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Genetically Engineered Salmon

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Summary

If approved by the Food and Drug Administration (FDA), Atlantic salmon would be the first genetically engineered (GE) animal to be marketed in the United States for human consumption. Genetic engineering techniques are used by scientists to insert genetic material from one organism into the genome of another organism. Genetically engineered salmon have been modified to grow more quickly and use feed more efficiently. However, some are concerned that, in this rapidly evolving field, current technological and regulatory safeguards are inadequate to protect the environment and ensure that these products are safe to be used as food.

Over seventeen years ago, AquaBounty Technologies Inc. first applied to the FDA for approval of a genetically engineered Atlantic salmon. In 2009, AquaBounty submitted to the FDA the last required study for their new animal drug (NAD) application. The FDA is regulating GE Atlantic salmon as an NAD under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §321). An NAD is approved by the agency only after the drug is shown to be safe and effective. On September 19-21, 2010, the FDA's Veterinary Medicine Advisory Committee (VMAC) met to consider the AquaBounty application for approval of GE salmon, trademarked as AquAdvantage salmon, for human consumption, and held a public hearing. On December 20, 2012, FDA announced the availability for public comment of (1) a draft environmental assessment of the proposed conditions specified by AquaBounty and (2) FDA's preliminary finding of no significant impact (FONSI) for AquaBounty's conditions. In the FONSI, FDA reiterated that food from AquAdvantage salmon is as safe as food from non-GE salmon and determined that there are no significant food safety hazards or risks associated with AquAdvantage salmon. FDA may still require a full environmental impact statement (EIS) prior to approval of AquaBounty's application. No further action has been taken by FDA, and the Aquabounty NAD application is still under consideration.

Environmental concerns related to the development of GE salmon include the potential for competition and interbreeding with wild fish. According to some, escaped GE salmon could spawn with wild Atlantic salmon and introduce the modified genetic material to the wild population. Sterilization and bioconfinement have been proposed as a means of isolating GE salmon to minimize the likelihood of harm to wild fish populations. To address these concerns, AquaBounty proposes to produce salmon eggs (all sterile females) in Canada, ship these eggs to Panama, grow and process fish in Panama, and ship table-ready, processed fish to the United States for retail sale. Additional concerns have been voiced concerning food safety, labeling of GE salmon, and economic effects on existing wild salmon fisheries.

Some have asserted that FDA approval of AquAdvantage salmon is overdue and that delays have hindered investment and development of the U.S. biotechnology sector. Others have questioned the adequacy of the FDA's review of GE salmon and whether the existing approval process is equipped to fully evaluate the risks of this technology, especially potential environmental harm. In response to food safety and environmental concerns, legislation has been introduced during the 113th Congress, including S. 246 and H.R. 1667, which would prohibit the transport, sale, possession, release, or use of GE fish. H.R. 584 and S. 248 would amend Section 403 of the FFDCA by adding a requirement to label genetically engineered fish, while H.R. 1699 and S. 809 would require labeling of foods produced using genetic engineering, including fish. No further action has been taken on these or other bills which would require additional regulation of genetically engineered organisms.

c11173008

c11173008

Contents

Introduction 1
U.S. Biotechnology Regulation and Oversight 2
Coordinated Framework for Regulation of Biotechnology 2
FDA Regulatory Framework 3
U.S. Department of Agriculture (USDA) 5
Labeling of Food Containing GE Material 6
General Mandatory Labeling Issues 7
GE Salmon Background 8
Wild Salmon Production 8
Salmon Aquaculture 9
Production and Trade 9
AquaBounty Case: The First Genetically Engineered Food Fish 10
AquAdvantage Salmon 10
AquaBounty Application 12
Food Safety Issues 16
Environmental Issues 17
Interbreeding with Wild Atlantic Salmon 17
Competition and Other Interactions 19
Future Concerns 20
Labeling Issues 20
Fishing Industry Interactions 21
Consumer Acceptance 23
Congressional Actions 23
Future Considerations 25

Figures

Figure 1. Driving Forces of Salmon Production 22

Tables

Table 1. Atlantic Salmon Farm Production and U.S. Imports of Atlantic Salmon 10

Contacts

Author Contact Information 26

c11173008

Introduction

By a broad definition, "genetic modification" refers to changes in an organism's genetic makeup that do not occur in nature. For millennia, farmers and scientists have modified the genetics of animals by selecting those individuals with desirable traits for further breeding. With the advent of modern biotechnology (e.g., genetic engineering or bioengineering), it is now possible to take a gene (or genes) for a specific trait from an organism and transfer it to another organism of a different species. For the purpose of FDA's guidance to industry, FDA defines genetically engineered (GE) animals as those animals modified by recombinant DNA (rDNA)[1] techniques, including the entire lineage of animals that contain the modification.[2]

Recombinant DNA techniques expand the range of traits that may be transferred to another organism and increase the speed and efficiency by which desirable traits may be incorporated into organisms. Desirable traits may reduce production costs and sometimes make the organism or products made from it more desirable to consumers. Genetically engineered plant varieties, such as herbicide-resistant corn and soybeans, have already been widely adopted by U.S. farmers. These techniques are now being used to develop genetically engineered organisms for the aquaculture industry.

Approximately 50 species of fish have been subject to genetic modification and more than 400 fish/trait combinations have been developed.[3] Fish and other marine organisms are being modified to reduce production costs of human food, to produce pharmaceuticals, to test water contamination, and for other uses.[4] Fish are particularly attractive candidates for genetic engineering because they produce eggs in large quantities and their eggs are more easily manipulated because they are fertilized and develop externally. Aquaculture also supplies a rapidly expanding market of different seafood products. Countries with active research programs for genetically engineered fish include China, Cuba, India, Korea, the Philippines, and Thailand.

Development of GE fish has prompted some advocacy groups to raise a number of environmental concerns.[5] If fish are accidently released into the environment they may spread quickly and be difficult to contain. GE fish that escape to the wild could compete with wild fish and harm wild populations. Another concern is that GE fish may interbreed with wild fish and allow the modified genetic material to become assimilated into the wild fish population.[6] Sterilization and

[1] Recombinant DNA (deoxyribonucleic acid) is formed by using laboratory methods to combine DNA from different sources to create DNA sequences that do not occur in nature.

[2] U.S. Department of Health and Human Services, Food and Drug Administration, *Guidance for Industry Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*, Rockville, MD, January 15, 2009. Hereinafter cited as FDA Guidance 2009.

[3] I.G. Cowx et al., *Environmental Risk Assessment Criteria for Genetically Modified Fishes to be Placed in the EU Market*, European Food Safety Authority, May 27, 2010, http://www.efsa.europa.eu/en/supporting/doc/69e.pdf.

[4] For a list of some of the genetically engineered organisms under research, see Table 2-2 in National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2002), http://books.nap.edu/books/0309084393/html/73.html#pagetop.

[5] Timothy Schwab, "Is FDA Ready to Regulate the World's First Biotech Food Animal?," *FDLI's Food and Policy Forum*, vol. 3, no. 12 (July 24, 2013). Hereinafter cited as Schwab 2013.

[6] Letter from Rebecca Wodder, President, American Rivers, Margie Alt, Executive Director, Environment America, and Vikki Spruill, President and CEO, Ocean Conservancy, et al. to Margaret Hamburg, M.D., Commissioner, FDA, November 8, 2010.

c11173008

bioconfinement have been proposed as a means of isolating GE fish to minimize the potential for interactions with wild fish populations and changes to related ecosystems.

Food safety concerns also have been expressed by consumer groups who question whether genetically modified organisms could pose unique hazards to public health.[7] Furthermore, some in the fishing industry are concerned that greater efficiency in the aquaculture industry could harm salmon fisheries.[8] Salmon farm production in the 1990s depressed salmon prices and affected fishing businesses and coastal communities that depend on wild fisheries.

Some have asserted that FDA approval of GE salmon is overdue and has been delayed due to political interference.[9] They conclude that delays have hindered investment and development of the U.S. biotechnology sector. They also question whether biotechnology industries in the United States will be able to compete with companies in other parts of the world. Moreover, they also infer that the availability of GE salmon could benefit consumers who are seeking low-fat and affordable options.[10]

During the 112th and 113th Congresses, the adequacy of the FDA's review of GE animals has been questioned. Several bills introduced in the 112th Congress would have amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to prevent approval of GE salmon or to require labeling of genetically engineered fish. None of these bills was enacted. Several bills have been introduced during the 113th Congress, including S. 246 and H.R. 1667, which would prohibit the possession or use of GE fish in the United States. H.R. 584, H.R. 1699, S. 248, and S. 809 would add a requirement under the FFDCA to label genetically engineered fish. No further action has been taken on these or other bills that would mandate additional regulation of genetically engineered organisms.

U.S. Biotechnology Regulation and Oversight

Coordinated Framework for Regulation of Biotechnology

Federal guidance for regulating biotechnology products is provided in the Coordinated Framework for Regulation of Biotechnology (51 *Fed. Reg.* 23302), published in 1986 by the White House Office of Science and Technology Policy (OSTP). A key regulatory principle of the U.S. biotechnology regulatory structure is that genetically engineered products should continue to be regulated according to their characteristics and unique features, not their production method—that is, whether or not they were created through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products, using

[7] Food and Water Watch, Consumers Union, and Center for Food Safety, *Petition to Deem ABT Technologies' Genetically Engineered AquAdvantage Salmon an Unsafe Food Additive*, February 7, 2012.

[8] Letter from Dale Kelly, Executive Director, Alaska Trollers Association, Brian Lynch, Executive Director, Petersburg Vessel Owners Association, and Buck Laukitis, President, North Pacific Fisheries Association, et al. to Aleta Sindelar, FDA, Center for Veterinary Medicine, April 26, 2013.

