

# REFORMING THE “UNCOORDINATED” FRAMEWORK FOR REGULATION OF BIOTECHNOLOGY

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## I. INTRODUCTION

The AquaBounty AquAdvantage salmon is symbolic of much that is wrong or inadequate with the regulatory framework for agricultural biotechnology in the United States.<sup>1</sup> The Food and Drug Administration (FDA) was recently

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1. See Helena Bottemiller, *Alaska Senators Seek GE Salmon Ban in Budget*, FOOD SAFETY NEWS, Oct. 19, 2011, <http://www.foodsafetynews.com/2011/10/alaska-senators-seek-ge-salmon-ban-in-budget-debate/> (“Developed by Massachusetts-based AquaBounty Technologies, the engineered fish, formally known as AquAdvantage salmon, are essentially Atlantic salmon with an inserted growth gene from a Chinook salmon and an antifreeze gene from an ocean pout. They grow twice as fast as typical Atlantic salmon and require approximately 10 percent less feed to achieve the same weight.”).

on the verge of approving AquAdvantage as the first genetically engineered salmon for human consumption when Congress stepped in to halt the approval process.<sup>2</sup> The mounting opposition that stopped the FDA approval not only cited major environmental, health, and economic concerns with the salmon, but also the failure of the FDA approval process to require adequate safety assessment, a general lack of transparency through the approval process, and public engagement expressing their concerns.<sup>3</sup> The FDA relied heavily on only four studies in the approval process, with one of the studies nearly twenty years old, and the other three supplied by AquaBounty itself.<sup>4</sup> In addition, while the National Environmental Policy Act (NEPA) requires the agency to prepare an environmental impact statement for any major regulatory action that could significantly impact the environment, it has not done so to date.<sup>5</sup> To make matters worse, even though a recent poll showed that an overwhelming seventy-eight percent of Americans do not want genetically engineered salmon to be approved without more research, the FDA considered putting the salmon on the market without requiring labeling.<sup>6</sup> In all, not only was the FDA resting its approval of the ge-

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2. Letter from Mark Begich et al., U.S. Senators, to Margaret A. Hamburg, M.D., Comm'r, U.S. Food & Drug Admin. (July 15, 2011), *available at* <http://stopgefish.files.wordpress.com/2011/07/senate-july-2011-hamburg-fda-ge-salmon-final.pdf>; Letter from Don Young et al., Members of Congress, to Margaret Hamburg, M.D., Comm'r, U.S. Food & Drug Admin. (July 15, 2011), *available at* <http://stopgefish.files.wordpress.com/2011/07/house-fish-letter-final-final-7-15-11.pdf>; *see also* Press Release, Ctr. for Food Safety, U.S. Congress Turns Up the Heat on Genetically Engineered Salmon (July 18, 2011) [hereinafter Congress Turns Up the Heat], *available at* <http://www.centerforfoodsafety.org/2011/07/18/u-s-congress-turns-up-the-heat-on-genetically-engineered-salmon/> (describing Congressional action opposing genetically engineered salmon).

3. Begich, *supra* note 2; Young, *supra* note 2.

4. *Meeting on AquAdvantage Salmon Veterinary Med. Advisory Comm.*, U.S. Food & Drug Admin. 293 (2010) (statement of Wenonah Hauter, Exec. Dir., Food & Water Watch), *available at* <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230471.pdf>.

5. Press Release, Food & Water Watch, Troubling Emails Reveal Federal Scientists Fear FDA Approval of Genetically Engineered Salmon: "May They [the FDA] Should Watch Jurassic Park" (Nov. 15, 2010) [hereinafter Troubling Email], *available at* <http://www.foodandwaterwatch.org/pressreleases/troubling-emails-reveal-federal-scientists-fear-fda-approval-of-genetically-engineered-salmon/>.

6. *Meeting on AquAdvantage Salmon*, *supra* note 4, at 292–93; *see also* Press Release, Food & Water Watch, National Consumer Organization: Halt Approval of Genetically Engineered Salmon Until FDA Conducts Tests on Long-Term Health Effects of Consuming Genetically Engineered (GE) Meat (Sept. 20, 2010) [hereinafter Halt Approval of Salmon], *available at* <http://www.foodandwaterwatch.org/> (search "halt approval"; then follow "National Consumer Organization: Halt Approval . . . (GE) meat" hyperlink) (explaining that a poll, conducted by Food & Water Watch and Lake Research Partners, further demonstrated that ninety-one percent of Americans

netically engineered salmon on flawed scientific principles, it was doing so without adequate risk assessment and safety testing, without a monitoring plan in place for post-market risk management, and without coordination with the Environmental Protection Agency (EPA) to adequately evaluate potential environmental risks.

Biotechnology<sup>7</sup> has the potential to yield significant benefits to mankind, particularly in the area of agriculture and food production, but can also present considerable risks to human health and the environment if left unchecked. In the United States, no body of law specifically governs biotechnology.<sup>8</sup> Recognizing that some oversight was necessary, the White House Office of Science and Technology Policy (OSTP) promulgated the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework) in 1986, which utilized existing laws rather than enact new ones.<sup>9</sup> Historically, the United States has paid little attention to the process of biotechnology, reasoning that it was not inherently risky.<sup>10</sup> OSTP's underlying focus was the promotion of growth and competitiveness for what was then an emerging and highly promising biotechnology industry.<sup>11</sup> Since then, despite significant flaws and a history of deficiencies in oversight, this outdated framework and its policies continue to be the framework for regulating agricultural biotech products in the food system.

believe that until the agency can perform adequate safety studies, the FDA should not approve transgenic pigs, chicken, and cattle into the food supply).

7. See Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,906 (Dec. 31, 1984) (defining biotechnology as the application of "biological systems and organisms to technical and industrial processes"); see also PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 2 fig.1.1 (2004) [hereinafter PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION], available at [http://www.pewhealth.org/uploadedFiles/PHG/Content\\_Level\\_Pages/Reports/food\\_biotech\\_regulation\\_0404.pdf](http://www.pewhealth.org/uploadedFiles/PHG/Content_Level_Pages/Reports/food_biotech_regulation_0404.pdf) (explaining that biotechnology "encompasses techniques used for centuries, including traditional plant and animal breeding techniques and the use of microorganisms in fermentation and food processing" and defining "modern biotechnology" to include "techniques that involve the direct manipulation of genetic materials, including recombinant DNA (rDNA) techniques and cell fusion," whereas "recombinant DNA technology generally involves the isolation and *in vitro* manipulation of discrete DNA segments containing the genetic material of interest and their insertion into a host organism").

8. See PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 1, 3.

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

10. Gregory N. Mandel, *Toward Rational Regulation of Genetically Modified Food*, 4 SANTA CLARA J. INT'L L. 21, 21 (2006) [hereinafter Mandel, *Toward Rational Regulation of Genetically Modified Food*].

11. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302-03.

The root of numerous controversies surrounding genetically engineered (GE)<sup>12</sup> foods can be traced, in large part, to an inadequate regulatory system that divides power and oversight among three government agencies: the EPA, FDA, and USDA.<sup>13</sup> The Coordinated Framework implicates at least twelve existing federal laws, none of which are designed to handle novel genetically engineered foods or to address the potential risks these products may present.<sup>14</sup> The agencies were left to creatively interpret each statute to fulfill their regulatory objectives. This system has “led to a regulatory approach that is passive rather than proactive about risks, has difficulty adapting to biotechnology advances, and is highly fractured.”<sup>15</sup> As a result, it fails to adequately protect consumers and safeguard the environment and our ecosystems.

Potential commercial benefits cannot be fully realized from the biotech industry’s perspective because the regulatory scheme over-regulates and subjects members to multiple agency jurisdictions and a complex, but haphazard maze of overlapping rules, regulations, and processes.<sup>16</sup> It creates uncertainties that deter

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12. “New varieties of animals, plants, and microorganisms created through genetic engineering are referred to as being ‘genetically engineered,’ ‘bioengineered,’ or ‘transgenic.’ The term ‘genetically modified’ is technically imprecise since virtually all food has been modified on a genetic level by humans through selection and conventional breeding.” PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 2 fig.1.1. Genetic engineering involves inserting genes responsible for particular traits in one species of organism into the genome of a different, unrelated species. *Id.* A “transgene” is a gene or genetic material that has been transferred naturally or by GE techniques from one organism to another. *See id.* at 103 fig.4.1. These terms will be used interchangeably throughout this Article.

13. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,303 (describing the relevant agencies and their functions in the administration of the Coordinated Framework).

14. *See* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 7 tbl.1.1 (identifying the twelve federal laws as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Plant Protection Act (PPA), the Virus Serum Toxin Act (VSTA), the Animal Health Protection Act (AHPA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA), the Animal Damage Control Act (ADCA), the Animal Welfare Act (AWA), and the National Environmental Protection Act (NEPA)). *See generally* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (describing the applicable laws).

15. Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2172 (2004) [hereinafter Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*] (arguing that most problems and concerns arising in this field are the result of a deficient statutory and regulatory structure).

16. *Id.* at 2172.

investment in new technologies or firms and discourages research and development efforts.<sup>17</sup>

This Article will focus on how the United States can reform the current regulatory system for agricultural biotechnology given the significant political, economic, and social challenges the regulations governing this industry pose. The proposed reform will emphasize four key objectives to be achieved through legislative mandates. First, the Coordinated Framework was built upon dated scientific principles<sup>18</sup> that have since proven to be flawed, and the doctrine of “substantial equivalence,”<sup>19</sup> the premise and driving force behind the U.S. regulatory system, is no longer credible and should be abandoned. Second, systematic risk assessment and safety testing must be incorporated into the pre-release or pre-market review process. Third, post-market monitoring must be instituted as part of the overall risk management program. Lastly, a system of coordination should be developed for the three agencies involved in biotech monitoring.

Aside from legislative changes, policy objectives should strive to encourage independent research and investments. Transparency should be improved because continual success for the industry will depend on society’s willingness to purchase and consume food produced through biotechnology.<sup>20</sup> In order for this to take place, consumers must trust that regulators are being forthright with them while exercising proper oversight.<sup>21</sup>

## II. LOOKING BACK: LESSONS LEARNED

### A. *Still Forcing Square Pegs Into Round Holes—Who Is Regulating What?*

Currently, determining which laws apply and which agency governs agricultural biotechnology depends on the nature of the organism and the product’s intended use.<sup>22</sup> Based on the characterization and claims the producer makes, a GE product can be subjected to multiple and overlapping rules and processes of

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17. Mandel, *Toward Rational Regulation of Genetically Modified Food*, *supra* note 10, at 38–39.

18. See generally Don Lotter, *The Genetic Engineering of Food and the Failure of Science—Part 1: The Development of a Flawed Enterprise*, 16 INT’L J. SOC. AGRIC. & FOOD 31 (2009) (describing the scientific developments related to genetically engineered food).

19. *Genetic Engineering at a Historic Crossroads*, SIERRA CLUB (Mar. 2001), <http://www.sierraclub.org/biotech/report.asp>.

20. Rebecca M. Bratspies, *Biotechnology, Sustainability and Trust*, 18 KAN. J.L. & PUB. POL’Y 273, 275 (2010) [hereinafter Bratspies, *Biotechnology, Sustainability and Trust*].

21. *Id.*

22. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 8.

the three regulatory agencies under the Coordinated Framework.<sup>23</sup> It can also bypass the framework entirely.<sup>24</sup> The Government Accountability Office (GAO) pointed to these types of problems in a November 2008 report.<sup>25</sup> Among the shortcomings mentioned is the lack of a coordinated program “for monitoring and evaluating the use of marketed GE crops to determine whether they are causing (1) undesirable effects to the environment or economic harm to non-GE segments of agriculture through the unintended spread of GE traits or (2) food safety concerns, such as the unintentional introduction of pharmaceutical or industrial compounds into the food supply.”<sup>26</sup> GAO advised the three agencies to develop a risk-based strategy to monitor the use of GE crops, which remained mostly unimplemented a year later.<sup>27</sup>

Since many statutes utilized under the Coordinated Framework predated the advent of biotechnology, each of the three agencies, over time, adopted its own haphazard patchwork of rules and guidelines to address the competing needs of the industry, its duty to protect the public and the environment, and to compensate for the deficiencies in the statutory and regulatory structure.<sup>28</sup>

## 1. *USDA*

The USDA is responsible for protecting and promoting American agriculture.<sup>29</sup> In that role, a primary duty is to regulate potential noxious weeds<sup>30</sup> and

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23. *See id.* “For example, the development of crop plants that were genetically engineered to make their own pesticides presented the agencies with a product that was simultaneously a potential plant pest, a food, and a pesticide.” *Id.*

24. *See* discussion *infra* Part III.B.4.

25. U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-09-60, GENETICALLY ENGINEERED CROPS: AGENCIES ARE PROPOSING CHANGES TO IMPROVE OVERSIGHT, BUT COULD TAKE ADDITIONAL STEPS TO ENHANCE COORDINATION AND MONITORING (2008).

26. *Id.* at 4; *see also* Carey Gillam, *Special Report: Are Regulators Dropping the Ball on Biocrops?*, REUTERS, Apr. 13, 2010, <http://www.reuters.com/article/2010/04/13/us-usa-gmos-regulators-idUSTRE63C2AJ20100413> (describing the GAO report).

27. GOV’T ACCOUNTABILITY OFFICE, *supra* note 25, at 46; Gillam, *supra* note 26.

28. *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–03 (June 26, 1986) (calling for the application of preexisting laws to the regulation of the developing biotechnology industry); *see also* Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2172 (“Though the history of biotechnology is relatively short, it already is filled with numerous regulatory lapses . . . . Considering that genetically modified products are regulated pursuant to statutes enacted decades prior to the advent of biotechnology itself, these deficiencies are not entirely surprising.”).

29. USDA, STRATEGIC PLAN FY 2010–2015 iv (2010).

30. Plant Protection Act, 7 U.S.C. § 7702(10) (2006) (defining “noxious weed” to include “any plant or plant product that can directly or indirectly injure or cause damage to crops . . . ,

plant pests<sup>31</sup> that can harm the agricultural industry.<sup>32</sup> In the exercise of authority derived from predecessors to the Plant Protection Act (PPA),<sup>33</sup> the Animal and Plant Health Inspection Service (APHIS) within the USDA classified most GE plants as plant pests or potential plant pests.<sup>34</sup> Thus, APHIS became responsible for the regulation of GE organisms and products pursuant to the PPA.<sup>35</sup> Under the PPA, a “regulated article”<sup>36</sup> must receive authorization from APHIS prior to introduction or release into the environment.<sup>37</sup>

Authorization from APHIS can come through a notification or permitting process.<sup>38</sup> Simple notification to APHIS prior to release is sufficient for most GE plants. In fact, nearly ninety-nine percent of field tests, imports, and interstate movement of GE plants take place under the notification, rather than the permit requirements of the PPA.<sup>39</sup> “Prior to conducting a field trial of a new transgenic plant, a developer must perform a risk evaluation on the plant to determine whether the plant may be a plant pest. No consideration of any other risks, such as other human health or environmental risks” is required.<sup>40</sup> When the permit

livestock, poultry, or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment”).

31. *Id.* § 7702(14) (defining “plant pests” to include any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: (A) A protozoan, (B) A nonhuman animal, (C) A parasitic plant, (D) A bacterium, (E) A fungus, (F) A virus or viroid, (G) An infectious agent or other pathogen, (H) Any article similar to or allied with any of the articles specified in the preceding subparagraphs).

32. *Id.* § 7712 (granting the Secretary of Agriculture the authority to regulate noxious weeds and plant pests).

33. *See* Mandel, *Toward Rational Regulation of Genetically Modified Foods*, *supra* note 10, at 31 (noting the Plant Protection Act, enacted in 2000, essentially consolidated authority from two previous statutes, the Federal Plant Pest Act and the Federal Plant Quarantine Act). Both were originally enacted to regulate non-indigenous plant species. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,342–43 (June 26, 1986).

34. 7 C.F.R. § 340.2 (2012).

35. *See* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 7.

36. 7 C.F.R. § 340.1 (defining “regulated article” to include “[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any genera or taxa designated in § 340.2 [a list of known plant pests] and meets the definition of plant pest, or is an unclassified organism . . . altered or produced through genetic engineering which [APHIS] determines is a plant pest . . .”).

37. Plant Protection Act, 7 U.S.C. § 7711(a); 7 C.F.R. § 340.0.

38. 7 C.F.R. §§ 340.3–.4.

39. COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. III: HERBICIDE-TOLERANT SOYBEAN 4 (2001), available at [http://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study4.pdf](http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study4.pdf).

40. Mandel, *Toward Rational Regulation of Genetically Modified Food*, *supra* note 10, at 33 (citing 7 C.F.R. § 340).



process is triggered for the remaining one percent, the primary emphasis is confinement in the field site to prevent the plants or their progeny from cross-contamination with other plants and from persisting in the environment.<sup>41</sup> An applicant can also petition APHIS to declare that a GE plant is not a plant pest and therefore should be given “non-regulated status.”<sup>42</sup> Once the petition is granted, the plant is no longer subject to any APHIS oversight.<sup>43</sup> Thus, there is no post-market surveillance to monitor how the GE plant will fare over time.

