Salmon with a Side of Genetic Modification: The FDA's Approval of AquAdvantage Salmon and Why the Precautionary Principle is Essential for Biotechnology Regulation

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INTRODUCTION

Over the last thirty years, once abundant wild salmon populations in the Pacific and Atlantic Oceans have declined to a mere fraction of their historic levels. As of 2016, salmon populations in Washington State's Columbia River region are either failing to make any progress towards recovery or showing very little signs of improvement; Puget Sound salmon are only getting worse.[1] In the Gulf of Maine, salmon populations dropped from five-hundred spawning adults in 1995 to less than fifty adults in 1999.[2] Atlantic salmon, *Salmo salar*, were first designated as "endangered"[3] in November 2000—the Fish and Wildlife Service (FWS) expanded the listing nine years later to include critical habitat along the coast of Maine as a result of little improvement to the population's numbers.[4] In the Pacific Ocean, FWS classified four significant salmon species as endangered for protection under the Endangered Species Act

* Juris Doctor Candidate, Seattle University School of Law 2018. I would like to extend thanks to Professor Carmen G. Gonzalez for her valuable insight of the precautionary principle, her extensive knowledge on environmental regulations in the United States, and her unwavering support of this Note.

1. Governor's Salmon Recovery Office, *State of Salmon in Watersheds 2016*, WASH. ST. RECREATION & CONSERVATION OFF., http://stateofsalmon.wa.gov/governors-report-2016/ [https://perma.cc/6F3J-FKWE].

2. Endangered and Threatened Species; Final Endangered Status for a Distinct Population Segment of Anadromous Atlantic Salmon (*Salmo salar*) in the Gulf of Maine, 50 C.F.R. § 224.101 (June 19, 2009).

3. Pursuant to the ESA, the term "endangered" means any species which is in danger of extinction throughout all or a significant portion of its range other than a species of the Class Insecta determined by the Secretary to constitute a pest whose protection under the provisions of this Act would present an overwhelming and overriding risk to man. 16 U.S.C. § 1532(6).

4. *Atlantic salmon (*Salmo salar*)*, NOAA FISHERIES, http://www.fisheries.noaa.gov/pr/species/fish/atlantic-salmon.html [https://perma.cc/P7BF-3HWM].

(ESA) beginning in 1991;[5] of the four, only one species has been upgraded to the less severe "threatened" status.[6] As a keystone species in the Pacific Northwest, a healthy salmon population supports an entire ecosystem of species including grizzly bears, bald eagles, and orca whales—all of which have been or are considered endangered[7]—and as the salmon population continues to decline, other species will follow suit.[8] Protecting one of the last great salmon ecosystems is a daunting task requiring the collaboration of conservationists, policymakers, scientists, and many others.

In response to the global demand for salmon tripling since the 1980s and the declining wild salmon population, farmed salmon and aquaculture facilities have gained popularity in the United States.[9] In 2013, farmed salmon exceeded 70% of total salmon consumed globally.[10] Furthermore, the thirty-three hatcheries devoted to salmon production in the United States have helped mask the low-level return of wild salmon returning each year; scientists have recorded as little as 10% of Chinook salmon in the fall spawning season were born in the wild.[11] Biologist Rachel Johnson qualified the situation well, stating:

> [w]hen you use the raw fish counts, it looks like the population is doing well. But if you look at the number of fish that are produced in the wild and return to spawn in the wild, and you follow through the

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5. The ESA currently protects four salmon species native to Puget Sound in Washington State: Chinook (*Oncorhynchus tshawtscha*), Chum (*Oncorhynchus keta*), Coho (*Oncorhynchus kisutch*) and Sockeye (*Oncorhynchus nerka*). In November 1991, the Sockeye salmon was first listed as "endangered" in the Snake River; beginning in 1992, the Chinook salmon was listed as "threatened"; in 1999, the distinct population segment of the Upper Columbia River spring run was listed as "endangered"; beginning in 1999, Chum salmon was listed as "threatened." *Salmon Species Listed Under the Federal Endangered Species Act*, WASH. ST. RECREATION & CONSERVATION OFF., http://www.rco.wa.gov/salmon_recovery/listed_species.shtml [https://perma.cc/XP3B-M3LX].

6. The term "threatened" means any species that is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. 16 U.S.C. § 1532(20).

7. Endangered and Threatened Wildlife and Plants; Draft Revised Supplement to the Grizzly Bear Recovery Plan, 78 Fed. Reg. 17,708-09 (Mar. 22, 2013); Determination of Certain Bald Eagle Populations as Endangered or Threatened, 43 Fed. Reg. 6,230-33 (Feb. 14, 1978); NMFS: Endangered Status for Southern Resident Killer Whales, 70 Fed. Reg. 69,903-12 (Nov. 18, 2005).

8. *See Guido Rahr on Salmon Strongholds*, TEDX TALK (Jan. 9, 2015), https://vimeo.com/116385054 [https://perma.cc/J6HC-M9FD]; Guido Rahr, *Why Protect Salmon*, WILD SALMON CTR., https://www.wildsalmoncenter.org/work/why-protect-salmon/ [https://perma.cc/EGK2-Q3E8].

9. *See Farmed Salmon,* WORLD WILDLIFE FUND, http://www.worldwildlife.org/industries/farmed-salmon [https://perma.cc/ZLD8-XZE9].

10. In 2013, Americans consumed 353,000 tons of the farmed salmon. *See* Brian Clark Howard, *Salmon Farming Gets Leaner and Greener*, NAT'L GEOGRAPHIC (Mar. 19, 2014), http://news.nationalgeographic.com/news/2014/03/140319-salmon-farming-sustainable-aquaculture/ [https://perma.cc/7BWR-Q7AU].

11. *See* Tim Stephens, *Hatchery Fish Mask the Decline of Wild Salmon Populations,* U. CAL. SANTA CRUZ (Feb. 8, 2012), http://news.ucsc.edu/2012/02/hatchery-salmon.html [https://perma.cc/BL2T-DHUJ].

> cycle, you see that the wild fish don't survive at a high enough rate to replace their parents. So the habitat is not supporting a sustainable wild population.[12]

Still, the shift to dependency on farmed salmon has not been enough to replace the wild salmon runs.[13] Innovation and technology in the prior decade have led us to AquAdvantage—the first-of-its-kind, genetically engineered salmon produced by AquaBounty Technologies, Inc.[14] The biotech company claims that AquAdvantage salmon is better for the environment and for consumers, while also boasting a low-impact fish farming system that may result in healthier salmon.[15] The new take on traditional salmon aquaculture adds a growth hormone into the genetic makeup of Atlantic salmon in order to accelerate the growth period from three years to a swift eighteen months.[16] Moreover, the AquAdvantage salmon averages a final weight of 6,000 grams, almost a third heavier than a wild Atlantic salmon.[17] While AquaBounty implements farming practices that improve upon the negative impacts of aquaculture and stock ponds,[18] the already endangered salmon population faces the risk of the dominate AquAdvantage salmon compromising the Atlantic salmon's chance at survival.

The United States Food and Drug Administration (FDA) has asserted authority to rule on and approve genetically engineered (GE) salmon by classifying AquAdvantage as a "new animal drug."[19] Following an almost twenty year review process, the FDA issued a Final Rule on November 24, 2015 granting the use of AquAdvantage salmon for sale in the U.S.[20] Despite the fact that AquAdvantage has yet to be incorporated into the market for consumption, environmental advocates wasted no time filing

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12. *Id.*

13. The most recent report regarding the salmon returns to the Puget Sound area had mixed reviews. While some areas were told to expect strong levels, others are closed to non-tribal fishing until further notice. Despite the varying salmon returns across the state, the levels are still nowhere near the historical levels and are being closely monitored. RYAN LOTHROP & MARK BALTZELL, WASH. DEP'T FISH & WILDLIFE, 2017 PUGET SOUND SALMON FORECASTS: COHO AND CHINOOK (Mar. 01, 2017), http://wdfw.wa.gov/fishing/northfalcon/2017/2017_salmon_forecasts_fact_sheet.pdf [https://perma.cc/EQW3-5TQW].

