The Rise of Aquaculture: Is Farmed Salmon a Healthier Alternative than Wild Salmon?

Caleb N. Raspler

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THE RISE OF AQUACULTURE:
IS FARMED SALMON A HEALTHIER ALTERNATIVE THAN WILD SALMON?

Caleb N. Raspler

I. INTRODUCTION
II. OVERVIEW OF SALMON FARMING
   A. Wild Salmon Versus Farmed Salmon Generally
   B. Implications of Salmon Aquaculture in the United States
      1. Human Health Implications
         a. Carcinogens
         b. Toxins
         c. Antibiotics
      2. Environmental Implications
         a. Polluted Waters
         b. Escaped Salmon
         c. Net Pens
III. REGULATORY STRUCTURE
   A. U.S. Environmental Protection Agency
      1. The Clean Water Act
      2. The Resource Conservation and Recovery Act
      3. The National Environmental Policy Act
   B. U.S. Food and Drug Administration
      1. United States Code and the Food, Drug, and Cosmetic Act
      2. Code of Federal Regulations
      3. New Animal Drugs
      4. The National Environmental Policy Act, Revisited
IV. FORWARD THINKING
   A. Whether EPA or FDA Adequately Address Aquaculture Health Concerns
   B. Suggestions for a Healthier Future
      1. Congressional Intervention for Unified Regulations
      3. Genetically Engineered Salmon
V. OVERALL THOUGHTS
THE RISE OF AQUACULTURE:
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Caleb N. Raspler*

Abstract
Increased population led to an increased demand for seafood, ultimately innovating the seafood industry and rise of aquaculture. This technique allows fish, such as salmon, to be farm-raised in controlled conditions in attempts to provide sustainable fish for consumers while allowing wild fish to repopulate. Aquaculture nevertheless initiated environmental and human health concerns, sparking a debate over whether farmed salmon is a healthier alternative than wild salmon. This article discusses such concerns and suggests tools to address them like increased federal agency regulation, congressional intervention, and genetically engineered salmon.

I. INTRODUCTION

United States’ waters once provided bountiful, unlimited resources.1 An increase in population led to a higher public demand for seafood in most diets. This demand is expected to continue increasing.2 Many fish in United States’ waters are now fished at or above its capacity to be

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* Caleb Raspler received his J.D. from California Western School of Law in January 2021. Caleb relocated to Washington, D.C. with ambitions to utilize his experience and passion to aid beneficial environmental policies.
2. Id. at 498; see generally, Arthur Cutillo, Comment, Do Recent Studies Prove that Farmed Salmon Are Toxic? A Commentary on Whether the Current FDA Guidelines Adequately Protect Consumers from Potential Toxins in Farmed Salmon, 16 VILL. ENV’T L.J. 89 (2005).
replenished. Primal methods for seafood consumption, such as taking fish found naturally in the wild, is no longer a sustainable approach; most federally managed fisheries are either stable or declining, and many are currently overfished or subject to overfishing. The amount of overfishing in past decades even caused some fisheries to collapse, raising concerns for the availability of a safe, affordable fish supply.

Beginning in the 1970s, numerous United States’ fisheries reached maximum sustainability. This drew attention to finding a sustainable solution to combat drastic decreases in fish stock and United States resources. Aquaculture—the farming of fish under controlled conditions—sought to alleviate adverse impacts of increased fishing while satisfying growing desires for fish consumption. Although aquaculture has been practiced for thousands of years globally, it has only recently been utilized in the United States. Congress recognized the enormous potential of aquaculture as a food supply for the United States because fisheries were being harvested at unsustainable rates and most United States seafood was imported. Congress declared that it was in the nation’s interest to develop aquaculture and enacted the National Aquaculture Act of 1980 (NAA) to economically encourage aquaculture.

Ever since, aquaculture became a thriving industry within the United States and is now the most rapid form of agriculture in the nation. Current predictions reveal aquaculture will remain one of the fastest growing food-producing techniques within the animal sector. Salmon is currently the most popular farmed fish due to its high global demand and declining wild population. Salmon is also suggested due to its health benefits and lower

3. Rychlak, supra note 1, at 498.
5. LISA HEINZERLING, FOOD LAW: CASES AND MATERIALS 373 (Georgetown University Law Center ed., 2017).
7. Id.
9. Johns, supra note 4, at 683; see also Williams, supra note 8, at 718.
10. Johns, supra note 4, at 687.
11. Id.
12. Rychlak, supra note 1, at 502; see also Johns, supra note 4, at 683.
13. HEINZERLING, supra note 5, at 393.
14. Kara M. Van Slyck, Note, Salmon with a Side of Genetic Modification: The FDA’s Approval of AquAdvantage Salmon and Why the Precautionary Principle is Essential for
mercury levels. Almost a quarter of fish market sales are derived from salmon.

Part I of this Note presents an overview of a comparison between wild and farmed salmon, specifically the health and environmental implications of salmon aquaculture in the United States. Part II addresses the regulatory structure related to salmon and aquaculture in the United States, with respect to the U.S. Environmental Protection Agency (EPA) and U.S. Food and Drug Administration (FDA). Part III discusses whether current regulations and legislation adequately address health and environmental concerns associated with salmon aquaculture and concludes with possible solutions as aquaculture progresses.

