

**HJR**

**8**

<TARGET><BILL>HJR 8</BILL><SUBJECT>HJR  
8</SUBJECT><COMM>HRES27</COMM></TARGET>



# Representative Scott Jiu Wo Kawasaki

Alaska State Legislature

District 9 Fairbanks

## **Sponsor Statement for HJR 8**

### **"Urging the United States Food and Drug Administration to Deny an Application to Sell Genetically Engineered Salmon in the United States"**

House Joint Resolution 8 (HJR8) is introduced to urge the United States Food and Drug Administration (FDA) to deny any application to sell genetically engineered salmon in the United States. HJR8 also calls on Congress to enact product labeling requirements that include the words "Genetically Modified" which are prominently displayed on the package if the application is approved by the FDA.

Recently, the FDA held hearings to approve a hybrid Atlantic salmon as the first genetically engineered animal for human consumption. The FDA's consideration for approval of this "frankenfish" is a risky precedent and a threat to Alaska's wild salmon. The hybrid Atlantic salmon has been engineered by crossing Chinook salmon growth genes and an antifreeze gene from an eel, the ocean pout. The genes allow the new creation dubbed the AquAdvantage salmon to grow about twice as fast as its natural cousin.

Salmon farms in Canada, Europe and South America have been criticized for crowded conditions, fecal contamination, use of chemicals, proliferation of disease and escapees. Atlantic salmon have been caught in Alaska's waters, escaping from neighboring fish farms in British Columbia; many infested with sea lice. They are considered an invasive species by Alaskans.

HJR8 will send the clear message to the Federal Government, Alaska's Congressional Delegation, the Food and Drug Administration and President Obama that the Alaska State Legislature does not condone the growth, sale or release of genetically engineered salmon in the United States. Please join me in supporting House Joint Resolution 8 and help make Alaska's salmon safe.

**CS FOR HOUSE JOINT RESOLUTION NO. 8(RES)  
IN THE LEGISLATURE OF THE STATE OF ALASKA  
TWENTY-SEVENTH LEGISLATURE - FIRST SESSION**

**BY THE HOUSE RESOURCES COMMITTEE**

**Offered:  
Referred:**

**Sponsor(s): REPRESENTATIVES KAWASAKI, Miller, Peggy Wilson, Kerttula, Thompson, Gara, Seaton, Austerman, Herron**

**A RESOLUTION**

1 **Urging the United States Food and Drug Administration to deny any application to sell**  
2 **genetically engineered salmon in the United States; urging compliance with the**  
3 **provision of P.L. 110-85 (Food and Drug Administration Amendments Act of 2007) that**  
4 **requires the Commissioner of Food and Drugs to consult with the National Marine**  
5 **Fisheries Service of the National Oceanic and Atmospheric Administration regarding a**  
6 **report on environmental risks associated with genetically engineered seafood products;**  
7 **and urging that product labeling requirements include the words "Genetically**  
8 **Modified" prominently displayed on the front of the package if the application is**  
9 **approved by the United States Food and Drug Administration.**

10 **BE IT RESOLVED BY THE LEGISLATURE OF THE STATE OF ALASKA:**

11 **WHEREAS** an application has been submitted to the United States Food and Drug  
12 Administration to market genetically engineered salmon for human consumption in the United  
13 States; and

1           **WHEREAS** this is the first genetically engineered animal intended to be used as food  
2 in the United States; and

3           **WHEREAS** a biological opinion issued by the United States Fish and Wildlife  
4 Service and the National Marine Fisheries Service of the National Oceanic and Atmospheric  
5 Administration to the United States Army Corps of Engineers in 2003 expresses concerns that  
6 transgenic salmon would threaten and adversely affect wild Atlantic salmon, currently on the  
7 Endangered Species List; and

8           **WHEREAS** federal agencies are required by 16 U.S.C. 1536(a) (sec. 7 of the  
9 Endangered Species Act) to consult with fisheries agencies when an action may affect a  
10 protected species; and

11           **WHEREAS** the applicant proposes fertilization and incubation on Prince Edward  
12 Island, Canada, and shipment of the eyed-eggs to Panama for grow-out and processing, all  
13 processes that would occur outside the jurisdiction of the United States; and

14           **WHEREAS** the applicant has already bred and produced transgenic salmon and  
15 shipped them for commercial market tests; and

16           **WHEREAS** the applicant proposes shipment of processed fish to the United States for  
17 retail sale; and

18           **WHEREAS** the proposed activities pose a threat to wild salmon in the Pacific  
19 Northwest and Alaska; and

20           **WHEREAS** genetically engineered fish has not been the subject of thorough scientific  
21 research and testing to ensure that its consumption by humans is safe in the long term; and

22           **WHEREAS** many consumers of wild salmon purchase the product for its widely  
23 recognized health benefits, and lack of testing could weaken consumer confidence in all  
24 salmon products; and

25           **WHEREAS** the state's wild seafood industry, which is extremely important to the  
26 state and local economies, could be severely affected by the sale of genetically engineered  
27 salmon;

28           **BE IT RESOLVED** that the Alaska State Legislature urges the United States Food  
29 and Drug Administration to deny any application to sell genetically engineered salmon in the  
30 United States; and be it

31           **FURTHER RESOLVED** that the Alaska State Legislature urges compliance with the

1 provision of P.L. 110-85 (Food and Drug Administration Amendments Act of 2007) that  
2 requires the Commissioner of Food and Drugs to "consult with the Assistant Administrator of  
3 the National Marine Fisheries Service of the National Oceanic and Atmospheric  
4 Administration to produce a report on any environmental risks associated with genetically  
5 engineered seafood products, including the impact on wild fish stocks"; and be it

6 **FURTHER RESOLVED** that, if the application is approved by the United States  
7 Food and Drug Administration despite strong environmental and human health concerns,  
8 product labeling requirements should include the words "Genetically Modified" prominently  
9 displayed on the front of the package.