[9] Alison L. Van Eenennaam, William M. Muir, and Eric M. Hallerman, "Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?," *Food and Policy Forum*, vol. 3, no. 13 (July 24, 2013).

[10] Henry I. Miller, "With a Forked Tongue: How the Obama Administration Stymies Innovation in Food Production," *Forbes*, March 19, 2014.

c11173008

existing statutory authority and previous agency experience with traditional breeding techniques. The three lead agencies are USDA's Animal and Plant Health Inspection Service (APHIS), the Food and Drug Administration (FDA) at the Department of Health and Human Services, and the Environmental Protection Agency (EPA).

In 2002, the National Research Council (NRC) published its report on animal biotechnology.[11] Some newer applications of biotechnology did not exist when the current regulatory framework was enunciated. The NRC animal biotechnology report concluded that this General Framework "might not be adequate to address unique problems and characteristics associated with animal biotechnologies" and that federal agency responsibilities are not clear.[12]

FDA Regulatory Framework

FDA regulates food, animal feed additives, and human and animal drugs, including those from biotechnology, primarily to ensure that they pose no human health risks, mainly under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §301 et seq.) and the Public Health Service Act (42 U.S.C. §201 et seq.). Under the FFDCA, all food and feed manufacturers must ensure that the domestic and imported products they market, except for most meats and poultry, are safe and properly labeled, including those developed through genetic engineering.

FDA has stated that most—although probably not all—gene-based modifications of animals for production or therapeutic claims fall within the purview of the agency's Center for Veterinary Medicine (CVM), which regulates them under the FFDCA as new animal drugs (NAD) (21 U.S.C. §321).[13] Under the FFDCA, drugs are defined in Section 201(g) as "articles intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and articles (other than food) intended to affect the structure or any function in the body of man or other animals."[14]

On January 15, 2009, CVM released its industry guidance for producers and developers of GE animals and their products. The guidance provides an approach to satisfy applicable statutes and regulations.[15] The guidance states (on page 6): "The rDNA construct in a GE animal that is intended to affect the structure or function of the body of the GE animal, regardless of the intended use of products that may be produced by the GE animal, meets the FFDCA drug definition."

[11] National Research Council (NRC), *Animal Biotechnology: Science-Based Concerns*, (Washington, DC, National Academy Press, 2002). Hereinafter cited as NRC, *Animal Biotechnology* 2002.

[12] NRC, *Animal Biotechnology*, 2002. p. 14.

[13] FDA Guidance 2009. FDA noted that much of the new guidance also will be relevant to non-heritable rDNA constructs (such as modifications intended for gene therapy); a separate guidance for non-heritable constructs might come later.

[14] Also, part of the FFDCA definition of "new animal drug" is one intended for use in animals that is not generally recognized as safe and effective for use under the conditions prescribed or recommended, and that has not been used to a material extent or for a material time.

[15] The agency states at the outset: "This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

c11173008

A new animal drug (NAD) is assumed to be "unsafe" unless FDA has approved a new animal drug application (NADA) for that particular use, or the NAD is for investigational use and subject to an exemption from the drug approval requirement (among a few other specified exemptions). FFDCA and federal regulations describe information that must be submitted to FDA as part of NADAs.[16] The industry guidance lays out the pre-market approval process, including the information required of applicants which fulfills the regulatory requirements. Required information is broken out into six categories, which include product identification, molecular characterization of the construct, molecular characterization of the GE animal lineage, phenotypic characterization of GE animal, genotypic and phenotypic durability assessment, and the food/feed safety and environmental safety assessments.

The food safety assessment includes examination of both the direct toxicity (including allergenicity) potential of food from a GE animal as well as any indirect toxicity. Food and feed will be considered safe if the composition of edible materials from the GE animal can be shown to be "substantially equivalent" to that from a non-GE animal. Therefore, if animals of the same or comparable type are commonly and safely consumed, there is a presumption that food from the GE animal is safe[17] and the product will not have to be labeled.

An FDA decision regarding an NADA is a federal action subject to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321).[18] NEPA requires federal agencies to consider the environmental consequences of an action *before* proceeding with it and to involve the public in its decision-making process. To demonstrate compliance with NEPA, federal agencies must prepare an environmental impact statement (EIS) for federal actions anticipated to have "significant" impacts on the environment. The EIS is a detailed evaluation of the proposed action and provides opportunity for the public, other federal agencies, and outside parties to provide input into the process. In this case, the FDA is ultimately responsible for determining whether or not an EIS is necessary.[19]

To assist the agency in making the determination of whether an EIS is necessary, an applicant for an NAD must submit documentation to support a claim for a categorical exclusion or for drafting a preliminary environmental assessment (EA). Actions that, based on an agency's past experience with similar actions, have no significant impacts are categorically excluded from the requirement to prepare an EA or EIS. If an EA is developed and it is found that the NAD would have no significant environmental impacts, the agency would issue a finding of no significant impact (FONSI). If the EA determines that the environmental consequences of an NAD are anticipated to be significant, an EIS is prepared. In cases where significant impacts are anticipated, the federal agency may decide to prepare an EIS without first preparing an EA.

Under the NAD regulatory protocols, FDA must keep all information about a pending drug application confidential, with the exception of information publicly disclosed by the manufacturer, to protect proprietary information. This approach can limit the opportunity for public comment before approval. Given that the AquaBounty salmon could be the first GE animal

[16] Sections 512 and 571 of the FFDCA and Title 21 CFR 514 of associated federal regulations.

[17] Michael P. McEvilly, "Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon," *Duke Law and Technology Review*, vol. 17, no. 2 (2013), p. 421.

[18] The FDA guidance discusses how NEPA requirements will apply to the GE animal approval process.

[19] Section 514.1(b)(14).

c11173008

approved for human consumption, some critics have called for more transparency during the pre-market approval process.[20]

The FDA guidance does not require evaluation of genetically engineered organisms such as GE salmon as a food additive. A food additive is "any substance, the intended use of which results directly or indirectly, in it becoming a component or otherwise affecting the characteristics of food."[21] Food additives require pre-market approval from FDA, unless the additive has been evaluated by scientific experts and determined to be "generally regarded as safe" (GRAS). If made subject to a food additive review, products such as GE salmon would have to undergo comprehensive toxicological studies. Critics have questioned whether the NAD regulatory review is sufficient and have petitioned for evaluation of GE salmon under FDA's food additive requirements.

U.S. Department of Agriculture (USDA)

Several USDA agencies, operating under a number of statutory authorities, also have at least potential roles in the regulation of transgenic and cloned animals and their products. As several critical reviews have indicated, USDA has not had a clearly spelled out policy in this area, including whether it intends to exercise these authorities to regulate GE animals.[22] USDA's Animal and Plant Health Inspection Service earlier had expressed its intention to publish an advance notice of proposed rulemaking (ANPR) on GE animals, possibly in 2008.[23] Instead, in concert with FDA's notice on its draft guidance, APHIS published, in the September 19, 2008, *Federal Register*, a request for information from the public and scientists on how GE animals might affect U.S. animal health.[24] Over 670 comments were received by November 18, 2008, as they had been for the FDA draft guidance. Most of the comments were outside APHIS's authority under the Animal Health Protection Act. FDA issued its final guidance for developers of GE animals on January 15, 2009. The guidance states that FDA intends to develop a memorandum of understanding with APHIS to determine its role in the comprehensive oversight of GE animals.

APHIS has broad authority, under the Animal Health Protection Act (AHPA; 7 U.S.C. §8301 et seq.), to regulate animals and their movement to control the spread of diseases and pests to farm-raised animals. APHIS also administers the Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. §151-159), aimed at assuring the safety and effectiveness of animal vaccines and other biological products, including those of GM origin, and the Animal Welfare Act (7 U.S.C. §2131 et seq.), portions of which govern the humane treatment of several kinds of warm-blooded animals used in research (but generally not agricultural animals or cold-blooded animals such as fish). Elsewhere at USDA, the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety and proper labeling of most food animals and meat and related

[20] Michael P. McEvilly, "Lack of Transparency in the Premarket Approval Process for AquAdvantage Salmon," *Duke Law and Technology Review*, vol. 11 (2013), pp. 413-433.

[21] FFDCA, Section 201(s).

[22] See, for example, Pew Foundation, *Issues in Regulation*. Beginning on p. 139, the report contains an extensive discussion on how these and several other USDA authorities might be used for oversight of animal biotechnology.

[23] APHIS in 2007 established an Animals Branch within its Biotechnology Regulatory Services "to develop a regulatory framework for the possible regulation of genetically engineered animals." Source: APHIS website, "Regulation of Genetically Engineered Animals," at http://www.aphis.usda.gov/biotechnology/news_transgenic_animals.shtml.

[24] *Federal Register*, vol. 73, no. 183, September 19, 2008, at http://edocket.access.gpo.gov/2008/pdf/E8-21917.pdf.

c11173008

products derived from them under the Federal Meat Inspection Act (21 U.S.C. §601 et seq.) and Poultry Products Inspection Act (21 U.S.C. §451 et seq.).

Labeling of Food Containing GE Material

Federal food labeling policy, including the labeling of foods containing bioengineered material, is regulated under the Federal Food, Drug, and Cosmetic Act of 1938 (21 U.S.C. §§301 et seq.) and the Fair Packaging and Labeling Act of 1966 (P.L. 89-755;15 U.S.C. §§1451 et seq.).[25] Section 403 of the FFDCA governs food labeling. Under Section 403(a)(1), a food is considered misbranded if its labeling is false or misleading. Section 201(n) of the FFDCA provides additional guidance on how food labeling may be misleading. It states that a label is misleading if it fails to reveal facts that are material in light of representations made or suggested in the labeling, or material with respect to consequences that may result from the use of the food prescribed in the labeling, or under such conditions of use that are customary or usual.

