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SWIMMING UPSTREAM: THE NEED TO RESOLVE INCONSISTENCY IN THE FDA'S FISHY REGULATORY SCHEME

*Kelsie Kelly**

The citizens of the United States rely on the federal government to maintain the safety of their food through effective regulation. As the technology used to develop food has advanced, the outermost limits of the current regulatory framework are being tested. The result has been a circuitous and ineffective attempt to regulate transgenic organisms, intended for human consumption, using multiple agencies and a patchwork of laws. The ability to incorporate DNA from nearly any organism into the genome of another provides immense potential for innovative new food products, but may also allow for unintended health and environmental consequences. Proper regulation of genetically engineered organisms is necessary in order to safely and effectively utilize biotechnology to benefit the American people.

INTRODUCTION

On November 19th, 2015, the Food and Drug Administration ("FDA")[1] approved the first transgenic[2] animal for human

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[1] U.S. Food and Drug Admin., *FDA Mission*, U.S. DEP'T OF HEALTH AND HUMAN SERV., https://www.fda.gov/aboutfda/whatwedo/default.htm (last visited November 27, 2018).

consumption.[3] Through genetic engineering,[4]AquAdvantage was able to produce an Atlantic salmon that grows at twice the speed of its non-transgenic peers.[5] The AquAdvantage Salmon can be produced more quickly and cheaply, and therefore provides a more sustainable method of production than the alternative aquaculture techniques currently available.[6] Because the FDA's regulations of genetically modified organisms are based on a regulatory framework developed in the 1980's, the agency's policies have

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[2] NICOLE EDGAR & ETTENNE SIBILLE, *GENETICALLY MODIFIED ANIMALS*, ENCYCLOPEDIA OF NEUROPSYCHOPHARMACOLOGY 554 (Ian Stolerman ed., 2015); Sheryl Lawrence, *What Would You Do with a Fluorescent Green Pig: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 ECOLOGY L.Q. 201, 211 (2007) ("Transgenic' refers to organisms, and their resulting products, which have been engineered to contain the genetic material from more than one variety of life form.").

[3] Heidi Ledford, *Salmon is First Transgenic Animal to Win U.S. Approval for Food*, NATURE (Nov. 19, 2015), https://www.nature.com/news/salmon-is-first-transgenic-animal-to-win-us-approval-for-food-1.18838.

[4] *See* NAT'L RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS, 1 (2004) ("Genetic engineering, the targeted manipulation of genetic material, and nontargeted, nontransgenic methods—including chemical mutagenesis and breeding—are components of the entire range of genetic modification methods used to alter the genetic composition of plants, animals, and microorganisms."); T.J. Pandian, *Guidelines for Research and Utilization of Genetically Modified Fish*, 81 CURRENT SCIENCE 1172, 1172 (2001) ("Genetic engineering is defined as the technique by which heritable material, which does not usually and/or naturally occur in the organism or the cell concerned, but is generated outside the organism or cell, is inserted into the said cell or organism and results in its genetic modification. However, a broader version of GMO includes progenies of hybridization, ploidy induction, and transgenesis.").

[5] Ledford, *supra* note 3 ("The fish grow to full size in 18 months rather than 3 years."); Brady Dennis, *The FDA Just Approved the Nation's First Genetically Engineered Animal: A Salmon that Grows Twice as Fast*, WASH. POST (Nov. 19, 2015), https://www.washingtonpost.com/news/to-your-health/wp/2015/11/19/the-fda-just-approved-the-nations-first-genetically-engineered-animal-a-salmon-that-grows-twice-as-fast/?utm_term=.8763d79e3712.

[6] Andrew Pollack, *Genetically Engineered Salmon Approved for Consumption*, N.Y. TIMES, Nov. 19, 2015, at A1 (discussing the use of AquAdvantage Salmon as a sustainable alternative to the current practice of using wild caught salmon as a food source).

failed to keep pace with the rapid advancement of science with respect to food and agriculture.[7] AquaAdvantage's development of the transgenic salmon, forced the FDA to apply its current regulatory system for transgenic organisms, which, had previously only been used for biologics and pharmaceutical development, to a novel product intended for human consumption.[8] This resulted in the classification of the AquAdvantage Salmon as a new animal drug.[9]

As a new animal drug, the application for approval by the AquAdvantage Salmon was reviewed by the Veterinary Center of Medicine within the Food and Drug Administration.[10] Regulating transgenic organisms as new animal drugs[11] when salmon are neither a drug, nor intended for use in animals is misleading, and

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[7] Lawrence, *supra* note 2, at 201–02; *see also* Michael P. McEvilly, Note, *Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon*, 11 DUKE L. & TECH. REV. 413, 413 (2013).

[8] Lawrence, *supra* note 2, at 220 ("By fitting the products of bioengineering into the FDCA's existing regulatory categories, the FDA applies the general concepts of product approval, adulteration, and misbranding to regulate safety and effectiveness across the spectrum of GM food and drug products. However, GM products are becoming more innovative as genetic engineers combine genes from completely unrelated organisms to create novel life forms. Such combinations create organisms that express chemicals not native to conventional organisms. As GM products become more innovative, categorizing the resulting organisms and their derivative products challenges existing food and drug definitions."); *see generally* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 5 (2011) [hereinafter U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY].

[9] McEvilly, *supra* note 7, at 420; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, *supra* note 8, at 5.

[10] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM FOR BIOTECHNOLOGY PRODUCTS: FINAL VERSION OF THE 2017 UPDATE TO THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY 19 (2017) [hereinafter U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM].

[11] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 201(g)(1)(C) (2018) ("The term 'drug' means . . . [a]rticles (other than food) intended to affect the structure or any function of the body of man or other animals[.]"); U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY, *supra* note 8, at 5; U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10, at 18.

further works to encourage public distrust of the scientific community and genetically engineered organisms.[12] The FDA's approval of the AquAdvantage Salmon represents the junction between scientific innovation and our community's dinner table. If society is to safely and effectively reap the benefits of recent biotechnological[13] advancements, we must begin with the consistent application of a more accurate and comprehensive regulatory framework.[14]

This Note examines the current federal scheme under which genetically engineered animals are regulated and determines its effectiveness in monitoring biotechnological advancements intended for human consumption. Part I of this Note will set forth a brief history of transgenic organisms and their present role in the United States' agricultural practices. It will also provide an explanation of the scientific principles utilized in the creation of transgenic organisms. Part II will analyze the current U.S. federal regulatory framework used for the regulation of transgenic organisms in light of the rapidly developing scientific field, and

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[12] *See* Anne Miller, *Time for the Government to Get Mooo-ving: Facing up to the RBST Labeling Problem*, 18 HAMLINE L. REV. 503, 511–12 (1995) (discussing the potential for statements such as "RBst-free" to mislead consumers into believing that there is a compositional difference between milk from treated and untreated cows or that "milk from untreated cows is safer or of higher quality than milk from treated cows").

[13] Lawrence, *supra* note 2, at 211 ("[T]he term 'biotechnology' is used to refer to the field of genetic manipulation, as it is commonly used in public discourse, although discrete genetic modification is in fact just one segment of the greater field of biotechnology.").

[14] *See* Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2171–72 (2004) ("Effective and efficient regulation is the mediator that will determine whether society reaps the spectacular advantages of biotechnology or succumbs to its potential dangers. Without proper regulation, society will face unnecessary risks, the benefits of biotechnology will be slowed severely and made more expensive, and the public will lack confidence in biotechnology products."); *see also* Rebecca Bratspies, Note, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 MINN. J.L. SCI. & TECH. 457, 460 (2004) ("Getting regulatory policy right is critical. Only appropriate and consistent regulatory structures will ensure that this new technology is explored in a fashion that protects human health and the environment, while still encouraging innovation.").

how these regulations have been applied to genetically engineered animals. Part III will discuss the regulatory paradigm used by Canada for classifying and evaluating genetically modified organisms for human consumption. Finally, Part IV will outline a more accurate and comprehensive set of regulatory guidelines for use in the United States.

I. GENETIC ENGINEERING

A. History of Genetic Engineering in Agriculture

Genetic engineering of animals and plants is a deeply entrenched agricultural practice within society.[15] Traditional methods of genetic modification allowed for the modification of crops to better suit human needs.[16] Over time, farmers have modified live stock to fit their needs through methods such as selective breeding[17] and hybridization.[18] As science has advanced,

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[15] Heath R. Ingram, Note, *Got Bacon?: The Use of A Bioethics Advisory Board in Assessing the Future of Transgenic Animal Technology*, 14 NW. J. TECH. & INTELL. PROP. 393, 396 (2017) ("Humans have been modifying crops and selectively breeding animals since the beginning of humanity."); Lawrence, *supra* note 2, at 209 ("[F]armers, ranchers, and even the creatures themselves have used selective breeding and culling to influence the genes of future generations for centuries.").