II. OVERVIEW OF SALMON FARMING

A. Wild Salmon Versus Farmed Salmon Generally

Salmon is categorized into two types: wild and farmed. While wild salmon only constitutes an estimated ten percent of all salmon consumption in the United States, farmed salmon encompasses the remaining ninety percent. Unlike wild salmon, aquaculture provides consumers with fresh salmon year-round. Additionally, pregnant and breastfeeding women are recommended to pay special attention to local advisories when eating seafood from wild means such as rivers, streams, and lakes due to potential exposure to increased mercury levels. Although salmon is beneficial to human health generally, science reveals that farmed salmon contains notably more cancer-causing chemicals than wild salmon; farmed salmon is likely the most carcinogenic protein source consumed. For this reason, there is much debate whether farmed or wild seafood—thereby encompassing salmon—is healthier than the other.

Biotechnology Regulation, 41 Seattle U. L. Rev. 311, 312 (2017); see also Williams, supra note 8, at 717.
15. Cutillo, supra note 2, at 89.
16. Id.
17. Id.
18. Id.
20. Heinzerling, supra note 5, at 392.
21. Cutillo, supra note 2, at 89.
22. Heinzerling, supra note 5, at 373.
visual breakdown comparing wild salmon to farmed salmon is available online.23

B. Implications of Salmon Aquaculture in the United States

1. Human Health Implications

The human health concerns discussed below explain why consumers should limit their consumption of farmed salmon to once a month.24 It is important to note health concerns associated with farmed salmon are contingent upon the exposure of contaminants based on the location of aquaculture sites.25

a. Carcinogens

Compared to other fish, salmon may provide additional health advantages due to its lower levels of mercury and higher levels of fatty acids and omega-3s, like eicosapentaenoic acid and docosahexaenoic, per serving, which benefit the heart and brain.26 However, as stated above, science demonstrates farmed salmon includes a higher degree of cancer-causing chemicals.27 These carcinogenic chemicals occur because farmed salmon contains pesticides, specifically known as polychlorinated biphenyls (PCBs), in attempts to prevent or contain diseases and parasites.28 PCBs have the potential to remain in the human body—and environment—for decades.29

24. Cutillo, supra note 2, at 90.
25. HEINZERLING, supra note 5, at 391.
27. Cutillo, supra note 2, at 89.
29. Cutillo, supra note 2, at 90.
b. Toxins

Bacteria contained in farmed salmon may even be transferred to humans through handling salmon at aquaculture sites. Additionally, effluent discharge (liquid waste released into a river or ocean) at aquaculture sites cause these toxins to enter our waters, and in turn the seafood and water we consume. This also holds true for mercury, copper, and zinc—only a few of the many metals added to United States’ waters from salmon aquaculture. Toxins, such as mercury, dispersed from salmon aquaculture sites into United States’ waters may cause serious health issues amongst individuals. Harmful human health effects from mercury include effects on the nervous, digestive, or immune systems, in addition to the lungs, kidneys, skin, or eyes.

Mercury is amongst the top ten chemicals regarding major public health concerns. Exposure to methylmercury (not to be confused with ethylmercury, which is used as a preservative in some vaccines) in many individuals occurs through fish and shellfish consumption. Methylmercury biomagnifies, meaning that the chemical increases in concentration as it travels up the food chain. Specifically, large predatory fish are more likely to contain higher levels of mercury than smaller fish because of the larger fish’s consumption of smaller fish that have acquired mercury through plankton ingestion.

c. Antibiotics

The use of antibiotics in aquaculture poses human health consequences as well. United States aquaculture uses a range of 204,000 to 433,000 pounds of antibiotics annually for various purposes, although most usage is to combat bacterial diseases amongst salmon. High

31. Williams, supra note 8, at 724.
32. Id. at 725.
34. Id.
35. Id.
36. Id.
38. WORLD HEALTH ORGANIZATION, supra note 33.
40. Wilson, supra note 30, at 360.
antibiotic use in farmed salmon threatens human health because it can cause human resistance to certain microbes through consumption; many bacteria in farmed salmon belong to the same group as human pathogens. Antibiotic usage in fish farms continues to raise concern that the aquaculture industry contributes to issues surrounding human resistant microbes.

2. Environmental Implications

a. Polluted Waters

Salmon aquaculture impacts the United States environment by discharging waste into United States’ coastal and offshore waters. Excretions of increased organic matter from feeding farmed salmon and the use of chemicals in salmon farms result in the release of toxic metals, such as mercury, which contaminates water and marine life. The use of antibiotics and pesticides, as well as hormones and fertilizers among other things, in the aquaculture industry disperses chemical pollutants into United States’ waters. These pollutants eventually sink towards the bottom of waters, damaging the seabed environment.

Aquaculture and farmed salmon may also contribute to polluting United States’ waters through eutrophication from uneaten fishmeal. Eutrophication is a nutrient overload in water such that the water becomes too enriched with organic material and results in harmful concentrations of nutrients. The fishmeal contains elevated levels of nutrients like nitrogen and phosphorus; uneaten, nutrient-rich fishmeal disperses throughout the water, triggering dead zones (areas with low oxygen), marine life death, murky water, and potentially harmful algae. Practically one quarter of fishmeal at aquaculture sites—roughly fifteen to twenty percent—goes uneaten by farmed salmon, contributing to the effects of polluted waters.

