THE KENAN INSTITUTE FOR ETHICS at DUKE UNIVERSITY

Institutions in Crisis

FISHY BUSINESS?
AquaBounty Technologies, the FDA, and Genetically Modified Foods

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On September 19, 2010, 13 members in a special Veterinary Medicine Advisory Committee (VMAC) of the Food and Drug Administration (FDA) convened for public hearings to discuss the approval for biotechnology company AquaBounty Technologies' AquAdvantage salmon. This particular salmon is genetically modified (GM) to grow twice as fast as conventional Atlantic salmon. If authorized, the product would mark the first FDA-approved GM animal for human consumption. To AquaBounty, the AquAdvantage salmon would be a profitable solution to meet increasing fish demand in the coming years. Critics of the GM salmon, however, pointed to the flawed FDA approval process—the public was only given 14 days to review all documents before the public hearing, and several organizations questioned the makeup of VMAC and whether the studies provided by AquaBounty adequately addressed ecological and human health concerns.

This case considers the FDA approval process for genetically modified animals in light of AquaBounty Technologies' push to bring AquAdvantage salmon to the market. Issues of effective governance, transparency, and antiquated policies highlight challenges for the FDA in regulating biotechnology enhancements.

The case and teaching notes for this case were completed under the direction of Dr. Rebecca Dunning, the Kenan Institute for Ethics.

Introduction

In 2006, approximately 110.4 million metric tons of fish were consumed, with almost half of that from aquaculture, the commercial farming of fish. Seventy percent of salmon consumed are from farmed sources. The Food and Agricultural Organization (FAO) of the United Nations has estimated that by 2030, annual commercial production will need to increase by an additional 28.8 million metric tons in order to maintain per capita fish consumption at current levels.[1] Biotechnology company AquaBounty Technologies' hopes to meet this demand through the production of a genetically engineered fish that grows twice as fast as conventional Atlantic salmon, an advantage that would significantly cut production costs for fish farmers while providing a potentially large source of revenue for the company.[2]

AquaBounty Technologies first filed for U.S. approval of its AquAdvantage salmon in 1995. In 2010, the FDA announced that there was enough information available to review the GM salmon. However, criticisms of the FDA approval process have brought up issues of transparency and accountability. The FDA released 255 pages of technical information regarding the GM salmon on Sept 5, 2010, giving the public only 14 days to review the document before the public hearings would begin September 19. The Consumer Union, the nonprofit watchdog group and publisher of *Consumer Reports,* formally submitted comments noting the shortened time frame for public comments, the questionable composition of the review board, and lack of data rigor present in AquaBounty's research.[3]

This case considers the FDA approval process for genetically modified animals in light of AquaBounty Technologies' push to bring AquAdvantage salmon to the market. Issues of effective governance, transparency, and antiquated policies highlight challenges for the FDA in regulating biotechnology advancements. This case also highlights how accountability frameworks within public institutions are reacting to rapid scientific innovations that may pose threats to human and environmental safety.

"The Magician's Wand": AHistory of Agricultural Science and Genetics

The process of modifying crops through agricultural science has been occurring for several centuries. In the late 1840s, Justus von Liebig published *Organic Chemistry and Its Applications in Agriculture and Physiology*. Thousands of copies of the book were sold in America, and his letters were published in newspapers around the world, making Liebig a better known international figure than Abraham Lincoln by the start of the Civil War in 1861.[4] The publication discussed soil fertilizer and its implications for agriculture, and the first application of agricultural science was coincidentally in fertilizer by James Murray in 1842. His treatment of fertilizer was further investigated by other scientists, which led to the advent of the modern nitrogen fertilizer industry, which has produced both greater yields and environmental problems.[5]

Concerted scientific research on genetics can be traceed back to the work of evolutionary biologist Charles Darwin, who in 1859 brought to light the laws of heredity and natural selection in *The Origins of Species*. Darwin's research was influenced by William Youatt, an agriculturalist who understood the principle of selection as a tool that one could use to "not only modify the character of the flock, but to change it altogether."[6] In this sense, the laws of heredity were a "magician's wand" that enabled agriculturalists to alter their stock.

1 From www.fao.org/newsroom/en/news/2008/1000930/index.html, accessed 11/10/2010.
2 From http://www.aquabounty.com/products/aquadvantage-295.aspx, accessed 10/25/2010.
3 From http://www.consumersunion.org/pub/core_food_safety/016884.html, accessed 10/25/2010
4 Fedoroff, Nina and Nancy Marie Brown. *Mendel in the Kitchen.* Washington, D.C.: Joseph Henry Press, 2004. Page 49.
5 Ibid. Page 50. See *Modern Applications of Genetics in Food* section of this case for more information
6 Fedoroff, Nina and Nancy Marie Brown. 2004. *Mendel in the Kitchen.* Washington, D.C.: Joseph Henry Press. Page 51.

It was not until Gregor Mendel, the Moravian monk, that the significance of the hereditary factors, or genes, was established as he examined the breeding of two types of peas in his monastery garden. He mathematically documented the outcomes of crossbreeding round, yellow peas with wrinkled, green peas. His observations led to the development of Mendel's laws of genetic inheritance, which was published in 1866. His work was mostly forgotten until 1886, when Dutch botanist Hugo De Vries recovered Mendel's publication while Vries himself was developing his theories of plant heredity and mutation. Mendel's work has been cited as the groundwork for contemporary molecular techniques for plant improvement.[7]

Traditional methods of crossbreeding and hybridizations as employed by Mendel involve artificial selection, which is the genetic improvement of cultivated plants and domesticated animals by way of direct human interference.[8] Genetic modification, which began in the 1990s, is an extension of artificial selection, whereby new genetic material is created and directly inserted in plants and animals, a method not seen in traditional methods of hybridization and cloning.[9] There are various names for foods that contain genetic modification, the most popular being "genetically modified," "genetically engineered," "genetically altered," "transgenic," or "advance-hybrid."

