural Biotechnology Through Uniform Regulation*, 35 J. MARSHALL L. REV. 433, 443-45 (2002).

43. *See* Debra M. Strauss, *The International Regulation of Genetically Modified Organism: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 174 ("When [GM crops and non-GM crops] are not significantly different the two are regarded as 'substantially equivalent,' and therefore, the GM food crop is regarded as safe as its conventional counterpart. . . . [The] FDA relies on this substantial equivalence for its view that no additional labeling or animal testing is required.").

command,[44] construing bioengineered foods as equivalent to natural foods.[45] This standard, however, is a false equivalence since bioengineered products contain foreign and unknown agents.[46] Continued practice of this type of presidential control, without consistent input from experts, could lead to greater harm to the population.[47] Considering the high stakes, a more precautionary standard is warranted.

Food agencies' failure to adopt a precautionary standard begs the question as to whether the rule furthers the interests of corporations, lobbyists, and biotech companies rather than the public's interests.[48] The commingling of interests without apparent concern for the public also endangers traditional farmers' and food producers' ability to achieve sustainability.[49] This harm, among others, illustrates the danger posed by presidential rulemaking.[50] Experts are best suited to decide administrative issues, in absence of congressional guidance, especially when the technology is so new that little information is available to lay people.[51] Expert opinion and public input, common elements of the administrative process,[52] are all the more important in such a fragile context. Only with the participation of the experts and the public can we hope to counter the disproportionate effects that political agendas can have on such decisions.[53]

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44. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302-01 (June 26, 1986).

45. Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77, 83-84 (2000).

46. Robertson, *supra* note 38, at 168-70 ("For example, scientists have inserted chicken genes into apples, human genes into corn, rice and potatoes, and cow genes into soybeans and sugarcane.").

47. Ellison, *supra* note 33, at 362 ("Although there have been recent developments in the regulation of GMOs, it is clear that the current regulatory system is insufficient to protect American consumers and the environment from the possible adverse effects of genetically engineered foods. The fragmented regulatory system that delegates specific responsibilities to various federal agencies has failed to adequately determine the effects of GMOs on humans and the environment. Moreover, the decision by the FDA to not require the labeling of genetically modified foods leaves consumers in the dark." (footnotes omitted)).

48. Sarah L. Kirby, Note, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 DRAKE J. AGRIC. L. 351, 366 (2001).

49. George E.C. York, Note, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agriculture Trade*, 7 COLUM. J. EUR. L. 423, 432-33 (2001).

50. Kagan, *supra* note 2, at 2246, 2250.

51. Strauss, *supra* note 43, at 190-91 (stating that 47% of Americans are aware that they can buy genetically modified foods and 75% of Americans believed strict regulations would be necessary to protect them from the dangers of genetic modification).

52. Dorit Rubinstein Reiss, *Tailored Participation: Modernizing the APA Rulemaking Procedures*, 12 N.Y.U. J. LEGIS. & PUB. POL'Y 321, 326-27 (2009) (outlining the "basic framework for informal rulemaking specified in section 553 of the APA").

53. *See generally* Wendy A. Bach, *Welfare Reform, Privitization, and Power: Reconfiguring Administrative Law Structures from the Ground Up*, 74 BROOK. L. REV. 275, 294-95 (2009).

For these reasons, this Article takes issue with the particular manifestation of Presidential Administration present in the non-regulation of GMOs ("Genetically Modified Organisms"). As an alternative, it proposes a more adequate regulatory framework that better balances biotech corporations' and the public's interest in adequate and equitable regulation. The proposed regulatory framework will focus on providing proper environmental safeguards against the harm caused by bioengineered crops and foods, as well as considering how an improved framework could encourage biotech companies to work with small farmers in order to help foster sustainability. Finally, the Article considers possible changes to laws affecting administrative agencies to help reduce the exercise of undue influence by interest groups on future regulations.

To do so, this Article is divided into the following parts: Part I discusses the application of the Presidential Administration doctrine to biotechnology; it identifies the flaws with that particular approach and explains why a better approach is needed. Part II outlines the sources of laws and the agencies responsible for regulating genetically altered foods. Part III discusses the Supreme Court's first ruling regarding genetically modified crops in *Monsanto Co. v. Geertson Seeds Farms*[54] as an example of the conflicts congressional silence creates. Part IV discusses problems with the current judicial standard of review applied to agencies' decisions. Part V explores the detrimental impact of biotechnology on poor farmers, both in the United States and abroad. Part VI proposes better paradigms for dealing with bioengineered foods and calls for specific congressional guidance in that area. Finally, Part VII presents the European approach as a potential model for grassroots lobbying.

I. THE DANGERS OF PRESIDENTIAL ADMINISTRATION IN ADMINISTRATIVE LAW GENERALLY AND IN THE BIOENGINEERED CONTEXT PARTICULARLY

The development of bioengineered foods is rooted in contradictory policies. On the one hand, the proponents of bioengineered foods argue that the new products may, someday, be essential in preventing famine, surviving in extreme conditions.[55] In addition, certain scientists view bioengineered, pest-resistant plants as ultimately helpful to the traditional farming industry.[56] Opponents[57] of biotechnology, on the other hand, point to the great harm[58] that these products

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54. 130 S. Ct. 2743 (2010).

55. Homer, *supra* note 11, at 90-92.

56. Holly Beth Frompovicz, Comment, *A Growing Controversy: Genetic Engineering in Agriculture*, 17 VILL. ENVTL. L.J. 265, 268-69 (2006).

57. Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220, 226-29 (2009) (discussing risks of genetically modified foods).

58. Homer, *supra* note 11, at 92-99 (discussing the "[r]isks of [g]enetically [e]ngineered [f]ood").

will cause in the long run.[59] Considering that the bioengineered food market has grown into a market worth over $2.5 billion in the last decade—some estimate that it is two/third of the food market—these opponents also contend that the interests of the regulating agencies are misplaced, unevenly favoring biotech companies at the expense of customers.[60] The unchecked use of presidential authority at the inception of biotechnology seems to strengthen these arguments.

Over the years, unitarians[61] and traditionalists[62] have disagreed on the degree of presidential power warranted in the area of administrative law. In the last decade, however, Justice Kagan, then Professor Kagan, departing from both schools of thought, put forth a more nuanced argument. In her article, *Presidential Administration*, Justice Kagan posited that a form of deference should be accorded to the President's involvement in administrative law as a more efficient form of policy setting.[63] As Justice Kagan documented, deliberate and aggressive policy setting by the President has been occurring in administrative law these last few decades.[64] Justice Kagan aptly coined this trend as "Presidential Administration."[65] Justice Kagan's proposal and observations are laden with import both for our traditional exploration of administrative law and for new technology—like biotechnology—that Congress has not yet expressly regulated. Added deference to agencies because of the President's involvement in this context has deep ramifications.

Party politics that lead to stagnation in the legislature have encouraged the use of Presidential Administration for regulatory and non-regulatory purposes.[66]

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59. Van Tassel, *supra* note 57, at 229-30.

60. GOVERNING RISKS IN GM AGRICULTURE 26 (Michael Baram & Mathilde Bourrier eds., 2011) [hereinafter GOVERNING RISKS].

61. Kagan, *supra* note 2, at 2325-26 ("[U]nitarians argue that . . . Article II of the Constitution establishes a President with plenary control over all heads of agencies involved in executing, implementing, or administering federal law. . . . [U]nitarians insist that the Court has allowed Congress too much power to insulate the agencies from the President. Although focusing on the question of removal, the unitarian position equally would bar legislative inroads into the President's directive authority." (footnotes omitted)).

62. Keith Werhan, *Delegalizing Administrative Law*, 1996 U. ILL. L. REV. 423, 427-28 ("Thus, under the traditional model of administrative law, the agencies have the dominant decisionmaking authority, not the White House.").

63. Kagan, *supra* note 2, at 2363-64.

64. *Id.* at 2318.

65. *Id.* at 2246 ("Because of the stakes of the contest and the strength of the claims and weapons possessed by the contestants, no single entity has emerged finally triumphant, or is ever likely to do so. But at different times, one or another has come to the fore and asserted at least a comparative primacy in setting the direction and influencing the outcome of administrative process. In this time, that institution is the Presidency. We live today in an era of presidential administration.").

66. *Id.* at 2312 ("The strengthened role of party leadership within Congress and the increased use of the filibuster both reflect and exacerbate this heightened polarization—and thereby further dim the prospect for real legislative achievement in the context of divided government. It is not

For example, Justice Kagan argues that while Presidents Bush and President Reagan exercised Presidential Administration to de-regulate,[67] President Clinton exercised it to foster a regulation-focused trend in certain areas.[68] Justice Kagan paints an attractive picture of presidential control over administrative rule making as a multi-faceted tool, capable of encouraging efficiency and accountability.[69] Justice Kagan argues that this practice is most useful and benign in instances when Congress delegates broad powers to agencies without specific mention of authority delegation to an independent agency head.[70] Justice Kagan is not the first to propose that some type of broad power should be granted to the President in administrative law.[71] Unlike, the unitarians, however, Justice Kagan's proposal limits the President's power to participate in rulemaking to non-independent agencies.[72] By excluding independent agencies, Justice Kagan received substantial criticism from the unitarians for not going far enough in recognizing presidential power.[73] Traditionalists, on the other hand, concerned with

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surprising, given these changes in the political landscape, that a President would turn to administration—a sphere in which he unilaterally can take decisive action. The more the demands on the President for policy leadership increase and the less he can meet them through legislation, the greater his incentive to tap the alternate source of supply deriving from his position as head of the federal bureaucracy.").

67. *See, e.g.*, *id*. at 2247 ("In the first month of his tenure, Reagan issued an executive order creating a mechanism by which the Office of Management and Budget (OMB), an entity within the Executive Office of the President (EOP), would review all major regulations of executive branch agencies. As Reagan's and then Bush's terms proceeded, the antiregulatory effects of this system of review became increasingly evident . . . .").

68. *See, e.g.*, *id*. at 2247-48 ("President Clinton issued his own executive order providing for OMB review of regulations . . . in a way generally sympathetic to regulatory efforts.").

69. *Id*. at 2348-49 (proposing that presidential influence over administrative action is more desirable than congressional influence, as presidential action is less functional, while also being more representative and efficient, than that of the legislature).

70. *Id*. at 2251 (accepting "Congress's broad power to insulate administrative activity from the President," but arguing "that a statutory delegation to an executive agency official—although not to an independent agency head—usually should be read as allowing the President to assert directive authority . . . over the exercise of the delegated discretion").

71. *See, e.g.*, *id*. at 2248 n.5 (discussing various authors whose views are consistent with that of then Professor Kagan for extending presidential influence in administrative decision making).

72. *Id*. at 2326 ("I do not espouse the unitarian position in this Article, instead taking the Supreme Court's removal cases, and all that follows from them, as a given."); *id*. at 2327 ("When the delegation in question runs to the members of an independent agency, the choice" as to whether Presidential Administration is authorized "seems fairly obvious. In establishing such an agency, Congress has acted self-consciously, by means of limiting the President's appointment and removal power, to insulate agency decisionmaking from the President's influence . . . . [M]aking the heads [of these independent agencies] subordinate in [any] single way would subvert the very structure and premises of the agency.").

73. *See, e.g.*, Thomas O. Sargentich, *The Emphasis on the Presidency in U.S. Public Law: An Essay Critiquing Presidential Administration*, 59 ADMIN L. REV. 1, 15 (2007) ("The chief point

presidential overreaching, think her proposal goes too far.[74] Their concerns are all the more relevant in light of renewed debates over the creation of an imperial presidency.