41. Id.; see also Johns, supra note 4, at 697.
42. Wilson, supra note 30, at 356.
43. Williams, supra note 8, at 715.
44. Id. at 724-25.
45. Johns, supra note 4, at 697.
46. UPTON & COWAN, supra note 19, at 9.
47. Id. at 10; see also Williams, supra note 8, at 724; Johns, supra note 4, at 696.
49. Id.
50. Williams, supra note 8, at 723.
b. Escaped Salmon

Farmed salmon that escape from farm pens provide additional environmental implications. Escaped salmon (which can amount to millions) are not native species and a release of farmed salmon into the wild, whether intentional or accidental, may harm native fish populations. For example, escaped farmed salmon may ultimately affect the genetic makeup of wild salmon through interbreeding. Specifically, farmed salmon are treated to grow larger at a faster rate than wild salmon and any interbreeding with wild salmon may alter wild salmon characteristics. If interbreeding occurs, escaped farmed salmon carrying diseases may transfer diseases to the wild salmon it breeds with. Scientists deem escaped salmon from aquaculture farms contribute to the endangerment, and even extinction of various wild fish species.

c. Net Pens

The aquaculture industry utilizes gear such as net pens to contain the salmon, in which marine life inadvertently becomes entangled. Net pens damage the environment by affecting the seabed; farmed salmon waste such as feces and uneaten feed flow out from pen openings into United States’ waters and sink to the bottom. Additionally, net pens disturb the ecological balance of United States’ waters because salmon are carnivorous; salmon confined in net pens have few, if any, predators on aquaculture farms.

III. REGULATORY STRUCTURE

United States fishing activities were largely unregulated in the past, with many individuals agreeing regulation is necessary to develop aquaculture while minimizing any damaging effects. Such regulations would assist in safeguarding and developing the United States aquaculture
industry in a sustainable and beneficial way.\textsuperscript{61} As the rise of aquaculture in the United States gained momentum, this uncharted territory necessitated regulatory action from governmental agencies due to the various aspects of fishing and aquaculture within the United States.\textsuperscript{62} Two agencies, EPA and FDA, possess the jurisdictional oversight for such regulation; both agencies must work in a cohesive manner to provide effective regulation.\textsuperscript{63}

\textit{A. U.S. Environmental Protection Agency}

EPA uses the Clean Water Act (CWA) as its regulatory framework for fish, encompassing both wild and farmed salmon.\textsuperscript{64} Salmon farms that threaten United States water quality to unsafe levels may be held liable pursuant to EPA regulations, such as the CWA.\textsuperscript{65} EPA regulates wild salmon due to pollutants, especially those from aquaculture sites, into United States’ waters.\textsuperscript{66} Through the CWA, EPA sets limits on hazardous materials, like PCBs in wild salmon, to safeguard consumers and carry out its mission to protect human health and the environment.\textsuperscript{67} EPA standards use a scientific approach to determine associated risks and health concerns with pollutants and other harmful materials.\textsuperscript{68} Additionally, the Toxic Substances Control Act (TSCA) provides EPA additional authority to regulate PCBs and therefore aspects of fish because individuals may be exposed to PCBs through fish or water consumption.\textsuperscript{69}

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{61} Johns, \textit{supra} note 4, at 686.
\item \textsuperscript{62} Wheeler, \textit{supra} note 28, at 302-03.
\item \textsuperscript{63} Id.
\item \textsuperscript{64} 33 U.S.C. § 1251.
\item \textsuperscript{65} Wheeler, \textit{supra} note 28, at 307.
\item \textsuperscript{66} Cutillo, \textit{supra} note 2, at 90-91; see also UPTON & COWAN, \textit{supra} note 19, at 17.
\item \textsuperscript{68} Cutillo, \textit{supra} note 2, at 97.
\item \textsuperscript{69} U.S. ENV’T. PROT. AGENCY, \textit{Polychlorinated Biphenyls (PCBs)}, https://www.epa.gov/pchs/learn-about-polychlorinated-biphenyls-pcbs#what (last visited Sep 28, 2020) [https://perma.cc/4GC6-BAMA].
\end{itemize}
\end{footnotesize}
1. The Clean Water Act

The CWA is a federal statute Congress passed aimed to restore and preserve United States water quality standards.\textsuperscript{70} The CWA is regulated pursuant to 33 U.S.C. § 1251.\textsuperscript{71} Using the CWA as its fundamental basis to regulate pollutants from aquaculture sites affecting wild salmon and United States’ waters, EPA restricts the discharge of such pollutants using a national permit program, known as the National Pollutant Discharge Elimination System (NPDES).\textsuperscript{72}

EPA categorizes aquaculture as “concentrated aquatic animal production facilities (CAAP).”\textsuperscript{73} Under NPDES, aquaculture facilities require regulation for discharges associated with CAAP pursuant to 40 C.F.R. Part 122.24.\textsuperscript{74} Salmon are cold water species because they need cold water to survive.\textsuperscript{75} Therefore, salmon aquaculture is regulated under EPA CAAP, covering facilities raising cold water fish as long as the farmed salmon discharge at least thirty days per year.\textsuperscript{76} Aquaculture facilities that produce less than 20,000 pounds of farmed salmon per year or feed less than 5,000 pounds of food during the calendar month of maximum feeding do not require a NPDES permit under CAAP.\textsuperscript{77}

In 2004, EPA established national standards for effluent limits and CAAP under the CWA pursuant to 40 C.F.R. Part 451; these regulations apply to current and future CAAP regarding aquaculture.\textsuperscript{78} EPA’s 2004

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\item UPTON & COWAN, supra note 19, at 14.
\item Wheeler, supra note 28, at 307; see also UPTON & COWAN, supra note 19, at 14; U.S. ENV’T. PROT. AGENCY, supra note 70.
\item U.S. ENV’T. PROT. AGENCY, NPDES Aquaculture Permitting, supra note 73; see also 40 C.F.R. § 122.24 (2019).
\item U.S. ENV’T. PROT. AGENCY, NPDES Aquaculture Permitting, supra note 73.
\item Id.
\item Effluent Limitations Guidelines and New Source Performance Standards for the Concentrated Aquatic Animal Production Point Source Category, 69 Fed. Reg. 51891
\end{enumerate}
\end{footnotesize}
rule set effluent standards for CAAP that produce at least 100,000 pounds of aquatic animals annually; if a salmon farm produces at least 100,000 pounds the farm must abide by EPA regulation standards.79