Since APHIS is required to carry out its regulatory mandates while promoting agriculture, including the biotech industry, critics have argued that this conflict of interest would prevent APHIS from objectively assessing the safety of new biotech products.<sup>44</sup> This criticism is particularly valid as the next generation of GE products comes online with significant profit outlooks for the biotech industry, but potentially even greater impact to human health and the environment. Field-testing, for example, of transgenic pharmaceutical-producing plants can pose significant risks to humans if the plants contaminate other food plants, and the approval and release of transgenic insects for pest management on farmland can have widespread ecological consequences and impact to food sources. The current regulatory framework for the USDA to regulate GE plants and products is wholly insufficient in managing these types of risks. In fact, contamination from pollen “drift” has already proven to be economically devastating.<sup>45</sup> It is estimated that GE contamination to U.S. corn crops alone could lead to lost income of over ninety million dollars for organic farmers.<sup>46</sup> An example was Terra Prima, a small organic tortilla chips producer who suffered a loss of \$150,000 and was forced to recall 87,000 bags of chips it exported to Europe after scientific testing detected GE corn in the chips, which was unacceptable under European Union (EU) regulations.<sup>47</sup>

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41. See 7 C.F.R. § 340.4.

42. 7 C.F.R. § 340.6.

43. *Id.*

44. BD. ON AGRIC. & NATURAL RES., NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 19 (2002).

45. See generally K.L. HEWLETT & G.S.E. AZEEZ, THE ECONOMIC IMPACTS OF GM CONTAMINATION INCIDENTS ON THE ORGANIC SECTOR (2008), available at [http://orgprints.org/12027/1/The\\_Economic\\_Impacts\\_of\\_GM\\_Contamination\\_Incidents\\_on\\_the\\_Organic\\_Sector.pdf](http://orgprints.org/12027/1/The_Economic_Impacts_of_GM_Contamination_Incidents_on_the_Organic_Sector.pdf) (highlighting the economic costs of GM contamination on organic production).

46. *Id.*

47. *Id.*; see also Sarah L. Kirby, *Genetically Modified Foods: More Reasons to Label than Not*, 6 DRAKE J. AGRIC. L. 342, 358 (2001) (discussing instances of problems with genetic drift).

## 2. FDA

The FDA is responsible for the safety of all food products and animal feeds in the United States, with the exception of meat and poultry.<sup>48</sup> Meat and poultry are regulated by the USDA.<sup>49</sup> The Center for Food Safety and Applied Nutrition within the FDA is charged with overseeing the safety of food created from GE crops.<sup>50</sup> The primary statutory authority is the Federal Food, Drug, and Cosmetic Act (FFDCA), even though no provisions expressly cover GE foods.<sup>51</sup> The FFDCA simply authorizes the FDA to regulate “adulterated foods” and “food additives.”<sup>52</sup> Pursuant to FDA regulations, GE plants are not treated any differently from conventionally modified plants.<sup>53</sup> The FDA has determined that “[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,” and therefore will be generally recognized as safe (GRAS) by experts.<sup>54</sup> This regulatory policy is based solely on chemical similarity, with no risk assessments or safety reviews, and “no biological, toxicological, or immunological data to back up the assumption of safety.”<sup>55</sup>

Further, it is the manufacturer, not the FDA, which makes the initial determination whether a food or food additive is GRAS.<sup>56</sup> The manufacturer does

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48. *What Does FDA Regulate?*, FOOD & DRUG ADMIN. (June 21, 2012), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>.

49. *See* Poultry Products Inspection Act, 21 U.S.C. §§ 451–472 (2006); Federal Meat Inspection Act, 21 U.S.C. §§ 601–695 (2006); Egg Products Inspection Act, 21 U.S.C. §§ 1031–1056 (2006).

50. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 7.

51. *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399d (2006); *see also* Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2218 (noting that FFDCA does not specifically address GE foods).

52. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 342, 348. Adulterated food is defined as food that “bears or contains any poisonous or deleterious substance which may render it injurious to health.” *Id.* § 342(a). Food additives are defined as “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food.” *Id.* § 321(s).

53. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984–85 (May 29, 1992).

54. *Id.* at 22,985.

55. Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 KAN. J.L. & PUB. POL’Y 393, 409 (2007) [hereinafter Bratspies, *Some Thoughts*].

56. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,989.

not need to, but may report to the FDA that it has made a GRAS determination to benefit from an FDA affirmation.<sup>57</sup> Because of the lax oversight, the FDA's regulations governing GE foods and food products could be considered primarily voluntary.<sup>58</sup> The FDA believes that manufacturers would voluntarily consult with the agency regarding each GE product prior to introduction to the marketplace.<sup>59</sup> In addition, the FDA does not require labeling to identify GE foods because they do not differ materially from their conventional counterparts.<sup>60</sup> In practice, this policy creates few incentives for manufacturers to investigate possible risks or to collect information that would enable a complete risk assessment.<sup>61</sup> To the contrary, it allows concealment of important safety information concerning the GE foods.

Lastly, despite a seemingly straightforward mandate for food safety, FDA's actual regulatory authority in relation to GE food products can be less than obvious. The Agency, for example, explicitly waived exercising its authority over pest-resistant plants intended for the food system.<sup>62</sup> The FDA elected to punt these food plants to the EPA instead, as discussed below,<sup>63</sup> as long as the plants have not also been modified to express other non-pesticidal proteins.<sup>64</sup> On the other hand, the FDA decided to assert authority over GE animals pursuant to the "new animal drug" provisions of the FFDCA, which allows the FDA to evaluate the animal drug's safety in relation to human or animal health.<sup>65</sup> The FDA further interpreted this authority to include the evaluation of environmental effects that affect the health of humans or animals other than those intended to receive the drug,<sup>66</sup> even though the EPA is the agency charged with protecting the environment, and is better equipped and qualified to perform such evaluation.

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57. 21 C.F.R. § 170.35 (2011).

58. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2219.

59. See *Completed Consultations on Bioengineered Foods*, U.S. FOOD & DRUG ADMIN., (July 31, 2012), <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=bioListing> (listing ninety-four completed consultations on bioengineered foods).

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

61. Bratspies, *Some Thoughts*, *supra* note 55, at 409.

62. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 23,005.

63. See discussion *infra* Part II.A.3.

64. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 23,005.

65. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360b (2006).

66. COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POLICY, CASE STUDY NO. I: GROWTH-ENHANCED SALMON 14 (2001), available at [http://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study2.pdf](http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study2.pdf).

### 3. EPA

The EPA currently regulates GE products primarily through its authority to regulate pesticide use pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and through its authority to set allowable tolerances for pesticide residue in food products pursuant to the FFDCA.<sup>67</sup> The EPA regulates plants as “plant-incorporated protectants”(PIPs), and requires registration under FIFRA prior to commercialization if the plant is bioengineered to produce its own pesticides.<sup>68</sup> Most of the EPA-approved PIPs promote insect resistance in crops through inclusion of *Bacillus thuringiensis* (Bt), a toxin that kills insects.<sup>69</sup> EPA regulates the genetic material inserted into Bt crops and the products the genetic material expresses, not the actual plant.<sup>70</sup>

The primary problem with using FIFRA to regulate PIPs is that the EPA ensures the safe use of a pesticide through pesticide labeling.<sup>71</sup> Distributors and users are required to comply with restrictions on labels.<sup>72</sup> “In the case of PIPs, however, the [pesticide] is produced in the tissues of the growing plant and is not present in the seed[s] . . . that [are] distributed and sold.”<sup>73</sup> Thus, there is no requirement to label bags of GE seeds in order to give notice of the FIFRA use restrictions.<sup>74</sup> In turn, the farmers who plant the GE seeds are not legally obligated to comply with any planting restrictions.<sup>75</sup>

In addition, FIFRA does not authorize entry onto farms to monitor compliance with label use restrictions.<sup>76</sup> Therefore, the regulatory scheme under FIFRA is inadequate in addressing some of the key environmental concerns.

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67. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136–136y; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 346a(b)(1).

68. 40 C.F.R. §§ 174.1, .3 (2011).

69. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 43.

70. *See* 40 C.F.R. §§ 174.1–.705.

71. 40 C.F.R. § 156.10.

72. *See id.*

73. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 41.

74. *Id.*

75. *See* 40 C.F.R. §§ 156.3–.212, 174.1–.705; *see also* MICHAEL R. TAYLOR & JODY S. TICK, PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, POST-MARKET OVERSIGHT OF BIOTECH FOODS: IS THE MARKET PREPARED? 22, 23 (2003) (explaining that since EPA does not consider the bag of seed a pesticide, it does not have a FIFRA label and farmers are therefore not subject to planting restrictions).

76. Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136g (2006) (detailing the inspection of establishments but omitting authorization for on-farm inspections); *see also* TAYLOR & TICK, *supra* note 75, at 22. Enforcement primarily involves the inspection of records and relevant documents. *See* 7 U.S.C. § 136(f).

These concerns include the fear that GE plants will “escape cultivation, persist in the environment, and become weeds.”<sup>77</sup> GE plants “could also cross-pollinate with wild or weedy relatives, creating new, more adaptable and aggressive weeds,” which then crowd out “natural flora and fauna and degrade ecosystems.”<sup>78</sup>

Under the Coordinated Framework, the Toxic Substances Control Act (TSCA) is another law that could potentially “provide[] the EPA with additional authority to regulate some types of GE organisms, possibly including plants and plant products.”<sup>79</sup> As TSCA was enacted to regulate conventional chemical substances, the EPA had to creatively interpret the definition of “chemical substances” to cover intergeneric microorganisms.<sup>80</sup> To date, the EPA has yet to “indicate[] whether or how TSCA might apply to GE plants or plant products.”<sup>81</sup> It is likely that the EPA will encounter even greater challenges in applying TSCA to the next generation of GE products, such as microorganisms that might be used for “specialty chemical and enzyme production, bioremediation, biosensors of environmental contaminants, biofertilizers, ore mining, oil recovery, and biomass conversion,” or other uses.<sup>82</sup>

## B. *Twenty-Five Years of Experience with the Coordinated Framework*

### 1. *The GE Genie Is Out of the Bottle*

Biotechnology and GE foods are here to stay—too many resources have been invested into developing the agricultural biotech industry and the products have already been in use for many years. Thus, it is unrealistic to advocate for wholesale rejection or a complete ban of genetically engineered food crops today.

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77. See PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 25.

78. *Id.*

79. *Id.* at 44.

80. Toxic Substances Control Act, 15 U.S.C. §§ 2601–2697. The TSCA defines chemical substances as “any organic or inorganic substance of a particular molecular identity” except for drugs, cosmetics, food and food additives, pesticides, medical devices, firearms and tobacco.” *Id.* § 2602(2)(A)–(B). See also PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 17 n.13 (2001), [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food\\_and\\_Biotechnology/hhs\\_biotech\\_0901.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf) [hereinafter PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE] (defining intergeneric microorganisms as “microorganisms resulting from the deliberate combination of genetic material originally isolated from organism classified in a different genera”).

81. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 44.

82. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE, *supra* note 80, at 17.

Between 1996 and 2002, the number of acres planted with GE crops worldwide increased over thirty-four times, from 4.25 to 146.8 million acres.<sup>83</sup> By 2010, GE crops were grown in twenty-nine countries on more than 360 million acres.<sup>84</sup> During 2002, nearly 100 million acres of GE crops were planted in the United States alone.<sup>85</sup> As of June 2012, ninety-three percent of soybeans, ninety-four percent of cotton, and eighty-eight percent of corn grown in the United States came from genetically engineered seed stock.<sup>86</sup> In fact, genetically engineered organisms (GEOs) are in such wide circulation and so fully entrenched in the global ecosystem that experts believe that it is beyond our scientific knowledge and capabilities to fully extricate them at this point.<sup>87</sup>

Todd LaPorte, a University of California, Berkeley professor, recognized for his work in the containment of radioactive wastes and man-made hazards, noted that while “nuclear waste does not reproduce,” a population of living GE-Os can multiply, reproduce, cross-contaminate, and thus “end[s] up being significantly much more difficult to contain than radioactive sludge.”<sup>88</sup> It is not feasible to cancel or recall GEOs after they are released into the environment. Any proposed regulatory solutions, therefore, must encompass more vigorous pre-market or pre-release risk assessments and post-market monitoring in the risk management process. The stakes are now higher with the pervasiveness of GEOs in the food chain.

## 2. *Where GE Proponents Missed the Mark*

Since the advent of agricultural biotechnology, proponents have argued emphatically that genetic engineering techniques are safe.<sup>89</sup> Although most observers will acknowledge the lack of evidence of harm to human health or envi-

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83. Sheldon Krimsky, *The Birth of Synthetic Biology and the Genetic Mode of Production*, in GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION 11 (Iain E.P. Taylor ed., 2007) [hereinafter Krimsky, *The Birth of Synthetic Biology*].

84. Nina V. Federoff, *Engineering Food for All*, N.Y. TIMES, Aug. 18, 2011, <https://www.nytimes.com/2011/08/19/opinion/genetically-engineered-food-for-all.html>.

85. Krimsky, *The Birth of Synthetic Biology*, *supra* note 83, at 11.

86. NAT'L AGRIC. STATISTICS SERV., USDA, ACREAGE 25–27 (2012), *available at* <http://usda01.library.cornell.edu/usda/current/Acre/Acre-06-29-2012.pdf>.

87. *See generally* Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2176–79 (providing background on the extent to which GE products are present in the food system).

88. DENISE CARUSO, INTERVENTION: CONFRONTING THE REAL RISKS OF GENETIC ENGINEERING AND LIFE ON A BIOTECH PLANET 8 (2006) [hereinafter CARUSO, INTERVENTION].

89. *See, e.g.*, NAT'L RESEARCH COUNCIL, *supra* note 44, at 52 (noting “[t]ransgenic crops do not pose unique categories or kinds of environmental hazards” when compared to conventional crops).

ronment from GE crops introduced to date, they might also question whether there have been systematic, scientific efforts to look for such harm.<sup>90</sup> As one National Research Council report concluded, “absence of evidence of an effect is not evidence of absence of an effect.”<sup>91</sup> The panel explained that the conclusion that there were no environmental effects from the large-scale planting of commercial GE crops was “nonscientific” because there has been no environmental monitoring of the crops.<sup>92</sup>

Concerns about genetically altered crops and the lack of broad testing hit a boiling point in 2009. Twenty-six leading academic entomologists issued a public statement to the EPA complaining that Monsanto and other companies were restricting them from engaging in independent research by using technology agreements attached to the biotech seeds that the companies sell to growers.<sup>93</sup> Scientists claimed the technology agreements not only prevent growers from supplying GE seeds or plants as samples to the researchers, they prohibit any research from being conducted without first being approved by the companies.<sup>94</sup> In doing so, the companies have the power to shut out all independent research efforts and control any potential negative outcomes from ever being released to the public.<sup>95</sup> Some of the concerns involve corn engineered to resist corn root-worm pests, as crops harvested in four states during the prior season showed damage and disease, while others fear biotech corn could sicken livestock.<sup>96</sup> Although the technology engineered into the plants has many benefits, the entomologists agree that more research is needed on effects, and that EPA ought to have independently verifiable information beyond what the company provides prior to making decisions.<sup>97</sup>

Further, there is now growing evidence that widespread use of transgenic crops engineered to be Roundup (glyphosate) tolerant or “Roundup Ready” has led to the evolution of new strains of superweed that are now resistant to the

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90. *Id.* at 79.

91. *Id.*

92. *Id.*

93. Anonymous Public Submission to the FIFRA Scientific Advisory Panel, EPA-HQ-OPP-2008-0836-0043 (Feb. 10, 2009), *comment on* Notice of Public Meeting, 73 Fed. Reg. 75,099 (Dec. 10, 2008), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0836-0043>.

94. *Id.*

95. *Id.*

96. Gillam, *supra* note 26.

97. *Id.*; *see also* Anonymous Public Submission to the FIFRA Scientific Advisory Panel, *supra* note 93 (articulating the entomologists’ position that independent research is impossible to conduct on these engineered seeds).

herbicide and far more difficult to eradicate.<sup>98</sup> Roundup is a trademarked weed killer manufactured by Monsanto.<sup>99</sup> It is the world's top selling broad-spectrum herbicide, with \$11 billion in annual sales tied to crops genetically engineered to tolerate its use.<sup>100</sup> Roundup Ready seeds were first introduced to the market over fifteen years ago.<sup>101</sup> Growers enthusiastically embraced the planting of the GE seeds as they allowed them "to easily dispatch hundreds of types of weeds with a single herbicide [Roundup] while leaving crops unscathed."<sup>102</sup> Roundup Ready seeds were sold as the ultimate solution to weed problems, and Roundup was touted to be environmentally safe compared to other chemical herbicides commercially available.<sup>103</sup> Today, many of those growers are no longer so enthusiastic as they face new weed species that are Roundup resistant.<sup>104</sup> Many have resorted to older methods of applying a cocktail of more harmful chemicals and restarting the time and labor-intensive tasks of soil tilling and plowing, which are environmentally damaging as they exacerbate topsoil erosion and chemical runoff into waterways.<sup>105</sup>

According to the International Survey of Herbicide Resistant Weeds, the unrelenting use of Roundup has caused at least twenty-four weed species to evolve resistance to glyphosates in the United States and abroad.<sup>106</sup> One estimate from Chuck Foresman, Syngenta's head of corn crop protection, shows 14 million acres of cotton, soybean, and corn have already been invaded by resistant weeds, and that number is expected to double by 2015.<sup>107</sup> Another study sponsored by Dow Chemical found as many as 20 million acres of corn and soybeans infested.<sup>108</sup> The irony of this development is that scientists warned about this long ago, but were routinely ignored or dismissed.<sup>109</sup> Even more alarming, how-

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98. Jack Kaskey, *Attack of the Superweed*, BLOOMBERG BUS. WK., Sept. 8, 2011, <http://www.businessweek.com/magazine/attack-of-the-superweed-09082011.html>.