This Article is limited to analyzing the import of presidential control on administrative agencies' treatment of bioengineered foods. It further argues that a form of the Presidential Administration defined by Justice Kagan has already taken place in regard to bioengineering. Then Professor Kagan argued that, in the absence of congressional restriction, courts, when reviewing administrative decisions, should infer that Congress anticipated presidential control of the administrative process.[75] According to Kagan,

> [i]f Congress, in a particular statute, has stated its intent with respect to presidential involvement, then that is the end of the matter. But if Congress, as it usually does, simply has assigned discretionary authority to an agency official, without in any way commenting on the President's role in the delegation, then an interpretive question arises. One way to read a statute of this kind is to assume that the delegation runs to the agency official specified and to that official alone. But a second way to read such a statute is to assume that the delegation runs to the agency official specified, rather than to any other agency official, but still subject to the ultimate control of the President. The lawfulness of a President's use of directive power depends on the choice between these two readings.[76]

This presidential presumption should, according to then Professor Kagan, lower the level of scrutiny applied by courts in reviewing agencies' decisionmaking related to errors of process.[77] This, then, would change the hard look doctrine, which requires that courts scrutinize whether agencies have taken a hard look at all the evidence and alternatives before making a decision.[78] Under Kagan's

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of distinction between the perspective of Dean Kagan and unitarian executive branch theorists involves the constitutionality of independent regulatory agencies. The authorizing statutes of such agencies, among other things, limit presidential authority to remove the agency heads, providing for their removal only for inefficiency, neglect of duty, or malfeasance in office. Unlike such officials, executive agency heads can be removed by the President for any reason, or at will. The unitarian theorists argue that constraining the President's ability to remove any agency heads offends the constitutional text, structure, and original intent." (footnotes omitted)).

74. Karl Manheim & Allan Ides, *The Unitary Executive*, 29 L.A. LAW. 24, 29 (2006) ("At its extreme, unitary executive theory holds that executive power is as broad as the executive says it is. The unitary executive theory—when blended with other theories of inherent power, especially during wartime—too often leads to excesses, such as those that have occurred in the conduct of the war on terror.").

75. Kagan, *supra* note 2, at 2326-27.

76. *Id.*

77. *Id.*

78. Scott A. Keller, *Depoliticizing Judicial Review of Agency Rulemaking*, 84 WASH L. REV. 419, 438-39 (2009).

proposal, evidence of presidential involvement in the decisionmaking would relax the "hard look" standard.[79]

This proposal sets up a deep entanglement between the President's office and the regulatory agencies that goes beyond mere reporting and, instead, substantially changes the courts' approach to congressional silence in matters of administrative law.[80] What is more, giving deference to Presidential Administration seems to conflate the legislative and executive branches in a way that makes it more difficult for the two branches to check each other.[81] It is true, as then Professor Kagan argues, that reliance on Congress alone as a check on Presidential Administration can be limited.[82] Still, the dangers of Presidential Administration become salient when one examines the case of genetically altered foods. In 1986, the President's Office of Science and Technology Policy announced

> A "Coordinated Framework" for federal regulation of "biotechnology products" . . . . It stands as the only policy guidance on federal oversights and regulation of genetically engineered products, including GM crops and foods. It assigns oversight roles to four federal agencies, asserts that previously enacted laws that empower these agencies are sufficient for regulating GM products risks, and warns the agencies that any GM product regulations they enact should be based solely on end product risks without consideration of biotechnological processes involved in making the products. Because Congress has not acted to amend or

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79. Kagan, *supra* note 2, at 2380 ("A revised ["hard look"] doctrine would acknowledge and, indeed, promote [a] vision centered on the political leadership and accountability provided by the President. This approach, similar to the one I have considered in discussing the Chevron doctrine, would relax the rigors of hard look review when demonstrable evidence shows that the President has taken an active role in, and by so doing has accepted responsibility for, the administrative decision in question." (footnote omitted)).

80. *See* Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-44 (1984).

81. *See* Kagan, *supra* note 2, at 2350.

82. *Id*. ("In two different respects, the answer to this threat of presidential lawlessness cannot lie in the hands of the current Congress. First, and apparently compounding the threat, Congress possesses neither the tools nor the incentives effectively to counter wrongful assertions of presidential authority. Congress cannot easily obtain the two-thirds vote in each house necessary (given the President's veto power) to overturn a presidential order. And the Congress existing at the time of the order may have no desire to enforce the enacting Congress's determination of the appropriate scope of administrative discretion. But second, and now placing the threat in some perspective, this very lack of continuity in congressional preferences suggests that in the absence of strong presidential control over administration, a similar, even if not fully equivalent, threat of congressional lawlessness might arise to fill the resulting vacuum. For any given Congress (or more precisely, its committees and subcommittees) also may be disposed to press agencies to engage in conduct unauthorized by prior statute. The threat of lawlessness thus cannot exclusively be associated with presidential control.").

> override this presidential policy it has been dutifully followed by the designated agencies, including the assigned to GM crops and foods.[83]

A more detailed version of this policy was reissued in 1992.[84] According to the directives, the agencies were to use a cost-benefit analysis in assessing risks and determining if the value of additional oversight outweighed its cost.[85] In addition, regulators were "further directed to minimize regulatory burdens on product developers, accommodate rapid advances in product development and commercialization, and use flexible performance-based standards rather than rigid prescriptive or design standards to deal with end product risks."[86] The directives gave developers the benefit of the doubt regarding the level of care, review, and testing required prior to placing products on the market.[87] The initial policy statements regarding the treatment of bioengineered foods purported that

> (1) U.S. policy would focus on the product of GM techniques, not the process itself, (2) only regulation grounded in verifiable scientific risks would be tolerated, and (3) GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products. Within these tenets, industry would be encouraged to continue its rapid pace of development without regulatory impediments.[88]

This is radical considering that little was known of this new technology and its potential effect on traditional crops and/or health risks.[89] To recommend full support for these products without a rigorous vetting process[90] denotes a desire to encourage market growth to the exclusion of other concerns.[91] Under the above guidelines, agencies have felt free to develop a minimum approach to regulation of bioengineered foods.[92] Additionally, this approach pushed agencies

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83. GOVERNING RISKS, *supra* note 60, at 26.

84. *See* Announcement of Policy, Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753-01 (Office of Sci. & Tech. Pol'y Feb. 27, 1992).

85. *Id*. at 27.

86. *Id*.

87. *Id*. at 27-28.

88. Marden, *supra* note 39, at 738.

89. *See* Sheryl Lawrence, Comment, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 244 (2007) ("However, because the field of genetic engineering is relatively new and has advanced so quickly in recent years, there is tremendous uncertainty regarding the existence and degree of risk presented by GMOs and their progeny.").

90. *See generally* Francer, *supra* note 15, at 277-90 (discussing "Genetically Modified Food Regulation in the European Union").

91. Lawrence, *supra* note 89, at 244 ("The policy decisions made in the Coordinated Framework were inspired, at least in part, by the goal of limiting regulatory restrictions that might hamper the development of the promising and fledgling biotechnology industry.").

92. Marden, *supra* note 39, at 741 ("The Report characterized federal agencies as

to instantaneously treat biotech foods as identical to traditionally grown foods.[93] Congress, even in the face of great objections and public concern, has not deemed it fit to intervene,[94] thereby leaving the agencies to implement presidential directives. This is still the case in the face of current evidence available on the effects of bioengineered crops on the traditional farming market, even if the health effects are still too remote to determine.[95] As observers have argued,

> The FDA's presumption that GM plant foods are bioequivalent to traditional food is a consequence of the remarkable growth in the development of new technologies, which far outpaces the science necessary to identify the human health risks associated therewith. This scientific lag time creates a period when there is an information void with regard to risks to human health.[96]

The unrestrained freedom granted to biotech companies has culminated in the pending approval of the first genetically modified salmon.[97] The bioengineered context demonstrates, thus, that Presidential Administration, even if capable of positive outcomes, should not remain unchecked. In cases of first impression and great public concern, as with biotechnology, it is imperative that Congress provides a balance by issuing specific guidelines. Congressional directives provide the added element necessary for adequate, even if not always perfect, checks and balances of the three branches of government.[98]

'gatekeepers' to the development and use of biotechnology. The document specified that in order to not inhibit growth, the government should presume that a product poses a minimal risk in the absence of any evidence to the contrary. On this basis the document indicated '[that the Administration would seek] to eliminate unneeded regulatory burdens on all phases of the development of new biotechnology products—laboratory and field experiments, products development, and eventual sales and use.'" (alteration in original) (footnote omitted)).

93. *See id*. at 748 ("Ultimately, the 1992 FDA Policy's GM definition facilitated the view that the risks associated with the technology were no different from those posed by traditionally produced foods.").

94. Rich, *supra* note 14, at 904 (footnotes omitted) (recognizing Congress's lack of response to address agency interpretations of issues related to genetically modified products, leading to broad judicial deference to such agency interpretations).

95. *See* Van Tassel, *supra* note 57, at 229.

96. *Id*.

97. Homer, *supra* note 11, at 85-86.

98. Harold J. Krent, *Separating the Strands in Separation of Powers Controversies*, 74 VA. L. REV. 1253, 1293 (1988) ("The Constitution does not place comparable internal checks upon the executive branch. . . . [T]he framers presumably believed that such internal checks, aside perhaps from the appointments clause, were not necessary because the Constitution already circumscribed executive action considerably by confining it to the terms of congressional directives. Ensuring fidelity to congressional directives provided a measure of accountability because the legislative enactment itself had previously been 'checked' in a constitutional sense. In addition, the need for dispatch in enforcing the laws militated against any cumbersome requirements delaying executive action. Generally, the executive may therefore act free of any procedural hurdles within the sphere

As it stands, due to presidential directives at its inception, biotechnology is still not substantially checked and evaluated by agencies.[99] For example,

> [t]he USDA issues permits for trials of new GM crops, but once they enter into commercial production, the agency has no mandate to oversee them. The EPA has responsibility for any new variety producing its own insecticide, but relies on company-provided data, and is not required to do follow-up inspections or independent monitoring. The FDA is responsible for regulating new foods and food additives under the authority of the Federal Food, Drug, and Cosmetic Act. In 1992, the FDA decided that genetically modified foods would not require FDA approval, except when food safety questions exist sufficient to warrant pre-market review.[100]

This lack of supervision and follow-through is mind-boggling. It can only be understood in light of the presidential policy encouraging economic growth in an unknown area, without substantially monitoring the potential health risks and the negative impact on small farmers. Such unilateral policy setting runs counter to the purposes of administrative policy setting and overall governance. Still, to fully understand how genetically modified crops and foods are regulated, one must understand the delineation of responsibilities in that context.

II. SOURCES OF LAW FOR REGULATING BIOENGINEERED FOODS

A. Agencies' Structure and Responsibilities

Three major federal agencies, whose powers are established by the Administrative Procedure Act ("APA"), monitor our food supply[101]—The Food and Drugs Administration ("FDA"), the United States Department of Agriculture ("USDA"), and the Environmental Protection Agency ("EPA").[102] These three agencies delegate authorities to subsidiaries that are controlled by various statutory review procedures. In the case of bioengineered foods, the National Environmental Policy Act ("NEPA")[103] and the Plant Protection Act ("PPA")[104] provide guidelines and requirements for regulating foods and plants. Courts, in evaluating compliance under these acts, abide by specific standards of review. For example, in the context of plants, the PPA authorizes the Secretary of the

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of action allowed by Congress." (footnote omitted)).

99. *See* Rich, *supra* note 14, at 901-02 ("Proponents of GMOs, including the federal government, enthusiastically embraced biotechnology without serious investigation of the potential problems in what amounted to a 'don't look, don't see policy.'").

100. *Id*. (footnotes omitted).

101. 5 U.S.C. §§ 551-559 (2006 & Supp. V 2011).

102. Ellison, *supra* note 33, at 349.

103. 42 U.S.C. §§ 4321-4370 (2006 & Supp. V 2011).

104. 7 U.S.C. §§ 7701-7786 (2006 & Supp. V 2011).

USDA to regulate plant pests.[105] The Animal and Plant Health Inspection Service ("APHIS"), a subsidiary of the USDA, oversees "the introduction of organisms and products altered or produced through genetic engineering that are plant pests or are believed to be plant pests" or "regulated articles."[106] Furthermore, the EPA regulates plants that emit pesticides.[107]

B. The Regulatory Framework: The FDA, the USDA and the EPA

The regulatory system of biotech products is a tri-partite collaboration:

> [T]he US Department of Agriculture (USDA), the US Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) share primary responsibility for regulating biotechnology. The United States Department of Agriculture reviews biotechnology-derived applications, which contain or are produced using potential plant pests. The United States Department of Agriculture also regulates veterinary biologics, which are products derived from living sources, such as blood products and vaccines, and is largely responsible for assuring the safety of meat and poultry products. The Environmental Protection Agency regulates biotechnology-derived plant or microbial pesticides or new chemical substances. The Food and Drug Administration, which regulates the safety of most foods, drugs for human or animal use, biologics for human use, and medical devices, is the lead regulatory agency with respect to these products.[108]

A division of the USDA, the Animal and Plant Health Inspection Service ("APHIS"), regulates field tests and the shipment of bioengineered products; provides permits "for the import, interstate movement, and field testing of genetically altered plants, microorganisms, and invertebrate;"[109] and oversees "the

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105. *Id*. §§ 7701(2)-(3), 7702(16), 7711-12.

