

Genetically Engineered Salmon

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Summary

On November 19, 2015, the Food and Drug Administration (FDA) approved AquaBounty Technologies' application to produce AquAdvantage Salmon, a genetically engineered (GE) Atlantic salmon, for human consumption. This is the first GE animal that has been approved for human consumption in the United States. FDA also has proposed voluntary guidelines for using labels that indicate whether food products are derived from GE salmon.

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 to 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 eat.

Nearly twenty years ago, AquaBounty Technologies Inc. began the application process to obtain FDA approval for a genetically engineered Atlantic salmon. In 2009, AquaBounty submitted the last required study for its 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. FDA has concluded that 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 the product.

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. To address these concerns, AquaBounty will 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. AquaBounty will limit production to land-based facilities to isolate GE salmon from the environment and minimize the likelihood of harm to wild fish populations. Production from these facilities is limited to approximately 100 metric tons, which is a small fraction of the current U.S. fresh and frozen salmon supply of 700,000 metric tons.

Some have asserted that FDA approval of AquAdvantage Salmon was overdue and that delays have hindered investment and development of the U.S. biotechnology sector. Others have questioned the adequacy of 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. Additional concerns have been voiced concerning food safety, labeling of GE salmon, and economic effects on existing wild salmon fisheries.

In response to concerns related to the production and use of GE salmon as food, legislation has been introduced during the last several Congresses to restrict the production and require the labeling of GE organisms. Legislation introduced in the 114th Congress related to labeling GE salmon specifically or to GE organisms generally includes H.R. 393, S. 738, H.R. 913, S. 511, and H.R. 1599. Two FY2016 appropriations bills for Agriculture, Rural Development, Food and Drug Administration and Related Agencies (S. 1800 and S. 2129) include provisions that would provide funds to implement labeling requirements for GE salmon. H.R. 394 would prohibit most uses of GE fish, with some exceptions or if certain conditions are met. In addition to labeling requirements, S. 738 would require an environmental impact statement for any application to produce GE salmon intended for human consumption. H.R. 1599 has been passed by the House, and H.R. 1800 has been reported by the Senate Committee on Appropriations. Since they were introduced, no further action has been taken on the other bills related to genetic engineering.

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Introduction

On November 19, 2015, the Food and Drug Administration (FDA) approved AquaBounty Technologies' application to produce AquaAdvantage Salmon, a genetically engineered (GE) Atlantic salmon, for human consumption.¹ This is the first GE animal that has been approved for human consumption in the United States.² FDA also has proposed voluntary guidelines for using labels that indicate whether food products are derived from GE salmon.

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 deoxyribonucleic acid (DNA), known as rDNA,³ techniques, including the entire lineage of animals that contain the modification.⁴

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.⁵ 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.⁶ 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.⁷

¹ See U.S. Department of Health and Human Services (HHS), Food and Drug Administration (FDA), “AquAdvantage Salmon,” at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm>.

² 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.² Since Glofish™ are not meant for human consumption, FDA determined that the Glofish™ was not under its jurisdiction.²

³ 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.

⁴ HHS, FDA, *Guidance for Industry Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*, Rockville, MD, January 15, 2009. Hereinafter cited as FDA Guidance 2009.

⁵ 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, at <http://www.efsa.europa.eu/en/supporting/doc/69e.pdf>.

⁶ 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), at <http://books.nap.edu/books/0309084393/html/73.html#pagetop>.

⁷ Alison L. Van Eenennaam, *Genetic Engineering and Fish*, University of California, Genetic Engineering Fact Sheet

Some have claimed that FDA's approval of GE salmon has been long overdue and the delays have been caused by political interference.⁸ 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 hypothesize that the availability of GE salmon at relatively low prices could benefit consumers who are seeking low-fat and affordable options.⁹

Development of GE fish has prompted some advocacy groups to raise a number of environmental concerns.¹⁰ For example, if fish are accidentally released into the environment, they may spread 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.¹¹ Sterilization and bioconfinement have been proposed to isolate GE fish from wild fish populations.

Food safety concerns also have been expressed by consumer groups who question whether genetically modified organisms could pose unique hazards to public health.¹² These groups also support mandatory labeling of GE products because they believe consumers have a right to make informed choices.

In addition, some in the fishing industry are concerned that greater efficiency in the aquaculture industry could harm salmon fisheries.¹³ Salmon farm production in the 1990s depressed salmon prices and affected fishing businesses and coastal communities that depend on wild fisheries.

In response to these concerns, legislation has been introduced during the last several Congresses to restrict the use and require the labeling of GE organisms. In the 114th Congress, two bills have been introduced (H.R. 393 and S. 738), which would require labeling of GE salmon. In addition, two more general bills (H.R. 913 and S. 511) would require labeling of GE food products, including GE salmon. H.R. 1599 would preempt any state authority over GE labeling in favor of a voluntary National Genetically Engineered Food Certification Program under the federal Agricultural Marketing Act of 1946.¹⁴ The certification program would establish national standards for labeling both GE and non-GE foods. Two FY2016 appropriations bills for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (S. 1800

8, Davis, CA, 2005.

