Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology

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The federal regulatory system for biotechnology, and genetically engineered (GE) animals in particular, is in critical need of modification. Relying on a creative interpretation of the Federal Food, Drug, and Cosmetic Act (FDCA), the U.S. Food and Drug Administration (FDA) has assumed sole responsibility for the regulation of GE animals, despite the agency's lack of expertise in dealing with agricultural and environmental concerns. This Note examines the pending approval of AquaBounty's GE salmon, the first GE animal submitted to the FDA for approval for human consumption, in order to highlight the flaws and resulting dangers in the current federal regulatory scheme for biotechnology, and proposes changes to assure a safer and more thorough regulation of novel GE animals. Moreover, this Note argues that the pending approval of GE salmon in particular makes these proposed changes both especially urgent and, for the first time, politically feasible.

I. INTRODUCTION

In 2000, 25% of all corn,[1] 54% of all soybeans,[2] and 61% of all cotton[3] planted in the United States had been genetically engi-

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neered. By 2011, these percentages had soared to 88%,[4] 94%,[5] and 90%,[6] respectively. According to recent estimates, between 70% and 75% of all processed foods on supermarket shelves contain genetically engineered (GE) ingredients,[7] while GE corn alone is an ingredient in items as varied as salad dressings, hot dogs, soups, and vitamins.[8]

The genetic engineering of food has become a uniquely controversial topic over the past few decades, as vehement debate has ensnared those in the realms of science,[9] nutrition,[10] agriculture,[11] politics,[12] and ethics.[13] Proponents believe that genetic engineering holds the key to global food security.[14] Over the next forty years, the planet's population is predicted to rise from 6.9 billion[15]

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1. U.S. DEPT. OF AGRIC. ECON. RESEARCH SERV., ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S.: CORN VARIETIES (2011), *available at* http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable1.htm.

2. U.S. DEPT. OF AGRIC. ECON. RESEARCH SERV., ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S.: SOYBEAN VARIETIES (2011), *available at* http://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable3.htm.

3. U.S. DEPT. OF AGRIC. ECON. RESEARCH SERV., ADOPTION OF GENETICALLY ENGINEERED CROPS IN THE U.S.: UPLAND COTTON VARIETIES, *available at http*://www.ers.usda.gov/Data/BiotechCrops/ExtentofAdoptionTable2.htm.

4. CORN VARIETIES, *supra* note 1.

5. SOYBEAN VARIETIES, *supra* note 2.

6. UPLAND COTTON VARIETIES, *supra* note 3.

7. Saundra Young, *Safety of genetically modified salmon debated*, CNN (Sept. 20, 2010, 8:10 PM), http://www.cnn.com/2010/HEALTH/09/20/genetically.engineered.salmon/index.html.

8. MICHAEL POLLAN, THE OMNIVORE'S DILEMMA: A NATURAL HISTORY OF FOUR MEALS 19 (2006).

9. *See infra* Part II.B.

10. *See infra* Part II.B.

11. *See, e.g.*, Mark Tester, *GM Food Tarnished by Urban Myth*, THE SYDNEY MORNING HERALD, Feb. 17, 2011, http://www.smh.com.au/opinion/society-and-culture/gm-food-tarnished-by-urban-myths-20110216-1awim.html.

12. *See infra* Part V.B.

13. *See, e.g.*, *What Are Genetically Modified (GM) Foods?*, HUMAN GENOME PROJECT INFORMATION (Nov. 5, 2008), http://www.ornl.gov/sci/techresources/Human_Genome/elsi/gmfood.shtml (listing ethical controversies surrounding GE food, including "[t]ampering with nature by mixing genes among species" and "[s]tress for animal").

14. *See, e.g.*, *GM Food: Head to Head*, BBC NEWS (May 18, 1999, 10:20 PM), http://news.bbc.co.uk/2/hi/special_report/1999/02/99/food_under_the_microscope/278490.stm. Clive Rainbird, Biotechnology Communications Manager for crop protection manufacturer AgrEvo, writes "[t]he key benefits from this new[GE] technology are food security — there is a need to double the food supply by 2025 due to population increases, changes in diets and natural disasters brought about by climate change." *Id.*

15. *U.S. & World Population Clocks*, U.S. CENSUS BUREAU (Sept. 9, 2011, 3:23 PM), http://www.census.gov/main/www/popclock.html.

to 9.1 billion,[16] and the amount of food that will be required to feed the world over that span is equal to the total amount of food produced throughout the entire history of mankind.[17] Genetic engineering may improve agricultural efficiency, reduce the costs of food production, and increase the nutritional content of food, while simultaneously reducing the environmental impacts of agriculture[18] — theoretically leading to an increase in food production despite using less land and more sustainable production methods.[19]

Critics meanwhile focus on the scientific uncertainty surrounding a technology as powerful as genetic engineering, particularly the unpredictable effects of placing GE foods into the food chain.[20] Potential negative consequences, some of which have already been realized, range from human health risks, such as unintended allergenicity, toxicity, and antibiotic resistance in humans, to harmful environmental or ecological impacts, including the spread of GE material to natural organisms, the loss of biodiversity, and the extinction of natural species.[21]

The increasingly widespread prevalence of GE food suggests that fundamental genetic alterations will forever[22] remain a part of the American diet, but these alterations have thus far been limited to GE crops. The United States must now decide whether or not to take the next great leap forward, as the U.S. Food and Drug Administration (FDA) is currently evaluating whether to approve the commercial cultivation of GE salmon.[23] The prece-

16. Press Release, United Nations, World Population to Increase by 2.6 Billion over Next 45 Years, With All Growth Occurring in Less Developed Regions (Feb. 24, 2005), *available at* http://www.un.org/News/Press/docs/2005/pop918.doc.htm.

17. *Talk of the Nation: Sustainable Agriculture*, National Public Radio (Aug. 9, 2002) (downloaded using iTunes).

18. *See infra* Part II.B.1.

19. *GM Food: Head to Head*, *supra* note 14.

20. *See, e.g.*, *id.*; Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology under the Federal Coordinated Framework*, 12 DRAKE J. AGRIC. L. 439, 442 (2007).

21. *See infra* Part II.B.2.

22. *See, e.g.*, Mairi Anne Mackenzie, *Industry Reaps GM Bonanza, but We Will Pay*, THE AGE (Apr. 15, 2006), http://www.theage.com.au/news/business/industry-reaps-gm-bonanza-but-we-will-pay/2006/04/14/1144521507502.html (noting how GM technology creates "deep-seated, inaccessible, permanent, self-perpetuating changes to the living things around us").

23. *See, e.g.*, Paul Voosen, *Panel Advises More Aggressive FDA Analysis of Engineered Salmon*, N.Y. TIMES (Sept. 21, 2010), http://www.nytimes.com/gwire/2010/09/21/21greenwire-panel-advises-more-aggressive-fda-analysis-of-71171.html?pagewanted=all;

dential importance of this approval process is tremendous: the GE salmon is set to become the first[24] GE fish approved for human consumption in the United States,[25] and approval would open the door for many other GE animals in development.[26] It is therefore critical that the federal government exercise diligence and caution throughout the approval process.

Unfortunately, this does not appear to be happening.[27] The approval process has thus far been marred by secrecy and institutional incompetence by the FDA, the only federal agency proclaiming jurisdiction over the regulation of GE animals intended for human consumption. The approval process has provoked fierce criticism from countless advocacy groups, and has spurred eleven U.S. Senators and twenty-nine U.S. Representatives to write the FDA, demanding the agency "stop the approval process

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Mary Clare Jalonick, *Super Salmon or Frankenfish'? FDA to Decide*, MSNBC.COM (Sept. 20, 2010, 7:21 PM), http://www.msnbc.msn.com/id/39265727/ns/health-food_safety/.

24. One other GE animal has been approved for commercial use in the United States: ATryn, a human antithrombin protein and anticoagulant extracted from the milk of GE goats. Britt Erickson, *FDA Approves Drug from Transgenic Goat Milk*, CHEMICAL & ENGINEERING NEWS, Feb. 16, 2009, at 9. Antithrombin "is an anticoagulant intended to prevent bloodclots during surgery or childbirth for people with a rare blood disorder . . . [ATryn] is an alternative to antithrombin derived from human plasma, which is in short supply." *Id.* ATryn GE goats are not, however, intended for human consumption, and thus are not of primary concern for this Note, which focuses on the FDA's regulation of GE food.

Similarly, while GloFish (novelty GE fish that glow red under ultraviolet light) are available for purchase commercially, they were never actually approved for commercial use. *See* Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 MINN. J. L. SCI. & TECH. 457, 475–77 (2005) (containing a discussion of the lack of regulation of Glofish). The FDA found that since these "tropical aquarium fish are not used for food purposes, they pose no threat to the food supply." *Id.* at 476 n.84 (quoting FDA Statement Regarding Glofish, U.S. Food & Drug Admin. (Dec. 9, 2003), *available at* http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm161437.htm); *see also* Sheryl Lawrence, Comment, *What Would You Do with a Fluorescent Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 256–59 (2007).

25. *See, e.g.*, Voosen, *supra* note 23. Dicky Dee Griffin, a professor of cattle of production at the University of Nebraska, Lincoln, notes that "[i]t is extremely important how this precedent gets set . . . [a]nd it's not an economic issue. It may be, but it can't be. Economics is the shovel with which we dig the grave at the very end of these [deliberations]." *Id.*

26. Jalonick, *supra* note 23.

27. *See infra* Part IV.B.

immediately" because potential human health and environmental risks have not been adequately reviewed.[28]

By examining the approval process of GE salmon, this Note explores the federal regulatory process for biotechnology and illustrates the inefficiencies and dangers created by the current regulatory regime. Over the past few years, compelling evidence has been produced demonstrating that both the proclaimed benefits and risks of GE technology are very real, and should not be treated carelessly.[29] In order to harness the benefits, minimize the risks, and maintain consumer confidence in the food people choose to eat, it is imperative that the United States alter its current regulatory system for GE animals, before these animals become a permanent part of the food supply.

Part II of this Note contains a brief history of the genetic engineering of food, from the traditional breeding of crops and animals to the current technology of recombinant DNA engineering, and then addresses the benefits and risks of GE food generally. Part III analyzes the federal regulatory process for biotechnology, from its historical foundations up to the present approval process for GE salmon. Part IV provides the approval process for GE salmon as a case study, in order to illustrate the flaws and inefficiencies in the current federal regulatory system for GE animals. Part V proposes modifications to the regulatory system to increase effectiveness, safety, and consumer confidence, and argues that such modifications are both urgently needed and politically feasible.

II. HISTORY OF GENETIC ENGINEERING AND RESULTING BENEFITS AND RISKS

While the term "genetic engineering" may trigger thoughts of space-age scientists and futuristic technologies, the practice has

28. Letter from Mark Begich, U.S. Senator, et al., to Margaret A. Hamburg, FDA Comm'r (Sept. 28, 2010) [hereinafter Begich Letter], *available at* http://stopgefish.files.wordpress.com/2010/09/100928-hamburg-fda-ge-salmon-final.pdf; Letter from Peter DeFazio, U.S. Representative, et al., to Margaret A. Hamburg, FDA Comm'r, (Sept. 29, 2010) [hereinafter DeFazio Letter], *available at* http://www.defazio.house.gov/index.php?option=com_content&task=view&id=629; *see also infra* Part V.B.

29. *See infra* Part II.B.

technically been around for thousands of years.[30] Part II.A briefly explores the history of genetic engineering, leading up to the discovery of recombinant DNA (rDNA) genetic engineering in the twentieth century. Part II.B then addresses the potential benefits and risks of the genetic engineering of food.

A. THE HISTORY OF GENETICALLY ENGINEERED FOOD

Humans have long exploited genetic advantages in differing genetic variants of crops by saving and propagating those crop variants that produced the highest yield, proved the most resistant to insects, pathogens, drought, and disease, and yielded crops with enhanced nutritional content.[31] From as early as the 1500s, farmers have intentionally bred crops in order to further exploit these desirable genetic advantages.[32] Humans also have a great deal of experience genetically altering animals for their own benefit, as signs of the domestication and artificial selection of animals date back as far as 8000 years ago.[33]

These conventional breeding techniques took a leap forward at the turn of the twentieth century, with the rediscovery of Gregor Mendel's work on the heritability of genetic traits, particularly his finding that characteristics are genetically inherited in a logical and predictable manner.[34] Traditional breeding techniques thus began to allow for the directed evolution of plants and animals, resulting in "hybrid" variants with superior characteristics.[35]

While enormously beneficial in earlier agricultural systems, this form of conventional genetic engineering faced severe limitations. Breeding could only take place between varieties of the same, or closely related, species, and therefore resulting hybrids

30. NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 37 (2002), *available at* http://www.nap.edu/openbook.php?isbn=0309082633 [hereinafter TRANSGENIC PLANTS].

31. *Id.*

32. Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2174–75 (2004).

33. NAT'L RESEARCH COUNCIL, ANIMAL BIOTECHNOLOGY: SCIENCE-BASED CONCERNS 4 (2002), *available at* http://www.nap.edu/openbook.php?record_id=10418 [hereinafter ANIMAL BIOTECHNOLOGY].

34. Mandel, *supra* note 32, at 2174.

35. *Id.* at 2174–75.

could only introduce traits found in close relatives.[36] The hybridization process was "relatively crude and largely uncontrollable."[37] Moreover, conventional genetic engineering through plant and animal breeding was very labor intensive, as typically only one out of thousands of hybrids would become a useful variety.[38] The entire process was also very slow, as a decade was generally required to achieve the desired results.[39]

Recombinant DNA (rDNA) genetic engineering has shattered these limitations. This modern form of genetic engineering involves isolating discrete DNA segments responsible for a particular trait in a living organism, and inserting the genetic material into another organism, even an organism from a completely different species, class, phylum, or kingdom, and thus achieving the desired characteristic in the second organism.[40] While the goal of modern genetic engineering remains the same as traditional breeding — improved agricultural products — modern rDNA engineering dramatically expands the range of potential improvements.[41] Unlike traditional breeding, which involves the uncontrolled hybridization of parent cells, rDNA techniques allow for the production of specific, tailor-made GE organisms.[42] Theoretically, any trait with an identifiable gene can be isolated and introduced into another organism — with no limitations as to the sexual compatibility of the organisms — using a technique that is much faster and far more precise and predictable than traditional breeding.[43]

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

37. Michael A. Whittaker, Comment, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Modified Foods*, 35 SAN DIEGO L. REV. 1215, 1218–19 (1998).

38. Mandel, *supra* note 32, at 2175.

39. *Id.*

40. Statement of Policy, *supra* note 36, at 22,986.

41. Whittaker, *supra* note 37, at 1218–19.

42. Lawrence, *supra* note 24, at 209–10.

43. Whittaker, *supra* note 37, at 1218–19.

B. BENEFITS AND RISKS OF GENETICALLY ENGINEERED FOOD

In the past fifteen years, 121 different varieties of GE crops have been commercialized in the United States,[44] while countless GE animals are currently being developed.[45] This section explores the benefits and risks yielded by the widespread cultivation of these novel food products.