106. 7 C.F.R. § 340.0(a)(2) & n.1 (2013).

107. Marden, *supra* note 39, at 777 ("In the proposed policy, EPA coined the term 'plant-pesticide' to refer to GM products under EPA authority. By definition, a 'plant-pesticide' was a 'pesticidal substance that is produced in a living plant and the genetic material necessary for the product of the pesticidal substance, where the pesticidal substance is intended for use in the living plant.' EPA also made clear that it considered its existing review and risk assessment procedures adequate for GM products. Like FDA, EPA stated that its approach would be product-based: 'EPA indicates that it proposes to focus its regulatory attention on the plant-pesticide and not on the plant per se.'" (footnote omitted)).

108. Neil A. Belson, *US Regulation of Agricultural Biotechnology: An Overview*, 3 J. AGROBIOTECHNOLOGY MGMT. & ECON. 268, 269 (2000), *available at* http://www.agbioforum.org/v3n4/v3n4a15-belson.pdf; *see also* Bratspies, *supra* note 41, at 407 ("At its most superficial, the regulatory regime established by the Coordinated Framework is very easy to describe: the FDA is responsible for food safety, the EPA is responsible for microbes and pesticides, and . . . (APHIS) is responsible for all plants.").

109. Ellison, *supra* note 33, at 350 (internal quotation marks omitted).

movement of plants . . . developed through genetic engineering" in the event they cause "a risk of plant pest introduction, spread or establishment."[110] A "plant pest" is an organism "which can harm plants either directly or indirectly."[111] Ultimately, then, APHIS is in charge of protecting US agriculture from pests and diseases. When a bioengineered plant is developed for testing or interstate shipment, it falls under the statutory definition of "regulated article," which triggers a duty to notify APHIS:

> A "regulated article" is defined in APHIS regulations as "any organism which has been altered or produced through genetic engineering" if the donor organism, recipient organism, vector or vector agent is a "plant pest." The Animal and Plant Health Inspection Service defines a plant pest broadly to include "any living stage" of insects, bacteria, fungi, viruses, or various other organisms which can damage or cause injury to plants or plant parts. Many plant pathogens commonly used as vectors or promoters in agricultural biotechnology, such as Agrobacterium species and cauliflower mosaic viruses, are considered "plant pests" under APHIS regulations. Use of any of these "plant pests" to make a transgenic plant makes that plant a "regulated article." The Agency may also designate as a regulated article any product of genetic engineering which the Agency determines or has reason to believe is a plant pest.[112]

Additionally, a plant must be deemed by the APHIS "deregulated" in order to be commercialized and transported. Theoretically, once a company petitions for deregulation, researchers are to conduct research and tests for a length of time to determine the potential effects of the plant on others.[113] This fact and similar mandates should give the APHIS and other agencies broad power to regulate bioengineered plants, regardless of the modification. In reality, however, strict monitoring of modified plants does not occur.[114] Instead, major problems have arisen in the regulation of genetically altered foods, the regulation of pesticidal plants by the APHIS, the FDA, and the EPA pursuant to the Federal Food, Drugs, and Cosmetic Act ("FDCA").[115]

Similarly, the power to regulate food additives can be instrumental to the FDA's oversight of bioengineered foods. Section 402(a)(1) of the FDCA provides the agency with the power to regulate noxious foods and to monitor substitutions in food composition.[116] According to the Act, a substance contains:

> (a) Poisonous, insanitary, etc., ingredients

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110. Frompovicz, *supra* note 56, at 280-81.

111. *Id*. at 281.

112. Belson, *supra* note 108, at 270 (footnotes omitted).

113. *Id*. at 270-71.

114. *Id*. at 271 (explaining that after de-regulation, "neither the product nor its offspring require further APHIS review for movement or release within the United States").

115. 21 U.S.C. §§ 301-399f (2006 & Supp. V 2011).

116. McGarity, *supra* note 40, at 432.

> (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health[; or] (2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; or (ii) a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation . . . .[117]

This section could cover some bioengineered products. It speaks to the big elephant in the room in the bioengineering debate: though the FDA regulates poisonous and deleterious substances, which are hazardous to health, it has not classified bioengineered products as such.[118] In reality, the FDA has refused to avail itself of the power provided by statute.[119] Consequently, most genetically modified foods are not classified as harmful because of the application of the mandate that they be treated like their traditional counterparts.[120]

In addition, foods can also be classified as adulterated:

> (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.[121]

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117. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(a)(1) (2006 & Supp. V 2011).

118. Francer, *supra* note 15, at 268-69.

119. *See* Bratspies, *supra* note 41, at 407.

120. *Id.* at 407-09.

121. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(b)(1) (2006 & Supp. V 2011).

This last characterization applies squarely to bioengineered foods. Despite the fact that some GM foods are the result of genetic substitutions and modifications, "the agency has not invoked its authority."[122] As a result, agency regulations determine that most GM foods are unadulterated.[123]

Instead, the FDA has relied on its power to implement regulations[124] in ways that absolve biotech companies of responsibilities. While the statute provides support for closer scrutiny of these foods during the approval process,[125] the FDA seems to have relinquished that role. The FDA is only permitted to approve a food additive petition if the applicant is able "to demonstrate to a reasonable certainty that no harm will result from the intended use of the additive."[126] Such a review triggers closer scrutiny by the agency and imposes higher burdens on the company to submit materials proving lack of harm.[127] Nonetheless, the agency allows genetically modified foods to undergo a less burdensome process whereby the GMO products can be "generally regarded as safe" (GRAS).[128] Consequently, "[i]n most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food, such as proteins, fats and oils, and carbohydrates."[129] Due to the presumption that modified foods have GRAS status, the FDA has also decided not to mandate specific labeling of foods derived from genetically modified plants.[130] Further, determining whether a proposed food is GRAS is left to the manufacturer, with only a voluntary consultation process in place in the event the manufacturer wants to consult and seek approval from the FDA prior to marketing.[131] In essence, the FDA seems to have wholly delegated its power of review to the very manufacturers whose economic interests run counter to the regulations. Moreover, this deference discourages manufacturers from thoroughly investigating possible risks and latent defects in their proposed products.[132] This lack of regulation is directly connected to the

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122. McGarity, *supra* note 40, at 434.

123. *See generally* Ed Wallis, *Fish Genes into Tomatoes: How the World Regulated Genetically Modified Foods*, 80 N.D. L. REV. 421, 426-27 (2004).

124. *See, e.g.*, McGarity, *supra* note 40, at 434-35 (recognizing the FDCA's broad authority to regulate food additives under § 402(a)(2)(c) of the FDCA).

125. *Id.* at 436-40 ("Ultimately, the [FDA] leaves it up to the manufacturer to determine whether an added substance is [generally recognized as safe].").

126. *Id.* at 435 (internal quotation marks omitted).

127. *Id.* at 434-36.

128. *Id.* at 438-40.

129. Bratspies, *supra* note 41, 408-09.

130. Marden, *supra* note 39, at 759-60.

131. *Id.* at 747 ("The 1992 FDA Policy had two purposes. First, it outlined the agency's view that most GM products were presumed or likely to be GRAS, and therefore not subject to food additive review. In addition, it established a voluntary pre-market consultation process to reassure companies and the public that the food supply was being safeguarded.").

132. Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the StarLink Corn*

initial command in 1986, at the inception of biotechnology, from the White House OST directing agencies to treat modified foods as substantially equivalent to traditional foods.[133] In the absence of guidance and checks from Congress and courts, this policy has led to an inadequate approval process for bioengineered foods. As a result, since 1986, the President's office—rather than Congress, the courts, the administrators, or even the public—has had the most enduring influence on the legal treatment of bioengineered foods. Under our governmental structure, this should not be the case. In addition, there is still too much to uncover regarding the safety of bioengineered foods.[134]

The other source of regulatory power for the FDA, with respect to bioengineered products, relates to the supervision of genetically modified, pest-resistant plants. FDA regulations divide these types of plants into two categories: (a) plants genetically modified to express pesticides and (b) plants genetically enhanced to be resistant to herbicides.[135] The FDA regulates the latter, but it

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Fiasco, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 609 (2003) [hereinafter Bratspies, *Myths of Voluntary Compliance*] ("In developing this policy, FDA conducted no independent research on the effects of genetic engineering on foods, nor did the agency require manufacturers to engage in such research. Instead, the policy was the product of a political decision to smooth a path for this new technology. Even more troubling, FDA allows manufacturers to make this GRAS determination unilaterally. This approach transfers a tremendous amount of discretion from the regulatory authority to the regulated community. Manufacturers need not submit vetted scientific data to convince FDA that a GM crop is GRAS. Instead, FDA permits manufacturers to make this evaluation entirely on their own. Not surprisingly, most manufacturers have concluded that their GM products are GRAS and thus exempt from expensive and rigorous pre-market review. Of course, even without regulation these manufacturers do have powerful incentives not to market products they know or suspect to be harmful. A GM food that causes an allergenic reaction or otherwise threatens human health would be subject to FDA seizure, and the company, including its responsible officers, might face criminal prosecution. And that is not to mention tort liabilities or the devastating effect such a product would have on the company's reputation." (footnotes omitted)).

133. *See* Marden, *supra* note 39, at 747 ("Thus, a memorandum from FDA Commissioner David Kessler, M.D., to the Secretary of Health and Human Services, dated March 20, 1992, states, 'The approach and provisions of the [1992 FDA Policy] are consistent with the general biotechnology policy established by the Office of the President in the recently published 'scope' document. It also responds to White House interest in assuring the safe, speedy development of the U.S. biotechnology industry.'" (alteration in original)).

134. Peck, *supra* note 22, at 256 (suggesting that the 1992 FDA Policy is not rooted in "objective scientific principles" since the 1992 FDA Policy, the Final Statement, and OSTP documents in support of the Policy "state conclusions about the safety of biotechnology without articulating the scientific methods, research, areas of debate or uncertainty, or means of arriving at a consensus opinion that biotechnology poses no distinct risks from other methods of modification").

135. Notice, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984-01 (Food & Drug Admin. May 29, 1992).

delegated authority in 1992 to the EPA to regulate the former.[136] The EPA's authority to regulate these items is discussed below.

C. The EPA's Power to Regulate Bioengineered Foods

While the FDA regulates foods and bioengineered products, the EPA has the power to regulate bioengineered foods that express or emit pesticides.[137] The EPA[138] "exercises the primary authority for regulating pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Food Drug and Cosmetic Act (FDCA)."[139] Much like the FDA, however, the EPA has the power to authorize pesticides only if it determines that they are safe.[140]

Under this standard, the EPA deems that a product may be exempt if it "possesses a low probability of risk to the environment, and that is not likely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight under FIFRA."[141] Similarly, under the FDCA, a product may be exempt from being considered adulterated if the EPA demonstrates a tolerance for the pesticide in the plant or has exempted the plant from the tolerance requirement.[142] The EPA must set their tolerance at a "safe" level;[143] the FDCA defines safety as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[144] The EPA may exempt a pesticide residue from the tolerance requirement only if the agency finds that the residue will remain "safe" in the absence of a tolerance in accordance with the same "reasonable certainty of no harm" standard.[145] Despite this strict standard, the EPA routinely deems classes of pesticides safe.[146]

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136. McGarity, *supra* note 40, at 433.

137. *Id.* at 465-66 (footnotes omitted).

138. Belson, *supra* note 108, at 272, 274 (explaining that the EPA's "enabling statutes are "the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and the Toxic Substances and Control Act (TSCA)," and that the FDA derives its authority from the FFDCA, which "is the nation's principal statute for regulating the safety of the nation's food and drug supplies").

139. McGarity, *supra* note 40, at 464 (footnotes omitted). The FIFRA is codified at 7 U.S.C. §§ 136-136y (2006 & Supp. V 2011).

140. 7 U.S.C. § 136(a)(5)(D) (2006 & Supp. V 2011).

141. McGarity, *supra* note 40, at 465 (internal quotation marks omitted).

142. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 346a(a)(1) (2006).

143. *Id.* § 346a(b)(2)(A)(i).

144. *Id.* § 346a(b)(2)(A)(ii).

145. *Id.* § 346a.

146. Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 747 (2000).