10 **COPIES** of this resolution shall be sent to the Honorable Barack Obama, President of  
11 the United States; the Honorable Joseph R. Biden, Jr., Vice-President of the United States and  
12 President of the U.S. Senate; the Honorable John Boehner, Speaker of the U.S. House of  
13 Representatives; the Honorable Timothy F. Geithner, United States Secretary of the Treasury;  
14 the Honorable Tom Vilsack, United States Secretary of Agriculture; Margaret A. Hamburg,  
15 M.D., Commissioner of Food and Drugs, United States Food and Drug Administration; and  
16 the Honorable Lisa Murkowski and the Honorable Mark Begich, U.S. Senators, and the  
17 Honorable Don Young, U.S. Representative, members of the Alaska delegation in Congress.

passed  
H.C.

27-LS0376\M.1  
Kane  
3/9/11

AMENDMENT

OFFERED IN THE HOUSE  
TO: CSHJR 8(FSH)

BY REPRESENTATIVE KAWASAKI

- 1 Page 2, following line 13:
- 2       Insert a new clause to read:
- 3       "**WHEREAS** the applicant has already bred and produced transgenic salmon and
- 4 shipped them for commercial market tests; and"

*This is actually language requested  
by Rep Heron according to Kawa. Staff*

# FISCAL NOTE

STATE OF ALASKA  
2011 LEGISLATIVE SESSION

Fiscal Note Number \_\_\_\_\_  
Bill Version HJR 8  
( ) Publish Date \_\_\_\_\_

HJR8-LEG-COU-2-9-11  
Title "Oppose Genetically Engineered Salmon." Dept. Affected Legislature  
Appropriation Legislative Council  
Sponsor Representative Scott Kawasaki Allocation Council and Subcommittees  
Requester House Special Committee on Fisheries, Resources OMB Component Number 783

**Expenditures/Revenues** (Thousands of Dollars)

Note: Amounts do not include inflation unless otherwise noted below.

	Appropriation Required	Information						
		FY 2012	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
<b>OPERATING EXPENDITURES</b>								
Personal Services								
Travel								
Contractual								
Supplies								
Equipment								
Grants & Claims								
Miscellaneous								
<b>TOTAL OPERATING</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

<b>CAPITAL EXPENDITURES</b>								
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<b>CHANGE IN REVENUES</b>								
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**FUND SOURCE** (Thousands of Dollars)

1002 Federal Receipts								
1003 GF Match								
1004 GF								
1005 GF/Program Receipts								
1037 GF/Mental Health								
Other Interagency Receipts								
<b>TOTAL</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>

Estimate of any current year (FY2011) cost \_\_\_\_\_

**POSITIONS**

Full-time								
Part-time								
Temporary								

**Why this fiscal note differs from previous version**

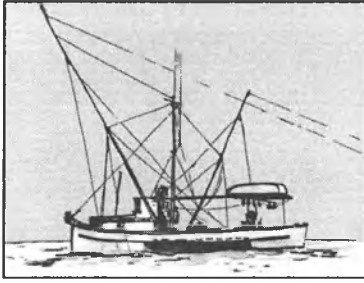
This Legislation has zero fiscal impact on the Legislative Affairs Agency.

Prepared by Shane Miller, Finance Manager  
Division Administrative Services Division  
Approved by Pamela Varni, Executive Director  
Legislative Affairs Agency

Phone 465-6626  
Date/Time 2/9/11 1:15 PM  
Date 2/9/2011

**Analysis**

This fiscal note has zero impact on the Legislative Affairs Agency.



## **Alaska Trollers Association**

130 Seward #205  
Juneau, AK 99801  
(907)586-9400 phone  
(907) 586-4473 fax  
ata@gci.net

March 10, 2011

Representative Eric Feige, Co-Chairman  
Representative Paul Seaton, Co-Chair  
Representative Peggy Wilson, Vice-Chairman  
House Resources  
Juneau, AK 99811

RE: HJR 8 Genetically Modified Salmon and Labeling Requirements

Dear Representatives Feige, Seaton, Wilson, and Committee Members:

The Alaska Trollers Association (ATA) strongly supports HJR 8, which seeks among other things to persuade the Food and Drug Administration (FDA) to deny the approval and marketing of genetically engineered salmon in the United States.

ATA is pleased to read the strong policy statements embodied in HJR 8. We believe the resolution appropriately reflects not only the concerns and wishes of most Alaskan's, but also those of a vast majority of American citizen's.