14. *See Sustainable,* AQUABOUNTY, https://aquabounty.com/sustainable/ [https://perma.cc/SV7X-TV5G].

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. 21 C.F.R. § 510 (2015).

20. FDA Final Rule, New Animal Drugs in Genetically Engineered Animals, 80 Fed. Reg. 73,104 (Nov. 24, 2015).

legal action to repeal the ruling.[21]AquAdvantage salmon has entered the production phase and will be ready for sale in grocery stores by the end of 2017.[22] Moving forward, the FDA has not been able to absolutely guarantee that AquAdvantage salmon are safe to eat and severe environmental degradation is likely to result from poor review of such a product. The new field of GE food products must be approached with caution and skepticism.

This Note seeks to address the issues concerning the FDA's approval of genetically modified salmon for consumption, arguing that the FDA did not properly vet AquAdvantage salmon, as well as relied on inappropriate criteria in their approval of its market use. Part I provides a brief history of AquAdvantage salmon's introduction to U.S. markets and the legal actions taken in response to the FDA ruling. Part II discusses the statutes and regulations fundamentally relevant to GE products, as well as a critique of the way each regulation was used to approve AquAdvantage. Part III offers a comparison to the European Union's methods of tackling GE regulation and details why the EU decided to ban AquAdvantage salmon. Part IV offers an analysis of the current issues surrounding the production of AquAdvantage salmon and explores the potential consequences following the FDA ruling. This Note concludes with a suggestion to parallel the U.S. regulatory system to the more succinct and rigorous process the European Union relies on to regulate GE animals, a system that operates under the precautionary principle. This Note will recommend that the FDA adhere to the crucial precautionary principle to ensure the effects of a new GE product, such as AquAdvantage, are safe for the environment before the effects of an unknown product cause irreversible damage.

I. BACKGROUND: A HISTORY OF GE SALMON AND THE PUBLIC RESPONSE

AquaBounty engineered a fast-growing, genetically engineered salmon by combining DNA from three distinct species: Atlantic salmon, deep-water ocean eelpout, and Pacific Chinook.[23] Together, the three

21. Complaint for Declaratory and Injunctive Relief, Inst. For Fisheries Res. v. Burwell, No. 3:16-cv-01574 (N.D. Cal. March 30, 2016) [hereinafter Fisheries A]. The Inst. for Fisheries Resources case has several pretrial motions that are cited to in this Note. To ensure clarity, each case has been labeled with a letter to distinguish between the various motions.

22. AquaBounty Techs., Inc., Quarterly Report (Form 10-Q) (Mar. 31, 2017) https://www.sec.gov/Archives/edgar/data/1603978/000160397817000035/aqb10-q2017x03x31.htm [https://perma.cc/7H5X-ZCY6].

23. *Genetically Engineered Salmon: What You Should Know,* EARTHJUSTICE (Sept. 1, 2016), http://earthjustice.org/features/what-you-should-know-about-ge-salmon?utm_source=crm&utm_content=blurb&curation=newsletter [https://perma.cc/93EG-ARU4] (The scientific names for the

species created a salmon that reaches maturity in half the time and is significantly larger than its non-GE Atlantic salmon counterpart.[24] The GE salmon consists of a growth hormone gene from the Chinook salmon to shorten the overall growth period and has been designed in a specific way that renders the salmon 98.9% sterile.[25]

A. The Development of AquAdvantage Salmon

In 1995, AquaBounty Technologies, Inc. submitted a proposal to the FDA, spurring a twenty year review process before ultimately receiving the approval last year to go forward with the production of AquAdvantage salmon.[26] Because AquAdvantage salmon is not a GE animal product intended for use in pharmaceuticals,[27] it is subject to approval as a New Animal Drug Application (NADA).[28] NADAs are submitted to the FDA and the Center for Veterinary Medicine to be evaluated for safety.[29] Previously under NADA, products such as tick control medication and pain medication have been approved for use on dogs.[30] No NADA approved product has ever gone on to be consumed directly by humans in the way AquAdvantage salmon would be. The AquAdvantage salmon is the FDA's first approval of a genetically engineered salmon for

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three species used to create AquAdvantage salmon are as follows: *Salmo salar, Macrozoarces americanus,* and *Oncorhynchus tshawytscha*. The Pacific Chinook salmon and the Atlantic are two separate species of salmon.).

24. FDA Environmental Assessment, *infra* note 25, at 1; Jim Kozubek, *FDA Decision Will Lead to First Ever Genetically-Modified Animal for Consumption,* TPM IDEA LAB (Oct. 10, 2011, 2:00 PM), http://talkingpointsmemo.com/idealab/fda-decision-will-lead-to-first-ever-geneticallymodified-animal-for-consumption [https://perma.cc/PZY2-EBK9].

25. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., AQUADVANTAGE SALMON ENVIRONMENTAL ASSESSMENT 101 (2015), https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM466218.pdf [https://perma.cc/DJ7H-HVVS].

26. HAROLD F. UPTON & TADLOCK COWAN, CONG. RES. SERV., R43518, GENETICALLY ENGINEERED SALMON (2015). For background, see *id.* at 8–10.

27. Pharmaceuticals are included under the definition of "drug" in the Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 321(g)(1).

28. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: REGULATION INTENTIONALLY ALTERED GENOMIC DNA IN ANIMALS 15 (2017) https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf [https://perma.cc/D8U9-6R4L]. The current draft can be found at 82 Fed. Reg. 17,844. Originally, Guidance 187 was titled "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs" and published in 2009. The FDA has since renamed it and republished it to the Federal Register for public comment.

29. CTR. FOR VETERINARY MED., U.S. FOOD & DRUG ADMIN. FINDING OF NO SIGNIFICANT IMPACT, AQUADVANTAGE SALMON (Nov. 12, 2015), https://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM466219.pdf [https://perma.cc/9CQM-AXGS].

30. *Recent Animal Drug Approvals*, U.S. FOOD & DRUG ADMIN. (May 01, 2017), https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/ucm363948.htm [https://perma.cc/4G43-AXP9].

consumption in the United States and the only approved GE animal in the world considered safe enough to eat.[31]

By 2009, AquaBounty provided the FDA with all of the necessary studies and in the following year, the NADA was officially evaluated by the agency to determine whether the new drug is safe and effective for its intended use.[32] On September 3, 2010, the FDA declared AquAdvantage salmon safe for human consumption as wild Atlantic salmon.[33] The FDA released its environmental assessment and official finding that GE salmon pose no significant risk to the environment on December 26, 2012, for public comment.[34] The assessment received more than 400,000 comments during the comment period (largely opposing the FDA's finding) but within a few months, reached well over 1.5 million negative comments in total.[35] The concern expressed in those comments was not incorporated into the Final Rule.

On November 19, 2015, a letter stating the approval for use of AquAdvantage salmon was delivered to the CEO of AquaBounty Technologies, Inc.[36] and the Final Rule was published in the Federal Register shortly after.[37]

B. Environmental Advocates and Public Opposition

Two major environmental non-profit organizations are responsible for generating public awareness and identifying the problems surrounding AquAdvantage salmon: The Center for Food Safety[38] and Earthjustice,[39]

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31. FINDING OF NO SIGNIFICANT IMPACT, *supra* note 29.

32. GUIDANCE FOR INDUSTRY, *supra* note 28, at 13. Effectiveness of an article intended to alter a characteristic of an animal is demonstrated by showing that the genetically engineered animal has the claimed altered characteristic. Additionally, the FDA requires the manufacturer to submit studies discussing the safety and effectiveness of the new animal drug and what risks it may pose to human health and/or environmental health.

33. *See* Andrew Pollack, *Modified Salmon is Safe, F.D.A. Says*, N.Y. TIMES (Sept. 3, 2010), http://www.nytimes.com/2010/09/04/health/policy/04salmon.html.

34. Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Availability, 77 Fed. Reg. 76,050 (available for public comment Dec. 26, 2012) (codified at 80 Fed. Reg. 73,104).

35. Press Release, Earthjustice, Nearly 1.5 Million Objections to Genetically Engineered Salmon Filed with FDA (Apr. 25, 2013) http://earthjustice.org/news/press/2013/nearly-1-5-million-objections-to-genetically-engineered-salmon-filed-with-fda [https://perma.cc/WTK4-FD9F].

