

Alaska Trollers Association

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RE: AquAdvantage Salmon Dockets:

FDA-2011-N-0899-0685 Environmental Assessment
FDA-2011-N-0899-0003 Finding of No Significant Impact

To Whom It May Concern:

The Alaska Trollers Association (ATA) represents hook and line salmon fishermen operating off the coast of Alaska, where our salmon resource is healthy and our fisheries are well-managed. Our members take quite seriously the job of delivering a safe, wholesome, high quality product to market and are firmly committed to sound science underpinning the decisions made regarding the food people eat.

ATA strongly opposes the genetic engineering (GE) of seafood and submitted comments to that effect to the FDA's Veterinary Medicine Advisory Committee (VMAC) in September 2010, and again during FDA's November 2010 comment period on Docket No. FDA-2010-N-0385 Labeling of AquAdvantage Genetically Engineered Salmon. ATA is signatory to one collaborative letter in the current docket. I refer you to all of our previous comments and request that this supplemental statement be included in the record as well. In addition, ATA supports the findings included in a number of well-supported comments that have been submitted, relative to deficits in the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI), and FDA's lack of due diligence in evaluating the long-term safety of GE salmon on humans, as well as their impact on the human environment.

While we appreciate FDA extending the comment period, it still did not allow adequate time for those of us who stand to be the most impacted to fully review and respond to the notice for comment. To simply say that the animal has been under review for many years is disingenuous at best, considering the public was just recently invited to review any of the documents – and certainly not all of them. The public's resources are scarce for these undertakings and this should be considered more seriously when the agencies decide to rule on such landmark decisions about our food supply. Winter and early spring are extremely busy months for the seafood harvesting sector. That's when we are confronted with the myriad regulatory and legislative forums that occur prior to the launch of fishing season. Most fishermen don't fish anywhere close to computers and internet connections.

Environmental Impact Statement v. Environmental Assessment

ATA requests an Environmental Impact Statement (EIS) be conducted on AquAdvantage Salmon. The Environmental Assessment (EA) has failed to reveal pertinent information about where and how this fish is likely to be raised, what it will be fed, or which diseases it might carry. FDA has disregarded the latest and best available science in its analysis of the potential impact of this fish on the human

environment, and instead relies on many dated studies.¹ There is no meaningful discussion about this animal as an invasive species should it escape, since FDA denies the likelihood that it will. The promoters tested fish that were often not market size, and none were reared in a large scale production setting. Human health risks have been glossed over, as evidenced by small sample sizes and the dearth of long term, peer reviewed studies. FDA has also chosen to ignore the economic and social impacts of producing fast growing genetically engineered salmon for market. For these reasons, and more, the EA fails the litmus test as a risk assessment of the expected long term wholesomeness and safety of GE salmon, and is therefore insufficient as the decisional document for what could be the first ever GE approved animal for human consumption. The weighty precedent that would be established through approval of the fish makes it crucial that FDA get it right. An EIS should help further flesh out the issues surrounding this fish and, hopefully, lead to a sound decision.

The agency must analyze the full range of direct, indirect, and cumulative effects of the preferred alternative, if any, and of the reasonable alternatives identified in the draft EIS. For purposes of NEPA, "effects" and "impacts" mean the same thing. They include ecological, aesthetic, historic, cultural, economic, social, or health impacts, whether adverse or beneficial. It is important to note that human beings are part of the environment (indeed, that's why Congress used the phrase "human environment" in NEPA), so when an EIS is prepared and economic or social and natural or physical environmental effects are interrelated, the EIS should discuss all of these effects.^{2 3}

Initial Regulatory Flexibility Analysis

Given the significant impact of farmed fish on the wild harvest seafood industry and its support sector, FDA's process for evaluating GE salmon and its Finding of No Significant Impact (FONSI) do not appear to meet the intent or spirit of Presidential Orders 12866⁴ or 13563⁵.

The FONSI lacks an analysis under the Regulatory Flexibility Act (RFA) regarding its impact on the thousands of small businesses that make up our nations seafood industry⁶.

The RFA requires federal agencies to consider the impact of regulations on small entities in developing the proposed and final regulations. If a proposed rule is expected to have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis must be prepared. The initial regulatory flexibility analysis or a summary of it must be published in the Federal Register with the proposed rule.⁷

ATA requests that FDA prepare an appropriate regulatory flexibility analysis⁸ assessing the impact on small entities of this, and any other, proposed or final rule related to AquaBounty GE salmon. In addition, we ask that such analyses be conducted for GE salmon or gametes which may be sold by the developer to other salmon producers; and, that such analyses occur for any other genetically modified species that is destined for the seafood market.