III. THE JUDICIARY SETTING THE TONE IN *MONSANTO V. GEERTSON*

Monsanto Co. v. Geertson Seed Farms[147] presents a warning about the potentially negative effects that might result from granting substantial deference to the President's involvement in administrative decisions. Though the Court stayed away from an explicit exploration of the issues related to Presidential Administration, the case is instrumental in showing why the traditional hard look doctrine, applied in judicial review of administrative decisions, is vital to the adequate balancing of governmental duties and justice in administrative law.[148] *Monsanto Co.* was the Supreme Court's first opportunity to tackle some of the issues raised by biotechnology.[149] Some of the burning issues, which raise the most concern for the public and small farmers, such as contamination and the economic impact on traditional farming, are present in this case.[150] In the absence of congressional guidance directly addressing the proper balancing of the various interests at issue, the most relevant statute in this instance is the National Environmental Policy Act ("NEPA"). NEPA imposes certain procedures, among which is the preparation of an Environmental Impact Statement ("EIS"), in relation to "'every recommendation or report on proposals for legislation and other major Federal actio[n] significantly affecting the quality of the human environment.'"[151] Plaintiffs in *Monsanto Co.* sued, alleging that the agency violated NEPA when it approved Monsanto's genetically modified strand of alfalfa "without first completing a detailed assessment of the environmental consequences of its proposed course of action."[152] The USDA

> is directed . . . to enhance American agriculture and forestry and protect these sectors from harmful organisms and products. . . . Pursuant to the PPA, APHIS has authority to restrict the import, shipment, field testing, and commercial planting of GM seeds and crops, but has used its discretion to create a permissive regulatory program in keeping with presidential policy.[153]

Monsanto, in this case, genetically modified a particular strand of alfalfa "genetically engineered to be tolerant of glyphosate, the active ingredient of the herbicide Roundup."[154] Monsanto owned the intellectual property rights in the

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147. 130 S. Ct. 2743 (2010).

148. *See id.* at 2764.

149. *See id.* at 2749 (describing the case as one about the deregulation of genetically engineered affirmed").

150. *Id.* at 2755-56.

151. *Id.* at 2750 (quoting 42 U.S.C. § 4332(2)(C) (2006 & Supp. V 2011)).

152. *Id.* at 2749 (quoting the Plant Protection Act, 7 U.S.C. § 7711(a) (2006)). The USDA delegated the authority to promulgate such regulations to APHIS pursuant to the Plant Protection Act ("PPA"); *see* 7 C.F.R. §§ 2.22(a), 2.80(a)(36) (2013).

153. GOVERNING RISK, *supra* note 60, at 28.

154. *Monsanto Co.*, 130 S. Ct. at 2750.

genetically modified alfalfa.[155] As such, the company could sue to stop the unapproved use of its seeds and crops.[156] It could, for example, seek relief, under intellectual property theories, against farmers whose crops had inadvertently mixed with its patented, genetically engineered seeds.[157] As a result, the Court determined that, in this case, the company had standing to appeal the district court's order to enjoin the APHIS's decision to deregulate the alfalfa strand. The potential exposure of traditional growers to these intellectual property claims and the restrictions that these patented rights impose on traditional farming are the added aspects of biotechnology that render traditional farmers, particularly small farmers, vulnerable.[158] A detailed exploration of the intellectual property ramifications of biotechnology is, however, beyond the scope of this Article, which focuses on the regulatory practices of the food agencies.

While intellectual property was not the focus of the Court's analysis in *Monsanto Co.*, the Court, tangentially, touched on the legal treatment of claims alleging contamination and economic loss by Monsanto's genetically modified alfalfa.[159] In a climate of ever-increasing public frustration with agencies' approach to these issues, this decision, which the public eagerly awaited, presented the Court with an opportunity to offer some guidance on the regulatory treatment of genetically altered crops. The interests at stake were numerous and diverse: protecting the public from harm and contamination; protecting the public's right to safe food as well as its right to be informed about the food it consumes; protecting the economic interests of traditional farmers; and considering the additional burdens caused by the risks of contamination. While many hoped that the Court would take a substantial stand in the biotechnology debate, the Court in *Monsanto Co.*, however, essentially restricted its analysis to the procedural issues of standing and the requirements for injunctive relief.[160] The opinion ultimately revolved around the standard used by the lower court in granting injunctive relief.[161] While this case does not squarely resolve the biotechnology debate, which still begs for congressional guidance, it, however, provided the Court with an opportunity to balance the interests of the various stakeholders in the debate regarding bioengineered crops, and to identify potential

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155. *Id.*

156. *See* Plant Patent Act of 1930, 35 U.S.C. §§ 161-164 (2016 & Supp. V 2011) (awarding a patent to the inventor/discoverer of a new plant variety along with the right to exclude others from reproducing, using, or selling the plant "or any of its parts").

157. Tempe Smith, Note, *Going to Seed?: Using Monsanto as a Case Study to Examine the Patent and Antitrust Implications of the Sale and Use of Genetically Modified Seeds*, 61 ALA. L. REV. 629, 632 (2010) ("As of October 26, 2007, Monsanto had filed 112 lawsuits against farmers for alleged violations of its Technology Agreement and/or its patents on genetically engineered seeds." (internal quotation marks omitted)).

158. *Monsanto Co.*, 130 S. Ct. at 2750, 2754-55.

159. *Id.* at 2754-56.

160. *Id.* at 2752-53, 2761-62.

161. *Id.* at 2754-55.

harms that have often been dismissed by proponents of biotechnology.[162] The Court, noticing that APHIS did not issue an EIS before deregulation, maintained the lower court's order to vacate the deregulation order (pending the EIS), but reversed the lower court's grant of injunctive relief.[163] Thus, despite the Court's determination that the lower court's standard for injunctive relief was improper, it provided an ephemeral relief to food watch groups by upholding the lower court's vacatur of the agency's deregulation order.[164] This, however, did not last as the agency swiftly completed the EIS after the Court's decision.[165] Still, this small step and the Court's concession that traditional growers have standing in these types of cases may open the door to future litigation on the substantive issues.

This ruling was, thus, a limited victory for food rights activists. The case, however, still served an important purpose. Though, the majority in *Monsanto Co.* saved the resolution of the substantive issues in biotechnological farming for another day,[166] the dissent's analysis might prove useful in later cases. Convinced by the district court's findings, the dissent would have affirmed the district court's ruling to enjoin the partial deregulation. This would have resulted in a prohibition against planting the modified alfalfa, which would have been a substantial victory for traditional farmers and food watch activists. The dissent recognized economic costs and contamination as harms that provide standing to complainants in these kinds of cases and considered that future lawsuits might be brought as a result of the APHIS's decision to partially deregulate.[167] As Justice Stevens pointed out, in the dissenting opinion, "Contamination cannot be undone; it will destroy the crops of those farmers who do not sell genetically modified alfalfa. And because those crops cannot be replanted for two to four years, that loss will be even greater."[168] On the other hand, although plaintiffs could decide to convert to modified seed, the companies were not overly prejudiced because

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162. *See* Lisa A. Cutts, Comment, *What's The Big Deal? The Let-Down That is the Landmark* Monsanto v. Geertson *Case*, 20 SAN JOAQUIN AGRIC. L. REV. 117, 145-46 (2011).

163. *Monsanto Co.*, 130 S. Ct. at 2761-62 ("In sum, the District Court abused its discretion in enjoining APHIS from effecting a partial deregulation and in prohibiting the possibility of planting in accordance with the terms of such a deregulation. Given those errors, this Court need not express any view on whether injunctive relief of some kind was available to respondents on the record before us. Nor does the Court address the question whether the District Court was required to conduct an evidentiary hearing before entering the relief at issue here. The judgment of the Ninth Circuit is reversed, and the case is remanded for further proceedings consistent with this opinion.").

164. *Id.*

165. *See* USDA Environmental Impact Statement on Roundup Ready Alfalfa Completed; Sales Could Resume in Early 2011, MONSANTO (Dec. 16, 2010), http://www.monsanto.com/newsviews/Pages/USDA-EIS-on-roundup-ready-alfalfa-completed.aspx.

166. *Monsanto Co.*, 130 S. Ct. at 2756, 2762.

167. *Id.* at 2764 (Stevens, J., dissenting).

168. *Id.* (alteration in original) (internal citations omitted).

the seeds could be stored.[169] Additionally, the defendants "'were [fully] aware of plaintiffs' lawsuit' and 'nonetheless chose to market.'"[170] Consequently, the companies had no "cause to claim surprise" for any loss.[171] This classification not only clearly anticipates future litigation involving concrete calculation of legal damages, but it also sends a message to the regulating agencies that failing to properly balance the interests at issue might lead to more complicated procedural issues and entangled judicial proceedings both for the agencies and the biotech companies. The *Monsanto Co.* opinion, while not providing the precise formula the parties sought, illustrates the type of checks and balances that judicial review establishes in difficult administrative law cases and demonstrates the importance of the judiciary's implementation of a clear and meaningful standard of review.[172] This balance is crucial when dealing with the conflicting interests present in the biotechnology context. Courts should follow the recommendations in *Monsanto Co.*'s dissent and afford putative plaintiffs an opportunity to litigate these issues.

Applying a lower level of scrutiny in cases where presidential control is evident, as recommended by then Professor Kagan,[173] would greatly hinder the important role that courts play in balancing interests. NEPA clearly requires the issuance of an EIS[174] before deregulation. Had courts incorporated additional deference to Presidential Administration in their analyses, the outcome in *Monsanto Co.* might have been even more limited. In addition, such added deference could eventually cause courts to find challenges to agencies' decisions related to biotechnology non-justiciable.

IV. INADEQUATE JUDICIAL REVIEW OF AGENCIES DECISIONS

Courts' approach to these issues already gives too much deference to the agencies. Disputes often arise regarding the agencies' regulations or interpretation of standards. This occurs when Congress does not speak directly on a particular issue. These types of disputes are common in the case of bioengineered foods because these foods are a fairly new manifestation. Courts, in reviewing these disputes, tend to analogize these types of food to existing foods.[175] This, however, is problematic because bioengineered foods are substantially different from regular foods.[176] In reviewing an agency's interpretation, courts have traditionally applied the familiar two-prong Chevron

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169. *Id.*

170. *Id.*

171. *Id.* (alteration in original) (internal quotation marks omitted).

172. Kagan, *supra* note 2, at 2342-44.

173. *See generally id.*

174. National Environmental Policy Act of 1969, 42 U.S.C. § 4332(2)(C) (2006 & Supp. V 2011).

175. *See* Frank J. Miskiel, Comment, *Voluntary Labeling of Bioengineered Food: Cognitive Dissonance in the Law, Science, and Public Policy*, 38 CAL. W. L. REV. 223, 236-37 (2001).

176. *See* Robertson, *supra* note 38, at 168 (explaining how "[g]enetic engineering represents a radical departure from traditional methods").

test. When it is determined that Congress has clearly spoken on an issue, congressional intent prevails.[177] When, however, Congress is ambiguous or has not spoken on an issue, courts do not apply its own interpretation of the statute. Instead, courts simply ask whether the agency based its action on a permissible construction of the statute.[178] Courts find agency decisions impermissible under this standard only if they are "arbitrary and capricious."[179] Courts will not substitute their judgment for what they deem to be the agency's reasonable interpretation.[180] This deference to administrative interpretations is one entrenched in administrative law. In fact, if the "choice represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned."[181] The Court's usual deference to agencies and to biotech agencies encounters a glitch, however, when applied to genetically modified foods. The biotechnology field raises a number of novel issues that no statute directly addresses.[182] Even more problematic, the food agencies' current treatment of genetically engineered foods is the product of a deliberate policy set by the President's office during the 1980s, not the result of congressional guidance.[183] Accordingly, courts have been implementing the dictates of the Executive rather than those of Congress without assessing whether this form of presidential control is valid in the given context.[184]

For example, agencies' presumption that genetically altered foods are safe until proven otherwise was challenged in *Alliance for Bio-Integrity v. Shalala* ("*Alliance*").[185] In *Alliance*, the district court upheld the FDA's "presumption that rDBA-engineered foods are GRAS."[186] *Alliance* was triggered by the publication of the FDA's "statement of Policy" on May 29, 1992, which stated that

> the agency would presume that foods produced through the rDNA

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177. Chevron, U.S.A., Inc., v. Natural Res. Def. Council Inc., 467 U.S. 837, 842-43.

178. *Id*. at 843-44.