36. Bernadette M. Dunham, FDA, Letter to Dr. Ronald Stotish, AquAdvantage Salmon Approval Letter and Appendix, NADA 141-454 (Nov. 19, 2015), https://www.fda.gov/AnimalVeterinary/ucm466214.htm [https://perma.cc/7Q4B-PBYN].

37. FDA Final Rule, New Animal Drugs in Genetically Engineered Animals, 80 Fed. Reg. at 73,104.

38. CENTER FOR FOOD SAFETY, http://www.centerforfoodsafety.org/# [https://perma.cc/KAA7-THYD].

39. EARTHJUSTICE, http://earthjustice.org (last visited May 30, 2017) [https://perma.cc/YATC-EFD5].

located in Washington, D.C. and San Francisco, respectively. The organizations are two of the primary named plaintiffs in the lawsuit filed against the FDA, joined by the Center for Biological Diversity, Friends of the Earth, and Food and Water Watch.[40] Both organizations involved have not only brought a legal challenge to the AquAdvantage ruling but have actively engaged the public to oppose the rule throughout the entire twenty-year review process. To date, over two million people have submitted comments in opposition to GE salmon.[41]

Critiques directed at the FDA and AquaBounty span far and wide, from environmental advocates claiming that "[the] federal government agencies are ill-equipped to handle genetically engineered animals"[42] to influential retailers announcing their refusal to stock the GE salmon out of concern for food safety and environmental impact to wild salmon runs.[43] The national campaign launched by the Center for Biological Diversity helped yield a large number of the public comments and signatures posted to the Federal Register following the FDA's decision.[44] The Center for Food Safety created a platform for grocers, restaurateurs, and other food suppliers to pledge against buying, selling, or serving genetically engineered salmon in their establishments.[45] Earthjustice continues to oppose the ruling in court while also educating consumers about the food safety concerns, the environmental impact, and the labeling issues surrounding GE salmon.[46] In addition to the millions of public comments received opposing the issue, several news sources, as well as politicians

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40. *See* Fisheries A, *supra* note 21.

41. *See Genetically Engineered Salmon*, *supra* note 23.

42. 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) (quoting Dana Perls, food and technology campaigner at Friends of the Earth), 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=.3ac90b4ffd70 [https://perma.cc/5DJU-J45F].

43. Madelyn Kearns, *Here are the Retailers Who Won't Sell AquaBounty's GM Salmon*, SEAFOOD SOURCE (Nov. 23, 2015), http://www.seafoodsource.com/news/foodservice-retail/here-are-the-retailers-who-won-t-sell-aquabounty-s-gm-salmon [https://perma.cc/4KEF-6ZGJ].

44. *See* FDA Final Rule, New Animal Drugs in Genetically Engineered Animals, 80 Fed. Reg. at 73,104

45. Press Release, Ctr. for Food Safety, Costco Will Not Sell GMO Salmon (Nov. 24, 2015) http://www.centerforfoodsafety.org/press-releases/4141/costco-will-not-sell-gmo-salmon [https://perma.cc/3ATP-TK3Z]; *see also Join the Campaign to Stop GE Fish*, CTR. FOOD SAFETY, http://www.centerforfoodsafety.org/issues/309/ge-fish/join-the-campaign-to-stop-ge-fish [https://perma.cc/ES5E-VG9K].

46. In July 2013, the New York Times conducted a poll of its readers asking their opinion on whether GE food should be labeled in the grocery store. An overwhelming 93% of readers stated foods should be identified and 75% expressed concern with genetically engineered foods. *See* Allison Kopicki, *Strong Support for Labeling Modified Foods*, N.Y. TIMES (July 27, 2013) http://www.nytimes.com/2013/07/28/science/strong-support-for-labeling-modified-foods.html. *See generally Genetically Engineered Salmon*, *supra* note 23.

on either side of the aisle, added their support for the environmental advocates challenging the FDA.[47] Senator Lisa Murkowski spoke out in response to the FDA's announcement of the final rule, stating that she was "livid at the FDA's announcement to approve genetically engineered 'salmon'—what seems to be more science experiment than fish or food."[48]

C. Salmon's Day in Court

The Center for Food Safety, Earthjustice, and other environmental groups collectively filed a lawsuit challenging the FDA's approval of AquAdvantage salmon. They alleged that the Food, Drug, and Cosmetic Act (FDCA) does not grant authority to the FDA to regulate GE animals.[49] The plaintiffs challenged the validity of the 2009 Guidance for Industry declaration, and claimed that it was inadequate on the grounds that "it fails to consider environmental risks."[50] The claim also included a criticism of the FDA for failing to conduct an environmental impact statement as required by the National Environmental Policy Act (NEPA) to consider the "risk that man-made salmon could escape from facilities, interbreed with wild salmon, and compete with other animals for food and space."[51] The injunction against the FDA and the Fish and Wildlife Service was filed on March 30, 2016 in the United States District Court for the Northern District of California.[52]

Later, on August 30, 2016, the court granted the respondent's motion to dismiss on the grounds that a challenge may not be brought against EPA's "no effect" determination to endangered salmon because it was not a final agency action.[53] The court reasoned that the responses offered from the government were not final action because they were "purely advisory and lacked direct and appreciable legal consequences."[54] For the plaintiffs to bring a claim under the Administrative Procedure Act, the action must be a final agency action.[55] The court went on to say that the "no effect"

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47. *See supra* text accompanying note 46; *see also* William Yardley, *Genetically Engineered Salmon Is Fit For Dinner, FDA Says in First Decision of its Kind*, L.A. TIMES (Nov. 19, 2015), http://www.latimes.com/nation/la-na-sej-gmo-salmon-20151120-story.html [https://perma.cc/9AFC-NBK3].

48. Yardley, *supra* note 47 (quoting U.S. Senator Lisa Murkowski).

49. *See* Fisheries A, *supra* note 21. The lawsuit was filed under the Administrative Procedure Act, which grants a right of judicial review to a person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action. 5 U.S.C. § 702 (1976).

50. Fisheries A, *supra* note 21, at 11, 12.

51. *Id.*

52. *Id.*

53. Order for Motion to Dismiss, Inst. for Fisheries Res. v. Burwell, No. 16-cv-01574-VC (N.D. Cal. Aug. 30, 2016) [hereinafter Fisheries B].

54. *Id.* at 2.

55. 5 U.S.C. § 704. *See generally* Fisheries B, *supra* note 53.

determination may be argued as an arbitrary and capricious value by the plaintiffs at a future hearing, but that the claim was not valid in that proceeding.[56]

Litigation has continued with U.S. District Court Judge Chhabria delivering the most recent judgment on January 10, 2017.[57] The court granted the plaintiff's motion to compel the government to produce materials and documents related to the case, claiming that the administrative record was incomplete.[58] The judge concluded that no privilege applied to the materials and documents; therefore, the government must release all documents related to the agency's approval of AquAdvantage salmon.[59] The significance of the decision is twofold—the judicial system has signaled to agencies that they expect transparency of their approval process; and the ruling opens the door for further enforcement that proper evaluation of potential risks is completed before approving future GE products.

II. REGULATORY FRAMEWORK

Historically, Congress never considered the regulation of food genetically engineered in labs; therefore, no designation was made for which agency would hold proper jurisdiction to regulate GE products. When engineered corn and other major crops were increasingly used, the United States entered the era of biotechnology, and policymakers drafted regulations to cover this scope of new foods.

A. Regulatory Authority for the FDA

Biotechnology and the engineering of genetically engineered foods became popular in the 1980s; this pressured the White House to create the Coordinated Framework for Regulation of Biotechnology in 1986.[60] The Coordinated Framework identified three agencies—the U.S. Department of Agriculture, the Environmental Protection Agency, and the U.S. Food and Drug Administration—to share the regulatory responsibilities of biotechnology; the FDA was charged with evaluating food safety issues for all genetically engineered products.[61] The legislation most importantly

56. Fisheries B, *supra* note 53, at 3.

57. Order to Compel Completion of Administrative Record Inst. For Fisheries Res. v. Burwell, No. 16-cv-01574-VC (N.D. Cal. Jan. 10, 2017) [hereinafter Fisheries C].