The United States does not require mandatory labeling that identifies foods containing genetically modified material.[26] The notion of "substantial equivalence" guides food labeling requirements; if a food containing GE material is "substantially equivalent" to a food not containing GE material, federal regulations do not require that it be labeled as containing GE material. When there is no material difference between products, FDA does not have the authority to require labeling on the basis of consumer interest alone. If there is a material difference between GE and non-GE foods, FDA could require such differences to be identified in food labeling.[27] Companies that might wish to label their foods as not containing bioengineered products may do so, if they can definitively show that the foods do not contain GE products.

Genetically engineered crops became commercially available in the mid-1990s.[28] Generally, FDA has not found that food from GE organisms warrants different or greater safety concerns than non-GE organisms or exhibits different characteristics such as nutritional value or functional characteristics than from non-GE organisms. Today, oil from bioengineered soy and canola, soy protein, and high fructose corn syrup can be found in many manufactured foods, perhaps as high as 60%-70% of processed foods. The FDA has found most GE crops to be "substantially equivalent" to non-GE crops and approved their safety for human consumption in processed foods.

In 1992, FDA published a policy statement on foods derived from new plant varieties, including those developed through genetic engineering.[29] This policy statement did not establish any special labeling requirements for bioengineered foods as a particular class of foods. FDA stated that the agency had no basis for concluding that bioengineered foods differed in any meaningful way

[25] The Nutrition Labeling and Education Act of 1990 (P.L. 101-535; 21 U.S.C. §343), which amended the Federal Food, Drug, and Cosmetic Act, requires most foods to carry nutrition labeling and requires food labels with claims about nutrient content or certain health messages to comply with specific requirements.

[26] The labeling of GE foods is required by 68 other countries.

[27] Food and Drug Administration, Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, August 2010, http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm222608.htm.

[28] For more information see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues.*

[29] "Statement of Policy: Foods Derived from New Plant Varieties." Federal Register (57 FR 22984), May 29, 1992.

c11173008

from non-bioengineered foods, and therefore had no basis for requiring that such foods be labeled.[30]

Although the 1992 policy statement did not require special labeling for bioengineered foods, FDA did advise that any labeling requirements that apply to foods in general also apply to bioengineered foods. Under Section 201(n), the label of the food must reveal all "material facts" about the food. FDA currently requires special labeling of bioengineered foods if the food has a significantly different nutritional property. For example, if a new food contained an allergen that consumers would not expect to be present, or if a food contained a toxic ingredient above acceptable limits, FDA would require that the food be labeled as such.

FDA subsequently issued a 2001 draft guidance document for the voluntary labeling of foods that have or have not been developed by bioengineering. These guidelines address how the agency interprets revealing "material facts" about a food on a label. In their guidelines, FDA suggests that terms such as "GMO free" or "not genetically modified" could be technically inaccurate and misleading. On the other hand, labeling statements that the food or its ingredients were not created by bioengineering processes would likely be appropriate.[31] For example, currently, no bioengineered watermelons are on the market. A statement that a watermelon was not genetically engineered might be deemed misleading by FDA because it implies that other watermelons might be bioengineered.

General Mandatory Labeling Issues

Mandatory labeling of bioengineered products in the United States has been proposed at the national, state, and local levels. No labeling requirement has been enacted. Proponents of mandatory labeling for bioengineered foods argue that consumers should have the right to know what they are purchasing. Even if the FDA states that a bioengineered product is, from a food safety perspective, "substantially equivalent" to its traditional counterpart, labeling proponents assert that the consumer should be able to choose between those foods that may contain bioengineered products and those that do not. Some proponents of labeling also argue that for religious or ethnic reasons, many consumers may want to avoid eating animal products, including processed food products that contain animal genetic material.

With the widespread adoption of bioengineered plants and their now ubiquitous use in food processing, labeling opponents point to the logistical difficulties and costs of ensuring a food product does not contain bioengineered ingredients. As the global food system is currently constructed, segregating bioengineered products from non-bioengineered products would be technically complex and costly.[32] Labeling opponents also argue that the increased food prices as

[30] The basic federal guidance for regulating biotechnology products is the Coordinated Framework for Regulation of Biotechnology (51 Fed. Reg. 23302), published in 1986 by the White House Office of Science and Technology Policy. A key regulatory principle is that bioengineered products should continue to be regulated according to their characteristics and unique features, not their production method—that is, whether or not they were created through bioengineering. Under the Coordinated Framework, if a bioengineered product is "substantially equivalent" to a non-bioengineered product, no special regulations or labeling are required.

[31] U.S. Food and Drug Administration. 2001. *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.* http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm.

[32] Some assert that accurate labeling would require a commodity identity preservation system extending from the farmer to the consumer. From their perspective, such a system could require extensive testing and detailed record-
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c11173008

a result of labeling would be borne by all consumers, not just those who wish to avoid bioengineered products. Opponents also point out that, under the regulatory basis of "substantial equivalence," to label a bioengineered food product as such would suggest to a consumer that something is unhealthy about the bioengineered food product, and would be prejudicial.

GE Salmon Background

Wild Salmon Production

Salmon is a general name for anadromous species which belong to the taxonomic family known as *salmonidae*. Anadromous species live in fresh water during early stages of their life (egg, fry, and juvenile), migrate to the ocean to grow to adult size, and when sexually mature, return to freshwater to spawn. Most salmon production in the United States is from the wild and consists of five main species of Pacific salmon which include Chinook salmon *Onchorhynchus tshawytscha*; sockeye salmon *Onchorhynchus nerka*; coho salmon *Onchorhynchus kisutch*; pink salmon *Onchorhynchus gorbuscha*; and chum salmon *Onchorhynchus keta*.

Over 95% of wild commercial salmon production is from Alaskan stocks. These stocks are abundant and productive, largely because there have been relatively few human disturbances on major salmon rivers in Alaska such as dams. Stocks in the Pacific Northwest vary widely in health, but most are in relatively poor condition because of historic overfishing and degradation of riverine habitat. These stocks are of limited commercial importance although they still support recreational fisheries and contribute to local economies.[33] Production in both Alaska and the Pacific Northwest is enhanced by releases of salmon from hatcheries which are subsequently harvested after growing to adult size in the ocean. In 2012, total commercial landings of Pacific salmon were 288,400 metric tons with a value of $489.1 million.[34]

There are no commercial wild fisheries for Atlantic salmon in North America, and only limited numbers of Atlantic salmon *Salmo salar* spawn in New England rivers. Many Atlantic salmon runs are at historically low levels, especially in the southern parts of their range, such as New England. Population declines have been caused by overfishing, dams, and degraded environmental quality of rivers. The remaining Atlantic salmon runs in Maine are listed as endangered under the Endangered Species Act (16 U.S.C. §§1531-1543). A limited recreational fishery exists in Canada and small commercial fisheries remain in the North Atlantic.

(...continued)

keeping at each step along the food supply chain. Estimates of the costs of mandatory labeling vary from a few dollars per person per year to as much as 10% of a household food bill. See G. P. Gruere and S. R. Rao, "A review of international labeling policies of genetically modified food to evaluate India's proposed rule." *AgBioForum*, vol. 10, no. 1, 2007, http://www.agbioforum.org.

[33] Significant recreational fisheries exist for these stocks as well as aboriginal rights to harvest stocks in the Pacific Northwest.

[34] Fisheries Statistics Division, *Fisheries of the United States 2012*, National Marine Fisheries Service, Office of Science and Technology, Current Fisheries Statistics No. 2012, Silver Spring, MD, September 2013, http://www.st.nmfs.noaa.gov/Assets/commercial/fus/fus12/01_front2012.pdf.

c11173008

Salmon Aquaculture

For the aquaculture industry, salmon is a desirable candidate for genetic engineering because of high consumer demand for salmon products. Salmon aquaculture technology is well developed and commercial salmon farming has been established in many temperate countries. Of the salmon species used for aquaculture, Atlantic salmon account for most production. Atlantic salmon grow well under culture conditions and adapt well to culture conditions outside its range.[35] Most production is from net pens that are suspended in coastal waters, but salmon can be grown in freshwater raceways, tanks, or recirculating systems where adequate water supplies are available. Salmon farming has an advantage over the wild seasonal fishery because it can provide a consistent fresh product throughout the year.

During the 1970s intensive commercial salmon farming in net pens was adopted in Norway and production expanded rapidly. Salmon production in other countries with suitable coastal areas such as Great Britain, Chile, and Canada followed and also increased rapidly. Production costs decreased with improvements in broodstock quality, feed, disease management, and other production factors. During the period of rapid expansion of salmon farming, prices for both cultured and wild salmon have generally trended downward. Environmental concerns also emerged because of potential harm to wild fish stocks used for salmon feed, possible transfer of disease from farmed to wild salmon stocks, environmental effects of fish wastes and lost feed from open water cages, transfer of therapeutic agents used for cultured fish to the environment, and escapes of cultured fish.[36] The aquaculture salmon industry has reportedly made progress in addressing some of these concerns and has begun adopting best management practices to decrease external effects on the environment.[37]

Production and Trade

In 1996, world-wide salmon farm production exceeded commercial harvest of wild salmon,[38] and in 2011, aquaculture production of salmon, trouts, and smelts was 2.773 million metric tons (mmt) with a value of $15.174 billion.[39] Production of Atlantic salmon, the main species of this group, was 1.721 mmt with a value of $9.710 billion.[40] Norway led production followed by Chile and the United Kingdom (**Table 1**). In 2011, farmed production of Atlantic salmon in the United States was 18,595 metric tons with a value of $104 million.

[35] Chile is a major aquaculture producer of Atlantic salmon, but there are no native anadromous salmon stocks in Chile.

[36] For example Atlantic salmon have escaped from culture sites in British Columbia and survived in the wild.

[37] Ken Coons, "Global Salmon Initiative does outreach at Seafood Expo," *Seafood.com*, March 18, 2014.