179. *Id*. at 842-43 (1984); *see* Jack M. Beermann, *The Turn Toward Congress in Administrative Law*, 89 B.U. L. REV. 727, 728, (2009) ("Some of the most important developments in administrative law in recent years arise out of federal courts reviewing administrative action and reinforcing Congress's primacy as the most powerful policymaking branch of the federal government. This movement in the law spans seemingly unrelated doctrinal areas, and is best explained as a continuing affirmation and reaffirmation of the superior legitimacy of Congress as policymaker.").

180. *Chevron, U.S.A.*, 467 U.S. at 844.

181. *Id*. at 845 (quoting United States v. Shimer, 367 U.S. 374, 383 (1961)).

182. *See* Lawrence, *supra* note 89, at 245-46.

183. *See* Peck, *supra* note 22, at 250-52.

184. *See* Marden, *supra* note 39, at 763 ("FDA's approach to GM labeling has been upheld by the courts.").

185. 116 F. Supp. 2d 166 (D.C. Cir. 2000).

186. *Id*. at 175.

> process were "generally recognized as safe" (GRAS) under the Federal Food, Drug and Cosmetic Act ("FDCA"), and therefore not subject to regulation as food additives. While FDA recommended that food producers consult with it before marketing rDNA-produced foods, the agency did not mandate such consultation.[187]

The types of GM foods in question in the lawsuit involved products developed through "[o]ne of these advances, recombinant deoxyribonucleic acid (rDNA) technology" which "enabled scientists to alter the genetic composition of organisms by mixing genes on the cellular and molecular level in order to create new breeds of plants for human and animal consumption. These new breeds may be designed to repel pests, retain their freshness for a longer period of time, or contain more intense flavor and/or nutritional value."[188] *Alliance* involved the development of plants expressing pesticidal products as well as plants resistant to pesticides.[189] The FDA should scrutinize these products closely.[190]

The *Alliance* court admitted that "[m]uch controversy has attended such developments in biotechnology, and in particular the production, sale, and trade of genetically modified organisms and foods."[191] The *Alliance* court also determined that the FDA did not have to provide a notice and comment period because the policy was not a substantive ruling.[192] Nor did the FDA violate NEPA[193] by failing to complete an EIS along with its Statement of Policy because the FDA's statement did not constitute a "major federal action."[194] By not classifying the agency's decision as an "action," as defined by the NEPA, the *Alliance* court held that the statement of policy did not trigger liability on the part of the FDA.[195]

Furthermore, the court determined that the policy violated neither the FDA's standard for additives nor its labeling mandates.[196] As discussed above, under the

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187. *Id*. at 170 (internal citations omitted); *see also* Notice, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984-01 (Food & Drug Admin. May 29, 1992).

188. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 169.

189. *Id*.

190. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 342 (2006 & Supp. V 2011).

191. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 169.

192. *Id*. at 172-73.

193. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370h (2006 & Supp. V 2011).

194. *Alliance for Bio-Integrity*, 116 F. Supp. at 173-74. *See* 42 U.S.C. § 4332(e)(c)(i) (2006); 40 C.F.R. § 1508.18(b)(1)-(4) (2003); Notice, Statement of Policy: Foods Deemed from New Plant Varieties, 57 Fed. Reg. 22, 984-01 (Food & Drug Admin. May 29, 1992).

195. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 173-74.

196. *Id*. at 175-79 (stating that the court would defer to the agency's expertise regarding whether the substances were exempt from the additives regulations because they "are generally recognized to be safe" and that the FDA's labeling determination was entitled to deference because the level of consumer demand did not affect the FDA's finding that "rDNA modification does not 'materially' alter foods").

standard for adulterated products, any substance that may become a part of food is a food additive.[197] This classification requires the producer to submit a food additive petition to the FDA.[198] A producer will be exempt from this requirement, however, if the FDA determines that experts have demonstrated that the additive is safe.[199] In the Statement of Policy in question in *Alliance*, the FDA determined that rDNA products are safe since the only items added to the rDNA-engineered foods are nucleic acids, which are found in the cells of all organisms.[200] Consequently, rDNA foods are presumed to be GRAS, unless proven otherwise.[201] This illustrates the agencies' built-in presumption favoring GM foods and over reliance on the evidence provided by manufacturers.

Finally, the district court determined that the FDA did not err when it did not require labeling of the bioengineered products.[202] Section 321(n) of the FDCA grants the FDA the authority to require labeling.[203] In general, foods shall be deemed misbranded if their labeling "fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."[204] Here again, the court's implicit endorsement of presidential control is palpable. Plaintiffs challenged the FDA's interpretation of the term "material."[205] The *Alliance* court determined that because Congress had not specifically defined materiality, the agency was entitled to deference.[206] Even more problematic was the court's reference to the failure to show "material difference" between traditional foods and bioengineered foods. Quoting *Stauber v. Shalala*,[207] the court reiterated, "[I]n the absence of evidence of a material difference between [milk from cows treated with a synthetic hormone] and ordinary milk, the use of consumer demand as the rationale for labeling would violate the Food, Drug, and Cosmetic Act."[208] This analysis[209]

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197. Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(s) (2006) (defining "food additive").

198. *Id*. § 348(b); *see also* 21 C.F.R. § 171.1 (2013).

199. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s) (2006).

200. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177 ("To be generally recognized as safe, a substance must meet two criteria: (1) it must have technical evidence of safety, usually in published scientific studies, and (2) this technical evidence must be generally known and accepted in the scientific community. Although unanimity among scientists is not required, 'a severe conflict among experts . . . precludes a finding of general recognition.'" (alterations in original) (internal citations omitted)); *see* 21 C.F.R. § 170.30(a)-(b) (2013).

201. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 177.

202. *Id*. at 179, 181.

203. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n) (2006).

204. *Id*.

205. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178.

206. *Id*.

207. 895 F. Supp. 1178, 1193 (W.D. Wis. 1995).

208. *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179 (alterations in original).

209. Int'l Dairy Foods Ass'n v. Boggs, 622 F.3d 628, 634, 639, 650 (6th Cir. 2010) (striking

indicates that the hurdle faced by plaintiffs in such cases has less to do with proving potential harm[210] and more to do with their ability to adequately prove a material difference between bioengineered foods and natural foods.[211] Yet, there was evidence, which was not submitted as part of the record in *Alliance*, that the FDA should not have granted the products a safe status (GRAS) because of apparent disagreements among scientists in the company.[212]

Courts' endorsement of these policies reflects the need for specific guidance from Congress.[213] Courts' and agencies' treatment of these products as identical to traditionally grown foods fails to deal with the crucial issues regarding their genetic alteration and the lack of adequate knowledge about their potential effects.[214] We could begin to address some of the inequalities present in administrative agencies' treatment of genetically modified products if Congress were to pass a statute creating an independent agency charged with oversight, independent expert reviews and implementation of proper labeling standards. As it stands, our current approach is in stark contrast to Europe, which has adopted a precautionary approach to GMOs.[215]

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down a provision of a state rule that characterized dairy product labels which contained production claims that "this milk is from cows not supplemented with rbST" as misbranded, while upholding the provision of the rule requiring disclosure that "[t]he FDA has determined that no significant difference has been shown between milk derived from rbST-supplemented and non-rbST-supplemented cows" as reasonably related to the state's interest in preventing consumer deception, but not requiring the disclosure be contiguous with the production claim).

210. *See* Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 73-74 (2d Cir. 1996) (striking down a state labeling law requiring dairy manufacturers to label products derived from dairy cows treated with synthetic growth hormones because there was no material difference in the milk, and strong consumer concern alone was not a substantial state interest to justify a restriction on commercial speech).

211. *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 178 ("Thus, the question is again one of statutory interpretation. As is apparent from the statutory language, Congress has not squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest. Accordingly, interpretation of the § 321(n)'s broad language is left to the agency.").

212. *Id.* at 177; *see also* McGarity, *supra* note 40, at 440 (recognizing the *Alliance* court's perfunctory analysis of the FDA's "presumption of GRAS status to GM foods," despite evidence of "numerous internal agency documents produced during discovery that strongly suggested that there was 'significant disagreement' among the agency's own scientists as to the safety of GM foods" and a requirement under the 1992 Policy Statement that manufacturers seeking "GRAS status for a GM plant" must present published scientific evidence of the plant's safety that is generally accepted by the scientific community (alteration in original) (footnotes omitted)).

213. Ellison, *supra* note 33, at 356-57 (footnotes omitted) ("The court first considered the plain language of the statute by determining whether Congress spoke directly to the issue. The court concluded that when Congress passed the Food Additives Amendment in 1958, 'it obviously could not account for the late twentieth-century technologies that would permit genetic modification of food.'").

214. McGarity, *supra* note 40, at 430.

215. *See* Valerey Federici, Note, *Genetically Modified Food and Informed Consumer Choice:*

V. BIOENGINEERED FOODS AND POOR FARMERS HERE AND ABROAD

Biotech companies, such as Monsanto, place four main restrictions on their seed growers: (1) requiring growers to only use seeds containing Monsanto's patented biotechnology for planting a single crop; (2) prohibiting transfer or re-use of seeds containing the biotechnology for replanting; (3) prohibiting research or experimentation; and (4) requiring payment of a "technology fee."[216] This structure creates the potential for privatization and monopolization of the food industry.[217] This concern, aside from all others regarding the potential threat[218] posed by these products, provides a good basis for a conservative approach to these products.[219] If the government wishes to encourage genetically engineered products to help prevent future famine and to encourage development, then the concentration of power[220] in this structure has, thus far, created the opposite result.[221] As commentators have observed, biotech companies' overwhelming control over seeds has destabilized conventional farming.[222] Traditionally, storing, sharing, and reusing seeds are a part of conventional farming.[223] The ability to do so, particularly for poor farmers, has been greatly compromised by

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Comparing U.S. and E.U. Labeling Laws, 35 BROOK. J. INT'L L. 515, 536-37 (2010).

216. *See* Smith, *Who Owns Your Dinner?*, *supra* note 11, at 192 (internal quotation marks omitted).

217. David Daniel, Note & Comment, *Seeds of Hope: How New Genetic Technologies May Increase Value to Farmers, Seed Companies, and the Developing World*, 36 RUTGERS COMPUTER & TECH. L.J. 250, 251-52, 255-56, 260, 274, 277-80 (2010) (discussing GM-technology, the debate about its role in food production, perceived social and environmental costs, and how the law should address property rights and the resulting torts).

218. GREENPEACE, THE SOCIAL AND ECONOMIC IMPACTS OF GMOS (2008), *available at* http://www.greenpeace.org/eu-unit/en/publications/2009-and-earlier/social-and-economic-impacts-of-GMOs/.

219. Justin T. Rogers, Note, *The Encroachment of Intellectual Property Protections on the Rights of Farmers*, 15 DRAKE J. AGRIC. L. 149, 157-64 (2010) (discussing "[t]he Effect of Government Regulation and Seed Piracy Litigation on Rural Farmers").

220. Peter Straub, *Farmers in the IP Wrench—How Patents on Gene-Modified Crops Violate the Right to Food in Developing Countries*, 29 HASTINGS INT'L & COMP. L. REV. 187, 192-200 (2006) (discussing the impact of GM patents on developing countries and violations of the right to food).

221. Kanchana Kariyawasam, *Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture*, 19 PAC. RIM L. & POL'Y J. 459, 465-66 (2010) ("[C]ontrol over the world's seeds constitutes an overwhelming threat to agricultural genetic diversity and small-scale traditional farming systems.").

222. *Id.* at 465-66 ("One commentator has argued that the multinational seed corporations' 'control over the world's seeds constitutes an overwhelming threat to agricultural genetic diversity and small-scale traditional farming systems.'").