58. *Id.* A complete administrative record includes all documents and materials directly or indirectly considered by agency decision-makers.

59. *Id.*

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

61. For the purposes of this Note, only the role of the FDA will be discussed in detail because the roles assigned to the Dept. of Agriculture and the EPA do not include GE animals. *Id.* at 23, 303.

states that GE products are not inherently riskier than their natural analogs and, therefore, GE products can be adequately regulated by the pre-existing statutory and regulatory structure.[62]

The category of genetically engineered plants and animals was not included in the original text outlining the scope of products subject to FDA regulation. The term GE is applied to any plant, crop, or animal once their genetic material has been modified using rDNA techniques to produce a new trait, such as reaching a larger adult size or a faster growing rate.[63] When GE crops began to appear on the market, the FDA relied on an inventive interpretation of the FDCA to claim regulatory authority over the new plant and crop products. Congress enacted the FDCA in 1938, granting the FDA authority to oversee the safety of food, drugs, and cosmetics.[64] Specifically, the FDA relied on language in Section 409 to regulate GE plants; the agency interpreted "food additives" to encompass genetic material as part of the definition.[65] The provision defines food additives as "any substance intended for the use in food, that may reasonably be expected to become a component of food, or that may otherwise affect the characteristics of food."[66]

Section 409 goes on to say that FDA approval is not required if the food additive in question is "generally recognized among experts to be safe under the conditions of its intended use."[67] In 1992, the FDA made its position to industry regarding GE foods blatantly clear: the agency would presume GE plants and crops to be "generally recognized as safe," releasing manufacturers from waiting for the official go-ahead from the FDA before producing their GE products.[68] This places an enormous amount of trust in the industries to produce safe food that meet FDA standards, instead of in the FDA to evaluate the food's safety. To bridge the regulatory gap between GE plants and GE animals, the FDA issued its "Guidance for Industry 187: Regulation of Intentionally Altered Genomic DNA in Animals" to assert primary authority over GE animals in the United States based on logic utilized previously for GE plants and crops.[69]

The broad interpretation of terms for GE plants within the FCDA opened the door for the FDA to extend its authority regulating GE animals, specifically under the "new animal drug" provision. A "new animal drug"

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62. *Id.* at 23, 306.

63. *See* GUIDANCE FOR INDUSTRY, *supra* note 28.

64. Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 (1938).

65. *Id.* § 393 (1938).

66. *Id.* § 393(s).

67. *Id.*

68. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

69. *See* GUIDANCE FOR INDUSTRY, *supra* note 28.

is defined as "any drug intended for use in animals other than man;"[70] the term "drugs" is defined in the Act as "articles (other than food) intended to affect the structure or any function of the body of man or other animals."[71] These definitions, along with the classification of GE products, provide the language the FDA uses to include GE animals within the scope of its regulatory authority.[72] Specifically, the rDNA techniques used on a GE animal product to alter the structure or function of the natural animal, regardless of the intended use of products that may result from the production of the GE animal, satisfies the definition of "drug;"[73] analogous to the application implored by the FDA in order to regulate GE plants, the agency stretched the regulation's language to work for industry applications.

A new animal drug will not be considered safe by the FDA until it has approved a NADA, which will determine whether the new animal drug is safe and effective for its intended use.[74] The FDCA determines that the safety of a new animal drug is only within "reference to the health of man or animal" and "environmental effects that directly or indirectly affect the health of humans or animals."[75] AquaBounty received approval of its NADA along with an official notice approving AquAdvantage in November 2015.[76] The standard of review does not address negative implications to the environment unless a direct risk to man exists, nor does it provide opportunity for the public to comment on the NADA or even be aware of its filing.[77] When the district court issued a ruling to produce the materials the FDA used in its review process, it was intending to address this exact concern.[78]

When the FDA claimed regulatory authority over AquAdvantage salmon through the new animal drug definition, the agency effectively laid claim on any subsequent GE animal applications in the future. The critique of the FDA's conduct is intended to expose the negative details of the current GE approval process, as well as highlight the alarming issue of the

70. 21 U.S.C. § 393(v).

71. *Id.* § 321(g).

72. *Id.*

73. GUIDANCE FOR INDUSTRY, *supra* note 28, at 6.

74. GUIDANCE FOR INDUSTRY, *supra* note 28, at 13. Effectiveness of an article intended to alter a characteristic of an animal is demonstrated by showing that the genetically engineered animal has the claimed altered characteristic.

75. OFFICE OF SCI. & TECH. POLICY, EXEC. OFFICE OF THE PRESIDENT, CASE STUDY NO. 1: GROWTH-ENHANCED SALMON 14 (2001), https://clintonwhitehouse5.archives.gov/media/pdf/salmon.pdf [https://perma.cc/8U2H-HBVQ].

76. FDA Final Rule, New Animal Drugs in Genetically Engineered Animals, 80 Fed. Reg. at 73,104.

77. *Id.*

78. *See* Fisheries C, *supra* note 57.

FDA setting poor precedent for reviewing future GE animal products. First, the FDA acted quickly to regulate GE animals and, in doing so, was able to create its own set of standards with the goal of approving AquAdvantage. That set of standards will translate as the accepted policy for GE animal applications, creating a greater entanglement of problems in the future if the fundamental issues are not addressed. Second, when presented with a first of its kind GE application, the proper protocol for the FDA would be to table the application and craft the appropriate regulatory scheme, including consultation requirements to the appropriate agencies, before working through the application. Instead, the FDA chose to fashion its regulation around an application and a specific set of circumstances with very little thought to its effect in the future. The FDA ultimately is risking our natural food system, a variety of crucial environments, and human health.

B. The National Environmental Policy Act

In 1970, Congress enacted NEPA to encourage productive and enjoyable harmony between humans and the environment, to promote efforts that prevent or eliminate damage to the environment and biosphere, and to enrich the understanding of the ecological systems and natural resources important to the nation.[79]

Under NEPA requirements, the FDA is obligated to coordinate with any agency whose jurisdiction might be affected by the approval of a NADA and ultimately the GE animal,[80] unless the FDA included NEPA requirements in its initial review.[81] There are four general principles that the FDA's review would need to include: (1) whether the genetically engineered animal poses any threats to humans, animals, or the environment; (2) whether, in the event of a release, the genetically engineered animal poses any more environmental threat than the non-genetically engineered equivalent; (3) whether the disposal of genetically engineered animals poses any threats to humans, animals, or the environment; and (4) whether any other safety issues remain unaddressed by the sponsor.[82]

Under NEPA, a new animal drug applicant is then required to submit an Environmental Assessment (EA) to the agency; the agency will rely on the assessment to determine how an approved product would impact the

79. 42 U.S.C. § 4321 (1970).
80. 21 C.F.R. § 25.15(b) (2015).
81. GUIDANCE FOR INDUSTRY, *supra* note 28, at 7.
82. *Id.* at 8.

environment.[83] An EA can result in two major findings: either the product is categorically excluded, which would be preferred by the FDA as it ends their commitment to NEPA[84] or a possibility of significant risk of adverse environmental impact, which would require the FDA to submit to a more rigorous review process and complete an environmental impact statement.[85]

The EA for AquAdvantage salmon was issued, ending the requirement for ongoing consultation with NEPA. The agency reached its conclusion that there was no significant impact based on evidence that failed to address the many problems with AquAdvantage salmon. The FDA originally classified AquAdvantage salmon as having a "may effect" determination and adjusted the status to "no effect" upon receiving an informal suggestion from Fish & Wildlife to do so.[86] Aside from this suggestion, it is unclear how the "no effect" determination was reached; Judge Chhabria expressed his confusion over the determination by hypothesizing that the agency could have been looking for a way to avoid further obligation to complete the consultation with the FDA.[87] Until recently, the FDA has adamantly refused to provide details of the AquAdvantage approval process and its reasoning for allowing the project to move forward.[88] The recent order to release materials and documents related to the approval of AquAdvantage salmon will begin to provide insight on why the agency acted as it did, and will further provide answers to the questions surrounding the no effect determination.[89] Those materials and documents become crucial to understanding the faults in the current approval process and play a significant role in successful litigation.