1. *Benefits of Genetically Engineered Food*

The first GE crops were altered to provide agricultural benefits, such as insect resistance and herbicide tolerance.[46] These GE crops have yielded many benefits for farmers, consumers, and the environment, as the crops have allowed farmers to substantially decrease their use of pesticides and herbicides, thus decreasing the release of these toxins into the environment, and the amount of pesticide residues and contaminant digested by consumers.[47]

Next-generation GE technology has focused, in part, on making food more nutritious and easier to grow.[48] For instance, in 1999, Swiss researchers developed Golden Rice, containing enhanced amounts of vitamin A, and bred it into rice "traditionally grown in regions where vitamin A deficiency leads to high rates of blindness in children."[49] GE technology has also recently focused on making plants adaptable to harsh environments, and making plants grow faster.[50] Researchers are currently trying to create crops that are less affected by salt, drought, heat, and cold,[51] while GE giant Monsanto has created corn and soybean lines that require less water to grow.[52] Proponents of GE technol-

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44. U.S. FOOD & DRUG ADMIN., COMPLETED CONSULTATIONS ON BIOENGINEERED FOODS (2011), *available at* http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?filter=&sortColumn=%2C3\9LOE%29%2CC1%2C+D%25@%2C%0A&rpt=bioListing&displayAll=true.

45. Mandel, *supra* note 32, at 2178–79.

46. *See* Nina Fedoroff, *Genetically Modified Foods: Making the Earth Say Beans*, SCI. J. PENN ST. UNIV., Spring 2007, at 3, *available at* http://www.science.psu.edu/journal/Spring2007/Spring2007_FeatureStory_GMO.pdf.

47. Whittaker, *supra* note 37, at 1219.

48. Fedoroff, *supra* note 46, at 3.

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.*

ogy hope that these types of next-generation crops will have an important role to play as the world continues to struggle with rapidly depleting resources, a shrinking food supply, and food shortages.[53] For instance, researchers have developed a GE tomato that contains a particular gene from a mustard plant, resulting in a new tomato variety that can grow in salty soil and desalinate soil in which it grows.[54] As twenty-five million new acres of farmland become too salty for agriculture every year, the GE tomato and other similarly engineered crops have the potential to help sustain the world's acreage of agriculturally viable land.[55]

The benefits of rDNA genetic engineering have not been confined to crops. While AquaBounty's GE salmon is the principal example analyzed by this Note, as it is likely to become the first GE animal approved for commercial consumption in the United States,[56] dozens of other GE animals are in development. One such animal is "Enviropig," a pig engineered to better digest phosphates, making it more environmentally friendly and less expensive to feed.[57] Livestock such as cows, chicken, pigs, and goats, and numerous varieties of farmed fish, are being genetically engineered to enhance disease resistance and other qualities.[58] For example, researchers are currently developing dairy cows

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53. *See* NAT'L ACAD. OF SCIS., TRANSGENIC PLANTS AND WORLD AGRICULTURE 6 (2000), *available at* http://books.nap.edu/openbook.php?record_id=9889. The National Academy of Sciences issued a report in 2000 concluding that

> steps must be taken to meet the urgent need for sustainable practices in world agriculture if the demands of an expanding world population are to be met without destroying the environment or natural resource base. In particular, GM technology . . . should be used to increase the production of main food staples, improve the efficiency of production, reduce the environmental impact of agriculture, and provide access to food for small-scale farmers.

Id.

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

55. *Id.*

56. *See* Lawrence, *supra* note 24, at 205–06 (discussing that while one other GE animal has been approved for commercial use in the U.S., that "biopharm" animal was intended for pharmaceutical use, not human consumption).

57. Jeremy Cooke, *GM Pigs: Green Ham with Your Eggs?*, BBC NEWS (Jan. 4, 2011, 6:03 PM), http://www.bbc.co.uk/news/world-us-canada-12113859.

58. Mandel, *supra* note 32, at 2188.

resistant to mastitis,[59] cows resistant to bovine spongiform encephalopathy, or "mad cow disease,"[60] and chickens resistant to avian flu.[61] Other food animals are being developed with enhanced nutritional values for humans, such as hens genetically engineered to lay low-cholesterol eggs.[62]

Finally, it is worth noting briefly that there are many non-food-related benefits to be derived from GE animals as well.[63] However, as this Note primarily concerns the regulation of GE animals intended for human consumption, these other benefits will not be explored in greater detail.

2. *Risks of Genetically Engineered Food*

While there are innumerable potential benefits to be realized from GE crops and animals, the rise of biotechnology has simultaneously ushered in a plethora of potential risks, some of which

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59. U.S. Food & Drug Admin., Consumer Q&A (May 23, 2011), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113672.htm.

60. *Id.*

61. Pallab Ghosh, *World's First Flu-Resistant GM Chickens 'Created'*, BBC NEWS (Jan. 13, 2011, 2:01 PM), http://www.bbc.co.uk/news/science-environment-12181382.

62. Shelley Smithson, *Genetically Modified Animals Could Make It to Your Plate with Minimal Testing — and No Public Input*, GRIST (July 30, 2003, 9:00 AM), http://www.grist.org/article/and3/.

63. *See, e.g.*, Lawrence, *supra* note 24, at 268–69 (discussing biopharming). Biopharm animals undergo genetic engineering in order to produce particular substances for pharmaceutical use, such as ATryn and human insulin. *Id.* These biopharmed pharmaceuticals are much cheaper to produce than conventionally manufactured drugs, and have the potential to significantly lower drug costs domestically and make drugs available in developing countries. *Id.* at 275–76. Consequently, biopharm animals are perhaps some of the most promising GE animals. *See, e.g.*, *Anti-Cancer Chicken Eggs Produced*, BBC NEWS (Jan. 14, 2007, 6:49 PM), http://news.bbc.co.uk/2/hi/science/nature/6261427.stm (discussing scientists' development of hens whose eggs contain proteins utilized in cancer-fighting drugs).

Research animals have also been engineered to make them more susceptible to particular diseases, in order to better understand the disease and help develop new and better medical therapies. *See, e.g.*, Karen Weintraub, *In the Laboratory, Rats Are Upstaging Mice*, BOS. GLOBE (Dec. 27, 2010), http://www.boston.com/news/science/articles/2010/12/27/in_the_laboratory_rats_are_upstaging_mice/?page=full (discussing the increasing importance of GE rats in medical research, taking the place of GE mice, which had previously been of primary importance in genome manipulation since their creation in 1989).

Finally, animals have been genetically engineered to produce industrial and consumer products, such as the strong, web-like material called Biosteel, harvested from goats who have been engineered to produce spider's web protein in their milk. *GM Goat Spins Web Based Future*, BBC NEWS (Aug. 21, 2000, 1:16 PM), http://news.bbc.co.uk/2/hi/science/nature/889951.stm.

have already been realized. These risks can be broken down into three categories: human health risks, environmental impacts, and the risk of unpredictable genetic consequences.

a. Human Health Risks

The human health risks of consuming GE foodstuffs involve allergenicity, toxicity, and antibiotic resistance. Allergenicity — the tendency to provoke allergic reaction — becomes a risk when genes from allergenic foods are transferred into otherwise non-allergenic foods.[64] Allergic consumers might then unsuspectingly ingest allergens, creating a serious safety risk since consuming mere trace amounts can cause death.[65] Moreover, while the potential allergenicity of genes originating from known allergenic sources can be easily predicted, genetic engineering often involves inserting genes from sources that have not historically been human food, and thus the potential allergenicity of the GE product is likely unforeseeable.[66] The National Research Council has found that "[a]ssessing the potential allergenicity of transferred proteins remains one of the most difficult aspects in the overall safety assessment of transgenic foods."[67]

Two cases demonstrate that such concerns are far from unfounded. In the 1990s, a line of GE soybeans was engineered using certain proteins from Brazil nuts, resulting in soybeans with enhanced nutritional content; a 1996 study found that people with common nut allergies experienced significant allergic reactions to these GE soybeans.[68] Similarly, Australian scientists spent ten years developing GE peas that expressed a green bean

64. WORLD HEALTH ORGANIZATION, 20 QUESTIONS ON GENETICALLY MODIFIED (GM) FOODS 2, *available at* http://www.who.int/entity/foodsafety/publications/biotech/en/20questions_en.pdf (last visited Sept. 9, 2011) [hereinafter WORLD HEALTH ORGANIZATION].

65. Whittaker, *supra* note 37, at 1221. Many allergists believe that food allergies have substantially increased in prevalence in recent years, with up to 30% of American adults self-reporting food allergies. *See* Rhoda Sheryl Kagan, *Food Allergy: An Overview*, ENVTL. HEALTH PERSPECTIVES, Feb. 2003, at 223, *available at* http://ehp03.niehs.nih.gov/article/fetchObjectAttachment.action?uri=info%3Adoi%2F10.1289%2Fehp.5702&representation=PDF.

66. ANIMAL BIOTECHNOLOGY, *supra* note 33, at 68.

67. *Id.* "Transgenic" and "genetically engineered" are synonymous.

68. Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENGLAND J. MED. 688 (1996).

protein found to protect naturally against weevils.[69] Prior to market release, animal testing of the protein produced allergic reactions in test mice, and alarmingly caused the mice to become susceptible to other allergens as well.[70] The GE pea experiment provides a particularly cautionary tale: while the Brazilian nut protein expressed in the GE soybeans was a known allergen, prompting developers to look for possible allergies,[71] the green bean protein expressed in the GE peas had no history of allergenicity whatsoever,[72] thus creating a false sense of safety in the novel GE product.

Toxicity is another important safety concern when analyzing GE products.[73] As mentioned above, many GE crops are insect resistant, a trait typically introduced by engineering the crops to express increased levels of either inherent natural toxins or new toxins.[74] Upon consumption, these toxins pose an even greater risk to human health than traditional pesticide residues, putting the segments of the population that consume large amounts of the same GE food especially at risk.[75] A recent study analyzed blood and organ system data from rats who were fed three of the most popular commercialized GE corn varieties, all of which were engineered to naturally express pesticide residues and have since come into widespread use.[76] Frighteningly, given the prevalence of GE corn,[77] the study found that all three corn varieties caused serious negative side effects in the rats' hearts, adrenal glands, spleens, hematopoietic systems, and, especially, kidneys and livers — finding that "these [GE] maize varieties induce[d] a state of hepatorenal toxicity."[78] The study concluded by "strongly recom-

69. Van Tassel, *supra* note 54, at 232–33.

70. *Id.* at 233. This discovery led the scientists to end the project to bring the GE peas to market. *Id.*

71. *GM Food: Head to Head*, *supra* note 14.

72. Van Tassel, *supra* note 54, at 232–33; *see also* Michael Hansen, *Comments of Consumers Union on Genetically Engineered Salmon*, CONSUMERS UNION, at 13–14 (Sept. 16, 2010), http://www.consumersunion.org/pdf/CU-comments-GE-salmon-0910.pdf.

73. WORLD HEALTH ORGANIZATION, *supra* note 64, at 2.

74. *See supra* Part II.B.1; Mandel, *supra* note 32, at 2192.

75. Diane Thue-Vasquez, *Genetic Engineering and Food Labeling: A Continuing Controversy*, 10 SAN JOAQUIN AGRIC. L. REV. 77, 97 (2000).

76. Joël Spiroux de Vendômois et al., *A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health*, 5 INT'L J. BIOLOGICAL SCI. 706 (2009), *available at* http://www.biolsci.org/v05p0706.htm.

77. *See supra* notes 1, 4 and accompanying text.

78. Spiroux, *supra* note 76, at 706–17.

mend[ing]" additional long-term studies, highlighting the finding of a "clear negative impact on the function of [the kidneys and livers] in rats consuming [GE] maize varieties for just 90 days."[79]

The transfer of antibiotic resistance genes poses another potential health threat.[80] Antibiotic resistance genes are used in creating GE products, as they are used by scientists to determine whether gene transfer has successfully taken place;[81] these genes are then expressed in all successfully transformed GE products.[82] When they are consumed, they have the potential to be transferred from the GE products to cells of the human body, "render[ing] commonly used antibiotics less effective by inhibiting their uptake,"[83] or to be transferred to bacteria in the gastrointestinal tract,[84] creating bacteria strains that are resistant to antibiotics.[85] As the FDA recently published in a draft guidance for industry, "[a]ntimicrobial resistance, and the resulting failure of antimicrobial therapies in humans, is a mounting public health problem of global significance."[86]

Finally, there is the related, indirect risk of "outcrossing" or "crop contamination" — the inadvertent transfer of genes from

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79. *Id.* at 717–18.

80. WORLD HEALTH ORGANIZATION, *supra* note 64, at 2.

81. *See* Mandel, *supra* note 32, at 2193. Genetic engineering is not 100% efficient, and scientists must determine which GE products have successfully been incorporated into the donor gene. *Id.* In order to separate successfully engineered plants from plants not expressing the desired gene, scientists typically attach antibiotic resistance genes to the desired donor gene and then insert both into the target host's DNA. *Id.* The target hosts are then exposed to the corresponding antibiotic, so that those host plants failing to express the desired gene will be killed off by the antibiotic, leaving only the successfully engineered, antibiotic resistant host plants. *Id.*

82. *Id.*

83. Whittaker, *supra* note 37, at 1221–22.

84. WORLD HEALTH ORGANIZATION, *supra* note 64, at 2.

85. Mandel, *supra* note 32, at 2193.

86. U.S. FOOD & DRUG ADMIN., THE JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS 4 (2010) [hereinafter JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS], *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf. This draft guidance addressed the widespread use of subtherapeutic (preventive rather than curative) antibiotic use in livestock, recommending limiting medically important antibiotic drugs to uses in food-producing animals that are necessary for assuring animal health. *Id.* The guidance addressed and summarized forty years of reports from scientific committees, task forces, and other organizations studying the issue, all of which recommended limiting the use of antibiotics in food-producing animals due to increasing antibiotic resistance in humans. *Id.* at 3–13.

GE plants into conventional crops.[87] Critics worry about the potential for pollen from GE crops to cross-pollinate with non-GE crops, introducing novel genes never approved for human consumption into the food supply and triggering the risks for allergenicity and toxicity discussed above.[88] The notorious StarLink incident demonstrates the validity of this concern.[89] StarLink corn, a GE strain of pesticide-resistant corn, was approved by the Environmental Protection Agency (EPA) in 1998 for commercial use as animal feed and for certain other non-food uses.[90] The makers of the GE corn requested approval for use of StarLink in human food, but the EPA denied the application due to concerns that it could potentially trigger food allergies.[91] Despite the use of EPA-mandated "buffer zone[s]" and other "mandatory segregation methods to prevent StarLink from commingling with other corn,"[92] in the fall of 2000, StarLink corn was discovered in Kraft Foods' taco shells.[93] More than 2.5 million boxes of the shells were recalled, as well as over 300 other products found to have been contaminated by StarLink;[94] the total cost of the StarLink incident to the manufacturer could run as high as $1 billion.[95] Further, while StarLink is the most notorious example of crop contamination, it should not be taken to reflect an isolated incident.[96]

87. WORLD HEALTH ORGANIZATION, *supra* note 64, at 2–3.

88. Farquhar & Meyer, *supra* note 20, at 443.

89. *See, e.g.*, Andrew Pollack, *Aventis Gives Up License to Sell Bioengineered Corn*, N.Y. TIMES, Oct. 13, 2000, at C5; Mandel, *supra* note 32, at 2203–07.