2. The Resource Conservation and Recovery Act

Additionally, EPA may regulate the safety of wild salmon in United States waters under the Resource Conservation and Recovery Act (RCRA).80 Congress authorized the passage of RCRA into public law, creating regulation for the “treatment, storage, and disposal of hazardous and non-hazardous solid waste.”81 RCRA categorizes standards for waste under “listed wastes” and “characteristics wastes.”82 Listed wastes occur from manufacturing and industrial processes, while characteristic wastes exhibit at least one of the following characteristics: ignitability, corrosivity, reactivity, or toxicity.83

Waste generated from aquaculture sites include fish feces and chemical discharges in addition to the various types of wastes as discussed above.84 These wastes are pollutants which may be deemed as both listed wastes and characteristic wastes; consequently, salmon farms may be subject to regulation under RCRA.85

3. The National Environmental Policy Act

Federal law mandates United States’ agencies to evaluate any environmental effects and possible consequences of any proposed action prior to proceeding with that action under the National Environmental

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79. U.S. ENV’T. PROT. AGENCY, NPDES Aquaculture Permitting, supra note 73.
82. Wheeler, supra note 28, at 303.
84. Wheeler, supra note 28, at 303-04.
85. Id.
Policy Act (NEPA).\textsuperscript{86} NEPA is regulated pursuant to 42 U.S.C. § 4321 and 40 C.F.R. §§ 1500-1508 and is managed by the Council on Environmental Quality (CEQ) within the Executive Office of the President.\textsuperscript{87} Federal agencies must prepare an Environmental Impact Statement (EIS) to demonstrate compliance with NEPA.\textsuperscript{88} EPA is responsible for regulating all EISs pursuant to 40 C.F.R. §§ 1506.9 and 1506.10.\textsuperscript{89}

EISs are detailed assessments of a proposed action that may impact the environment.\textsuperscript{90} Regarding fisheries, NEPA guides EPA assessors responsible for EIS for Fishery Management Plans (FMPs) and related amendments.\textsuperscript{91} FMPs and their amendments detail how a specific fishery will be managed; significant potential fishery issues; and conservation and management methods to resolve such issues.\textsuperscript{92} FMPs and their amendments have a purpose to continuously achieve and maintain the “optimum yield” from each fishery.\textsuperscript{93} An optimum yield is the amount of fish from a fishery that will be most beneficial to the United States regarding food production and the protection of marine ecosystems.\textsuperscript{94} If EPA reviewers of an EIS notice an issue, for example, harmful water quality effects affecting a fishery’s optimal yield, the reviewers evaluate and provide feedback on the fishery’s management activities.\textsuperscript{95} EISs may also assist EPA in furthering statutory goals like the CWA, achieving fishable waters where possible, and ensuring its mission to protect human health and the environment.\textsuperscript{96}

\begin{itemize}
\item \textsuperscript{88} UPTON & COWAN, \textit{supra} note 19, at 4-5.
\item \textsuperscript{89} 40 C.F.R. §§ 1506.9-1506.10 (2019).
\item \textsuperscript{90} UPTON & COWAN, \textit{supra} note 19, at 4-5.
\item \textsuperscript{92} \textit{Id.} at 9.
\item \textsuperscript{93} \textit{Id.}
\item \textsuperscript{94} \textit{Id.}
\item \textsuperscript{95} \textit{Id.} at 30–32, 35.
\item \textsuperscript{96} \textit{Id.} at 3, 61.
\end{itemize}
B. U.S. Food and Drug Administration

The need for potential fish diseases to be prevented and infected fish to be treated acknowledges FDA’s involvement in aquaculture regulation, though it may be broad and at times may seem vague.\(^\text{97}\) Unlike EPA which limits PCBs surrounding matters to wild salmon, FDA limits PCB amounts in farmed salmon, but more generally in commercially sold fish; it may therefore be understood EPA regulates aspects of living fish while FDA regulates fish as food that are no longer living.\(^\text{98}\) FDA sets standards for PCBs in seafood at a range of two parts per million (ppm) pursuant to its current regulatory standard 21 C.F.R. Part 109.30.\(^\text{99}\) Compared to EPA’s standard to limit PCB consumption, FDA’s standards are essentially forty times less protective.\(^\text{100}\) If FDA sets standards for farmed salmon and aquaculture sites that are similar to current EPA regulations, farmed salmon would greatly surpass minimum permitted PCB levels under FDA regulations.\(^\text{101}\)

It is significant to note FDA’s PCB health limit standards for commercial seafood have not been updated since they were originally issued in 1984.\(^\text{102}\) FDA states contamination is unavoidable in certain types of food, such as fish, and carcinogen quantity is below the established minimum safety level for commercial fish.\(^\text{103}\) But to reiterate, this level was established in 1984, when FDA first issued its PCB regulations; any scientific data FDA relied upon may be outdated.\(^\text{104}\)

EPA uses a scientific method to determine tolerable carcinogen levels in setting PCB limits surrounding aspects that may impact fish, whereas FDA utilizes a non-scientific balancing method.\(^\text{105}\) FDA considered various aspects to determine a balance of adequately protecting public health with avoiding excessive food loss within the United States.\(^\text{106}\) It may


\(^{98}\) Cutillo, supra note 2, at 90-91.