[16] *See* NAT'L RESEARCH COUNCIL, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 3 (2004) ("The oldest approach to plant genetic modification is simple selection, where plants exhibiting desired characteristics are selected for continued propagation. Modern technology has improved upon simple selection with the use of molecular analysis to detect plants likely to express desired features. Plants that are selected for desired traits, such as reduced levels of chemicals that produce unpalatable taste, may diminish the ability of plants to survive in the wild because they are also more attractive to pests. Selection for other traits, such as chemicals that increase the resistance of plants to disease, may also be harmful to humans. Another approach, crossing, can occur within a species or between different species.").

[17] Mike Adams, *The Anti-GMO Way: Modern Corn Was Created Through Thousands of Generations of Selective Breeding by Indigenous Mesoamericans*, NATURAL NEWS (Sept. 30, 2012), https://www.naturalnews.com/037381_maize_corn_selective_breeding.html ("Selective breeding occurs when humans facilitate the reproduction of only

so too has our ability to create organisms suited to the specific needs of individual communities.[19] Scientists remain optimistic that these advancements in genetic engineering will translate to the development of "new and improved strains of livestock."[20]

Through the "introduction of 'foreign' deoxyribonucleic acid (DNA)[21] into preimplantation embryos," the genetics of different organisms can be introduced into a plant or animal, resulting in the expression of unique characteristics.[22] There are a variety of techniques used in the production of genetically modified organisms, and the characteristics of the resulting genetically modified organism can appear surprisingly different from those of their non-modified counterparts.[23] However, these changes do not

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those plant or animal varieties that contain the traits most beneficial for themselves.").

[18] A.F. Raybould & A.J. Gray, *Genetically Modified Crops and Hybridization with Wild Relatives: A UK Perspective*, 30 J. OF APPLIED ECOLOGY 199, 199 (1993) ("For centuries the only technique for introducing genetic variation into crops was sexual hybridization. Two parental types, each having traits of interest, would be crossed, and the progeny examined and selected for use or further rounds of hybridization. Often this process was carried out unwittingly in early agriculture, but present-day breeding can entail highly complex crossing designs. Although this approach has been enormously successful in improving crop quality and productivity.").

[19] *See id.* at 199–200 (discussing new techniques utilized by plant breeders in order to circumvent the constraints of traditional breeding methods, which allow for an increased range of genetic variation due to a "virtually limitless" gene pool).

[20] M.B. Wheeler et al., *Transgenic Animals in Biomedicine and Agriculture: Outlook for the Future*, 79 ANIMAL REPRODUCTION SCIENCE 265, 266 (2003).

[21] *DNA*, NATURE, https://www.nature.com/subjects/dna (last visited Dec. 5, 2017) ("DNA (deoxyribonucleic acid) is the nucleic acid polymer that forms the genetic code for a cell or virus. Most DNA molecules consist of two polymers (double-stranded) of four nucleotides that each consist of a nucleobase, the carbohydrate deoxyribose and a phosphate group, where the carbohydrate and phosphate make up the backbone of the polymer.").

[22] A.F. Raybould & A.J. Gray, *supra* note 18, at 200; M.B. Wheeler et al., *supra* note 20, at 265.

[23] M.B. Wheeler et al., *supra* note 20, at 266 ("There are several methodologies that can be used for the production of transgenic animals, including: (1) DNA transfer by retroviruses, (2) microinjection of genes into pronuclei of fertilized ova; (3) injection of embryonic stem (ES) cells and/or

stray too far from those achieved through the meticulous crossbreeding of organisms over many generations.[24] Oftentimes, the goals of genetic engineering simply mirror those of traditional farming practices by improving and solving problems associated with a crop.[25]

The concept of genetically engineered food is nothing new.[26] On May 18, 1994, the Flavr Savr tomato became the first genetically modified food to be approved by the FDA.[27] The Flavr Savr tomato was designed to maintain firm flesh as it ripened on the vine.[28] The increased firmness was intended to prevent bruising as the tomatoes were shipped to market and to abolish the need for artificial ripening treatments.[29] Since the FDA first granted field testing permits for genetically engineered plants in 1986, a multitude of modified agricultural varieties have proliferated the domestic food market.[30]

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embryonic germ (EG) cells, previously exposed to foreign DNA, into the cavity of blastocysts; (4) sperm-mediated exogenous DNA transfer during in vitro fertilization; (5) liposome-mediated DNA transfer into cells and embryos; (6) electroporation of DNA into sperm, ova or embryos; (7) biolistics, and (8) nuclear transfer (NT) with somatic cells, ES or EG cells.").

[24] Statement of Policy: Foods Derived From New Plant Varieties, 57 (104) Fed. Reg. 1, 6 (May 29, 1992) (to be codified FR Doc. 92-12660) ("Recombinant DNA techniques are used to achieve the same types of goals as traditional techniques: The development of new plant varieties with enhanced agronomic and quality characteristics.").

[25] *See* Bratspies, *supra* note 14, at 464.

[26] *See A History of Genetic Engineering*, SCIENCE GROUP (Apr. 23, 2005), http://www.sciencegroup.org.uk/ifgene/history.htm (discussing the long history of genetic engineering).

[27] Ross H. Pifer, *Mandatory Labeling Laws: What Do Recent State Enactments Portend for the Future of GMOs?*, 118 PENN ST. L. REV. 789, 794 (2014); *see* Dept. of Health and Human Serv., *Statement of Policy - Foods Derived From New Plant Varieties*, U.S. FOOD & DRUG ADMIN. (May 29, 1992), https://www.fda.gov/Food/GuidanceRegulation/ GuidanceDocumentsRegulatoryInformation/ Biotechnology/ucm096095.htm.

[28] G. Bruening & J.M. Lyons, *The Case of the FLAVR SAVR Tomato*, CALIFORNIA AGRICULTURE 54(4) 6-7 (2000); Pifer, *supra* note 27, at 794.

[29] Pifer, *supra* note 27, at 794.

[30] David J. Earp, Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1637 (1994).

In 2011, it was estimated that 88% of corn planted in the United States was grown from genetically modified seed varieties.[31] Today, "more than 90 percent of the corn, soybeans, and cotton grown in the U.S. have foreign genes inserted into the DNA to make the crops resistant to herbicides, insects, or both."[32] With the Approval of the AquAdvantage Salmon, the FDA has set the stage for similar innovation with respect to farmed livestock.

B. The Creation of the AquAdvantage Salmon

AquaBounty Technologies, a Massachusetts based company,[33] gained FDA approval to commercialize genetically engineered salmon (the AquaAdvantage Salmon) after completing a nearly twenty year review process.[34] The AquAdvantage Salmon is created through the insertion of a recombinant DNA complex[35] containing a promoter sequence from the ocean pout (*Zoarces americanus)* and a growth hormone gene from the Chinook salmon (*Oncorhynchus tshawytscha*) into an Atlantic salmon (*Salmo salar).*[36] Atlantic salmon do not ordinarily produce growth

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[31] McEvilly, *supra* note 7, at 416.

[32] Lynn L. Bergeson & Carla N. Hutton, *Biotechnology: White House Announces Effort to Modernize the Regulatory System for Biotechnology Products*, PESTICIDE LAW AND POLICY BLOG (July 6, 2015), http://pesticideblog.lawbc.com/entry/biotechnology-white-house-announces-effort-to-modernize-the-regulatory-syst.

[33] Madelyn Kearns, *AquaBounty Sells First Batch of Genetically Engineered Salmon*, SEAFOODSOURCE (Aug. 7, 2017), https://www.seafoodsource.com/news/supply-trade/aquabounty-sells-first-batch-of-genetically-engineered-salmon.

[34] Tess Doezema, *Skepticism About Biotechnology Isn't Anti-Science*, SLATE (Apr. 26, 2017), http://www.slate.com/articles/technology/future_tense/2017/04/the_aquadvantage_salmon_debate_and_skepticism_about_biotechnology.html.

[35] Yolanda Smith, *What is Recombinant DNA?*, NEWS MEDICAL LIFE SCI. (May 4, 2015), https://www.news-medical.net/life-sciences/What-is-Recombinant-DNA.aspx ("Recombinant DNA, or rDNA, is the term used to describe the combination of two DNA strands that are constructed artificially. Genetic scientists can do this to create unique DNA strand for different purposes, using several types of techniques.").