The FDA defines genetically engineered (GE) animals as "those animals modified by recombinant DNA (rDNA) techniques, including the entire lineage of animals that contain the modification."[10]

Modern Applications of Genetics in Food

The application of Mendel's laws of plant breeding spurred the creation of high-yielding hybrid seed varieties that resulted in the dramatic increase in crop yields from 1950 to 1984. This period is known as the "Green Revolution," and was particularly promising in the developing world. For example, wheat and rice production increased by about 75 percent between 1965 and 1980.[11] In America, the hybrid seed varieties led to a 242% increase in production of the 17 most important domestic crops, while area only increased by 3 percent between 1940 and 1980.[12] Today, applications of biotechnology in foods are abundant. According to the International Service for the Acquisition of Agri-biotech Applications, a non-profit international organization that supports biotechnology as a means of helping farmers in developing nations, 14 million farmers in 25 countries planted 134 million hectors (i.e. 330 million acres) of biotech crops in 2009, a 80-fold increase from 1996.[13]

In addition to biotech crops, the genetic modification of animals and fish is becoming a growing area of research. Transgenic cattle, sheep, pigs, chickens and other animals have been used in biomedical research, and show potential for farming. These animals have faster growth rates, lower fat levels and increased disease resistance.[14] The genes transferred to the animals are generally ones that regulate the production of growth hormones, or chemicals that regulate growth, thus making the process of growing animals more economical.

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7 Ibid. Page 56.
8 Nottingham, Stephen. 2003. *Eat Your Genes: How Genetically Modified Food is Entering Our Diet*, Second Edition. New York: Zed Books.
9 Biologist Stephen Nottingham differentiates the distinction between cross breeding and genetic modification as such: "[Traditional plant breeding] is constrained by limitations in sexual compatibility, which prevents cross-fertilization between species. This limits the potential gene pool, that is the total number of genes and their different alleles, available for crop improvements. Genetic engineering extends this potential by creating new genetic material for breeders to work on. Once a foreign gene has been engineered into a variety, it can be passed into hybrids like any other gene using traditional breeding methods." Further reading can be found in : Nottingham, Stephen. 2003. *Eat Your Genes: How genetically modified food is entering our diet*, Second Edition. New York: Zed Books.
10 From http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf, accessed 10/20/2010.
11 Nottingham, Stephen. 2003. *Eat Your Genes: How Genetically Modified Food is Entering Our Diet*, Second Edition. New York: Zed Books.
12 Ibid. Page 4.
13 From http://www.isaaa.org/resources/publications/briefs/41/executivesummary/default.asp, accessed 11/15/2010.
14 Nottingham. Stephen. 2003. *Eat Your Genes: How Genetically Modified Food is Entering Our Diet*, Second Edition. New York: Zed Books. Page 9.

The benefits of biotech foods have been established on several fronts. Proponents recognize biotechnological advancements as a way to increase crop yield, create herbicide- and insect-resistant crops, and design crops that are tolerant to various conditions, including droughts and frost.[15] Supporters of biotechnology see biotech crops as an innovative approach to world hunger. One example is the "Golden Rice" initiative, begun in 1984 by Dr. Peter Jennings. The goal of the venture was to alleviate Vitamin A deficiency by inserting beta-carotene into rice.[16] Others, such as philanthropist Bill Gates and the Director-General of the FAO, endorse biotech advancements as an important method to tackle the problem of resource constraints. At the 2009 World Summit on Food Security, world leaders discussed key challenges facing the world, including the increase to a world population of 9 billion inhabitants by 2050. The goal of eradicating world hunger is paired with an emphasis on international development. A declaration stemming from the World Summit on Food Security, states,

> We recognize that increasing agricultural productivity is the main means to meet the increasing demand for food given the constraints on expanding land and water used for food production. […] We will seek to mobilize the resources needed to increase productivity, including the review, approval, and adoption of biotechnology and other new technologies and innovations that are safe, effective, and environmentally sustainable.[17]

However, not all outcomes of biotech food production have been positive. Following the "Green Revolution," the yield outputs after 1984 leveled off and declined due to the high levels of expensive agrochemicals, high water volumes for irrigation, and the increase in farm machinery. These new crops favored large farms, and poorer farmers could not benefit from new seed varieties. It was also found that agrochemicals degraded the environment and polluted water, and an overuse of pesticides created resistance in pests.[18] Critics point to issues of resource efficiency, resource allocation, and ecological risks as downfalls of biotech advancements.

There are also several notable ecological concerns with regards to GM crops. For example, genetically modified crops may become weeds to agricultural or natural habitats, diverting nutrients from the crops in the soil. The new genes may also be transferred from the GM plants to the wild population, whose hybrid offspring could have an effect on the existing environmental landscape. For transgenic fish, there is also the potential for reproduction between GM and wild species.[19]

Additionally, opponents have cited GM foods as having negative impacts on human health. Biologist Dr. Stephen Nottingham notes the possibility of food allergies to GM foods and bacterial buildup in the human gut that could lead to antibiotic resistance.[20] Critics also bring up the lack of labeling for genetically modified foods as another cause for concern. Consumer advocates believe the public should have the right to information about their food. Currently, genetically modified crops do not require labeling, and the issue of labeling has been brought up again with regards to the potential of GM animals for human consumption. Further, Carol Tucker Foreman, director of the Food Policy Institute at the Consumer Federation of America, a consumer advocacy group in Washington, D.C., feels that when it comes to animals, labeling may not appease consumers—many individuals object to the genetic engineering of animals on humane or ethical grounds more so than on concerns for human safety.[21]

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15 Ibid..
16 Pringle, Peter. 2003. Food, Inc. New York: Simon & Schuster. Page 19.
17 From http://www.fao.org/fileadmin/templates/wsfs/Summit/Docs/Final_Declaration/WSFS09_Declaration.pdf, accessed 12/4/2010.
18 Nottingham, Stephen. 2003. *Eat Your Genes: How Genetically Modified Food is Entering Our Diet*. Second Edition. New York: Zed Books. Pages 4-5.
19 Ibid. Page 88.
20 Ibid. Page 91.
21 Pollack, Andrew. "Without U.S. Rules, Biotech Food Lacks Investors. " *The New York Times* (July 30, 2007).

The Genetic Era and U.S. Regulations

The Genetic Era dawned when the U.S. Department of Agriculture approved Petition No. 92-196-01P on October 19, 1992, which approved the commercialization of the Flavr Savr Tomato by Calgene Incorporated.[22] In 1994, the Flavr Savr tomato was the first genetically modified product to reach U.S. supermarkets. The tomato was supposed to soften at a slower speed compared to conventional tomatoes. The Flavr Savr tomato was not a success with the public, however, given its (ironic) lack of flavor.