⁸ 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).

⁹ Henry I. Miller, "With a Forked Tongue: How the Obama Administration Stymies Innovation in Food Production," *Forbes*, March 19, 2014.

¹⁰ 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.

¹¹ 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.

¹² 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.

¹³ 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.

¹⁴ On July 23, 2015, H.R. 1599 was passed by the U.S. House of Representatives.

and S. 2129) include provisions that would provide funds to implement labeling requirements for GE salmon.¹⁵

H.R. 394 would prohibit most uses of GE fish, with some exceptions or if certain conditions are met. Applications for uses that would be prohibited under H.R. 394 would require an environmental assessment (EA) with a finding of no significant impact in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321) or an environmental impact statement (EIS). The EIS also would be required to include analysis of the risk associated with the escape of GE fish. In addition to labeling requirements, S. 738 would require an EIS before approval of any application to produce GE salmon intended for human consumption.

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 existing statutory authority and previous agency experience with traditional breeding techniques. The three lead agencies are the U.S. Department of Agriculture’s (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.¹⁶ 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.¹⁷

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. Most of FDA’s regulatory authority to regulate food safety is provided by 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.

¹⁵ On July 16, 2015, S. 1800 was reported by the Senate Committee on Appropriations. S. 2129 was subsequently introduced and includes language contained in S. 1800.

¹⁶ National Research Council (NRC), *Animal Biotechnology: Science-Based Concerns*, (Washington, DC, National Academy Press, 2002). Hereinafter cited as NRC, *Animal Biotechnology* 2002.

¹⁷ NRC, *Animal Biotechnology*, 2002. p. 14.

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 (NADs) (21 U.S.C. §321).¹⁸ 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.”¹⁹

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.²⁰ 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.”

An 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.²¹ 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 safe²² 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).²³ 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

¹⁸ 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.

¹⁹ 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.

²⁰ 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.”

²¹ Sections 512 and 571 of the FFDCA and Title 21 C.F.R. 514 of associated federal regulations.

²² 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.

²³ The FDA guidance discusses how NEPA requirements will apply to the GE animal approval process.

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.²⁴

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 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. Some critics called for more transparency during the pre-market approval process for AquAdvantage Salmon.²⁵

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.”²⁶ 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 petitioned for evaluation of GE salmon under FDA’s food additive requirements. FDA did not evaluate AquAdvantage Salmon as a food additive before approval as an NAD.

U.S. Department of Agriculture

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 clearly spelled out a policy in this area, including whether it intends to exercise these authorities to regulate GE animals.²⁷ USDA’s Animal and Plant Health Inspection Service (APHIS) earlier had expressed its intention to publish an advance notice of proposed rulemaking (ANPR) on GE animals, possibly in 2008.²⁸ Instead, in concert

²⁴ Section 514.1(b)(14).

²⁵ 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.

²⁶ FFDCA, Section 201(s).

²⁷ 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.

²⁸ 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.

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.²⁹ APHIS received more than 670 comments by November 18, 2008. Most of the comments did not focus on APHIS's authority under the Animal Health Protection Act (AHPA; 7 U.S.C. §8301 et seq.). FDA issued its final guidance for developers of GE animals on January 15, 2009.

APHIS has broad authority, under AHPA, 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 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.).³⁰ 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.³¹ 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.³² 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.

²⁹ *Federal Register*, vol. 73, no. 183, September 19, 2008, at <http://edocket.access.gpo.gov/2008/pdf/E8-21917.pdf>.

³⁰ 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.

³¹ The labeling of GE foods is required by 68 other countries.

³² FDA, Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, August 2010, at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm222608.htm>.

Genetically engineered crops became commercially available in the mid-1990s.³³ 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.³⁴ 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 from non-bioengineered foods, and therefore had no basis for requiring that such foods be labeled.³⁵

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.³⁶ 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. In 2014, Vermont became the first state to pass a mandatory labeling law that will go into effect in 2016. Connecticut and Maine also passed mandatory labeling laws in 2013 and 2014, respectively, but these laws will not go into effect until five

³³ For more information see CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, by Tadlock Cowan.

³⁴ “Statement of Policy: Foods Derived from New Plant Varieties.” Federal Register (57 FR 22984), May 29, 1992.

³⁵ 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.

³⁶ FDA, *Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering*, 2001, at <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059098.htm>.

contiguous states also pass mandatory labeling laws. Proponents of mandatory labeling for bioengineered foods argue that consumers should have the right to know what they are purchasing. Even if 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 genetically engineered products.

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.³⁷ Labeling opponents also argue that the increased food prices as 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.³⁸ 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 2014, total commercial landings of Pacific salmon were 327,000 metric tons (720.2 million pounds) with a value of \$616.7 million.³⁹

³⁷ 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-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, at <http://www.agbioforum.org>.