[36] Lars Noah, Colloquium, *Whatever Happened to the "Frankenfish"?: The FDA's Foot-dragging on Transgenic Salmon*, 65 ME. L. REV. 605, 608

hormone during the winter, and therefore only grow during the warmer months.[37] The added genes from the Chinook salmon and ocean pout work in concert to allow the Atlantic salmon to grow year-round, thereby allowing it to achieve its maximum size twice as quickly as its non-transgenic peers.[38]

In addition to the rapid growth of its salmon, AquAdvantage boasts the efficiency and sustainability of its aquaculture method stating that "[o]ur AquAdvantage Salmon grows to market size using 25 percent less feed than traditional Atlantic salmon on the market today."[39] AquAdvantage further indicates that production of the AquAdvantage Salmon may result in a carbon footprint that is "23 to 25 times less than for traditional farmed salmon."[40] Furthermore, by raising the AquAdvantage Salmon in tanks rather than farming them in ocean based aquaculture facilities, they do not encounter the parasites or diseases which regularly afflict farmed salmon.[41] Due to the genetically modified salmon's competitive advantage, steps have been taken to mitigate the

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(2013); Emily Waltz, *First Genetically Engineered Salmon Sold in Canada: U.S. Firm AquaBounty Technologies Says That Its Transgenic Fish Has Hit the Market After a 25-Year Wait*, NATURE NEWS (Aug. 4, 2017), https://www.nature.com/news/first-genetically-engineered-salmon-sold-in-canada-1.22116 (providing the scientific names of each fish species utilized in the creation of the AquAdvantage Salmon); Ashifea Kassam, *GM Salmon Hits Shelves in Canada - But People May Not Know They're Buying It*, THE GUARDIAN (Aug. 9, 2017), https://www.theguardian.com/world/2017/aug/09/genetically-modified-salmon-sales-canada-aqua-bounty.

[37] Noah, *supra* note 36, at 608; *see also* Michael Homer, Note, *Frankenfish . . . It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. SOC. PROBS. 83, 108 (2011).

[38] Homer, *supra* note 37, at 108.

[39] *Low Impact Fish Farming*, AQUABOUNTY, http://aquabounty.com/sustainable/ (last visited Dec. 2, 2017).

[40] *Id.*

[41] Waltz, *supra* note 36; *See* Patrick Whittle, *Literally Lousy: Parasite Plagues Workld Farmed-Salmon Industry*, SEATTLE TIMES (Sep. 17, 2017) https://www.seattletimes.com/life/food-drink/any-lice-with-that-salmon-parasite-plagues-global-industry/.

ecological impacts and risks.[42] To reduce the likelihood of escape or accidental release and to prevent cross-breeding, the AquAdvantage Salmon are raised in landlocked tanks.[43] Moreover, all of the AquAdvantage Salmon are sterile females.[44] This additional layer of protection ensures that the salmon cannot reproduce naturally within the aquaculture facility, and they are prevented from interbreeding with the wild salmon population in the event of an escape.[45] The implementation of steps to greatly reduce the likelihood that unintended consequences will result from the consumption of genetically engineered fish has played a large role in the FDA's approval of the AquaAdvantage salmon.[46]

C. The Importance of Biotechnological Innovation

The approval of genetically engineered fish as food represents an enormous opportunity for technological, social, and economic development.[47] Salmon have become a valuable commodity within the global market resulting in high demand.[48] However, concern about the sustainability of the salmon market has grown as the United States' salmon fisheries have been in unremitting decline since the early 1900s.[49] Scientists have noted, "in spite of massive

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[42] AQUABOUNTY, *supra* note 39; Anastasia Bodnar*, Risk Assessment and Mitigation of AquAdvantage Salmon*, BIOLOGY FORTIFIED, (Oct. 16, 2010) https://www.biofortified.org/2010/10/salmon/.

[43] David Reid, *Salmon Becomes World's First Genetically-Modified Animal to Enter Food Supply*, CNBC NEWS (Aug. 9, 2017), https://www.cnbc.com/2017/08/09/salmon-becomes-worlds-first-genetically-modified-animal-to-enter-food-supply.html.

[44] *Id.*; William Saletan, *Don't Fear the Frankenfish*, SLATE (Nov. 20, 2015), http://www.slate.com/articles/health_and_science/science/2015/11/genetically_engineered_aquabounty_salmon_safe_fda_decides.html.

[45] Saletan, *supra* note 44.

[46] *Id.*

[47] *See* Waltz, *supra* note 36.

[48] STEFANO B. LONGO ET AL., THE TRAGEDY OF THE COMMODITY OCEANS FISHERIES AND AQUACULTURE 164, 198 (2015).

[49] J. Lichatowich et al., *Depletion and Extinction of Pacific Salmon (Oncorhynchus spp.): A Different Perspective*, 56 ICES J. OF MARINE SCI., 467, 467 (1999) ("Salmon yields in various rivers of the Pacific Northwest states of

funding for programs attempting to restore populations to earlier levels of abundance, there is no evidence of a sustained recovery."[50] Due to overfishing and development,[51] salmon have become extinct in over 40% of their original range.[52] Currently, over 95% of the Atlantic salmon consumed in the U.S. is imported.[53] Since commercial fishing for wild Atlantic salmon is prohibited, and some populations of Atlantic salmon are considered endangered,[54] the development of environmentally friendly and economically feasible aquaculture methods has grown increasingly important.[55] The salmon industry has led the way in aquaculture development by establishing intensive fish farming methods;[56] however, these traditional aquaculture practices come at significant financial and environmental cost.[57] As traditional

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Oregon, Washington, and California peaked between 1882 and 1915. Since then the salmon and their fisheries have been in continuous decline.") (citation omitted).

[50] Lichatowich et al., *supra* note 49, at 467.

[51] NAT'L RESEARCH COUNCIL, UPSTREAM SALMON AND SOCIETY IN THE PACIFIC NORTHWEST 167–69 (1996).

[52] *See* Lichatowich et al., *supra* note 49, at 467.

[53] Steve Connor, *Genetically Modified Salmon Becomes the First to be Approved for Human Consumption – But It Won't Have to Be Labelled as GM*, INDEPENDENT NEWS (Nov. 19, 2015), www.independent.co.uk/news/science/genetically-modified-salmon-becomes-first-to-be-approved-for-human-consumption-but-it-wont-have-to-a6741031.html.

[54] *Farmed Atlantic Salmon*, NOAA FISHERIES, https://www.fisheries.noaa.gov/species/farmed-atlantic-salmon (last visited Dec. 2, 2017).

[55] *See* Jean-Michel Cousteau, *The Future of Sustainable Fish Farming*, JEAN-MICHEAL COUSTEAU'S OCEAN FUTURES SOCIETY (Mar. 17, 2014), http://www.oceanfutures.org/news/blog/future-sustainable-fish-farming; Kassam, *supra* note 36.

[56] LONGO ET AL., *supra* note 48, at 230.

[57] RONALD ROSS, GENETICALLY MODIFIED ORGANISMS IN FOOD 162 (Patricia Oshorn eds., 2016) ("A main criticism of conventional salmon aquaculture is that it results in a net loss of fish from the World Ocean. This is because rearing carnivorous marine species such as salmon requires aquafeeds that include the appropriate amounts of protein and lipids in order for the species to develop and grow. The source of these proteins and lipids has often been other fish. The process of feeding captive carnivorous salmon pelleted food, significant portions of which are made from other fish, continues to exacerbate

aquaculture techniques have failed to slow the progressive degradation of marine and aquatic habitats due to pollution, overfishing, and development, scientists have turned to biotechnological innovation for solutions.[58] The heightened need for new technologies has resulted in the rapid growth of the biotechnological industry.[59] It is predicted that jobs relating to the field of biotechnology will experience employment growth of approximately sixty-two percent through 2020.[60] Furthermore, policy makers in favor of the genetically engineered fish argue that these salmon are beneficial to the economy "because they can be grown near metropolitan areas rather than being flown in from overseas, bringing salmon-farming jobs back to the United States[.]"[61]

Accordingly, the socioeconomic and environmental benefits of genetic engineering go beyond salmon.[62] Researchers around the world are using a variety of fish species to develop new kinds of genetically engineered fish.[63] In China, for example, scientists are aiming to develop a line of genetically modified carp containing a growth hormone gene from a species of salmon.[64] The worldwide

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the decline of marine fisheries overall. AquaBounty, however, presents their captive production of genetically modified salmon as a solution to the inefficient ratio of fish-in to fish-out, typically associated with existing aquaculture. With faster growing transgenic salmon, the assumption is that less fishmeal and fish oil will be required over the species' life span, therefore reducing the amount of marine organisms included in feeds and the ecological footprint in general[.]").

[58] *See id.*

[59] *See* Terry Robinson, *What Degree Do I Need to Be a Genetic Engineer?*, DEGREE QUERY (Mar. 23, 2015), https://www.degreequery.com/what-degree-do-i-need-to-be-a-genetic-engineer/.

[60] *Id.*

[61] Waltz, *supra* note 36.

[62] PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, FUTURE FISH: ISSUES IN SCIENCE AND REGULATION OF TRANSGENIC FISH 5, 5 (2002), https://www.pewtrusts.org/-/media/legacy/uploadedfiles/wwwpewtrustsorg/reports/protecting_ocean_life/hhsbiotech011403pdf.pdf (discussing how researchers have genetically modified at least fourteen additional species of fish).