\(^{100}\) Cutillo, supra note 2, at 91-92.

\(^{101}\) Id. at 91.

\(^{102}\) ENVIRONMENTAL WORKING GROUP, PCBs in Farmed Salmon, (July 31, 2003), https://www.ewg.org/research/pcbs-farmed-salmon [https://perma.cc/W4WC-SJQ8].

\(^{103}\) Cutillo, supra note 2, at 99.

\(^{104}\) Id. at 101.

\(^{105}\) Id. at 90, 97, 99, 103.

\(^{106}\) Id. at 99.
be observed that EPA has a strict regulation for salmon compared to a relaxed standard utilized by FDA.\footnote{107}

1. United States Code and the Food, Drug, and Cosmetic Act

FDA regulates food and animal feed additives, among other things, for health risks pursuant to 21 U.S.C. § 301, the Food, Drug, and Cosmetic Act (the FD&C Act).\footnote{108} The use of animal drugs in the United States (discussed below) is also regulated under the FD&C Act.\footnote{109} However, the FD&C Act provides general definitions and information rather than specific standards for aquaculture or farmed salmon regulation.\footnote{110} Additionally, FDA provides more advice and guidelines generally rather than specific federal regulations regarding fish and fish farms.\footnote{111} For example, FDA provides various guidelines and information that appear beneficial regarding fish consumption such as “Eating Fish: What Pregnant Women and Parents Should Know,” “Selecting & Serving Fresh & Frozen Seafood Safely,” and “Safe Food Handling.”\footnote{112}

2. Code of Federal Regulations

FDA has regulations in place for aquaculture farmers such as Fish and Fishery Products pursuant to 21 C.F.R. § 123.\footnote{113} Pursuant to this regulation, fish farmers must understand aquaculture hazards (i.e. animal drugs in the aquaculture industry) and develop preventative hazard tools for aquaculture products (i.e. safeguarding consumers from illegal animal
drugs to protect human health and the environment).\textsuperscript{114} Specifically, 21 C.F.R. § 123.5, titled Current Good Manufacturing Practice, calls for regulation of whether fish and fishery products are safe and sanitary.\textsuperscript{115} Meanwhile, 21 C.F.R. § 123.6, titled Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan, mentions a hazard analysis shall be performed to determine whether food safety hazards regarding fish are reasonably likely to occur, and if so, an implemented HACCP plan shall be followed to provide resolutions in cleaning the hazard.\textsuperscript{116}

3. New Animal Drugs

In addition to regulating salmon—and fish generally—as food, FDA has discretion to approve or deny antibiotic use on farmed fish.\textsuperscript{117} The Center for Veterinary Medicine (CVM), an FDA division responsible for regulating food additives and drugs given to animals, sets forth various rules governing aquaculture antibiotics.\textsuperscript{118} Antibiotics on fish farms must be proven safe and effective by manufacturers in order to be used.\textsuperscript{119} FDA considers an antibiotic safe and effective if there is a “reasonable certainty of no harm to human health from the proposed use in food-producing animals”; simply put, an antibiotic must be generally recognized as safe (GRAS).\textsuperscript{120}

For an antibiotic to be considered GRAS and used in aquaculture, manufacturers must first submit an Investigational New Animal Drug Application (INADA) to receive permission for testing.\textsuperscript{121} FDA defines new animal drugs as a drug intended for use in an animal and animal feed.\textsuperscript{122} Once an INADA is submitted and approved, that manufacturer

\textsuperscript{115} 21 C.F.R. § 123.5 (2019).
\textsuperscript{116} 21 C.F.R. § 123.6 (2019).
\textsuperscript{117} Wheeler, supra note 28, at 314-15.
\textsuperscript{118} Id.; see also Wilson, supra note 30, at 357.
\textsuperscript{119} Wheeler, supra note 28, at 315.
\textsuperscript{121} Wilson, supra note 30, at 357-58.
must then submit a New Animal Drug Application (NADA) demonstrating the drug is GRAS.\textsuperscript{123} NADAs are federal actions authorized under the FD&C Act which state that a new animal drug may not be used until it is GRAS.\textsuperscript{124} Only three antibiotics are currently approved by FDA CVM for aquaculture use: oxytetracycline, sulfadimethoxine, and sulfamerazine.\textsuperscript{125}

4. The National Environmental Policy Act, Revisited

As mentioned above, federal law mandates United States’ agencies to evaluate any environmental effects and possible consequences of any proposed action prior to proceeding with that action under NEPA.\textsuperscript{126} As such, FDA must comply with NEPA and review factors that may negatively impact the United States environment.\textsuperscript{127} NADAs fall under regulation by NEPA, therefore FDA must review any new animal drugs for environmental concerns and prepare an EIS; for example, if a salmon farm hopes to use antibiotics in its salmon, FDA must review that antibiotic and ensure it is safe for the United States environment and consumers alike.\textsuperscript{128}

IV. FORWARD THINKING

Aquaculture provides various benefits including a larger production of seafood for human consumption, an overall seafood price decrease, and more accessible methods for seafood consumption.\textsuperscript{129} However, evidence suggests aquaculture facilities pose science-based concerns that lead to human health risks and harmful environmental factors.\textsuperscript{130} The confined areas farmed salmon are kept in can lead to disease outbreak of the salmon, demonstrating how aquaculture practices may not be fully sustainable.\textsuperscript{131}

\textsuperscript{123} Wilson, supra note 30, at 357-58.
\textsuperscript{124} U.S. FOOD & DRUG ADMIN., supra note 122.
\textsuperscript{125} Wilson, supra note 30, at 358.
\textsuperscript{127} Id.
\textsuperscript{128} UPTON & COWAN, supra note 19, at 4-5.
\textsuperscript{130} UPTON & COWAN, supra note 19, at 16-17.
\textsuperscript{131} Henson, supra note 8.
Increased salmon consumption causes our bodies added exposure to carcinogens and toxins from antibiotics and polluted United States’ waters, which are only some of the associated health risks the aquaculture boom has triggered. Additionally, farmed salmon as it is currently regulated negatively impacts our environment; escaped farmed salmon may breed with wild salmon altering the genetic makeup of species, and net pens pollute United States’ waters by releasing salmon waste through pen openings.