[38] Gunnar Knapp, Cathy A. Roheim, and James L. Anderson, *The Great Salmon Run: Competition Between Wild and Farmed Salmon*, TRAFFIC North America, Washington DC, 2007.

[39] United Nations Food and Agriculture Organization, Fishery Statistical Collections, Global Aquaculture Production, Accessed October 15, 2013, http://www.fao.org/fishery/statistics/global-aquaculture-production/en. Hereinafter cited as FAO Global Aquaculture Production 2013. In this case, value is the revenue obtained by the aquaculturalist from the first buyer of the product.

[40] FAO Global Aquaculture Production 2013.

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Table 1. Atlantic Salmon Farm Production and U.S. Imports of Atlantic Salmon

Country	2011 Atlantic Salmon Production (metric tons)	2011 Atlantic Salmon Value (US Dollars 000s)	2011 Exports to the United States (metric tons)	2011 Exports to the United States (US Dollars 000s)
Norway	1,059,958	4,855,561	18,850	222,054
Chile[a]	264,319	2,223,175	54,607	563,398
United Kingdom	158,018	942,642	15,863	113,566
Canada	102,064	613,523	70,995	478,342
Faroe Islands	60,473	413,999	14,935	97,208
Australia	35,198	419,850	1	-
United States	18,595	104,132	-	-
Ireland	12,196	101,987	322	3,796
Others	10,433	35,913	5,652	41,853
Total	1,721,254	9,710,782	181,225	1,520,228

Source: FAO, Fisheries and Aquaculture Department, Fisheries Statistics and Information, Global Aquaculture Production 1950-2011 Online Query, http://www.fao.org/fishery/statistics/global-aquaculture-production/query/en.

National Marine Fisheries Service, U.S. Foreign Trade, Imports of Fishery Products, Online Query, http://www.st.nmfs.noaa.gov/commercial-fisheries/foreign-trade/raw-data/imports-exports-annual#1.

Notes:

a. U.S. imports from Chile rebounded in 2012 with an increase to 93,552 thousand metric tons. For 2009 to 2011, disease problems on Chilean fish farms decreased salmon production and imports to the United States.

Global trade of salmon products has continued to increase with gains in farmed production. Although the United States is a major producer and consumer of wild Pacific salmon, in 2011, U.S. imports of fresh and frozen farmed Atlantic salmon totaled 181.2 thousand metric tons with a value $1.520 billion. During the last decade, Atlantic salmon imports have accounted for approximately 50% to 60% of the total U.S. fresh and frozen salmon supply.[41]

AquaBounty Case: The First Genetically Engineered Food Fish

AquAdvantage Salmon

The Atlantic salmon is the first genetically engineered fish to be considered for commercial production and human consumption.[42] AquaBounty Technologies, Inc. is currently seeking regulatory approval from the FDA to sell its AquAdvantage salmon for human consumption in the

[41] U,S. Department of Commerce, National Oceanic and Atmospheric Administration and National Marine Fisheries Service, *Fisheries of the United States 2012*, Silver Spring, MD, September 2012, http://www.st.nmfs.noaa.gov/commercial-fisheries/fus/fus12/index.

[42] Glofish™ is a genetically altered version of the popular aquaria zebrafish (*Danio rerio*). The zebrafish was made fluorescent after the insertion of a sea anemone gene into the zebrafish egg.[42] This fish is currently legal to be sold in all states except California. Since Glofish™ are not meant for human consumption, FDA determined that the Glofish™ was not under its jurisdiction.[42]

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United States.[43] In 2011, the company also received a grant from the U.S. Department of Agriculture's National Institute of Food and Agriculture for work on technologies to render transgenic fish sterile to reduce the risk of gene flow to wild populations.[44]

Genetic engineering technology can be used to introduce a desirable trait(s) into an organism by transferring genetic material (DNA) from another organism. The process creates recombinant DNA (rDNA)—the result of combining two or more DNA sequences that would not normally occur together in nature. Unlike the natural process of genetic recombination, rDNA is engineered by isolating and combining DNA in a laboratory. The DNA that carries the code for a desirable protein such as a hormone is then introduced to an existing organism such as an Atlantic salmon. The introduced DNA becomes part of the organism's genetic makeup and may be passed on to the organism's offspring. Some sequences of DNA are promoters which tell the organism's cells when to make certain substances. Promoters can be spliced to the desired gene that has specific instructions to make a protein such as a growth hormone. When genes are moved from one organism to another a transgenic organism is created.

GE salmon were developed by injecting rDNA composed of a promoter from another fish, an ocean pout, and a growth hormone gene from a Pacific Chinook salmon into fertilized eggs of Atlantic salmon. Subsequent selection and breeding led to the development of the AquAdvantage salmon line, which produces growth hormone throughout the year. The year-round production of growth hormone allows for continuous feeding and growth of AquaAdvantage salmon. Growth hormone production of non-GE Atlantic salmon decreases during the winter months, and Atlantic salmon stop feeding and growing during this period.

The AquAdvantage salmon also increases the efficiency of salmon production because of faster growth and better feeding efficiency than non-GE Atlantic salmon. GE Atlantic salmon reach smolt size[45] more quickly than non-GE Atlantic salmon and grow to a market size of 1 to 3 kilograms in 16 to 18 months instead of the typical three years.[46] Although AquAdvantage salmon grow more quickly, they do not reach an overall larger size than non-GE Atlantic salmon. According to AquaBounty, analysis of AquAdvantage salmon has shown that they consume 25% less feed to achieve the same size as non-GE Atlantic salmon.[47] Feed is the most significant cost for commercial salmon aquaculture operations. Characteristics exhibited by GE salmon include accelerated growth, elevated metabolism, greater feeding motivation and efficiency, increased aggression and foraging activity, and reduced anti-predator response.[48] Similar traits have been observed for domesticated Atlantic salmon developed through selective breeding.

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[43] AquaBounty Technologies, Inc., http://www.AquaBounty.com/.

[44] See http://www.nifa.usda.gov/newsroom/news/2011news/brag_awards.html.

[45] Atlantic salmon go through several stages including egg, alevin, fry, parr and smolt. Salmon make the transition from fresh to salt water environments during the smolt stage. The age of this transition may vary widely depending on Atlantic salmon stock.

[46] According to the Development Fund, the Norwegian aquaculture industry has developed strains of salmon through selective breeding that grow as fast or faster than AquAdvantage salmon. See http://www.utviklingsfondet.no/files/uf/documents/GMO-Salmon_Fast_Growing_Hype_web.pdf.

[47] "As Final U.S. decision Nears, A Lively Debate on GM Salmon," *Environment 360*, April 18, 2013, p. http://e360.yale.edu/feature/as_final_us_decision_nears_a_lively_debate_on_gm_salmon/2641/. Hereinafter cited as Environment 360, 2013.

[48] U.S. Food and Drug Administration, *AquaAdvantage Salmon*, Draft Environmental Assessment, May 4, 2012, http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf. Hereinafter cited as FDA Draft Environmental Assessment 2012.

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Faster growth confers an advantage to using GE salmon relative to non-GE salmon and, according to some, could make land-based closed aquaculture systems competitive with cage culture currently used in coastal areas. Proponents of GE salmon maintain that this is a significant development because of environmental harm caused by salmon cage culture.

AquaBounty Application

Proposed Operations

The AquAdvantage salmon would be produced and imported into the United States under specified conditions proposed by AquaBounty. AquaBounty would produce eyed eggs at a specific facility on Prince Edward Island (PEI), Canada.[49] Eggs would be shipped to Panama and reared to market size in land-based facilities. The grow-out facility would be based in the Panamanian highlands to reduce the risk of salmon escapes and interactions with wild salmon populations.[50] Salmon would be processed in Panama before being shipped to the United States for retail sale and no live fish would be imported into the United States.

AquaBouuty has stipulated that they would only produce sterile female GE Atlantic salmon by a process which manipulates salmonid reproductive biology. The production of monosex salmon is considered to be 100% effective. In addition, pressure treatment of the eggs induces triploidy (an extra set of chromosomes) which results in sterility. When done on a commercial scale, batches of eggs are on average 99.8% triploid and rates greater than 98% are expected for most inductions.[51] All-female lines of triploid fish are considered to be one of the best current methods to insure nonbreeding populations of GE fish. Therefore, the risk of an independent breeding population of GE salmon is considered to be extremely low.

Growing GE marine fish in isolated onshore tanks rather than in offshore or nearshore pens may substantially lower the risk of escape into the wild. Both facilities currently used by AquaBounty confine production to land-based freshwater areas and proposed production would be continued in this manner. The egg production facility on Prince Edward Island is currently licensed to conduct research on GE fish under Canadian regulations. The facility has incorporated redundant measures to provide for physical containment and ensure that neither brood stock nor eggs can escape. Security is also provided at the PEI facility to stop unauthorized or unintentional access.

The grow-out facility in the highlands of Panama is located at the upper portion of a watershed at 5,000 feet above sea level. The river which supplies the facility runs into several other tributaries and discharges into the Pacific Ocean. Water is diverted from the river into a basin which supplies the facility's grow-out tanks. Screens are used wherever water flows out of the facility to prevent the escape of fish while security is provided to deter human or animal intrusion. The Panama site is geographically isolated from the range of salmon species, and environmental conditions in the river's estuary and the Pacific Ocean are unfavorable for salmon survival. According to FDA's Draft Environmental Assessment, in the event that AquAdvantage Salmon escape, geographical

[49] Questions have been raised concerning AquaBounty's approval by Environment Canada for producing and transporting the GE salmon eggs. See http://lists.cban.ca/pipermail/cban-e-news/2011-October/000346.html.

[50] There are no native populations of salmon in rivers or adjacent marine areas of Panama because these areas are not suitable for wild Atlantic salmon.