[63] *Id.* (discussing various research initiatives in China, Cuba, and Canada to genetically modify species of carp, trout, salmon, catfish, loach, tilapia, and pike).

[64] *Id.*

trend of biotechnological innovation is vital due to the ongoing crisis faced by global fisheries.[65] Fisheries of economically important species around the world are currently under serious threat as fish stocks steadily decline.[66] The unsustainable harvest of fish has resulted in the collapse of many fish stocks and the decline of biodiversity.[67] Aquabounty's request for FDA approval for their genetically engineered AquAdvantage Salmon represents only the beginning, as other species of genetically engineered fish are developed with the needs of other fisheries in mind.[68] Furthermore, other species of animals are also being genetically engineered in order to reduce costs and protect the environment on land.[69] The EnviroPig, for example, is a genetically engineered pig designed to digest phosphates with increased efficiency.[70] By reducing the phosphate levels excreted by the pigs, this lessens the detrimental impact of runoff from pig farms on downstream ecosystems.[71] The FDA's approval of the AquAdvantage Salmon represents the first step in utilizing biotechnological innovation to solve the complex issues faced by modern society. Though a transgenic fish may not seem significant, effective regulation of genetically engineered organisms is essential if society is to reap the rewards of technological innovation. This must be balanced with maintaining trust in the FDA's review of food products and avoiding potentially devastating environmental disasters.

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[65] *See* J. David Allan et al., *Overfishing of Inland Waters*, 55 BIOSCIENCE 1041, 1041 (2005).

[66] *Id.* ("Although the global production of fish and fishery products continues to grow, the harvest from capture fisheries has stagnated over the last decade. Today numerous fish stocks and species have declined since their historical peaks, and some have even collapsed, leading to urgent calls for more stringent management and the establishment of protected areas.").

[67] *Id.*

[68] *See* Alison L. Van Eenennaam, *Genetic Engineering and Fish*, U.C. DIVISION. OF AGRIC. & NAT. RESOURCES, 2005 at 1.

[69] Anne Minard, *Gene-Altered "Enviropig" to Reduce Dead Zones?*, NAT'L GEOGRAPHIC NEWS (Mar. 30, 2010), https://news.nationalgeographic.com/news/2010/03/100330-bacon-pigs-enviropig-dead-zones/.

[70] *Id.*

[71] *Id.*

II. THE ROLES OF THE FEDERAL REGULATORY BODIES

The Food and Drug Administration (FDA)[72] is a federal regulatory agency within the U.S. Department of Health and Human Services,[73] which has the sole responsibility of regulating genetically engineered organisms.[74] The FDA is "responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation."[75] The FDA,

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[72] *See* U.S. Food and Drug Admin., *About FDA*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (Apr. 4, 2017), https://www.fda.gov/AboutFDA/WhatWeDo/default.htm ("The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation . . . FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.").

[73] *See* U.S. Dep't of Health & Human Serv., *About HHS*, https://www.hhs.gov/about/index.html (last visited Dec. 2, 2017) ("It is the mission of the U.S. Department of Health & Human Services (HHS) to enhance and protect the health and well-being of all Americans. We fulfill that mission by providing for effective health and human services and fostering advances in medicine, public health, and social services.").

[74] U.S. Dep't of Agric., *How the Federal Government Regulates Biotech Plants* (July 31, 2017), https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_regulations/ct_agency_framework_roles [hereinafter U.S. Dep't of Agric.] ("The FDA is responsible for ensuring the safety and proper labeling of all plant-derived food and feed, including those developed through genetic engineering. All food and feed, whether imported or domestic and whether derived from crops modified by conventional breeding techniques or by genetic engineering techniques, must meet the same rigorous safety standards.").

[75] U.S. Food and Drug Admin., *supra* note 72 ("FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.").

along with the United States Department of Agriculture[76] (USDA), and the Environmental Protection Agency[77] (EPA) form the mosaic of federal regulatory bodies that oversee the approval and regulation of biotechnology products.[78] Together, these agencies rely on a "patchwork of laws" to oversee the development of genetically engineered organisms.[79] This regulatory scheme was initially set forth by the Reagan Administration in 1986 with the development of the Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework").[80]

A. The Tri-agency Regulatory Mosaic

The Coordinated Framework allowed for the oversight of the development of biotechnological products using each agency's pre-existing statutory roles[81] and "remains the cornerstone of the biotechnology regulatory scheme today."[82] Developers of the Coordinated Framework considered the need to establish a new entity responsible for assessing the risks and challenges presented

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[76] *See* U.S. Dep't of Agric., *supra* note 74 ("Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering.").

[77] *See* Rekha K. Rao, Note, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish*, 57 ADMIN. L. REV. 903, 910–11 ("Under [the Federal Insecticide, Fungicide, and Rodenticide Act], EPA has the authority to regulate genetically-engineered microorganisms formed by deliberate combinations of genetic material from dissimilar source organisms[.]").

[78] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10.

[79] Albert C. Lin, Symposium, *Mismatched Regulation: Genetically Modified Mosquitoes and the Coordinated Framework for Biotechnology*, 51 U.C. DAVIS L. REV. 205, 205 (2017).

[80] Bratspies, *supra* note 14, at 471; *see* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986).

[81] Bratspies, *supra* note 14, at 471.

[82] Homer, *supra* note 37, at 100.

by biotechnological innovation; however, it was ultimately determined that the existing agencies were capable of responding to any new technological developments.[83] The reliance of the Coordinated Framework and subsequent FDA guidance on the presumption that the current framework is adequate, solidifies the additional presumption that genetically engineered organisms are substantially similar to non-genetically modified organisms.[84] Inherent in this supposition is the idea that genetically engineered animals pose no additional risk to human health or the environment.[85] In this underlying assumption lies the true danger of using the Coordinated Framework to regulate genetically engineered organisms intended for human consumption.

Following a decree from President Barack Obama, calling for an update to the Coordinated Framework in order "to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products,"[86] the FDA, USDA, and EPA began working to modernize the regulatory

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[83] *See* Coordinated Framework for the Regulation of Biotechnology, *supra* note 80.

[84] Lawrence, *supra* note 2, at 241 ("The Coordinated Framework also formalized the assumption that existing laws are sufficient for the regulation of GM products. This is a logical offshoot of the presumption that the products of genetic engineering are no different from their conventional counterparts. The Coordinated Framework expected that existing regulations for foods, crops, medicines, and pesticides could be applied to the products of genetic engineering. Implicit in the decision to regulate GM products under existing statutes is the belief that the products of genetic engineering, be they plant or animal, or foods or drugs, are not significantly different from their conventional counterparts."); *see* Mandel, *supra* note 14, at 2242.

[85] *See generally* U.S. Food & Drug Admin., *Statement Regarding Glofish*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (Apr. 4, 2017), https://www.fda.gov/AboutFDA/AboutThisWebsite/ucm450631.htm (search Glofish 2003; then select "Statement Regarding Glofish" hyperlink) (indicating that the genetically engineered fish do not pose any substantial risk).

[86] EXECUTIVE OFFICE OF THE PRESIDENT, MEMORANDUM FOR HEADS OF FOOD AND DRUG ADMINISTRATION, ENVIRONME NTAL PROTECTION AGENCY, AND DEPARTMENT OF AGRICULTURE 1 (July 2, 2015), https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf.

system.[87] In 2017, these agencies released an update to the 1986 Coordinated Framework ("Update").[88] The Update further clarified the roles and responsibilities of the agencies, and provided examples demonstrating the procedures involved in the regulation of genetically engineered organisms.[89] The memorandum from the Executive Office of the President[90] combined with the commitment from the FDA,[91] and the EPA[92] to fulfill the Update's strategic goals, indicates the government's understanding of the need to keep pace with technological advancements.[93] Though the

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[87] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10, at 1.

[88] *Id.*

[89] *Id.* at 8–35.

[90] EXECUTIVE OFFICE OF THE PRESIDENT, *supra* note 86, at 1 ("Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation. This memorandum initiates a process to modernize the Federal regulatory system for the products of biotechnology and to establish mechanisms for periodic updates of that system. The objectives are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.").

[91] U.S. Food and Drug Admin., *Modernizing the Regulatory System for Biotechnology Products*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/ucm520998.htm (last updated Dec. 4, 2017).

[92] *Update to the Coordinated Framework for the Regulation of Biotechnology*, ENVTL. PROT. AGENCY (June 7, 2017), https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/update-coordinated-framework-regulation-biotechnology (last updated June 7, 2017) ("The 2017 Update to the Coordinated Framework for the Regulation of Biotechnology represents the first time in 30 years that the federal government has produced a comprehensive summary of the roles and responsibilities of the three principal regulatory agencies with respect to regulating biotechnology products. In order to help product developers and the public understand what the regulatory pathway for products might look like, this 2017 update to the coordinated framework presents information about agency roles and responsibilities[.]").