It is time the public be allowed the opportunity to openly consider and debate the issues surrounding the most intimate of topics – our nation's food supply. The scientific community is not yet done analyzing the risks of genetically engineered foods, but it is well known that there are professional disagreements regarding its safety. Poll after poll has reveals the public's distrust of genetically engineered foods, yet the FDA has been allowed to conduct its analysis under a cloak of secrecy, in order to protect the patent rights of the companies involved. How can that be?

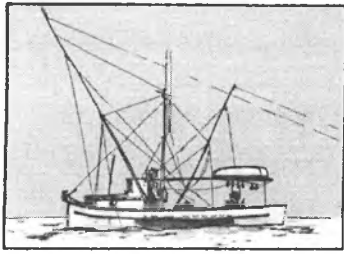
Here in Alaska our concerns extend beyond the food on our plates to the fish with tails that transit our waters. Farmed fish from British Columbia and Washington State escape on a regular basis and are already harvested in our fisheries. Our members are concerned about the impact of those fish on our wild stocks - everything from disease transmission to disruption on the spawning grounds. What new impacts will genetically engineered fish bring? At this point, we just don't know, but the risk seems far too high for a fish dependent state like our own.

I have attached for the record ATA's comments to the FDA on genetically engineered salmon and labeling requirements. This issue is of significant concern to our association. Should you have additional questions, or if I can otherwise be of help, please don't hesitate to contact me.

Thank you for considering ATA's point of view on this matter.

Best regards,

Dale Kelley, Executive Director



## Alaska Trollers Association

130 Seward #205  
Juneau, AK 99801  
(907) 586-9400 phone  
(907) 586-4473 fax

November 21, 2010

Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852

RE: **Docket No. FDA-2010-N-0385** Labeling of AquAdvantage genetically engineered salmon

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 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 of seafood. For the record, ATA requests FDA reconsider its basis and rationale for approving GE animals for consumption and conduct the appropriate studies to prove the claim that this product, and how it will be raised, will ultimately be safe for human health and the environment.

FDA does not appear to have conducted the necessary science, and has not allowed the public access to adequate information, time, and forums to have meaningful input into the issue, yet all signals suggests that the product will be approved. Therefore we are also compelled to say that our members strongly support mandatory labeling to distinguish GE salmon if it ever should reach the marketplace.

Fishermen are particularly alarmed by the cavalier approach the nation has taken on the issue of genetically engineered foodstuffs. One quickly called hearing on the East Coast, during fishing season, where participation was limited – with small amounts of information released just days before the hearing -- does not amount to an acceptable public process.

The failure of our country to vision a transparent approval process and strict regulatory program for genetically engineered animals/foods is shameful. FDA's own published, non-binding, *Guidance for Industry Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* includes this qualifier:

*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.*

Does this mean that FDA has no intention of regulating the corporations who will hold valuable patents to GE animals that likely have a ready market worth untold amounts of money? As small businessmen who operate under significant international, national, and state regulatory burdens in order to produce healthy food for the nation and world, it is our hope that FDA, and our nation's policymakers, will further clarify their intent in this regard.

In reading through FDA's documents it was interesting to see the emphasis on the need to prevent mislabeling of a product. We completely agree and believe that identifying GE salmon with a label would simply be a matter of truth in advertising.

How could an Atlantic salmon – essentially a sea-run trout – that is gene spliced with a true Pacific salmon and a non-salmonid -- be considered anything BUT genetically engineered? Once you allow it to be modified, it becomes different and the level of risk changes, period. Your own scientists pointed that out during the 1990s debate on FDA's policy on GE plants. It stands to reason that GE salmon should bear a label revealing the very basic fact that it is engineered, simply so the consumer can make an informed choice.

While FDA and industry backgrounders try to calm the public by explaining that these fish will be just like any other Atlantic salmon, that's simply not true. Wild Atlantic salmon are not genetically modified. Farmed Atlantic salmon are selectively bred, but not yet modified. Engineered salmon certainly aren't like any other salmon, yet the public could easily become confused about which fish are modified and which are not, and opt out of salmon altogether. Those of us in the seafood industry know far too well that there exists a great deal of confusion when it comes to the seafood market. Our industry could bear a direct cost if this happens.

Most importantly, how are you so certain that the salmon, chemically, is the same as wild Atlantic salmon, at the minutest levels? Where are the rigorous, published studies to back that up? What about over generations of breeding and under different conditions and production rules? Will biomarkers have any affect now, or in the future, on the composition of the fish (not to mention the health risk)?

It is already well documented that when it comes to safe food production and GE, the jury is out amongst the scientific community. FDA's own veterinary advisory committee suggested that the science presented was incomplete, particularly if these fish will be raised outside of the two test farms and under full scale production scenarios.

For many years, a variety of scientists – from federal agency staff, to academics, and farm and fisheries professionals – have questioned whether or not genetically modified animals and plants are safe. At minimum, questions regarding toxicity and allergens do not appear to have been thoroughly vetted and resolved. FDA's own regulations mandate that new substances be subjected to peer reviewed studies prior to determining them 'safe' (21 CFR Sec. 170.30 (a-b)). How can FDA move ahead without adequate science?