[51] Food and Drug Administration Center for Veterinary Medicine, *Briefing Packet AquaAdvantage Salmon*, September 20, 2010, p. 57.

c11173008

and geophysical containment would preclude or significantly reduce the probability of survival, dispersal, and long-term establishment.

Application History

In 1993, AquaBounty first approached the FDA concerning the commercial use of GE salmon, and in 1995 they formally applied for approval. In 2009, AquaBounty provided FDA with the last required study of AquAdvantage Atlantic salmon for their New Animal Drug Application (NADA). On September 19-20, 2010, FDA's Veterinary Medicine Advisory Committee (VMAC) met to consider issues regarding the safety and effectiveness of the NADA. The public was also given the opportunity to provide written submissions and oral testimony to the committee. On December 20, 2012, FDA announced the availability for public comment of (1) the draft environmental assessment of impacts associated with NADA submitted by AquaBounty[52] and (2) FDA's preliminary finding of no significant impact (FONSI).[53] A 60-day public comment period initially ran through February 25, 2013, but was extended through April 26, 2013.[54] On November 23, 2013, Environment Canada granted AquaBounty permission to export up to 100,000 eggs a year from a hatchery in Prince Edward Island to Panama. A land-based research facility is currently operating and raising GE salmon in Panama.[55] On March 13, 2014, the FDA Commissioner, Dr. Margaret Hamburg, stated that the Aquabounty NAD application is still under consideration and that FDA will be moving forward in a deliberate science-driven way.[56]

Food Safety

The VMAC briefing pack included a section on food safety which concluded that there are no direct or indirect food consumption hazards related to AquAdvantage salmon.[57] Although the VMAC concluded that test results established similarities and equivalence between AquAdvantage salmon and non-GE Atlantic salmon, the chairman's report added that it cannot be concluded from the data submitted that AquAdvantage Salmon would be more or less allergenic than Atlantic salmon.[58] FDA has maintained that people who are allergic to Atlantic salmon will likely be allergic to AquAdvantage Salmon because it is a finfish, but not because it has been genetically engineered.[59] In the preliminary finding of no significant impact released on December 20, 2012, FDA reiterated that food from AquAdvantage salmon is as safe as food from

[52] FDA Draft Environmental Assessment 2012.

[53] U.S. Food and Drug Administration, *Preliminary Finding of No Significant Impact AquAdvantage Salmon*, May 4, 2012, http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf.

[54] 78 *Federal Register* 10620-10621 (February 14, 2013).

[55] It has been reported that if the FDA approves imports of GE salmon, AquaBounty will request Panama's permission to convert the research facility into a production facility.

[56] U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions, *Protecting the Public Health: Examining FDA's Initiatives and Priorities*, 113th Cong., 2nd sess., March 13, 2014.

[57] Food and Drug Administration, *Briefing Packet AquaAdvantage Salmon*, FDA Center for Veterinary Medicine, September 20, 2010, p. 61, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf.

[58] Chairmen's Report, 2010.

[59] Food and Drug Administration, *Key Facts Commonly Misunderstood*, http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm226223.htm.

c11173008

non-GE salmon and determined that there are no significant food safety hazards or risks associated with AquAdvantage salmon.[60]

The Veterinary Medicine Advisory Committee and GE Salmon

The Center for Veterinary Medicine regulates transgenic animals intended for human consumption under the same authority it uses to regulate NADs.[61] As a first step in the review process, on September 19-21, 2010, FDA's Veterinary Medicine Advisory Committee met to consider the application and held a public hearing.[62] The FDA uses advisory committees and panels to obtain expert advice on science, technology, and policy. The VMAC is composed of members with technical expertise such as veterinary medicine, animal science, microbiology, biostatistics, and food sciences. Opponents of the AquaBounty application have been critical of the committee's composition and have argued for more experts in fisheries and ecology. The FDA charged the VMAC with reviewing issues regarding the safety and effectiveness of the new animal drug application. The VMAC Chairmen's report provided the following four basic questions and responses to issues related to AquAdvantage Salmon.[63]

1. Do the data and information demonstrate that the rDNA construct is safe to AquAdvantage salmon?

The committee found no evidence in the data to conclude that the introduction of the construct was unsafe to the animal.

2. Do the data and information demonstrate that there is a reasonable certainty of no harm from consumption of foods derived from AquAdvantage salmon? (safety of food from AquAdvantage Salmon was considered in the context of non-GE Atlantic salmon)

The committee deemed the studies selected to evaluate this question to be overall appropriate and a large number of test results established similarities and equivalence between AquAdvantage Salmon and Atlantic salmon.

3. Do the data indicate that AquAdvantage Salmon grow faster than their conventional counterparts?

The committee found evidence in support of this claim.

4. Are any potential environmental impacts from AquAdvantage Salmon production adequately mitigated by AquaBounty Technologies' proposed conditions of use?

Although the committee recognized that the risk of escape from either facility could never be zero, the multiple barriers to escape at both the Prince Edward Island and Panama facilities were extensive. Because part of the containment strategy is dependent on management standard operating procedures, the committee felt that rigorous adherence to policy would need to be maintained at both sites to sustain the barriers.

Evaluation of Potential Environmental Impacts

To assess potential environmental impacts, FDA has released a draft EA and consulted with the Fish and Wildlife Service and the National Marine Fisheries Service (NOAA Fisheries). In 2007, legislation was passed to require the FDA to consult with the National Marine Fisheries Service and to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks.[64] According to FDA, the two agencies

[60] Food and Drug Administration, *Preliminary Finding of No Significant Impact*, AquAdvantage Salmon, May 4, 2012, http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf.

[61] The FDA Center for Veterinary Medicine's "Questions and Answers about Transgenic Fish," http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm133255.htm.

[62] Background documents for this public hearing are available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm. Also see 75 *Federal Register* 52602-52605, August 26, 2010.

[63] David Senior, Interim Chair, VMAC, *Chairman's Report*, Food and Drug Administration, VMAC Meeting, September 20, 2010, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230467.pdf.

[64] 21 U.S.C. §2106.

c11173008

have consulted on this matter, but this report has not been developed and no target date for its completion has been specified.

FDA has made a "no effect" determination under the Endangered Species Act (ESA; 16 U.S.C. 1531 et seq.) and concluded that approval of the AquAdvantage Salmon NADA will not jeopardize the continued existence of Atlantic salmon listed as threatened or endangered or result in the destruction or adverse modification of their critical habitat. FDA and NMFS engaged in technical discussions during 2010 and 2011 and based on those discussions NMFS did not object to the proposed action. However, critics have questioned whether FDA has sufficient expertise to identify and protect against all potential ecological damage that might result from the widespread use of transgenic fish.[65]

Summary of FDA Conclusions Concerning the Environmental Impacts of AquaAdvantage Salmon

The Draft EA attempted to address potential hazards and harms to the U.S. environment if AquAdvantage Salmon were to escape. The EA posed the following risk related questions and provided the corresponding answers.[66]

1. What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?

Due to multiple, redundant containment measures at the sites of egg production and grow-out, the possibility of AquAdvantage Salmon (or the broodstock used to produce these fish) escaping to the environment is extremely remote.

2. What is the likelihood that AquAdvantage Salmon will survive and disperse if they escape the conditions of confinement?

In the unlikely event of an escape or release, environmental conditions at both the egg production and grow-out sites are sufficiently inhospitable to limit long-term survival and spread of AquAdvantage Salmon to other locations.

3. What is the likelihood that AquAdvantage Salmon will reproduce and establish if they escape the conditions of confinement?

AquAdvantage Salmon would be produced as all-female, triploid fish. As such they would be effectively sterile. The combination of triploidy and an all-female population is expect to render AquAdvantage Salmon effectively and functionally sterile resulting in complete reproductive containment.

4. What are the likely consequences to, or effects on, the environment of the United States should AquAdvantage Salmon escape the conditions of confinement?

The collective information on the potential for survival, dispersal, reproduction and establishment indicates that exposure pathways for AquAdvantage Salmon to reach the United States are incomplete; therefore, no effects are expected on the environment of the United States.

The draft environmental assessment evaluated the potential environmental impacts associated with approving the NADA for AquAdvantage Salmon. According to FDA, it has verified that AquAdvantage Salmon would be produced and grown in secure facilities. The escape and survival of GE salmon from containment into the local environments of PEI and Panama is considered by FDA to be extremely remote. The environment around the egg producing facility and the grow-out facility are described by FDA as inhospitable. In the event that fish escape and survive, reproduction in the wild would be unlikely because the AquAdvantage salmon will be all

[65] See the Center for Food Safety's "Genetically Engineered Fish," http://www.centerforfoodsafety.org/geneticall3.cfm.

[66] Food and Drug Administration, *AquAdvantage Salmon*, Draft Environmental Assessment, May 4, 2012, http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf. Hereinafter cited as Draft Environmental Assessment, 2012.

c11173008

female triploid fish which are nearly all sterile.[67] In the draft EA, FDA concluded that it "found no evidence that approval of an NADA for AquaAdvantage Salmon would result in significant impacts on the environment in the United States."[68] If significant new information or challenges arise in the public comments, FDA may determine that a full environmental impact statement is required prior to approval of AquaBounty's application.

NEPA does not require an analysis of environmental effects in other countries and therefore, potential effects on the environment in Canada and Panama were not considered. These effects would be evaluated only if potential exposure pathways exist which could cause significant effects on the environment in the United States. Social and economic effects were not analyzed in the EA because the proposed action, if implemented as required, is not anticipated to significantly affect the physical environment of the United States.

In an effort to broaden the evaluation of the AquaBounty application, a coalition of environmental groups called on FDA to prepare an EIS on this action and to consult more closely with federal agencies about possible threats to endangered wild Atlantic salmon.[69] On May 25, 2011, these groups filed a formal citizen petition urging FDA to withhold approval until an EIS has been completed.[70] Some VMAC members also stated that an EIS would be needed if the company proposes additional facilities for growing salmon.