¹ Flash in the Pan, Interview with Dr. Anne Kapuscinski, March 11,2013 <http://www.flashinthepan.net/?p=1019>

² A Citizen's Guide to the NEPA, p. 22 http://ceq.hss.doe.gov/nepa/Citizens_Guide_Dec07.pdf

³ CEQ NEPA Regulations, 40 C.F.R. §§ 1508.7, 1508.8, § 1508.14.

⁴ http://www.reginfo.gov/public/jsp/Utilities/EO_12866.pdf

⁵ www.reginfo.gov/public/jsp/Utilities/EO_13563.pdf

⁶ 5 U.S.C. 600 et. seq.

⁷ <http://www.fws.gov/policy/library/rgSBAGuide.pdf>

⁸ 5 U.S.C. 603 and 604

Value of Wild Harvested Seafood to the Nation and Alaska

NOAA recently published a report highlighting the impacts of the seafood industry and its support sector, which includes fishermen, processors, wholesalers, distributors, gear suppliers, retailers, and a wide range of other small business interests. In 2011, U.S. fishermen landed 9.9 billion pounds of seafood valued at \$5.3 billion dollars, up 20% and 17% respectively over the previous year. This harvest created \$129 billion in sales and \$55 billion in value-added impacts. Over 1.2 million people were employed as a result, with combined earnings of \$37 billion. The seafood industry contributed \$42.2 billion to the U.S. GNP.⁹

Alaska alone contributed 5.3 billion pounds of seafood for which fishermen were paid \$1.9 billion. The 2011 harvest allowed for \$4.7 billion in seafood sales and created 63,000 jobs, which paid \$2 billion in salaries. Over 70% of the seafood jobs in Alaska were attributed to the harvesting sector (44,713). The vast majority of commercial fishermen in Alaska are residents who live in rural communities.

Salmon provides the biggest benefits to the most Alaskan's and the commercial catch was worth \$565 million in 2011, compared to an average of \$325 million in 2002-2011. And though salmon made up just 14% of the North Pacific seafood landings, it contributed 30% of the total value of this region's harvest. Overall, salmon ranked 3rd in landings and 2nd in value for domestically landed species.

In 2011, recreational fisheries in the U.S. provided \$70 million in sales and 455,000 jobs with a payroll of \$20 billion; an estimated 6,300 jobs were created in Alaska to support the sport anglers. Over a quarter of a million recreational anglers fished in saltwater off Alaska in 2011 and 124,000 were residents of the state. From 2002-11, an average of 304,000 anglers fished the North Pacific. Salmon and halibut are the primary sport target species.¹⁰

Seafood and Southeast Alaska

ATA represents hook and line fishermen in Southeast who primarily target Chinook and coho salmon. Many also fish halibut, cod, and shellfish. With over 2,000 troll permit holders, our fishery ranks among the largest in the state and is 86% resident. Most trollers reside in the Southeast region and a large number live in small coastal communities. Nearly one out of every 35 people in our region works on the back deck of a troll boat. When you add in the processing and support sectors, the health of the troll industry proves vital to securing the economic and social well-being of Southeast Alaska. Salmon are also critical to thousands of other fishermen in our region. Seven of the U.S.'s top 83 fishing ports are in our region; 3 made NOAA's Top 50 list (Attachment).

In addition, our state relies on the availability of healthy resources for subsistence and personal use fisheries for food and cultural purposes. While subsistence activities produce relatively low amounts of revenue, it is a well-known fact that a large number of subsistence users rely on commercial fishing to enable them to subsistence fish. Fishermen often save back some subsistence or personal use fish from their commercial harvest, or use the money earned commercial fishing for the fuel and gear necessary to catch fish for home use; fisheries often blend together for Alaska fishing families.

The value of this nation's seafood industry, particularly as it relates to jobs and income in small, rural communities, must not be underestimated. In most of these small towns there are no other options for work. The markets that our fleets cater to are easily impacted, as we can see with significant price

⁹ <http://www.st.nmfs.noaa.gov/Assets/economics/documents/feus/2011/FEUS%202011-Revised.pdf>

¹⁰ <http://www.st.nmfs.noaa.gov/Assets/economics/documents/feus/2011/FEUS2011%20-%20North%20Pacific%20%28Alaska%29.pdf>

drops, particularly in years when farmed fish production is up.