Furthermore, the impending agency budget cuts will hinder its ability to produce scientific reports and necessary environmental assessments. If agency funding is drastically reduced, as proposed by the current

83. Typically, an EA will address any area that has a potential to affect the environment and provides evidence or analysis done by the applicant that the agency may review. Most applications will also include mitigation strategies to lessen any environmental impact and present alternatives to the proposed plan of action. 21 C.F.R. § 514.1(b)(14) (2015).

84. *Id.* at § 25.33 (2015).

85. *Id.* at § 25.40. *See generally* 21 C.F.R. § 25.15 (2015).

86. Fisheries B, *supra* note 53, at 1. To be classified as "no effect," the agency is signaling that the product will not significantly affect the human environment. The agency fills out a Finding of No Significant Impact (FONSI) document briefly stating its reasoning and determines that there is no need for an environmental impact statement. In contrast, a "may effect" determination moves the agency forward in conducting further studies about the environmental impact the product may have and how significant the impact is. 21 C.F.R. § 25.41 (1997).

87. Fisheries B, *supra* note 53, at 3.

88. *Id.*

89. Fisheries C, *supra* note 57.

presidential administration,[90] the United States will continue to approve threatening products and move blindly into the consequences from those decisions.

C. Endangered Species Act

Since its enactment in 1973, the ESA has been the cornerstone of conservation efforts to preserve animals, plants, and ecosystems in the United States.[91] The ESA's primary objectives are to prevent species extinction and facilitate the recovery of listed species, while striving to maintain healthy ecosystems and a vast network of biological diversity.[92]

The U.S. Fish and Wildlife Service and the National Marine Fisheries Service (together, the "Services") oversee and manage the listed plants or animals and marine species, respectively.[93] When a species is considered for listing, the Services use two categories, threatened or endangered, to make its final determination for each particular species.[94] The ESA defines an endangered species as one that is in danger of extinction throughout all or a significant portion of its habitat range, while a threatened species is one that is likely to become endangered in the foreseeable future.[95] Once federal protection has been extended to a species, the Services will designate critical habitat boundaries, a recovery plan, and any other necessary protections that will aide in the species' revival.[96] To date, the ESA has succeeded in restoring a remarkable 99% of the species listed, making it one of the most effective pieces of environmental legislation in history.[97]

As stated in the introduction of this Note, the Atlantic salmon was first listed as endangered on November 17, 2000.[98] The Services identified

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90. Press Release, The White House Office of the Press Secretary, Press Briefing by OMB Director Mick Mulvaney Previewing the President's FY18 Budget, (Mar. 15, 2017, 11:27 AM) https://www.whitehouse.gov/the-press-office/2017/03/16/press-briefing-omb-director-mick-mulvaney-previewing-presidents-fy18 [https://perma.cc/VNL7-XESF]; *see also* Hiroko Tabuchi, *What's at Stake in Trump's Proposed E.P.A. Cuts*, N.Y. TIMES (Apr. 10, 2017), https://www.nytimes.com/2017/04/10/climate/trump-epa-budget-cuts.html?_r=0.

91. Endangered Species Act, 16 U.S.C. §§ 1531–44 (1973).

92. *Id.* § 1532(3).

93. *Id.* § 1537 (8)(A).

94. *Id.* §§ 1531–44.

95. *Id.* § 1532(6).

96. SARAH MATSUMOTO ET AL., EARTHJUSTICE & ENDANGERED SPECIES COALITION, CITIZEN'S GUIDE TO THE ENDANGERED SPECIES ACT, 18–24, (2003) [hereinafter CITIZEN'S GUIDE], http://earthjustice.org/sites/default/files/library/reports/Citizens_Guide_ESA.pdf [https://perma.cc/KPE4-7A76].

97. Robert B. Semple, Jr., *The Law that Saved the Bald Eagle*, N.Y. TIMES (Dec. 31, 2013) *reprinted in* A WILD SUCCESS: AMERICAN VOICES ON THE ENDANGERED SPECIES ACT AT 40 2 (Feb. 2014), http://www.biologicaldiversity.org/campaigns/esa_wild_success/pdfs/A_Wild_Success.pdf [https://perma.cc/7SZC-TW7R].

98. *See* 50 C.F.R. § 224.101 (2009).

the Gulf of Maine as critical habitat for salmon due to its quality spawning grounds.[99] Coincidentally, the designated habitat overlaps with the location of AquaBounty's production facilities in southeastern Canada. The location has prompted a majority of the criticism directed at AquAdvantage salmon because it poses adverse risk to a critically endangered species; the significance of the production location to the endangered salmon population will be discussed in detail in section IV.

Section 7 of the ESA designates the responsibility to consult with either FWS or NOAA fisheries whenever a federal agency is authorizing a rule that may impose harm to endangered or threatened species.[100] This provision is crucial to protecting sensitive species from any future activity that could adversely affect individuals or their designated critical habitat. The principal takeaway from this section of the ESA is the conservation provision which requires the agency, with the help of the Services, to develop a biological opinion and plan that will preserve listed species from harmful conduct.[101] Ultimately, the agency is charged with the responsibility to insure that any action authorized, funded, or carried out is not likely to jeopardize the continued existence of any endangered species or threatened species, or result in the destruction or adverse modification of habitat of such species.[102] The biological opinion is meant to act as guidance for rule makers to conform agency action to the parameters of endangered species.

The take prohibition in Section 9 outlines one of the enforcement clauses provided by the ESA.[103] Take is defined as "to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct" to any individual or population of an endangered or threatened species.[104] Other interpretations have expanded this definition to include not only direct harm to the species, but also indirect harm by impairing the habitat in a way that may cause death or injury by disrupting feeding, breeding, or essential behavior patterns.[105] On several occasions, the Supreme Court has upheld the Services determination of harm[106] stating, "the ESA's prohibition against harming a species included habitat destruction severe enough to adversely affect a

99. *Id.*
100. CITIZEN'S GUIDE, *supra* note 96, at 29.
101. 16 U.S.C. § 1536 (1973).
102. *Id.* § 1536(a)(2).
103. *Id.* § 1538(1)(A)–(D).
104. *Id.* § 1532(19).
105. *See* CITIZEN'S GUIDE, *supra* note 96.
106. Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or., 515 U.S. 687 (1995).

listed species as a whole" and, as a result, industry challenges to this definition have failed.[107]

If AquaBounty follows through with their production plans, their actions most certainly will constitute a takings claim with respect to the harm caused to the endangered Atlantic salmon populations in Maine. Once a species has been listed on the ESA, the protections in place do not allow for any harm to be inflicted upon the species; evidence of disrupted breeding patterns or death to one individual will trigger the statute's safeguards and immediately result in a violation. The failure to account for the outward harm to endangered salmon and their designated habitat is a major oversight and will most certainly result in lawsuits once harm is inflicted. The Atlantic salmon populations face immediate danger if AquaBounty's facilities on Prince Edward Island, Canada are built;[108] if successful, AquaBounty may eventually build facilities in the Pacific Northwest, placing the four populations of endangered salmon at risk.

III. ACROSS THE STOCK POND: THE EU REGULATORY STRUCTURE

In 2001, the European Council adopted Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms.[109] Pursuant to Article IV, applicants are required to apply and submit an environmental risk assessment in order to gain the Council's approval for use of GE products, as well as submit an application to each Member State in which they wish to market genetically modified products.[110] The Member States will then designate competent authorities to examine notifications of GE products, and establish inspection measures.[111] Applicants must also be able to ensure traceability of marketed products. Subsequent to the Directive Order, debates arose all over Europe regarding GE corn and soy bean products, which were largely focused on labeling requirements and fighting the negative public opinion regarding GE products.[112] Directive

107. Palila v. Haw. Dept. of Land & Nat. Res., 639 F.2d 495, 497 (1981). Following *Palila*, the Secretary of Interior issued a new definition of harm that included habitat modification that injures wildlife by impairing essential behavioral patterns such as breeding, feeding, or sheltering, which has become the widely accepted definition of a taking.

108. *See infra* note 159 (discussing the impacts on Canadian salmon populations).