Food Safety Issues

A National Research Council study maintains that there is a low to moderate food safety risk from GE seafood.[71] Since genetic engineering can introduce new protein into a food product, there are concerns that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a "new" food.

On February 7, 2012, three non-governmental organizations petitioned the FDA's Office of Food Additive Safety (OFAS) to review the AquaBounty application under the FFDCA food additive provisions.[72] The petitioners argued that the gene expression product (GEP) of the genetic construct creating the AquAdvantage salmon, is a food additive under FFDCA (§201(s), 21 U.S.C. §321). AquAdvantage salmon exhibit an elevated level of Insulin Growth Factor-1 (IGF-1), which they asserted is a novel food additive and constitutes a "material fact" about the GE-salmon compared to its non-GE counterpart.[73] They have requested that FDA make a finding

[67] Triploid salmon have an extra set of chromosomes and triploidy renders them sterile. On average, treatment is expected to result in 99.8% triploid fish, and according to FDA with rates of over 98% for most inductions.

[68] Draft Environmental Assessment, 2012.

[69] Letter from Rebecca Wodder, President, American Rivers, et al. to Margaret Hamburg, Commissioner, U.S. Food and Drug Administration, November 8, 2010, http://www.eenews.net/assets/2010/11/08/document_pm_01.pdf.

[70] Ocean Conservancy et al., *Citizen Petition Regarding AquaBounty Technologies' Application for Approval of Genetically Engineered Salmon*, Citizen Petition Before the U.S. Food and Drug Administration, May 25, 2011, http://earthjustice.org/sites/default/files/FinalGESalmonCitizenPetition.pdf.

[71] National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects,* (Washington, DC: National Academies Press, 2004), http://books.nap.edu/openbook.php?record_id=10977&page=R1.

[72] Food and Water Watch, Consumers Union, and The Center for Food Safety, *Petition to Deem ABT Technologies' Genetically Engineered AquaAdvantage Salmon An Unsafe Food Additive*, February 7, 2012.

[73] IGF-1 is a hormone that helps accelerate the growth of the bioengineered salmon. According to the petition, IGF-1 (continued...)

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that neither the AquAdvantage salmon nor the GEP used to create it is "generally regarded as safe" (GRAS).[74] In particular, the petition requested extensive pre-market testing, arguing that "[t]he Agency's general classification of rDNA constructs as new animal drugs does not displace or override the Agency's regulations and guidelines, and nothing precludes the Agency from also regulating GE salmon and its components as food additives."

Opponents of approval also question the validity of data supplied by AquaBounty for risk assessment.[75] They contend that FDA should have AquaBounty re-conduct its studies, or FDA should either conduct the studies themselves or ask an independent laboratory to undertake the studies. If the AquAdvantage Salmon were shown to have materially different nutritional or health characteristics from a non-GE salmon, while still being deemed safe, FDA could require that the fish be labeled.

FDA has continued to review the AquaBounty proposal solely under the NAD protocol. Because the review process of the AquAdvantage Salmon could become precedent-setting for review of other GE animals, the issue of the appropriate agency regulatory protocol—NAD or that of a food additive—is likely to remain a significant point of contention in the regulatory process.

Environmental Issues

The potential harm that might be caused by GE organisms which escape from aquaculture facilities is of great concern to some scientists and environmental groups.[76] A National Research Council report stated that transgenic fish pose the "greatest science-based concerns associated with animal biotechnology, in large part due to the uncertainty inherent in identifying environmental problems early on and the difficulty of remediation once a problem has been identified."[77] For AquAdvantage Salmon, concerns include interbreeding and competing with wild Atlantic salmon and competition with fish both within and outside the range of Atlantic salmon.

Interbreeding with Wild Atlantic Salmon

Experiences with farmed Atlantic salmon may provide some insights regarding potential interactions of GE Atlantic salmon and wild Atlantic salmon. Farmed Atlantic salmon frequently escape from fish farms in areas both within and outside their native ranges.[78] Escaped farmed

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has been shown in some studies to be linked to breast, colon, prostate, and lung cancers.

[74] The petition also argues that the AquaBounty salmon raises safety concerns because the salmon exhibits higher levels of the growth hormone IGF-1 that could have increased allergen potential.

[75] Tim Schwab, "Is FDA Ready to Regulate the World's First Biotech Food Animal?" *Food and Drug Policy Forum*, vol. 3 (July 24, 2013).

[76] See also Matthew Morgan, "The AquAdvantage Salmon: Who Owns Escaped Genetically Modified Animals?" *Ocean and Coastal Law Journal*, v. 17, no. 1 (2011): 127-161.

[77] National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2004), http://books.nap.edu/openbook.php?record_id=10418&page=R1.

[78] Eva B. Thorstad, Ian A. Fleming, and Philip McGinnity, *Incidence and impacts of escaped farmed Atlantic salmon Salmo salar in nature*, Norwegian Institute for Nature Research, Norway, 2008. Hereinafter cited as Thorstad et al. 2008. For example, Atlantic salmon have escaped from areas within their ranges such as coastal farms in the North (continued...)

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salmon have been found on spawning grounds during the period when wild Atlantic salmon spawning occurs.[79] Farmed salmon also spawn in these areas, but with lower success than wild Atlantic salmon. Successful spawning appears to have most frequently occurred between farmed females and wild males. The offspring of farmed and farmed and wild salmon (hybrids) occupy areas also inhabited by wild salmon. It is not known whether the presence of farmed and hybrid juveniles limit food and resources for wild fish and competitively displace native juveniles. The outcomes of interactions between farmed and wild juveniles are likely to vary depending on specific circumstances such as the quality and availability of habitat and associated resources.

Domestication of farmed salmon has changed their genetic composition and reduced genetic variation. These changes have occurred because limited numbers of brood fish are used for spawning farmed fish and farmers select for specific traits.[80] Much of present-day farm production of Atlantic salmon is now based on five Norwegian strains. Farmed and wild hybrids and backcrossing of hybrids in subsequent generations may change genetic variability and the frequency and type of alleles present in wild populations.[81] The extent and nature of these changes to genetic variability may affect survival (fitness) of these populations. Changes in the genetic profiles of wild populations have been shown to have occurred in several rivers in Norway and Ireland where inter-breeding of wild and farmed fish is common.[82] Large-scale experiments in Norway and Ireland show highly reduced survival and lifetime success of farmed and hybrid salmon compared to wild salmon.[83]

Given previous experiences with farmed salmon, opponents hypothesize that farmed GE salmon will eventually escape from aquaculture systems and interbreed with wild Atlantic salmon. GE salmon may exhibit different fitness-related traits such as higher feeding and growth rates. Researchers have questioned whether the flow of a gene or genes from transgenic fish such as GE salmon may confer specific advantages to hybrids relative to wild fish resulting in population-wide consequences.[84] The "Trojan gene hypothesis" speculates that populations could become extinct when a gene that confers a reproductive advantage also renders offspring less able to survive in the natural environment. However, comments to the VMAC from one of the researchers who framed the hypothesis stated that the Trojan gene effect only occurs when there is a conflict between mating success (if GE salmon were to mate more successfully) and viability fitness (offspring were less likely to survive in the wild). He concluded that the risk of harm is low because data conclusively show that in this case there is no Trojan gene effect and the transgene will be purged by natural selection.[85] However, the potential consequences of the

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Atlantic (Canada, Norway, and Great Britain) and from areas outside their range in the Pacific (Chile and British Columbia).

[79] There are no recorded cases of hybridization in nature between Atlantic and Pacific salmonid species.

[80] Oystein Skaala, Vidar Wennevik, and Kevin A. Glover, Evidence of temporal genetic change in wild Atlantic salmon, *Salmo salar*, populations affected by farm escapees, "ICES Journal of Marine Sciences," vol. 63 (2006), pp. 1224-1233. Fitness can be generally described as the ability to survive and reproduce.

[81] An allele is one of two or more versions of a gene occupying a specific spot on a chromosome that control a specific trait.

[82] Thorstad et al. 2008.

[83] Thorstad et al. 2008.

[84] Kelly M. Pennington, Anne R. Kapuscinski, and Michale Morton, et al., "Full Life-cycle assessment of gene flow consistent with fitness differences in transgenic and wild-type Japanese medaka fish (*Oryzias latipes*)," *Environmental Biodiversity Research*, vol. 9 (2010), pp. 41-57.

[85] Draft Environmental Assessment 2012, p. 91.

c11173008

interbreeding of farm (including GE salmon) and wild Atlantic salmon remains a long-term concern of those attempting to conserve wild Atlantic salmon populations.

Competition and Other Interactions

Critics are also concerned that AquAdvantage Salmon could become established in the wild and compete with native fish, including both Atlantic salmon and other species, for food, habitat, mates, and other resources.[86] This is a concern both within and outside the range of Atlantic salmon. Previous deliberate attempts to introduce Atlantic salmon have failed and no self-sustaining populations of anadromous Atlantic salmon have been established outside the natural range of the species. In British Columbia, Atlantic salmon which escaped from fish farms have spawned and produced wild-spawned juvenile Atlantic salmon, but it is uncertain whether they have established self-reproducing breeding populations.[87] Experimental crosses between GE Atlantic salmon and wild brown trout (*Salmo trutta*) have been shown to be viable and to confer a growth advantage to the hybrid. Researchers concluded that transgenic hybrids could detrimentally affect wild salmon populations, but that introgression of the gene into the brown trout genome through backcrossing is unlikely.[88]

If GE salmon were to escape and establish self-sustaining populations, competition for resources is another potential concern. Since GE salmon grow faster, it has been suggested that they may outcompete wild fish for habitat and food.[89] Laboratory experiments on AquAdvantage relatives indicate that they are more likely to feed in the presence of a predator than non-GE controls.[90] Another study which compared GE and non-GE salmon fry under food-limited conditions in simulated environments showed no difference in territorial dominance, growth, or survival of first feeding fry at high densities.[91] Biotechnology proponents argue that GE fish, if they escape, would be less likely to survive in the wild, especially when they are reared in protected artificial habitats and have not learned to avoid predators.