The first profitable genetically modified plant was Monsanto Company's Roundup Ready soybean, which was approved by the Department of Agriculture on May 19, 1994. This spurred subsequent government approval for GM corn, potatoes, cotton, squash, papaya, radicchio, and tomatoes. In 1996, the first GMO crops were grown commercially. These crops generally included two new gene traits. One was herbicide tolerance, mostly using the Monsanto-created Roundup formulation; the other was insect resistance, in which a bacterium, *Bacillus thuringienis*, would cause plants to produce a protein fatal to pests.[23]

The United States leads all other countries in the production of genetically modified crops, planting 64.0 million hectares of GM crops. In 2009, over 75% of the 90 million hectares of soybeans and almost 50% of the 33 million hectares of cotton were biotech.[24] An additional 32 countries granted regular approvals for biotech crops between 1996 and 2009.[25] With regards to consumption, it is estimated that 70% of processed foods sold in the USA and Canada contain approved GM ingredients.

The Regulatory Framework of Genetically Engineered Foods in America

Coordinated Framework for Regulation of Biotechnology

Federal policy first addressed biotechnology in 1986. The "Coordinated Framework for Regulation of Biotechnology" stated that no new laws were needed to regulate the products of biotechnology. This piece of policy was based upon the assumption that "upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately."[26] Under the "Coordinated Framework," three lead federal agencies— the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA/APHIS), the Department of Health and Human Services' Food and Drug Administration (HHS/FDA), and the Environmental Protection Agency (EPA)—have the responsibility for implementing the nation's biotechnology regulatory framework.[27]

Furthermore, the policy stated that a commercial product should be regulated based on the product's composition and intended use, regardless of its manner of production—essentially implying that biotech food would be regulated

22 Lambrecht, Bill. 2001. *Dinner at the New Gene Café: How Genetic Engineering is Changing How We Eat, How We Live, and the Global Politics of Food*. New York: Thomas Dunne Books. Page 6.
23 Ibid. Page 7.
24 Nottingham, Stephen. 2003. *Eat Your Genes: How Genetically Modified Foods ars Entering Our Diet*, Second Edition. New York: Zed Books. Page 3.
25 Ibid. Page 15.
26 From http://usbiotechreg.nbii.gov/CoordinatedFrameworkForRegulationOfBiotechnology1986.pdf, accessed 11/10/2010.
27 From http://usa.usembassy.de/etexts/tech/biotechreg.pdf, accessed 11/10/2010

in the same manner as other foods produced through conventional processes.[28] The result is that no single statute and or single federal agency specifically governs the regulation of biotechnology products.[29]

The FDA, CVM, and Transgenic Animal Regulation

The FDA is the oldest comprehensive consumer protection agency in the U.S. federal government, and its modern regulatory framework was established under the 1906 Pure Food and Drugs Act.[30] Below is the stated mission statement of the agency as provided on the FDA website:

> The FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

One of the major pieces of legislation related to the regulation of the United States Food Safety system is the Federal Food, Drug, and Cosmetic Act (FFDCA) of 1938. It was passed after a legally marketed toxic elixir killed 107 people. This incident led the FFDCA to overhaul the public health system. The law authorized the FDA to demand evidence of safety for new drugs, issue standards for food, and conduct factory inspections.[31]

Specific to genetically modified animals, in January 2009 the FDA issued a final version of "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs."[32] Within the FDA, the Center for Veterinary Medicine (CVM) oversees the application process and works with developers of genetically engineered (GE) animals. The agency issued the industry guidance for the following reasons:

> As GE animals approach commercialization, we think it is important to issue guidance to clarify our regulatory process, and to gather input from the public and the regulated industry. In addition, we think publishing the guidance is timely in light of the recent adoption of the Codex Alimentarius guideline on assessing the safety of food from GE animals.[33]

The 26-page document outlines new regulatory steps scientists and companies need to take in order to seek approval for GE animals, which is regulated under the "new animal drug provision" of the FFDCA (see Appendix A for reasons for approval).

A drug, in section 201(g) of the FFDCA (21 U.S. 321 et seq.), is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;" and "articles (other than

28 Pew Initiative on Food and Biotechnology. "Guide to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products." The full document is available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf,

29 It should be noted that the lack of differentiation between process and product has significant implications for the topic of food labeling. The United States does not currently have a mandate for the agribusiness industry to label GM foods. In 2001, the FDA proposed voluntary labeling guidelines for both non-genetically modified and genetically modified foods (for more information, see the FDA's "Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering." In Europe, public pressure pushed the European Commission to establish mandatory GM food labeling in foods with higher than 0.9% of genetically modified ingredients.

30 From http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm, accessed 11/27/2010.

31 From http://www.fda.gov/RegulatoryInformation/Legislation/default.htm, accessed 11/27/2010.

32 For the complete 26-page document, visit http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052463.pdf.

33 From http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113660.htm, accessed 11/27/2010. The Codex Alimentarius Commission was formed in 1963 as a joint venture between the World Health Organization and the Food and Agriculture Organization of the United Nations. The goals of the Commission are to promote fair trade practices in the food industry and promote coordination of all food standards undertaken by international governmental and non-governmental organizations. For more information, visit http://www.codexalimentarius.net/web/index_en.jsp.

food) intended to affect the structure or any function of the body of man or other animals." A new animal drug is defined as "any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed."[34] The rDNA construct used to create a transgenic animal affects the structure or function of the body of the GE animal, and thus qualifies as an animal drug that requires FDA approval under the new animal drug definition.[35]

In the FDA Veterinarian Newsletter 2008, the oversight goals of the CVM were as follows: "As with any review of a new animal drug, CVM will be considering the safety of the gene construct to the animal, the safety of any food derived from the animal (if it is intended to enter the food supply), the effectiveness of the construct, and any possible threat to the environment."[36]

It has been noted that FDA officials have said that treating a gene inserted into an animal's DNA as a drug was "the best approach, because it was unlikely Congress would pass entirely new laws governing genetically engineered livestock."[37]

AquaBounty Technologies

Originally incorporated in 1991, AquaBounty Technologies is a biotechnology company focused on the commercial aquaculture industry. Executive Director, CEO, and President of AquaBounty stated the following as the company's mission:

> Our mission is to play a significant part in "The Blue Revolution" – bringing together biological sciences and molecular technology to enable an aquaculture industry capable of large-scale, efficient, and environmentally sustainable production of high quality seafood. Increased growth rates, enhanced resistance to disease, better food-conversion rates, manageable breeding cycles, and more efficient use of aquatic production systems are all important components of the sustainable aquaculture industry of the future.[38]

The company first originated as A/F Protein, through which they sought to pursue the commercial development of antifreeze protein-based technology under license from the University of California at Berkeley.[39] In 1996, they acquired a license for AquAdvantage technology from the University of Toronto and Memorial University of Newfoundland. The company then reorganized itself into two separate entities in 2000, one remaining A/F Proteins, the other named AquaBounty Farms, and in 2004 owners officially changed the name to AquaBounty Technology.