³⁸ Significant recreational fisheries exist for these stocks as well as aboriginal rights to harvest stocks in the Pacific Northwest.

³⁹ Fisheries Statistics Division, *Fisheries of the United States 2014*, National Marine Fisheries Service, Office of

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.

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.⁴⁰ 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 the escape of cultured fish from cages.⁴¹ 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.⁴²

Production and Trade

In 1996, worldwide salmon farm production exceeded commercial harvest of wild salmon.⁴³ In 2013, aquaculture production of salmon, trouts, and smelts was 3.177 million metric tons (mmt), with a value of \$17.628 billion.⁴⁴ Production of Atlantic salmon, the main species of this group,

Science and Technology, Current Fisheries Statistics No. 2014, Silver Spring, MD, September 2015, at <http://www.st.nmfs.noaa.gov/commercial-fisheries/fus/fus14/index>.

⁴⁰ Chile is a major aquaculture producer of Atlantic salmon, but there are no native anadromous salmon stocks in Chile.

⁴¹ For example Atlantic salmon have escaped from culture sites in British Columbia and survived in the wild.

⁴² Ken Coons, "Global Salmon Initiative does outreach at Seafood Expo," *Seafood.com*, March 18, 2014.

⁴³ 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.

⁴⁴ United Nations Food and Agriculture Organization, Fishery Statistical Collections, Global Aquaculture Production, Accessed November 30, 2015, at <http://www.fao.org/fishery/statistics/global-aquaculture-production/en>. Hereinafter cited as FAO Global Aquaculture Production 2015. In this case, value is the revenue obtained by the aquaculturalist from the first buyer of the product.

was 2.087 mmt, with a value of \$12.904 billion.⁴⁵ Norway led production, followed by Chile and the United Kingdom (**Table 1**). In 2013, farmed production of Atlantic salmon in the United States was 18,685 metric tons, with a value of \$105.4 million.

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

Country	2013 Atlantic Salmon Production (metric tons)	2013 Atlantic Salmon Value (in thousands of U.S. dollars)	2013 Exports to the United States (metric tons)	2013 Exports to the United States (in thousands of U.S. dollars)
Norway	1,168,324	6,461,049	18,430	201,562
Chile	492,329	3,667,851	108,726	1,080,860
United Kingdom	154,200	897,416	12,615	110,351
Canada	100,027	616,065	67,504	473,729
Faroe Islands	75,821	495,871	15,557	124,564
Australia	35,198	479,064	—	—
Russian Fed.	22,500	90,000	—	—
United States	18,685	105,383	—	—
Ireland	9,125	74,534	391	4,419
Others	10,902	16,282	10,768	86,565
Total	2,087,111	12,903,515	233,991	2,082,050

Sources: FAO, Fisheries and Aquaculture Department, Fisheries Statistics and Information, Global Aquaculture Production 1950-2013 Online Query, at <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, at <http://www.st.nmfs.noaa.gov/commercial-fisheries/foreign-trade/raw-data/imports-exports-annual#1>.

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 2013, U.S. imports of fresh and frozen farmed Atlantic salmon totaled 234,000 metric tons, with a value \$2.082 billion. In 2013, Atlantic salmon imports accounted for approximately one-third of the total U.S. fresh and frozen salmon supply of 701,000 metric tons.⁴⁶

AquaBounty Case: The First Genetically Engineered Food Fish

AquAdvantage Salmon

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.

⁴⁵ FAO Global Aquaculture Production 2015.

⁴⁶ U.S. Department of Commerce, National Oceanic and Atmospheric Administration and National Marine Fisheries Service, *Fisheries of the United States 2013*, Silver Spring, MD, September 2013, at <https://www.st.nmfs.noaa.gov/commercial-fisheries/fus/fus13/index>.

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 AquaAdvantage 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 AquaAdvantage 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 size⁴⁷ 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.⁴⁸ Although AquaAdvantage Salmon grow more quickly, they do not reach an overall larger size than non-GE Atlantic salmon. According to AquaBounty, analysis of AquaAdvantage Salmon has shown that they consume 25% less feed to achieve the same size as non-GE Atlantic salmon.⁴⁹ 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.⁵⁰ Similar traits have been observed for domesticated Atlantic salmon developed through selective breeding.

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

Operations

The AquaAdvantage Salmon will be produced and imported into the United States under conditions specified by AquaBounty in its application.⁵¹ AquaBounty plans to produce eyed eggs

⁴⁷ 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.

⁴⁸ According to the Development Fund, the Norwegian aquaculture industry has developed strains of salmon through selective breeding that grow as fast or faster than AquaAdvantage Salmon. See at http://www.utviklingsfondet.no/files/uf/documents/GMO-Salmon_Fast_Growing_Hype_web.pdf.

⁴⁹ "As Final U.S. decision Nears, A Lively Debate on GM Salmon," *Environment* 360, April 18, 2013, at http://e360.yale.edu/feature/as_final_us_decision_nears_a_lively_debate_on_gm_salmon/2641/. Hereinafter cited as *Environment* 360, 2013.