[93] Lin, *supra* note 79, at 213–14 (discussing how the update to the Coordinated Framework has generally remained unchanged over time).

document succeeded in elucidating the scope of each agencies' role in regulating genetically engineered animals, it merely codified existing procedures, without adding to the regulatory scheme.[94]

B. The Classification of Genetically Engineered Organisms as Drugs

Under the existing regulatory scheme, genetically engineered animals do not fall neatly within an existing category as either a food, drug, cosmetic, or medical device.[95] The FDA has therefore chosen to regulate these creatures as new animal drugs within the meaning of the Federal Food, Drug, and Cosmetic Act.[96] Under the Act, the term "drug" is identified as such:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
> C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

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[94] *Id.*

[95] *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(f)-(j) (2018).

[96] U.S. FOOD & DRUG ADMIN., NO. 187, GUIDANCE FOR INDUSTRY: REGULATION OF INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS 6–7 (2017), https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf ("[T]he altered genomic DNA in an animal is a drug within the meaning of section 201(g) of the FD&C Act because such altered DNA is an article intended to affect the structure or function of the body of the animal, and, in some cases, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in the animal."); Lawrence, *supra* note 2, at 232 ("The FDA can assert primary regulatory authority over a GMO by virtue of its new animal drug authority.").

> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D) [21 USCS § 343(r)(1)(B) and (r)(3) or (r)(1)(B) and (r)(5)(D)], is made in accordance with the requirements of section 403(r) [21 USCS § 343(r)] is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) [21 USCS § 343(r)(6)] is not a drug under clause (C) solely because the label or the labeling contains such a statement.[97]

The FDA has established that the integration of recombinant DNA into an animal's genome, which "is intended to affect the animal's structure or function," is by definition, a drug under the Federal Food, Drug, and Cosmetic Act.[98] This is in direct conflict with the Coordinated Framework's core principle that genetically modified organisms are substantially similar to their unmodified counterparts, as new animal drugs are presumed unsafe until reviewed and approved by the FDA.[99]

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[97] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(g)(1) (2018).

[98] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10, at 18; *accord* Lawrence, *supra* note 2, at 232 ("The FDA interprets the pertinent NAD statutes to authorize the regulation of GMOs intended for human or livestock food uses because the inserted genes, and the proteins they produce, may affect the "structure and function" of the recipient animal in a manner analogous to the impact of a veterinary drug. Therefore, the genetic modification itself may be considered a new animal drug.").

[99] Lawrence, *supra* note 2, at 241 ("Implicit in the decision to regulate GM products under existing statutes is the belief that the products of genetic engineering, be they plant or animal, or foods or drugs, are not significantly different from their conventional counterparts."); U.S. Food & Drug Admin., *What FDA Does and Does Not Regulate*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, https://www.fda.gov/animalveterinary/resourcesforyou/animalhealthliteracy/ucm374203.htm#top (last updated Oct. 19, 2017).

Furthermore, since the recombinant DNA complex is a drug which has been incorporated into the structure of the genetically engineered animal, the responsibility for regulating the entirety of the genetically engineered animal has been misguidedly relegated to the Center for Veterinary Medicine.[100] The review process for a new animal drug includes the examination of the effects of the drug on human and animal health, in addition to environmental safety.[101] The decision to allow the Center for Veterinary Medicine to regulate genetically engineered animals as new animal drugs received backlash from the public as critics, concerned with the mischaracterization of an animal intended for human consumption as a veterinary drug, spoke out following the release of the FDA's Draft Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs for public comment.[102] In response, the FDA defended its decision stating:

Because this definition applies to the rDNA construct intended to alter the structure or function of an animal, and for the reasons explained in the guidance, the NADA provisions of the Act apply to GE animals. See Guidance at 4-5. We believe that these provisions are adequate to address the safety concerns associated with such animals. Our experience to date in reviewing pending, but not yet approved, applications is that the NADA requirements work very well as a means of regulating GE animals.

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[100] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10, at 19 ("Within FDA, the Center for Veterinary Medicine (CVM) is responsible for evaluating the safety and effectiveness of the regulated article (the rDNA construct inserted in a specific site of the GE animal's genome). This includes the safety of any food derived from the GE animal as well as the safety of the article to the target animal.").

[101] Lawrence, *supra* note 2, at 232–33.

[102] U.S. Food & Drug Admin., *FDA's Response to Public Comments on Draft Guidance for Industry #187, Released 9/18/2008*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (Dec. 1, 2017), https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/BiotechnologyProductsatCVMAnimalsandAnimalFood/AnimalswithIntentionalGenomicAlterations/ucm113612.htm (discussing comments noting that the new animal drug provisions were not designed to cover genetically engineered animals and questioning the adequacy of regulating genetically engineered animals using new animal drug requirements).

A number of comments questioned why FDA issued a guidance, noting that regulations rather than guidances are needed to set out regulatory requirements. We note that requirements that apply to new animal drugs are established by statute and implementing regulations. The guidance document explains how those existing provisions apply to GE animals. We do not believe it necessary to promulgate new regulations because the existing regulatory structure is adequate to review the safety and effectiveness of GE animal-related applications.[103]

Although the FDA maintains that the experts conducting the review of new animal drug applications are "technically qualified experts in their field," questions as to the adequacy of a veterinary drug expert's knowledge of genetically engineered organisms have arisen.[104]

In the case of the AquAdvantage Salmon, the FDA made a feeble attempt to mitigate the deficiency in expertise by adding four temporary members to the thirteen-person review committee.[105] An insufficient balance of expertise resulted in a powerful rebuke by the Consumer Union's Director of Food, in a letter elucidating concerns about the committee's capability of reviewing the AquAdvantage Salmon despite the addition of the four new members.[106] This letter further highlighted concerns

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[103] *Id.*

[104] Homer, *supra* note 37, at 122–23 (2011).

[105] *See* Jill Richardson, *Why is the FDA About to Rubber-Stamp GE Salmon?*, GRIST (Sept. 21, 2010), http://www.grist.org/article/2010-09-20-why-is-the-fda-about-to-rubber-stamp-ge-salmon/.

[106] Letter from Jean Halloran, Dir., Food Policy Initiatives, to Margaret Hamburg, Comm'r, Food & Drug Admin. (Sept. 15, 2010), https://advocacy.consumerreports.org/press_release/cu-letter-to-fda-regarding-review-of-aquavantages-application-for-approval-of-genetically-engineered-ge-salmon/ ("We must also object to the current composition of the VMAC, announced last week. Even with four new temporary voting members, the Committee is not constituted so as to provide scientifically sound advice to FDA on this topic. The topic of GE salmon is very different from the veterinary medicine topics this Committee normally addresses. There is, at present, not one single food safety scientist specializing in food allergies on the Committee despite the relative frequency of acute allergies to fish in the US population. Nor is there an endocrinologist knowledgeable about growth hormones – which are at issue here – on the Committee. There is also not one single fish ecologist.

about the committee's credibility with the public.[107] The Director proposed a more satisfactory committee composition stating "[w]e believe that three fish ecologists, four food safety experts (including specialists in food allergies and in the effects of hormones on human health), and scientists from the consumer and environmental community must be added to the Committee, to provide appropriate balance and expertise."[108] The concern over the paucity of expertise is further compounded by the lack of transparency involved in the new animal drug application process.[109] The new animal drug application process is protected by federal regulations, which prevents the FDA from disclosing information about a new animal drug before a determination is established.[110] Though information regarding the AquAdvantage Salmon was made available due to the release of the information by AquaBounty, the concerns surrounding the adequacy and lack of transparency, were largely disregarded by the FDA.[111]

Despite the regulator's insistence that the current system adequately protects human and environmental health with regards to new biotechnologies,[112] concerns as to the effectiveness of the Coordinated Framework have been established since the inception

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Nine of the 13 members are veterinarians or hold doctorates in animal science. Two more have been involved in developing genetically engineered animals themselves, including one who has worked for Monsanto. The consumer representative, though knowledgeable, is a lawyer rather than a scientist. We question how the Committee can accurately assess the safety of this salmon for humans and the environment when it lacks the essential expertise to do so . . . We believe that without the extension of the review period, and the addition of certain scientific experts to the VMAC, the Committee's findings will not have the needed credibility with the public. We also believe that without these experts, FDA will fail to get the sound scientific advice it needs and deserves.").

107 *Id.*

108 *Id.*

109 McEvilly, *supra* note 7, at 422–23.

110 21 U.S.C. § 331(j) (2006); 21 C.F.R. § 514.11(b)–(d) (2012).

111 *See* Homer, *supra* note 37, at 125–27.