AquAdvantage Salmon

AquaBounty is working toward developing "advanced-hybrid" salmon, trout, and tilapia. The AquAdvantage salmon is the fish that the company is seeking FDA approval for currently. According to the company's web site,

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34 From http://www.FDA.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm, accessed 11/27/2010.
35 From http://www.FDA.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm, accessed 11/27/2010
36 http://www.FDA.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm109295.htm
37 Pollack, Andrew. "Rules Near for Animals' Engineering." *The New York Times* (September 17, 2008).
38 From http://www.prnewswire.com/news-releases/aquabountys-response-to-the-press-release-titled-coalition-demands-fda-deny-approval-of-first-genetically-engineered-food-animal-101927263.html, accessed 11/27/2010.
39 From http://www.aquabounty.com/company/company-history-292.aspx, accessed 10/20/2010.

> AquAdvantage® Salmon (AAS) reach market size twice as fast as traditional salmon. This advancement provides a compelling economic benefit to farmers (reduced growing cycle) as well as enhancing the economic viability of inland operations, thereby diminishing the need for ocean pens. AAS are also reproductively sterile, which eliminates the threat of interbreeding amongst themselves or with native populations, a major recent concern in dealing with fish escaping from salmon farms.[40]

The AAS is an Atlantic salmon that contains a growth hormone gene from a Chinook salmon, in addition to a genetic on-switch from the ocean pout, a distant relative of the salmon.[41] The genetic on-switch allows the salmon to grow year-round, rather than just during the warmer months. AAS can reach market weight in about 18 months, versus the 30 months of conventional Atlantic salmon, though the company states that the GM salmon will not end up any bigger than a conventional fish. In addition to the shortened growth time frame, the fish produced are also reproductively sterile, according to the company, which addresses certain environmental concerns about the threat of inbreeding among the genetically modified and wild salmon population.

The FDA and AquaBounty's AAS

AquaBounty first filed for FDA approval of its AquAdvantage salmon in 1995. According to Elliot Entis, the company's chief executive, by 2007 the company had already given the agency studies showing that the fish were healthy and that implanted genes remained stable over several life cycles. Additionally, the company affirmed that it had conducted tests revealing that the GM salmon were essentially identical to other farmed salmon, containing the same levels of fats, proteins and other nutrients, and would not set off allergic reactions.[42] However, at that point, the FDA was still seeking more data from the biotech company on safety and environmental risks on the wild salmon population.[43]

According to news reports from June 2010, AquAdvantage Salmon seemed on a path to becoming approved by the FDA. This announcement was important, because the approval of AAS would set a precedent for other GM animals. For example, cattle resistant to mad cow disease or pigs that could supply healthier bacon may be next in line for possible approval.[44]

On September 3, 2010, the VMAC informed the public that it was hosting a three-day meeting from September 19 to 21 to discuss the approval of AquaBounty's salmon. FDA staff, company officials and public speakers would speak the first two days before the agency provided its opinion; the third day was set aside to discuss the issue of labeling the genetically modified salmon.

In the 172-page briefing packet provided by VMAC to the public, the committee analyzed the following seven elements based upon the new hierarchical "risk-based approach to assessing GE animals": Product Definition; Molecular Characterization of the Construct; Molecular Characterization of the GE Animal Lineage; Phenotypic Characterization of the GE Animal; Durability: Genotypic and Phenotypic Plan; Food/ Feed/Environmental Safety; and Claim Validation. Appendix B outlines in more depth the risk-based approach the FDA has developed in analyzing the AAS.

40 From http://www.aquabounty.com/products/products-295.aspx, accessed 10/20/2010.
41 Pollack, Andrew. "Genetically Altered Salmon Get Closer to the Table." *The New York Times* (June 25, 2010).
42 Pollack, Andrew. "Without U.S. Rules, Biotech Food Lacks Investors. " *The New York Times* (July 30, 2007).
43 Ibid
44 Pollack, Andrew. "Genetically Altered Salmon Get Closer to the Table." *The New York Times* (June 25, 2010).

In a preliminary analysis prepared for the meeting in this briefing packet, VMAC concluded that the GM salmon is "as safe to eat as food from other Atlantic salmon" and that the altered fish had "no biologically relevant differences" in vitamins, minerals or fatty acids.[45]

Opposition and Support

The FDA's announcement for the panel discussion to take place on September 19 was greeted with a great amount of national attention. On August 27, 2010, a coalition of 31 consumer, animal welfare, environmental and fisheries groups banned together to oppose AAS's consideration for approval. In their joint press statement (see Appendix C), the main concerns cited included the potential for salmon escape into the wild and the possibility for the GM salmon to outcompete the wild salmon population for food and mates.[46]

Though AquaBounty makes claims that the fish will be grown inland, addressing worries of salmon escape from open-water net pens, the reality of the situation may be different: "Most salmon farmers in the real world ply their trade in low-lying coastal areas and competing corporations will no doubt race to produce GE fish in crowded open ocean facilities already in use for fish production," the press release stated. "Backsliding on its original claims, reports have circulated that AquaBounty may only suggest producers raise GE fish in 'inland waters'—presenting novel threats to our nation's lakes, rivers, and estuaries – many of which are already under attack by invasive fish species like the Asian carp and Northern snakehead." Margaret Mellow, a senior scientist and director of the food and environment program at the Union for Concerned Scientists, also does not think the FDA should settle for AquaBounty's answer that there is "redundant biological and physical containment." "It's a mistake we know well," Mellow said. "The deep-water well at issue in the BP incident also contained simultaneous, multiple, redundant measures to keep a spill from happening. But despite all that, a spill happened."[47]

The coalition also expressed concern over the shortened review period and the "lack of information available to judge the impact of the fish." Andrew Kimbrell, executive director for the Center for Food Safety, comments that the "FDA has been sitting on this application for 10 years and yet it has chosen not to disclose any data about its decision until just a few days before the public meeting."