90. Mandel, *supra* note 32, at 2203.

91. *Id.*

92. *In re* StarLink Corn Prods. Liab. Litig., 212 F. Supp. 2d 828, 834 (N.D. Ill. 2002).

93. Pollack, *supra* note 89.

94. Mandel, *supra* note 32, at 2204.

95. James Cox, *StarLink Fiasco Wreaks Havoc in the Heartland: Developer Wants EPA To Approve Seed for Food Supply*, USA TODAY, Oct. 27, 2000, at 1B.

96. *See, e.g.*, GREENPEACE, GM Contamination Register, http://www.gmcontaminationregister.org/index.php?content=default (last visited Jan. 28, 2011). The GE Contamination Register, maintained by Greenpeace International and GeneWatch UK, records all incidents of contamination arising from the release of GE crops. *Id.* Only incidents which have been publicly documented are recorded, and it is thus likely that there are many other undetected incidents of crop contamination. *Id.*

b. Environmental Impacts

GE crops can adversely impact the environment in two ways: pesticide and herbicide tolerance, and loss of biodiversity. First, as discussed above, one benefit of GE crops is the reduced usage of conventional pesticide.[97] However, whereas farmers conventionally apply pesticide at intervals throughout the year, when certain insects are particularly problematic, GE crops self-deposit pesticide residue into the soil throughout the entire growing season.[98] This heightened exposure to pesticide increases the likelihood that insects will develop pesticide resistance, rendering both GE pesticides and the natural pesticides used by organic farmers less useful.[99] An example of this phenomenon is the bollworm, a pest insect that developed resistance to an insect-resistant GE cotton crop.[100]

GE crops pose a similar environmental risk with regard to herbicide resistance. GE plants with herbicide resistance can withstand unnaturally large amounts of herbicide, thus enabling farmers to use greater amounts to control weeds. As with pesticide, this heightened use of herbicide leads to herbicide-resistant weeds, necessitating even greater use of herbicide[101] and potentially threatening the surrounding environment.[102] Moreover, the herbicide resistance genes may — and have[103] — spread from GE crops to wild, weedy relatives, resulting in increased weediness.[104]

The most serious environmental threat is the extinction of wild species. GE species may cause the extinction of wild species through either invasiveness or outcrossing. Invasive GE species may possess evolutionary advantages over their natural relatives

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97. *See supra* Part II.B.1.
98. Mandel, *supra* note 32, at 2197.
99. Mandel, *supra* note 32, at 2197–98.
100. *First Documented Case of Pest Resistance to Biotech Cotton*, SCIENCEDAILY (Feb. 8, 2008), http://www.sciencedaily.com/releases/2008/02/080207140803.htm (describing Bt cotton, an insect-resistant GE cotton); *see also* Bruce E. Tabashnik et al., *One Gene in Diamondback Moth Confers Resistance to Four Bacillus Thuringiensis Toxins*, 94 PROC. NAT'L. ACAD. SCI. 1640, 1640 (1997).
101. Thue-Vasquez, *supra* note 75, at 100.
102. Whittaker, *supra* note 37, at 1220.
103. *See* TRANSGENIC PLANTS, *supra* note 30, at 67.
104. *Id.* The National Research Council has noted that "the potential for enhanced weediness is the major environmental risk perceived for introductions of genetically modified plants." Mandel, *supra* note 32, at 2195 (quoting NAT'L RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 3 (1989)).

and out-compete them, thus posing an existential threat to wild species when introduced into their native habitats.[105] This concern is far from unfounded, as invasive species cause environmental damages of up to $120 billion per year.[106] Only habitat destruction threatens native species more than the introduction of invasive species.[107] Similarly, wild species may face extinction through outcrossing,[108] as studies have shown that populations of wild species may be wiped out by mating with certain types of GE species.[109]

c. Unpredictable and Unintended Genetic Consequences

According to the National Research Council, "the introduction of any type of biological novelty can have unintended and unpredicted effects on the recipient community and ecosystem."[110] As the examples of realized risks above illustrate, some of these effects are already clear. But perhaps the biggest risk posed by the genetic engineering of food encompasses all of the human health and ecological risks described above — we simply cannot know all the possible consequences of genetic engineering.[111] Moreover, these consequences themselves may also have unpredictable negative impacts in their own right, as, for instance, it is difficult to predict the impact on the ecosystem.[112]

The best example of this once again, unfortunately, concerns GE corn.[113] In late 2008, the Austrian government released the results of a University of Vienna study finding that mice that were fed GE corn demonstrated reduced fertility across four gen-

105. Farquhar & Meyer, *supra* note 20, at 442; Mandel, *supra* note 32, at 2196.

106. Juliet Eilperin, *Tough Choices Follow in Wake of Invasive Species*, WASH. POST, Jan. 31, 2010, http://www.washingtonpost.com/wp-dyn/content/article/2010/01/30/AR2010013000939.html.

107. Mandel, *supra* note 32, at 2196.

108. *See* WORLD HEALTH ORGANIZATION, *supra* note 64, at 2–3.

109. *See infra* note 207 and accompanying text.

110. TRANSGENIC PLANTS, *supra* note 30, at 29.

111. *See, e.g.*, Graham M. Wilson, Note, *A Day on the Fish Farm: FDA and the Regulation of Aquaculture*, 23 VA. ENVTL. L.J. 351, 374 (2004).

112. *See* ANIMAL BIOTECHNOLOGY, *supra* note 33, at 78. The National Research Council noted that the dangers of GM terrestrial animals "escaping and establishing themselves in the environment are considerable," and that such a situation could "pose significant ecologic harm." *Id.* at 87.

113. *See supra* note 1, 4 and accompanying text (discussing the widespread prevalence of GE corn throughout the American food supply).

erations.[114] "Mice fed the GE corn diet had fewer litters, fewer total offspring, and more females with no offspring" than mice fed a diet of conventional corn.[115] These troubling effects "were particularly pronounced in the third and fourth [generations], after the mice had consumed the GE corn for a longer period of time."[116] The authors of the study acknowledged that the reduced fertility "might be related to unintended effects of the genetic modification process."[117]

III. THE FEDERAL REGULATORY PROCESS FOR BIOTECHNOLOGY

The flaws in the federal regulatory system for GE animals are largely attributable to the first developments in the regulatory scheme for GE crops. An introduction to the Coordinated Framework, the foundation of all biotechnology regulation, is therefore necessary to understand the current regulatory system for GE animals. After laying this foundation, this Part discusses the FDA's particular role in the system.

A. THE COORDINATED FRAMEWORK

As the biotechnology industry emerged in the 1980s, the application of then-existing statutes to the regulation of the new technology created a great deal of confusion among the federal regulatory agencies.[118] Many agencies appeared to have overlapping responsibilities, and questions surfaced regarding the potential for inconsistencies in each agency's approach to GE regulation.[119] Responding to these considerations, the Reagan Administration created a Domestic Policy Council Working Group and charged the group "with drafting an overall framework for regulating bio-

114. *Austrian Study Finds Eating Genetically Engineered Corn May Reduce Fertility*, CTR. FOR FOOD SAFETY (Nov. 13, 2008), http://www.centerforfoodsafety.org/2008/11/13/austrian-study-finds-eating-genetically-engineered-corn-may-reduce-fertility/.

115. *Id.*

116. *Id.*

117. *Id.*

118. *See* THE PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS 5 (2001), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf [hereinafter PEW 2001].

119. *Id.*

technology."[120] The result was the promulgation in 1986 of the "Coordinated Framework for Regulation of Biotechnology" by the White House Office of Science and Technology Policy (OSTP).[121] Despite enormous advances in the GE field over the past few decades, the twenty-five year old Framework remains the cornerstone of the biotechnology regulatory scheme today.

The Coordinated Framework provides a "comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products."[122] Although it is not a legally binding legislative enactment, many of the Coordinated Framework's principles have provided "a foundation for subsequent policy and regulation."[123] Most significantly, the Coordinated Framework specifies that GE products are not inherently riskier than their natural analogs, and, therefore, that GE products can be adequately regulated by the pre-existing statutory and regulatory structure.[124] Products derived from genetic engineering are thus subject to the same type of regulation as products produced in conventional manners.[125]

The Coordinated Framework distributes regulatory responsibilities based on the pre-existing statutory mandates of the various agencies, with three agencies — the U.S. Department of Agriculture ("USDA"), the Environmental Protection Agency ("EPA"), and the FDA — dominating regulatory oversight of GE products.[126] The basic responsibilities of these three agencies have remained largely the same since the promulgation of the Coordinated Framework: the USDA oversees GE products that could have an adverse effect on agriculture, the EPA regulates environmental risks posed by crops genetically engineered to express natural pesticides, and the FDA evaluates food safety issues of all GE products intended for human consumption.[127]

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120. *Id.*

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

122. *Id.* at 23,302.

123. PEW 2001, *supra* note 118, at 6.

124. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,202, 23,306 (June 26, 1986).

125. *Id.*

126. *Id.* at 23,304.

127. *See* TRANSGENIC PLANTS, *supra* note 30, at 19; *see also Roles of U.S. Agencies*, UNITED STATES REGULATORY AGENCIES UNIFIED BIOTECHNOLOGY WEBSITE, http://usbiotechreg.nbii.gov/roles.html (last visited Sept. 10, 1011).

However, this distribution of responsibilities vastly oversimplifies what has become a complex, piecemeal approach to regulation. In deciding that existing laws are sufficient for biotechnology regulation, the Coordinated Framework instructs the agencies to rely on laws for their regulatory authority that were enacted decades earlier, long before rDNA genetic engineering was even scientifically conceivable.[128] This forces the agencies to reinterpret old statutes in order to fit new biotechnology products into decades-old legal frameworks.[129] With no single law ever passed that specifically addresses biotechnology,[130] and no single federal agency responsible for governing its regulation,[131] the various agencies have had to "interpret their authority in creative ways to ensure that all new agricultural biotechnology products are reviewed."[132] As a result, the agencies currently exercise their regulatory jurisdiction under at least twelve different statutes.[133]

B. THE FDA'S ROLE IN THE REGULATION OF GENETICALLY ENGINEERED CROPS[134]

Along with the USDA, the FDA is tasked with ensuring the safety of all food products in the United States.[135] The FDA primarily exercises its jurisdiction under the Federal Food, Drug and Cosmetic Act (FDCA), enacted in 1938.[136] Section 402 of the

128. *See* PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, ISSUES IN THE REGULATION OF GENETICALLY ENGINEERED PLANTS AND ANIMALS 10–11 (2004) [hereinafter PEW 2004], *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/food_biotech_regulation_0404.pdf.

129. *Id.*

130. *See id.* at 11.

131. *See* PEW 2001, *supra* note 118, at 8.

132. PEW 2004, *supra* note 128, at 10–11.

133. *See* Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 4, 9 (2006); *see also* PEW 2001, *supra* note 118, at 19.

134. This Note is primarily concerned with the regulation of GE food products intended for human consumption. Therefore, the FDA's role in biotechnology regulation will be the main focus of this section and, more broadly, the Note. For a more detailed analysis of the various regulatory roles of the USDA and EPA, see generally PEW 2001, *supra* note 118; PEW 2004, *supra* note 128; Mandel, *supra* note 32.

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

136. *See* 21 U.S.C.A. § 393 (West 2011).

FDCA authorizes the FDA to regulate "adulterated foods"[137] — food that "bears or contains any poisonous or deleterious substance which may render it injurious to health."[138] Furthermore, and crucial for the FDA's claim of statutory authority over GE food, Section 409 of the FDCA authorizes the FDA to regulate "food additives," defined as any substance intended for use in food, that may reasonably be expected to become a component of food, or that may otherwise affect the characteristics of food.[139] Section 402 further provides that "food additives" can render food "adulterated," thus requiring FDA approval prior to being used in food.[140] However, manufacturers do not need FDA approval if a food additive is "generally recognized, among experts . . . to be safe under the conditions of its intended use . . . ."[141]

In 1992, in order to clarify its regulatory authority under its interpretation of the FDCA and to provide guidance for industry, the FDA issued its "Statement of Policy: Foods Derived From New Plant Varieties."[142] This policy statement announced that the FDA would presume GE crops to be "generally recognized as safe" (GRAS) and therefore not subject to food additive regulation under the FDCA.[143] The FDA reasoned that the only substances added to GE crops are nucleic acids, which are not only GRAS but are essential to human existence, and that GE crops thus did not present any different safety concerns than traditionally-derived food.[144] The FDA added that "[u]ltimately, it is the food producer who is responsible for assuring safety,"[145] and hence the producer typically determines whether a food additive is GRAS, not the FDA.[146] The result of this policy has been that most GE food is not subject to any food safety review whatsoever.[147]

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137. 21 U.S.C. § 342(a)(1) (2006). "Food" is defined as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C.A. § 321(f) (West 2009). "Food" includes human food, animal feed, pet food, and substances migrating to food from food-contact articles. 21 C.F.R. § 170.3(m) (2011).

138. 21 U.S.C. § 342(a)(1).

139. 21 U.S.C.A. § 321(s) (West 2009).

140. 21 U.S.C. § 348(a)(2).

141. 21 U.S.C.A. § 321(s).

142. 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter Statement of Policy].

143. *Id.* at 22,990.

144. *Id.*

145. *Id.* at 22,991.

146. *Id.* at 22,989.

147. Van Tassel, *supra* note 54, at 221.

Nonetheless, the FDA recommended that food producers voluntarily consult with the agency before marketing GE crops,[148] and the agency published guidance documents in 1996[149] and again in 2006[150] describing procedures for such consultations. The 2006 guidance document encourages the developer of a novel GE food product to meet with the FDA and to submit an "early food safety evaluation" containing food safety and nutritional information.[151] The 1996 guidance document explicitly states that "[d]uring the consultation process, the FDA does not conduct a comprehensive scientific review of data generated by the developer" but rather evaluates the developer's conclusions to ensure that "all safety and regulatory issues are resolved."[152] This consultation process is entirely voluntary, and only considers risks to humans from consumption — it does not consider the potential for environmental and ecological consequences at all.[153]

Interestingly, the presumption of safety for GE food stands in marked contrast to the FDA's review of traditional food products, where, under the FDCA, the burden is on the food producer to establish that a novel food product should be treated as GRAS.[154] The FDA has yet to issue a presumption of GRAS for any food product created through traditional methods;[155] the 1992 policy

148. *See* Statement of Policy, *supra* note 142, 57 Fed. Reg. at 22,991. "In November 2004, the FDA claimed that all new GM plant varieties intended for food or feed use that were marketed in the United States completed the consultation process before they entered the market." Lawrence, *supra* note 24, at 226.