109. 2001 O.J. (L 106) 1. This Directive not only states the EU policy on genetically modified organisms in the environment but also repeals the previous Directive from 1990 (90/220/EEC). Furthermore, the EU materials use the phrase GMO, instead of GE, when discussing these products. For consistency and clarity I have edited all terms to be "GE" unless directly quoting EU documents.

110. *Id.* These Member States have the right to object to such marketing within their countries' borders, based on where the testing will occur. Pursuant to Article 16, any EU Member State may "provisionally restrict or prohibit the use of sale of a product if it has justifiable reason that an approved product poses a risk to human health or the environment."

111. *Id.* (L 106) 6.

112. In 1994, a British company began to market genetically modified canola oil and met severe backlash during its approval process before gaining approval in 1997. *See* David Vogel & Diahanna

2001/18/EC further requires consultation with its scientific risk agency in cases where a competent authority raises objections regarding the risks of the GE product to human health or the environment, and in which the assessment report of the authority that received the notification indicates that the GE product should not be released onto the market.[113]

The European Food Safety Authority (EFSA) is an agency in the EU that provides independent scientific advice and comments on existing and emerging risks to food safety. The EFSA published guidance on the environmental risk assessment of GE animals, which provided information for applicants and risk assessors on how to conduct an ERA of living GE animals placed on the EU market.[114] The document outlines three primary aspects that should be included for a thorough risk assessment: (1) applicants must complete a six-step assessment procedure that will identify potential hazards and the extent of human, animal, and environmental exposure to them, consistent with EU legislation; (2) applicants must address seven areas of potential risk for GE animals; and (3) applicants must consider viable alternatives, including cross-cutting considerations, surrogate animals, and recommendations specific to the environment into which GE animals are likely to be released.[115] This process ultimately includes a comment period and consideration of the societal and economic aspects of approving a GE animal in the EU; however, the EFSA solely examines the risk factor of the decision.[116]

The fundamental theme throughout the EU's regulatory system is the precautionary principle, an approach that guarantees a high standard of environmental protection through preventative decision-making in the case that risks are reasonably suspected.[117] Encouragement for nations to adopt the precautionary approach is well established in the UN Global Compact. Rio Principle 7 specifically addresses the importance of

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Lynch, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics,* COUNCIL ON FOREIGN REL. 9–11 (Apr. 5, 2011), http://www.cfr.org/agricultural-policy/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688 [https://perma.cc/6RWF-NWVV]. Additionally, corn and soybean crops met opposition in the late 1990s for similar reasons. *Id.* at 10.

113. Directive 2001/18/EC at (L 106) 14.

114. *Genetically Modified Animals,* EUR. FOOD SAFETY AUTH., https://www.efsa.europa.eu/en/topics/topic/gmanimals [https://perma.cc/ATF2-X5M4].

115. *Id.* In the second step, the EFSA expands on the seven potential risk areas they require applicants to consider: (1) persistence and invasiveness of the GE animal, including vertical gene transfer; (2) horizontal gene transfer; (3) interactions of the GE animal with target organisms; (4) interactions of the GE animal with non-target organisms; (5) environmental impacts of the specific techniques used for the management of the GE animal; (6) impacts of the GE animal on biogeochemical processes; and (7) impacts of the GE animal on human and animal health. *Id.*

116. *Id.*

117. *Commission White Paper on Precautionary Principle*, COM(2000) 1 Final (Feb. 2, 2000).

implementing preventative measures over remedial ones.[118] The concept of the precautionary principle is easily distinguished from what is known as the principle of prevention because of the effort to apply caution to scientific information that is either incomplete or inconclusive.[119] In contrast, the principle of prevention allows action first and reaction only when something goes awry; currently, the United States operates under the latter approach.[120]

The first formal inclusion of the principle was published in 2000 in the European Commission's documents, establishing the use of the precautionary principle: "[W]here a full risk assessment is not possible, measures should be based on the precautionary principle" and only applied after the maximum possible scientific assessment of the risks.[121] Within the Communication are the guidelines for applying the principle to regulation, stating that measures based on the precautionary principle should be

> [p]roportional to the chosen level of protection, non-discriminatory in their application, consistent with similar measures already taken, based on an examination of the potential benefits and costs of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), subject to review in the light of new scientific data, and capable of assigning responsibility for producing the scientific evidence necessary for a more comprehensive risk assessment.[122]

In the case of GE products, the EU and its environmental agencies have been able to gain a wider breadth of knowledge about how the proposed animal or plant product will impact human health and the environment, as well as provide a greater level of assurance to the EU population that food is held to a high safety standard, despite its new genetic makeup.

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118. U.N. Conference on Environment and Development, *Rio Declaration on Environment and Development*, U.N. Doc. A/CONF.151/26 (Vol. I), annex I (Aug. 12, 1992); *see also* The Ten Principles of the UN Global Compact, *Principle Seven: Environment*, UNITED NATIONS GLOBAL COMPACT [hereinafter *Principle Seven*], https://www.unglobalcompact.org/what-is-gc/mission/principles/principle-7 [https://perma.cc/37J4-2QWA].

119. *Principle Seven*, *supra* note 118.

120. Arie Trouwborst, *Prevention, Precaution, Logic and Law: The Relationship Between the Precautionary Principle and the Preventative Principle in International Law and Associated Questions*, 2 ERASMUS L. REV. 105, 110 (2009).

121. *Commission White Paper on Precautionary Principle*, *supra* note 117, at 23–24.

122. *Id.* at 3.

The United States and Canada remain the only two countries to approve applications for AquAdvantage salmon.[123] The former Chair of the European Food Safety Authority GMO Panel spoke on the possibility of AquaBounty filing for approval in the EU market following the FDA approval for U.S. markets in 2015, expressing great concern for the notion and holding the opinion that the GE salmon had not had the rigorous review it ought to have been subjected to:

> My view is that if an application were to be made for such GM salmon to be released in Europe, then the risk assessment would require considerably more data to demonstrate the efficacy of the induced sterility in these GM salmon than were required by the Food and Drug Administration.[124]

Health Canada, the Canadian agency equivalent to the FDA, approved AquAdvantage salmon on May 19, 2016.[125] In defending its decision, the agency stated that the GE salmon is "identical to other farmed salmon" and assured Canadians opposing the approval that their scientists conducted a thorough analysis of all potential dangers.[126] Similar to the court proceedings currently underway in the U.S., several Canadian environmental groups attempted to block AquaBounty, Inc., but were unsuccessful in their efforts.[127] These groups echoed the same concerns that Earthjustice and the Center voiced in regards to escape and endangerment to the endangered Atlantic salmon populations.[128] As far as the precautionary principle is concerned, Health Canada has faced legal challenges to its past decisions on the basis that the agency has ignored its commitment to utilize the precautionary approach.[129] Petitioners to the

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123. Andrew MacKendrick, *Health Canada and Canadian Food Inspection Agency Approve AquAdvantage Salmon,* AQUABOUNTY (May 19, 2016), https://aquabounty.com/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon/ [https://perma.cc/6RM3-UW6H].

124. Sarah Knapton*, First Genetically Modified Salmon Cleared to Enter Human Food Chain,* TELEGRAPH UK (Nov. 19, 2015) (quoting Dr. Joe Perry), http://www.telegraph.co.uk/news/science/science-news/12006398/First-genetically-modified-salmon-cleared-to-enter-human-food-chain.html.

125. Press Release, Health Canada, Health Canada and Canadian Food Inspection Agency Approve AquAdvantage Salmon (May 19, 2016), https://www.canada.ca/en/health-canada/news/2016/05/health-canada-and-canadian-food-inspection-agency-approve-aquadvantage-salmon.html [https://perma.cc/3F5V-EMWL].

126. *Id.*

127. Ann Hui, *Genetically Modified Salmon Approved for Consumption in Canada*, GLOBE & MAIL (May 19, 2016), http://www.theglobeandmail.com/news/national/health-canada-approves-genetically-modified-salmon-as-safe-for-consumption/article30094235/ [https://perma.cc/W69R-NUXW].

128. Food & Agric. Org. of the U.N., Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals, U.N. Doc. CAC/GL 68-2008 (2008).