Add to that the complication of farmed GE salmon, which may be fed some combination of GE foods and be subjected to a variety of pharmaceuticals and pesticides during the culture phase. Many of these farms, including the two GE test farms, aren't even in the US and all countries and states are likely to be governed by a variety of conflicting laws. How will modified animals respond to various foods, chemicals, and conditions? How can FDA be sure it and other agencies can foresee, monitor, and control any changes in toxicity, or the development of new metabolites that may result from genetic engineering of animals across generations? Will inspections of foreign and domestically farmed seafood have to be increased to monitor such issues? There is a raft of potential dangers to the environment should these fish escape, and even if they don't, since no one has analyzed or discussed with the public the impact of large, production scale closed containment. Where will the funding for this, and more, come from?

Who will be doing the necessary research, monitoring, and enforcement – FDA? And, where are the appropriate human and environmental and economic risk analyses? Previous statements from FDA give us little hope and make us wonder what other agency, if any, will take on this role? In 1998 FDA stated that it had, *...not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants*. Your policies haven't changed much since that time. FDA has also claimed that it has no public process obligation under NEPA for this issue, nor does it have labeling authority, since it is not regulating GE salmon. So, who is in charge of exploring this issue in a more meaningful, scientific, and bioethical way? Why should the animal be approved before that's done?

It appears that FDA and the nation are more than willing to place the burden of proving or disproving food safety on either a multi-national industry that stands to gain financially from GE salmon; or the small seafood industry that stands to lose by being overwhelmed by increased farmed production or consumer fears about salmon; or, perhaps even the consumer themselves.

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.

While FDA might not currently believe that GE salmon is markedly different, we have to wonder what other countries might think, and why, since so many of them have strongly disagreed with the US on this and other policy questions swirling around GE foods. While current trade agreements and the tendency to lean towards agency discretion may be forcing the hand of the courts and nations, there is obviously no consensus amongst scientists on the matter of GE food and policy. In the court of public appeal, we suggest most people do believe GE salmon is different, and most aren't certain it's safe, therefore, it should be labeled.

Furthermore, there are many reasons beyond food safety that people may choose to avoid GE foods. Social, cultural, religious, and other factors all have a role in food selection. Respect for those choices can also be accomplished through labeling.

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 exists to underpin decisions with regard to what, if any, genetically engineered foods belong in the food chain and environment.

Additionally, a clearly articulated set of publicly negotiated policies, along with relevant statutory, regulatory, research, monitoring, enforcement, and remediation programs do not even appear to be in development.

Until such time as the public is adequately brought into the debate; appropriate, peer reviewed, science shows genetically engineered salmon to be safe for human health and the environment; 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 a vast majority of Americans, then labeling of any GE seafood product should be mandatory.

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

Best regards,

Dale Kelley  
Executive Director



Food & Water Watch • 1616 P St. NW, Suite 300 • Washington, DC 20036  
www.foodandwaterwatch.org • T: +1.202.683.2500 • F: +1.202.683.2501

Members of the House Committee on Resources  
120 E 4<sup>th</sup> Street  
Juneau, AK 99801

February 26, 2011

**RE: Support for HJR 8 pertaining to Genetically Engineered Salmon and Labeling**

Dear Co-Chairs Feige and Seaton, Vice-Chair Wilson, and Members of the House Committee on Resources,

Food & Water Watch (FWW) is a national consumer advocacy organization that advocates for safe, wholesome food produced in a humane and sustainable manner, and public rather than private control of water resources, including oceans, rivers and groundwater. We work with various community outreach groups around the world to create an economically and environmentally viable future. The FWW Fish Program works specifically to promote safe and sustainable seafood for consumers, while helping to protect the environment and support the long-term well being of coastal and fishing communities.

We support HJR 8, sponsored by Representative Kawasaki, which would urge the United States Food and Drug Administration (FDA) to deny *any* application to sell genetically engineered (GE) salmon in the United States. In the case that an application is approved, the resolution calls on the agency to have strict labeling requirements, including a prominent "Genetically Modified" label on the front of product packaging.

The adoption of HJR 8 is of particular urgency due to an application before the FDA to approve the sale of AquaBounty's GE AquaAdvantage salmon for human consumption in the United States. If the application is approved, a dangerous precedent will be set that could open the door to GE fish farming in the United States, threatening fisheries nationwide, including those in Alaska.

One of the most serious consumer concerns regarding AquaBounty's GE salmon is that FDA has no adequate means to assess the fish as a GE animal intended as a human food product. FDA is currently proceeding to approve the GE fish through its process for reviewing a *new animal drug*.<sup>1</sup> This is wholly inappropriate. This process is meant for review of new drugs used on animals, not for production of new animals, especially those that will be eaten by humans as a source of nourishment. While the current law makes this an animal drug issue, there should also be a formal evaluation with public meetings by FDA's Center for Food Safety and Applied Nutrition (CFSAN) to review this product's potential health effects on humans.

Additionally, as disclosed to us through a Freedom of Information Act request, the FDA did not properly consult with National Oceanic and Atmospheric Administration or with the National Marine Fisheries Service on the environmental risks associated with



Food & Water Watch • 1616 P St. NW, Suite 300 • Washington, DC 20036  
www.foodandwaterwatch.org • T: +1.202.683.2500 • F: +1.202.683.2501

AquaBounty's application. Therefore, we support HJR 8's call for the agency to follow proper procedures when reviewing applications for GE salmon.