149. Guidance on Consultation Procedures: Foods Derived From New Plant Varieties, U.S. FOOD & DRUG ADMIN. (Oct. 1997), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096126.htm [hereinafter 1996 Guidance].

150. Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use, U.S. FOOD & DRUG ADMIN. (June 2006), http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096156.htm#ftnref6 [hereinafter 2006 Guidance].

151. *Id.*

152. 1996 Guidance, *supra* note 149.

153. *See id.* For a discussion of the potential environmental and ecological risks of cross-pollination, see *supra* Part II.B.2.b–c.

154. 21 U.S.C. § 348(b) (2006); Alison Peck, *Leveling the Playing Field in GMO Risk Assessment: Importers, Exporters and the Limits of Science*, 28 B.U. INT'L L.J. 241, 253 (2010).

155. Peck, *supra* note 154, at 253.

statement applies the GRAS presumption exclusively to GE food.[156]

C. THE FDA'S ROLE IN THE REGULATION OF GENETICALLY ENGINEERED ANIMALS

Like the agency's regulatory authority over GE crops, the FDA's authority over GE animals relies on the Coordinated Framework and creative interpretations of the FDCA. In order to clarify its legal authority to regulate GE animals, and to provide recommendations to developers to help them meet their legal obligations, the FDA in 2009 issued its "Guidance for Industry 187: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs" (GFI 187).[157] In this guidance, the FDA claimed primary regulatory authority over GE animals by virtue of its "new animal drug" authority under the FDCA.[158]

The FDA, in addition to being the primary federal agency responsible for ensuring food safety, is also the primary agency responsible for ensuring the safety of pharmaceuticals.[159] This responsibility covers both drugs intended for human use as well as drugs intended for animals.[160] In order to market a new animal drug, a developer must first file a New Animal Drug Application (NADA) and receive FDA approval.[161] The FDCA defines a "new animal drug" as "any drug intended for use for animals other

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156. *Id.* at 252; Statement of Policy, *supra* note 142, 57 Fed. Reg. at 22990. As Peck points out,

> [B]y treating biotech products more favorably than other types of new modified foods (for which the burden of proving they are GRAS remains on the producer), the FDA's GRAS presumption for novel biotech products actually does something different than [the OSTP's Final Statement of Scope] suggests. . . . Rather than creating a level playing field for products altered through biotechnology and products altered through traditional methods, the FDA policy instead favors biotech products, treating them as fungible with traditional (non-altered) varieties.

Peck, *supra* note 154, at 254.

157. *See* Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, U.S. FOOD & DRUG ADMIN. (Jan. 15, 2009), http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf [hereinafter 2009 Guidance].

158. *See id.* at 4; 21 U.S.C.A. §§ 331(a) (West 2011), 360b(a) (West 2008).

159. *See* Mandel, *supra* note 32 at 2229; 21 U.S.C. §§ 301–399 (2006).

160. *See* 21 U.S.C. §§ 354.

161. *See* 2009 Guidance, *supra* note 157, at 6.

than man, including any drugs intended for use in animal feed."[162] The Act further defines "drugs" as, among others, "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[163] The FDA has interpreted this authority to cover GE animals, since an engineered rDNA construct itself is a non-food article "intended to affect the structure or function" of a GE animal, in a manner presumably analogous to that of a veterinary drug.[164]

As the FDA's express purpose under the FDCA is to protect American consumers from the risks of unsafe food and drugs, the FDA is "predominantly concerned with questions of how consumption of [a new animal drug (NAD)] may affect human health."[165] Therefore, under the FDCA, the safety of a NAD is defined only with "reference to the health of man or animal."[166] The FDA has interpreted this statutory language to cover "environmental effects that directly or indirectly affect the health of humans or animals," but not potential adverse environmental effects that are purely environmental, in that they do not pose a direct risk to man or animal.[167] Questions surrounding adverse effects to the environment are therefore not of primary concern to the FDA.[168] Meanwhile, the EPA, the primary federal agency responsible for protecting the environment, has determined it lacks any regulatory authority over GE animals.[169] As a result, no federal agency asserts regulatory authority over examining the purely environmental effects of GE animals.

While the approval process for GE animals will be fleshed out more fully in the following section's GE salmon case study, two last observations are worthy of note here. First, the FDCA's definition of "new animal drug" expressly specifies that such drugs are not GRAS,[170] and thus the FDA's claim of regulatory authority

162. 21 U.S.C.A. § 321(v).
163. *Id.* § 321(g).
164. 2009 Guidance, *supra* note 157, at 6.
165. *See* Bratspies, *supra* note 24, at 473.
166. 21 U.S.C.A. § 321(u).
167. *See* OFFICE OF SCI. & TECH. POLICY, EXEC. OFFICE OF THE PRESIDENT, CASE STUDY NO. 1: GROWTH-ENHANCED SALMON 14 (2001), *available at* http://www.whitehouse.gov/galleries/Issues/ceq_ostp_study2.pdf [hereinafter CASE STUDY NO. 1].
168. *See* Bratspies, *supra* note 24, at 473.
169. *See* Mandel, *supra* note 32, at 2209, 2223.
170. 21 U.S.C.A. § 321(v).

over GE animals starkly conflicts with the FDA's presumption of safety for GE crops[171]: according to the FDA, rDNA added to GE crops are "generally recognized as safe" and thus not subject to food safety review,[172] while rDNA added to GE animals are "new animal drugs" and are not GRAS.[173] Moreover, because GE animal food products are evaluated under the rules governing veterinary drugs, NADA's are reviewed and ultimately approved or rejected by the Center for Veterinary Medicine (CVM), rather than the Center for Food Safety and Applied Nutrition (CFSAN), the FDA center typically responsible for food safety evaluations.[174] This is a curious regulatory fit for prospective GE animals intended for human consumption. But such is the necessary consequence of evaluating GE animal food products under the rules governing new veterinary drugs — itself a result of expansively interpreting the world "article" in section 201 of the FDCA to encompass rDNA genetic engineering, a technology inconceivable for the Congress that enacted the FDCA in 1958.[175]

IV. GENETICALLY ENGINEERED SALMON: A CASE STUDY

As of 2002, at least fourteen different GE fish species had been developed to enhance growth rates in a variety of fish.[176] While there is no way for the public to determine how many applications for GE animals the FDA is currently reviewing,[177] it is increasingly probable that GE salmon will become the first GE animal approved for human consumption in America.[178] This Part analyzes the FDA's ongoing approval process for AquaBounty's GE salmon in order to illustrate the deficiencies of the current regulatory regime for GE animals.

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171. *See supra* Part III.B.
172. *See supra* note 143 and accompanying text.
173. *See supra* note 170 and accompanying text.
174. *See* 2009 Guidance, *supra* note 157, at 4–5.
175. *See* Mandel, *supra* note 32, at 2210.
176. Lawrence, *supra* note 24, at 264.
177. *See, e.g.*, Andrew Pollack, *Genetically Altered Salmon Gets Closer to the Table*, N.Y. TIMES, June 25, 2010, at A1, *available at* http://www.nytimes.com/2010/06/26/business/26salmon.html.
178. *Id*.

A. AQUADVANTAGE SALMON

The Trade Secrets Act prohibits the FDA from revealing any information acquired through the NAD approval process, including even the fact that a NADA has been filed.[179] The public therefore rarely knows about a new GE food product until the product has already been approved for sale.[180] However, AquaBounty Technologies has publicly disclosed that it has filed a NADA for GE salmon, enabling the FDA to give the public a limited view into the approval process.[181]

In 1995, AquaBounty submitted preliminary data to the FDA; they have since gathered information on ten generations of GE salmon,[182] ultimately completing "all outstanding FDA submissions and requests for information in 2009."[183] The CVM convened its Veterinary Medicine Advisory Committee (VMAC) in September 2010 in order to obtain independent expert advice on the GE salmon, as well as to provide the public with detailed information concerning the salmon.[184] While the general public has acquired some information about the salmon from AquaBounty's press releases, the vast majority of public information concerning the salmon has come from the VMAC meeting.

The GE salmon, named AquAdvantage salmon, has been developed to grow to adult or market size twice as fast as conventional, non-GE salmon.[185] The salmon is created by inserting genes from an ocean pout (an eel-like fish, distantly related to salmon) into growth hormone genes from a Chinook salmon, and then inserting this altered growth hormone gene into an Atlantic

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179. *See* CASE STUDY NO. 1, *supra* note 167, at 16; 21 U.S.C.A. § 331(j) (West 2011); 18 U.S.C. § 1905 (2006).

180. CASE STUDY NO. 1, *supra* note 167, at 16.

181. *See, e.g.*, Pollack, *supra* note 177.

182. Gautam Naik, *Gene-Altered Fish Closer to Approval*, WALL ST. J., Sept. 21, 2010, http://online.wsj.com/article/SB10001424052748703989304575503891676987232.html.

183. Aqua Bounty Fact Sheet, AQUABOUNTY TECHNOLOGIES, http://www.aquabounty.com/documents/press/2010/AquaBounty%20Fact%20Sheet%20-%20Corfin.pdf (last visited Sept. 10, 2011).

184. *See infra* Part IV.B.2.

185. *See* Pollack, *supra* note 177; *see generally* U.S. FOOD & DRUG ADMIN., CTR. FOR VETERINARY MED., VETERINARY MED. ADVISORY COMM., BRIEFING PACKET at 8 (2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf [hereinafter BRIEFING PACKET].

salmon.[186] Atlantic salmon typically do not produce growth hormone in cold weather, but the pout's genes, which essentially function as an "on switch," enable the Atlantic salmon to keep producing the growth hormone year round.[187] This increased growth hormone results in salmon that can grow twice as fast as conventional salmon.[188] If approved by the FDA, AquaBounty would sell the eggs of its GE salmon to aquaculture companies, more commonly known as "fish farms," where the salmon would grow and eventually be sold for human consumption.[189]

Proponents of GE fish point to many potential benefits of approval. Most obviously, approval would allow for more efficient and less expensive production of salmon, since the fish require less feed and can be sold twice as quickly.[190] Proponents of GE salmon also claim the novel fish could "help reduce pressure on wild fish stocks" since it is cheaper to grow and farm than conventional salmon, which in turn is cheaper to produce than catching wild salmon.[191] An increasing demand for salmon has resulted in natural salmon stocks becoming so depleted that many varieties are now listed as endangered under the Endangered Species Act (ESA).[192] For example, "Atlantic salmon are extinct in 84% of the rivers in New England that historically supported salmon," and are in "critical condition" in the remaining 16%.[193] The GE salmon are similarly claimed to dramatically reduce the carbon footprint of production and overfishing.[194] Proponents also claim that the potential for cheaper salmon aquaculture in America "would spur investment into [the aquaculture] industry in our

186. Pollack, *supra* note 177.

187. *Id.*

188. *Id.*

189. FOOD & WATER EUROPE, ISSUE BRIEF, GE SALMON WILL NOT FEED THE WORLD 2 (2010), *available at* http://documents.foodandwaterwatch.org/GEsalmonWillNotFeedtheWorldEURev.pdf.

190. *See* Press Room, Aquaculture Facts, AquaBounty Tech., http://www.aquabounty.com/PressRoom/#l3 (last visited Sept. 10, 2011).

191. Press Room, Benefits of Land-Based Aquaculture Systems, AquaBounty Tech., http://www.aquabounty.com/PressRoom/#l4 (last visited Sept. 10, 2011)

192. *An Overview of Atlantic Salmon, Its Natural History, Aquaculture, and Genetic Engineering*, U.S. FOOD & DRUG ADMIN., VETERINARY MED. ADVISORY COMM. (Aug. 27, 2010), http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222635.htm.

193. *Id.*

194. Press Room, Benefits of Land-Based Aquaculture Systems, AquaBounty Tech., http://www.aquabounty.com/PressRoom/#l4 (last visited Sept. 10, 2011).

country";[195] the majority of the salmon consumed in the United States come from fish farms, but 97% of the farmed salmon is currently imported, rather than produced domestically.[196] Finally, the president and CEO of AquaBounty has claimed that allowing GE salmon into the global food supply and thus increasing aquaculture productivity would "very effectively help to meet the demand for food from the growing world population."[197]

B. THE APPROVAL PROCESS

When the FDA released its GFI 187,[198] it held the document open to public comment for sixty days.[199] The agency received roughly 29,000 comments, the vast majority of which were critical of the proposed regulatory process for GE animals outlined in the guidance.[200] Once the comment period closed, the FDA published a general summary of the principal issues addressed in the comments, along with the agency's responses to those issues.[201]

Three main criticisms were levied against the FDA: (1) the FDA lacks the expertise necessary to properly address environmental concerns surrounding GE animal approval; (2) the GE animal approval process is not transparent and does not provide sufficient opportunity for public input; and (3) the NADA process,

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195. Press Room, Benefits of Land-Based Aquaculture Systems, AquaBounty Tech., http://www.aquabounty.com/PressRoom/#l4 (last visited Sept. 10, 2011).

196. Elliot Entis, *New Salmon Can Address a Myriad of Problems*, THE HILL'S CONGRESS BLOG (Oct. 11, 2010, 9:53 AM), http://thehill.com/congress-blog/technology/123607-new-salmon-can-address-myriad-problems. Entis is the co-founder of AquaBounty Technologies. *Id.*

197. Press Release, AquaBounty Technologies, VMAC Meeting to Consider AquAdvantage Salmon (Aug. 25, 2010), *available at* http://www.aquabounty.com/documents/press/2010/2010%2008.25%20-%20VMAC%20Meeting%20Date%20Set.pdf. Some advocacy groups have rejected the plausibility of this claim. Food and Water Europe, for instance, has described the claim as completely "unsubstantiated," and it has stated that GE salmon cultivation may actually be more costly to raise than conventional farmed salmon due to increased input costs. *See* FOOD & WATER EUROPE, ISSUE BRIEF, *supra* note 186, at 3.

198. *See supra* note 157 and accompanying text.

199. *FDA's Response to Public Comments*, U.S. FOOD & DRUG ADMIN. (May 23, 2011), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113612.htm [hereinafter FDA's Response].

200. *Id.*

201. *Id.*

and consequently the CVM's primary role in regulation, is inappropriate for GE animal food safety regulation.[202]

Despite the FDA's responses to these criticisms, which aimed to reassure the public of the adequacy of the regulatory process outlined in GFI 187, the FDA's handling of the approval process for AquAdvantage salmon has demonstrated the validity of the public's concerns. Addressing each of these three criticisms in turn, alongside the FDA's responses as they were instituted in the AquAdvantage salmon approval process, illustrates the flaws in the current regulatory scheme for GE animals.