Other critics have also cited the lack of robustness in the studies presented by AquaBounty that may point to human health risks. "The FDA is basically just assuming these fish are okay to eat," said Jaydee Hanson, a policy analyst for the nonprofit Center for Food Safety. According to Hanson, the company tested "one of the smallest samples of fisheries research that [he's] seen." For example, the study looking at possible allergic reactions only had a sample size of six fish.[48] Adding to issues of allergens, the studies put forth by AquaBounty also point to the presence of increased levels of growth hormone i-GF1, which has been associated with greater risk of a number of cancers, including prostate, breast, colorectal, and lung.[49] Dr. Michael Hansen, a senior scientist of the Consumers Union, the non-profit consumer watchdog organization that publishes *Consumer Reports,* found trouble with the conclusions that the FDA made about the lack of biological differences in the levels of growth hormones between AAS and conventional Atlantic salmon:

> How can FDA conclude that there are no biologically relevant differences in growth hormone levels between GE and non-GE salmon when the study uses a methodology that cannot detect growth hormone in these fish? This would be like the police using

45 Richwine, Lisa. "Biotech Salmon Safe For Eating." *Reuters* (September 3, 2010).
46 Pollack, Andrew. "Modified Salmon is Safe, F.D.A. says." *The New York Times* (September 3, 2010).
47 Fulton, April. "Biotech Battle: Are Genetically Engineered Fish Safe?" *NPR* (September 20, 2010).
48 Richwine, Lisa. "Biotech Salmon Safe For Eating." *Reuters* (September 3, 2010).
49 From http://www.consumersunion.org/pdf/CU-comments-GE-salmon-0910.pdf, accessed 11/3/2010.

> a radar gun that cannot detect speeds below 120 mph and concluding that there is no "relevant difference" in the speed of cars versus bicycles.[50]

The Consumers Union has also noted strong opposition to the approval process. In their letter to the FDA (see Appendix D), they noted similar disappointment that the public was only given 14 days to review over 255 pages of materials released by the FDA. In addition to echoing statements made by the coalition, the Consumers Union also cited structural issues in the composition of the VMAC overseeing the process. [51]

The FDA, understanding that the VMAC lacked specific expertise, added four temporary voting members to sit on the board. However, "Even with four new temporary voting members, the Committee is not constituted so as to provide scientifically sound advice to FDA on this topic," the Consumer Union said. "The topic of GE salmon is very different from the veterinary medicine topics this Committee normally addresses." Additionally, the Union points out that no food safety scientist specializing in food allergies sits on the committee, which is important in addressing issues of acute allergies to fish among the U.S. population. An endocrinologist, who is knowledgeable about growth hormones, was also lacking.

Issues of conflicts of interest have also surfaced. Two of the temporary voting members, Alison L. Van Eenennaam and Kevin G. Wells, are involved with developing genetically engineered animals themselves, the former who has worked for Monsanto in the past. Gregory Jaffe, the consumer representative on the board, is a lawyer, rather than a scientist, who represents the Center for Science in the Public Interest, an organization that favors the use of agricultural biotechnology.[52]

Supporters of the GM fish, including Professor Yonathan Zohar of the University of Maryland, argue that people should not be afraid of biotechnology, and that consumers should be more open to eating farmed salmon. Zohar has been studying fish farming for 30 years and runs a land-based aquaculture project in Baltimore. "People eat chicken. It's all farmed. People don't think twice about it. A switch of the mindset has to happen for the consumer for seafood," Zohar says. He does, however, feel that the FDA should require more information regarding the risks that GM salmon would pose if they escaped into ocean waters.[53]

Post-Script

At the conclusion of the two-day meetings from September 19 and 20, 2010, no final decisions were made. VMAC recommended further study of the fish's potential to trigger allergies or other health problems in some consumers. Based upon preliminary data, it seems that AAS is safe for people to eat and does not pose a significant environmental risk.[54]

In late September 11 senators asked the FDA to halt the process for approval for AquaBounty's salmon. The senators' press release suggested that AAS should undergo a formal evaluation by FDA's Center for Food Safety and Applied Nutrition to explore any potential health affects on humans. They also criticized the agency for not holding hearings "in a more central location and with outreach to regions dependent on wild salmon production."[55]

Further studies have since come out assessing the FDA approval process. In the November 2010 issue of *Science*, a Duke University-led team researched more thoroughly the approval procedures and concluded the FDA failed to

50 Ibid.
51 From http://www.consumersunion.org/pub/core_food_safety/016884.html, accessed 10/20/2010.
52 Richardson, Jill. "Why is the FDA about to rubber-stamp GE salmon?" Grist (September 20, 2010).
53 Fulton, April. "Biotech Battle: Are Genetically Engineered Fish Safe?" *NPR* (September 20, 2010).
54 "Foes of GE salmon raise specter of 'Trojan gene' effect." *The Los Angeles Times* (November 26, 2010).
55 Bottemiller, Helena. "Senators Ask FDA to halt GM Salmon Consideration." *Food Safety News* (September 29, 2010).

weigh the full impacts that widespread production of the GM salmon could have on human and ecological safety.[56] The researchers also concluded that the FDA should broaden its definition of its terms "safe" and "health" in FDA statutes so the approval process could be more encompassing: "Instead of focusing on the safety of a food taken one portion at a time, or whether it was produced through genetic modifications or through classic breeding, a more useful approach would be to evaluate whether society is better off overall with the new product on the market than without it," says Jonathan Wiener, a professor of law at Duke.[57] A push for a stronger approval process, one that "assesses the full portfolio of impacts to ensure that such decisions serve society's best interests," is recommended by Martin Smith, associate professor of environmental economics at Duke's Nicholas School of the Environment.[58]

In November 2010, *TIME Magazine* included AquaBounty's AquAdvantage salmon in their "50 Best Inventions of 2010."[59]

56 Smith, Martin D., Asche, Frank, Guttormsen, Atle G., and Jonathan B. Wiener. "Genetically Modified Salmon and Full Impact Assessment." *Science* 330(6007): 1502.
57 From http://www.law.duke.edu/news/story?id=5841&u=11, accessed 12/14/2010.
58 Ibid.
59 Walsh, Bryan. "The 50 Best Inventions of 2010: Faster-Growing Salmon." *TIME* (November 22, 2010).

Appendix A

Six Board Classes Based on the Intended Purpose of Genetic Modification
Found in "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs"
http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf

"GE animals currently being developed can be divided into six broad classes based on the intended purpose of the genetic modification:
(1) to enhance production or food quality traits (e.g., pigs with less environmentally deleterious wastes, faster growing fish);
(2) to improve animal health (e.g., disease resistance);
(3) to produce products intended for human therapeutic use (e.g., pharmaceutical products or tissues for transplantation; these GE animals are sometimes referred to as "biopharm" animals); (4) to enrich or enhance the animals' interactions with humans (e.g., hypo-allergenic pets);
(5) to develop animal models for human diseases (e.g., pigs as models for cardiovascular diseases); and
(6) to produce industrial or consumer products (e.g., fibers for multiple uses)."