We thank you for the opportunity to comment on HJR 8 and look forward to working with the State legislature to ensure the health of Alaskan fisheries and safe seafood for consumers.

Sincerely,

A handwritten signature in cursive script, appearing to read "Christina Lizzi".

Christina Lizzi  
Policy Analyst, Fish Program  
clizzi@fwwatch.org

A handwritten signature in cursive script, appearing to read "Marianne Cufone".

Marianne Cufone, Esq.  
Director, Fish Program  
mcufone@fwwatch.org

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<sup>1</sup> Food and Drug Administration. "Consumer Q&A: Genetic Engineering." Page updated October 28, 2009. Available at <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113672.htm>

## Southeast Alaska Fishermen's Alliance

9369 North Douglas Highway

Juneau, AK 99801

Phone: 907-586-6652

Fax: 907-523-1168

Email: [seafa@gci.net](mailto:seafa@gci.net)

Website: <http://www.seafa.org>



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February 10, 2011

Representative Steve Thompson, Chairman  
House Special Committee on Fisheries  
Alaska State Legislature  
State Capitol, 120 Fourth Street  
Juneau, AK 99801-1182

Dear Chairman Thompson and Committee Members,

RE: Support HJR 8

Southeast Alaska Fishermen's Alliance (SEAFa) supports HJR 8, a resolution urging FDA to deny an application to sell genetically engineered salmon in the US and requiring product labeling if the product is approved.

SEAFa has been in opposition to genetically engineered fish since the beginning of the permit process in approximately 2000. As you know the process to consider the application has been flawed as the FDA only looked at the aspect if the fish were safe for human consumption but failed to consult adequately with NMFS. Genetically engineered fish must be considered in light of the effect to the environment as well much as you would evaluate the effect of an invasive species.

Salmon is an important resource in the State of Alaska for commercial, personal use, subsistence, and sport fishermen and approval of genetically modified salmon into the environment and market place can be damaging. SEAFa members fully support the House Joint Resolution 8 and urges a speedy approval by the Alaska State Legislature.

Sincerely,

A handwritten signature in cursive script that reads "Kathy Hansen". A horizontal line extends from the end of the signature to the right.

Kathy Hansen  
Executive Director



# THE CENTER FOR FOOD SAFETY

February 10, 2011

## Testimony to Alaska House of Representatives on House Joint Resolution 8 (HJR8)

Jaydee Hanson  
Senior Policy Analyst

Good afternoon. My name is Jaydee Hanson and I am the Senior Policy Analyst for the Center for Food Safety, an organization based in Washington, D.C. that works to protect human health and the environment by curbing the proliferation of harmful food production technologies. Thank you for allowing me the opportunity to provide testimony today on this important and precedent setting decision.

### Overview of Flawed Process

As you are aware, on August 25, 2010, U.S. Food and Drug Administration (FDA) officials announced their process for making a decision on an application relating to the first genetically engineered (GE) animal intended for human consumption, the AquaAdvantage Salmon (AA Salmon) produced by Aqua Bounty Technologies. FDA held two back to back public meetings in September less than three weeks after announcing they would probably approve the application to discuss the AA Salmon. The first FDA meeting was a convening of the Veterinary Medicine Advisory Committee (VMAC) on September 19-20 to consider issues regarding the safety and effectiveness of the transfer of genes from two fish species into an Atlantic salmon as a "new animal drug" (NAD) that is the subject of the GE fish new animal drug application (NADA). Unlike other animal drugs, these new "drugs" reside in every cell of the animal while it is eaten. The second meeting was a public hearing on September 21 to present the public with FDA's existing legal framework for food labeling, and to receive public input on whether food from GE Salmon should be labeled."

The decision-making process proposed by FDA failed to provide the public with sufficient time or available data that would have allowed for full and meaningful participation prior to the VMAC and labeling meetings. The exceedingly short timelines for public comment were exacerbated by the lack of transparency. AquaBounty filed a New Animal Drug (NAD) application for AquaAdvantage salmon with FDA in 2001, yet the agency chose not to disclose any data relating to its decision until just 10 working days before the public meeting. Despite the short time line, some 79,000 people wrote the FDA asking them not to approve the salmon.

FDA's announcement regarding its process is the first of its kind, for any GE food animal. Similarly the decision whether to label any such GE animal if approved will be a first. FDA and the VMAC recognize that whether or not to approve the first GE animal for use as food is a critical and precedent-setting decision. As such, the public must demand that FDA must require additional environmental and food safety data as well as gather as much information as possible about its next steps from all interested parties, especially the public.

The data the FDA provided to the public on food safety was altogether deficient given that the FDA had 10 years to review the product. The study on changes in the morphology of the new GE salmon involved only 12 fish. The limited study on possible allergic reactions involved only 6 fertile GE fish and 6 infertile GE fish. These small sample sizes are completely inadequate for a full review of the health and safety of these fish when they are raised in a commercial operation. The absence of data on disease resistance and inadequate nutritional composition data leave the safety of these animals largely unknown. Additionally, the Environmental Assessment (EA), a less comprehensive review, compiled by AquaBounty for the FDA is inherently flawed and does not take into account the full and broad range of impacts the approval of the GE salmon will have on the environment, such as what would happen if these fish escaped.