1. *The FDA Lacks the Expertise Necessary to Properly Address the Environmental Concerns Surrounding Genetically Engineered Animals*

Some of the most serious risks surrounding approval of GE salmon appear to be environmental.[203] For example, critics note the potential for catastrophic environmental impact if GE salmon were to escape from production facilities.[204] As mentioned above, wild Atlantic salmon are currently on the Endangered Species List.[205] One factor contributing to their diminishing populations has been the "genetic and fitness impairments caused by inbreeding with farmed salmon escaping from net pens."[206] Multiple studies have suggested that if GE salmon were to escape their pens and mate with wild Atlantic salmon, entire wild fish populations could become permanently wiped out.[207] Escape also would create the risk for unpredictable environmental impacts on the ecosystem.[208]

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202. *Id.*

203. *See, e.g.*, Letter from Envtl. Advocacy Grps. to Margaret Hamburg, FDA Comm'r (Nov. 8, 2010) [hereinafter Wodder Letter], *available at* http://act.oceanconservancy.org/site/DocServer/110810-FDALetterGESalmonFinal.pdf?docID=6541; *see infra* notes 207–13 and accompanying text.

204. Wodder Letter, *supra* note 203.

205. *See supra* note 192 and accompanying text.

206. Wodder Letter, *supra* note 203.

207. *Id.*; *see also* PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH 17 (2003), *available at* http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_011403.pdf [hereinafter Future Fish].

208. *See* Future Fish, *supra* note 207, at 17; CASE STUDY NO. 1, *supra* note 167, at 6–7; Wodder Letter, *supra* note 203, at 1.

The Pew Initiative on Food & Biotechnology, the National Research Council, and the National Academy of Sciences have all released studies documenting the risks of environmental impact following the escape of GE salmon from their production facilities.[209] One study[210] found that if just sixty GE fish were released into a population of 60,000 wild fish, the entire wild population could become extinct within forty generations.[211] A Canadian study concerning one variety of growth-enhanced GE salmon[212] found that when the GE salmon and natural salmon were held together in a laboratory and experienced low food availability, both populations went extinct, as the "GE salmon are more aggressive [than their natural counterparts] and sometimes resort to cannibalism."[213] Moreover, aside from these studies, there is no data covering the possible impact that escape of the GE salmon — a completely novel, non-natural organism — could have on different aquatic ecosystems or local food chains.[214] According to the Pew report, "given the limitations of current science, it is ex-

209. *See* Future Fish, *supra* note 207, at 17–26; ANIMAL BIOTECHNOLOGY, *supra* note 33; William M. Muir & Richard D. Howard, *Possible Ecological Risks of Transgenic Organism Release When Transgenes Affect Mating Success: Sexual Selection and the Trojan Gene Hypothesis*, 96 PROC. NAT'L ACAD. SCI. 13,853 (1999).

210. The study concerned the "Trojan gene scenario," which suggests that if a GE fish species, exhibiting both enhanced mating success and reduced adult viability due to its enhanced growth rate, were introduced into a wild population, the result could be a "rapid decline of the wild population." Future Fish, *supra* note 207, at 22. The mating advantage of the GE fish would result in the spread of the transgene (the engineered gene) into the wild salmon population, while the lower survival rate of subsequent generations would "eat away at the population size." *Id.*

211. Muir & Howard, *supra* note 209, at 13,855; *see also* Wodder Letter, *supra* note 203. Dr. Muir, the author of the Trojan gene hypothesis, has since stated that the Trojan gene effect should not be an issue with the AquAdvantage salmon, since he believes that the GE salmon would not have the mating advantages originally presumed for enhanced-growth rate GE fish. U.S. Food & Drug Admin., Transcript for Veterinary Med. Advisory Comm. Meeting, at 317 (Sept. 20, 2010) [hereinafter VMAC Transcript], *available at* http://www.fda.gov/downlaods/AdvisoryCommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230471.pdf. Other critics and environmental organizations do believe there is adequate data to support this concern. *See, e.g.*, Wodder Letter, *supra* note 203; *see also* Begich Letter, *supra* note 28. Other studies point to different environmental risks, such as the "spread scenario": if the net fitness of a GE fish is greater than that of a wild fish, "gene flow is likely to occur and the genes of the [GE] fish will spread through the wild population," reducing biodiversity and potentially eliminating the wild population over time. Future Fish, *supra* note 207, at 21.

212. This study concerned a different type of GE salmon, not AquAdvantage. Wodder Letter, *supra* note 203.

213. *Id.*

214. *Id.*; Future Fish, *supra* note 207, at 24.

tremely difficult to predict and assess the consequences of those impacts on fish populations and the broader aquatic communities to which those populations belong."[215]

Critics of the approval process for GE animals worry that the FDA is not competent to adequately address these environmental risks.[216] The FDA believes it has no authority under the FDCA to consider potential adverse environmental effects that are purely environmental, in that they do not pose a direct risk to man or animal.[217] Similarly, the agency lacks the statutory authority under the FDCA to deny approval of a NADA solely because approval would harm the environment.[218] Critics also note that the EPA, the federal agency primarily responsible for protecting the environment, has no regulatory authority over GE animals, and thus has no role in the approval of products whose principal risks are environmental.[219]

In response to these concerns, the FDA has given assurances that it is capable of properly addressing any environmental risks, despite the agency's lack of authority under the FDCA.[220] Specifically, the agency has pointed to its authority under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the Endangered Species Act (ESA), and the National Environmental Protection Act (NEPA).[221]

Section 1007 of the FDAAA requires that the FDA consult with the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (NOAA) to produce a report concerning potential environmental risks associated with approval of any new GE seafood product, explicitly "including the impact on wild fish stocks."[222] Section 7 of the ESA similarly requires the FDA to consult with NMFS as well as the Interior Department's U.S. Fish and Wildlife Service (FWS) if ap-

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215. Future Fish, *supra* note 207, at 24.

216. *See, e.g.*, Wodder Letter, *supra* note 203; Begich Letter, *supra* note 28.

217. *See* CASE STUDY NO. 1, *supra* note 167 at 14.

218. *See* FDA's Response, *supra* note 199.

219. *See supra* note 169 and accompanying text. While this Note principally concerns GE animals, it is worth noting that the EPA similarly has no role in the approval of GE crops, other than those crops engineered to be pest-protected. *See* Mandel, *supra* note 32, at 2231.

220. *See* FDA's Response, *supra* note 199.

221. *Id.*; *see also* CASE STUDY NO. 1, *supra* note 167, at 17–18.

222. Food and Drug Administration Act Amendments of 2007, Pub. L. No. 110-85, § 1007, 121 Stat. 823 (2007).

proval of the NADA might adversely affect a species listed under the ESA as endangered.[223] Finally, while the EPA, as mentioned above, has determined it has no regulatory authority over GE animals, the FDA is required under NEPA to coordinate with any agency whose jurisdiction might be affected by the approval of the NADA.[224] Thus, when questioned about the FDA's perceived inability to effectively address the environmental risks of GE salmon, a senior regulatory review scientist for the CVM responded that the FDA was working with the EPA and the FWS to conduct a thorough review of those risks.[225]

Additionally, granting a NADA constitutes a "federal action" under NEPA,[226] which requires the FDA to comply with NEPA's requirements throughout the NAD approval process.[227] Under NEPA, an applicant for a NAD must submit an "environmental assessment" (EA) to the FDA.[228] The EA provides information relevant to determining if approval would create any adverse environmental impact.[229] If the EA demonstrates that approval would not significantly affect the environment, the FDA can issue a "finding of no significant impact" (FONSI), thus satisfying its requirements under NEPA.[230] But if the EA shows even the possibility of a significant risk of adverse environmental impact, then the FDA must complete a much more comprehensive environmental analysis called an "environmental impact statement" (EIS).[231] If the EIS, in turn, shows that approval of the NADA could cause significant harm to the environment, the FDA can require that the NADA's sponsor take certain precautions to mi-

223. *See* CASE STUDY NO. 1, *supra* note 167, at 17.
224. *See id.* at 27.
225. Smithson, *supra* note 62.
226. NEPA is the "basic national charter for protection of the environment," and is "intended to help public officials make decisions that are based on understanding of environmental consequences, and take actions that protect, restore, and enhance the environment." 40 C.F.R. § 1500.1 (2011).
227. 2009 Guidance, *supra* note 157, at 8.
228. 21 C.F.R. §§ 25.15, 511(b)(10), 514.1(b)(14) (2011). This excludes a NADA that might qualify for categorical exclusion (which is typically reserved for investigational studies on GE animals, not applications seeking approval for commercial food-use cultivation). *See* 2009 Guidance, *supra* note 157, at 12.
229. 2009 Guidance, *supra* note 157, at 12. The specific information required in an EA is outlined in 21 C.F.R. § 25.40 (2011).
230. 2009 Guidance, *supra* note 157, at 19.
231. 21 C.F.R. § 25.15 (2011); *see also id.* §§ 511(b)(10), 514.1(b)(14) (2011).

tigate environmental harms, or if the environmental impacts are immitigable, refuse approval altogether.[232]

Thus, the FDA's ability to analyze environmental risks has two components: it is required by NEPA, the FDAAA, and the ESA to consult with other federal agencies that might be affected by approval, and it is required by NEPA to prepare an EA and possibly an EIS.

a. FDA Has Failed to Consult with Other Federal Agencies with Environmental Expertise, as Required by Law

Although AquaBounty first submitted its NADA for GE salmon over ten years ago, the FDA has yet to consult with other federal agencies with environmental expertise as required by law, and instead appears to be intentionally freezing out the FWS and NOAA.[233] This information, along with many of the criticisms of the approval process that follow in this Section, comes from leaked e-mails between senior scientists at the FWS and NOAA that chronicle many troubling concerns about the FDA's handling of the GE salmon.[234] As for the FDA's failure to adequately consult with other federal agencies, the e-mails reveal that:

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232. CASE STUDY NO. 1, *supra* note 167, at 15. Importantly, NEPA still does not allow the FDA to refuse approval if the environmental impacts are purely environmental. *Id.* ("FDA relies on its authority under the FFDCA to require, where appropriate, environmental safety instructions on product labels, to enforce compliance with mitigations that are required as a condition of the product approval, and to refuse to approve or to withdraw approval of products that cause unexpected and unmitigatable environmental impacts *that adversely affect, directly or indirectly, the health of humans or animals*." (emphasis added)).

233. *Newly Disclosed Government Documents Conclude GE Salmon Pose a Critical Threat to Marine Environments*, CTR. FOR FOOD SAFETY (Oct. 27, 2010), http://truefoodnow.org/2010/10/27/newly-disclosed-government-documents-conclude-ge-salmon-pose-a-critical-threat-to-marine-environments/ [hereinafter Disclosed Gov't Documents].

234. *Id.*; *see F.W.S. Internal Documents*, FOOD & WATER WATCH, http://documents.foodandwaterwatch.org/FOIA-Exhibits-Letter-FDA-FWS.pdf (last visited Sept. 11, 2011) [hereinafter FWS Internal Documents]. The documents were obtained by the consumer group Food & Water Watch through the Freedom of Information Act and then disclosed to the public. Press Release, Food & Water Watch, Troubling Emails Reveal Federal Scientists Fear FDA Approval of Genetically Engineered Salmon: "Maybe They [the FDA] Should Watch Jurassic Park." (Nov. 15, 2010), *available at* http://www.foodandwaterwatch.org/pressreleases/troubling-emails-reveal-federal-scientists-fear-fda-approval-of-genetically-engineered-salmon.

> Shortly after the Atlantic salmon was listed as endangered, several of us from USFWS and NMFS spent 2 days down in Maryland meeting with Aqua Bounty and FDA about development of genetically modified salmon and discussion around the need for FDA to engage in Section 7 consultation with the Services. We never heard a peep out of FDA or Aqua Bounty after that.[235]

The Atlantic salmon was listed as endangered on November 13, 2000;[236] the relevant inter-agency e-mail was sent November 7, 2008,[237] almost eight years later.

An e-mail from October 2010 documents how the FWS and NOAA followed up on this initial meeting a year later, by sending the FDA a letter in October 2001 regarding AquaBounty's NADA.[238] Specifically, the letter noted "the listing of Gulf of Maine Atlantic salmon as an endangered species under the ESA" and the FDA's "responsibility under the ESA to consult with the [FWS and NMFS] agencies to ensure that any action will not jeopardize an endangered species . . . ."[239] The e-mail describing this letter also suggested that the FDA had failed to consult with NMFS as required by Section 1007 of the FDAAA.[240] These e-mails make clear that after ten years of reviewing the NADA, the FDA has yet to fulfill its legal obligations under the ESA or the FDAAA to consult with other federal agencies.[241]

b. FDA Has Failed to Fulfill Its Statutory Obligations Under NEPA and Prepare an Environmental Impact Statement

The FDA has suggested that it will be fulfilling its NEPA duties by issuing a FONSI and that it will thus not be preparing an EIS for AquAdvantage salmon.[242] This determination likely re-

235. Disclosed Gov't Documents, *supra* note 233.
236. Press Release, NOAA Nat'l Fish and Wildlife Serv., Wild Atlantic Salmon in Maine Protected as Endangered Species (Nov. 13, 2000), *available at* http://www.publicaffairs.noaa.gov/releases2000/nov00/noaanfws1113.html.
237. FWS Internal Documents, *supra* note 234.
238. *Id.*
239. *Id.*
240. *Id.*
241. *Id.*
242. BRIEFING PACKET, *supra* note 185, at 131–32.

sults in part from the multiple containment measures proposed by AquaBounty in the EA that it submitted to the FDA. The EA states that FDA approval is conditioned on the following specific production process: a hatchery in Canada's Prince Edward Island will produce the GE salmon eggs; the eggs will then be shipped to a grow-out facility in Panama; and once the fish grow to market size and are processed at this grow-out facility, the table-ready fish will be shipped to the U.S. for sale.[243] Significantly, both the hatchery and the grow-out facility are land-based, dramatically reducing the possibility of escape of the salmon, as opposed to the near certainty of escape from traditional open-water net pens.[244] Moreover, AquaBounty states that the facilities will institute several other physical containment measures, such as multiple screens and filters, to further prevent escape, and the company points to geographic containment measures as well.[245] Finally, the company plans to utilize biological containment by sterilizing the salmon before they are shipped for grow-out in Panama, thus significantly reducing the risk of breeding with wild salmon and the resulting gene spread upon escape.[246] This is accomplished by producing only female fish and by engineering the females to be triploid (i.e., expressing three sets of chromosomes), rendering most of the females sterile.[247]

While these containment measures reduce the threat of adverse environmental impact, the FDA would nonetheless fail to satisfy its legal obligation under NEPA if it issues a FONSI and fails to conduct an EIS. The FDA can only issue a FONSI if it determines that the EA demonstrates that there is no risk of significant adverse environmental impact.[248] However, the EA simp-

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243. U.S. FOOD & DRUG ADMIN., CTR. FOR VETERINARY MED., ENVIRONMENTAL ASSESSMENT FOR AQUADVANTAGE SALMON 10 (2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf [hereinafter EA].

244. *Id.* at 10–11.

245. *Id*. According to AquaBounty,

> [T]he environment surrounding the egg-production site in Canada is inhospitable to early-life stages of Atlantic salmon due to high salinity; and, the environment downstream of the grow-out site in Panama is inhospitable to all life stages of Atlantic salmon due to high water temperatures, poor habitat, and physical barriers (e.g., several hydro-electric facilities).