Given these economic times, U.S. policymakers should be exceedingly careful when making economic decisions that can impact such fragile economies now and into the future.

The Farming of ‘Frankenfish’

FDA in both the EA and FONSI claims that the AquAdvantage GE salmon will only be allowed to be farmed under very specific set of rearing conditions – in two countries outside of the United States.

Under the proposed action, AquAdvantage Salmon would not be produced or grown in the United States, or in net pens or cages, and no live fish would be imported for processing (FONSI, 2012).

This begs the question why the U.S. is expending its limited resources on the approval of this animal at all? Turning to the review documents, FDA provides the probable answer:

The commercial intent of AquAdvantage Salmon is to benefit commercial salmon farming by significantly reducing time-to-market and improving the economics of land-based production (EA, 2012).

FDA goes on to state that:

Any modifications that the sponsor may propose to the conditions of an approval would require notification of FDA. Major and moderate changes require the filing and review of a supplemental NADA. Approvals of such supplemental applications would constitute agency actions and trigger environmental analyses under NEPA (EA, 2012).

So what will the supplemental NADA entail, and what if someone besides ‘the sponsor’ wishes to rear these fish in different places, under different conditions than FDA approves under its initial approval? This is not made clear. However, it is of very large concern to many of us, particularly since a recent Freedom of Information Act request revealed that agencies have already received permit applications to import eggs, most likely to raise the GE salmon for market. AquaBounty has also stated publically that there are a number of interests in the US and other countries that are anxious to farm these fish. What kind of control will FDA have over the matter once the GE salmon is approved?

We are also not convinced that all pertinent information has been provided to the public for discussion through this comment period, whether it is possible scenarios that would allow GE fish to be raised somewhere besides Panama in the near-term, or the fact that some of the GE salmon were found to have the virulent ISA virus, or any number of other significant issues that might exist.

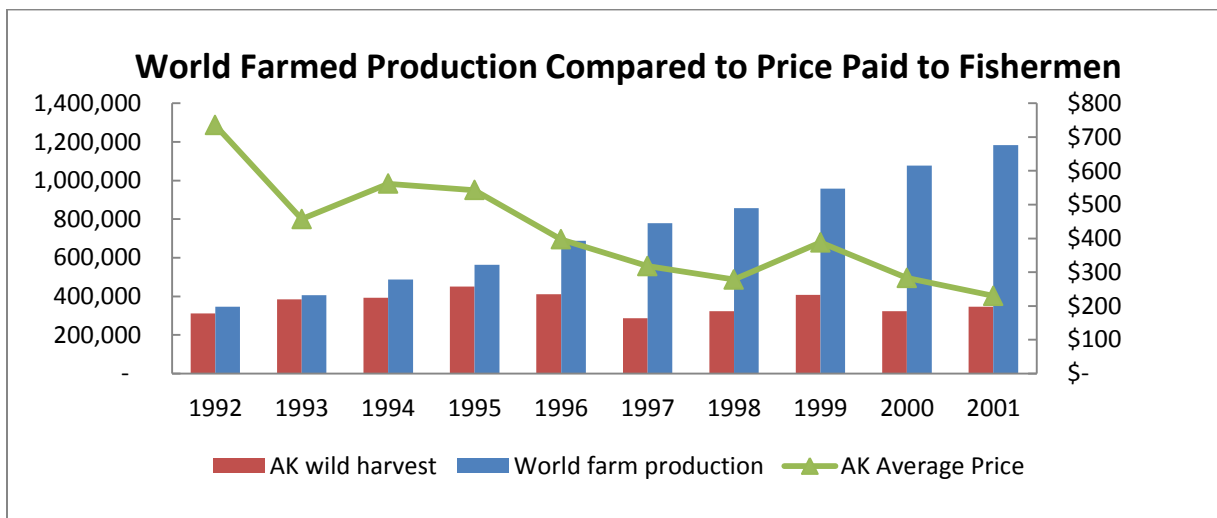
Anything that threatens the health of humans who eat fish, or wild fishes, or the vitality of wild seafood markets, will have significant, negative effects on commercial harvesters, sport anglers, guides, subsistence, and personal use fishermen, processors, the support sector, and consumers of seafood. FDA is well aware, as stated in its documents, that the goal of gaining approval for GE salmon is to ramp up production of farmed salmon and reducing farmer’s costs, wherever the fish are allowed. The FDA also knows that those producers will compete with the existing U.S. seafood industry. The EA speaks to expanding seafood consumption, but not about the people and industry that currently bring fish to market. The use of GE fish to expand fish farm production must be analyzed with respect to its impact on existing fish related industries and jobs.