99. *Id.*

100. *Id.*

101. *Id.*

102. *Id.*

103. William Neuman & Andrew Pollack, *Farmers Cope with Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, <https://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html>.

104. Kaskey, *supra* note 98.

105. *Id.*; Neuman & Pollack, *supra* note 103 (describing efforts by seed companies to develop seeds that are resistant to glyphosate, glufosinate, dicamba, and 2,4-D).

106. *Glyphosates (G/9) Resistant Weeds by Species and Country*, INT'L SURV. OF HERBICIDE RESISTANT WEEDS, <http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12>.

107. Kaskey, *supra* note 98.

108. *Id.*

109. *See, e.g., id.* (noting that Charles Benbrook, chief scientist at the Organic Center, and William G. Johnson, a weed scientist at Purdue University, are two scientists echoing this message).



ever, is that Monsanto's competitors are viewing this as a prime opportunity to break Monsanto's grip on the herbicide market.<sup>110</sup> Dow Chemical "expects to begin collecting \$1.5 billion in additional profit in 2013 by selling GE seeds for crops that tolerate a reformulated version of 2,4-D, . . . one of the chemicals used in the Vietnam War era defoliant Agent Orange."<sup>111</sup> According to Bill Freese, a science policy analyst for the Center for Food Safety, "[t]he biotech industry is taking us into a more pesticide-dependent agriculture when they've always promised, and we need to be going in, the opposite direction."<sup>112</sup>

Recently, Don Huber, distinguished emeritus professor at Purdue University and a plant pathologist of over fifty years, wrote a confidential letter to Secretary of Agriculture Tom Vilsack that unleashed a storm of public fury after it was leaked.<sup>113</sup> Huber informed the Secretary that an electron microscopic pathogen had been discovered that is "widespread, very serious, and is in much higher concentrations in Roundup Ready (RR) soybeans and corn."<sup>114</sup> He alleged that lab results "confirmed the presence of this organism in a wide a variety of livestock that have experienced spontaneous abortions and infertility."<sup>115</sup> Huber requested USDA's participation and dedication of resources "to examine whether the side-effects of glyphosate [Roundup] use may have facilitated the growth of this pathogen, or allowed it to cause greater harm to weakened plant and animal hosts."<sup>116</sup> Even critics of Huber agree that if his controversial allegation later turns out to be without merits, it has at least started the dialogue.<sup>117</sup> Huber has gotten people to evaluate the potential relationship between the use of Roundup and sudden death syndrome, a plant disease that has plagued the country's soybean industry.<sup>118</sup>

Along with Roundup related problems, there is also now documented evidence of the threat of pest resistance in Bt crops. Bollworms are serious cotton

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110. *Id.*

111. *Id.*

112. Neuman & Pollack, *supra* note 103.

113. Chris Walters, *GMOs, Glyphosate & Tomorrow: Distinguished Professor, Scientist Reveals Growing, Multi-Faceted Problems in Glyphosate & Crops Created to Survive It*, ACRES USA, May 2011, at 50, 54–55, available at <http://farmandranchfreedom.org/sff/Huber-May2011-Acres.pdf>.

114. *Id.* at 54.

115. *Id.* at 55.

116. *Id.*

117. P.J. Huffstutter, *Plant Disease Raises Questions on Modified Crops: Scientist Alleges a Link to a Disease That's Killing Soybeans*, L.A. TIMES, Apr. 2, 2011, <http://articles.latimes.com/2011/apr/02/business/la-fi-gmo-mystery-20110402>.

118. *Id.*

pests in the southeastern United States and Texas.<sup>119</sup> In a study conducted between 2003 and 2006, scientists found Bt-resistant populations of bollworm in more than a dozen crop fields in Mississippi and Arkansas.<sup>120</sup> As this was part of a larger study that also monitored pests of Bt crops in Australia, China, and Spain, scientists believe it is “one of the largest selections for insect resistance ever known.”<sup>121</sup>

Long-term environmental impact aside, another claim that GE proponents cannot substantiate is that consuming GE foods has harmed nobody. Most consumers do not even know when they have consumed GE foods, including GE ingredients, and without labeling requirements, there is no way for health officials to know whether particular GE foods are triggering allergic or other adverse reactions.<sup>122</sup> If a consumer becomes ill, it is impossible for him to connect his symptoms to specific GE foods in order to report the suspected impact to a health care provider.<sup>123</sup> The health care provider, in turn, will not be able to establish or eliminate any causal relationship between the symptoms or illnesses to specific GE foods.<sup>124</sup>

GE proponents also created an enormous disconnect attempting to justify the use of biotechnology to save the world from hunger.<sup>125</sup> Multinational corporations such as Monsanto, Syngenta, and Dow Chemicals, have developed and patented most transgenic crops on the market today to address large-scale commercial farming production problems in the developed world.<sup>126</sup> This has the effect of trapping farmers into continually buying GE seeds and entering a vicious cycle of buying and using more pesticides and herbicides without the bene-

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119. Mari N. Jensen, *First Documented Case of Pest Resistance to Biotech Cotton*, UNIV. OF ARIZ. BIO5 INST., <http://bio5.arizona.edu/node/1143> (last visited Sept. 25, 2012).

120. *Id.*

121. *Id.*

122. 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, 245–46 (2009) [hereinafter Van Tassel, *Genetically Modified*]; Press Release, PEW Initiative on Food & Biotechnology, How Consumers Process Information at Heart of Debate over Labeling of Genetically Modified Foods (Jun. 27, 2002), available at [http://www.pewtrusts.org/news\\_room\\_detail.aspx?id=33460](http://www.pewtrusts.org/news_room_detail.aspx?id=33460).

123. Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1662 (2004).

124. *Id.*

125. See Bratspies, *Biotechnology, Sustainability and Trust*, *supra* note 20, at 285 (discussing the discrepancies in the relationship between biotech foods and food insecurity); see also MARION NESTLE, *SAFE FOOD: THE POLITICS OF FOOD SAFETY* 145–50 (Darra Goldstein, ed., 2010 ed.) (discussing the purported benefits of GE foods).

126. Bratspies, *Biotechnology, Sustainability and Trust*, *supra* note 20, at 285.

fit of higher crop yield.<sup>127</sup> These innovations, on the other hand, do not serve the needs of small-scale farmers, as they tend to rotate multiple crops rather than mono-crop, save seeds for replanting rather than purchase new seeds every season, and lack the financial resources to purchase herbicides, pesticides, or other chemicals.<sup>128</sup> More importantly, feeding the world is a complex social problem. Long-term solutions will depend on a combination of societal interventions such as education, housing, health care, employment, and income.<sup>129</sup> Therefore, although promising, the jury is still out on how much genetic engineering can contribute to this effort.<sup>130</sup>

Golden Rice is a classic example of the agricultural biotech industry overselling and under-delivering on its promises.<sup>131</sup> It is also an example of a solution in search of a problem.

[R]ice is the principal source of energy (calories) for one-third or more of the world's population, but it is not a source of vitamin A . . . . The lack of vitamin A is the single most important cause of blindness among children in developing countries and a major contributor to deaths among malnourished children and adults.<sup>132</sup>

As such, Golden Rice, genetically engineered to contain beta-carotene, a precursor of vitamin A, was the biotech "industry's primary advertising tool to promote the humanitarian benefits of food biotechnology."<sup>133</sup> The industry engaged in an aggressive public relations campaign long before the product was even in production.<sup>134</sup>

It did not take long before environmental activists were able to unravel some of the lofty claims.<sup>135</sup> Based on estimates that Golden Rice scientists provided, adults would have to consume at least twenty pounds, and young children consume six pounds, of cooked Golden Rice in order to meet the daily vitamin A requirement.<sup>136</sup> Further, "the 'bioavailability' of beta-carotene, the amount that is

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127. See DOUG GURIAN-SHERMAN, UNION OF CONCERNED SCIENTISTS, FAILURE TO YIELD: EVALUATING THE PERFORMANCE OF GENETICALLY ENGINEERED CROPS 25 (2009), available at [http://www.ucsusa.org/assets/documents/food\\_and\\_agriculture/failure-to-yield.pdf](http://www.ucsusa.org/assets/documents/food_and_agriculture/failure-to-yield.pdf) (describing the limited yield increases from GE crops); NESTLE, *supra* note 125, at 149–50 (discussing the expansion of the biotech seed industry).

128. Bratspies, *Biotechnology, Sustainability and Trust*, *supra* note 20, at 285.

129. NESTLE, *supra* note 125, at 165.

130. *Id.* at 165–66.

131. *See id.* at 159–65.

132. *Id.* at 159.

133. *Id.* at 153.

134. *See id.* at 154 fig.12.

135. *Id.* at 162.

136. *Id.*

absorbed and converted to vitamin A,” is estimated at less than ten percent.<sup>137</sup> Beta-carotene is a fat-soluble pigment that “requires some fat in the diet to aid its absorption and transport.”<sup>138</sup> Thus, people who are malnourished, those most at risk of vitamin A deficiency, are precisely the same people who are least able to efficiently convert and make use of the nutrient, as they have very little fat in their diets.<sup>139</sup> In addition, they are also the people least able to afford the purchase of high-tech rice to begin with.<sup>140</sup> As Golden Rice was not even ready for production, it would appear that a simpler solution was to provide vitamin A supplements to those in need. As such, it was a clear example of an expensive solution in search of a problem. Gordon Conway, then-president of the Rockefeller Foundation, agreed that the agricultural biotech industry oversold the promise of Golden Rice.<sup>141</sup>

### 3. *Where GE Opponents Missed the Mark*

Fear mongering among GE opponents has been shown to be counterproductive. Albeit controversial, Stewart Brand, a lifelong ecologist and veteran defender of the earth’s health said, “[T]he environmental movement has done more harm with its opposition to genetic engineering than with any other thing we’ve been wrong about. We’ve starved people, hindered science, hurt the natural environment, and . . . repel the scientists whose help we most need to develop a deeply sustainable agriculture . . . .”<sup>142</sup> “Genetic engineering has entered that special domain, long occupied by animal-rights activists and antiabortion activists, where violence is deemed justifiable.”<sup>143</sup> “Vandalism of GE research crops and facilities, along with intimidation of researchers,” is common.<sup>144</sup> The Federal Bureau of Investigation (FBI) believes that “[t]ogether, eco-terrorists and animal rights extremists are one of the most serious domestic terrorism threats in the U.S. today,” accounting for over 2000 crimes and costing \$110 million in eco-

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137. *Id.* at 164.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.* at 163–64; Gordon Conway, *Grain of Hope*, THE GUARDIAN, Mar. 20, 2001, <http://www.guardian.co.uk/environment/2001/mar/21/food.gm>. “Since 1984, the Rockefeller Foundation has dispensed about \$4 million annually to fund genetic projects to improve one characteristic or another of rice plants, and it considers Golden Rice to be the greatest achievement of this program.” NESTLE, *supra* note 125, at 159.

142. STEWART BRAND, *WHOLE EARTH DISCIPLINE: WHY DENSE CITIES, NUCLEAR POWER, TRANSGENIC CROPS, RESTORED WILDLANDS, AND GEOENGINEERING ARE NECESSARY* 121–22 (Penguin Books 2009).

143. *Id.* at 162.

144. *Id.*

conomic impact since 1979.<sup>145</sup> In addition, the victims are wide ranging, from international corporations to genetic research firms, and the rhetoric and tactics are increasingly violent.<sup>146</sup> Eco-terrorism was suspected for a recent Big Island, Hawaii incident, for example, where thousands of GE papaya trees were chopped down by machete and the fruits left to rot on ten acres of farmland under the cover of the night.<sup>147</sup>

One consequence of the precautionary principle that GE opponents subscribe to is that it can be counterproductive, particularly when applied to GE research.<sup>148</sup> The principle basically advocates that due to the risks and uncertainties surrounding GE, people should be cautious and wait for the results of further research before taking any action.<sup>149</sup> On the other hand, in the name of the principle, activists engage in violence and declare that the research efforts to discover the risks are too dangerous.<sup>150</sup> “[This] is a formula for paralysis.”<sup>151</sup> Properly regulated research is the only way to determine the likelihood of whether something risky will ultimately be harmful. Thus, stopping research entirely is a barrier to progress and counterproductive.

Another area where GE opponents have missed the mark is the failure to acknowledge that circumstances exist where there are no viable alternatives and genetic engineering represents the last resort and the only solution available. The following are two examples of why continual support to the agricultural biotech industry is not only beneficial but also absolutely necessary.

Aphids from weeds and other wild plants spread the papaya ringspot virus.<sup>152</sup> When infected, the papaya plants “are stunted and their fruit is misshapen and tasteless.”<sup>153</sup> The trees eventually die.<sup>154</sup> In the United States, the Hawaiian Islands host the only climate conducive to growing papayas, with an “annual production of over 50 million pounds of fruit . . . valued at \$17 million.”<sup>155</sup> “It

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145. News Release, Fed. Bureau of Investigation, Putting Intel to Work Against ELF and ALF Terrorists (June 30, 2008), available at [http://www.fbi.gov/news/stories/2008/june/ecoterror\\_063008](http://www.fbi.gov/news/stories/2008/june/ecoterror_063008).

146. *Id.*

147. Jennifer Sinco Kelleher, *Hawaii Papaya Trees Attacked—Eco-Terror Feared*, S.F. CHRON., Aug. 21, 2011, <http://www.sfgate.com/news/article/Hawaii-papaya-trees-attacked-eco-terror-feared-2334208.php>.

148. BRAND, *supra* note 142, at 164.

149. *Id.*

150. *Id.*

151. *Id.*

152. NINA V. FEDOROFF & NANCY MARIE BROWN, MENDEL IN THE KITCHEN: A SCIENTIST’S VIEW OF GENETICALLY MODIFIED FOODS 138 (2004).

153. *Id.*

154. *Id.*

155. *Id.* at 138–39.

takes an aphid less than a minute to infect a plant” and “[i]nsecticides provide no relief.”<sup>156</sup>

The virus first wiped out all papaya farms on Oahu in the 1950s, which prompted the farmers to move production to the Big Island.<sup>157</sup> There, they attempted to keep the infection under control by burning infected trees, but farmers continued to go out of business.<sup>158</sup> “Millions of dollars [were] spent on conventional breeding programs to create a papaya that could withstand the ringspot virus, but with little success.”<sup>159</sup> In 1987, with no solution in sight, the University of Hawaii researchers finally began to apply genetic engineering techniques to attempt to create a virus resistant papaya.<sup>160</sup> Following success in field trials, negotiations with patent holders, vetting by government agencies and much paperwork for the regulators, the transgenic papaya seeds were finally distributed to farmers free of charge to save the industry.<sup>161</sup> This case demonstrates that GE crops can be introduced successfully in a controlled manner and under the right circumstances.

The second example involves a tiny, lethal bacterium called *Xylella fastidiosa* that is threatening to destroy the wine industry in California with potential state economic impact of \$61.5 billion annually.<sup>162</sup> The bacterium causes the deadly Pierce’s disease and is transmitted by an insect known as the glassy-winged sharpshooter.<sup>163</sup> “As the insect sucks the nutritious liquids out of grape leaf veins, it injects the bacterium, which then multiplies, spreads, and clogs the veins that supply the plant with water.”<sup>164</sup> Infected vineyards possess mottled leaves and slowly die over a period of a few years.<sup>165</sup> All control measures are implemented to manage the spread in order to buy more time for the research community to come up with a more permanent solution.<sup>166</sup> “[S]cientists are now trying to genetically engineer the grape vines using a method similar to that suc-

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156. *Id.* at 139.

157. *Id.* at 138.

158. *Id.* at 138, 140.

159. *Id.* at 139.

160. *Id.*

161. *Id.* at 140.

162. *California Wine Profile 2011*, THE WINE INST. (Apr. 9, 2011),

[http://www.wineinstitute.org/files/CA\\_EIR\\_Flyer\\_April\\_2012\\_0.pdf](http://www.wineinstitute.org/files/CA_EIR_Flyer_April_2012_0.pdf); *Pierce’s Disease*, THE WINE INST., <http://www.wineinstitute.org/initiatives/issuesandpolicy/piercesdisease> (last visited Sept. 25, 2012).