⁵⁰ FDA, *AquaAdvantage Salmon*, Environmental Assessment, November 12, 2015, p. 34, at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM466218.pdf>. Hereinafter cited as *Environmental Assessment*, 2015.

⁵¹ AquaBounty Technologies, Inc., at <http://www.AquaBounty.com/>.

at a specific facility on Prince Edward Island (PEI), Canada.⁵² Eggs will be shipped to Panama and reared to market size in land-based facilities. The grow-out facility is based in the Panamanian highlands to reduce the risk of salmon escapes and interactions with wild salmon populations.⁵³ Salmon will be processed in Panama before being shipped to the United States for retail sale. No live fish will be imported into the United States.

AquaBounty has stipulated that they will produce only sterile female GE Atlantic salmon by a process that 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.⁵⁴ 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. According to the application, production will continue in this manner. The egg production facility on PEI 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 environmental assessment, in the event that AquaAdvantage Salmon escape, geographical 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 AquaAdvantage Atlantic salmon for its 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

⁵² 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>.

⁵³ 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.

⁵⁴ Food and Drug Administration Center for Veterinary Medicine, *Briefing Packet AquaAdvantage Salmon*, September 20, 2010, p. 57.

environmental assessment (EA) of impacts associated with NADA submitted by AquaBounty⁵⁵ and (2) FDA's preliminary finding of no significant impact (FONSI).⁵⁶ A 60-day public comment period initially ran through February 25, 2013, but was extended through April 26, 2013.⁵⁷ On November 23, 2013, Environment Canada granted AquaBounty permission to export up to 100,000 eggs a year from a hatchery in PEI to Panama. A land-based research facility is currently operating and raising GE salmon in Panama.⁵⁸ On March 13, 2014, the FDA Commissioner, Dr. Margaret Hamburg, stated that the AquaBounty NADA is still under consideration and that FDA will be moving forward in a deliberate science-driven way.⁵⁹ On November 19, 2015, FDA approved the AquaBounty application to produce GE Atlantic salmon and to sell this product in the United States.

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 AquaAdvantage Salmon.⁶⁰ Although the VMAC concluded that test results established similarities and equivalence between AquaAdvantage Salmon and non-GE Atlantic salmon, the chairman's report added that it cannot be concluded from the data submitted that AquaAdvantage Salmon would be more or less allergenic than Atlantic salmon.⁶¹ FDA has maintained that people who are allergic to Atlantic salmon will likely be allergic to AquaAdvantage Salmon because it is a finfish, but not because it has been genetically engineered.⁶² In the preliminary finding of no significant impact released on December 20, 2012, FDA reiterated that food from AquaAdvantage Salmon is as safe as food from non-GE salmon and determined that there are no significant food safety hazards or risks associated with AquaAdvantage Salmon.⁶³

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.⁶⁴ As a first step in the review process, on September 19-21, 2010, FDA's

⁵⁵ FDA, *AquaAdvantage Salmon*, Draft Environmental Assessment, May 4, 2012, at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf>.

⁵⁶ FDA, *Preliminary Finding of No Significant Impact AquaAdvantage Salmon*, May 4, 2012, at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf>.

⁵⁷ 78 *Federal Register* 10620-10621 (February 14, 2013).

⁵⁸ 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.

⁵⁹ 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.

⁶⁰ FDA, *Briefing Packet AquaAdvantage Salmon*, FDA Center for Veterinary Medicine, September 20, 2010, p. 61, at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>.

⁶¹ Chairmen's Report, 2010.

⁶² FDA, *Key Facts Commonly Misunderstood*, at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm226223.htm>.

⁶³ FDA, *Preliminary Finding of No Significant Impact*, AquaAdvantage Salmon, May 4, 2012, at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf>.

⁶⁴ The FDA Center for Veterinary Medicine's "Questions and Answers about Transgenic Fish," at <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm133255.htm>.

Veterinary Medicine Advisory Committee met to consider the application and held a public hearing.⁶⁵ 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.⁶⁶

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 developed an 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.⁶⁷ According to FDA, the two agencies have consulted on this matter, but this report has not been developed and no target date for its completion has been specified.

FDA 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 under the ESA 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.⁶⁸

⁶⁵ 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.

⁶⁶ David Senior, Interim Chair, VMAC, *Chairman's Report*, FDA, VMAC Meeting, September 20, 2010, at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230467.pdf>.

⁶⁷ 21 U.S.C. §2106.

⁶⁸ See the Center for Food Safety's "Genetically Engineered Fish," at <http://www.centerforfoodsafety.org/genetically3.cfm>.