Appendix B

Risk-Based Approach to Assessing GE Animals
Found in Veterinary Medicine Advisory Committee (VMAC) Briefing Packet for AquAdvantage Salmon

Source: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113660.htm, accessed 11/27/2010.

B. Risk-Based Approach to Assessing GE Animals

FDA has developed a new hierarchical risk-based approach to assess GE animals and their edible products. It does not rely on a single "critical" study, but rather on the cumulative weight of the evidence provided by all of the steps in the review. It is risk-based because it examines both the potential hazards (that is, components that may cause an adverse outcome) identified at each step along the hierarchical pathway and likelihood of harm among the receptor populations (that is, those individuals or populations exposed to the GE animal(s) or their products).

Consistent with other FDA reviews of the products of biotechnology, this approach is, in general, "event-based." An event can be defined as the result of an insertion(s) of a recombinant DNA construct that occurs as the result of a specific introduction of the DNA to a target cell or organism. Animals derived from different events, even if they are based on the previously approved construct(s), would require separate evaluations.

Weight-of-evidence evaluation

In our weight-of-evidence evaluation of GE animals, we draw on data from a number of sources. These include the following, listed in rank order (from highest to lowest) of importance in the overall weight-of-evidence evaluation: (1) controlled studies conducted on the specific animals being considered for approval; (2) other non-controlled studies on these same animals; (3) historical records and data for these animals; and (4) studies reported in the scientific literature investigating these same animals or their relatives. Each source, in turn, is given appropriate deference with respect to its relevance to the risk or hazard identification question under consideration. Irrespective of the source or order of deference given to a given dataset, all of the data and information is evaluated in the context of basic scientific principles and external validity.

S***tep 1: Product Definition***
The hierarchical process is based on a product definition, which in turn drives subsequent data generation and review. Product definitions ultimately characterize the GE animal intended to enter commerce, and should include the following: the ploidy and zygosity of the GE animal; a description of the animal, including the common name, genus and species; the name and number of copies of the rDNA construct; the location of the insert; the name of the GE animal line; and the claim being made for the animal. CVM recommends that sponsors identify the GE animal's genomic DNA sequences flanking the integration site(s) of the inserted rDNA to protect their intellectual property. The construct may also be given a proprietary name for similar protection.

Step 2: Molecular Characterization of the Construct
CVM recommends that sponsors provide fundamental information for identifying and characterizing the rDNA

construct intended to be introduced into the GE animal intended for marketing. In general, information should be provided to describe the purpose of the modification; source(s) of the introduced DNA; details of how the rDNA construct was assembled; the intended function(s) of the introduced DNA; the sequence of the introduced DNA; and its purity prior to introduction into the initial animal or cell to be used as a nuclear donor to produce an animal via nuclear transfer.

Step 3: Molecular Characterization of the GE Animal

In this step, FDA evaluates the data and information supplied on the event that identifies and characterizes the subsequent GE animal, the production of the GE animal(s) intended to enter commerce, and the potential hazards that may be introduced into the animal as part of its production. Key data and information include the method by which the rDNA construct was introduced into the initial GE animal, whether the resulting animal was chimeric, and the nature of the breeding strategy used to produce the lineage progenitor.

The lineage progenitor is defined as the animal from which the animals intended to be commercialized are derived; it contains the final stabilized version of the initial event. To characterize this key animal, sponsors should provide information on the genomic location(s) of the rDNA construct's insertion site(s); number of copies of the rDNA construct at each insertion site; whether the insertion occurs in an active transcriptional region; and whether analysis of flanking sequences can help determine whether harm is likely to result from the interruption of a coding or regulatory region (insertional mutagenesis).

Step 4: Phenotypic Characterization of the GE Animal

In this and the following steps, the agency seeks to determine whether any production of the GE animal poses any public health risks (risks to human health, risks to animal health, or risks to the environment). It does so by evaluating the expression of the introduced trait and its effect(s) on the resulting GE animal. First evaluated are the data that characterize whether the rDNA construct or its expression product(s) cause any direct toxicity – that is, whether there are any adverse effects attributable to the intrinsic toxicity of the construct or its expression product(s). Indirect effects also are evaluated (indirect effects are those that may be caused by the perturbations of physiological systems by the construct or its expression product(s) (e.g., the expression product may change the expression level of another protein). In general, CVM recommends that sponsors compile and submit data and information addressing the health of the GE animals, including veterinary and treatment records, growth rates, reproductive function, and behavior. In addition, CVM recommends that data on the physiological status of the GE animals, including clinical chemistry, hematology, histopathology, and post-mortem results, be submitted for evaluation.

Step 5: Durability: Genotypic and Phenotypic Plan

This step is intended to provide information to ensure that the specific event defining the GE animal being evaluated is durable — that is, that there is a reasonable expectation that the gene construct is stably inherited and that the phenotype is consistent and predictable. FDA's specific intention for this step is for the sponsor to provide a plan to ensure that the GE animals for which data are submitted and evaluated for approval are equivalent to those intended for distribution in commerce over the commercial lifetime of the GE animal (or its products). Particular attention should be paid to the identification of GE animals derived immediately from the lineage progenitor, and the preservation of genetic material that could be used to regenerate the genetic line of the lineage progenitor, if necessary. As part of the plan, CVM recommends that sponsors maintain accurate and comprehensive records of their breeding strategy, as well as the actual breeding.

For genotypic stability, CVM recommends that sponsors use the results of studies demonstrating that the inserted transgene is consistently inherited. To demonstrate phenotypic durability, CVM recommends that sponsors submit data on the consistency of the expressed trait (based on the claim being made) over multiple generations. CVM

recommends that sponsors gather data on inheritance and expression from at least two generations, preferably more, and recommends that at least two of the sampling points be from non-contiguous generations (e.g., F_2 and F_4).

The Durability Plan is inextricably linked to post-approval reporting requirements. These generally include information on the quantity of the regulated article (interpreted as the quantity of GE animals produced), any adverse events that have been reported, and any changes that may be made to the product (the GE animal). It is developed if a positive decision should be made on approving an application, and will take into account the nature and structure of the durability plan.

Step 6: Food/Feed/Environmental Safety

a. Food/Feed Safety

The food and feed safety step of the hierarchical review process addresses the issue of whether food or feed from the GE animal poses any risk to humans or animals consuming edible products from GE animals compared with the appropriate non-transgenic comparators.