112 U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10, at 1, 3, 5.

of recombinant biotechnology.[113] Though questions prevail as to the functionality of the Coordinated Framework approach and the appropriateness for regulation by the Center for Veterinary Medicine, the true issue surrounding the regulation of genetically engineered animals lies in the FDA's inconsistent application of its current regulatory scheme.[114] To fully understand the regulatory void faced by the AquAdvantage Salmon, it is essential to examine the FDA's regulation of the first food product derived from genetically engineered animals and the first commercialized genetically engineered animal.

C. The FDA's Approval of Transgenic Milk

The AquAdvantage Salmon is the first genetically engineered animal approved for use as a food product; however, this is not the first product derived from a genetically engineered animal that the FDA has allowed for human consumption.[115] With the approval of milk produced through the use of recombinant DNA technology, the FDA began its journey down what has become a slippery slope of inconsistent regulation.[116] Furthermore, concerns about the standards for the regulation of genetically engineered products derived from animals is not a modern dilemma.[117] In fact, concerns skyrocketed in 1986, as Monsanto[118] began the process of bringing milk produced by cows treated with a genetically engineered

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[113] *See* Robert A. Bohrer, *Food Products Affected by Biotechnology*, 55 U. PITT. L. REV. 653, 665–70 (1994) (discussing the controversy surrounding the regulation of the first genetically engineered foods).

[114] *See* Lawrence, *supra* note 2, at 241.

[115] Miller, *supra* note 12, at 520. (discussing how milk produced by genetically engeneered cows was the first food product derived from an animal).

[116] *Id.*

[117] *See* Mara Bovsun, *Hormone Battle Takes to Streets After BST Finally Hits U.S. Market*, BIOTECHNOLOGY NEWSWATCH, 1, 2 (1994) (discussing the mixed response to FDA approval of recombinant bovine somatotropin).

[118] *About Monsanto Company*, MONSANTO, https://monsanto.com/company/ (last visited Dec. 5, 2017) ("Monsanto is a global modern agriculture company. We develop products and tools to help farmers around the world grow crops while using energy, water, and land more efficiently.").

substance to market.[119] By approving the use of recombinant bovine somatotropin ("rbST"),[120] a growth hormone analog used to increase milk production in dairy cows,[121] the FDA sanctioned the first use of genetic engineering on an animal used to produce products intended for human consumption in 1993.[122]

At the time, there was some discrepancy with respect to which regulatory agency would provide the primary oversight of rbST, as the product "could have been regulated as a new animal biological product by the USDA under the Virus-Serum-Toxin Act, or by the FDA as a new animal drug."[123] Since the FDA was thought to be a "more credible agency" by consumers, the agency was given the primary responsibility for regulating rbST.[124] In addition to the relatively arbitrary determination to regulate the production of rbST milk as a new animal drug, the Center for Veterinary Medicine failed to fully implement the safety provisions required for the approval of a new animal drug application.[125] The safety provisions required by 21 U.S.C. §360b (b)(1)(G) and 21 U.S.C. §360b (b)(1)(H) are as follows:[126]

> (b) Filing application for uses of new animal drug; contents; patent information; abbreviated application; presubmission conference
> (1) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application
> (G) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and

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119 Kristine Cerro, Note, *High-Tech Cows: The BST Controversy*, 6 SAN JOAQUIN AGRIC. L. REV. 163, 163 (1996).

120 Bohrer, *supra* note 113, at 668; Cerro, *supra* note 119, at 192.

121 Cerro, *supra* note 119, at 163.

122 *Id.*

123 *Id.* at 185.

124 *Id.* at 186.

125 *Id.* at 164.

126 21 U.S.C. § 360b (b)(1)(G)–(H) (1994).

> (H) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

During the approval process for rbST, the FDA did not require Monsanto to submit a method for determining the quantity of rbST in the milk derived from the treated cows as a part of their application.[127] The FDA also did not require the submission of a proposed tolerance level of rbST, which would indicate the amount of rbST that would be permitted to remain in the milk without rendering it unadulterated[128] under the Federal Food, Drug, and Cosmetic Act.[129] This failure to enforce the regulatory requirements of the first commercialized genetically engineered animal product has continued; so much so that some have referred to the regulatory system as "woefully inadequate."[130]

D. The FDA's Refusal to Regulate the GloFish

The inconsistent application of the federal regulatory guidelines is further illustrated by the FDA's more recent failure to oversee the commercialization of the first transgenic animal, the GloFish.[131] The GloFish is genetically engineered using recombinant DNA technology to contain DNA constructs from sea

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[127] Cerro, *supra* note 119, at 189.

[128] *Id.*

[129] Fed. Food, Drug, and Cosmetic Act, 21 U.S.C. § 342(a)(1) (2012) ("A food shall be deemed to be adulterated . . . [i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health[.]").

[130] Michael Baram et al., *Transgenic Agriculture: Biosafety and International Trade*, 4 B. U. J. SCI. & TECH. L. 156, 167 (1998).

[131] *FDA Statement Regarding Glofish*, U.S. FOOD & DRUG ADMIN., (Dec. 9, 2003), https://wayback.archive-it.org/7993/20170404230909/https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm; *see* Bratspies, *supra* note 14, at 458–59, 467 ("Rather than engaging in heightened or even ordinary regulatory scrutiny, the Food and Drug Administration (FDA), the lead agency for regulating transgenic animals, instead announced in 2003 that it would permit GloFish to enter into interstate commerce wholly unregulated.").

coral.[132] The introduction of the coral DNA results in a florescent ornamental fish, which glow when exposed to specific light conditions.[133]

In *Int'l Ctr. for Tech. Assessment v. Thompson*, the plaintiffs alleged that, "the FDA improperly refused to regulate the GloFish, and that the FDA's failure to assert regulatory authority over the GloFish violates the NADA, [new animal drug application] provisions of the FDCA, [Federal Food, Drug, and Cosmetic Act]."[134] The plaintiffs argued in favor of regulation by the FDA, emphasizing the potential for accidental release, resulting in environmental impacts and introduction into the human food supply.[135] The court dismissed the claims, reaffirming the FDA's discretion in determining whether or not to enforce new animal drug applications.[136] The high level of discretion afforded to the FDA's determination of what and how genetically engineered organisms are regulated further highlights the need for thorough and consistent regulation.[137]

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[132] *See* Int'l Ctr. for Tech. Assessment v. Leavitt, 468 F. Supp. 2d 200, 202 (D.D.C. 2007); Andrew Pollack, *Business; So the Fish Glow. But Will They Sell?*, N.Y. TIMES (Jan. 25, 2004), http://www.nytimes.com/2004/01/25/business/business-so-the-fish-glow-but-will-they-sell.html.

[133] *Leavitt*, 468 F. Supp. 2d at 202; Lawrence, *supra* note 2, at 256.

[134] Int'l Ctr. for Tech. Assessment v. Thompson, 421 F. Supp. 2d 1, 6 (D.D.C. 2006).

[135] *Id.* at 4 ("Although GloFish are intended for use in home aquariums, the plaintiffs allege that they 'could be put to other uses and readily enter the animal and human food chains through accidental or intentional releases.'") (quoting Am. Compl. ¶ 35).

[136] *Id.* at 6 ("The court dismissed the two claims, argued in the alternative, because the FDA's 'enforcement decisions relating to unapproved new animal drug products are discretionary and are not subject to judicial review under the APA.'") (quoting Mem. Op. at 18).

[137] *See* Maria R. Lee-Muramoto, *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, 17 DRAKE J. AGRIC. L. 311, 348, 362 (2012) (discussing the ineffectiveness of the Coordinated Framework and the concerning assumption by the FDA that the GloFish was "safe" without supporting evidence); Lawrence, *supra* note 2, at 228 (discussing the high degree of deference afforded to the FDA following their decision not to regulate the GloFish and the need for effective regulatory processes for addressing the risks posed by genetically modified organisms).

In a similar case brought approximately one year later, the plaintiffs argued that, "the FDA had failed to regulate the GloFish solely on the mistaken belief that it did not have jurisdiction to regulate the commercialization of the fish."[138] The court determined that, "[a]t most, . . . the FDA was, for some time, undecided on the issue of whether to regulate GloFish (not on the issue of whether it could regulate GloFish)[.]"[139] Taken together, these cases make it clear that the FDA had the power to regulate a commercialized, genetically engineered organism, which had the potential to impact both the environment and human food supply, yet did not take steps to fully evaluate the impact by regulating the GloFish as a new animal drug.[140] Although GloFish meet the FDA's definition of a drug, due to the incorporation of the recombinant DNA construct within the fish, the FDA chose to ignore the fact that, as a drug, GloFish is inherently unsafe.[141] In response to concerns surrounding the commercialization of GloFish, the FDA released a short statement explaining the rationale behind the decision not to regulate the genetically engineered fish:

> Because tropical aquarium fish are not used for food purposes, they pose no threat to the food supply. There is no evidence that these genetically engineered zebra danio fish pose any more threat to the environment than their unmodified counterparts which have long been widely sold in the United States. In the absence of a clear risk to the public health, the FDA finds no reason to regulate these particular fish.[142]

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138 *Leavitt*, 468 F. Supp. 2d at 204.