Summary of FDA Conclusions Concerning the Environmental Impacts of AquAdvantage Salmon

The environmental assessment posed the following questions and provided corresponding answers to address potential hazards and harms to the U.S. environment if AquAdvantage Salmon were to escape.⁶⁹

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 expected 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 EA evaluated the potential environmental impacts associated with approving the NADA for AquAdvantage Salmon. According to FDA, it has verified that AquAdvantage Salmon will 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 female triploid fish which are nearly all sterile.⁷⁰ In the EA, FDA concluded that it “found no evidence that approval of an NADA for AquAdvantage Salmon would result in significant impacts on the environment in the United States.”⁷¹ If significant new information or challenges arose in the public comments, FDA could have required a full EIS prior to the 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

⁶⁹ FDA, *AquAdvantage Salmon*, Environmental Assessment, November 12, 2015, p. 21, at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM466218.pdf>. Hereinafter cited as Environmental Assessment, 2015.

⁷⁰ 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.

⁷¹ Environmental Assessment, 2015, p. 119.

agencies about possible threats to endangered wild Atlantic salmon.⁷² On May 25, 2011, these groups filed a formal citizen petition urging FDA to withhold approval until an EIS has been completed.⁷³ FDA decided that the AquaBounty application did not require an EIS. However, some VMAC members stated that an EIS would be needed if the company were to propose additional production facilities.

Food Safety Issues

A National Research Council study maintains that there is a low to moderate food safety risk from GE seafood.⁷⁴ 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 nongovernmental organizations petitioned the FDA’s Office of Food Additive Safety (OFAS) to review the AquaBounty application under the FFDCA food additive provisions.⁷⁵ The petitioners argued that the gene expression product (GEP) of the genetic construct creating the AquaAdvantage Salmon is a food additive under FFDCA (§201(s), 21 U.S.C. §321). AquaAdvantage 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.⁷⁶ They requested that FDA make a finding that neither the AquaAdvantage Salmon nor the GEP used to create it is “generally regarded as safe” (GRAS). In particular, the petition requested extensive pre-market testing, arguing that “[t]he Agency’s general classification of rDNA constructs as new animal drugs (NADs) 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 questioned the validity of data supplied by AquaBounty for risk assessment.⁷⁷ They contended that FDA should have made AquaBounty re-conduct its studies or that FDA should either conduct the studies itself or ask an independent laboratory to undertake the studies. If the AquaAdvantage Salmon were shown to have materially different nutritional or health-related characteristics from a non-GE salmon, while still being deemed safe, FDA could have required labeling of the GE salmon.

⁷² Letter from Rebecca Wodder, President, American Rivers, et al. to Margaret Hamburg, Commissioner, FDA, November 8, 2010, at http://www.eenews.net/assets/2010/11/08/document_pm_01.pdf.

⁷³ Ocean Conservancy et al., *Citizen Petition Regarding AquaBounty Technologies’ Application for Approval of Genetically Engineered Salmon*, Citizen Petition Before the FDA, May 25, 2011, at <http://earthjustice.org/sites/default/files/FinalGESalmonCitizenPetition.pdf>.

⁷⁴ National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, (Washington, DC: National Academies Press, 2004), at http://books.nap.edu/openbook.php?record_id=10977&page=R1.

⁷⁵ 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.

⁷⁶ IGF-1 is a hormone that helps accelerate the growth of the bioengineered salmon. According to the petition, IGF-1 has been shown in some studies to be linked to breast, colon, prostate, and lung cancers.

⁷⁷ Tim Schwab, “Is FDA Ready to Regulate the World’s First Biotech Food Animal?” *Food and Drug Policy Forum*, vol. 3 (July 24, 2013).

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.⁷⁸ 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.”⁷⁹ 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.⁸⁰ Escaped farmed salmon have been found on spawning grounds during the period when wild Atlantic salmon spawning occurs.⁸¹ 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.⁸² 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.⁸³ 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

⁷⁸ 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.

⁷⁹ National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2004), at http://books.nap.edu/openbook.php?record_id=10418&page=R1.

⁸⁰ 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 Atlantic (Canada, Norway, and Great Britain) and from areas outside their range in the Pacific (Chile and British Columbia).

⁸¹ There are no recorded cases of hybridization in nature between Atlantic and Pacific salmonid species.

⁸² 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.

⁸³ An allele is one of two or more versions of a gene occupying a specific spot on a chromosome that control a specific trait.

Norway and Ireland where inter-breeding of wild and farmed fish is common.⁸⁴ Large-scale experiments in Norway and Ireland show highly reduced survival and lifetime success of farmed and hybrid salmon compared to wild salmon.⁸⁵

Given previous experiences with farmed salmon, opponents hypothesize that farmed GE salmon eventually will 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.⁸⁶ 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 occurs only 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 because the data suggest that the transgene will be purged by natural selection.⁸⁷ However, the potential consequences of the interbreeding of farm (including GE salmon) and wild Atlantic salmon remain 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.⁸⁸ 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 that 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.⁸⁹ 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.⁹⁰

If GE salmon were to escape and establish self-sustaining populations, competition for resources would be another potential concern. Because GE salmon grow more quickly and may be more aggressive than wild fish, it has been suggested that they may outcompete wild fish for habitat

⁸⁴ Thorstad et al. 2008.