Impact of Fish Farms on the Wild Harvest Salmon Industry

Alaska fishermen and processors are well acquainted with the impact of farmed salmon gluts on their industry. In fact, the situation became so dire in the 1990's that in 2003, fishermen were approved for assistance under the USDA's Trade Adjustment Act for the first time in history. As farmed production grew, price paid for salmon products dropped, which toppled some salmon related businesses and threatened many more.¹¹

Alaska's governor Tony Knowles even expressed concerns about the negative economic impacts of farmed salmon on the seafood industry when the U.S. was negotiating its Fair Trade Agreement with Chile.¹²

The Southeast troll fleet lands the highest quality salmon with hook and line. Each fish is carefully handled, cleaned, and iced or frozen quickly after it comes out of the sea. From 1979-2012, average gross earnings for the fleet were \$23.7 million. The recent 5 year average is \$28.3 million, and farmed production has been down. By contrast, from 1996-2001 - years when farmed production nearly doubled - earnings plummeted to \$15.8 million. By 2002, the troll fleet earned just \$12.5 million, which was the lowest amount since 1979 and the troll fleet's 4th worst year on record.¹³ Future over-production of farmed salmon is cause for concern for individual seafood businesses, our fishing communities, region, and state. Worse still, most fishermen are diversified into other species fisheries and we know there are many other GE fish in development.



The impact of farmed fish on wild fish markets is arguably complex. However, supply and demand will always affect price, as will the attitudes of consumers. Poll after poll shows that most people in the U.S. and abroad have at least some concern about GE food, with the vast majority rejecting outright the notion of GE seafood and animals. Still, FDA has stated that they will not even require a label for this product. If consumers can't tell the difference, it's possible they will avoid buying salmon, just in case it's GE. Dozens of countries around the world either do not permit the sale of GE foods, or require labeling of GE products. Many of their citizens buy our fish, but will they continue to do so if they can't tell the difference? Why should the seafood industry bear the added burden of paying to distinguish our product from GE, when it is the fish farm industry that will be mass producing the 'widgets' likely to harm our markets?

¹¹ <https://www.fas.usda.gov/info/fasworldwide/2005/06-2005/TAA.htm>

¹² <http://www.commerce.state.ak.us/ded/dev/seafood/pub/soacomment.pdf>

¹³ Changes in Gross Total Earnings in Alaska Salmon Troll Fisheries 1975 – 2012, CFEC, April 2013

While the use of genetic engineering may be appropriate and beneficial for a variety of purposes, such as medical advancement, it does not appear that the science currently exists to underpin decisions with regard to whether GE salmon belong in the food chain and environment.

Labeling of GE foods boils down to one of the most fundamental of human needs and rights - access to wholesome foods and information about how they are produced. While the GE salmon may ultimately prove safe and wholesome, there is no doubt that it is unlike any other salmon available today. It is a processed food at its most basic level, and should be labeled accordingly, particularly when no independent science exists to prove that it is safe. Such a label is not misleading, nor is it in any way false, it is simply telling the consumer the truth about a type of food that until just a few years ago was inconceivable. People should have the right to choose.

Finally, a clearly articulated set of publicly negotiated policies, along with relevant statutory, regulatory, research, monitoring, enforcement, and remediation programs do not even appear to exist, though a look at FDA's webpage suggests that regulations are in development. How will we know if these animals are brought into our country – will you be able to distinguish them from other farmed fish in net pens in Maine and Washington, or from wild stocks in East Coast streams? And how will you keep them separate in the marketplace and study the effects of GE salmon over the long haul?

Until such time as the public is adequately brought into the debate; long term, peer reviewed, science shows genetically engineered salmon to be safe for human health and the environment; an EIS and regulatory impact analysis have been completed; and, the appropriate statutory and regulatory sideboards are in place, ATA does not believe FDA should issue its approval for GE seafood products.

If FDA goes against what appears to be the will of the majority of Americans, and approves AquAdvantage Salmon, then labeling of any GE seafood product should become mandatory.

Thank you for considering ATA's point of view. Please let me know if I can answer questions regarding our position, or be of any assistance to FDA as you work through this matter.