223. Rogers, *supra* note 219, at 157 ("Traditionally, the process of a farmer saving seed for planting during the following year's harvest has been a fundamental principle in agriculture.").

the dissemination of bioengineered seeds.[224] Yet, the saving and sharing of seeds among small farmers account, in great part, for small farmers' success and ability to sustain themselves. The seeds that small farmers collect and save are seeds that have been tested against the local environment for decades.[225] In addition, small farmers have to contend with the risk of litigation stemming from the accidental use of genetically modified seeds.[226] For example, "[f]armers that use GM seed have to contract with the seed company not to grow the seeds they harvest."[227] If a farmer replants a seed or accidentally experiences contamination with a GM seed, he/she has to seek permission from the multinational GM companies to continue to use that seed.[228] Beyond the ethical debate over whether extending patent rights to the use of plants is proper,[229] this poses an enormous burden on traditional growers. In fact, growers have been organizing around the world to remedy the detriments they have suffered as a result of this changing landscape.[230]

Of great concern is the detrimental effect of biotech companies in countries that do not have any regulatory structure in place to evaluate products and to protect their environments. It is reported that

> the acreage of GM crops has consistently grown each year with the number of countries increasing from 6 in 1996 to 25 and a global area of 134 million hectares in 2009. Herbicide-tolerant soybean continued to be the principal GM crop, followed by insect and/or herbicide tolerant maize, cotton, and rapeseed. The United States, Brazil, Argentina, India, Canada, China, Paraguay, and South Africa are the major growers with

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224. *Id*. at 161-62 ("The creation of terminator technology, as well as intellectual property protections, has taken away the farmer's traditional right to save seed. These developments have had both economic and social consequences. An economic consequence results every time a farmer replants a saved seed, resulting in a loss of potential sale to the seed company. Thus, precluding a farmer from saving seed forces the farmer to spend money on new seed every year. A resulting social consequence is the trespass on a farmer's traditional and historical practice of saving seed." (footnotes omitted)).

225. *See* Kariyawasam, *supra* note 221, at 466 ("The ability of farmers to select and save seeds that have been adapted to local conditions is essential for the success of local agriculture.").

226. *See, e.g.*, Rogers, *supra* note 219, at 164 ("The most remarkable legal battle stemming from a violation of a gene-licensing agreement is a case involving genetic drift. Genetic drift occurs when proprietary genetic material finds its way to a neighboring farmer's organic field, rendering the neighboring farmer liable for patent infringement." (footnotes omitted)).

227. Kariyawasam, *supra* note at 221, at 466 (alteration in original).

228. *See id*. at 465 ("Moreover, farmers who choose to raise non-genetically engineered crops intended for GM-free markets could, at times, be held liable if crops test positive for GM, even if the patented plant or seed was acquired unintentionally." (internal quotation marks omitted)).

229. *See, e.g.*, *id*. at 466 ("Critics have also questioned the ethics of extending patent rights to plant genes, forcing non-GM farmers to seek a licence to allow them to replant seeds from an earlier year's crop or to purchase new seeds from multinational companies." (footnotes omitted)).

230. Hamilton, *supra* note 28, at 95.

> 64 to 2.1 million hectares of GM crops, followed by Uruguay, Bolivia, the Philippines, Australia, Burkina Faso, Spain, and Mexico with .08 to 0.1 million hectares of GM crops. Among the ten countries that grew less than 50,000 hectares are the European Union (EU) member-states Czech Republic, Portugal, Romania, Poland and Slovakia.[231]

It is telling that the United States is leading in the cultivation of GMO crops,[232] given that other countries are deliberately proceeding with caution.[233] This approach signals a disproportionate emphasis on market growth, rather than on safety and environmental concerns.[234] However, emphasizing economic growth via intellectual property rights may backfire because biotech companies endanger the livelihood of small-to-medium farmers through contamination and cross-pollination.[235] In addition, the added costs, shouldered by traditional farmers to remain desirable to the public and health conscious consumers by taking measures to prevent contamination, place an added burden on traditional farmers.[236]

VI. PROPOSALS FOR DEALING WITH CURRENT DEFICIENCIES PRESENT IN COURTS' AND AGENCIES' TREATMENT OF BIOENGINEERED FOODS

A. Lessons from Massachusetts v. EPA

The judiciary's handling of issues raised by bioengineered foods is made difficult because there is no statute that squarely addresses how courts are to treat issues related to biotech foods.[237] In the absence of a congressional statute, *Massachusetts v. EPA*[238] provides the most pointed guidance on the issue. While not dealing squarely with bioengineered foods, in that case, the Supreme Court nonetheless considered an important question: what should be done when an

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231. GOVERNING RISKS, *supra* note 60, at 57.

232. Peck, *supra* note 22, at 265 (stating that the United States grows about half of all "biotech crops").

233. Federici, *supra* note 215, at 526, 534-35.

234. Peck, *supra* note 22, at 266, 268.

235. Renee T. Wilkerson, Comment, *Man Vs. Nature: Should the Offspring of Transgenic Animals be Patentable Subject Matter*, 37 U. DAYTON L. REV. 257, 271 (2012).

236. Debra M. Strauss, *The Application of Trips to GMOs: International Intellectual Property Rights and Biotechnology*, 45 STAN. J. INT'L. L. 287, 295-97 (2009).

237. *See, e.g.*, Lawrence, *supra* note 89, at 282 (footnote omitted) ("The Coordinated Framework must be changed to support the development of new law when existing statutes and regulations are shown to be inadequate for identified regulatory problems. The reliance on food and drug statutes and statutory definitions enacted long before genetic modification was foreseeable has been shown to be inadequate to address current technological realities. The need for new law to adequately protect the public and the environment from harm must be balanced against the costs of any proposed restrictions and requirements incurred by the regulated entities and the regulatory agency.").

238. 549 U.S. 497 (2007).

agency refuses to regulate despite the existence of a statute giving it authority to do so?[239] In *Massachusetts v. EPA*, the EPA refused to draft policies regulating carbon dioxide emissions, alleging that despite evidence that carbon dioxide causes damage to the atmosphere, the science was still too uncertain, and regulations might hamper the President's ability to negotiate with foreign governments.[240] The Court, taking a hard look at the statute and the agency's decisionmaking, ruled that the standard used by the EPA was arbitrary, capricious, and unsupported by the text of the statute.[241] The Court reasoned that Congress clearly delegated the duty to regulate pollutants to the EPA[242] and that carbon dioxide fit under the definition of "air pollutant."[243] Furthermore, the Court ruled that Congress had not delegated any powers to the State Department under the statute[244] and that any concerns for negotiations with foreign governments by the EPA were misplaced.[245]

The facts of this case are, of course, distinguishable from the facts of cases involving bioengineered foods. First, the product at issue was carbon dioxide, not a genetically manufactured product, and second, in *Massachusetts*, the Court could point to a specific statute delineating the EPA's responsibilities regarding pollutants.[246] While agency regulations and policies addressing bioengineered foods exist, Congress has yet to enact a statute encapsulating its intent and relevant regulations. Consequently, there is less room to infer "silence" on the part of Congress in *Massachusetts* than in the case of bioengineered foods.

These distinctions, nonetheless,[247] highlight key elements that are sorely missing and greatly needed in the area of biotechnology. For example, a congressional statute holistically addressing the issues raised by biotechnology is necessary. In *Massachusetts v. EPA*, unlike in the case of bioengineered foods, there was a statute and an agency regulating pollutants with an express mandate by Congress.[248] Furthermore, the Court took clear notice of congressional findings and scientific studies that indicated carbon dioxide emissions' great harm

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239. *Id*. at 528.

240. *Id*. at 513-14.

241. *Id*. at 534.

242. *Id*. at 533.

243. *Id*. at 532.

244. *Id*. at 534.

245. *Id*. at 533-34.

246. *Id*. at 533.

247. *Id*. at 504.

248. *Id*. at 528-29 ("The Clean Air Act's sweeping definition of 'air pollutant' includes 'any air pollution agent or combination of such agents, including any physical, chemical . . . substance or matter which is emitted into or otherwise enters the ambient air . . . .' On its face, the definition embraces all airborne compounds of whatever stripe, and underscores that intent through the repeated use of the word 'any.' Carbon dioxide, methane, nitrous oxide, and hydrofluorocarbons are without a doubt 'physical [and] chemical . . . substance[s] which [are] emitted into . . . the ambient air.' The statute is unambiguous." (alterations in original) (footnotes omitted) (internal citation omitted) (quoting 42 U.S.C. § 7602(g) (2006))).

to the atmosphere.[249] Despite the rapid growth of bioengineered products and the development of genetically altered fish, a similar congressional fact-finding process has not occurred in the context of bioengineered foods. This reveals the need for Congress to step in and take the steps necessary to create both policies and an agency tailored to monitor bioengineered foods and technology. The novel issues and circumstances progressively evolving as a result of this new technology indicate that congressional avoidance of this issue and/or merely chastising the existing agencies is no longer enough. Some scholars have suggested that a new agency should oversee the regulation of bioengineered foods.[250] This idea has merit; an independent agency specifically authorized to deal with biotechnology would address issues of imbalance and foster greater accountability.

B. Reform Proposals

There are a number of changes necessary to achieve an equitable review of cases involving disputes over bioengineered foods. Currently, there exist many hurdles facing consumers challenging agencies' treatment and wholesale approval of bioengineered foods. In order to fully increase the likelihood of succeeding in such cases, these groups must battle problems on a number of fronts. Advocacy groups should focus on regulatory, judicial, and grassroots lobbying.

The Chevron doctrine's deference to agencies in the absence of clear guidance from Congress might limit judicial action.[251] As a result, clear and efficient congressional guidance is necessary. Particularly, Congress should consider creating an independent agency,[252] an administrative entity most removed from presidential control. In the statute creating such an independent agency, Congress should require that biotechnology experts head the agency. Reliance on manufacturers' scientific reports, rather than on the agencies' own neutral and disinterested scientists, is one of the problems present in the agencies' current treatment of bioengineered foods.[253] Take, for example, the fact the manufacturers' own scientists in *Monsanto Co.* disagreed over whether the alfalfa was safe. Yet, the Court did not consider the issue since the company omitted it from the record. Agencies' overreliance on manufacturers' data can lead to the

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249. *Id.* at 507-10.

250. *See, e.g.*, Ellison, *supra* note 33, at 363 (advocating "an independent federal agency" to regulate GMOs).

251. Chevron, U.S.A., Inc. v. Natural Res. Def. Council, 467 U.S. 837, 842-43 (1984).

252. Ellison, *supra* note 33, at 352 ("The StarLink scare made clear that as long as the government relies on developers of bio-engineered foods to test their own products, there is a danger that foods not approved for human consumption will find their way onto market shelves. This lends support for creation of an independent government regulatory system to ensure that consumers are not exposed to bio-engineered foods that have not been approved for human consumption.").

253. Bratspies, *Myths of Voluntary Compliance*, *supra* note 132, at 609-10.

courts doing the same.[254] More disturbing, however, is the fact that the FDA's reliance on the conclusions and research provided by manufacturers prevented a reasonable and thorough review of the scientific issues and data related to the genetically modified alfalfa.

A model statute creating an independent[255] agency for bioengineered products should also include specific mandates requiring a multi-step review process that uses neutral experts to review proposals for bioengineered foods and technology. This multi-step process should consist of reviews by two or more committees made up of scientists and policy experts capable of polling and determining consumers' preferences and needs. Every stage of the review process should also include mandatory disclosure to the public, through notices and public announcements, and opportunities for the public to submit comments and requests.

A provision stipulating that biotechnology and policy experts must make up the review committees would help balance the tension caused by the lag between technological advances and scientific understanding of their potential risks.[256] In addition, this hybrid composition would also help balance the public's concern for safety, the preference for a precautionary approach, and the government's and agencies' desire to encourage market growth.[257] To the extent that the public's desire for a precautionary approach conflicts with the desire for market growth, biotechnology and policy experts can join forces to determine whether the approval of certain products presents risks that might destabilize traditional farmers, lead to consumer dissatisfaction and angst, or constitute such an unknown factor that it would be best to hold off dissemination until more information is gathered. In addition, lawmakers and policy experts should encourage the funding of independent research in order to balance the research funded by manufacturers.[258] For example, additional tax deductions for non-profit organizations that fund independent research about the risks of

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254. Monsanto v. Geertson Seeds Farms, 130 S. Ct. 2743, 2758 (2010).

255. *See* Kagan, *supra* note 2, at 2250-51 ("Accepted constitutional doctrine holds that Congress possesses broad, although not unlimited, power to structure the relationship between the President and the administration, even to the extent of creating independent agencies, whose heads have substantial protection from presidential removal.").

256. *See generally* Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93 (2007) (discussing the actual and potential "environmental, human health, and economic risks" associated with the commercialization and use of genetically modified organisms).

257. *See* J.M. Migai Akech, Developing Countries at Crossroads: Aid, Public Participation, and the Regulation of Trade in Genetically Modified Foods, 29 FORDHAM INT'L L.J. 265, 296-97 (2006) (noting the need to balance the interests of all of the stakeholders when approving and implementing biotechnology to ensure public acceptance, inclusiveness, and legitimacy).