139 *Id.* at 208.

140 *See* Lee-Muramoto, *supra* note 137, at 348.

141 *See* McEvilly, *supra* note 7, at 420 ("[A] new animal drug is 'deemed unsafe' under the Act unless the FDA has approved a NADA for that particular use[.]").

142 U.S. Food & Drug Admin., *Statement Regarding Glofish*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES (Apr. 4, 2017), https://wayback.archive-it.org/7993/20170404230909/https://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm413959.htm.

By stating that the "genetically engineered zebra danio fish [do not] pose any more threat . . . than their unmodified counterparts," the FDA is simply using the Coordinated Framework's idea that transgenic organisms are substantially similar to their non-transgenic counterparts as a shield to avoid performing its regulatory duties.[143]

Due to the FDA's lead role in the regulation of genetically modified organisms,[144] the FDA's refusal to engage in the premarket review process for the GloFish allowed it to avoid review and become commercialized almost immediately.[145] The inconsistent application and enforcement of regulatory guidelines undermines the credibility of United States' regulatory agencies, and lends credence to the idea that "[w]hat we have amounts to a voluntary system for assessing the risks of transgenic food."[146] A lack of consistency is particularly dangerous when the United States is leading the international community into the uncharted waters of biotechnological innovation.[147] As the United States continues to cope with the aftermath of the approval of the AquAdvantage Salmon and new genetically engineered animals begin attempts to enter the food supply,[148] policymakers can look to other leading counties for guidance.[149]

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[143] *See id.*

[144] Bratspies, *supra* note 14, at 458–59.

[145] Lars Noah, *Managing Biotechnology's Revolution: Has Guarded Enthusiasm Become Benign Neglect*?, 11 VA. J.L. & TECH. 4, 60 (2006).

[146] Baram et al., *supra* note 132, at 21.

[147] *See* Law Library of Congress, *Restrictions on Genetically Modified Organisms: European Union*, LIBRARY OF CONGRESS, https://www.loc.gov/law/help/restrictions-on-gmos/eu.php (last updated June 9, 2015).

[148] *See* American Society of Animal Science, *Scientists Improve Transgenic "Enviropigs"*, SCIENCEDAILY (Mar. 7, 2013), https://www.sciencedaily.com/releases/2013/03/130307124802.htm.

[149] *See* Sabeera Bonala, *Countries Leading in Biotechnology Industry – Global Rankings*, BIOSTANDUPS (Nov. 29, 2016), http://www.biostandups.com/bio-tech/countries-leading-biotechnology-industry-global-rankings/.

IV. THE REGULATION OF FOOD DEVELOPED THROUGH NEW TECHNOLOGIES IN CANADA

The AquAdvantage Salmon is currently only available on the Canadian market.[150] As of September 2018, "4.5 tonnes" of AquAdvantage Salmon have been sold as food in Canada this year.[151] Though the United States was the first country to approve the genetically engineered salmon in November 2016,[152] Canada's regulatory agencies followed suit six months later.[153] With regard to allowing genetically engineered animals into the food supply, the Canadian system has proven comprehensive yet flexible.[154] Though Canada has implemented a regulatory system for biotechnology similar to that of the United States,[155] its slight differences allow it to more effectively keep pace with scientific advancements. Created in 1993, the Canadian framework relies on three main agencies to execute all regulatory provisions relating to

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[150] George Dvorsky, *Canadians Are Now the First to Eat Genetically Modified Salmon*, GIZMODO (Aug. 9, 2017), https://www.gizmodo.com.au/2017/08/canadians-are-now-the-first-to-eat-genetically-modified-salmon/; Waltz, *supra* note 36.

[151] Michael Drapack*, Maker of GMO Samlon Says it Sold 4.5 Tonnes in Canada This Year But Won't Say To Whom*, CBC NEWS (Sep. 06, 2018**),** https://www.cbc.ca/news/business/aquabounty-gmo-salmon-1.4813758**.**

[152] Carrie Dennett, *Seafood: Genetically Engineered Salmon*, 18 TODAY'S DIETICIAN 18, 18 (2016), https://www.todaysdietitian.com/newarchives/0816p18.shtml.

[153] *Health Canada and Canadian Food Inspection Agency Approve AquAdvantage Salmon*, HEALTH CANADA (May 19, 2016), https://www.canada.ca/en/health-canada/news/2016/05/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon.html; Waltz, *supra* note 36.

[154] *See* Douglas J.R. Moodie, *The Cautious 'Frankenfish': Environmental Protection and Other Canadian Regulatory Issues Relating to Transgenic Fish*, 1 MACQUARIE J. INT'L & COMP. ENVTL. L. 49, 76–78 (2004) (discussing several federal departments and agencies with adapting responsibilities).

[155] *See* Kara M. Van Slyck, Note, *Salmon with a Side of Genetic Modification: the FDA's Approval of the AquAdvantage Salmon and Why the Precautionary Principle is Essential for Biotechnology Regulation*, 41 SEATTLE U. L. REV. 311, 329 (2017) (discussing the United States' and Canada's approval of AquAdvantage Salmon).

biotechnology in the agriculture and food sectors:[156] the Canadian Food Inspection Agency,[157] Health Canada,[158] and Environment Canada.[159] As in the United States, Canada chose to elaborate upon its existing regulatory system.[160] This was done in order to

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[156] *Regulating Agricultural Biotechnology in Canada: An Overview*, GOV'T OF CAN., http://www.inspection.gc.ca/plants/plants-with-novel-traits/general public/overview/eng/1338187581090/1338188593891 (July 19, 2016).

[157] *Food*, CANADIAN FOOD INSPECTION AGENCY, http://www.inspection.gc.ca/food/eng/1299092387033/1299093490225 (last updated June 12, 2018) ("The Canadian Food Inspection Agency aims to mitigate risks to public health associated with diseases and other health hazards in the food supply system and to manage food safety emergencies and incidents. The CFIA . . . achieves its objectives by promoting food safety awareness through public engagement and verification of compliance by industry with standards and science-based regulations."); *Regulating Agricultural Biotechnology in Canada: An Overview*, *supra* note 156.

[158] Health Canada, *Genetically Modified (GM) Foods and Other Novel Foods*, GOV'T OF CAN., https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods.html (last updated Dec. 22, 2016) ("Health Canada assesses the safety of all genetically-modified and other novel foods proposed for sale in Canada. Companies are required to submit detailed scientific data for review and approval by Health Canada, before such foods can be sold."); *Regulating Agricultural Biotechnology in Canada: An Overview*, *supra* note 156.

[159] Environment and Climate Change Canada, *About Environment and Climate Change Canada*, GOV'T OF CAN., https://www.ec.gc.ca/default.asp?lang=En&n=BD3CE17D-1&wbdisable=true (last updated Dec. 1, 2016) ("At Environment and Climate Change Canada (ECCC), our business is protecting the environment, conserving the country's natural heritage, and providing weather and meteorological information to keep Canadians informed and safe . . . Environment and Climate Change Canada is a diverse organization where our programs, services, and people lead the way in implementing the Government of Canada's environmental agenda. We collaborate with our partners at home and abroad, to realize concrete progress on initiatives that will protect the health of our people and our planet."); *see Regulating Agricultural Biotechnology in Canada: An Overview*, *supra* note 156.

[160] *See Regulating Agricultural Biotechnology in Canada: An Overview*, *supra* note 156 ("In 1993, the federal government announced a framework for the regulation of biotechnology products in Canada. One of the principles of the framework was that existing legislation and regulatory bodies would be used to regulate biotechnology products, and that they would build on existing laws and

minimize costs and avoid the hassle of developing an entirely new regulatory body and implementing new laws.[161]

The main difference between United States and Canadian regulatory protocol is Canada's use of a "novel food" classification.[162] According to the Canadian Food and Drug Act:

> Novel food means:
>
> (a) a substance, including a microorganism, that does not have a history of safe use as a food;
>
> (b) a food that has been manufactured, prepared, preserved or packaged by a process that
>
> (i) has not been previously applied to that food, and
>
> (ii) causes the food to undergo a major change; and
>
> (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
>
> (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
>
> (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
>
> (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism. (aliment nouveau).[163]

This novel food category allows for the classification of newly developed products intended for human consumption without

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expertise, rather than developing entirely new laws and agencies. This means that agricultural products of biotechnology are regulated under the same broad legislation and structures, with the addition of some new regulations and administrative procedures, as agricultural products produced in more traditional ways."); Moodie, *supra* note 154, at 76 ("There is presently no separate and distinct responsible body or procedural approach for GM food products.").