⁸⁵ Thorstad et al. 2008.

⁸⁶ 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.

⁸⁷ Environmental Assessment 2015, p. 112.

⁸⁸ Atlantic salmon and Pacific salmon are unable to spawn because they are different species.

⁸⁹ Thorstad et al. 2008, p. 67.

⁹⁰ 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).

and food.⁹¹ Laboratory experiments on AquaAdvantage relatives indicate that they are more likely to feed in the presence of a predator than non-GE controls.⁹² 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.⁹³ 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, as in the case of many invasive species. This scenario would depend on reproduction of GE salmon in the wild.⁹⁴ Critics also express concerns that U.S. wild Atlantic salmon populations are at extremely low levels and especially vulnerable to ecological changes.

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.⁹⁵ 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 approved proposal would constitute major or moderate changes, which would require a supplemental NADA and analysis under NEPA. Although FDA has approved AquaBounty's application, FDA retains the authority to withdraw its approval should significant subsequent concerns arise.

Approval of GE salmon for consumption in the United States is likely to encourage additional applications in other geographic areas and for a variety of different grow-out or culture techniques. AquaBounty has been approved to produce GE salmon in a limited grow-out facility in Panama. Some have speculated that subsequent proposals will be subject to less scrutiny, and they question whether future proposals are more likely to be considered as benign.⁹⁶ 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 does not include the culture of AquaAdvantage Salmon in net pens,⁹⁷ 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 its company would approve the use of AquaAdvantage Salmon in cage culture.⁹⁸

⁹¹ Environmental Assessment 2015, p. 113.

⁹² Environmental Assessment 2015, p. 113.

⁹³ Environmental Assessment 2015 p. 113.

⁹⁴ Wild reproduction of GE fish is unlikely if only sterile triploid females are produced.

⁹⁵ FDA Environmental Assessment 2015, p.7.

⁹⁶ Northwest Environmental Defense Center, *The Newsletter of the Northwest Environmental Defense Center*, Critique of Genetically Engineered Salmon, 2013, at <http://law.lclark.edu/live/files/14124-articlecritique-of-genetically-engineered-salmon->.

⁹⁷ Grow-out in net pens is less costly than culture of salmon in land-based facilities.

⁹⁸ Environment 360, 2013.

States also have taken steps to regulate the transport and use of GE fish. For example, Maryland,⁹⁹ Florida,¹⁰⁰ Washington,¹⁰¹ Oregon,¹⁰² Michigan,¹⁰³ Minnesota,¹⁰⁴ Wisconsin,¹⁰⁵ and California¹⁰⁶ have passed laws on the use of GE fish in state waters. However, if GE fish were to escape from holding or production facilities, they could spread from regulated to unregulated states. If GE fish are approved for culture in the United States, it appears that consistent regulation across states will be needed.

Labeling Issues

On November 19, 2015, in addition to approving AquaBounty’s application, FDA also released draft guidance to industry for voluntary labeling of whether food has been derived from GE salmon. The question of how to label the food derived from the AquaAdvantage Salmon is separate from the decision about whether to approve an NADA. Although FDA is not required to address labeling issues prior to marketing of the food, FDA has considered these two issues simultaneously.¹⁰⁷

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 that it should be labeled 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 is different in ways that could be seen as negative. Although voluntary labeling is permissible—as long as the label is not false or misleading—proponents of the AquaBounty salmon believe such labeling could reduce retail demand for the fish.

FDA has proposed guidance for voluntary labeling that indicates whether food has been derived from GE Atlantic salmon. The guidance will offer FDA’s thinking on the topic and will not establish specific labeling requirements. Industry will be able to use alternative approaches as long as these approaches follow applicable statutes and regulations. For Atlantic salmon that has not been genetically engineered, FDA provides the following examples of voluntary statements that manufacturers may use:¹⁰⁸

- not genetically engineered;
- not genetically modified through the use of modern technology; or

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

¹⁰⁰ Fla. Admin. Code r. 5L-3.004 (2013)

¹⁰¹ Washington Administrative Code 220-76-100 (2003).

¹⁰² Oregon Administrative Rules 635-007-0595 (2004).

¹⁰³ Mich. Comp. Laws Ann. 324.41305-41325

¹⁰⁴ Minn. Stat. §§17.4982, 18B.285, §18B.01, 18F.01-.13 (2003).

¹⁰⁵ Wis. Stat. §146.60 (2002).

¹⁰⁶ California Fish & Game Code §15007 (2003) and Dept. of Fish and Game §671.1.

¹⁰⁷ FDA, “Background Document: The VMAAC Meeting on Science-Based Issues Associated with AquaAdvantage Salmon,” at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm>.

¹⁰⁸ See FDA, “Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived from Genetically Engineered Atlantic Salmon,” at <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm469802.htm>.