163. *Pierce’s Disease*, *supra* note 162.

164. PAMELA C. RONALD & RAOUL W. ADAMCHAK, *TOMORROW’S TABLE: ORGANIC FARMING, GENETICS, AND THE FUTURE OF FOOD* 63 (2008).

165. *Id.*

166. *Pierce’s Disease*, *supra* note 162.

cessfully used to protect papaya from papaya ringspot virus” in Hawaii.<sup>167</sup> At this time, there is no other foreseeable scientific solution in sight. As such, genetic engineering represents both the most promising and last resort to save the industry.

Ultimately, the potentials for developing drought, heat, flood, and salt tolerance in commodity crops through genetic engineering simply cannot be ignored in face of climate change. Likewise, the possibility of creating disease-resistant farm animals cannot be foreclosed. We can only hope that the United States will never have to experience a catastrophic event such as the mad cow epidemic that devastated Europe in the late 1990s.<sup>168</sup> Public distrust grew out of the manner in which British officials improperly handled the crisis and the distrust inspired rejection of GE foods.<sup>169</sup>

*C. Trade as a Key Driver: 2006 WTO Decision in U.S. v. EU*

Together the economies of the U.S. and EU comprise approximately “half the entire world GDP [Gross Domestic Product] and for nearly a third of the world trade flow.”<sup>170</sup> The United States and EU also have the largest bilateral trade relationship in the world.<sup>171</sup> Therefore, any dispute that has the potential to alter this relationship is paramount in the age of economic interdependence. The “transatlantic clash” between the United States and EU over agricultural biotechnology can be attributed to two fundamentally different regulatory systems.<sup>172</sup> Although the World Trade Organization (WTO) adjudicated the matter, the underlying dispute is still ongoing today.<sup>173</sup>

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167. RONALD & ADAMCHAK, *supra* note 164, at 63. *See generally id.* at 58–59 box 4.2, 159 box 12.1 (describing the use of genetic engineering to save the Hawaiian papaya industry from being overrun by the ringspot virus).

168. *See* NESTLE, *supra* note 125, at 250–53 (“[B]y 1999, [the disease] had infected at least 175,000 British cows. Its results were catastrophic: destruction of more than 4 million cattle, estimated costs of \$7 billion, transmission to at least 18 countries, and worldwide rejection of British beef.”).

169. *Id.* at 250.

170. *United States*, EUR. COMMISSION DIRECTORATE-GENERAL FOR TRADE (July 4, 2012), <http://ec.europa.eu/trade/creating-opportunities/bilateral-relations/countries/united-states/>.

171. *Id.*

172. MARK A. POLLACK & GREGORY C. SHAFFER, *WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS* 1–2 (2009).

173. *Id.* at 2.

### 1. *Fundamental Differences in Approach*

In May 2003, the United States, joined by Canada and Argentina, filed a formal complaint with the WTO against the EU over its five-year moratorium on approving GE crops.<sup>174</sup> The United States challenged the moratorium on grounds that it was an impediment to trade as it effectively excluded most U.S. agricultural products from being exported to any EU members because GE crops in the United States are not segregated from non-GE crops.<sup>175</sup> In May 2006, the WTO Panel issued a final ruling against the EU by finding several trade violations in its general moratorium and the failure to approve specific biotech products.<sup>176</sup> On the surface the ruling appeared to favor the U.S. biotech companies and growers of GE crops. As the moratorium ended, however, it became apparent that the United States was in no better position than it was prior to the WTO decision. The EU regulatory system regulates GE foods and crops according to “the process by which they are produced, rather than the characteristics of the products.”<sup>177</sup> “The regulatory process [is] based in part on scientific risk assessments, but [leaves] room for political actors [and member-states] to intervene.”<sup>178</sup> The United States, on the other hand, regulates “GE foods and crops according to the characteristics of the product rather than the process of genetic [engineering],” has standards that are “relatively lax,” with “no requirement for premarket authorization of new GE varieties,” and “no mandatory rules for traceability or labeling.”<sup>179</sup> The reality is that the United States and the EU are still fundamentally polar opposites in the way each approaches the risks associated with agricultural biotechnology.

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174. Request for the Establishment of a Panel by the United States, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/23 (Aug. 8, 2003) [hereinafter Request for Panel by the United States]; Request for the Establishment of a Panel by Canada, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS292/17 (Aug. 8, 2003); Request for the Establishment of a Panel by Argentina, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS293/17 (Aug. 8, 2003).

175. Request for Panel by the United States, *supra* 174; see also RAYMOND J. AHEARN, CONG. RESEARCH SERV., RL30732, TRADE CONFLICT AND THE U.S.-EUROPEAN UNION ECONOMIC RELATIONSHIP 19 (2007) (“The moratorium halted some \$300 million in annual U.S. corn shipments.”).

176. See generally Reports of the Panel, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006) [hereinafter EU Panel Report] (explaining that the EU moratorium was inconsistent with WTO obligations).

177. POLLACK & SHAFFER, *supra* note 172, at 277.

178. *Id.*

179. *Id.*



## 2. *What Did the United States Really Win?*

The scope of the WTO decision was extremely limited and more “noteworthy for what it did not decide [rather than] what it did.”<sup>180</sup>

[T]he panel largely took a procedural [rather than substantive] approach in its decision, finding that the EU had engaged in “undue delay” in its approval process and that member states had failed to base their national bans on a risk assessment as required not only under WTO law as confirmed, but also by the EU’s own risk assessment body EFSA [European Food Safety Authority].<sup>181</sup>

The Panel, however, did not determine (1) “whether biotech products in general are safe;” (2) “whether biotech products at issue in this dispute are ‘like’ their conventional counterparts;” (3) “whether the European Communities has a right to require pre-marketing approval of biotech products;” or (4) “whether the European Communities approval procedures . . . are consistent with the European Union’s obligations under the WTO agreements.”<sup>182</sup> More importantly, the Panel failed to resolve whether there was a scientific justification for EU to restrict the import of GE foods, which was the central issue in the dispute.<sup>183</sup> The Panel also did not “evaluate the past and current regulations under which the EU continues to restrict the import of GE foods through its more stringent labeling and monitoring requirements.”<sup>184</sup> Therefore, the victory was a hollow one for the United States. In fact, studies have found very “limited evidence of meaningful convergence between the two systems” following this decision.<sup>185</sup>

Based upon the precautionary principle,<sup>186</sup> the EU system remains essentially unchanged, and “ongoing tinkering” has actually produced regulatory requirements that are far stricter than those in place prior to the WTO decision.<sup>187</sup> In part shaped by the food safety crisis of the mid-1990s, particularly the mad

180. Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775, 788 (2008).

181. POLLACK & SHAFFER, *supra* note 172, at 178.

182. EU Panel Report, *supra* note 176, at ¶ 8.3.

183. Strauss, *supra* note 180, at 788–89.

184. Commission Regulation 641/2004, 2004 O.J. (L102/14) (EC); Commission Regulation 65/2004, 2004 O.J. (L10/5) (EC); Regulation 1830/2003, 2003 O.J. (L268/24) (EC); Regulation 1829/2003, 2004 O.J. (L268/1) (EC); Directive 2001/18/EC, 2001 O.J. (L106/1); *see also* Strauss, *supra* note 180, at 789 (noting that the EU continues to limit GE foods through its labeling and monitoring regime).

185. POLLACK & SHAFFER, *supra* note 172, at 277.

186. *See* Strauss, *supra* note 180, at 781 (“In the face of insufficient scientific evidence as to the potential dangers, [risky] products must be restricted or prohibited in order to protect against future unforeseen problems.”).

187. POLLACK & SHAFFER, *supra* note 172, at 277.

cow outbreak, the public grew distrustful of regulators and rejected the consumption of GE foods, EU growers continued to resist planting GE crops, and retailers resisted selling GE foods, which “led to a flight of biotech investment from Europe,” and ultimately undermined political support by member states across the EU.<sup>188</sup> The final regulation established three increasingly stringent thresholds.<sup>189</sup> The third of these was a “zero-tolerance” threshold that went into effect in 2007 and “established a three-year window after which no residues of such non-approved [GEOs] would be allowed in food or feed product.”<sup>190</sup> It was this threshold that caused conflict with the United States due to the impossibility of segregating grains for bulk shipment in international trade.<sup>191</sup>

“On July 13 2010, the Commission presented a package aimed at allowing MS [Member States] to decide whether or not they cultivate approved biotech crops on their individual territories.”<sup>192</sup> “Several MS . . . opposed . . . the Commission proposal because of the disruption of the single internal market and potential WTO issues.”<sup>193</sup> As of 2011, only six of twenty-seven member states in the EU are GE crop producers and welcome the technology, while nine states continue to strongly oppose production, and nine states are ready to adopt production practices but do not currently cultivate GE crops.<sup>194</sup> The stronger dairy and cattle producing states, such as the Netherlands, appear to be more influenced by economic realities as they must rely on imports for animal feeds and would prefer less stringent regulations in order to be able to import feeds from

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188. *Id.*

189. *Id.* at 242. The first threshold

provided that food products need not be labeled as containing [GEOs] if they contain material consisting of or produced from EU-approved [GEOs] ‘in a proportion no higher than 0.9 per cent of the food ingredients considered individually . . . provided that this presence is adventitious or technically unavoidable.’ Second, the regulation established . . . a stricter threshold of 0.5 per cent for [GEOs] not yet approved for environmental release in the EU, provided that they have received a favorable EU scientific risk assessment.

*Id.*

190. *Id.*

191. *Id.*

192. Marie-Cecile Henard et al., USDA Foreign Agric. Serv., *GAIN Report No. FR9074*, AGRIC. BIOTECHNOLOGY ANN. 10 (2011).

193. *Id.* at 11.

194. *Id.* at 19–22 (listing the six pro-GE member states as the Czech Republic, Poland, Portugal, Romania, Slovakia, and Spain).

the United States, Brazil, and Argentina.<sup>195</sup> However, due to the limited data available, the true cumulative economic impact on the EU to date for maintaining an anti-GE stance is uncertain.<sup>196</sup>

Thus, a valid argument can be made that regulatory polarization and trade conflicts will continue in the same trajectory in the near future.<sup>197</sup> Neither the United States nor the EU is willing to make fundamental changes to accommodate the other.<sup>198</sup> “For the time being, the world’s two largest economies are clearly the principle drivers of worldwide regulatory activit[ies].”<sup>199</sup> As other countries such as China, Brazil, India, Japan, and Russia adopt their own agricultural biotech policies, however, both the United States and the EU will likely battle for influence and attempt to “entice, coerce, or cajole” them into one camp or the other.<sup>200</sup> Thus, real regulatory reform may ultimately be driven by forces beyond either the United States’ or EU’s control as other players enter the GE market.

### III. REASONS WHY THE COORDINATED FRAMEWORK MUST CHANGE

#### A. *The Premise of the Coordinated Framework Is Flawed and Outdated, but Other Factors Conspire to Maintain the Status Quo*

The science of molecular biology and sub-field of molecular genetics have advanced dramatically since 1986. What scientists know now has essentially shattered the foundation upon which the Coordinated Framework was built. Why, one might ask, did this not already trigger a restructuring of the regulatory system? One reason might be, as many experts believe, that U.S. government regulators are still on a path to promote global acceptance of GE foods rather than to protect the public and the environment from potential risks.<sup>201</sup> Unless a sensational event occurs and the media brings it to the public’s attention, no one will bother to protest. When consumers fail to react, there may be little reason for regulators to take action.<sup>202</sup> In fact, studies have shown that the “worst case of

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195. *Id.* at 20–21; *see also* Eur. Comm’n, *Agricultural Products*, EUROSTAT, tbl.2 (Sept. 2011), [http://epp.eurostat.ec.europa.eu/statistics\\_explained/index.php/Agricultural\\_products](http://epp.eurostat.ec.europa.eu/statistics_explained/index.php/Agricultural_products) (showing the distribution of dairy and cattle production in the EU).

196. Henard et al., *supra* note 192, at 18–19. France is the only state that includes socio-economic review in addition to scientific review in its biotech regulatory framework. *Id.* at 19.

197. THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 13–14 (2003).

198. *Id.*

199. *Id.* at 14.

200. *Id.*

201. Gillam, *supra* note 26.

202. CARUSO, INTERVENTION, *supra* note 88, at 198.

ossification seems most likely to occur in circumstances where the new information is technical or scientific, the payoff to the public” is “modest or diffuse,” and the regulated parties have plenty of resources to spend to delay or block any regulatory action.<sup>203</sup> Hence, over time, these factors all contributed to the dysfunctional state that the Coordinated Framework is in today.

### 1. *Science Then and Now*

Genetically engineered foods are regulated in the same manner as conventional foods based on the doctrine of substantial equivalence or bioequivalence.<sup>204</sup> In accordance with this principle, any GE crop varieties produced using recombinant DNA (rDNA) technique are considered to be essentially the same as the conventional varieties produced using traditional breeding methods.<sup>205</sup> Hence, it is the composition of the food product that is important, not the method or process, by which it was produced. Regardless “whether the transgene originated in an animal, a plant, or from some variety of microbe— it [is] of no material interest to the FDA’s safety considerations.”<sup>206</sup> Consistent with this principle, therefore, the FDA is not required to conduct any independent safety, allergy, or other testing, and no labeling is required to distinguish the GE foods from their conventional counterparts unless the product contains an allergen that people would not generally expect in that particular food.<sup>207</sup> In fact, the FDA insists that “labels would erroneously imply that genetically modified foods differ from conventional foods and that conventional foods are in some way superior.”<sup>208</sup> In cases where milk producing cows are treated with genetically engineered Bovine Growth Hormone (rBGH), for example:

[T]he agency views *BGH-free* as misleading because all milk contains some natural BGH. The term *rBGH-free* also is misleading because the recombinant and natural cow hormones cannot be distinguished. Dairy companies may use such terms only

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203. Lynn E. Blais & Wendy E. Wagner, *Use and Abuse of Information: Emerging Science, Adaptive Regulation, and the Problem of Rulemaking Ruts*, 86 TEX. L. REV. 1701, 1712–13 (2008).

204. Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309, 23,310–12 (June 26, 1986); see also CARUSO, INTERVENTION, *supra* note 88, at 79.

205. CARUSO, INTERVENTION, *supra* note 88, at 78.

206. *Id.* at 79.

207. *Id.*

208. NESTLE, *supra* note 125, at 222.

if they provide an explanation of the context: “No significant difference has been shown between milk derived from rBGH-treated and non-rBGH-treated cows.”<sup>209</sup>

Also, in its Guidance for Industry, the Agency has ruled it misleading to use the term “GM” or “GMO free” on labels, and has placed the burden of proof on those who label their foods as being free of the products of bioengineering.<sup>210</sup> “The only time a [GE] food needs to be labeled is if it contains an allergen people wouldn’t ordinarily expect” from the food.<sup>211</sup> Further, it is “up to the food producer to ensure [that] the product is safe for consumption.”<sup>212</sup>

The doctrine of substantial equivalence, however, is grounded in the Central Dogma theory of molecular biology, a theory that is scientifically obsolete.<sup>213</sup> The theory is predicated upon “the ‘one gene—one protein’ model . . . , which, in its simplest form, posits that each gene in the organism’s genome governs the production of a single protein or a single process involving just a few proteins.”<sup>214</sup> The scientists who invented the rDNA technique based their work around the “one gene-one protein” principle.<sup>215</sup> Believed to be an elegant model, many scientists and entrepreneurs began to envision developing and patenting a plethora of GE crops,<sup>216</sup> which would undoubtedly lead to fame and fortune for feeding the world. Thus, scientists and government regulators began to operate on the assumption “that a gene from any organism can be precisely excised and neatly, predictably and safely moved into another organism.”<sup>217</sup>

By the mid-1980s, however, results from a series of studies already began to contradict the tenet of the Central Dogma: that a DNA gene exclusively

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209. *Id.* at 203 (citing Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somato tropin, 59 Fed. Reg. 6279, 6280 (Feb. 10, 1994)).

210. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Availability, 66 Fed. Reg. 4839, 4840 (Jan. 18, 2001).

211. CARUSO, INTERVENTION, *supra* note 88, at 79.

212. *Id.*

213. Van Tassel, *Genetically Modified*, *supra* note 122, at 221.

214. Lotter, *supra* note 18, at 38 (citing W. Wayt Gibbs, *The Unseen Genome: Gems Among the Junk*, SCI. AM., Nov. 2003, at 46–53).

215. Denise Caruso, *A Challenge to Gene Theory, a Tougher Look at Biotech*, N.Y. TIMES, July 1, 2007, at 33, [http://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?\\_r=1&pagewanted=all](http://www.nytimes.com/2007/07/01/business/yourmoney/01frame.html?_r=1&pagewanted=all) [hereinafter Caruso, *A Challenge to Gene Theory*].