129. Brief for Petitioner, Woodcock v. Health Canada, Env. Petition No. 289 (2009) http://www.oag-bvg.gc.ca/internet/English/pet_289_e_33553.html [https://perma.cc/68DH-W3BK].

Auditor General of Canada allege that Health Canada clearly abandoned its promise to adopt the precautionary principle in many recent decisions, including the decision to approve AquaBounty's GE salmon.[130]

IV. A NEW APPROACH TO THE REGULATION OF GE ANIMALS

The approval process the FDA relies on to regulate GE products has led us to a market that includes AquAdvantage salmon and opened the door for any number of GE animal products to enter the market in the future. As many environmental groups and health advocates have argued, the regulatory system needs to (1) consist of a more comprehensive consultation with the appropriate environmental agencies; (2) include a more robust use of the best available science that analyzes adverse impacts a product may cause; and (3) take a conservative approach when ruling on a proposed GE animal. Two leading biologists published a comment on the Federal Register, stating that they had "found major scientific inadequacies in this EA that set an unacceptably low bar for the scientific basis of future EA or EIS documents" and further expressing concern for the future approval of GE animals with "more ecologically disruptive traits."[131] This Note proposes a change to the FDA approval process that aligns with the EFSA requirements and includes a strategy that U.S. environmental legislation is already familiar with.

A. The Precautionary Principle

As discussed above, the core of the EU regulatory framework for environmental matters is the precautionary principle, a concept that aims to prevent harm before it occurs; prevention is key to enacting effective environmental legislation considering most of the injury sustained is permanent and not easily remedied with money. In contrast to the EU framework, the precautionary principle appears only a handful of times in U.S. regulation. For example, the FDCA bans the use of any food additive if tests reveal that it caused cancer in either laboratory animals or humans on the grounds that such chemicals could cause irreversible harm to consumers.[132]

Health Canada has received official petitions to their environmental division, and this one in particular alleges that Health Canada is not adhering to the precautionary principle.

130. *Id.*

131. Anne Kapuscinski & Fredrik Sundström, *Comments on Docket No. FDA-2011-n-0899 Draft Environmental Statement for AquAdvantage Salmon and Prelim Finding of No Significant Impact, Dated 4*, SEMANTIC SCHOLAR (2013), https://pdfs.semanticscholar.org/b803/22d30525c8fa85e5d7270e179b2b920eb0e5.pdf?_ga=2.215775572.233515052.1500527649-1344995263.1500527649 [https://perma.cc/ZR83-N6EC].

132. 21 U.S.C. § 348(c)(3)(A) (2012).

Successively, the EPA uses the principle in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to restrict the sale, distribution, or use of any pesticide unless granted express approval prior to entering the market.[133] Before the EPA may authorize a pesticide, the claimant must show that using the pesticide will not result in unreasonable, adverse effects on the environment.[134] In 1996, the Food Quality Protection Act (FQPA) was amended to require the re-examination of pesticides under its new risk-based registration, specifically to identify potential impacts resulting from the use of pesticides.[135] The FQPA marks the accepted use of the precautionary approach for risk management and the reliance on best available scientific data to approve use only if "there is a reasonable certainty that no harm will result," adding a great deal of protection to the environment.[136] Congress enacted the above policies to shift the burden of proof to industry; Congress did so to require industry to prove the safety of their products in order to prioritize a healthy environment and to slow the degrading effects to the global environment. By only reacting to environmental disasters instead of preventing injury, we have effectively expedited the negative implications to our environment.

B. A Case Study

When utilized, the precautionary principle is one of the most robust clauses in environmental legislation; it justly imposes a duty upon the industry and individual manufacturer to prove its product poses no significant threat or risk of safety to consumers and the environment. A precautionary approach toward risk regulation was enforced through several modern-era judicial decisions. *Ethyl Corp. v. EPA* marks the cornerstone interpretation of how the precautionary principle has an impact on industry; the court in *Ethyl Corp.* ruled that preventing harm is within the agency's discretion when significant risk exists.[137] As upheld consistently by federal courts, "where existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the

133. 7 U.S.C. § 136(a) (1996).

134. The term "unreasonable adverse effects on the environment" is defined as (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a ruse of a pesticide in or on any food inconsistent with the standard under section 346(a). Administrator is also required to consider the risks and benefits of pesticide exposure. *Id.* § 136(b).

135. 7 U.S.C. § 136a(c)(2)(B)(v) (1996).

136. 21 U.S.C. § 346a(b)(2)(A)(ii) (2012).

137. Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1 (D.C. Cir. 1976).

basis of available information."[138] The ruling in *Ethyl Corp.* certainly extends to the situation arising around AquAdvantage salmon; GE animals are a previously unregulated area of law and contradicting science suggests that serious negative side effects exist—calling on the agency to take a precautionary approach.[139] To rule on removing lead from gasoline, the court reached its conclusion by weighing public interest against the gasoline company's interests, effectively lowering the proof of harm the EPA was required to demonstrate.[140] *Ethyl Corp.* established the need to allow environmental agencies to act preventatively while regulating industry, stating, "[a]waiting certainty will often allow for only reactive, not preventative, regulation."[141] Another court followed the example set out by *Ethyl Corp.* and held in *Sierra Club v. Sigler* that if "an agency is evaluating significant adverse effects on the human environment in an environmental impact statement and there are gaps in relevant information or scientific uncertainty, the agency shall always make clear that such information is lacking or that uncertainty exists."[142] *Sigler* gave way to the interpretation that the environmental impact provision of NEPA also required a worst-case analysis on the grounds that it was needed to assist decision-making when scientific uncertainty exists.[143]

Where there are threats of irreversible damage, a rule based on a lack of full scientific certainty should not be used as justification for postponing cost-effective measures, thus accelerating further environmental and public health degradation. In the case of AquAdvantage salmon, the full review of the product was not completed to the extent required by environmental agencies.[144] This is in part due to the fact that the FDA is simply unfit to rule on the safety of animals; their interpretation that AquAdvantage salmon qualified as a new animal drug was inappropriate, seeing as this specimen is a new species entirely. Moving forward, the FDA must either adopt a system that better analyzes and studies an applicant's product—akin to the precautionary principle—or repeal its regulatory authority over GE animal species. As is, the regulatory structure will lead to devastating effects to our ecosystems, our citizens' health, and our natural resources.

138. *Id.* at 27.
139. *Id.*
140. *Id.* at 54.
141. *Id.* at 25.
142. Sierra Club v. Sigler, 695 F.2d 957, 969 (5th Cir. 1983).
143. Vogel & Lynch, *supra* note 112, at 4.
144. Fisheries A, *supra* note 21.

C. Remaining Questions

While AquaBounty has addressed some of the major criticisms and taken steps to prevent escapes into wild salmon runs, a number of unanswered questions remain as the project moves forward. First and foremost, AquaBounty has failed to consider that salmon escapes are still a significant possibility.[145] If GE salmon escape into wild streams and rivers, there is no recapture plan in place by AquaBounty and it is nearly impossible to recover those individuals.[146] The intermixing of the two distinct salmon species will create competition for resources that the larger GE salmon will easily win; the FDA believes that this is not an unlikely situation.[147] While the two facilities of production are currently in Panama and southeastern Canada,[148] AquaBounty has spoken on several occasions of its intent to open multiple facilities in the United States. On June 13, 2017, AquaBounty acquired its first U.S. fish farm in Albany, Indiana; the facility will support a capacity of 1,200 metric tons of salmon per year.[149] The company expects its first harvest from the Indiana site to be ready by late 2019.[150] The company is moving quickly to establish its presence in U.S. grocery stores,[151] and it is inevitable that GE salmon will come closer to our vulnerable wild populations if production continues to proceed.

Regardless, AquaBounty has already incurred environmental safety violations with only two land-based facilities in operation.[152] In 2014,

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145. *See generally* Rosamond Naylor et al., *Fugitive Salmon: Assessing the Risks of Escaped Fish from Net-Pen Aquaculture,* 55 BIOSCIENCE 427–37 (May 1, 2005).