Id. at 10.

246. *Id.* at 59.

247. *Id.*

248. *See supra* note 229–231 and accompanying text.

ly does not contain the reliable information necessary for the agency to make such a determination,[249] and the FDA is poised to abuse its discretion under NEPA by issuing a FONSI instead of preparing its own EIS.[250] This abuse of discretion, while certainly troubling in and of itself, further demonstrates that the FDA is not the appropriate agency to evaluate environmental risks, as there is no reason to believe that the agency would demonstrate any greater capacity — or willingness — to competently evaluate these risks with future GE animal applications.

To begin with, an EA is prepared entirely by the NAD applicant, in contrast to an EIS, which must be prepared by the FDA. Thus, all of the information that the FDA uses to analyze environmental risk is produced by AquaBounty, not independently collected by the FDA, and is therefore likely to understate any potential risk.[251] In addition to understating the risk, the EA is likely to obfuscate the real issues at stake; as noted in a letter written by a dozen of the nation's largest environmental advocacy organizations and sent to FDA Commissioner Hamburg, "the only environmental analysis before [the] FDA consists of an environmental assessment prepared by AquaBounty that sidesteps the weighty issues [the] FDA must address."[252]

A leaked FWS letter addressed to the FDA and written by scientists with actual environmental expertise further accuses the EA of being "overly simplistic" and "fall[ing] short of providing an actual risk assessment of putative environmental damages in the event of escapement."[253] While the EA explains the different types of containment measures that the production facilities will employ, nowhere does it quantify the actual risk of escape, or the degree of harm to wild Atlantic salmon or the ecosystem upon escape.[254] Furthermore, as one FWS geneticist pointed out in an e-mail to FWS coworkers, "there is no data [in the EA] to support

249. *See infra* note 252 and accompanying text.
250. *See supra* note 242 and accompanying text.
251. EA, *supra* note 243, at 16.
252. Wodder Letter, *supra* note 203.
253. Letter from U.S. Fish and Wildlife Service, Conservation Genetics Cmty. of Practice, U.S. Food & Drug Admin. (Oct. 6, 2010), *available at* http://documents.foodandwaterwatch.org/FOIA-Exhibits-Letter-FDA-FWS.pdf [hereinafter Cmty. of Practice Letter].
254. *See id.*; EA, *supra* note 243, at 70–71.

the claims of low survival in the event of escape, which . . . is a big concern."[255]

There are also concerns with the methods proposed by AquaBounty in the EA. One FWS geneticist doubted the efficacy of engineering the salmon to be triploid and therefore sterile, noting that "using triploid fish is not foolproof."[256] The concerns expressed by these FWS scientists are especially disconcerting since AquaBounty admits that "their sterilization techniques to induce triploidy are not effective in up to [five percent] of all eggs treated," a potentially large number given the quantity of eggs the company will ultimately harvest.[257] Moreover, there is no oversight policy for assessing, monitoring, or enforcing any of these proposed containment procedures following approval.[258] As one internal e-mail between FWS geneticists concludes, "[no] matter what precautions you take, fish escape and once they do, there is no closing that door. [S]o, that being said, [I] think it is very bad precedent to set . . . ."; "I do think the chance of escape is huge."[259]

The precedential significance of the environmental review is perhaps the most troubling aspect of the EA. AquaBounty limited its risk assessment in the EA to its proposed facilities in Canada and Panama.[260] Yet the company has indicated that, upon approval, it plans to sell its GE salmon eggs to as many growers as possible, including fish farms here in the United States.[261] Joe McGonigle, Vice President of AquaBounty, has already contacted FWS scientists with a proposal to build an all-in-one hatchery and grow-out facility off the coast of Maine; while this would also be a land-based facility,[262] the final wastewater

255. FWS Internal Documents, *supra* note 234; *see* BRIEFING PACKET, *supra* note 185, at 139.

256. FWS Internal Documents, *supra* note 234.

257. Wodder Letter, *supra* note 203.

258. Cmty. of Practice Letter, *supra* note 253.

259. FWS Internal Documents, *supra* note 234.

260. Wodder Letter, *supra* note 203.

261. *See id.*

262. Notably, growing GE salmon in ocean net-pens in Maine was banned by the FWS and NMFS in order to "eliminate the potentially adverse disease and ecological risks posed by the use of transgenic salmonids in aquaculture." NAT'L MARINE FISHERIES SERV. & U.S. FISH & WILDLIFE SERV., BIOLOGICAL OPINION 75 (2003), *available at* http://stopgefish.files.wordpress.com/2010/10/corp-bo-full-file.pdf. This seemingly important fact was never brought up by the FDA during the VMAC meeting. VMAC Transcript, *supra* note 211; BRIEFING PACKET, *supra* note 185.

from the facility would discharge into a segment off the Gulf of Maine that is protected under the ESA due to its endangered native population of wild Atlantic salmon.[263] Unfortunately, NADA regulations do not require the FDA to disclose to the public future EAs prior to approval, and the FDA can extend NAD approval to cover new manufacturing facilities with truncated environmental review.[264] The EA thus should have been required to comprehensively analyze the possible cumulative environmental effects resulting from the proliferation of facilities handling the GE salmon, since the environmental assessment in this first application carries enormous precedential value.[265] As the FWS Assistant Director for Endangered Species aptly noted in another leaked e-mail, "there's only one bite at this apple . . . ."[266]

NEPA mandates the FDA to prepare an EIS whenever approval "*may* significantly affect the quality of the human environment."[267] The potential devastation caused by the escape of the GE salmon, the questions surrounding the containment measures, and the lack of data supporting the company's claims of low survival in event of escape — all of the aforementioned concerns with AquaBounty's EA suggest that the FDA should prepare a comprehensive EIS to properly assess these risks before approving the NADA. One would not be alone in wondering how the FDA could possibly conclude, given the variety of enormous environmental risks posed by this precedent-setting approval, that GE salmon present no risk of significant environmental impact.[268] Such a conclusion would demonstrate that the FDA is either incapable of evaluating — or unwilling to properly evaluate — the environmental risks associated with approving GE animals.

263. *See* Disclosed Gov't Documents, *supra* note 233.
264. Wodder Letter, *supra* note 203.
265. *See id.*; FWS Internal Documents, *supra* note 234; Cmty. of Practice Letter, *supra* note 253.
266. FWS Internal Documents, *supra* note 234.
267. 21 C.F.R. § 25.22(b) (2011) (emphasis added).
268. BRIEFING PACKET, *supra* note 185, at 131–32 (explaining the FDA's conclusions).

2. *The Genetically Engineered Animal Approval Process Is Not Transparent and Does Not Provide Sufficient Opportunity for Public Input*

Critics have further chastised the approval process as lacking transparency and opportunity for public input. As mentioned above, the Trade Secrets Act prohibits the FDA from revealing any information to the public that is part of a NADA; the public is only aware of the existence of AquAdvantage salmon because AquaBounty decided to publicly disclose that it had filed a NADA.[269] This prohibition usually means that the public has no way of knowing that a NAD is even under review until after the FDA has issued approval, which the FDA itself has acknowledged "is particularly inappropriate for products of a new and controversial technology such as the genetic engineering of animals."[270]

To address these concerns and increase the transparency of the GE animal review process, the FDA announced that it would hold a public advisory committee meeting prior to approving the GE salmon.[271] The FDA typically utilizes its advisory committees to obtain independent expert advice on scientific and technical matters when reviewing applications for approval.[272] By making this veterinary medicine advisory committee (VMAC) meeting for AquAdvantage salmon public, the FDA provided an opportunity for public comments.[273] Moreover, before the meeting convened, the FDA provided the public with the same briefing packets — containing much of the technical data in the NADA and the EA — that were given to the VMAC members as the basis for their independent analysis of the NADA.[274]

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269. *See supra* notes 179–181 and accompanying text.

270. *See* FDA's Response, *supra* note 199.

271. *Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon*, U.S. FOOD AND DRUG ADMIN., VETERINARY MED. ADVISORY COMM. (Aug. 25, 2010), http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm.

272. U.S. FOOD AND DRUG ADMIN., ADVISORY COMMITTEES (last updated Sept. 14, 2011), *available at* http://www.fda.gov/AdvisoryCommittees/default.htm ("The Food and Drug Administration, to assist in its mission to protect and promote the public health, uses 49 committees and panels to obtain independent expert advice on scientific, technical, and policy matters.").

273. *Id.*

274. *Id.*; BRIEFING PACKET, *supra* note 185, at ii.

These measures, however, did not alleviate the critics' concerns, which are best summarized by three letters strongly urging FDA Commissioner Hamburg to immediately stop the approval process: one written by Senator Mark Begich on behalf of eleven U.S. Senators,[275] another written by Representative Peter DeFazio on behalf of twenty-nine U.S. Congressmen,[276] and the third written by Consumers Union, the non-profit publisher of *Consumer Reports*.[277] First, the letters note that while the FDA has had eleven years to review the NADA, the agency released the briefing packets to the public only two weeks before the VMAC meeting.[278] Given that the briefing packets contained 255 pages of technical information concerning the food and environmental safety of the GE salmon, the letters complain that the FDA should have given the public far more time to review the enormous amount of data.[279] The House letter states that this extremely short time period "strongly contradicts the agency's claim of commitment to transparency."[280] The Consumers Union letter further points out that the short time period is especially troubling in light of the fact that the approval process for most pharmaceuticals and medical devices normally allows sixty to ninety days of public review, despite the urgent demand for these life-saving products — in contrast to the paltry fourteen days allowed for GE salmon — whose approval is not in any way time-sensitive.[281]

The Senate letter also criticized how the public meeting was organized, noting "hearings on such a contentious issue should not have been held in Rockville, Maryland, but rather in a more

275. Begich Letter, *supra* note 28.
276. DeFazio Letter, *supra* note 28.
277. Letter from Jean Halloran, Director, Food Policy Initiatives, to Margaret Hamburg, Comm'r, Food & Drug Admin. (Sept. 15, 2010) [hereinafter Halloran Letter], *available at* http://www.consumersunion.org/pdf/FDA-ltr-GE-salmon.pdf.
278. Begich Letter, *supra* note 28; DeFazio Letter, *supra* note 28; Halloran Letter, *supra* note 277. One VMAC member noted that despite the fact that "FDA and AquaBounty have been in discussions for over 10 years . . . the public got its first look at some safety data and FDA's analysis at the eleventh hour of the decision process." Gregory Jaffe, *Congress Should Improve FDA's Ability to Regulate GE Animals*, THE HILL'S CONGRESS BLOG (Sept. 29, 2010, 12:20 AM), http://thehill.com/blogs/congress-blog/energy-a-environment/121601-congress-should-improve-fdas-ability-to-regulate-genetically-engineered-animals.
279. Halloran Letter, *supra* note 277.
280. DeFazio Letter, *supra* note 28.
281. Halloran Letter, *supra* note 277.

central location and with outreach to regions dependent on wild salmon populations."[282] Others have similarly accused the FDA of intentionally scheduling the "public" panel at a time and place that would significantly restrict public involvement, as the VMAC meeting began on a Sunday and in a remote location, and attendees were required to complete a complicated registration process.[283]

3. *The NADA Process, and Consequently the CVM's Primary Role in Regulation, Is Inappropriate for Genetically Engineered Animal Food Safety Regulation*

Finally, critics have charged that the creation of a novel GE animal intended for human consumption should not be reviewed through the same regulatory process used to evaluate a new veterinary drug. The critics' main contention is that the CVM and VMAC do not have the necessary expertise in food safety to adequately assess GE salmon's potential health effects on humans.

The FDA has repeatedly insisted that "the NADA requirements work very well as a means of regulating GE animals."[284] While the agency has noted that VMAC members are generally technically qualified experts in their field, the FDA may occasionally determine that additional scientific expertise is needed on a VMAC for a particular product under review.[285] As one senior regulatory review scientist for the CVM stated, "[w]hen we have expertise deficiencies in a particular area, we go out and get experts."[286] Thus, in the case of GE salmon, the CVM added four additional members to the VMAC to ensure that the advisory

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282. Begich Letter, *supra* note 28.

283. Press Release, Food & Water Watch, Advocacy Groups Ask FDA to Reject Controversial Genetically Engineered Salmon; Demand Increased Transparency (Sept. 9, 2010), *available at* http://www.foodandwaterwatch.org/pressreleases/advocacy-groups-ask-fda-to-reject-controversial-genetically-engineered-salmon-demand-increased-transparency/. Moreover, advisory committee meetings are usually scheduled "at least two months after their announcement in the Federal Register. However, in this case, the public was given less than a one month notice." DeFazio Letter, *supra* note 28.

284. *See* FDA's Response, *supra* note 199.

285. *Id.*

286. Smithson, *supra* note 62.

committee could properly provide the CVM with advice and recommendations regarding approval.[287]

Once again, the agency's response to criticism appears to have fallen dramatically short, as evidenced by the VMAC's new membership for the GE salmon review. Of the thirteen members on the Committee, nine are veterinarians or hold doctorates in animal science — not a surprising number given the VMAC's normal role of evaluating new animal drugs.[288] There is not, however, a single food safety scientist specializing in food allergies, despite the fact that allergenicity is one of the greatest human health risks posed by consuming GE salmon.[289] Nor is there a single endocrinologist knowledgeable about growth hormones, the other major human health issue posed by consumption of GE salmon, nor a single fish ecologist, despite the numerous environmental risks described above.[290]

The four "temporary voting members" added to the committee by the FDA to better assess the risks posed by GE salmon engender similarly little confidence. One new member, a genetic engineering expert, holds a senior position at Revivicor Inc., a company currently working on "genetically engineering pigs for use in human medicine."[291] Another member is a former employee of Monsanto who has promoted GE animals on YouTube and serves on the USDA's pro-GE Advisory Committee on Biotechnology and 21st Century Agriculture.[292] Yet another new member, the lone consumer advocate on the VMAC, is a lawyer.[293] Tellingly, he authored a paper stating his "unequivocal support for agricultural biology and his belief that . . . GE crops are safe for humans and the environment.[294] These apparent conflicts of interest prompted Consumers Union to write FDA Commissioner

287. Jill Richardson, *Why is the FDA About to Rubber-Stamp GE Salmon?*, GRIST (Sept. 20, 2010, 3:16 PM), http://www.grist.org/article/2010-09-20-why-is-the-fda-about-to-rubber-stamp-ge-salmon/.