216. *Id.*

217. Van Tassel, *Genetically Modified*, *supra* note 122, at 221–22 (citing Mark B. Gerstein et al., *What is a Gene Post-ENCODE? History and Updated Definition*, 17 GENOME RES. 669, 670–71 (2007)).

governs the molecular processes that give rise to a particular inherited trait.<sup>218</sup> In fact, experimental data have been accumulating for decades, long before the first GE crop began to appear in our fields, according to prominent biologist Dr. Barry Commoner.<sup>219</sup> The Central Dogma “collapsed under the weight of fact” when tested over a period of ten years in “one of the largest and most highly publicized scientific undertakings of our time, the [\$3 billion] Human Genome Project.”<sup>220</sup> The project entailed counting all genes in the human genome and characterizing them using computerized gene sequencing.<sup>221</sup> Scientists found approximately 27,000 genes in the human genome, a number dramatically lower than 1–2 million proteins previously believed to be in the human body.<sup>222</sup> The study “completely undermined the foundation of the ‘one gene–one protein’ doctrine.”<sup>223</sup>

In 2006, British scientists further explored this finding in the review article “Mutational Consequences of Plant Transformation.”<sup>224</sup> The authors found that “[e]ven with the limited information currently available it is clear that plant transformation is rarely, if ever, precise.”<sup>225</sup> Thus, the claim that a gene can be removed from one organism, reinserted or spliced into another organism in a precise, neat, and safe manner using rDNA technique simply cannot be substantiated. Scientists can no longer assume the genes they insert into plants would always produce only the desired effect without any corollary impact on the plant’s genetics. While the “DNA gene clearly exerts an important influence on inheritance,” it “acts only in collaboration with a multitude of protein-based processes that prevent and repair incorrect sequences,” and “provide crucial added genetic information well beyond that originating in the gene itself.”<sup>226</sup> Hence, “no single DNA gene is the sole source of a given protein’s genetic information and therefore of the inherited trait.”<sup>227</sup> “The fact that one gene can give rise to

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218. Barry Commoner, *Unraveling the DNA Myth: The Spurious Foundation of Genetic Engineering*, HARPER’S MAG., Feb. 2002, at 39–40.

219. *Id.* at 43–44.

220. *Id.* at 40.

221. Lotter, *supra* note 18, at 40.

222. *Id.*

223. *Id.*

224. Jonathan R. Latham et al., *The Mutational Consequences of Plant Transformation*, J. BIOMEDICINE & BIOTECHNOLOGY 1–7 (2006).

225. *Id.* at 5. The authors examined the evidence from various published reports showing that mutations, which occur in the process of transgene insertion, include deletions and rearrangements of host chromosomal DNA as well as introduction of superfluous DNA. *Id.* at 1–4. They concluded that, “much remains to be discovered about genome-wide and insertion-site mutations. In particular, lack of information . . . means that plant transformation may be even more damaging than is apparent from [its] review . . . and that [may] pose a significant biosafety risk.” *Id.* at 5.

226. Commoner, *supra* note 218, at 45.

227. *Id.*

multiple proteins . . . destroy[ed] the theoretical foundation” upon which the GE food industry is built.<sup>228</sup>

The final and fatal blow to the Central Dogma theory came in 2007 from a report published by the ENCODE (ENCyclopedia of DNA Elements) Consortium from the U.S. National Human Genome Research Institute.<sup>229</sup> Contrary to the Central Dogma theory, the ENCODE report revealed that many genes actually overlap one another and share stretches of molecular code.<sup>230</sup> This “network effect,” in turn, “can have a significant effect on protein expression,” which is not detectable by regulators, as GE food products are not tested prior to marketing to consumers.<sup>231</sup> More important are the safety issues raised. “Evidence of a networked genome shatters the scientific basis for virtually every official risk assessment of today’s commercial biotech products, from genetically engineered crops to pharmaceuticals.”<sup>232</sup> Up until this point, just about every attempt to challenge safety claims for biotech products was categorically dismissed and ridiculed as unscientific by GE proponents.<sup>233</sup> Now that the consortium’s findings have essentially discredited the one gene-one protein theory, it is time for legislators to update the Coordinated Framework accordingly to reflect the current state of scientific discoveries.

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228. *Id.*

229. The ENCODE Project Consortium, *Identification and Analysis of Functional Elements in 1% of the Human Genome by the ENCODE Pilot Project*, 477 NATURE 799 (2007).

230. *Id.* at 799.

231. Van Tassel, *Genetically Modified*, *supra* note 122, at 232.

232. Caruso, *A Challenge to Gene Theory*, *supra* note 215.

233. *See* Commoner, *supra* note 218.

[T]he theory has been protected from criticism by a device more common to religion than science: dissent, or merely the discovery of a discordant fact, is a punishable offense, a heresy that might easily lead to professional ostracism. Much of this bias can be attributed to institutional inertia, a failure of rigor, but there are other, more insidious, reasons why molecular geneticists might be satisfied with the status quo; the central dogma has given them such a satisfying, seductively simplistic explanation of heredity that it seemed sacrilegious to entertain doubts. The central dogma was simply too good not to be true.

*Id.* *See generally* Gregory Conko and Henry I. Miller, *The Rush to Condemn Genetically Modified Crops*, 165 POLICY REV., Feb. 1, 2011, <http://www.hoover.org/publications/policy-review/article/64231> (illustrating how GE proponents continue to vigorously defend the status quo despite scientific evidence to the contrary).

## 2. *Innumeracy as an Excuse*

Regrettably, most people in the United States are not mathematically literate.<sup>234</sup> Innumeracy, the inability to understand or apply complex mathematical concepts, of the general population is a key reason why most scientists and other technical experts would not engage in serious conversations about the risks of genetic engineering with those outside of their circle.<sup>235</sup> GE proponents, to that end, have obfuscated the fact that scientists and other technical experts often inject their own value judgments and biases into the assumptions upon which their scientific findings are based.<sup>236</sup> Both regulatory agencies and industries “willfully downplay or deny the risks that are already known.”<sup>237</sup> Even our legal system appears to have an aversion to delving deeply into the substance of science and technology. Likewise, government regulators have learned to “use science to mask policy judgments they’ve embedded in their risk assessments. Presenting the public as well as the courts with scientific explanations that bamboozle the nontechnical reader and don’t explain their assumptions is particularly appealing when those policies are likely to be controversial.”<sup>238</sup>

“The scientific explanation given by the FDA [to justify the ‘substantial equivalence’ policy,” for example] “was that transgenic food was deemed by the tenets of nutritional science to be equivalent to the food we were already eating.”<sup>239</sup> “This explanation purposely left out the critical assumption made by the agency: that the process of genetic engineering had no bearing on the safety of its products.”<sup>240</sup> In turn, the courts implicitly reinforce this behavior by rewarding the regulators with deference when confronted with issues of science or tech-

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234. CARUSO, INTERVENTION, *supra* note 88, at 65.

235. *Id.* at 65–66.

236. *Id.* at 148–151 (discussing studies by Carnegie Mellon risk professor Baruch Fischhoff showing that “subjective judgments made by experts have just as much effect on the accurate assessment and analysis of risk as hard scientific data”). In fact, Fischhoff observed that experts are often just “taking their best guess” and the very act of becoming an expert is hidebound with bias. *Id.* at 150–51.

237. *Id.* at 21.

238. *Id.* at 166–67 (citing Wendy Wagner, Professor of Law, Univ. of Tex., The Science Charade in Regulatory Risk Assessment, Presentation at the Society for Risk Analysis Annual Meeting (Dec. 5, 2004)).

239. *Id.* at 167 (asserting that FDA’s explanation that transgenic foods are substantially equivalent to their conventional counterparts inaccurately assumes that the process of genetic engineering has no effect on human health); *see also* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,983, 22,991 (May 29, 1992).

240. CARUSO, INTERVENTION, *supra* note 88, at 167.



nology.<sup>241</sup> As a result, GE proponents were able to successfully shape the conversation regarding the safety of genetically engineered foods.

### 3. *American Consumers: Lack of Knowledge and Apathy*

Lastly, consumers' attitude also plays a significant role in maintaining the status quo for the Coordinated Framework. As a basic necessity, food is essential to human survival. More importantly, however, food is also socially and culturally fundamental, and therefore highly personal. In a majority of cultures around the world, food is often a common language that people share and a subject about which people are passionate. Thus, whenever people perceive that their food source is being tampered with, manipulated, or threatened, the debates are often highly charged, emotional, and unyielding.<sup>242</sup>

In the United States, however, it is surprising how uninformed American consumers are about the penetration of GE foods in the food system. Approximately seventy percent of the packaged food in supermarkets today contains GE ingredients.<sup>243</sup> A public opinion poll published in 2006 confirmed that “[p]ublic knowledge and understanding of biotechnology remains relatively low,” and “[c]onsumers know little about the extent to which their foods include [GE] ingredients.”<sup>244</sup> In addition, “Americans’ attitudes [on the subject] remain fluid, and the opportunity to shape public opinion is ripe.”<sup>245</sup> Hence, for the past twenty-five years, the agricultural biotech industry and government regulators have been able to take full advantage of this laissez-faire attitude of the American public to aggressively advance the biotech industry’s agendas while simultaneously reinforcing the laxity of the Coordinated Framework.

#### *B. The Coordinated Framework Is Substantively Deficient: Examples of Past and Current Failures*

The five case studies discussed below share a common characteristic. They all illustrate significant and glaring defects in the regulatory framework for

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241. See *id.* (citing Wagner, *supra* note 238).

242. See, e.g., RONALD & ADAMCHAK, *supra* note 164, at 68–78 (recounting a spirited and contentious discussion between the author Pamela Ronald, a geneticist, Professor of Plant Pathology and GE proponent, and her sister-in-law in which she attempted unsuccessfully to convince her sister-in-law that GE foods are safe to eat and safe for the environment).

243. Press Release, PEW Initiative on Food & Biotechnology, *supra* note 122.

244. Memorandum from the Mellman Group, Inc., to the Pew Initiative on Food and Biotechnology (Nov. 16, 2006), available at [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public\\_Opinion/Food\\_and\\_Biotechnology/2006summary.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf).

245. *Id.* at 2.

agricultural biotechnology including: (1) a lack of systematic risk assessment prior to the release or marketing of the GE product in question, (2) a lack of surveillance or monitoring of the GE product after it has been released into the environment or marketplace, and (3) a lack of coordination between the agencies during all stages of the risk management process. Only one conclusion can be drawn from these examples—the Coordinated Framework is substantively deficient and in dire need for reform.

### 1. *StarLink*

One of the most high profile GE food scares in the United States was the discovery of StarLink corn in the human food chain in 2000.<sup>246</sup> StarLink was not approved for human consumption because it carried a gene that expressed a protein containing attributes of known human allergens.<sup>247</sup> Thus, the EPA approved it only for commercial use as animal feed and nonfood industrial uses.<sup>248</sup> Due to the limited approval, the EPA imposed special procedures including “mandatory segregation methods to prevent StarLink from commingling with other corn,” a buffer zone around StarLink to prevent cross-pollination, and a requirement that the manufacturer inform growers of such limitations and have the growers sign an agreement acknowledging such requirements.<sup>249</sup> Since the EPA only has authority over the inserted genetic material and the products it expresses pursuant to FIFRA, and not the plant itself, it had to rely upon the manufacturer to enforce the special procedures with the growers of StarLink.<sup>250</sup> In September 2000, StarLink corn was discovered in Kraft’s taco shells and other food products.<sup>251</sup> Eventually over three hundred products were recalled and the manufacturer of StarLink agreed to buy back the year’s entire crop at a cost of approximately \$100 million to prevent further contamination.<sup>252</sup> The company also voluntarily cancelled its registration with the EPA.<sup>253</sup>

This case demonstrates that despite the EPA’s expertise in protecting the environment, it clearly lacks knowledge of the agricultural system. It also

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246. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828, 835 (N.D. Ill. 2002).

247. *Id.* at 834.

248. *Id.*

249. *Id.* at 834–35.

250. *Id.* at 834.

251. ALEJANDRO E. SEGARRA & JEAN M. RAWSON, CONG. RESEARCH SERV., RS20732, STARLINK CORN CONTROVERSY: BACKGROUND 4 (2001).

252. *Id.*

253. Andrew Pollack, *Aventis Gives up License to Sell Bioengineered Corn*, N.Y. TIMES, Oct. 13, 2000, <http://www.nytimes.com/2000/10/13/business/technology-aventis-gives-up-license-to-sell-bioengineered-corn.html>.

demonstrates the complete failure to coordinate under the Coordinated Framework. In the United States, the harvesting, storage, processing, and transport equipment for corn and other grains are often the same for human and animal food.<sup>254</sup> As a commodity, corn crops from different farms are often commingled as customary practice.<sup>255</sup> According to one agricultural expert, “[a]nyone who understands the grain handling system . . . would know that it would be virtually impossible to keep StarLink corn separate from corn that is used to produce human food.”<sup>256</sup> If the EPA had been aware of this fact or coordinated the StarLink approval with the USDA, it would have discovered that the conditions and special procedures could not have been enforced. The registration for StarLink should not have been approved.

## 2. ProdiGene

The controversy surrounding biopharming—the use of GE crops to produce pharmaceuticals—is likely to grow stronger given the economics and potential market for such products. This discord is attributable to fear of contamination of the food supply stemming from lax regulatory oversight, as shown in the ProdiGene incident.<sup>257</sup> In 2001, ProdiGene had planted experimental corn in two open fields, one in Nebraska and one in Iowa.<sup>258</sup> The corn had been genetically engineered to produce a pharmaceutical for preventing diarrhea in pigs.<sup>259</sup> USDA discovered violation of APHIS containment requirements in both fields by the fall of 2002.<sup>260</sup> In Iowa, the grower failed to remove the old ProdiGene corn plants fully from the field.<sup>261</sup> The corn sprouted from seeds left over and the pollen traveled and contaminated nearby soybean fields.<sup>262</sup> The USDA had to order

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254. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 834; see Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2207.

255. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d at 834.

256. George Anthan, *OK Sought for Corn in Food*, DES MOINES REG., Oct. 26, 2000, at D1.

257. BILL FREESE & RICHARD CAPLAN, PLANT-MADE PHARMACEUTICALS: FINANCIAL RISK PROFILE 4 (2006), [http://www.biosafety-info.net/file\\_dir/588748857a1ce4e33.pdf](http://www.biosafety-info.net/file_dir/588748857a1ce4e33.pdf) (providing a summary of the ProdiGene contamination incident and its impact).

258. CARUSO, INTERVENTION, *supra* note 88, at 59.

259. *Id.*

260. *Biotechnology: Noncompliance History*, USDA ANIMAL & PLANT HEALTH INSPECTION SERV. (Aug. 4, 2011), [http://www.aphis.usda.gov/biotechnology/compliance\\_history.shtml](http://www.aphis.usda.gov/biotechnology/compliance_history.shtml).

261. *Id.*; see also Ann Thayer, *ProdiGene Woes: Biopharm Firm Faces USDA, FDA Actions over Corn Contamination*, CHEM. & ENG’G NEWS, Nov. 25, 2002, <http://pubs.acs.org/cen/topstory/8047/8047notw3.html> (noting the contamination locations in Iowa and Nebraska).

262. *Biotechnology: Noncompliance History*, *supra* note 260.

destruction of the harvest and 155 acres of crops surrounding the test site.<sup>263</sup> In Nebraska, the same violation occurred and the USDA impounded and destroyed 500,000 bushels of soybeans.<sup>264</sup> This case demonstrates the Coordinated Framework is seriously deficient in systematic post-release or post-market surveillance as part of the overall risk management program.

### 3. *Monarch Butterfly*

The effect of Bt corn on monarch butterflies was one of the most hotly debated examples of unintended consequences of GE crops on friendly or non-target insects.<sup>265</sup> A research note written by Cornell University entomologists titled “Transgenic Pollen Harms Monarch Larvae” outlined the results of an experiment where forty-four percent of monarch caterpillars fed pollen from Bt corn over the course of four days died.<sup>266</sup> Monarch butterflies have a close association with corn because they generally lay their eggs on milkweed plants that grow throughout cornfields.<sup>267</sup> Bt toxin is supposed to be lethal to insect larvae.<sup>268</sup> Thus, when the entomologists dusted “milkweed leaves with pollen from Bt corn, the results were [as] expected.”<sup>269</sup> “[T]he test larvae grew more slowly and died more quickly than those fed leaves dusted with pollen from conventional [non-Bt] corn.”<sup>270</sup>

The story hit the front page of the New York Times and elicited immediate outrage.<sup>271</sup> The monarch butterflies instantly became the symbol of anti-biotech protests and GE opponents continue to repeat the story today.<sup>272</sup> “Subsequent exhaustive field research showed that the actual effect of Bt corn pollen would kill, at most, three monarch caterpillars out of ten thousand,”<sup>273</sup> and a collection of six papers published in the Proceedings of the National Academy of Sciences in 2001 further concluded that “the portion of the monarch population

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263. Thayer, *supra* note 261.