A. Whether EPA or FDA Adequately Address Aquaculture Health Concerns

The aquaculture industry surrounding farmed salmon is making strides to address associated human health and environmental concerns as demonstrated through the regulations from EPA and FDA.\(^\text{132}\) Despite various regulations and guidelines these agencies implemented to address the rise of aquaculture, human health and the environment continue to face adverse effects with these regulations in place; this is troublesome. This clearly demonstrates neither EPA nor FDA adequately address health concerns associated with the rise of aquaculture.

Congress suggested a need for a science-based approach in governmental regulation.\(^\text{133}\) This approach is utilized by EPA as a basis for its regulatory framework, while FDA utilizes a non-scientific balancing method.\(^\text{134}\) FDA health limit standards for commercial seafood has also not been updated since it was originally issued in 1984.\(^\text{135}\) EPA regulations pertaining to aquaculture such as the CWA and RCRA appear more stringent, most likely due to its scientific approach. Although FDA provides regulations for commercial salmon under the FD&C Act, FDA regulations do not appear to state specifics regarding farmed salmon or the aquaculture industry and appear extremely vague. FDA regulations in this regard appear too broad due to the aspect of general definitions and information rather than specific standards for aquaculture or farmed salmon regulation.\(^\text{136}\) FDA provides more of a guideline approach rather than a regulatory one, at least regarding aquaculture and farmed salmon.

\(^{132}\) Upton & Cowan, supra note 19, at 9, 24.

\(^{133}\) Cutillo, supra note 2, at 102.

\(^{134}\) Id. at 84.

\(^{135}\) Environmental Working Group, supra note 102.

B. Suggestions for a Healthier Future

1. Congressional Intervention for Unified Regulations

To assist fish consumers in making healthy, informed decisions—specifically women who are or may become pregnant, breastfeeding mothers, and parents of children over two years old—FDA and EPA are jointly revising advice issued in January 2017 due to Congressional directive.\(^\text{137}\) The 2017 advice encouraged weekly fish consumption dependent upon designated best choices, good choices, or choices to avoid; FDA’s current fish advice is available at https://www.fda.gov/media/102331/download, and EPA’s science-based fish advice is available at https://www.epa.gov/fish-tech/epa-fda-fish-advice-technical-information.\(^\text{138}\) In Public Law 116-6, Section 773 (the Consolidated Appropriations Act of 2019), Congress declared the 2017 advice be updated in a manner consistent with nutrition science recognized by FDA on effects of seafood consumption.\(^\text{139}\) Although Congress is making strides to address adverse health effects from fish, any updated advice is exactly that: advice; it is not intended to have any lawful effect.\(^\text{140}\) There is a need for actual lawful regulation to ensure fish consumption, whether wild or farmed, is healthy for consumers.

As mentioned above, Congress enacted the NAA to encourage and develop aquaculture in the United States.\(^\text{141}\) However, the NAA only established a comprehensive aquaculture strategy and did not enforce any regulatory oversight authority regarding aquaculture.\(^\text{142}\) To avoid future harmful human health and environmental effects from the rise of aquaculture and farmed salmon, and combat current negative practices, EPA and FDA must be provided governmental oversight authority and greater regulatory action.\(^\text{143}\) This power is provided to United States governmental agencies from Congress through legislative efforts. A unified, national regulation for aquaculture standards may assist in combating associated negative effects. Due to the different regulatory framework and jurisdictions between EPA and FDA, this may be a difficult, time-consuming process in which Congress will need to

\(^{137}\) Advice About Eating Fish: For Women Who Are or Might Become Pregnant, Breastfeeding Mothers, and Young Children, 84 Fed. Reg. 32, 747 (July 8, 2019).
\(^{139}\) Advice About Eating Fish, supra note 137.
\(^{140}\) Id.
\(^{141}\) Johns, supra note 4, at 687.
\(^{142}\) Wheeler, supra note 28, at 306.
\(^{143}\) Henson, supra note 8, at 12.
determine if it is able to allocate the resources to accomplish this task. It is important to note loopholes may occur in any unified regulations and pose additional concerns for the aquaculture industry and federal government because EPA and FDA both have many different, complicated regulations and separate jurisdictional boundaries.\textsuperscript{144}

Any unified regulation would need Congressional bipartisanship to pass the floor and become public law. Due to the environmental and health issues surrounding the aquaculture industry, amongst many others that may be incorporated, bipartisan efforts will certainly be challenging. If Congress does in fact choose to move forward with a unified standard, the aquaculture industry itself may fight back. The seafood industry is large, and any potential laws implicating its credibility, consumer outreach, or profits will certainly receive pushback. This may ultimately call for lobbying efforts against the aquaculture industry; some potential ideas may be regulating the space between aquaculture sites or monitoring the chemicals administered to farmed fish.\textsuperscript{145} Regardless, EPA and FDA are regulatory agencies that must revamp aquaculture because of its associated human health and environmental detriments.