Respectfully submitted,

Dale Kelley
Executive Director

"We all know interspecies romance is weird." -- Tim Burton

Attachment

Southeast/Yakutat Seafood Industry

The seafood industry is the largest private employer in Alaska and second largest contributor to the general fund. Alaska is responsible for 60% of all US seafood landings. 2011 deliveries exceeding 738 million pounds and the ex-vessel value was nearly \$565M, up 12% from 2010. In 2009, over 53,000 people worked in the harvesting and processing sector, with nearly as many providing support through research, regulation, transportation, and services industries. Roughly \$100 million is generated from the seafood industry each year, through taxes, fees, and enhancement assessments.¹⁴ In 2012, the seafood industry was responsible for 57% of the shared taxes and fees distributed to Alaska communities.¹⁵

Seafood is responsible for one-half of all exports from Alaska. Seventeen of the top 83 seafood ports in the U.S. are Alaskan; seven of those ports are located in the Southeast/Yakutat region.¹⁶ Three Southeast ports made the 'Top 50' for landings: Sitka, Petersburg, and Ketchikan.¹⁷ In 2011, nearly 400 million pounds of fish were landed in Southeast with an ex- vessel value of \$392 million¹⁸ and a first wholesale value of \$612 million¹⁹. In 2011, the state's general fund and Southeast/Yakutat cities shared roughly \$36 million in fishing related taxes.¹⁵

About 25% of the entire private sector workforce in Southeast Alaska can be attributed to seafood harvesting and processing. In 2011, 5,017 resident permit holders and crewmembers from Southeast/Yakutat participated in commercial fisheries; when non-resident fishermen are added, that number swells to 9,100.¹⁸

Each year, about 60 seafood processors in Southeast employ upwards of 5,000 workers. These processors sold their products for well over half a billion dollars in 2011.¹⁸ That year, Sitka ranked 9th in the nation by posting \$85 million in ex-vessel value and 10th among the ports for its seafood landings in excess of 113 million pounds.¹⁷ In 2009, the first wholesale value of Southeast/Yakutat seafood products outpaced that of the combined gold production at both Greens Creek and Kensington mines.¹⁴

Hatcheries are important contributors to all fisheries in Southeast and Yakutat and most are owned and operated by commercial salmon fishermen, who pay a 3% hatchery tax on every landing. In 2010, three of the largest hatchery operators alone produced 37 million salmon landed by commercial fishermen who were paid \$131.2 million ex-vessel.²⁰

Even Alaska's capitol city, Juneau, ranked 28th in value and 39th in landings amongst U.S. seafood ports in 2011¹⁷, with 18 million pounds of seafood landings worth over \$28 million ex-vessel and \$50 million first wholesale.¹⁹ Local processing payrolls totaled \$4.5 million.²¹ Juneau is home to 398 permit holders, 407 crewmembers, and hundreds of processing workers.²² Seafood is also responsible for about 500 state and federal jobs in Juneau each year.¹⁴

¹⁴ E. McDowell, Transcript, Blessing of the Juneau Fleet, 2011

¹⁵ Alaska Department of Revenue Tax Division Annual Reports, <http://www.tax.alaska.gov/programs/sourcebook/index.aspx>

¹⁶ National Marine Fisheries Service, 2012 [2011 Commercial Fishery Landings by Port Ranked by Dollars](http://www.st.nmfs.noaa.gov/Assets/commercial/fus/fus11/02_commercial2011.pdf)

¹⁷ National Marine Fisheries Service, 2012 http://www.st.nmfs.noaa.gov/Assets/commercial/fus/fus11/02_commercial2011.pdf

¹⁸ 2012 Juneau and Southeast Alaska Economic Indicators 11/1/12, JEDC <http://www.jedc.org/sites/default/files/12%20Seafood%20Industry.pdf>

¹⁹ ASMI, 2011 <http://www.alaskaseafood.org/>

²⁰ Alaska Salmon Fisheries Enhancement 2010 Annual Report, ADFG 2011 <http://www.adfg.alaska.gov/FedAidPDFs/FMR11-04.pdf>

²¹ Alaska Department of Labor, 2011 <http://labor.alaska.gov/research/seafood/statewide/AKSFPBorca.pdf>

²² Commercial Fisheries Entry Commission, 2011 <http://www.cfec.state.ak.us/gpbycen/2011/mnu.htm>