264. *Biotechnology: Noncompliance History*, *supra* note 260; Thayer, *supra* note 261.

265. NESTLE, *supra* note 125, at 189.

266. BRAND, *supra* note 142, at 145; John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214–15 (1999).

267. NESTLE, *supra* note 125, at 189.

268. *Id.*

269. *Id.*

270. *Id.*

271. See BRAND, *supra* note 142, at 145–46; see also NESTLE, *supra* note 125, at 189 (explaining that the research note provoked political firestorms as neither the farmers nor Congress wanted to be known as “butterfly-killers”).

272. BRAND, *supra* note 142, at 145.

273. *Id.*

that is potentially exposed to toxic levels of Bt corn pollen is negligible and declining.”<sup>274</sup>

The more important message from this case study is that it called attention to the deficiency in risk assessment under the Coordinated Framework. Although the EPA considered the potential impact on monarch butterflies prior to approving the initial registration for Bt corn, some argue the assumptions that it made were scientifically unsound.<sup>275</sup> It took the negative publicity to trigger a collaborative research effort, in which the USDA was also a participant, to conduct a formal risk assessment of the impact of Bt corn on monarch butterfly populations and to ultimately conclude that the risk was low or negligible.<sup>276</sup>

#### 4. *GloFish*

Since the FDA claimed jurisdiction over GE animals by virtue of its “new animal drug” authority under the FFDCFA, one would assume that *GloFish*, the first commercially available transgenic animal, would have gone through the FDA’s regulatory process.<sup>277</sup> In addition, since *GloFish* is an aquarium fish genetically engineered to glow in the dark, one might even have expected an environmental analysis.<sup>278</sup> The risk is that pet animals can escape or are released into the wild when no longer wanted. They move on to breed with native, non-GE species that could result in the unintended side effects of crowding out the native species, monopolizing their food sources and upsetting and the ecological balance.<sup>279</sup>

“Rather than engaging in heightened or even ordinary regulatory scrutiny the [FDA] . . . announced in 2003 that it would permit *GloFish* to enter into inter-

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274. See, e.g., Mark K. Sears et al., *Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, 98 PROC. NAT’L ACAD. SCI. 11,937, 11,942 (2001).

275. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2213; see also COUNCIL ON ENVTL. QUALITY & OFFICE OF SCI. & TECH. POL., CASE STUDY II: BT MAIZE 25 (2001), available at [http://www.whitehouse.gov/files/documents/ostp/Issues/ceq\\_ostp\\_study3.pdf](http://www.whitehouse.gov/files/documents/ostp/Issues/ceq_ostp_study3.pdf) (“This conclusion [that Bt corn poses no risk to monarch butterflies] rested on an expectation that there would be relatively few milkweed plants . . . near or in maize fields and on an expectation that the amounts of MON810 pollen which might land on adjacent milkweed plants would be below toxic levels.”).

276. See Sears et al., *supra* note 274.

277. Rebecca M. Bratspies, *Glowing in the Dark: How America’s First Transgenic Animal Escaped Regulation*, 6 MINN. J. L. SCI. & TECH. 457, 458–59 (2005) [hereinafter Bratspies, *Glowing in the Dark*].

278. *Id.*

279. See *id.* at 495–99 (providing an overview discussion of environmental risks posed by transgenic fish upon escape or release into the wild).

state commerce wholly unregulated.”<sup>280</sup> The FDA based its decision on the fact that “[b]ecause tropical aquarium fishes are not used for food purposes, they pose no threat to the food supply.”<sup>281</sup> Further, relying on the principle of ‘substantial equivalence’, the FDA unilaterally declared that there was no evidence that these GE fish would “pose any more threat to the environment than their unmodified counterparts . . . . In the absence of a clear risk to the public health, the FDA [found] no reason to regulate these particular fish.”<sup>282</sup> These conclusions left the GloFish, the first commercially-available transgenic animal, completely unregulated.<sup>283</sup>

The irony in this case is that the technology was so new that there was no way the FDA could determine with certainty the long-term costs or benefits of the GloFish. In addition, because the FDA’s expertise and mandate is to protect the human food and drug supply rather than to protect the environment, it should at least have coordinated with the EPA for an environmental assessment or analysis of potential ecological consequences.

Lastly, the FFDCRA “does not require a ‘clear risk to public health,’ nor indeed any evidence of threat, to trigger regulation. On the contrary, the statute expressly requires evidence of safety before sale of a product can be approved.”<sup>284</sup> The FDA unequivocally failed to meet this burden as it assumed GloFish was safe without any *evidence of safety*. This is another example of a major deficiency in the Coordinated Framework that must be corrected. Although there is no documented negative impact to date, California, Canada, Australia, and Europe continue to ban GloFish.<sup>285</sup>

##### 5. *AquaBounty’s AquaAdvantage Salmon*

As previously discussed, the FDA is currently reviewing the AquaBounty Farms’ application for the approval of a fast growing transgenic salmon for human consumption. The rationale that the FDA used to justify approval is mis-

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280. *Id.* at 458–59; see Statement, U.S. Food & Drug Admin, FDA Statement Regarding GloFish (Dec. 9, 2003), available at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm161437.htm>.

281. Statement, U.S. Food & Drug Admin., *supra* note 280.

282. *Id.*

283. Bratspies, *Glowing in the Dark*, *supra* note 277, at 459.

284. *Id.* at 477 (citing Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(w) (2000)).

285. See *Glofish Florescent Fish FAQ: Glofish in California*, GLOFISH, <http://www.glofish.com/faq.asp> (last visited Sept. 25, 2012) (citing time and cost of complying with the more stringent environmental review under the California Environmental Quality Act (CEQA) for the unavailability of Glofish in that state); *Glofish Florescent Fish FAQ: Where to Purchase Glofish*, GLOFISH, <http://www.glofish.com/faq.asp> (last visited Sept. 25, 2012) (noting the complex approval processes for export of GE animals to Canada, Australia, and Europe).

guided and incredulous. The background documents released contain multiple examples of how the limited data supplied to the agency prohibited the agency from drawing more developed conclusions.<sup>286</sup> The nutrition and allergenicity studies that the FDA relied upon examined relatively small numbers of fish and were conducted by AquaBounty or its contractors.<sup>287</sup> The nutritional composition study looked at 144 fish, while the allergenicity study included only six GE salmon.<sup>288</sup> “The only peer reviewed publicly available data for assessing the science behind the AquaAdvantage salmon [was] a single paper” written by AquaBounty scientists.<sup>289</sup> This paper not only contained basic errors that prevented readers from checking the author’s conclusions, it presented data that contradicted its written conclusions regarding the nature of the integrated transgene.<sup>290</sup> In addition, it failed to characterize the transgene insertion site.<sup>291</sup> Hence, even by a layperson’s standard, these studies do not come close to meeting the scientific rigor necessary to assure the public that the product is safe to eat. Most troubling, however, is that the FDA ultimately does not fully understand the product it is being asked to approve.<sup>292</sup>

In addition, similar to the GloFish, GE salmon presents serious environmental risks.<sup>293</sup> This include the concern of the transgenic fish becoming an invasive species, bearing Trojan genes that increase mating success but ultimately decrease viability, thereby reducing fitness of the wild population and driving them to extinction.<sup>294</sup> Further, even with biological containment methods proposed, escaped, sterile fish might still engage in mating behavior that disrupts

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286. *Meeting on AquaAdvantage Salmon*, *supra* note 4, at 293 (statement of Wenonoh Hauter, Exec. Dir., Food & Water Watch).

287. *Halt Approval of Salmon*, *supra* note 6.

288. *Id.*; see also *Meeting on AquaAdvantage Salmon*, *supra* note 4, at 222 (statement of Kevin Greenlees, Ph.D., DABT).

289. Jonathan Latham & Allison Wilson, *The AquaBounty Salmon: Will the World’s First Commercial GE Animal Be an Albatross?*, INDEP. SCI. NEWS, Oct. 6, 2010, <http://independentsciencenews.org/health/aquabounty-salmon/> (citing E.S. Yaskowiak et. al., *Characterization and Multigenerational Stability of the Growth Hormone Transgene (EO-1alpha) Responsible for Enhanced Growth Rates in Atlantic Salmon*, 15 TRANSGENIC RES. 465 (2006)).

290. *Id.*

291. *Id.*

292. *Id.* The authors established the following: (1) “inadequate molecular characterization means that there is no definitive description of the transgenic event contained in the AquaBounty salmon,” (2) “without an accurate molecular characterization of the insertion site, the effectiveness of the [FDA] approval process is compromised,” and 3) because “characterization of the insertion is the first and most basic step in this process,” but instead “AquaBounty and the FDA . . . bypassed this scientific hurdle and settled for assumption-based reasoning.” *Id.*

293. Bratspies, *Glowing in the Dark*, *supra* note 277, at 504.

294. *Id.* at 496–99.

breeding in the wild populations.<sup>295</sup> In fact, “[d]espite AquaBounty’s claim to produce only sterile salmon, the company admitted that up to 5 percent of their GE salmon eggs could be fertile prompting the FDA to label the company’s claim as ‘potentially misleading.’”<sup>296</sup> Further, transgenic salmon might have enhanced ability to transfer disease as they might act as “reservoirs for diseases and parasites to which they are resistant.”<sup>297</sup>

Salmon aquaculture, even of non-transgenic salmon, is already quite controversial, with many scientists claiming that aquaculture endangers the survival of wild salmon. Aquaculture of transgenic salmon may pose enhanced or different risks to wild salmon, and it is not at all clear that the FDA has either the scientific competence or the inclination to consider those risks.<sup>298</sup>

At minimum, the FDA should prepare an environmental impact statement pursuant NEPA or coordinate with the EPA in the approval process in order for environmental risks to be properly evaluated. Unfortunately, this has not been the case to-date.

### C. *The Current System Cannot Accommodate the Next Generation of GE Products*

#### 1. *The Trends with GE Foods*

Historically, technological progress has consistently outpaced the development of rules and regulations to govern.<sup>299</sup> The first generation of genetically engineered food crops focusing on single-gene, single-trait modifications for pest/insect resistance or herbicide tolerance<sup>300</sup> have become so established in the United States that many scientists and researchers have already moved on to target newer, more exciting, and potentially more lucrative GE projects. Although

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295. *Id.* at 501.

296. Troubling Email, *supra* note 5.

297. Bratspies, *Glowing in the Dark*, *supra* note 277, at 501 (citing O. Tully et al., *Spatial and Temporal Variation in the Infestation of Sea Trout (Salmo trutta L.) by the Caligic Copepod Lepeophtheirus Salmonis (Krøyer) in Relation to Sources of Infection in Ireland*, 119 PARASITOLOGY 41 (1999)).

298. *Id.* at 495–96.

299. *See generally* Lotter, *supra* note 18, at 33–37 (describing the development of transgenic crops followed by regulation).

300. *Id.* at 34. “The main two transgenic traits are resistance to glyphosate herbicide,” (Monsanto’s Roundup) and “insect resistance in which the plant systemically produces an insecticide derived from the Cry gene of the bacterium *Bacillus thuringiensis*,” or Bt. *Id.*



the long-term impact to health<sup>301</sup> and the environment<sup>302</sup> for first generation products are only now starting to materialize and become apparent, the second generation, which represents a significant departure from the first, is already progressing full speed ahead. The food pipeline includes GE animals such as faster-growing fish that can be harvested sooner than their wild counterparts,<sup>303</sup> functional foods with enhanced nutritional values, specialty crops with improved taste, freshness and other traits, and crops designed to be flood, drought, heat or salt tolerant and capable of withstanding other vagaries likely brought about or exacerbated by climate change.<sup>304</sup> Recent headlines include Chinese scientists announcing the successful engineering of human genes into dairy cows to produce milk with the same properties and characteristics as human breast milk<sup>305</sup> and farmers in Columbia importing GE marijuana seeds from the United States and Europe to produce plants that are more powerful and profitable.<sup>306</sup> Outside of the food system, the scientific potentials are even more amazing, including plants engineered to produce pharmaceuticals (biopharming), plants for absorbing hazardous materials for use in environmental remediation, and animals that produce

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301. See, e.g., Aziz Aris & Samuel Leblanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, 31 REPROD. TOXICOLOGY 528 (2011). Although more research is necessary to confirm these findings, this was the first published study to reveal that the insecticide in GE corn is now showing up in human bloodstream and the umbilical cord blood of pregnant women. *Id.* Thus, this calls into question the repeated claim by GE proponents that eating GE crops has harmed no human being. The issue raised is also one of cumulative impact, whether the consumption is in fact introducing new toxins into our bodies over time. *Id.*

302. Jessica Marshall, *GM Plants Escape into American Wild*, DISCOVERY NEWS, Aug. 6, 2010, <http://news.discovery.com/earth/gm-plant-canola-wild.html>. Survey results “suggest[ed] that [GE] plants are reproducing on their own, making this the first report of an established population of [GEOs] in the wild.” *Id.* Researchers have found hundreds of transgenic, herbicide-resistant canola plants across North Dakota and two instances of multiple transgenes in single individuals, suggesting that feral populations are reproducing and have become established outside of cultivation. *Id.* These observations have serious ecological consequences and important implications for the management of native and weedy species and the management of biotech products in the United States.

303. Joe Commins, *Transgenic Fish Coming*, INST. OF SCI. IN SOC’Y, Dec. 15, 2003, <http://www.i-sis.org.uk/TFC.php>. Aside from the AquaBounty salmon discussed earlier in this paper, other GE fish include tilapia, trout, and carp. See *id.*

304. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 3, 4 fig.1.2.

305. Richard Gray, *Genetically Modified Cow Produce ‘Human’ Milk*, THE TELEGRAPH, Apr. 2, 2011, <http://www.telegraph.co.uk/earth/agriculture/geneticmodification/8423536/Genetically-modified-cows-produce-human-milk.html>.

306. Luis Robayo, *GM Marijuana Problem Growing in Columbia*, P’SHIP FOR A DRUG-FREE N.J., June 24, 2011, [http://www.drugfreej.org/2011\\_marijuana\\_columbia/](http://www.drugfreej.org/2011_marijuana_columbia/).

tissues or organs for human transplants.<sup>307</sup> Thus, facing an avalanche of GE innovations, it is more important now than ever for the United States to catch up on the regulatory front.

In addition, with Brazil, Argentina, China, and other countries aggressively moving forward with new GE initiatives,<sup>308</sup> it is only a matter of time before the table is turned and these countries will seek to export their GE crops and products to the United States. In 2010, Brazil and Argentina were the second and third largest growers of biotech crops in the world.<sup>309</sup> China presently grows five biotech crops commercially and is field testing twelve others.<sup>310</sup> Unless the Coordinated Framework is reformed to properly regulate the United States' own biotech industry by updating scientific standards, mandating stringent risk assessments and risk management processes, it would be hard pressed for the United States to legitimately reject any GE products from other nations.

## 2. *The Need to Feed an Ever-Growing Population*

It is estimated that the world's population will grow from seven billion now to over nine billion in 2050.<sup>311</sup> Significant questions presented by this population increase are whether there will be enough food to feed all these people and what role biotechnology will play. A combination of factors has exacerbated the food crisis.<sup>312</sup> GE proponents argue that if we try to feed "six billion people using the mainly organic farming methods of 1961, we would need to cultivate 82

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307. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 4 fig.1.2.

308. See *Biotech Country Facts and Trends*, INT'L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, [http://www.isaaa.org/resources/publications/biotech\\_country\\_facts\\_and\\_trends/default.asp](http://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/default.asp) (last visited Sept. 25, 2012).

309. *Biotech Facts & Trends: Brazil*, INT'L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, 1 (July 13, 2012), [http://www.isaaa.org/resources/publications/biotech\\_country\\_facts\\_and\\_trends/download/Facts%20and%20Trends%20-%20Brazil.pdf](http://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/download/Facts%20and%20Trends%20-%20Brazil.pdf); *Biotech Facts & Trends: Argentina*, INT'L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, 1 (July 13, 2012), [http://www.isaaa.org/resources/publications/biotech\\_country\\_facts\\_and\\_trends/download/Facts%20and%20Trends%20-%20Argentina.pdf](http://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/download/Facts%20and%20Trends%20-%20Argentina.pdf).

310. *Biotech Facts & Trends: China*, INT'L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, 1 (July 13, 2012), [http://www.isaaa.org/resources/publications/biotech\\_country\\_facts\\_and\\_trends/download/Facts%20and%20Trends%20-%20China.pdf](http://www.isaaa.org/resources/publications/biotech_country_facts_and_trends/download/Facts%20and%20Trends%20-%20China.pdf).