Congressional legislative attempts were made in previous years. The House of Representatives (the House) tried to pass resolutions in the 108\textsuperscript{th} Congress for the Federal Government to authorize a unified regulation to establish a national policy regarding aquaculture.\textsuperscript{146} Neither of these resolutions—H.Res. 301 and H.Res. 308—passed the House. In the 111\textsuperscript{th} Congress, the House introduced H.R. 4363, the National Sustainable Offshore Aquaculture Act of 2009, to establish a regulatory system for sustainable offshore aquaculture in the United States.\textsuperscript{147} This bill went nowhere in the 111\textsuperscript{th} Congress and was reintroduced as H.R. 2373, the National Sustainable Offshore Aquaculture Act of 2011, in the 112\textsuperscript{th} Congress.\textsuperscript{148} This bill did not pass the House in the 112\textsuperscript{th} Congress and received zero cosponsors.\textsuperscript{149} The most prominent piece of legislation in making strides to create a unified regulation in the aquaculture industry may be the National Offshore Aquaculture Act of 2007 discussed below. In the current 116\textsuperscript{th} Congress, there does not appear to be any indication of a bill for a unified regulation regarding aquaculture in the United States.

\begin{thebibliography}{99}
\bibitem{144} Wheeler, \textit{supra} note 28, at 316.
\bibitem{145} Henson, \textit{supra} note 8.
\bibitem{146} H.R. Res. 301, 108\textsuperscript{th} Cong. (2003); \textit{see also} H.R. Res. 308, 108\textsuperscript{th} Cong. (2003).
\bibitem{147} National Sustainable Offshore Aquaculture Act of 2009, H.R. 4363, 111\textsuperscript{th} Cong. (2009).
\bibitem{148} National Sustainable Offshore Aquaculture Act of 2011, H.R. 2372, 112\textsuperscript{th} Cong. (2011).
\bibitem{149} Johns, \textit{supra} note 4, at 720.
\end{thebibliography}

The National Offshore Aquaculture Act of 2007 (the Act) was introduced in the 110th Congress as H.R. 2010 in the House and as S. 1609 in the Senate as requested by former President George W. Bush’s administration.150 These two bills described the necessity for aquaculture regulation in United States’ waters.151 Specifically, the Act provided the Secretary of the Department of Commerce the authority to establish and implement regulation for offshore aquaculture in the United States Exclusive Economic Zone (EEZ)—a zone of coastal water and seabed 200 nautical miles from the United States and its territories.152

The Act addressed beneficial regulatory actions which may in turn promote healthier alternatives for our environment and human health. Significant provisions of the bill supported an offshore aquaculture industry to produce valuable food sources; protect wild fish and marine ecosystems through environmentally responsible operations; and encourage the public and private sector to work together to promote research and development for the aquaculture industry.153 Additionally, the Act discussed the need for federal agencies to consult one another to ensure aquaculture techniques adhere to existing laws and regulations.154 The Act also outlined specific enforcement procedures and penalties such as business suspensions, sanctions, and fines for those found not in compliance with any provision.

Environmental and human health concerns discussed in this article were denoted in provisions of the Act. Specifically, impacts on fish stocks and fisheries, the transmission of diseases or parasites, prevention of escaped aquatic species, chemical risks regarding water quality, and issues with aquaculture feed and waste were all discussed.155 The Act mentioned that the Secretary of Commerce shall prepare an analysis under NEPA; similarly, this article discussed ways to be environmentally compliant with current governmental regulations. Despite the Act not mentioning NPDES permits, it addressed the need for permits generally by stating it will make offshore aquaculture in EEZs available for development and operation to those with the proper, required permits.156 The Act also established a

150. UPTON & COWAN, supra note 19, at 16.
151. Id.
153. Id.
154. Id.
155. Id.
156. Id.
permit process to address potential environmental and human health risks and impacts from offshore aquaculture.

Although no action was taken, the House Committee on Natural Resources, Subcommittee on Fisheries, Wildlife, and Oceans, held a hearing on H.R. 2010. If reintroduced, the Act to move forward in regulating the aquaculture industry to make it healthier for both the environment and individuals. The Act already provides a framework for Congress. If reintroduced, the legislation should contain certain provisions the Act has already included such as matters to protect the environment and human health; encouraging the public and private sector to collaborate to promote research and development for the aquaculture industry; federal agencies consulting one another to ensure aquaculture techniques adhere to existing regulations; and specific enforcement procedures and penalties for those found not in compliance with any provision. The Act also authorized specific appropriations of $4,052,000 in fiscal year 2008 for purposes of carrying out its provisions. If reintroduced in Congress, the legislation should discuss specific appropriations, but it should not use the same amount of funds. Congress must account for inflation rates, as it is now more than a decade since the Act was passed in the House and Senate.

Additionally, although the Act fosters federal agencies to work together to promote aquaculture efficiency, it never mentioned EPA or FDA directly—two crucial federal agencies involved in the regulatory process regarding aquaculture matters. If reintroduced in Congress, EPA should be mentioned specifically to assist in enforcing the provisions, since this legislation addresses the regulation of offshore aquaculture in United States’ waters. The Act did not even mention the CWA and NPDES, and if reintroduced these regulations should be addressed because these regulations are associated with aquaculture facilities. The Act did not mention FDA either, and if reintroduced, Congress should include this agency in its provisions because FDA regulates commercial fishing and seafood from the aquaculture industry. If reintroduced, the legislation should mention EPA and FDA responsibilities and include aspects of the CWA and NPDES permits. The Act, as it was previously drafted, does not give enough deference to crucial agencies that should be involved in the regulatory process of offshore aquaculture sites, such as EPA and FDA. Congress should consider adding these provisions to the legislation if reintroduced.