146. Brettny Hardy, *What Will Happen When Genetically Engineered Salmon Escape Into the Wild?*, EARTHJUSTICE (Apr. 08, 2016), http://earthjustice.org/blog/2016-april/what-will-happen-when-genetically-engineered-salmon-escape-into-the-wild [https://perma.cc/3W65-T9PK].

147. FDA Final Rule, New Animal Drugs in Genetically Engineered Animals, 80 Fed. Reg. at 73,104. *See generally* Naylor, *supra* note 145.

148. *Questions and Answers on FDA's Approval of AquAdvantage Salmon*, U.S. FOOD & DRUG ADMIN. (Dec. 21, 2015), http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm473237.htm [https://perma.cc/9W5J-PTQS].

149. Press Release, AquaBounty, Inc., AquaBounty Acquires Fish Farming Facility in Indiana (June 13, 2017), http://phx.corporate-ir.net/phoenix.zhtml?c=197553&p=irol-newsArticle&ID=2280501 [https://perma.cc/4HAN-HCR2]. AquaBounty purchased facilities from Bell Fish Company for $14 million dollars.

150. *Id.*

151 As of August 4, 2017, Canadian grocery stores began selling AquAdvantage salmon without labeling or otherwise distinguishing the product from non-GE salmon. Jenna Gallegos, *GMO Salmon Caught in U.S. Regulatory Net, but Canadians have eaten 5 tons*, WASH. POST (Aug. 4, 2017) https://www.washingtonpost.com/news/speaking-of-science/wp/2017/08/04/gmo-salmon-caught-in-u-s-regulatory-net-but-canadians-have-eaten-5-tons/.

152. *AquaBounty Fined for Repeated Environmental Violations on Genetically Engineered Salmon*, FOOD & WATER WATCH (Oct. 28, 2014), http://www.foodandwaterwatch.org/news/aquabounty-fined-repeated-environmental-violations-genetically-engineered-salmon [https://perma.cc/95CY-GW39]. Original document available, in Spanish, at: http://

Panamanian officials fined the company for water discharge violations and failing to address a storm-related incident that led to lost salmon.[153] Wenonah Hauter, the Executive Director for Food and Water Watch, made the following statement in the organization's release of the safety report, "FDA has always assured the public that it is checking, monitoring and regulating AquaBounty's production platform to ensure the company can mitigate the well-documented environmental impacts of escaped GE salmon . . . AquaBounty is unwilling or unable to follow basic rules and regulations, and FDA is unable to enforce them."[154] Furthermore, the FDA expressly stated in its Finding of No Significant Impact report that it did not consider the impacts that either facility would have on the surrounding environment and only granted the application because production would not occur on U.S. soil.[155]

Second, while the AquAdvantage salmon are treated to create sterile individuals, the methods are only about 97% effective.[156] When the remaining 3–5% is stacked up to the hundreds of thousands of eggs AquaBounty plans to produce, thousands of fish will be left fertile; this failure to render 100% of its stock sterile creates a greater risk to an already fragile wild salmon population.[157] Finally, whether the claim that GE salmon is actually healthier for human consumption than wild salmon is split by contradicting research; biologists maintain the position that there is little research showing that long-term consumption of fish with added growth hormones is completely safe for humans, while AquaBounty insists the AquAdvantage salmon is a healthier choice. Over the last few decades, reports ranging from the reproductive risks of chemicals in sunscreens to the carcinogens in pesticides applied to crops have been presented to the public; this demonstrates the necessary research of a product to ensure safety before use is routinely omitted from legislative requirements. In these cases, opposition from similar stakeholders had been presented and ignored. The "wait and see approach" the FDA is inclined to utilize for AquAdvantage salmon is not only unsuitable for food but unsubstantiated by the record of past products assumed to be fine.

The threshold question for many scientists, consumers, and environmental advocates opposing GE salmon asks whether the FDA

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www.centerforfoodsafety.org/files/resolucion-arach-071_2014-sancion-a-aquabounty_53203.pdf [https://perma.cc/9AKE-52KF].

153. *Id.*

154. *Id.*

155. FINDING OF NO SIGNIFICANT IMPACT, *supra* note 29, at 3.

156. Tillmann J. Benfey, *Effectiveness of Triploidy as a Management Tool for Reproductive Containment of Farmed Fish: Atlantic salmon* (Salmo salar) *as a Case Study*, 8 REVS. AQUACULTURE, 264–82 (Sept. 2016).

157. *Id.*

ruling has established a dangerous precedent for our food system and what will follow next. By simply following the manufacturers' claims of greener methods and sustainable farming, we are buying into a science-driven food structure and allowing labs to create our nourishment. Submitting to AquaBounty puts into question all other sources of protein consumed in the US; will we now become accustomed to GE cows and farms stocked with chickens three times their normal size?

Pursuant to the ESA and the take prohibition in Section 9, any species of salmon listed under the ESA may not be exposed to foreseeable risks; any caused harm is a direct violation of the ESA.[158] In the immediate future, Atlantic salmon are at risk of harm if the AquAdvantage salmon raised near the Gulf of Maine escape into the bordering designated critical habitat.[159] Assuming AquaBounty will follow through with its plan to build additional production facilities across the U.S., beginning in Indiana, what is to say the four salmon species of the Puget Sound will not soon experience the pressures of AquAdvantage salmon? Considering the millions of consumers and retailers that are vocal about their opposition to GE salmon, will this refusal to buy or sell anything but wild-caught salmon add extra strains to the wavering wild salmon runs? The GE market poses many direct and indirect effects to salmon populations that further put into question the survival of the five endangered species in the U.S.

CONCLUSION

The salmon case study is a disturbing example of the key weakness of the FDA's approach but also serves as a great example of the strengths of the precautionary approach. Public interest and the environment would be better served by a policy shift and the granting of jurisdictional authority to a more qualified agency, with the expertise to determine safety of GE animal products, than the FDA. The precautionary principle is not a novel idea to U.S. legislators; by adhering to the millions of people opposing GE salmon and enacting the approach that ensures all foreseeable and reasonable risks have been addressed, we are more likely to have a healthy environment independent of engineered food sources.

The purpose of environmental law is to protect natural resources even when uncertainty of the long-term effects exists. The lasting

158. *See* 16 U.S.C. § 1532(19) (1973).

159. The production facility in Canada will be located on Prince Edward Island in Ontario County, which borders the state of Maine. According to the designated critical habitat for Atlantic salmon (established in 2009), the boundary reaches the border shared with Canada and puts the AquAdvantage salmon in close geographic proximity to the endangered Atlantic salmon. *See generally Atlantic Salmon Critical Habitat Map*, NAT'L MARINE FISHERIES SERV. (2009), http://www.nmfs.noaa.gov/pr/pdfs/criticalhabitat/atlanticsalmon.pdf [https://perma.cc/C4ZA-RQDE].

consequences of losing species, damaging habitat, and degrading human health all grossly outweigh the benefits of cheaper production today. AquaBounty does not present a solution to address the underlying problem of species extinction caused by unsustainable fishing methods and overfishing. The efforts being made to skirt around these issues ought to instead be spent preserving the natural salmon resource, while still in existence, and in doing so tackle the root of the problem. What needs to happen now goes beyond bigger and faster-growing fish. The AquAdvantage salmon case becomes another important cause to advocate for,[160] especially in light of a presidential administration dedicated to rollback environmental measures.[161] Failure to act on the approval of AquAdvantage salmon places the United States atop a very slippery slope that descends into a food system completely dependent on lab concoctions and processing plants, all at the risk of a healthy environment. We cannot manufacture an entire ecosystem to compensate for the impending damage caused by allowing genetically engineered salmon now.

160. Press Release, United States Senate, Chairman Barrasso: The Endangered Species Act Needs to be Modernized (Feb. 15, 2017), https://www.epw.senate.gov/public/index.cfm/2017/2/chairman-barrasso-the-endangered-species-act [https://perma.cc/5CHQ-P9TW].

161. Press Release, The White House Office of the Press Secretary, Remarks by President Trump at Signing of Executive Order to Create Energy Independence (Mar. 28, 2017), https://www.whitehouse.gov/the-press-office/2017/03/28/remarks-president-trump-signing-executive-order-create-energy [https://perma.cc/UHL6-XSV5].