311. John Parker, *The 9 Billion-People Question*, ECONOMIST, Feb. 24, 2011, <http://www.economist.com/node/18200618>.

312. *Id.* ("A combination of factors—rising demand in India and China, a dietary shift away from cereals towards meat and vegetables, the increasing use of maize as fuel, and developments outside agriculture, such as the fall in the dollar—have brought to a close a period starting in the early 1970s in which the real price of staple crops (rice, wheat and maize) fell year after year.").

percent of the earth's land surface instead of the current 38 percent."<sup>313</sup> "The world has no 'surplus' of farmland, in the United States, Western Europe, or anywhere else."<sup>314</sup> "Forests are the first areas likely to be cultivated when farmland expands."<sup>315</sup> Thus, discussions of farming methods today "must take into account the environmental consequences of expanding the food supply," as "[n]ew land put under cultivation is land taken away from the dwindling wildlands that are the planet's ecological underpinnings."<sup>316</sup>

Klaus Ammann, curator of the Botanical Garden at the University of Bern in Switzerland, and Jim Cook, a prominent plant pathologist, are among those who believe that scientists can encourage both organic agriculture and biotechnology at the same time.<sup>317</sup> "Cook has been studying no-till agriculture as a way for [farmers] . . . to cut erosion and to enrich the soil."<sup>318</sup> In fact, "Cook's research shows unequivocally that [GE] crops [such as herbicide-tolerant wheat] can contribute to sustainable agriculture."<sup>319</sup> Likewise, in 2003 Klaus Ammann produced a report on biodiversity and agricultural biotechnology and concluded that we need an "eco-technology revolution," and "to make peace with the people in organic agriculture."<sup>320</sup> Ammann founded a group called Ecogene in the 1990s to investigate the biosafety and gene flow of GE plants.<sup>321</sup> As GE proponents, Cook and Ammann clearly support biotech as the solution to feeding the ever-growing population. However, as discussed earlier, feeding the world is a complex social problem that biotechnology alone is unlikely to resolve, and the first generation of GE crops has failed to improve yield as claimed.<sup>322</sup> It remains to be seen whether the second generation will fare better with traits other than pest resistance and herbicide tolerance.

### 3. *The Impact of Climate Change*

In a recently published report, Oxfam, the international relief group, projected that food prices would increase by seventy to ninety percent by 2030 with

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313. FEDOROFF & BROWN, *supra* note 152, at 264.  
 314. DENNIS AVERY, SAVING THE PLANET WITH PESTICIDES AND PLASTIC: THE ENVIRONMENTAL TRIUMPH OF HIGH-YIELD FARMING (1995).  
 315. FEDOROFF & BROWN, *supra* note 152, at 264–65.  
 316. *Id.* at 268.  
 317. *Id.* at 269–74.  
 318. *Id.* at 270–71.  
 319. *Id.* at 270.  
 320. *Id.* at 269 (quoting KLAUS AMMANN, BIODIVERSITY AND AGRICULTURAL BIOTECHNOLOGY: A REVIEW OF THE IMPACT OF AGRICULTURAL BIOTECHNOLOGY ON BIODIVERSITY (2003)).  
 321. *Id.*  
 322. *See* discussion *supra* Part II.B.2.

climate change potentially causing them to double again.<sup>323</sup> The food system is buckling under the intense pressure of crop failures caused by extreme weather, crop yields suppressed due to increased exposure to drought and floods, and growing conflicts over water.<sup>324</sup> Scientists who previously predicted that climate change would be relatively manageable for agriculture are now heading back to the drawing boards.<sup>325</sup> Researchers suggest it is possible, with genetic engineering, to create crop varieties more resistant to drought and flooding, better able to withstand withering heat, and able to respond well to increased concentrations of carbon dioxide in the atmosphere.<sup>326</sup> Oxfam, however, argues that GE crop varieties developed in the past for large-scale industrial farms have failed to provide for poor farmers or make a significant contribution to tackling hunger, poverty, or development.<sup>327</sup> Given the gravity of the circumstances, however, the logical solution is not to foreclose any options at this point. We need to explore biotechnology to the fullest extent possible. To this end, having a strong regulatory system can only help rather than hinder the agricultural biotech industry going forward.

#### IV. MOVING FORWARD—PROPOSALS FOR CHANGE AND KEY OBSTACLES

##### A. *Legislative and Policy Initiatives are Necessary*

Reforming the agricultural biotech regulatory system will require passing new legislation and amending existing laws. Despite serious shortcomings, this is best accomplished within the Coordinated Framework. Given the current economic crisis and budgetary constraints, any attempt for overly drastic, comprehensive reform is improbable and likely to be politicized and compromised in the legislative process.

Although aggressive changes have been proposed in the past, none were able to generate sufficient support to move forward. Legislative efforts to develop a single statutory scheme specifically governing all GE food products, or a statutory scheme governing only one specific aspect, such as mandatory labeling,

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323. OXFAM, GROWING A BETTER FUTURE: FOOD JUSTICE IN A RESOURCE-CONSTRAINED WORLD 12 (2011), available at <http://www.oxfam.org/sites/www.oxfam.org/files/cr-growing-better-future-170611-en.pdf>; Justin Gillis, *A Warming Planet Struggles to Feed Itself*, N.Y. TIMES, June 4, 2011, [https://www.nytimes.com/2011/06/05/science/earth/05harvest.html?\\_r=1&page\\_wanted=all](https://www.nytimes.com/2011/06/05/science/earth/05harvest.html?_r=1&page_wanted=all).

324. Gillis, *supra* note 323.

325. *Id.*

326. *Id.*

327. OXFAM, *supra* note 323, at 35.

have been unsuccessful.<sup>328</sup> Others have contemplated moving all oversight of GEOs to one agency,<sup>329</sup> or creating a new division within one agency to specifically govern GE products.<sup>330</sup> These proposals were overly ambitious—valuable institutional expertise developed within each agency would likely be sacrificed.

In addition, any attempts to divest power and resources from a government agency will likely face strong political opposition. Thus, the more practical approach is not to dismantle the Coordinated Framework, but to work within it through targeted restructuring in order to better confront the realities and uncertainties of novel GE food products. To accomplish this, any new legislation must not only reflect current scientific discoveries, it must also facilitate a regular amendment process as the science of molecular biology and molecular genetics continue to rapidly evolve.

### 1. *Discard the Concept of “Substantial Equivalence”*

In light of the collapse of the Central Dogma theory, the first step to effective reform is to acknowledge that the concept of substantial equivalence no longer applies. Although the stated “policy remains that genetically engineered products should receive the same regulatory treatment as similar, conventionally produced products” based on the concept of substantial equivalence, in reality, each agency has already “developed a hybrid system that effectively treats biotech products differently.”<sup>331</sup> This occurred precisely because of the difficulties in attempting to fit biotech products into existing laws and “the perceived public

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328. See, e.g., Genetically Engineered Food Right to Know Act, H.R. 5577, 111th Cong. (2010); Genetically Engineered Food Right to Know Act, H.R. 5269, 109th Cong. (2006); Genetically Engineered Foods Act, S. 2546, 108th Cong. (2004); Genetically Engineered Food Right to Know Act, H.R. 3377, 106th Cong. (1999).

329. See John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 863 (2001) (proposing that Congress enact a new statute entitled the Transgenic Release Act to be administered solely by the EPA and be the only legislation governing GEOs).

330. See Sheryl Lawrence, *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, 285–86 (2007) (proposing the creation of an Office of Transgenic Products, a unit to be housed within the FDA, as the sole authority to oversee all forms of genetically engineered products).

331. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 10; see also Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309 (June 26, 1986); Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,312 (June 26, 1986); Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336 (June 26, 1986).

interest in affording GE products greater scrutiny.”<sup>332</sup> The FDA’s policy of encouraging biotech companies to submit safety data prior to marketing food from a new GE crop variety effectively, for example, applies a higher level of scrutiny to the GE crop than to conventionally bred crops.<sup>333</sup> The USDA’s rule requiring notification and permitting for field trials of GE plants rests on the process by which the plants are genetically engineered.<sup>334</sup> Further, the EPA created special regulations for “plant-incorporated protectants,” or PIPs, to deal with plants that were genetically engineered to make their own pesticides, because these GE plants are potentially a plant pest, a food, and a pesticide.<sup>335</sup> Thus, it is disingenuous to continue applying substantial equivalence as the scientific underpinning and guiding concept for our regulatory system.

## 2. *Incorporate Systematic Risk Assessment into Regulations*

The Coordinated Framework also can no longer rely on the argument that rDNA technique is precise and safe without the Central Dogma theory.<sup>336</sup> Once the concept of substantial equivalence is abandoned, the path is cleared for new or amended legislation to incorporate systematic risk assessment into the review or approval process for all GE foods. In fact, environmental risk assessments (ERAs) are already required for the regulatory approval of GEOs in most countries in the world.<sup>337</sup> ERAs evaluate “risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of [GEOs] may pose.”<sup>338</sup> In addition, “potential cumulative long-term effects” should be analyzed.<sup>339</sup>

In order for the United States to adequately protect human health and the environment and to effectively manage risks arising from the next generation of GE products, it is essential for the Coordinated Framework to move toward the

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332. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 10.

333. *Guidance on Consultation Procedures: Foods Derived from New Plant Varieties*, U.S. DEPT. OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN. (1997), <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm>.

334. 7 C.F.R. § 340.3(a) (2012).

335. 40 C.F.R. pt. 174 (2011).

336. See Van Tassel, *Genetically Modified*, *supra* note 122, at 221–22.

337. Angelika Hilbeck et al., *Environmental Risk Assessment of Genetically Modified Plants—Concepts and Controversies*, 23 ENVTL. SCI. EUR. 1, 1 (2011), <http://www.enveurope.com/content/23/1/13>; see also Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 15, Jan. 29, 2000, 22 U.N.T.S. 208 (providing for risk assessments).

338. Directive 2001/18/EC, *supra* note 184, at art. 2(8).

339. *Id.* at pmb1. (19).

precautionary approach where risk assessments are performed systematically. Rather than stubbornly clinging onto a flawed and outdated system, harmonizing our regulatory framework with the EU and the rest of the world can only support the agricultural biotech industry in the long run. The WTO decision in the EU Biotech case has made clear that it is not necessarily the best forum to resolve trade disputes surrounding GE products.<sup>340</sup> If the EU or other nations continue to reject GE foods from the United States, it is incumbent upon the United States to reconsider its position and start shifting toward a regulatory framework that will not only better protect human health and the environment, but is also more beneficial to our economic interests and trade relations.

Assessing risks is rarely a simple task. Assessing human health and environmental risks associated with the release of a novel genetically engineered organism is even more complex and problematic.<sup>341</sup> This stems from a lack of understanding of the complete function of our ecosystems and how these novel organisms can affect them cumulatively over time.<sup>342</sup> “Furthermore, there are a large number of routes through which a novel organism could affect other species.”<sup>343</sup> Finally, “the potential for collateral impacts is not limited to species that interact directly with the novel organism,” but can cascade into indirect effects on unconnected species in unanticipated manners.<sup>344</sup>

Until now, the approaches used to support the safety of GE crops in the United States relied primarily on “(1) Conducting small (meaning poorly replicated) trials to test for effects and (2) Citing published and unpublished studies or using letters from expert scientists to establish an absence of risk.”<sup>345</sup> “These approaches generally provide feeble evidence of safety” as it is “typically much more difficult to satisfactorily demonstrate the absence, rather the presence, of an effect.”<sup>346</sup> Although there are no internationally agreed upon standard protocols,

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340. See EU Panel Report, *supra* note 176.

341. Michelle Marvier & Sabrina West, *Ecological Risk Assessment of GE Crops: Getting the Science Fundamentals Right*, in GENETICALLY ENGINEERED CROPS, INTERIM POLICIES, UNCERTAIN LEGISLATION 57–58 (Iain E.P. Taylor ed., 2007).

342. *Id.* at 58.

343. *Id.*

344. *Id.*

345. *Id.* at 59 (citing Ingrid M. Parker & Peter Kareiva, *Assessing the Risks of Invasion for Genetically Engineered Plants: Acceptable Evidence and Reasonable Doubt*, 78 BIOLOGICAL CONSERVATION 193 (1996)); see also Michelle Marvier, *Improving Risk Assessment for Nontarget Safety of Transgenic Crops*, 12 ECOLOGICAL APPLICATIONS 1119 (2002) (evaluating the risk assessment process and noting areas for improvement).

346. Marvier & West, *supra* note 341, at 59 (citing A.J. Underwood, *Environmental Decisionmaking and the Precautionary Principle: What Does this Principle Mean in Environmental Sampling Practice?*, 37 LANDSCAPE & URBAN PLANNING 137 (1997)); Michelle Marvier, *Ecology of Transgenic Crops*, 89 AM. SCIENTIST 160 (2001).

such as minimum data requirements, levels of acceptable risk, or evaluation of risk control measures, it is apparent from the case studies in this paper that risk assessment is not sufficiently vigorous and not systematically conducted in the United States. Reform of the Coordinated Framework, therefore, must entail new legislation to require risk assessment be performed on all GEOs or GE products prior to market or release into the environment. Further, in order to develop a robust regulatory system, stringent scientific protocols and independent reviews must also be instituted as part of the risk assessment process.

Proper risk assessment also means that regulatory responsibilities must be organized based on each agency's expertise.<sup>347</sup> This can be achieved through legislative amendments to the Coordinated Framework to alter the authority given each agency. To this effect, Mandel suggests

the FDA should bear responsibility for the human health risks posed by genetically modified plants or animals intended for use as human food or pharmaceuticals; the EPA should take responsibility for evaluating the environmental risks posed by transgenic products; and the USDA should regulate the impact of genetically engineered products on agricultural crops and livestock.<sup>348</sup>

No agency should be able to circumvent the review or approval process if its area of expertise is involved. While the FDA is reviewing AquaBounty's transgenic salmon for human consumption under the FFDCA's 'new animal drug' provision, for example, the EPA should be coordinating with the FDA to perform environmental impact statement simultaneously. AquaBounty's salmon should not be released for market until both agencies have completed the review process and provided its approval or conditions for approval. Currently, the EPA is not involved in the approval process despite the serious environmental risks and potential consequences for farming GE salmon.<sup>349</sup>

### 3. *Post-Market Monitoring as Part of the Risk Management Process*

In addition to systematic pre-market risk assessment, it is equally important for "agencies to monitor the use of biotechnology to ensure that no unanticipated adverse effects occur, and to confirm that any restrictions are working as expected."<sup>350</sup> Failure to follow agency restrictions has led to costly problems

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347. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2249.

348. *Id.*

349. See Bratspies, *Glowing in the Dark*, *supra* note 277, at 496–99 (describing the environmental risks of GE fish).

350. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 15.



as discussed earlier in the StarLink and ProdiGene cases.<sup>351</sup> Thus, amending the Coordinated Framework must necessarily provide adequate authority for each agency to conduct post-market surveillance for GE products and the authority to act in the event that problems are discovered.<sup>352</sup> Under the current system, for example, “[n]ew food products that are ‘generally recognized as safe’ can legally go directly to market without FDA approval.<sup>353</sup> The FDA does not track such products and may not know whether they are being sold.”<sup>354</sup> Should a problem arise, the FDA can only take action “after a problem has been discovered”, brought to its attention, and even then it must “act in an enforcement proceeding and prove that the food product is ‘adulterated’ or unsafe for human use.”<sup>355</sup> Likewise, once APHIS determines that a GE crop is not a plant pest and permits it to be grown commercially without restrictions, the “plant is no longer subject to APHIS’s legal authority.”<sup>356</sup>

APHIS has no authority to monitor [the crop] after it has gone to market, and the manufacturer has no legal obligation to monitor or report unanticipated problems. Should a problem occur, APHIS would have to have new evidence showing that the previously deregulated crop was indeed a plant pest in order to take action.<sup>357</sup>

In light of the second generation of GE products expected to come online and the potential risks that they might bring, it is imperative that any reform for the Coordinated Framework must encompass the closing of this significant gap on post-market monitoring authority for the three agencies.

#### 4. *Institute a System of Coordination Among the Three Agencies*

If the Coordinated Framework is to work as intended, a system of coordination must be instituted between the FDA, USDA, and EPA. A truly coordinated framework means that no GE products should be able to bypass the system entirely or bypass an agency that clearly has the expertise to perform the neces-

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351. *In re StarLink Corn Prods. Liab. Litig.*, 212 F. Supp. 2d 828; *Biotechnology: Non-compliance History*, *supra* note 260.

352. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 15.

353. *Id.* at 16; *see also* Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23,309, 23,310–11 (June 26, 1986) (detailing agency considerations in determining the safety of biotech products).

354. PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, ISSUES IN REGULATION, *supra* note 7, at 16.

355. *Id.*; *see* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342 (2006) (regulating “adulterated foods”).

356. *Id.*

357. *Id.*

sary risk assessment prior to approval or release. A case in point is the recent unilateral decision by the USDA to not regulate a Roundup-Ready strain of Kentucky bluegrass.<sup>358</sup> The USDA conceded that the GE bluegrass “‘can be considered for regulation as a Federally listed noxious weed’ that shows potential to cause damage to crops and natural resources of the United States. But to avoid actually declaring it a noxious weed, the agency simply claimed that the weed risks posed by [GE] and conventional [bluegrass] are ‘essentially the same.’”<sup>359</sup> This rationale is absurd. Like most grasses, bluegrass is prolific and spreads rapidly and unwanted turf grass is extremely difficult to control.<sup>360</sup> Thus, the question is not whether the GE bluegrass is essentially the same as conventional bluegrass. Instead regulators should question what environmental risks the GE bluegrass will pose when it cross contaminates and damages other species of grass or establishes itself as noxious weed and damages other crop plants. In addition, the USDA “‘confirmed that the agency would not be conducting an environmental-impact statement on Roundup-Ready bluegrass, and by extension, any other crops that [do not qualify] as plant pests or noxious weeds.’”<sup>361</sup> Despite the environmental impacts, there was no mention of the EPA being involved in the review process or any consultation with the EPA in reaching the decision to deregulate.<sup>362</sup> This complete lack of coordination defies logic and common sense. It is a defect in the Coordinated Framework that must be corrected.