The risk questions involved can be divided into two overall categories. The first asks whether there is any direct toxicity, including allergenicity, via food or feed consumption associated with the expression product of the construct or components of the construct. The second category of questions addresses potential indirect toxicity associated with both the transgene and its expressed product (e.g., will expression of the transgene affect physiological processes in the resulting animal such that unintended food/feed consumption hazards are created, or existing food/feed consumption risks are increased). Potential adverse outcomes via the food/feed exposure pathway can be identified by (1) determining whether there are any biologically relevant changes to the physiology of the animal (assessed partly in Step 3: Phenotypic Characterization of the GE Animal), and (2) whether reasons for toxicological concern are suggested by any biologically relevant changes in the composition of edible products from the GE animal compared with those from the appropriate non-transgenic comparator.

b. Environmental Safety

Because of the requirements set forth in the National Environmental Protection Act (NEPA) and FDA environmental impact regulations in 21 CFR 25, the agency typically must prep an environmental assessment (EA) for each NADA approval action. The EA generally focuses on potential impacts related to the use and disposal of the GE animal. In general, the EA should describe and discuss the following: (1) the genotype, phenotype and general biology of the GE animal; (2) potential sources and pathways of escape (or release) and spread of the GE animal; (3) the types and extent of physical and biological confinement, if any that will be implemented; and (4) the potentially accessible ecosystems and their characteristics. CVM recommends that the sponsor contact CVM before proceeding with preparation of the EA in order to insure that it is appropriately focused. In the event that the EA results in a finding that a significant environmental impact may result, an Environmental Impact Statement may need to be prepared.

Step 7: Claim Validation

The previous steps of the hierarchical review approach primarily address identity and safety issues. In the last step of pre-market review, the "effectiveness" portion of the proposed claim for the GE animal is validated. In order to demonstrate effectiveness, sponsors must present substantial evidence—that is, one or more adequate and well controlled investigations (21 U.S.C. 360b(d)(3)) to validate the claim that is being made. Because the product definition contains the eventual claim, CVM recommends that sponsors contact the Center early in the development of the GE animal to reach agreement on (1) what would constitute a suitable claim, and (2) the nature and conduct of studies.

Appendix C

Press Release from 31 Organizations and Fishery Associations Demanding FDA Deny Approval of AquAdvantage Salmon
http://truefoodnow.files.wordpress.com/2010/08/final-joint-press-statement-coalition-demands-fda-deny-approval-of-ge-fish-8-27-10.pdf

CENTER FOR FOOD SAFETY – FOOD AND WATER WATCH – SALMONAID NORTHWEST ATLANTIC MARINE ALLIANCE - ORGANIC CONSUMERS ASSOCIATION – FRIENDS OF THE EARTH – THE LIVING OCEANS SOCIETY – SMALL BOAT COMMERCIAL SALMON FISHERMEN'S ASSOCIATION – THE GEORGIA STRAIT ALLIANCE – CALIFORNIANS FOR GE-FREE AGRICULTURE – THE ORGANIC & NON-GMO REPORT – PLANETARY HEALTH, INC. – SIERRA CLUB – SAY NO TO GMOS! – CENTER FOR ENVIRONMENTAL HEALTH – CANADIAN BIOTECHNOLOGY ACTION NETWORK – INSTITUTE FOR FISHERIES RESOURCES – AMERICAN ANTI-VIVISECTION SOCIETY – PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATION – MANGROVE ACTION PROJECT – FOOD FIRST / INSTITUTE FOR FOOD AND DEVELOPMENT POLICY – EDEN FOODS, INC. – THE NON-GMO PROJECT – NORTHWEST RESISTANCE AGAINST GENETIC ENGINEERING –PCC NATURAL MARKETS – AMBERWAVES – GLOUSTER FISHERMEN'S WIVES ASSOCIATION – FRESH THE MOVIE – WASHINGTON BIOTECHNOLOGY ACTION COUNCIL –OREGON PHYSICIANS FOR SOCIAL RESPONSIBILITY

August 27, 2010; JOINT PRESS STATEMENT FOR IMMEDIATE RELEASE

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COALITION DEMANDS FDA DENY APPROVAL OF CONTROVERSIAL GENETICALLY ENGINEERED FISH

FDA Considers Approval of GE Salmon--the First GE Food Animal--Yet Fails to Inform the Public of Environmental and Economic Risks

Washington, DC August 27, 2010 – A coalition of 31 consumer, animal welfare and environmental groups, along with commercial and recreational fisheries associations and food retailers submitted a joint statement criticizing an announcement this week by the U.S. Food and Drug Administration (FDA) that it will potentially approve the long-shelved AquAdvantage transgenic salmon as the first genetically engineered (GE) animal intended for human consumption.

The engineered Atlantic salmon being considered was developed by AquaBounty Technologies, which artificially combined growth hormone genes from an unrelated Pacific salmon, *(Oncorhynchus tshawytscha*) with DNA from the anti-freeze genes of an eelpout (*Zoarces americanus*).

This modification causes production of growth-hormone year-round, creating a fish the company claims grows at twice the normal rate. This could allow factory fish farms to crowd fish into pens and still get high production rates.
Each year millions of farmed salmon escape from open-water net pens, outcompeting wild populations for resources and straining ecosystems. "We believe any approval of GE salmon would represent a serious threat to the survival of native salmon populations, many of which have already suffered severe declines related to salmon farms and other man-made impacts," Marianne Cufone, director of Food and Water Watch's fish program said.

If the FDA opens this door, GE fish will likely be among the millions of salmon that currently escape from open ocean pens every year. This could be the last blow to wild salmon stocks and in turn the thousands of men and women who depend on fishing for their livelihoods.

"Approving genetically engineered salmon is a sharp contradiction to the agreements the United States has signed at NASCO, where transgenic salmonids are considered a serious threat to wild salmon" said Boyce Thorne Miller, Science and Policy Coordinator for the Northwest Atlantic Marine Alliance and accredited observer at the North Atlantic Salmon Conservation Organization.

Escaped GE salmon can pose an additional threat – genetic pollution resulting from what scientists call the "Trojan gene" effect." Research published in the *Proceedings of the National Academy of Sciences* notes that a release of just sixty GE salmon into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 generations.