- we do not use Atlantic salmon produced using modern biotechnology.

FDA also provided examples of voluntary statements that food manufacturers might use for food products derived from GE Atlantic salmon:¹⁰⁹

- genetically engineered;
- this salmon patty was made from Atlantic salmon produced using modern biotechnology; or
- this Atlantic salmon was genetically engineered so it can reach market weight faster than its non-genetically engineered counterparts.

In addition, Alaska requires GE fish to be labeled.¹¹⁰ 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.¹¹¹

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.¹¹² In 2002, prices paid to Alaska fishermen were less than half of the average prices paid from 1980 to 2005.¹¹³ 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 in turn may affect salmon production. Major categories of drivers include the regulatory framework, production, markets, and the public (**Figure 1**).¹¹⁴

¹⁰⁹ Ibid.

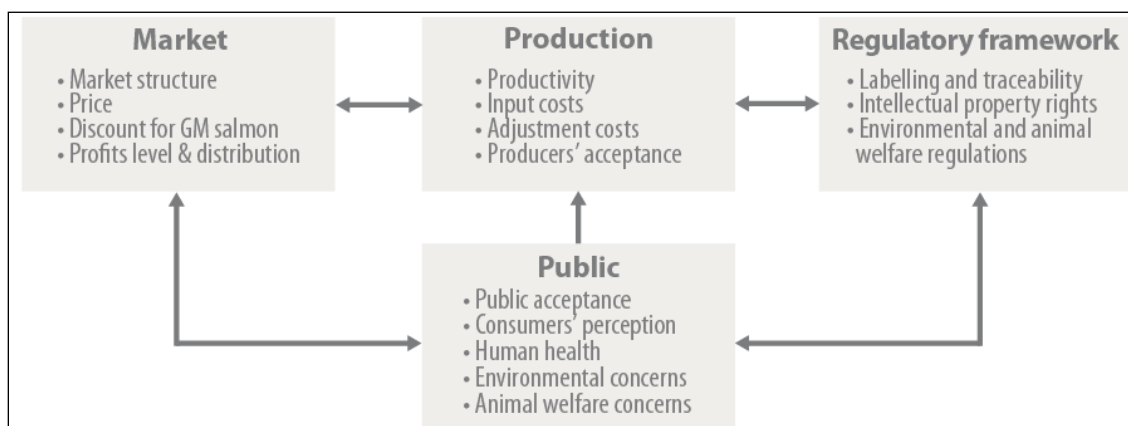
¹¹⁰ AK Food & Drug Code §17.20.040 (2005).

¹¹¹ Alaska salmon fisheries benefit from releases of salmon from hatcheries which grow-out in the ocean and enhance wild stocks.

¹¹² 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.

¹¹³ Great Salmon Run 2007. p. 213.

¹¹⁴ Davide Menozzi, Cristina Mora, and Alberto Merigo, “Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios,” *AgrBioForum*, vol. 15, no. 3 (2012).

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, this outcome is unlikely. At least initially, annual production at the AquaBounty Panama facility is limited to a capacity of approximately 100 metric tons compared to the total U.S. fresh and frozen salmon supply of approximately 700,000 metric tons in 2014.¹¹⁵ 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.¹¹⁶ 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, is 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.¹¹⁷ Some industry groups are concerned that such labeling might lead consumers to believe that wild fishery products also are genetically engineered and to perceive these products as unsafe for consumption.¹¹⁸

¹¹⁵ Total supply includes total U.S. commercial landings (486,000 metric tons) and imports (467,000 metric tons) minus exports (252,000 metric tons).

¹¹⁶ 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.

¹¹⁷ Erika Bolstad, "Alaskans say GM salmon threatens wild market as public FDA objections top 33,000," *Anchorage Daily News*, March 6, 2013.

¹¹⁸ See CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, by Tadlock Cowan.

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 to or at least skeptical of consuming the product.¹¹⁹ 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 perceptions, 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.¹²⁰ Reportedly, many major grocery retail chains have announced that they do not plan to sell the AquaBounty fish when it becomes commercially available.¹²¹

Demand for fish products, especially high-quality products such as Atlantic salmon, grew quickly during the past three decades and is expected to continue increasing. 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.¹²² The required discount likely would vary by country and depend on consumer characteristics, such as income and 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.¹²³ 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.¹²⁴

Congressional Actions

Members of the Alaska congressional delegation have expressed their disappointment with FDA's approval of AquaBounty's application. The delegation is now supporting GE salmon labeling to ensure that consumers are aware of the product's identity.¹²⁵ In the 114th Congress, two bills have been introduced (H.R. 393 and S. 738) that would require labeling of GE salmon. In addition, two bills (H.R. 913 and S. 511) would require labeling of GE food products, including GE salmon. H.R. 1599, which was passed by the House, would preempt any state authority over GE labeling in favor of a voluntary National Genetically Engineered Food Certification Program under the federal Agricultural Marketing Act of 1946. The certification program would establish national standards for labeling both GE and non-GE foods. Two FY2016 appropriations bills for

¹¹⁹ Shane O'Halloran, "Consumers not interested in genetically modified salmon," *Food Engineering*, April 23, 2013, at <http://www.foodengineeringmag.com/articles/90611-consumers-not-interested-in-genetically-modified-salmon>.