258. *See GMO Myths and Truths Report*, EARTHOPENSOURCE, *available at* http://earthopensource.org/index.php/3-health-hazards-of-gm-foods/3-3-myth-those-who-claim-that-gm-foods-are-unsafe-are-being-selective-with-the-data-since-many-other-studies-show-safety (last visited Apr. 12, 2013).

bioengineered foods to health, the environment, and traditional farming might be helpful.

These measures would shift the burden of risk assessment to the regulatory agency, rather than leaving it to manufacturers whose interests may conflict with those of consumers and traditional farmers. Furthermore, it would create more transparency in the approval process for bioengineered foods and restore credibility to the approving agencies.

The proposed congressional statute should also require a reformulation of a policy regarding GMO foods that reverses the "substantial equivalence" and "GRAS" presumptions.[259] For example, a standard that asks manufacturers to show cause as to why the genetic modification is not harmful to health and requires them to introduce evidence of consensus among scientists in the field would be a helpful start. Such a standard should also require more details from manufacturers and explicitly formulate rules regarding proper storage and dissemination of genetic products. The model statute should also contain a detailed standard as to what adequate storage, dissemination processes, and labeling practices are appropriate. To accomplish these goals, a congressional fact-finding investigation on the potential environmental and financial impact of bioengineered crops is needed to properly inform lawmakers. Previously litigated cases already provide information on the environmental detriments caused by bioengineered crops to farmers.[260] Litigation of these issues is expected to grow exponentially both by the Court's own admission, in its review of *Monsanto Co. v. Geertson Seed Farms*,[261] and according to the observations and measures under way by various consumer watch groups. A prudent Congress should resolve the issues quickly to avoid clogging the dockets and perpetuating additional inequities.

Congressional action will not occur without deliberate pressure from grassroots groups and advocates counterbalancing the existing pressure from biotech companies. To facilitate the creation of sophisticated grassroots efforts, more open and detailed educational programs regarding bioengineered foods are needed. These programs could help foster democratic participation in the proposed approval process during the administrative notice and comment period.

The creation of a temporary agency––having clear term limits, partial salaries, and partial performance bonuses––would serve as a great alternative, which could help cure the administrative inertia, lack of accountability and transparency that currently exist across the board in administrative governance. Whether it is an independent agency or a temporary renewable agency, the inclusion of a hybrid team of neutral biotechnology and policy experts as part of a multi-step review process is a necessary requirement.

An alternative to congressional action, particularly considering recognized

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259. Peck, *supra* note 22, at 260.

260. *See, e.g.*, Monsanto Co. v. Geertson Seeds Farms, 130 S. Ct. 2743 (2010); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.C. Cir. 2000).

261. 130 S. Ct. 2743.

congressional inertia in this area and recognized pressure from powerful public interest groups, would be to encourage reform movements at the state level. One possibility is to lobby for a uniform state code regulating genetically modified foods. At least one state, California, is leading the charge by contemplating legislation that would require adequate labels for genetically modified products.[262] This might prove to be a fruitful alternative, if preemption is not an issue. It remains to be seen whether the preemption doctrine will present an obstacle to these efforts. As it stands, unlike estate planning, marriage, and property, the federal government regulates foods.[263]

To the extent that Congress is not able to adequately address the interests of the states, perhaps a uniform bioengineering standard, which would permit the states to opt into the system, might be an option. The recent bills presented against bioengineered salmon and concerns from officials over how bioengineered foods might detrimentally impact their constituents indicate that the time might be ripe for such a measure.[264] In fact, *Massachusetts v. EPA*[265] indicates that states, as well as citizens, are wiling to take action against the regulating agencies' inertia in matters affecting the environment. Still, the value of congressional action lies in Congress's ability to engage all aspects of government and to provide a national forum to debate these issues. Ideally, such a debate would be most constructive if the reform could come from Congress so as to create clear expectations and responsibilities applicable to everyone.

In the meantime, judicial reform might be a fruitful avenue. From a judicial standpoint, pending congressional action, bioengineering might serve as a great test case for the evaluation of the ongoing and pervasive influence of presidential control over administrative issues. The Court has thus far avoided the issue of the constitutionality of presidential administration. It is telling, as Justice Kagan points out, that the Court has implemented the non-delegation doctrine, a pillar of administrative law, only twice—both times in 1935.[266] The non-delegation doctrine stands for the proposition that Congress must not delegate too broad a

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262. Proposition 37, which, if passed, would have made California the first state to require labeling of genetically modified foods. The California electorate ultimately voted against adoption of the bill by a vote of 48.6% to 51.4% on November 6, 2012, despite earlier indications of public preference for mandatory labeling. *See* SEC'Y OF STATE CAL., STATEMENT OF VOTE, NOVEMBER 6, 2012, GENERAL ELECTION 13 (Nov. 2012), *available at* http://www.sos.ca.gov/elections/sov/2012-general/sov-complete.pdf. Full text of the proposed change to the California Health and Safety Act can be found at SEC'Y OF STATE OF CAL., TEXT OF PROPOSED LAWS 110 (2012), *available at* http://vig.cdn.sos.ca.gov/2012/general/pdf/text-proposed-laws-v2.pdf#nameddest=prop37.

263. Ellison, *supra* note 33, at 351-52.

264. S. 229, 112th Congress (2011); S. 230, 112th Congress (2011); S., 1717, 112th Congress (2011).

265. 549 U.S. 497 (2007).

266. Kagan, *supra* note 2, at 2364 ("It is, after all, a commonplace that the nondelegation doctrine is no doctrine at all. In only two cases, both in 1935, has the Supreme Court struck down a federal statute on the ground that it delegated too much authority to the executive branch.").

power to the President.[267] Considering that the Court rarely checks congressional grants of power to the President, the Court's avoidance of the issue of Presidential Administration makes perfect sense. In *Public Citizen Health Research Group v. Tyson*,[268] the court avoided the issue of presidential participation in rulemaking.[269] In that case, "the court addressed the validity of a rule promulgated by the Occupational Safety and Health Agency governing ethylene oxide, including a challenge based on the argument that a critical portion of the proposed rule had been deleted based on a command from the Office of Management and Budget (OMB)."[270] Although it recognized that presidential involvement in the deletion of the rule presented a difficult constitutional issue, the court declined to address it, finding that the record did not support the claim.[271] A test case involving a challenge to the GRAS policy, based on the theory of improper exercise of control by the President's office in the food agencies' formulation of rules regarding bioengineered foods, might be a good point of attack. Such a suit might force the Supreme Court to determine once and for all whether Presidential Administration is constitutional. A successful challenge likely would invalidate the current GRAS standard. Still, there are no guarantees that, in the face of congressional silence and the Court's own endorsement of the substantial equivalent and GRAS presumptions, the Court would not limit its analysis to the Chevron doctrine and abstain from determining the validity of Presidential Administration. As a result, congressional action and statutory reform, as proposed above, remain the best route for change.

It seems clear that current congressional statutes delegating the authority to regulate traditional foods have not considered the advent of bioengineered foods.[272] Courts, in dealing with these issues, have, thus far, tried to extend the rationales applied to traditional foods to bioengineered foods. However, as

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267. Garry, *supra* note 8, at 926-27 (footnotes omitted) ("The textual basis for the nondelegation doctrine is found in Article I, Section 1 of the United States Constitution, which provides that 'all legislative Powers herein granted shall be vested in a Congress of the United States.' The Court has held that this vesting clause prohibits the delegating of legislative authority to the executive. However, because the Constitution empowers the executive branch to 'execute' the laws, the Court has also ruled that the nondelegation doctrine does not forbid administrative agencies from filling in the details of broad congressional statutes. Moreover, since the Constitution contains no express provision forbidding delegation, courts have held that Congress may constitutionally delegate rulemaking power to administrative agencies as long as Congress provides an 'intelligible principle' that limits the agency's decisionmaking authority.").

268. 796 F.2d 1479 (D.C. Cir. 1986).

269. *Id*. at 1507.

270. TODD B. TATELMAN, CONG. RESEARCH SERV., R41272, SUPREME COURT NOMINEE ELENA KAGAN: PRESIDENTIAL AUTHORITY AND THE SEPARATION OF POWERS 14 (2010), *available at* http://www.fas.org/sgp/crs/misc/R41272.pdf.

271. *Tyson*, 796 F.2d at 1507 (stating that the court had "no occasion to reach the difficult constitutional questions presented by OMB's participation" given its finding that the rulemaking record did not support agency's decision to delete the material in question).

272. *See* Federici, *supra* note 215, at 536-37.

discussed above, this analysis is flawed because it does not take into account the foreign nature of these foods.[273]

A change in the conceptual paradigm that has been guiding the regulatory agencies in assessing the potential risks of bioengineered foods is necessary to achieve a balanced treatment of genetically modified foods. The legal analysis underlying *Alliance for Bio-Integrity v. Shalala*,[274] and infringement cases like *Monsanto Co. v. Scruggs*,[275] reveals that courts have adopted a constrained rationale that agencies have followed since 1992.[276] That rationale, simply put, is that if a GMO product is deemed to have "substantial equivalence" to a natural product, then it is not harmful, and it deserves the same legal privileges and rights granted by patent law. These products also enjoy all the rights and acceptance given to foods that have been established for millennia.[277] The irony is that, though bioengineered foods are novel enough to be patented, food agencies still insist on treating them the same as traditional foods.[278] The fact remains that "genetically modified organisms" are still an unknown.[279] The decisions to treat them the same as regular foods was economically motivated rather than based on precautionary or safety concerns. In 1992,

> a [w]orking Group established by the Organi[z]ation of Economic Co-Operation and Development (OECD) to study how countries should go about evaluating the safety of GM foods. . . . The Working Group suggested that the substantial equivalence determination should be based upon three primary factors: (1) knowledge of the composition and characteristics of the traditional or parental product or organism; (2) knowledge of the characteristics of the new component(s) or trait(s) derived . . . ; (3) knowledge of the new product/organism with the new components or trait(s) . . . . For GM foods and food components determined to be substantially equivalent to the parental products, the Working Group believed that further safety concerns were likely to be "insignificant" and the GM food could be treated for regulatory purposes just like the natural counterpart. For foods and food components determined not to be substantially equivalent, the Working Group recommended that the regulatory agency focus on the identified differences between the GM food and its natural counterpart. Only when there was no basis whatsoever for comparisons with unmodified foods should the GM food be evaluated on the basis of "its own composition and properties.[280]

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273. *See* Ellison, *supra* note 33, at 362.

274. 116 F. Supp. 2d 166 (D.C. Cir. 2000).

275. 459 F.3d 1328 (Fed. Cir. 2006).

276. *See supra* notes 43-45 and accompanying text.

277. Lawrence, *supra* note 89, at 238-39.

278. *Id.*

279. Robertson, *supra* note 38, at 157, 168.

280. McGarity, *supra* note 40, at 428-29 (second and third alteration in original) (footnotes

The substantial equivalence[281] test also rears its head in the "materiality" test applied to determine whether to impose labeling requirements.[282] Courts need not even abandon the substantial equivalence test to reach more equitable results. For example, in the case of genetically modified salmon, there is an argument that the substantial equivalence rationale simply would not apply. Although a reviewing agency might determine that the genetically modified organism is equivalent to other elements found in natural salmons, a type of salmon, twice the size of a natural salmon and unlike other salmons, certainly runs the risk of contaminating the supply of natural salmon in the United States.[283] The visual of a fast reproducing salmon––despite the manufacturers' contention that there is only a 5% chance in fertility and that the fish will be contained in very restricted areas[284]––gives cause for pause.

The FDA's consideration of the approval of this salmon illustrates the impracticality of the substantial equivalence test.[285] As Justice Stevens pointed out in his dissent in *Monsanto*, a similar danger of contamination exists with

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omitted).

281. Erik Millstone et al., *Beyond 'Substantial Equivalence*,*'* 401 NATURE 525, 526 (1999) (contending that the substantial equivalence standard "should be replaced with a practical approach which would actively investigate the safety and toxicity of GM foods rather than merely taking them for granted, and which could give due consideration to public-health principles as well as to industrial interests").

282. Lara Beth Winn, *Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?*, 54 FOOD & DRUG L.J. 667, 670, 675 (1999) (arguing that the "FDA should have used the same materiality standard in the biotech food labeling context" and pointing to three examples in which the FDA considered whether certain information could "help consumers make better food decisions" if the FDA required manufacturers to disclose information).

283. Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 MINN. J. L. SCI. & TECH. 457, 459-61, 479-83 (2005) (discussing the failure of the FDA to regulate GloFish, the first commercially available transgenic animals on the market, and how this lack of regulation will affect the approval of transgenic salmon, giving rise to potential human and environmental consequences).

284. Smith, *Who Owns Your Dinner?*, *supra* note 11, at 194 ("AquaBounty has attempted to quash concerns in several ways. In response to concerns over the decimation of the wild salmon population, it claims that all the fish would be bred female and sterile—though if nature has taught us anything, a small percentage may be able to breed. Indeed, even AquaBounty has conceded that merely 5% may be able to breed. If so, the salmon would be bred in confined pools where the potential for escape would be minimal." (footnotes omitted)).

285. Jesse Male, Note, *The State of Genetically Engineered Crops in the European Union Following* Monsanto v. Italy *and the Adoption of a New Regulatory Framework for Genetically Modified Food and Feed*, 9 DRAKE J. AGRIC. L. 439, 441-52 (2004) (comparing the U.S. and EU approaches to regulating GMOs and describing the modified EU three-part regulatory framework for GMOs).

genetically modified seeds and plants.[286] Compared to the international approaches on these issues, we fall short. We could learn a great deal from the European Union's scientific review process that largely bases its decisionmaking on expert input. We have continuously applied old methods to a new field, and it is now time to create a separate agency with the expertise to target specific issues related to biotechnology. In an age where technology is progressing at a rapid rate, it is crucial for Congress and agencies to adopt a standard[287] that encapsulates the biotech companies' promises of benefits as well as concerns for consumers' health.[288]

VII. THE EUROPEAN APPROACH: A HELPFUL MODEL FOR GRASSROOTS LOBBYING?

In the absence of congressional action, grassroots lobbying continues to be a great tool for bringing awareness and exerting pressure on lawmakers. The European approach to bioengineered foods serves as a great model for the United States. Unlike the United States, Europe has used a precautionary policy for biotechnology.[289] This has, in great part, been due to the active and vocal role played by the European public in framing food policies.[290] From the inception, citizens in many European countries have made it clear that they want more transparency and precautions regarding these products.[291] This form of participation is not completely foreign to the American structure as public feedback from interest groups is built into the comments segment of administrative proceedings.[292] For many of our administrative decisions, however, there is no required hearing and comments procedure. Consequently, agencies rarely schedule them, and this has insulated us from the issues and inhibited our ability to remain informed. The European approach, in contrast, has

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286. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2762-63, 2768 (2010) (Stevens, J., dissenting) (recognizing "substantial evidence that [Monsanto's Roundup Ready Alfalfa] genes could transfer to other plants").

287. David L. Devernoe, Note, *Substantial Equivalence: A Valid International Sanitary and Phytosanitary Risk Assessment Objective for Genetically Modified Foods*, 51 CASE W. RES. L. REV. 257, 288 (2000) (stating that "where substantial equivalence evaluates characteristics of the GM food that are obvious from the type of modification, in-depth assessment evaluates all health-related criteria of the GM food, regardless of the type of modification" (footnote omitted)).

288. Vern R. Walker, *Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States*, 31 ENVTL. L. REP. 10040, at 6-7 (2001) (advocating for adherence to the "precautionary principle" and the adoption of a "reasonable certainty that no harm will result" standard as a substitute to current GRAS standards).

289. *See* Francer, *supra* note 15, at 278.

290. Marc Firestone, *A Quick Look at Two Areas of Doctrinal Difference Between EU and U.S. Decision Makers*, 20 TUL. J. INT'L. & COMP. L. 1, 3 (2011).

291. *Id.*

292. *See generally* Reiss, *supra* note 52.

incorporated more direct participation. For example, in the EU, authorization to place GMO products on the market

> [r]equires a case-by-case assessment of the potential risks to human and animal health of each GMO to be placed on the market. Applications are forwarded to the EU member-state where the GMO or derived product is to be placed on the market for the first time. The application must be accompanied by data and results obtained from laboratory and greenhouse research, as well as from developmental releases, concerning the ecosystems that could be affected by the use of product, and by an assessment of any risks to human health and the environment related to the GMO.
>
> The risk assessment is performed by the Competent Authority (CA) of the EU member states that receives the application. The other member-states are invited to provide comments. If the CA confirms in its opinion that the information provided by the applicant establishes that the placing on the market of the GMO would not pose a risk to human health and the environment, and if no objections are raised by other member-states, consent is given to the placing on the EU market by CA of the member[-]state that had received the application.[293]

Additional processes are in place to address the eventuality of an objection by any of the member states. The Commission also has its own scientific teams at its disposal to render an opinion on the subject of an objection. This multi-step governmental investigation could be a very useful model in the United States. Implementing checks on biotech companies, as well as on governmental agencies, through scientific review of the companies' research may eliminate some of the tension surrounding the apparent lack of transparency in U.S. agencies' evaluation of genetically modified foods. This system also facilitates accountability. For example, during the late 90's and in 2001, due to lack of support for Directive 90/220/EEC concerning GM maize and rapeseed varieties, member-states invoked the safeguard clause of the approval procedures, despite the supervising agencies' assessment of safety, "on nine separate occasions . . . three times by Austria, twice by France, and once each by Germany, Greece, Luxembourg, and the United Kingdom."[294] This invocation is a testament to the power of grassroots lobbying and to the transparency existing in these countries regarding such procedures. As a result, concerned citizens in these countries mounted such resistance that their governments refused to introduce these products into their market.[295] This type of transparency and willingness to

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293. GOVERNING RISKS, *supra* note 60, at 58-59.

294. *Id*. at 59, 62.

295. Jamie E. Jorg Spence, Note, *Right to Know: A Diet of the Future Presently Upon Us*, 39 VAL. U. L. REV. 1009, 1023-24 (2005) (footnotes omitted) ("The public perception of GM foods, like that of the scientific community, is certainly not uniform, especially across the Atlantic. In Europe the public sentiment has been quite negative. Between 1992 and 1996, consumers in

educate the public is lacking in the United States. In addition, agencies in the United States do not conduct as strict a review of the scientific data provided by the manufacturers.[296] The FDA's potential approval of a bioengineered salmon has revived concerns about the increasing presence of unlabeled, genetically altered foods in our food supply.[297] These concerns are currently uniting disparate groups, forcing certain members of Congress to speak on behalf of constituents who depend on the commercial farming of fish and livestock, of consumer groups, and of average consumers eager to be informed about their food consumption.[298] These grassroots pushes are bearing some fruit. Though courts still give great deference to the agency when evaluating the FDA's decision not to require labeling under the "material difference" standard,[299] the agency, itself, has had to be more transparent in its handling of the bioengineered salmon. For example,

> concerned about the negative public image they may receive should they approve the NADA relating to the AquaBounty salmon . . . the FDA allowed the public to participate in the hearing, and released a preemptive informational background document in August 2010 to better prepare the public for what it would hear. The FDA has stated that if it does approve the AguAdvantage salmon NADA, the approval will include a label that identifies the different types of rDNA constructs that accompany the separate forms of the fish to the growers. These different types include the fish eggs, the young fish, called fry, and the more mature fish that are sold to growers who then bring the fish to market for sale. However, the FDA has made it clear that these labels are much different than the labels that would be placed on the actual food in the marketplace, and the decision to label has not yet been made.[300]

As in Europe, pressure from an informed public is a necessary part of reforming our approach to biotechnology.[301]

Europe formed activist groups that protested the new foods, and by fall of 1999, successfully convinced the UK and EU regulatory agencies to place moratoriums on the growth of these products and to stifle their import. Furthermore, Europeans appear to be becoming less supportive of biotechnology in general.").

296. *See* Ellison, *supra* note 33, at 348 (describing the U.S. view that GMO technology is safe).

297. Consumers Diverge on GE Salmon Labels and "Material Difference," 16 FDA WEEK (Sept. 24, 2010).

298. *See, e.g.*, Letter from Sen. Mark Begich to Margaret A. Hamburg, Comm'r of Food & Drugs (Sept. 28, 2010), *available at* http:stopgefish.files.wordpress.com/2010/09/100928-hamburg-fda-ge-salmon-final.pdf.

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

300. Smith, *Who Owns Your Dinner?*, *supra* note 11, at 195. For additional information regarding the AguAdvantage Salmon, see *id*. at 193 and Graham M. Wilson, Note, *A Day on the Fish Farm: FDA and the Regulation of Aquaculture*, 23 VA. ENVTL. L.J. 351, 384, 390-93 (2004).

301. *See generally* Homer, *supra* note 11, at 106.

Furthermore, Monsanto's growing monopoly over seeds has generated growing concerns that genetically engineered foods, and their subsequent patents, will lead to privatization of the food supply, which would handicap traditional farming and create a subjugated farming system, rather than opening the food supply to less privileged markets.[302] In *Monsanto Co. v. Scruggs*,[303] for example, the court reaffirmed the principles of patent law, ruling that a farmer should not use replicate versions of a patented seed without permission.[304] It is particularly troubling that "Monsanto has been remarkably aggressive in its patent protection, hiring people to investigate farmers to expose possible patent infringement, and it has brought suits against several farmers and independent seed companies."[305] While food regulating agencies are becoming increasingly aware of these tensions, they seem to need guidance and additional grant of authority from Congress to adopt a precautionary approach.

If the current tension around these products is to be resolved, the interests of the public must become part of all administrative deliberations. In addition, Congress and regulating agencies must reconsider current presumptions of equivalence between biotechnology and traditional foods and must implement a thorough evaluation process with experts/scientists. A more open and detailed educational program regarding these foods and their processes also needs to occur to ensure democratic participation in the approval process during the administrative comment period.

CONCLUSION

The biotechnology context illustrates that deference to Presidential Administration in the absence of specific guidance by Congress renders agencies vulnerable to unilateral usurpation of power by one branch and to market interests. As a consequence, the goals of the doctrine of separation of powers are undermined. The European approach to biotechnology provides a good balance of all the interests at stake, while allowing public education and democratic

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302. *See* York, *supra* note 49, at 432-33.

303. 459 F.3d 1328 (Fed. Cir. 2006); *see also* Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010).

304. Smith, *Who Owns Your Dinner?*, *supra* note 11, at 192-93 ("In Monsanto v. Scruggs, Monsanto accused a farmer of illegally using its Roundup Ready technology, without properly compensating Monsanto. Scruggs argued that he purchased the seeds without ever signing a licensing agreement, and thus, under the doctrine of patent exhaustion, he had the right to use the seeds free from patent restriction. The doctrine of patent exhaustion states that the unrestricted first sale by a patentee of his patented article exhausts his patent rights in the article. However, the court found that the doctrine of patent exhaustion was inapplicable, stating, '[t]he fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology, [and furthermore] [a]pplying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder.'" (alterations in original) (footnotes omitted)).

305. *Id*. at 192.

participation. Permitting limited and strictly regulated GMO products to be disseminated in the market, the European approach views the interests and concerns of the public as primordial. Such a model constitutes an effective check on all branches of government and fosters greater trust in the democratic system.

The reforms proposed in this Article are necessary because bioengineered crops are already harming traditional farming both domestically and internationally, not the least of which is through contamination. Also, farmers around the world have become vulnerable to intellectual property suits by biotech companies; poor farmers in developing countries are particularly affected. Additionally, the FDA's consideration of bioengineered salmon raises a variety of other issues regarding the safety of our wildlife and containment of bioengineered animals released into the wild.[306] Little is known about the potential risks, and it is likely that this will remain the case for decades. In the meantime, safety measures must be put in place to protect citizens, the environment, and our wildlife.

The President, designated with established duties under the Constitution, is traditionally not part of lawmaking. A lower standard of scrutiny in cases evidencing presidential involvement, as proposed by then Professor Kagan, would be even more detrimental to the public's ability to demand transparency and participation in administrative processes. As it stands, and as exemplified by *Alliance for Bio-Integrity v. Shalala*,[307] courts' deference to regulatory agencies does not adequately question the assumptions inherent in the substantial equivalence presumption. The exercise of Presidential Administration in the case of biotechnology has contributed further to this lack of transparency. A lower standard of scrutiny that encourages presidential involvement and increases courts' deference to agencies' decision-making would be even more detrimental to the public and to our democratic system.

306. *See generally* Stephanie Sholwalter-Otts, *U.S. Regulatory Framework for Genetic Biocontrol of Invasive Fish*, J. BIOLOGICAL INVASIONS (2012).

307. 116 F. Supp. 2d 166 (D.C. Cir. 2000).