The consequences of potential competition would also depend on many factors, including the size and health of the wild population, the number and characteristics of the escaped fish, and local environmental conditions. Some argue that once transgenic fish become established, they could be difficult or impossible to eradicate such as many invasive species. This scenario would depend on reproduction of GE salmon in the wild.[92] Critics also express concerns that U.S. wild Atlantic salmon populations are at extremely low levels and especially vulnerable to ecological changes.

[86] Atlantic salmon and Pacific salmon are unable to spawn because they are different species.

[87] Thorstad et al. 2008, p. 67.

[88] Krista B. Oke, Peter A. H. Westley, and Darek T. R. Moreau, et al., "Hybridization between genetically modified Atlantic salmon and wild brown trout reveals novel ecological interaction," *Proceedings of the Royal Society: Biological Sciences*, vol. 280, no. 1763 (August 7, 2013).

[89] Draft Environmental Assessment 2012, p. 91.

[90] Draft Environmental Assessment 2012, p. 92.

[91] Draft Environmental Assessment 2012 p. 92.

[92] Wild reproduction of GE fish is unlikely if only sterile triploid females are produced.

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Future Concerns

According to the FDA, the NADA is for a specific set of conditions and any modification to these conditions would require notification of the FDA.[93] Major or moderate changes to these conditions would require a supplemental NADA which would trigger environmental analyses under NEPA. The FDA states that expansion or changes to facilities identified in the proposal would constitute major or moderate changes which would require a supplemental NADA and analysis under NEPA. If FDA approves AquaBounty's application, FDA retains the authority to withdraw its approval should significant subsequent concerns arise.

If GE salmon are approved for consumption in the United States, it is likely that additional applications will be made for additional geographic areas and for a variety of different grow-out or culture techniques. Under the current proposal, AquaBounty would produce GE salmon in a limited grow-out facility in Panama. Some have speculated that subsequent proposals would be subject to less scrutiny and question whether future uses will be as apparently benign.[94] If additional applications are approved, it is possible that future grow-out facilities would be located closer to the range of wild Atlantic salmon thereby decreasing the effectiveness of geographic containment. The NADA would not include the culture of AquAdvantage Salmon in net pens,[95] but if cage culture were used to produce GE salmon it would increase the probability of fish escaping to the wild. AquaBounty has denied that their company would approve the use of AquAdvantage Salmon in cage culture.[96]

Labeling Issues

The question of how to label the food derived from the AquAdvantage salmon is separate from the decision about whether to approve the new animal drug application. Although FDA is not required to address labeling issues prior to the food being marketed, FDA is considering these two issues simultaneously.[97] If the AquAdvantage salmon NADA is approved, FDA is to determine whether additional labeling is appropriate.

FDA has determined that the AquaBounty salmon is as safe for human consumption as non-GE salmon, in other words, that the AquaBounty salmon is "substantially equivalent" to non-GE salmon. Opponents of the AquaBounty salmon, however, have argued the need to label it as a GE product on a presumed basis of consumers' right-to-know. Proponents of the AquaBounty salmon argue that labeling a "substantially equivalent" food would imply that the GE fish was different in ways that could be seen as negative. Given that the labeling issue for GE foods remains unsettled, labeling the AquaBounty salmon, as potentially the first GE animal approved by FDA for human consumption, has become an important aspect of FDA's overall approval process. While

[93] FDA Environmental Assessment 2012, p. 2.

[94] Northwest Environmental Defense Center, *The Newsletter of the Northwest Environmental Defense Center*, Critique of Genetically Engineered Salmon, 2013, http://law.lclark.edu/live/files/14124-articlecritique-of-genetically-engineered-salmon-.

[95] Grow-out in net pens is less costly than culture of salmon in land-based facilities.

[96] Environment 360, 2013.

[97] FDA, "Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon," http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm.

c11173008

voluntary labeling would be permissible—as long as the label was not false or misleading—proponents of the AquaBounty salmon believe such labeling could reduce retail demand for the fish. Many major grocery retail chains, such as Safeway, Trader Joe's, Target, Kroger, and Whole Foods, have already announced that they would not sell the AquaBounty fish when it becomes commercially available.[98]

States have also taken steps to regulate the transport and use of GE fish. For example, Maryland,[99] Washington,[100] Oregon,[101] Minnesota,[102] Wisconsin,[103] and California[104] have passed laws banning the release of GE fish in some or all state waters. In addition, Alaska requires GE fish to be labeled.[105] No federal law specifically addresses labeling GE fish and seafood.

Fishing Industry Interactions

The success of farm-raised Atlantic salmon has made some who work in the commercial wild salmon fishing industry, particularly those in Alaska, especially sensitive to potential impacts of GE salmon. Fishermen have concerns related to further increases in salmon aquaculture production and environmental harm to wild stocks. The salmon fishing industry in Alaska does not produce intensively farmed fish salmon in net pens and would not benefit from the use of GE salmon.[106]

Over the last three decades, the rapid growth of farmed salmon and trout production has been one of the primary drivers of world salmon prices.[107] In 2002, prices paid to Alaska fishermen were less than half of the average prices paid from 1980 to 2005.[108] Changes to salmon markets were actually much more complex during this period because the industry was transformed by a variety of factors in addition to the growth in the total supply of salmon. Salmon markets were also affected by the availability of different types of salmon products, the timing of production, and development of market standards.

Some believe that the wide use of GE salmon would depress salmon prices. Potential interactions between GE salmon aquaculture, ongoing salmon aquaculture, and wild fisheries are difficult to fully assess. Part of the difficulty is related to the complex nature of interrelated drivers of aquaculture and wild salmon production. For example, public acceptance can affect prices which

[98] "Kroger, Safeway Will Nix GMO Salmon Regardless of FDA Decision," *Food Safety News*, March 4, 2014.

[99] Maryland Natural Resources Code Ann.§4-11A-02 (2003).

[100] Washington Administrative Code 220-76-100 (2003).

[101] Oregon Administrative Rules 635-007-0595 (2004).

[102] Minn. Stat. §§17.4982, 18B.285, §18B.01, 18F.01-.13 (2003).

[103] Wis. Stat. §146.60 (2002).

[104] California Fish & Game Code §15007 (2003) and Dept. of Fish and Game §671.1.

[105] AK Food & Drug Code §17.20.040 (2005).

[106] Alaska salmon fisheries benefit from releases of salmon from hatcheries which grow-out in the ocean and enhance wild stocks.

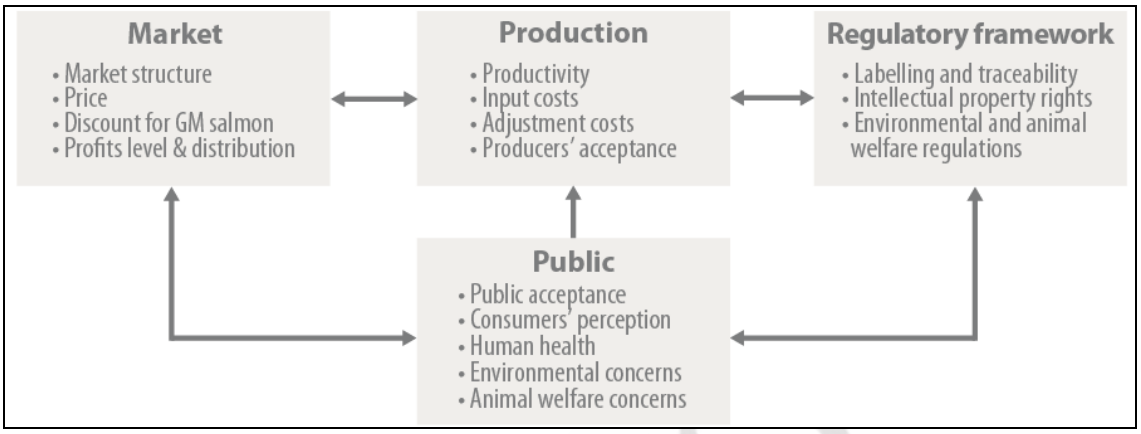
[107] Gunnar Knapp, Cathy A. Roheim, and James L. Anderson, *The Great Salmon Run: Competition Between Wild and Farmed Salmon*, Traffic North America, Washington DC, January 2007. Hereinafter cited as the Great Salmon Run 2007.

[108] Great Salmon Run 2007. p. 213.

c11173008

in turn may affect salmon production. Major categories of drivers include the regulatory framework, production, markets, and the public (**Figure 1**).[109]

Figure 1. Driving Forces of Salmon Production



Source: Davide Menozzi, Cristina Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios," *AgrBioForum*, vol. 15, no. 3 (2012).

Although some assume that approval of GE technology will be followed by a rapid increase in farmed salmon production, it is unlikely that this will occur. At least initially, annual production at the AquaBounty Panama facility is limited to a capacity of approximately 100 metric tons compared to current U.S. salmon consumption of approximately 180 thousand metric tons. Significant production increases would depend on approval of additional sites in salmon producing regions of the world. The regulatory framework will determine which production methods would be used and where they are allowed. If only land-based facilities are allowed, then greater aquaculture production would depend on whether the advantages of using GE salmon (higher growth rate and feed conversion efficiency) can outweigh the greater costs of land-based facilities. Currently, the economic viability of most land-based salmon grow-out facilities is questionable.[110] Significant increases in land-based production also may be constrained by the number of available sites with sufficient water quality and volume. Therefore, the magnitude and timing of greater salmon production, if it were to occur, would be very uncertain.