¹²⁰ See the Center for Food Safety's website and featured actions, "Tell Costco to Reject GE Salmon," at <http://www.centerforfoodsafety.org/geneticall3.cfm>.

¹²¹ "Kroger, Safeway Will Nix GMO Salmon Regardless of FDA Decision," *Food Safety News*, March 4, 2014.

¹²² Davide Menozzi, Cristina Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios," *AgrBioForum*, vol. 15, no. 3 (2012).

¹²³ 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.

¹²⁴ Smith et al. 2010.

¹²⁵ Representative Don Young, "Alaska Delegation Responds to Approval of GE Salmon," press release, November 19, 2015, at <http://donyoung.house.gov/news/documentsingle.aspx?DocumentID=398541>.

Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (S. 1800 and S. 2129) include provisions that would provide funds to implement labeling requirements for GE salmon.¹²⁶

Another bill introduced in the 114th Congress, H.R. 394, would make it unlawful

- (1) to 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) to 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) to engage in net-pen aquaculture of covered fish;
- (4) to release a covered fish into a natural environment; or
- (5) to 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. 394 would include any finfish modified or produced through the application of recombinant DNA technologies. H.R. 394 would include exceptions to these prohibitions for scientific research or for fish collected for the purpose of supporting the act. Applications for uses that would be prohibited under H.R. 394 would require an EA with a finding of no significant impact in accordance with NEPA or an EIS. The EIS would require an environmental risk analysis that assesses impacts of covered fish on wild and cultured fish stocks, best- or worst-case probabilities of confinement failure, costs to eradicate escaped covered fish, and economic damage of escaped covered fish. H.R. 394 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).

In addition to labeling requirements, S. 738 would require an EIS for any application related to the use of GE salmon intended for human consumption. The EIS would include requirements similar to those stipulated for the EIS under H.R. 394.

During the 113th Congress, concerns related to the approval process and implications of GE salmon approval were expressed by a number of Members of Congress. 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.¹²⁷ In particular, the letters stated that the FDA process had not been adequate to ensure GE salmon is safe for the 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. In addition, Members urged FDA to develop labeling requirements to distinguish the product as genetically engineered.

In the 113th Congress, several bills related to the production and labeling of GE salmon were introduced. S. 246 and H.R. 1667 included provisions that were similar to those in H.R. 394 (114th Congress). H.R. 584 and S. 248 would have required labeling of products which contain genetically engineered fish. H.R. 1699 and S. 809 would have required labeling of genetically engineered foods, including fish. On May 22, 2013, S.Amdt. 965 to S. 954 was proposed and would have permitted states to require 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.

¹²⁶ On July 16, 2015, S. 1800 was reported by the Senate Committee on Appropriations. S. 2129 was subsequently introduced to consolidate three appropriations bills including S. 1800.

¹²⁷ 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.

Future Considerations

Some have asserted that the FDA's approach to GE salmon evaluation has failed 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 AquaAdvantage Salmon approval. They argue 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 evaluated GE salmon as an NAD that 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.¹²⁸ An immediate issue is whether AquaAdvantage Salmon should have been 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 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 have reassured consumers and retailers who are skeptical of genetic engineering technology. More rigorous assessment also would set a precedent for future products that may warrant greater scrutiny.

Some have expressed concerns that such a lengthy process signals that the United States might cede its leadership position in agricultural biotechnology. The delays and uncertainties faced by the AquaBounty application send the message that science-based regulatory oversight is subject to political intervention.¹²⁹ Other countries that are likely to commercialize this technology may be less concerned with potential environmental effects. AquaBounty has reported that it has spent \$50 million developing the technology and 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 if the U.S. approval process remains so long and uncertain.

AquaAdvantage Salmon is likely to be the first of many transgenic candidates for commercial aquaculture production, and some question whether this case has established a proper or useful precedent for future assessment of this technology.¹³⁰ Some scientists assert that the FDA decision involves broader social costs and benefits of using genetic engineering, and they support wide-ranging interdisciplinary evaluation of GE salmon approval.¹³¹ According to one group of researchers, assessment of long-term effects of GE salmon requires the interrelated study of production systems, markets, consumer acceptance, and regulatory framework.¹³² 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. Questions remain as to

¹²⁸ 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/.

¹²⁹ 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).

¹³⁰ Smith et al. 2010.

¹³¹ Smith et al. 2010.

¹³² David Menozzi, Christena Mora, and Alberto Merigo, "Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios," *AgBioForum*, vol. 15, no. 3 (2012).

whether the current process can afford adequate safeguards for the public and the environment while allowing for the timely approval and use of new genetic technologies.

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