288. *Id.*

289. *Id.*

290. *Id.*

291. *Id.*

292. *Id.*

293. *Id.*

294. *Id.* The consumer advocate represents the Center for Science in the Public Interest, an organization that favors the use of agricultural biotechnology, and he also served on the Advisory Committee on Biotechnology and 21st Century Agriculture for five years. *Id.*

Hamburg, claiming that "three fish ecologists, four food safety experts . . . and scientists from the consumer and environmental community must be added to the [VMAC], to provide appropriate balance and expertise."[295] Otherwise, the organization warned that "the Committee's findings will not have the needed credibility with the public . . . [and the] FDA will fail to get the sound scientific advice it needs and deserves."[296]

Despite the questionable composition of the Committee, the VMAC still found ample reason to criticize the NADA, as well as the FDA's review of the application. In a study conducted by AquaBounty on the possible allergenicity of the GE salmon, one of the foremost potential health risks from consumption, the company relied on a sample size of only six salmon, and unblinded the samples before testing each one individually for allergenicity, a "violation of fundamental scientific method."[297] Despite the fact that the mean allergenicity of the GE salmon was twenty percent higher than the mean allergenicity of natural salmon, the FDA dismissed the findings since the tiny sample size rendered the increased allergenicity finding statistically insignificant, concluding that "[AquaBounty] salmon pose no additional allergenic risk than control Atlantic salmon."[298] AquaBounty then analyzed whether there were any qualitative changes in one particular major salmon allergen in each of the samples, but used a crude, old-fashioned test known as Western blotting instead of a more commonly used and more accurate technique.[299] The FDA determined that "the technical flaws in this study so limit its interpretation that we [cannot] rely on its results," citing "a lack of appropriate controls, experimental conditions . . . and poor quality of the Western blots."[300] Inexplicably, the FDA then stated, "[t]hat being said, we conclude there are no biologically meaningful differences" between the allergen in the GE salmon and the natural salmon.[301]

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295. Halloran Letter, *supra* note 277.
296. *Id.*
297. Wenonah Hauter, *Something's Fishy in the FDA*, THE HILL'S CONGRESS BLOG (Oct. 5, 2010, 3:31 PM), http://thehill.com/blogs/congress-blog/technology/122671-somethings-fishy-in-the-fda.
298. BRIEFING PACKET, *supra* note 185, at 106.
299. *Id.* at 104–05. .
300. *Id.* at 104.
301. *Id.*

The VMAC members came to a different conclusion, stating that "nothing reliable can be gained from this study," and calling the entire study "a bust."[302] Given the serious risks posed by allergenicity, the VMAC questioned why the study had not been repeated in a more scientifically sound manner.[303]

The VMAC's criticisms were not limited to the allergenicity test. One member questioned AquaBounty's decision to kill a large number of deformed GE salmon, prior to selecting fish for inclusion in studies comparing physical deformities between GE and natural salmon.[304] In these comparison studies, the company also chose to rely on data from 2007, which was both the best year for GE salmon and the worst year for natural salmon with respect to the prevalence of physical deformities.[305] On the other hand, in 2005 the GE salmon exhibited an incredibly high frequency of physical deformities, with fewer than eight percent of GE salmon found to be free of any malformations.[306]

Furthermore, the lone fish expert on the VMAC disagreed with the FDA's conclusion that the GE salmon did not pose a threat to the environment. He suggested that "considering this issue in a comprehensive way, together with other agencies through an environmental impact statement, would be the best way to proceed."[307] At the close of the meeting, the VMAC issued its recommendations to the FDA and suggested the potential "need for an EIS if the company proposes additional facilities for growing the salmon" — something AquaBounty has already unofficially done — due to "concern that cumulative impacts might be missed if each individual facility is looked at only by itself under an environmental assessment."[308]

Michael Hansen, a senior scientist with Consumers Union who testified during the public comment period, found a slew of problems with the "sloppy" science used to justify the salmon's

302. VMAC Transcript, *supra* note 211, at 215.
303. *Id.*
304. *Id.* at 178.
305. Briefing Packet, *supra* note 185, at 36.
306. *Id.*
307. *Id.* at 383.
308. David Senior, Chairman's Report for the September 20, 2010, Veterinary Medicine Advisory Committee Meeting (October 14, 2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230467.pdf [hereinafter Chairman's Report].

safety for human consumption.[309] Hansen pointed to serious flaws in the studies provided by AquaBounty regarding increased levels of growth hormone, the other major potential health risk from the GE salmon.[310] AquaBounty had provided the FDA with two such studies, one peer-reviewed study from 1992 and another study conducted by AquaBounty. Like the allergenicity studies, the 1992 study utilized a very small sample size: five AquAdvantage salmon and five control fish.[311] The study found the level of growth hormone in the GE salmon to be an astonishing ninety-five percent higher than in the natural salmon, but once again, this doubling in growth hormone level was not found to be statistically significant due to the extremely limited sample size.[312] The second study utilized a larger sample size, but employed a test to detect growth hormone that was so insensitive that growth hormone was detected in none of the seventy-three salmon tested, despite the fact that the GE salmon were engineered to produce growth hormone all year round, at twice the rate of natural salmon.[313] The FDA nonetheless concluded that "[n]o biologically relevant differences were detected in the levels of the gene product."[314] Hansen analogized the FDA's reasoning to "the police using a radar gun that cannot detect speeds below 120 mph and concluding that there is no 'relevant difference' in the speed of cars versus bicycles."[315]

Far more troubling were this same study's findings concerning IGF-1, an insulin-like growth hormone factor that has been linked with promoting the incidence of "a number of cancers, especially prostate, breast, colorectal, and lung."[316] Once again, the insensitive test utilized by AquaBounty detected IGF-1 in only seventeen of seventy-three salmon.[317] Despite this small amount of data, the GE salmon with detectable levels of IGF-1 exhibited 40% higher levels of the cancer-promoter than the natural sal-

309. Hansen, *supra* note 72, at 1.
310. *Id.* at 1, 4–6 (calling the studies "woefully inadequate" and exhibiting a "manipulation of data").
311. *Id.* at 4; BRIEFING PACKET, *supra* note 185, at 65–68.
312. Hansen, *supra* note 72, at 5; BRIEFING PACKET, *supra* note 185, at 65–68.
313. Hansen, *supra* note 72, at 5.
314. BRIEFING PACKET, *supra* note 185, at 61.
315. Hansen, *supra* note 72, at 5.
316. *Id.*
317. *Id.* at 6.

mon.[318] Nonetheless, in what can perhaps only be explained by the agency's desire to expedite the salmon's approval, the FDA concluded that the difference between the GE and non-GE salmon did not reach a level of statistical significance.[319] To reach this conclusion, the FDA had to manipulate the data from the seventeen fish with detectable levels of IGF-1, artificially dropping the average IGF-1 value for the GE salmon roughly 10% while artificially raising the average IGF-1 value for the natural salmon 20%; this manipulation was at best "scientifically unsound," and at worst, intentionally deceitful.[320]

Finally, Hansen claims that the data submitted by AquaBounty to the FDA violates NAD regulations.[321] Under the FDCA's NADA provisions, the approval of a particular NAD is granted for a specific production process; if a developer changes the production process, it must submit data to the FDA demonstrating that the changes do not have an effect on the NAD's safety.[322] Critics argue that all of the food safety data comes from GE salmon raised in the Prince Edward Island hatchery, while the GE salmon that people will actually consume will be raised in the grow-out facility in Panama.[323] Since the NAD in this case is the engineered rDNA construct itself, the husbandry and rearing conditions of the salmon constitute the production process.[324] The FDA even admitted that:

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318. *Id.*
319. *Id.*
320. *Id.* Instead of comparing the eleven detectable IGF-1 values for the natural salmon with the six detectable IGF-1 values for the GE salmon, the FDA (without explanation) decided to add a seventh value in computing the average IGF-1 level for the GE salmon: this 7th value represented one of the GE salmon below the detectable limit, and the FDA simply used that detectable limit as a proxy for the value for this seventh salmon. *Id.* at 5-7. This dropped the average IGF-1 value for the GE salmon roughly 10%. *Id.* To further conflate the data, the agency then determined the average IGF-1 value for the natural salmon by mysteriously only using seven of the eleven possible values that were detected in the natural salmon — the four values that the FDA decided to ignore were the four lowest values, thus raising the IGF-1 value for the natural salmon by over 20%. *Id.* This prompted Hansen to point out "[s]uch a manipulation of data — adding a lower number for the GE salmon, thereby reducing its average level, while deleting four low IGF-1 levels for the non-GE salmon, thereby increasing its average level — is scientifically unsound." *Id.* at 6.
321. *Id.* at 2–3.
322. 21 C.F.R. § 514.8(b) (2011); *see also* Hansen, *supra* note 72, at 3.
323. *See, e.g.*, Hansen, *supra* note 72, at 3.
324. *Id.*

> the culture conditions (e.g., water temperature, pH, alkalinity, etc.) were likely to be significantly different from the facility at [Prince Edward Island] as a result of differences in, among others, water surface, facility design, and environmental factors due to geographic location. . . . [T]he effect of the difference between the [Prince Edward Island] and Panama facilities, especially temperature, on the resulting AquAdvantage phenotype is unknown.[325]

Since the husbandry and rearing conditions, and thus the production processes, differ between the facilities in Canada and Panama, the FDA should require AquaBounty to submit data proving that the GE salmon grown in Panama will be safe for human consumption. However, the agency has not yet indicated that it will require this information, nor has it acknowledged this apparent violation of NAD regulations.

C. THE VMAC'S CONCLUSION

Despite the VMAC's stacked membership and the fact that AquaBounty had been submitting data to the FDA for more than ten years, the VMAC nonetheless concluded that the FDA should pursue a more rigorous analysis of the GE salmon's possible health effects and environmental risks before granting approval.[326] One VMAC member characterized the entire body of data as "preliminary work that would need to be validated and confirmed in other studies,"[327] while another noted "[t]here are questions that have not been answered by the data."[328]

AquAdvantage salmon will most likely become the first genetically engineered animal to enter the U.S. food supply, as the FDA has strongly suggested that it will approve the product in the very near future. One VMAC member opined: "All day the thing that has run through my mind about every two minutes is this is probably one of the most incredibly important precedents I have ever been involved in."[329] Another member emphasized that

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325. BRIEFING PACKET, *supra* note 185, at 23.
326. Chairman's Report, *supra* note 308; *see also* Voosen, *supra* note 23.
327. VMAC Transcript, *supra* note 211, at 341.
328. *Id.* at 354.
329. *Id.* at 342.

"it is extremely important how this precedent gets set. And it is not an economic issue. Well, it may be, but it cannot be. Economics is the shovel with which we dig the grave to bury any piece of science."[330] The FDA should set the bar high for solid, reliable science, signaling to companies developing GE animals that they must completely prove their product's safety if they wish to market their product to American consumers. Instead, the "FDA appears to have set its bar an inch from the ground . . . . No self-respecting scientist could conclude that these data demonstrate that AquAdvantage salmon are safe to eat."[331]

V. HOW TO FIX A BROKEN SYSTEM

The previous Part demonstrated that the current regulatory framework for GE animals is broken. To ensure that dangerous products do not find their way into the American food supply, and to maintain consumer confidence in GE animals, changes must be made to the regulatory system. This Part explores several proposals for change and argues that, for the first time, change is politically feasible.

A. CONGRESS SHOULD AMEND THE FDCA BY PASSING THE GENETICALLY ENGINEERED FOODS ACT

Senator Mark Begich, along with the ten senators who signed on to his letter demanding that the FDA immediately halt approval of AquAdvantage salmon,[332] wrote that "[o]ne of the most serious concerns regarding AquaBounty's application is the FDA has no adequate process to review a GE animal intended as a human food product."[333] The senators criticized the FDA's decision to consider the salmon through the NADA process as inappropriate and concluded that "[c]reation of a new genetically engineered species should not be treated as an animal drug issue but undergo formal evaluation by [the] FDA's Center for Food

330. *Id.* at 364.
331. Jeffrey Smith, *GE Salmon? Are You Out of Your Minds?!*, HUFFINGTON POST (Sept. 28, 2010, 4:34 PM), http://www.huffingtonpost.com/jeffrey-smith/ge-salmon-are-you-out-of_b_742413.html.
332. *See* Begich Letter, *supra* note 28.
333. *Id.*

Safety and Applied Nutrition to review the product's potential health effects on humans."[334]

Congress should amend the FDCA to fundamentally alter the way in which the government regulates biotechnology. Evaluating novel and potentially dangerous food products as though they were veterinary drugs is inappropriate. Stripping the CVM of its jurisdiction and giving authority instead to the FDA's Center for Food Safety and Applied Nutrition (CFSAN) would certainly be a logical improvement. Critics have also suggested that the FDCA be amended to divide regulatory authority among the appropriate federal agencies, based on each agency's expertise and general statutory mandate — another reasonable suggestion in light of the current haphazard system.[335] Plus, unlike the government's regulatory approach to GE crops,[336] the government has not yet become invested in the regulatory approach to GE animals, suggesting the feasibility of completely overhauling the fledgling system.

Such sweeping changes are nonetheless political impossibilities. When the FDA published Guidance for Industry 187 in 2009, outlining the FDA's decision to regulate GE animals through the NAD approval process, the biotechnology industry was thrilled.[337] The industry had spent roughly $70 million lobbying Congress the previous year, and roughly half a billion dollars on lobbying since 1999.[338] Biotech political action committees (PACs) had contributed more than $22 million to congressional candidates since 1999, with PAC donations more than doubling between the 2000 and 2008 election cycles.[339] Thus, when the FDA published its guidance on January 15, 2009, five days before the inauguration of President Obama and the resignation of then-FDA Commissioner Andrew Von Eschenbach, the Consumers Union stated in a news release: "This one-minute-to-midnight

334. *Id.*
335. Mandel, *supra* note 32, at 2249.
336. *See supra* Part III.B.
337. Stephen Clapp, *FDA Issues Final Guidance to Industry on Transgenic Animals*, FOOD CHEM. NEWS, Jan. 19, 2009, at 1.
338. FOOD & WATER WATCH, FOOD AND AGRICULTURE BIOTECHNOLOGY INDUSTRY SPENDS MORE THAN HALF A BILLION DOLLARS TO INFLUENCE CONGRESS 1 (2010) [hereinafter Biotech Lobbying], *available at* http://documents.foodandwaterwatch.org/BiotechLobbying-web.pdf.
339. *Id.* at 2–3.

regulation is a final favor to industry delivered as the current FDA Administrator goes out the door."[340] The biotechnology industry is simply too entrenched to allow for the kind of sweeping changes demanded by Senator Begich and his colleagues.[341]

Hope, however, may not be lost. The Genetically Engineered Foods Act,[342] introduced by Senator Richard Durbin in 2002, would do a great deal to alleviate the flaws in the current regulatory approach, and would be far more politically palatable than a complete overhaul to the system. The Act empowers the FDA to deny a NADA based solely on environmental risks,[343] and requires NAD applicants to submit a plan to eliminate or mitigate potential effects to the environment following the release of a GE animal.[344] It also authorizes the FDA to recall any animals if problems were to arise after commercialization, a power it currently lacks.[345]

More importantly, the Act directs the FDA to consult with the U.S. Department of Agriculture, the U.S. Fish and Wildlife Service, and any other federal agency with expertise of the animal species that is the subject of a NADA, and requires the FDA to disclose the results of those consultations in the EA.[346] This disclosure requirement would make it far more difficult for the FDA to shirk its legal obligations to consult with the relevant federal agencies, and would ensure that agencies with necessary expertise be consulted as part of the approval process.[347]

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340. Press Release, Consumers Union, FDA Will Not Require Labeling of Meat or Fish from Genetically Engineered Animals, Consumers Union Says Decision Ignores Consumer Right to Choose (Jan. 15, 2009) (internal quotation marks omitted), *available at* http://www.consumersunion.org/pub/2009/01/006531print.html.