Anticipating the stark danger to our fisheries and ocean environments - and trying to circumvent analyses of those dangers - AquaBounty has claimed that they will only raise their fish in land-based facilities. However most salmon farmers in the real world ply their trade in low-lying coastal areas and competing corporations will no doubt race to produce GE fish in crowded open ocean facilities already in use for fish production. Backsliding on its original claims, reports have circulated that AquaBounty may only suggest producers raise GE fish in "inland waters" – presenting novel threats to our nation's lakes, rivers, and estuaries – many of which are already under attack by invasive fish species like the Asian carp and Northern snakehead.

"FDA's decision to go ahead with this approval process is misguided and dangerous, and is made worse by its complete lack of data to review" said Andrew Kimbrell, Executive Director for the Center for Food Safety. "FDA has been sitting on this application for 10 years and yet it has chosen not to disclose any data about its decision until just a few days before the public meeting."

On Wednesday, FDA officials announced that they had begun the approval process for the engineered salmon and have scheduled public meetings beginning Sunday, September 19. Speakers wishing to present oral comments are expected to submit their requests in writing by September 7th; one day after the FDA has said it may post "some" of the data to its website. "This is not a process that leads to full and informed public participation," said Charles Margulis, Sustainable Food Program Coordinator for the Center for Environmental Health.

FDA announced the same day that it will hold a public comment period and a hearing on labeling for the transgenic salmon, which seems to presuppose that the controversial GE fish will be approved. If the GE fish is approved, Agency officials are undecided as to whether they will require any product labeling.

"We all know there is a great appetite for salmon, but the solution is not to 'farm' genetically engineered versions to put more on our dinner tables; the solution is to work to bring our wild salmon populations back" said Jonathan Rosenfield, PhD, a Conservation Biologist and President of the SalmonAID Foundation, a 28-member coalition of commercial, tribal, and sportfishing interests, conservation organizations and chefs. "The approval of these transgenic fish will only exacerbate the problems facing our wild fisheries."More specifically, aquaculture is becoming the dominant procedure for harvesting fish. The FAO reports that approximately half of all fish consumed in 2006 came from aquaculture; with regards to all the salmon eaten, about 70% were farmed commercially.[60]

60 From www.fao.org/newsroom/common/ecg/1000930/en/enfactsheet.pdf, accessed 11/15/2010.

Appendix D

Consumer Union Letter to the Commissioner and Principal Deputy Commissioner of the FDA Regarding AquaAdvantage Salmon Application

September 15, 2010

Dr. Margaret Hamburg, Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
White Oak 32, Room 2346
Silver Springs, MD 20993

Dr. Joshua Sharfstein, Principal Deputy Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
White Oak 1, Room 2220
Silver Springs, MD 20993

Dear Commissioner Hamburg and Deputy Commissioner Sharfstein:

Consumers Union (CU), the non-profit publisher of *Consumer Reports* magazine, writes to you regarding concerns about the Food and Drug Administration's (FDA) process regarding review of Aquavantage's application for approval of genetically engineered (GE) salmon. We have concerns both about the safety assessment review period and about the composition of the Veterinary Medicine Advisory Committee (VMAC) that will be reviewing the application.

First, we feel that the current fourteen-day review period on the safety assessment of the Aquavantage genetically GE salmon is far too short, and we respectfully request that it be extended to the standard sixty days.

We also respectfully request that you postpone the meeting of the VMAC, now scheduled for September 19-20, in order to add members to the committee with the appropriate expertise to address critical safety questions. The VMAC currently lacks any scientists whose primary expertise is in food allergies, endocrinology or fish ecology, the main topics on which the VMAC will have to render judgments in order to conclude that the salmon is safe. We strongly urge you not to make a decision on the safety of the first GE animal to be approved for human consumption without the input of scientists in these fields or without wide public input.

When CU, the Center for Food Safety, and the Union of Concerned Scientists met with FDA officials in May, we were assured that even though approval of a veterinary drug is not normally a matter on which FDA solicits public input, the agency would allow for public input in this matter given that a decision on GE salmon is an important and unusual use of FDA's authority on veterinary drugs, and because of the widespread public interest in this landmark decision.

While we appreciate the release of a summary of the scientific data underlying the FDA's review, we have strong concerns about giving the public only two weeks to review the data on the human and environmental safety of the GE salmon, contained in 255 pages of technical information. We are especially concerned about trying to undertake this review in such a constrained time period when there are serious issues of food safety involved. The FDA review discusses the presence of proteins to which some people are acutely allergic, and which may be elevated in the transgenic fish, as well as presence of increased levels of the growth hormone iGF-1. This material raises serious

health concerns. Fourteen days are not sufficient to review this material in proper depth.

Given that FDA has had eleven years to review the application of Aquabounty for approval, we question the extremely brief period allowed for public review and input. Since GE salmon is not in any way a lifesaving product such as certain pharmaceuticals or medical devices, we must question why the agency believes it is necessary to move forward so quickly, in a way that does not allow for the standard 60 to 90 days of public review.

We must also object to the current composition of the VMAC, announced last week. Even with four new temporary voting members, the Committee is not constituted so as to provide scientifically sound advice to FDA on this topic. The topic of GE salmon is very different from the veterinary medicine topics this Committee normally addresses. There is, at present, not one single food safety scientist specializing in food allergies on the Committee despite the relative frequency of acute allergies to fish in the US population. Nor is there an endocrinologist knowledgeable about growth hormones - which are at issue here - on the Committee. There is also not one single fish ecologist. Nine of the 13 members are veterinarians or hold doctorates in animal science. Two more have been involved in developing genetically engineered animals themselves, including one who has worked for Monsanto. The consumer representative, though knowledgeable, is a lawyer rather than a scientist. We question how the Committee can accurately assess the safety of this salmon for humans and the environment when it lacks the essential expertise to do so. We believe that three fish ecologists, four food safety experts (including specialists in food allergies and in the effects of hormones on human health), and scientists from the consumer and environmental community must be added to the Committee, to provide appropriate balance and expertise.

We believe that without the extension of the review period, and the addition of certain scientific experts to the VMAC, the Committee's findings will not have the needed credibility with the public. We also believe that without these experts, FDA will fail to get the sound scientific advice it needs and deseNes. For these reasons, we urge you to delay next week's VMAC meeting for two months, to allow a standard 60-day public review period of the data that has been released, and to allow FDA to add the necessary and appropriate expertise to the VMAC.

Thank you for considering our request.

Jean Halloran
Director, Food Policy Initiatives

Michael Hansen, Ph.D.
Senior Scientist

source: http://www.consumersunion.org/pu/core_food_safety/01684.html