Some in the commercial fishing industry have stated that it has successfully educated the public to discriminate among fish from different sources, such as wild and farmed salmon. On the other hand, some believe that a publicized escape of GE fish could lead to less public acceptance of their wild product. To differentiate wild and GE salmon, commercial Alaskan fishermen also have requested the labeling of GE salmon.[111] Some industry groups are concerned that such labeling might lead consumers to believe that wild fishery products are also genetically engineered and

[109] Davide Menozzi, Cristina Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios," *AgrBioForum*, vol. 15, no. 3 (2012).

[110] Production from salmon land-based systems is insignificant, but the David Suzuki Foundation has advocated for land-based systems and maintains that they are viable.

[111] Erika Bolstad, "Alaskans say GM salmon threatens wild market as public FDA objections top 33,000," *Anchorage Daily News*, March 6, 2013.

c11173008

perceived as unsafe for consumption.[112] An alternative considered by commercial interests would involve labeling of wild salmon as a product that was not produced with GE technology.

Consumer Acceptance

It is uncertain whether consumers will accept GE fish, but it appears that a broad segment of the U.S. population is opposed or at least skeptical of consuming the product.[113] GE salmon may taste the same and are expected, like other Atlantic salmon aquaculture products, to be less expensive than wild-caught fish. However, food safety issues, ethical concerns over the appropriate use of animals, and environmental concerns might affect public acceptance of GE fish as food. Ongoing campaigns by environmental and consumer groups have asked grocers, restaurants, and distributors to sign a pledge to not sell GE fish products, even if they are approved by FDA.[114]

Demand for fish products, especially those high in fish oils such as Atlantic salmon, grew quickly during the past three decades and is expected to continue growing. In the past, aquaculture productivity gains and reductions in cost have been passed on to the consumer in the form of lower prices. One study speculated that consumers would require a significant price discount to purchase the GE salmon product.[115] The discount would likely vary by country and depend on consumer demographic factors such as age.

Production increases could contribute to consumer benefits associated with lower prices and health benefits from consumption of salmon rather than less healthy protein sources. If GE salmon can be sold for a relatively low price, it could stimulate salmon consumption in low-income households.[116] Some researchers have questioned whether the potential benefits associated with the wide use of GE salmon also should be considered as part of the approval process.[117]

Congressional Actions

Some Members of Congress have raised concerns about FDA's approval process for GE salmon. On April 24, 2013, 20 Members of the House and 12 Members of the Senate sent similar letters that requested FDA Commissioner Margaret Hamburg halt the approval process.[118] In particular, the letters stated that the FDA process has not been adequate to ensure GE salmon is safe for the

[112] See CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, by Tadlock Cowan.

[113] Shane O'Halloran, "Consumers not interested in genetically modified salmon," *Food Engineering*, April 23, 2013, pp. http://www.foodengineeringmag.com/articles/90611-consumers-not-interested-in-genetically-modified-salmon.

[114] See the Center for Food Safety's website and featured actions, "Tell Costco to Reject GE Salmon," http://www.centerforfoodsafety.org/geneticall3.cfm.

[115] Davide Menozzi, Cristina Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios," *AgrBioForum*, vol. 15, no. 3 (2012).

[116] Martin D. Smith et al., "Genetically Modified Salmon and Full Impact Assessment," *Science*, v. 330 (November 19, 2010): 1052-1053. Hereinafter cited as Smith et al. 2010.

[117] Smith et al. 2010.

[118] Letter from Don Young et al. to Dr. Margaret Hamburg, Commissioner, FDA, April 24, 2013, and Letter from Senator Mark Begich et al. to Dr. Margaret Hamburg, April 24, 2013.

c11173008

environment and consumers. They also expressed concern with the precedent that this ruling could set for future applications for other genetically engineered fish such as tilapia and trout. If the agency still proceeds with approval of the product, Members also urged FDA to develop labeling requirements to distinguish the product as genetically engineered.

Bills focusing on regulating or prohibiting GE salmon have been introduced in the 113th Congress. S. 246 and H.R. 1667 are similar bills which would make it unlawful to:

> (1) ship, transport, offer for sale, sell, or purchase a covered fish (GE fish), or a product containing a covered fish, in interstate or foreign commerce;
>
> (2) have custody, control, or possession of, with the intent to ship, transport, offer for sale, sell, or purchase a covered fish, or a product containing covered fish, in interstate commerce;
>
> (3) release a covered fish into a natural environment; or
>
> (4) have custody, control, or possession of a covered fish with the intent to release it into a natural environment.

The definition of a covered fish under H.R. 1667 would include any finfish while S. 246 would include salmon, anadromous fish, or marine fish. H.R. 1667 also would explicitly make it illegal to engage in net-pen culture of covered fish. Both bills would include exceptions for scientific research, fish collected for the purpose of supporting the act, or if NOAA finds that there would be no significant impact in accordance with NEPA. The NEPA analysis would have to include an environmental risk analysis, assessment of best or worst case probabilities of confinement failure, costs to eradicate escaped covered fish, and assessment of economic damage of escaped covered fish. Both bills also would require completion of the report on environmental risks associated with GE seafood products which was required under Section 1007 of the Food and Drug Administration Amendments Act of 2007 (21 U.S.C. 2106).

H.R. 584 and S. 248 would amend Section 403 of the FFDCA (21 U.S.C. 343) by adding a requirement to label products which contain genetically engineered fish. H.R. 1699 and S. 809 would require labeling of genetically engineered foods including fish. On May 22, 2013, S.Amdt. 965 to S. 954 was proposed and would have required that any food offered for sale have a label indicating that the food contains a genetically engineered ingredient. On May 23, 2013, the amendment was defeated by a vote of 27-71.

In the 112th Congress, several bills also were introduced to address concerns related to GE fish including House and Senate bills which would have required labeling of GE fish (S. 229, H.R. 520, and H.R. 3553), deemed GE fish as unsafe for human consumption (S. 230 and H.R. 521) and prohibited the sale of GE fish (S. 1717). On June 16, 2011, Section 744 of H.R. 2112 was passed by the House which would have prohibited the FDA from spending FY2012 funds to approve any application for GE salmon. On September 7, 2011, the Senate Committee on Appropriations reported H.R. 2112 without the prohibition on FDA spending (S.Rept. 112-73), and the provision was not included in the subsequently enacted P.L. 112-55. On May 24, 2012, S.Amdt. 2108 to S. 3187 was defeated, which would have prohibited approval of GE fish by FDA unless NOAA concurred with such approval. No further action was taken on any of these bills during the 112th Congress.

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Future Considerations

Some have asserted that the FDA's approach to GE salmon evaluation fails to consider the full scope of potential impacts or to fully assess the risk of unintended consequences. They claim that neither the VMAC nor the EA have fully considered the broader potential risks of AquAdvantage salmon approval. They have argued that FDA is not suited to undertake biological and ecological studies of this nature and they question whether the regulatory system has kept pace with advances in GE technology. They support development of a comprehensive EIS to more fully assess the broader context of social, economic, and environmental implications of GE salmon.

FDA has evaluated GE salmon as a new animal drug which is safe for human consumption. Regulation of transgenic animals as NADs, however, suggests to some observers (e.g., the Center for Food Safety, Union of Concerned Scientists) the inherent weakness of existing regulatory structures to respond adequately to the complexities that arise with animal biotechnology innovations.[119] An immediate issue is whether AquaAdvantage salmon should be subject to a more rigorous assessment as a food additive by FDA's Office of Food Additive Safety. Some might argue that the NAD assessment has already covered issues related to food safety and found that GE salmon are essentially the same as non-GE salmon. However, in addition to ensuring the safety of GE salmon further assessment could reassure consumers and retailers who are skeptical of the new technology, and more rigorous assessment would set a precedent for future products which may warrant greater scrutiny.

Some have expressed concerns that a continued delay signals that the United States might cede its leadership position in agricultural biotechnology. Rejection of the AquaBounty application would send the message that science-based regulatory oversight is subject to political intervention.[120] Other countries which are likely to commercialize this technology may be less concerned with potential environmental effects. GE technology is likely to be adopted for aquaculture in other parts of the world and according to the FDA, implications of GE salmon disapproval in the United States and adoption of the technology elsewhere are unknown.[121] Aquabounty has reported that they have spent $50 million developing the technology and in applying for approval. Some would question whether technology industries in the United States will continue to attract investors and compete with companies in other parts of the world when there is such a long and uncertain approval process.

AquAdvantage salmon is likely to be the first of many transgenic candidates for commercial aquaculture production, and some question whether this case will establish a proper or useful precedent for future assessment of this technology.[122] Some scientists assert that the FDA decision involves broader social costs and benefits of using genetic engineering and support wide-ranging interdisciplinary evaluation of GE salmon approval.[123] According to one group of researchers,

[119] See Center for Food Safety website, at http://www.centerforfoodsafety.org/geneticall7.cfm; and the Union of Concerned Scientists website, at http://www.ucsusa.org/food_and_agriculture/.

[120] Alison L. Van Eenennaam, William M. Muir, and Eric M. Hallerman, "Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?," *Food and Policy Forum*, vol. 3, no. 13 (July 24, 2013).

[121] Draft Environmental Assessment 2012.

[122] Smith et al. 2010.

[123] Smith et al. 2010.

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assessment of long-term changes related to GE salmon will require the interrelated study of production systems, markets, consumer acceptance, and regulatory framework.[124] They also would include assessment of potential long-term changes associated with the wide use of GE salmon in major salmon-producing countries. Generally, it appears that many would prefer a comprehensive analysis rather than a piecemeal approach as new culture methods and areas are proposed by successive applications. Whether the current process affords adequate safeguards for the public while allowing for the application of new genetic technologies remains an open question.

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[124] David Menozzi, Christena Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenetic Salmon Marketing Scenarios," *AgBioForum*, vol. 15, no. 3 (2012).

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