The VMAC raised many concerns during the public meeting regarding small sample sizes, incomplete data, questionable culling practices, the numerous physical abnormalities that may occur after fish reach market size and poor scientific assessments. Regarding the potential allergenicity, one Committee member noted "I don't have adequate evidence to determine if it's safe." This was followed by his colleague who said "the short answer as a professor is I don't know." In light of the numerous unknowns raised throughout the VMAC meeting, FDA officials announced that any approval will require post-market review and data requirements. Yet the VMAC expressed its concerns with FDA's plan to require post-market reviews as sufficient for gaps in current safety data. Post-market review and labeling are not an adequate substitution for proper regulation and safety assessments. Additionally, Dr. Gary Thorgaard, the only fisheries biologist on the committee, called on FDA to conduct a full Environmental Impact Statement, a sentiment reiterated by other members of the Committee.

#### Human Health Risks of Genetically Engineered Salmon

We are very concerned about the potential toxicity, allergenicity, and diseases posed by the commercialization of transgenic fish. While data on human health impacts of GE fish are sparse, especially since FDA has yet to share all the data it has reviewed, there is cause for concern. With regard to food allergies, FDA stated: "the technical flaws in this [AquaBounty's allergy] study so limit its interpretation that we cannot rely on its results."<sup>10</sup> Additionally, AquaBounty salmon went largely untested for increased disease susceptibility, despite focal inflammations and elevated white blood cell counts suggestive of infection.<sup>11</sup>

Disease is a massive problem in crowded farmed salmon operations, and increased susceptibility would mean unhealthy fish treated liberally with antibiotics, resistant bacteria, and antibiotic residues in fish [6]. Some research suggests that transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities.<sup>12</sup> Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish; already farmed salmon are given more antibiotics than any other livestock by weight. Aqua Bounty Technologies provided no data on their antibiotic use with these fish. The absence of data on disease resistance and inadequate nutritional composition data leaves the safety of these animals largely unknown. By eating genetically engineered farmed fish treated with more antibiotics humans will be ingesting antibiotics that may be harmful.<sup>13</sup> Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.<sup>14</sup> Finally, if these genetically engineered fish increase the use of antibiotics in aquaculture, they would also exacerbate the significant problem of antibiotic resistant bacteria.

The potential human health concerns connected with the use of antibiotics in aquaculture, including the unique role transgenic fish may play in exacerbating such use, must be fully assessed by FDA.

A 2009 study commissioned by the European Union revealed that fish engineered to grow faster have a resultant high tolerance to environmental toxins.<sup>100</sup> The study's authors expressed grave concerns that both toxins and growth hormones engineered into the fish had a high potential to end up in consumers' bodies, calling for further tests to determine safety.

#### Ecological Risks of Genetically Engineered Salmon

Genetically engineered fish pose serious risks to wild populations of fish and our marine environment. 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.

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 fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations. It could be inferred that the fish could also breed with Atlantic salmon being farmed in the Pacific Basin.

In addition to the threat of these GE salmon displacing native salmon populations, such farming of these GE salmon could encourage the propagation of deadly fish diseases, the concentration of harmful wastes and industrial drugs and chemicals escaping into open waters, and the over-fishing of vast quantities of non-commercial fish to feed carnivorous farmed fish, such as salmon; it generally takes three pounds of wild fish to grow one pound of farmed salmon<sup>101</sup>. Since these salmon have been engineered for fast growth, it stands to reason that their feed requirements will be even higher.

#### Economic Risks to Fishermen

A potential escape of GE salmon will both directly and indirectly affect the livelihoods of the tens of thousands of salmon fishers and fishing communities in the U.S. and will have ripple effects throughout markets. In the Northeastern United States, wild Atlantic salmon is on the endangered species list and commercial fishing is prohibited. Therefore, the escape of GE salmon would pose serious risks to the restoration of wild populations of fish and any approval of GE fish will have direct and indirect effects on wild stocks as well as the fisheries themselves.

As you are well aware, in the Northwest the salmon industry is a paramount sector of the economy. The seafood industry in Alaska is the largest private sector employer creating 56,600 direct and 22,000 indirect jobs annually, more jobs than oil, gas and mining combined.<sup>102</sup> In 2007, the overall value of the Alaska seafood industry alone was over \$1.5 billion paid to fishermen and \$3.6 billion at the wholesale level. Total 2007 value at the dock for the non-Indian commercial salmon fisheries within Washington, Oregon and California was \$11.6 million.<sup>103</sup> Research published by Andrew Dyke and U. Rashid Sumaila notes that wild fisheries can also have significant economic impacts in other sectors, such as agriculture, forestry, manufacturing and financial services, observing that “changes in the fishing industry could affect livelihoods in and the viability of many economic sectors.” The researchers found that regionally, every \$1 of fisheries-sector output supports more than \$3 of output throughout the North American economy.<sup>104</sup> Many of Alaska's salmon processors are based in Seattle and elsewhere in Washington, Oregon or California, meaning that revenue and value is generated and spread across many states. At the same time, the increased demands by salmon farms for forage fish and fishmeal additionally affect the health of wild stocks and place an added stress on wild fisheries.