[161] Moodie, *supra* note 156, at 77–78 ("Canada is the only country where regulatory oversight is triggerd by 'novelty' rather than 'process.'"); *see also* CAN. BIOTECHNOLOGY ADVISORY COMM., IMPROVING THE REGULATION OF GENETICALLY MODIFIED FOODS IN CANADA 13 (2001).

[162] Food and Drug Regulations C.R.C., c. 870 B.28.001(c) (2017).

[163] *Id.*

regard for the technology used in the creation of the product.[164] The inclusion of the novel food category allows Canada to regulate new foods without having to anticipate the biotechnology used to produce it. This provides the governing agencies with the ability to develop guidelines specific to the new technologies as they come about rather than necessitating the development of creative ways to apply antiquated guidelines.[165]

V. A NOVEL SOLUTION

For over thirty years, the United States has inconsistently applied insufficient regulations and policy when it comes to the approval process for genetically engineered organisms.[166] Although no other genetically engineered organisms have yet been approved for human consumption by the FDA,[167] many are currently under development, and each new organism poses a unique set of regulatory challenges.[168] If we are to maximize the benefits of biotechnical advancements with respect to food, while reducing the potential health and environmental risks associated with the development of genetically engineered animals, we must develop a regulatory system that: 1) accurately classifies biotechnological products; and 2) consistently applies the regulatory measures which are put into place. Rather than looking backward and attempting to apply antiquated regulations to new and unforeseen technologies, we must adapt the framework to

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[164] Moodie, *supra* note 154, at 77.

[165] *See* Bratspies, *supra* note 14, at 471 (discussing the increasingly creative interpretations of existing regulatory laws as the conventional regulatory categories are twisted in order to apply to genetically modified organisms).

[166] *See* Lawrence, *supra* note 2, at 244 (explaining agencies' failure to meet the Coordinated Framework's objectives).

[167] *See* U.S. Food & Drug Admin., *Consumer Q & A*, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, https://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm473237.htm (last updated Dec. 1, 2017) (indicating that the AquAdvantage Salmon is the only approved genetically engineered animal in the food supply).

[168] *See* Jeremy Cooke, *GM Pigs: Green Ham with Your Eggs*?, BBC NEWS (Jan. 4, 2011), http://www.bbc.com/news/world-us-canada-12113859.

accommodate the products of our rapidly advancing world. The FDA's current focus on the classification of products based on the process by which they are made has led to the mischaracterization of genetically engineered animals as drugs.[169]

As the genetic engineering of animals progresses, the distinction between food and drugs will become increasingly difficult.[170] The rigidity of the FDA's regulatory policies combined with a lack of foresight into the potential for biotechnological advancements on behalf of the developers of the Coordinated Framework, has resulted in the inconsistent application of a framework plagued by gaps and conflicting policies.[171] Although the current framework is essentially unworkable as a tool for regulating current biotechnology, many of the building blocks used to create the present scheme can be molded to form a more effective set of regulatory guidelines.

To add flexibility and accuracy to the United States' regulation of genetically engineered animals, the government should implement the use of a novel category similar to the classification used in the Canadian regulatory framework. Under this scheme, the government will maintain the current tri-agency regulatory mosaic and simply amend the Food, Drug and Cosmetic Act to include a novelty category. By classifying genetically engineered animals as novel foods, and allowing review by a committee of qualified experts, the FDA can avoid the problems, such as expertise deficiency, associated with characterizing a living animal as a veterinary drug. Furthermore, with the development of more genetically engineered animals, the process for approval will become faster and more streamlined, as a history of safe use and anticipated ranges of characteristics become known.[172] In this way, the FDA can avoid the lose-lose dilemma of either forestalling

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169 *See* Moodie, *supra* note 154, at 77; Lawrence, *supra* note 2, at 281–82.

170 Lawrence, *supra* note 2, at 249–50.

171 *See* Lawrence, *supra* note 2, at 242.

172 *See* A. Constable, et al., *History of Safe Use as Applied to the Safety Assessment of Novel Foods and Foods Derived From Genetically Modified Organisms*, 45 FOOD AND CHEMICAL TOXICOLOGY 2513, 2513–16 (2007) (discussing the meaning of "safe use" and approval with respect to genetically modified animals intended for human consumption); *see* Food and Drug Regulations, *supra* note 162.

innovation by reviewing a product for nearly twenty years,[173] or by declining to thoroughly review a product thereby allowing for rapid commercialization.[174]

This increased efficiency, combined with the social benefits resulting from the development of new foods, will likely offset the costs of establishing a review committee similar to the Veterinary Center for Medicine, which would review novel food applications.[175] Additionally, by maintaining the tri-agency regulatory mosaic, the government will avoid the cost of creating a new regulatory agency dedicated solely to the review of products developed through use of biotechnology.[176] However, to prevent the problems associated with discordant discretionary application of regulations, it is essential that the FDA, as the primary agency responsible for the regulation of genetically engineered animals, consistently exercise its statutory authority to the full extent[177] provided by the Federal Food, Drug, and Cosmetic Act.[178]

The Update to the Coordinated Framework provides a useful starting point by delineating each agency's respective duties with regards to regulating genetically engineered animals;[179] however, the fundamental assumption that genetically engineered organisms are substantially similar to their non-transgenic counterparts should be eliminated.[180] Though facially this presumption appears in favor of genetic engineering, it is ultimately detrimental to scientific

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[173] Doezema, *supra* note 34 ("The regulatory process behind the approval of the AquAdvantage salmon took almost 20 years.").

[174] Noah, *supra* note 147, at 46.

[175] *See* WENDY GINSBERG, CREATING A FEDERAL ADVISORY COMMITTEE IN THE EXECUTIVE BRANCH 1 (2016).

[176] Regulating Agricultural Biotechnology in Canada: An Overview, *supra* note 156 (explaining the challenges associated with creating an entirely new government agency).

[177] Bratspies, *supra* note 14, at 504.

[178] 21 U.S.C. §§ 1-27 (1994).

[179] U.S. FOOD & DRUG ADMIN., MODERNIZING THE REGULATORY SYSTEM, *supra* note 10.

[180] *See generally* Trevor Findley, *Genetically Engineered Crops: How the Courts Dismantled the Doctrine of Substantial Equivalence*, 27 DUKE ENVTL. L. & POL'Y F. 119 (2016) (explaining the FDA's assumption that genetically engineered organisms are substantially similar to non-engineered organisms); *see also* Lawrence, *supra* note 2, at 241.

advancement as it fails to take into consideration the unique characteristics of genetically engineered organisms.[181] As genetic engineering becomes more advanced, potentially allowing for greater percentages of recombinant DNA within an organism, it will likely become increasingly difficult to distinguish, for example, whether an organism such as a GloFish is substantially similar to a Zebra fish or a sea coral.[182] The ability to incorporate DNA from nearly any organism into the genome of another provides immense potential for innovative new food products, but also provides potential for unintended environmental or moral consequences.[183] The addition of a novelty category requiring the review of genetically engineered organisms prior to commercialization will not only avoid challenges presented by a substantial similarity presumption, but will also ensure consistent regulation.

The FDA has been using its regulatory discretion as both a sword and a shield in order to selectively decide which genetically modified products it will regulate, and the extent to which it will exercise its statutory mandates.[184] To ensure public trust in the regulatory process, and minimize the potentially detrimental effects of genetically modified organisms, the decision to review a genetically engineered animal cannot be left to the FDA's discretion.[185] The addition of a novelty category will increase confidence in the government as a regulatory body, and in genetically engineered organism as food by providing greater transparency in the approval process. By removing the new animal

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[181] *See* Lawrence, *supra* note 2, at 241.

[182] *See id.* at 256–57.

[183] Ellen Rolfes, *When Does Genetic Modification of Animals Cross a Line?*, PBS NEWS HOUR (June 10, 2013), https://www.pbs.org/newshour/science/when-does-genetic-modification-of-animals-cross-a-line (discussing the ability to transfer genes across species); *see also* Lawrence, *supra* note 2, at 249 (discussing challenges associated with 'cross-kingdom' transgenic organisms).

[184] *See* Lee-Muramoto, *supra* note 137, at 343–48; *see generally* Findley, *supra* note 180, at 119 (discussing the FDA's selective regulation of products).

[185] *See* Homer, *supra* note 37, at 86 (discussing the need for "caution and diligence" in forthcoming FDA regulation).

drug label from genetically engineered animals, the FDA will no longer be prevented from disclosing information to the public.[186]

CONCLUSION

While the approval of the AquaAdvantage salmon is a testament to the remarkable advancements our technology has made, it highlights the weaknesses of the current regulatory framework. As the first genetically modified organism to become approved for human consumption, the AquAdvantage Salmon has opened the door to even greater possibilities. Accordingly, the FDA needs to prepare now for the future of genetically engineered food. Furthermore, the United States government must act swiftly in order to effectively lead the world into a new age of technological innovation.

[186] 21 U.S.C. § 331(j) (2006); 21 C.F.R. § 514.11 (2012).