To this end, reform might include the creation of a central liaison position for the agencies. The central liaison will assist applicants in navigating the regulatory process from start to finish and serve as the point-of-contact, particularly if more than one agency is involved in reviewing the case for approval. The liaison shall ensure that applicants submit all required data and documents to one

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358. News Release, USDA, Animal & Plant Health Inspection Service, USDA Responds to Regulation Requests Regarding Kentucky Bluegrass (July 1, 2011) [hereinafter News Release, Kentucky Bluegrass], available at [http://www.aphis.usda.gov/newsroom/2011/07/pdf/KY\\_bluegrass.pdf](http://www.aphis.usda.gov/newsroom/2011/07/pdf/KY_bluegrass.pdf).

359. Tom Philpott, *Wait, Did the USDA Just Deregulate All New Genetically Modified Crops?*, MOTHER JONES, July 8, 2011, <http://motherjones.com/environment/2011/07/usda-deregulate-roundup-gmo-tom-philpott> (citing ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, REVIEW OF PETITION TO ADD GENETICALLY ENGINEERED GLYPHOSATE-TOLERANT KENTUCKY BLUEGRASS TO THE FEDERAL NOXIOUS WEED REGULATIONS (2011), available at [http://www.aphis.usda.gov/plant\\_health/plant\\_pest\\_info/weeds/downloads/Kentucky-BG/KY-BG-FNW-PetitionReview.pdf](http://www.aphis.usda.gov/plant_health/plant_pest_info/weeds/downloads/Kentucky-BG/KY-BG-FNW-PetitionReview.pdf); News Release, Kentucky Bluegrass, *supra* note 358).

360. Philpott, *supra* note 359. Philpott provides another example where Scotts, the manufacturer of the Kentucky bluegrass, also grew experimental plots of bentgrass in Oregon in 2005. *Id.* “It escaped the boundaries of the experimental plots and is *still* creating problems for homeowners miles away.” *Id.*

361. *Id.*

362. See News Release, Kentucky Bluegrass, *supra* note 358.

centralized location, rather than answering to multiple overlapping inquiries separately from the different agencies involved. As one of the main criticisms of the current regulatory framework from industry participants is that it is overly cumbersome and tends to favor large corporations with ample resources to navigate the regulatory maze, the liaison proposal should be a step in the right direction to level the playing field for smaller and less capitalized firms.<sup>363</sup>

Further, the agencies should be mandated to collaboratively establish a common process to follow throughout their analysis of the risks that agricultural biotech products present instead of basing decisions on individual agency protocols. A recent agreement reached between the EPA, USDA, and the Department of Interior (DOI), for example, established a common environmental review process to analyze potential air quality impacts of proposed oil and gas projects.<sup>364</sup> This agreement outlined steps the agencies will take to ensure that federal laws protecting air quality, human health, and the environment are balanced with the nation's energy needs.<sup>365</sup> The agreement also provides for early interagency consultation throughout the NEPA process, common procedures for determining the appropriate air quality analyses, specific provisions for discussing impacts, and a dispute resolution mechanism to facilitate timely resolution of disputes among agencies.<sup>366</sup> Lastly, the agencies are committed to working together with project applicants to develop a mitigation plans to reduce potential impacts.<sup>367</sup> This is precisely the type of coordination that is necessary, but lacking with the Coordinated Framework. This interagency approach demonstrates that it is possible to support responsible industry growth and development while guarding human health and environmental protection.

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363. See, e.g., TADLOCK COWAN, CONG. RESEARCH SERV., RL 32809, AGRICULTURAL BIOTECHNOLOGY: BACKGROUND AND RECENT ISSUES 29 (2011) (describing criticism of anticompetitive behavior by large companies that produce GE seeds and how they have a competitive advantage due to their size and market reach).

364. News Release, Bureau of Land Mgmt., U.S. Dep't of Interior, Federal Agencies to Improve Coordination to Support Energy Department and Safeguard Air Quality (June 27, 2011), available at [http://blm.gov/wo/st/en/info/newsroom/2011/june/NR\\_06\\_27\\_2011.html](http://blm.gov/wo/st/en/info/newsroom/2011/june/NR_06_27_2011.html).

365. USDA, U.S. DEP'T OF INTERIOR, & EPA, MEMORANDUM OF UNDERSTANDING AMONG THE U.S. DEPARTMENT OF AGRICULTURE, U.S. DEPARTMENT OF THE INTERIOR, AND U.S. ENVIRONMENTAL PROTECTION AGENCY, REGARDING AIR QUALITY ANALYSES AND MITIGATION FOR FEDERAL OIL AND GAS DECISIONS THROUGH THE NATIONAL ENVIRONMENTAL POLICY ACT PROCESS 1 (2011).

366. *Id.* at 2.

367. *Id.*

### 5. *Improve Transparency: Building Consumer Trust and Confidence*

Under the current regulatory system, the lack of transparency is problematic not only in the pre-release or pre-marketing stage for GE foods due to the lack of public participation in the review or approval process, it is also problematic afterward due to the lack of labeling and traceability. Policy directives can correct these issues in tandem with legislative reform.

Unlike the first generation of GE crops, where pest resistance or herbicide tolerance were the key characteristics of the crops and consumers treated them with indifference, the same cannot be said of the next generation of GE foods. Consumer reactions appear to be much more visceral now that they are faced with the possibility of eating a GE animal.<sup>368</sup> Considering recent publicity surrounding FDA's near approval of the AquaBounty AquAdvantage salmon, there are signs of consumers beginning to demand more information on how food is produced.<sup>369</sup> The biotech industry, along with the FDA, continue to steadfastly oppose mandatory labeling, claiming that it will only bewilder a public that is not informed about genetic engineering.<sup>370</sup> To add insult to injury, the FDA defends their position saying, "it is simply following the law, which prohibits misleading labels on food."<sup>371</sup> GE beef, pork, and other types of fish are waiting for FDA review and approval if the salmon is approved, causing consumer advocates to worry.<sup>372</sup>

The FDA has the power and discretion to change this position. The FDA should be in the business of protecting consumers, but appears to be protecting the industry instead.<sup>373</sup> This is shortsighted because the next generation of GE foods cannot truly succeed in the marketplace without consumer trust and confidence.

The USDA and EPA also need to institute better consumer protection policies. Aside from labeling, which primarily impacts the retail level, the ability to trace and recall a product should unanticipated problems arise depends upon a

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368. See, e.g., Lyndsey Layton, *FDA Rules Won't Require Labeling of Genetically Modified Salmon*, WASH. POST, Sept. 18, 2010, <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/18/AR2010091803520.html>.

369. *Id.*

370. *Id.*

371. *Id.* The FDA sent an enforcement letter to B&G Foods informing the company that it could not use "GMO-free" on its Polaner All Fruit spread label "because GMO refers to genetically modified organisms and strawberries are produce, not organisms." *Id.* The FDA also informed the makers that their label containing the words "GMO" with a red line over the top was inappropriate, saying "the symbol suggested there was something wrong with genetically engineered food." *Id.*

372. *Id.*

373. *See id.*

system capable of identifying and segregating GE from non-GE products. Whether the GE crops or food products are in the fields, being processed, in storage, transport, or on store shelves, they must not be commingled with their non-GE counterparts in ways that would prevent them from being separated should a recall be necessary. Thus, establishing traceability is critical to gaining consumer trust and confidence, as it demonstrates that regulators can act quickly to contain potential problems.

#### 6. *Encourage Independent Research and Investments in Alternative Technological Paradigms*

To date, GE opponents have directed most of their energy and resources to banning GE crops or food products from being introduced into the environment or coming to market.<sup>374</sup> Given the global pervasiveness of GE crops and foods, and the next generation of GE products waiting to launch, a more realistic strategy may involve redirecting resources toward securing more effective regulations, particularly in the United States. In addition, an alternative approach is to devote resources toward a research agenda for alternative technological paradigms, such as agroecological innovation.<sup>375</sup> Agroecology “is the application of the ecological science to the study, design and management of sustainable agroecosystems.”<sup>376</sup> Currently, there are very few scientific organizations that back a strong research agenda on agroecology.<sup>377</sup> They possess “significantly less clout than the mainstream scientific organizations that support genetic engineering.”<sup>378</sup> By shifting focus and resources to support research in agroecology, Non-Governmental Organizations (NGOs) and other GE opponents have a more realistic chance of changing public opinions and making a long lasting impact. A recent study conducted by scientists in Africa “highlighted the dramatic positive effects of rotations, multiple cropping, and biological control on crop health, en-

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374. See, e.g., Press Release, Ctr. for Food Safety, Consumer Groups Petition FDA to Ban GE Salmon as an Unsafe Food Additive. Groups Say Fish Couldn’t Pass Proper Review (Feb. 7, 2012), available at <http://www.centerforfoodsafety.org/> (search “Consumer Groups Petition”; then follow “Consumer Groups Petition . . . proper review” hyperlink).

375. See Gaëtan Vanloqueren & Philippe V. Baret, *How Agricultural Research Systems Shape a Technological Regime that Develops Genetic Engineering but Locks Out Agroecological Innovations*, 38 RES. POL’Y 971, 975–80 (2009) (describing the imbalance of research efforts that favor genetic engineering over agroecological engineering).

376. *Id.* at 972 (citing MIGUEL A. ALTIERI, *AGROECOLOGY: THE SCIENCE OF SUSTAINABLE AGRICULTURE* (2d ed. 1995)).

377. *Id.* at 976.

378. *Id.*

vironmental quality, and agricultural productivity.”<sup>379</sup> New approaches “spear-headed by farmers, NGOs, and some local governments around the world are already making a sufficient contribution to food security at the household, national, and regional levels,” even under adverse conditions and without resorting to genetic engineering techniques.<sup>380</sup> Potential methods of improving agriculture by means other than genetic engineering include raising yields, product diversification, improved diets and income, natural resource conservation, and agrobiodiversity.<sup>381</sup> A recent UN report also showed that small-scale farmers can double food production within ten years in critical regions by using ecological methods.<sup>382</sup> Despite its potential, agroecology is insufficiently backed by public policies, and “[p]rivate companies will not invest time and money in practices that cannot be rewarded by patents and which don’t open markets for chemical products or improved seeds.”<sup>383</sup> Agroecology represents a viable alternative technological paradigm to genetic engineering and should be part of the arsenal in NGO campaigns against agricultural biotechnology.

### B. Real Obstacles to Moving Forward

#### 1. Lack of Political Will to Drive the Necessary Changes

Biotech lobbying dollars are constantly hard at work on Capitol Hill.<sup>384</sup> “Since 1999, the 50 largest agricultural and food patent-holding companies and two of the largest biotechnology and agrochemical trade associations have spent more than \$572 million in campaign contributions and lobby expenditures.”<sup>385</sup> The food and agricultural biotech industry is constantly flexing its muscle to

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379. Miguel A. Altieri, *Transgenic Crops, Agrobiodiversity, and Agroecosystem Function*, in GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION 37, 52 (Iain E.P. Taylor ed., 2007).

380. *Id.*

381. See, e.g., Miguel A. Altieri, *Agroecology: The Science of Natural Resource Management for Poor Farmers in Marginal Environments*, 93 AGRIC., ECOSYSTEMS AND ENV'T 1, 20 (2002) (providing examples of traditional methods to boost productivity).

382. Special Rapporteur on the Right to Food, *Agroecology and the Right to Food*, ¶ 18, U.N. Doc. A/HRC/16/49 (Dec. 20, 2010) (Olivier De Schutter).

383. News Release, Office of the High Commissioner, U.N. Human Rights, Eco-Farming Can Double Food Production in 10 Years, Says New UN Report (Mar. 8, 2011), available at <http://www.ohchr.org/en/NewsEvents/Pages/DisplayNews.aspx?NewsID=10819&LangID=E>.

384. See FOOD & WATER WATCH, FOOD AND AGRICULTURE BIOTECHNOLOGY INDUSTRY SPENDS MORE THAN HALF A BILLION DOLLARS TO INFLUENCE CONGRESS (2010), <http://documents.foodandwaterwatch.org/doc/BiotechLobbying-web.pdf>.

385. *Id.*

block regulatory efforts, even though strong arguments can be made that a more robust regulatory system would actually benefit the industry in the long run.

Recently, officials at the USDA made “statements that indicate a shift to accommodate the organic lobby, raising the possibility of the introduction of coexistence rules for [GE] crops similar to those used in Europe.”<sup>386</sup> This appears to signal stronger regulations on the horizon that would protect organic crops against gene flow and possible contamination by GE crops. Capitol Hill insiders, however, “also are hinting that the Obama administration is considering a radical overhaul of rules governing biotech crops to make it much easier to bring such products into commerce.”<sup>387</sup> This appears to be based on the age-old argument that there have been no harmful consequences from GE crops and the regulations that have been in place are unnecessary.<sup>388</sup> To relax or abandon regulations on this basis is misguided because the claim of no harmful consequences from the first generation of GE crops does not mean that there will be no consequences from the next generation. Evidence of impacts from the first generation are only now beginning to manifest themselves. In fact, the biotech industry is more likely to benefit from stronger regulations, as it will instill confidence in the public as well as trading partners around the world. If the criticism of the biotech industry is that the existing regulations are poorly suited, the solution is to amend the regulations, not to deregulate entirely.

Further, absent a high profile disaster, it is unlikely that a GE product developer or grower would ever bear the full burden of ecological damages or the cost of human health impacts due to problems with scientific proof of causation.<sup>389</sup> As such, market forces alone, without proper regulations, are rarely sufficient to protect society from the risks of these products.<sup>390</sup>

## 2. *True Reform Will Require Changes Beyond the Coordinated Framework*

This Article focused primarily on the deficiencies in the Coordinated Framework as the starting points for reforming the regulatory system for agricultural biotechnology. No reform can be meaningful, however, without also confronting other interconnected components of the complex biotech food industry. Although beyond the scope of this paper to analyze the details, there are a number of issues that must be raised for possible future research and discussion.

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386. Jeffrey L. Fox, *Mixed Messages from Washington*, 29 NATURE BIOTECHNOLOGY 303, 303 (2011).

387. *Id.*

388. *See id.* at 305.

389. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps*, *supra* note 15, at 2255–56.

390. *Id.*

One key issue concerns labeling and consumers' right-to-know.<sup>391</sup> Legislation to mandate labeling may be necessary if the agencies refuse to implement labeling and disclosure requirements through the rulemaking process. If the agricultural biotech industry is serious about gaining the trust and confidence of the American public and its global trading partners, it must take labeling issues seriously and begin applying proper disclosures of all GE products.

Another key issue is the need to reform patent laws. The right to 'own' patents and to reap profits from scientific discoveries fundamentally affects the economics of the biotech industry.<sup>392</sup> Many discoveries, particularly if they affect mankind and the environment, should rightfully belong in the public domain for all to benefit. The challenge that this policy presents is that research and development are extremely cost- and time-intensive. In addition, removing ownership and the ability to monetize on discoveries could stifle research. Removing corporate sponsorship could cause research in more esoteric or specialized areas of science to be abandoned.

Also, policies governing agribusiness subsidies and antitrust regulations have long been skewed in favor of big businesses getting bigger while discouraging entrepreneurial efforts. They have fostered an unhealthy consolidation and vertical integration of all stages of food production businesses and further magnified the conflict of interest that is pervasive among the scientific community, industry, and government regulators.<sup>393</sup>

Finally, as more animals are being genetically engineered for food and other purposes, the concern for animal welfare is paramount. These are issues that must be confronted in the future as we strive for true reform for the regulation of genetically engineered foods.

#### IV. CONCLUSION

The ultimate objective of regulatory reform for agricultural biotechnology is to foster peaceful co-existence among divergent interests with a view toward food security and a sustainable future. Raising the regulatory threshold now will allow scientific advances to more fully reach their potentials in the future. It is possible to embrace agricultural biotechnology in a responsible manner

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391. Press Release, PEW Initiative on Food & Biotechnology, *supra* note 122; *see also Meeting on AquAdvantage Salmon*, *supra* note 4, at 292 (statement of Wenonah Hauter, Exec. Dir., Food & Water Watch) (advocating labeling of GE foods).

392. COWAN, *supra* note 363, at 27–29.

393. *See generally id.* at 25 (describing dominance of the large, vertically integrated agricultural corporations).



while minimizing the risk of harm to human health and the environment. Reforming the Coordinated Framework is long overdue.