Additionally, the risk of market confusion or rejection resulting from GE salmon approval would have additional effects on the U.S. salmon and seafood industry. Consumer confusion about what types of salmon or seafood are genetically engineered may deter shoppers from purchasing such products. This confusion would be made worse by the absence of mandatory GE labeling requirements. Approving GE salmon is a sharp contradiction to the agreements the United States has signed at the North Atlantic Salmon Conservation Organization, where transgenic salmonids are considered a serious threat to wild salmon. Furthermore, GE salmon could result in trade disparities and the potential loss of foreign markets that may have differing opinions on labeling or safety assessments - for example in the EU, all GE animals must be labeled. Virtually, every European and Canadian fish farming association has announced that their members will not grow these GE salmon. If the US approves these GE salmon for growth in the US without labeling. Consumers will fear that every US salmon is genetically engineered. Concerns over potential food contamination or environmental impacts may also affect consumer choice in the U.S. which could lead to consumers' forgoing buying wild and farmed salmon altogether. A recent poll from Lake Research Partners found that 91 percent of Americans felt FDA should not introduce GE fish and meat into the marketplace.<sup>xiii</sup> A 2008 Consumer Reports poll found that 95 percent of respondents said they thought food from genetically engineered animals should be labeled.<sup>xiv</sup>

#### Labeling

To ensure meaningful public comment and confidence in the Agency's processes, the agency should have separately convened the labeling hearing, only if and after any initial decision on approval. To have a discussion about labeling presupposes that FDA has already made up its mind on the approval without proper input, yet even labeling is not an adequate substitution for proper regulation and safety assessments prior to approval. The deadline for comments on the labeling of the fish was Nov. 22, 2010 and this time some 400,000 people asked the FDA to require labeling. The public clearly wants these fish labeled.

Should FDA decide to approve the transgenic salmon despite overwhelming consumer opposition and potential threats to the environment, human health, and native salmon populations, mandatory labeling must be unconditional.

#### Conclusion

I would like to finish by expressing the Center for Food Safety's support for House Joint Resolution 8 (HJR8), which we feel takes the necessary strides toward protecting human health, the environment and Alaska's thriving fishing economy from the risks association with genetically engineered salmon.

Respectfully Submitted,

*Jaydee Hanson*

Senior Policy Analyst  
Center for Food Safety  
(202)547-9359 | [jhanson@icta.org](mailto:jhanson@icta.org)

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<sup>i</sup> Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52605. (Public VMAC Meeting)

<sup>ii</sup> Federal Register / Vol. 75, No. 165 / Thursday, August 26, 2010 / Notices/ pp. 52602. (Public Meeting on Labeling)

<sup>iii</sup> *AquAdvantage Salmon Briefing Packet for Veterinary Medicine Advisory Committee*, Center for Veterinary Medicine, Food and Drug Administration, Sept. 20, 2010, page 104

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<sup>iv</sup> Briefing Packet, p. 41: "Comprehensive disease challenge tests have not been conducted on these fish." "An increased presence of focal inflammation in various tissue types in AquAdvantage salmon has the **strongest correlation** with the presence of the AquAdvantage construct [inserted gene] among the findings in this study. That these fish *may* have been immunocompromised as a result of seasonality *or other factors* confounds the interpretation of these findings." In other words, FDA waves off the strongest finding of difference between GE and control salmon with airy speculation, and fails to demand further study to clarify these "confounded" findings. In particular, FDA does not demand "comprehensive disease challenge" tests to determine, based on SCIENCE and DATA, whether these GE salmon are more susceptible to disease. This is inexcusable, particularly given peer-reviewed literature showing that salmon engineered with a growth hormone gene are more susceptible to a significant salmon pathogen (*Vibrio anguillarum*) that causes the devastating salmon disease vibriosis than non-GE salmon. See Jhingian et al (2003). "Disease resistance, stress response and effects of triploidy in growth hormone transgenic coho salmon," *Journal of Fish Biology* 63: 806-823. For elevated white blood cell (lymphocyte) counts, see p. 35, and Figure 5, p. 147).

<sup>v</sup> William Muir et al., Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis, 96 PNAS 13853-13856, at 13853 (Nov. 23, 1999).

<sup>vi</sup> Rebecca Goldberg and Tracy Triplett, Murky Waters: The Environmental Effects of Aquaculture in the U.S. (p 44). Environmental Defense Fund (1997).

<sup>vii</sup> Id.

<sup>viii</sup> Centre for Aquaculture and Environmental Research. (2009) "Ecological Risk Assessment of Transgenic Salmon." Study commissioned by the European Union, the Swedish Research Council Formas and the University of Gothenburg, Vancouver, Canada.

<sup>ix</sup> Naylor et al, Effect of Aquaculture on World Fish Supplies. *Nature*, Vol.405, June 29, 2000, pg.1017-1024 and Dr. Rebecca Goldberg, Murky Waters: Environmental Effects of Aquaculture in the United States. Environmental Defense Fund, October 1997.

<sup>x</sup> Northern Economics of Anchorage (January 2009) The Seafood Industry in Alaska's Economy. Commissioned by the Marine Conservation Alliance, At-sea Processors Association and the Pacific Seafood Processors Association.