341. Moreover, at least 13 former members of Congress currently represent the biotechnology industry as lobbyists, including former U.S. Representative Charles Stenholm (D-Texas), one-time ranking member of the House Agriculture Committee, while the industry itself employs more than 300 former congressional and White House staff members. Biotech Lobbying, *supra* note 338.

342. Genetically Engineered Foods Act, S. 3095, 107th Cong. (2002), *available at* http://www.gpo.gov/fdsys/pkg/BILLS-107s3095is/pdf/BILLS-107s3095is.pdf.

343. *Id.* § 512(d)(1). As noted above, while NEPA allows the FDA to refuse approval of a NAD based on environmental risks, it does not allow the FDA to refuse approval if the environmental risks are purely environmental. *See supra* notes 226–232 and accompanying text.

344. S. 3095, § 512(b).

345. *Id.* § 421(b)(2)(C).

346. *Id.* § 512(e)(2).

347. *See supra* Part IV.B.1.a.

Perhaps most significantly, the bill also makes the entire approval process much more transparent. One of the most glaring deficiencies of the current regulatory scheme is the shroud of secrecy surrounding the approval process and the lack of opportunity for public participation.[348] The Act alleviates this by eliminating certain confidentiality requirements and requiring that the FDA provide public notice when a NADA is filed.[349] It also requires that the FDA provide the public with an opportunity to submit comments on new applications — explicitly mandating that such a comment period be at least 45 days long.[350] Furthermore, it requires the FDA to make applications and all supporting materials available to the public, while still providing for trade secret protection;[351] this, significantly, allows a NADA, as well as the FDA's analysis of a NADA, to be reviewed by independent experts before the FDA can grant approval.

B. THE POLITICAL CLIMATE IS RIPE FOR REFORM OF THE FEDERAL REGULATORY SCHEME FOR BIOTECHNOLOGY

There has never been a better political climate in which to pass this much-needed legislation. The Reagan Administration that devised the Coordinated Framework[352] was reluctant to impose regulatory restrictions on the young, economically promising biotechnology industry; an aversion to government regulation and support for the free market logically led the administration to choose to regulate the new industry under existing laws so as not to require detailed risk assessments for new biotechnology products.[353] These same values guided the Bush White House in the 1990s, with the President's Council of Advisors on Science and Technology recommending in 1992 that the federal government's biotech policy "foster[ ] a vigorous American biotechnology industry."[354] After the FDA published its Statement of Policy: Foods Derived From New Plant Varieties[355] that same year, codi-

348. *See supra* Part IV.B.2.
349. S. 3095, § 421(d)(2); § 512(c)(1)(A).
350. *Id.* § 512(c)(1)(C).
351. *Id.* § 512(c)(1)(B).
352. *See supra* notes 120–121 and accompanying text.
353. *See* Peck, *supra* note 154, at 266.
354. *Id.*
355. *See supra* note 142 and accompanying text.

fying the principles expounded in the Coordinated Framework by announcing that GE foods would be GRAS and not subject to FDA review, "Vice President Dan Quayle ensured representatives of the biotechnology industry that the new policy was designed to provide 'regulatory relief' for the fledgling industry so that it would remain a world leader."[356] Similar values influenced the second Bush Administration's decision to strike down a 2000 FDA regulation proposed by the Clinton Administration that implicitly rejected the FDA's increasingly controversial presumption of safety for GE crops[357] and would have required GE food developers to submit safety assessments for new GE foods prior to commercialization.[358]

Conversely, the Genetically Engineered Foods Act would be a good fit in President Obama's legislative agenda, and would find traction in Congress. In December 2010, despite a year of intense partisan strife and legislative gridlock, Congress, with bipartisan support, passed legislation that implemented significant reforms of the FDA.[359] The Act's purpose was to overhaul the FDA's mission statement, shifting the agency's regulatory approach from reaction-based to prevention-based, though it does not signifi-

356. Thomas McGarity, Seeds of Distrust: Federal Regulation of Genetically Modified Foods, 35 U. MICH. J.L. REFORM 403, 431–32 (2002).

357. This proposed regulation was prompted by a petition, signed in 2000 by over fifty advocacy organizations, urging the FDA to rescind the 1992 policy statement and subject GE foods to review under the food additive petition process. Center for Food Safety et al., Petition Seeking the Establishment of Mandatory Pre-Market Safety Testing, Pre-Market Envtl. Review & Labeling for All Genetically Engineered Foods (2000), *available at* http://www.centerforfoodsafety.org/pubs/PetitionGEFoodRegs3.2000.pdf. The petition, meanwhile, was prompted by new data detailing the risks of GE food, as well as by the court-ordered discovery of internal FDA documents criticizing the 1992 policy statement. *Id*. One FDA scientist's comments on the 1992 policy statement began,

> What has happened to the scientific elements of this document? Without a sound scientific base to rest on, this becomes a broad, general, 'What do I have to do to avoid trouble'-type document. . . . A scientific document is needed, because there is very little (even when things are called scientific) scientific information supplied. If the FDA wants to have a document based upon scientific principles these principles must be included, otherwise it will look like and probably be just a political document.

Memorandum from Dr. Louis J. Pribyl on Biotechnology Draft Document (Mar. 6, 1992), *available at* http://www.biointegrity.org/FDAdocs/04/04.pdf.

358. *See* Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons from the Starlink Corn Fiasco*, 27 WM. & MARY ENVTL. L. & POL'Y REV. 593, 611 (2003) ("Despite industry support for these regulations, one of the first acts of the incoming Bush administration was to suspend and withdraw these rules for further consideration.").

359. William Neuman, *House Passes Overhaul of Food Laws*, N.Y. TIMES, Dec. 21, 2010, at B1, *available at* http://www.nytimes.com/2010/12/22/business/22food.html.

cantly affect the FDA's approach to biotechnology regulation.[360] While a major accomplishment in and of itself, the Act's passage reflects the Obama Administration's commitment to improving food safety,[361] and reflects a legislature increasingly committed to doing the same.

The Act is not a lone instance of the Obama Administration's commitment to food safety. His administration has already: revived efforts to re-evaluate food serving sizes to help fight obesity;[362] notched a significant victory over many of the country's largest food manufacturers by pressuring them to abandon the "Smart Choices" plan, which gave prominent nutritional seals of approvals to items such as Froot Loops and mayonnaise on those products' labels;[363] proposed a ban on sub-therapeutic antibiotic use in farmed animals;[364] and took the first steps toward creating a system of mandatory regulations for the handling of produce.[365]

Moreover, as the Congressional letters demanding that the FDA halt approval of GE salmon make clear, many Congresspersons on both sides of the aisle share similar concerns with the White House. Senator Olympia Snowe, the ranking member of the Senate Commerce Committee's Subcommittee on Oceans, Atmosphere, Fisheries and Coast Guard, has also urged the FDA to halt its approval of GE salmon.[366] Representative Darrell Issa, the Chairman of the House Committee on Oversight and Gov-

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360. *Id.* Nothing in the legislative history of the Act indicates that biotechnology regulation was ever a considered component of the Act. The Act's major impetus was the recent outbreaks of food-borne illnesses, though there could be any number of reasons for the omission of biotechnology regulation from the legislative history. *Id.*

361. *See infra* notes 362–365 and accompanying text.

362. William Neuman, One Bowl = 2 Servings. FDA May Fix That., N.Y. TIMES, Feb. 5, 2010, at A1, *available at* http://www.nytimes.com/2010/02/06/business/06portion.html.

363. William Neuman, Food Label Program to Suspend Operations, N.Y. TIMES, Oct. 24, 2009, at B1, *available at* http://www.nytimes.com/2009/10/24/business/24food.html.

364. *See* JUDICIOUS USE OF MEDICALLY IMPORTANT ANTIMICROBIAL DRUGS IN FOOD-PRODUCING ANIMALS, *supra* note 86, at 17.

365. William Neuman, 2 Agencies Take Steps to Improve Food Safety, N.Y. TIMES, Aug. 1, 2009, at B3, *available at* http://www.nytimes.com/2009/08/01/health/policy/01food.html. President Obama's commitment can also be seen through his creation of a new Food Safety Working Group, to advise him on how to upgrade the U.S. food safety system. Gardiner Harris, President Promises to Bolster Food Safety, N.Y. TIMES, March 15, 2009, at A24, *available at* http://www.nytimes.com/2009/03/15/us/politics/15address.html#.

366. *Snowe Urges Halt of Review Process for Genetically Engineered Salmon*, THE FREE PRESS (Oct. 28, 2010, 12:14 PM), http://freepressonline.com/main.asp?SectionID=52&SubSectionID=78&ArticleID=9690.

ernment Reform, has promised to make food safety one of his committee's top priorities,[367] noting that his committee is "uniquely positioned to look at the coordination and cooperation amongst departments and agencies" in relation to food safety.[368] Finally, the Genetically Engineered Foods Act was originally introduced by Senate Majority Whip Dick Durbin, one of the most powerful members of the Senate.[369]

VI. CONCLUSION

According to consistent polling, the American public overwhelmingly feels that the FDA should not introduce GE salmon to the marketplace,[370] and most Americans have said they would not eat any seafood that had been genetically engineered.[371] Thus, the possibility remains that Americans will simply reject GE salmon despite FDA approval, much like consumer backlash forced two of the largest grocery retailers in the nation — Wal-Mart and Kroger — to pull milk produced with a controversial artificial growth hormone (rBGH) from their shelves in 2007, twelve years after FDA approval.[372]

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367. Helena Bottemiller, *Issa Says Food Safety Oversight Is a Priority*, FOOD SAFETY NEWS (Nov. 4, 2010), http://www.foodsafetynews.com/2010/11/issa-food-safety-an-oversight-priority-for-new-congress/.

368. Helena Bottemiller*, Issa Calls for Hearing on Food Safety Bureaucracy*, FOOD SAFETY NEWS (Sep. 10, 2010), http://www.foodsafetynews.com/2010/09/rep-issa-calls-for-hearing-on-food-safety-bureacracy/.

369. *See supra* note 342 and accompanying text.

370. *Polls on Genetically Engineered Fish*, CTR. FOR FOOD SAFETY, http://ge-fish.org/policy-comments/polls-on-genetically-engineered-fish/ (last visited Sept. 11, 2011) [hereinafter Food Safety Polls]; Memorandum from Celinda Lake et al., Lake Research Partners, on Attitudes Toward the FDA's Plan on Genetically Engineered Fish (Sept. 20, 2010) [hereinafter Lake Research Survey], *available at* http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf.

371. Food Safety Polls, *supra* note 370. The Lake Research national survey found that 78% of American adults believe the FDA should not approve GE salmon, compared to 16% who favored approval, with 64% of adults feeling "strongly" it should not be approved. Lake Research Survey, *supra* note 370. These figures were cited by Rep. Rosa DeLauro when introducing legislation requiring the labeling of GE fish and food from cloned animals. Helena Bottemiller*, DeLauro Bill Would Require Labeling on GE Fish*, FOOD SAFETY NEWS (Sept. 30, 2010), http://www.foodsafetynews.com/2010/09/delauro-introduces-to-bill-to-require-labeling-of-gm-fish/; *see also* Consumers Right to Know Food Labeling Act, H.R. 6325, 111th Cong. (2d Sess. 2010).

372. A. Bryan Endres, *United States Food Law Update: Consumer Protections and Access to Information: RBST, BPA, the ADA, and Color Additives*, 4 J. FOOD L. & POL'Y 263, 270–71 (2008); Press Release, Wal-Mart, Wal-Mart Offers Private Label Milk Produced without Artificial Growth Hormone, (Mar. 21, 2008), *available at*

Moreover, there are several other indirect stopgap measures that may help protect food safety and the environment if the FDA does approve GE salmon. FDA approval does not mean that states would have to allow farming of the GE fish within their jurisdictions, since states have the power to refuse to issue aquaculture permits.[373] Many states have already taken the extra step of banning GE fish to varying degrees.[374] Even private citizens may be able to make an impact: the Supreme Court's 2010 decision in *Monsanto v. Geertson Seed Farms* suggests that if the FDA refuses to prepare an EIS for a risky GE product, citizens may sue the FDA for violating NEPA.[375] A federal court could then issue an injunction to keep the product off the market until the agency fully analyzed potential environmental risks in an EIS.[376] One environmental group has already stated that it will consider following this route if the FDA goes ahead with the approval process.[377]

While these options provide some hope for those concerned with the consequences of the commercialization of GE salmon, they are still merely ad hoc stopgap measures. The only way to ensure that the risks posed by GE salmon, and by any future GE animal, are fully analyzed before such products are approved is for Congress to amend the FDCA and change the way the FDA

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http://walmartstores.com/ pressroom/news/8147.aspx. Many other developed nations have found that milk produced with rBGH is not safe. *See, e.g.*, Council Decision 1999/879 (L 331/71) (EC) (banning rBGH in all European Union nations); Christina Cusimano, Comment, *RBST, It Does a Body Good?: RBST Labeling and the Federal Denial of Consumers' Right to Know*, 48 SANTA CLARA L. REV. 1095, 1104 (2008) (noting that New Zealand, Europe, and Japan have banned rBGH). Notably, the hormone has been linked with increasing IGF-1, the insulin-like growth hormone that studies have shown increase risk of several types of cancer. Samuel Epstein, *An FDA Ban on Genetically-Engineered Milk is 20 Years Overdue*, HUFFINGTON POST (Jan 18, 2010, 2:53 P.M.), http://www.huffingtonpost.com/samuel-s-epstein/an-fda-ban-on-genetically_b_424913.html; *see also supra* note 316 and accompanying text (concerning IGF-1 found in AquAdvantage salmon).

373. Philipp Aerni, *Risk, Regulation and Innovation: The Case of Aquaculture and Transgenic Fish*, 66 AQUATIC SCI. 327, 336 (2004).

374. *See, e.g.*, MD. CODE ANN., NAT. RES. § 4-11A-02 (West 2011); MICH. COMP. LAWS ANN. § 286.874(9) (West 2011); OR. ADMIN. R. 635-007-0595 (2005); WASH. ADMIN. CODE § 220-76-100 (2011).

375. Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743, 2753–54 (2010).

376. *Id.*

377. *Genetically Modified Fish Lawsuit Threatened*, CBC NEWS (Dec. 20, 2010, 6:03 AM), http://www.cbc.ca/news/technology/story/2010/12/20/pei-trout-unlimited-aquabounty-584.html.

regulates these products. Given the great risks implicated by biotechnology, the FDA's pending approval of GE salmon, and the nascent stage of the GE animal industry, it is imperative that Congress act quickly. It should therefore consider the Genetically Engineered Foods Act as soon as possible, while the political climate is ripe, and before the current regulatory system leads to irreparable harm to our food supply and the environment.