157. UPTON & COWAN, supra note 19, at 16.
158. H.R. 2010; see also S. 1609.
Moving forward, any new legislation introduced regarding this matter should also include aspects the Act did not address, that are discussed in this Note, such as human health implications relating to carcinogens and antibiotics in farmed fish, as well as, environmental concerns regarding net pens and aquaculture materials. Although environmental factors affect human health, the Act appeared to primarily discuss environmental effects rather than discuss any direct human health implications. If reintroduced, the legislation should put more emphasis on human health implications. Bipartisanship will again be necessary, however stronger efforts will be needed to pass any new similar legislation into law. Of course, this is all contingent upon the political environment, such as the Administration and Congress at the time any similar legislation is reintroduced.

3. Genetically Engineered Salmon

Genetically engineered (GE) salmon is an increasingly used method and viable alternative; it provides a regulatory solution for the current aquaculture industry with the availability of technology and the use of science as a proven safety method. The first type of GE salmon, AquAdvantage salmon, is one potential solution to decrease the unhealthy effects caused by current farmed salmon and aquaculture methods.

The process of introducing a GE product into the market is a long, extensive, and complicated process due in part to the regulatory aspect. Because GE products introduce the use of a drug, they require compliance with FDA regulations under the FD&C Act. The specific processes for AquAdvantage began in 1993, when AquaBounty contacted FDA regarding commercial use of GE salmon. In 1995, AquaBounty formally applied for FDA approval, and in 2009, AquaBounty provided FDA with a NADA after extensive studies. FDA’s Veterinary Medicine Advisory Committee (VMAC) met in mid-September to consider potential human health and environmental impacts, among other issues, regarding the safety and effectiveness of the NADA.

Based on an analysis of the scientific evidence and NADA concerning this GE salmon, FDA determined AquAdvantage salmon satisfy current regulations under the FD&C Act and can be introduced in the United States. However, as discussed above, current farmed salmon on the

159. UPTON & COWAN, supra note 19, at 12-13.
160. Id.
market cause various health issues pertaining to humans and the environment, despite being FDA-approved. Nevertheless, AquAdvantage salmon as a GE product appears to be a healthier alternative than current farmed salmon due to its potential to combat health and environmental issues the current aquaculture industry causes.

Regarding environmental impacts, GE salmon cannot be raised in open water net pens like current farmed salmon; GE salmon are grown at specific land-based facilities from eggs.\textsuperscript{162} GE salmon are grown in tanks with barriers such as covers and overflow tanks, and include metal screens and incubatory trays at the bottom to prevent escape.\textsuperscript{163} Additionally, AquAdvantage salmon are produced as all-female to make them sterile, preventing uncontrolled reproduction.\textsuperscript{164} The use of land-facilities for growth and all-female GE salmon will assist in combatting environmental effects caused by interbreeding; the land facilities should also not pollute United States’ waters directly. FDA evaluated AquAdvantage salmon in compliance with NEPA and determined that this GE salmon does not cause significant impact on the United States’ environment.\textsuperscript{165} The use of land facilities and eggs to grow GE salmon may increase salmon production to address consumer demand and, therefore, decrease the effects of overfishing. Evaluating the Endangered Species Act, pursuant to 16 U.S.C. § 1531, FDA concluded that the approval of this GE salmon will not threaten endangered wild salmon.\textsuperscript{166} This, in turn, may provide environmental benefits such as allowing the wild salmon population to recover.

GE salmon may also benefit human health compared to current farmed salmon and aquaculture methods because studies of AquAdvantage salmon demonstrated twenty-five percent less food consumption to achieve the same size compared to non-GE salmon.\textsuperscript{167} This may result in less pollutants to human health because of the decreased use of food and potential additives involved. FDA stated food used for AquAdvantage salmon provides no significant safety hazards and is as safe as food for current farmed salmon.\textsuperscript{168} But as discussed above, current farmed salmon

\textsuperscript{162} Id.
\textsuperscript{163} Id.
\textsuperscript{164} UPTON & COWAN, supra note 19, at 14.
\textsuperscript{165} U.S. FOOD & DRUG ADMIN., supra note 161.
\textsuperscript{166} UPTON & COWAN, supra note 19, at 15.
\textsuperscript{167} Id. at 11.
\textsuperscript{168} Id. at 14.
food can negatively affect human health so further studies and regulation are still necessary to combat related adversaries.

V. OVERALL THOUGHTS

Neil deGrasse Tyson once said, “The good thing about science is that it's true whether or not you believe in it.” Current scientific research and findings imply farmed salmon is unhealthier than wild salmon because of its harmful effects on humans and the environment. Many people may be under the impression farmed salmon is a healthier option due to governmental regulation but that does not appear to be the case. Nevertheless, aquaculture can promote significant benefits like assisting in meeting the increased public demand for seafood in diets and may allow wild salmon populations to repopulate.

Fortunately, alternatives to combat negative impacts current aquaculture methods cause and ways to promote healthier practices are available. EPA and FDA, with assistance from congressional legislation and scientific studies, have additional steps to take to ensure aquaculture is a safe option for consumers and the environment. Aquaculture should remain in the United States if regulated properly to address human and environmental health concerns.