<sup>xi</sup> Pacific Fishery Management Council. 2008. Review of 2007 Ocean Salmon Fisheries. (Document prepared for the Council and its advisory entities.) Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, Oregon 97220-1384

<sup>xii</sup> Dyck, A.J. and U.R. Sumaila. 2010. Economic impact of ocean fish populations in the global fishery. *Journal of Bioeconomics*. DOI: 10.1007/s10818-010-9088-3 [See attached summary by PEW Environment Group]

<sup>xiii</sup> Lake Research Partners, Commissioned by Food and Water Watch. 9/20/10  
<http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf>

<sup>xiv</sup> Consumer Reports. 11/11/08 <http://www.greenerchoices.org/pdf/foodpoll2008.pdf>

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**From:** nis@mosquitonet.com  
**Sent:** Wednesday, February 09, 2011 7:42 PM  
**To:** Rep. Scott Kawasaki  
**Subject:** GE Salmon

**Categories:** GM Fish Bill

Scott, Sen Begich has introduced S 230 to ban genetically engineered salmon so if this becomes federal law it should solve the problem. But i agree that any genetically engineered food if approved, should be conspicuously labeled as such so the public can make the decision to buy or not to buy the product. If the feds won't establish this requirement, the state should for sale of such products in AK.

Thanks for your service.

Herbert R.Melchior  
[nis@mosquitonet.com](mailto:nis@mosquitonet.com)

---

**From:** Kristine Niles [krniles@alaska.edu]  
**Sent:** Wednesday, February 09, 2011 4:08 PM  
**To:** Rep. Scott Kawasaki  
**Subject:** thank you for taking on the farmed salmon propositions

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

**Categories:** GM Fish Bill

Scott,

I thank you for introducing bills that will protect our wild salmon from the potential ravages of farming and hybridizing salmon. It has happened time and again that by farming salmon- inevitably some escape and decimate the local populations of salmon because they are usually much more aggressive hybrid salmon species or they introduce pathogens that in turn decimate the local salmon populations through infection, and yet companies continue to farm salmon.

Dipnetting at Chitna is my family's main source of meat throughout the year. It is a healthy source of omega-3's and they have such low mercury levels that I can eat them throughout my pregnancy. It is vital to my family that the salmon remain strong and healthy!

I also support your efforts to ensure that all genetically modified salmon along with farmed salmon are required to be labeled as such. I, for one, will always purchase wild salmon over farmed or genetically modified.

Thank you for fighting to maintain our wild Alaskan salmon populations,  
Kristine Niles

--

Kristine Niles, B.S.  
Nutrition Research Technician  
Center for Alaska Native Health Research  
University of Alaska Fairbanks  
(907)474-5486

# Congress of the United States

Washington, DC 20510

February 8, 2011

The Honorable Mike Chenault  
Speaker  
Alaska State House of Representatives  
State Capitol Room 208  
Juneau AK, 99801

Dear Speaker Chenault:

Alaska's Congressional delegation supports passage of House Joint Resolution 8 (HJR8) to urge the United States Food and Drug Administration (FDA) to deny any application to sell genetically engineered salmon in the United States. HJR8 also calls on Congress to enact product labeling requirements to include the words "Genetically Modified" prominently displayed on the package if the application is approved by the FDA.

HJR8 would support comparable legislation now pending before the U.S. Senate and House of Representatives and send a clear signal of disapproval of "frankenfish" by the Alaska State Legislature.

The FDA's consideration of a hybrid Atlantic salmon as the first genetically engineered animal for human consumption is a risky precedent and a threat to Alaska's wild salmon. The genes allow the creation to grow about twice as fast as its natural cousin and raise serious questions about the potential impacts of this engineered species on human health, wild salmon and its habitat, and the economy of coastal fishing communities.

The FDA process to review this proposal has taken place mostly behind closed doors, without meaningful consultation with the National Marine Fisheries Service and leaves much to be desired.

Alaska was correct in banning finfish farming in state waters over 20 years ago and instead focusing its attention on the sustainable management of wild salmon stocks. Last summer's harvest of 169 million salmon worth \$534 million to fishermen demonstrates the productivity and economic value of Alaska's wild salmon.

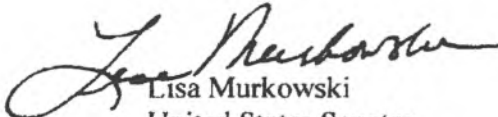
Salmon farms in Canada, Europe and South America have been criticized for crowded conditions, contamination, use of chemicals, proliferation of disease and escapees. Atlantic salmon have been caught in Alaska's waters after escaping from neighboring fish farms in British Columbia with many infested with sea lice. They are rightly considered an invasive species by Alaskans.

The Honorable Mike Chenault  
February 8, 2011  
Page 2

HJR8 will send a clear message to the Food and Drug Administration and President Obama that the Alaska State Legislature does not condone the growth, sale or release of genetically engineered salmon in the United States.

We applaud the leadership of Representatives Scott Kawasaki, Bob Miller, Peggy Wilson, Beth Kerttula, and Steve Thompson in this matter and urge full passage of HJR8 by the Alaska State Legislature.

Sincerely,

  
Lisa Murkowski  
United States Senator

  
Mark Begich  
United States Senator

  
Don Young  
Congressman

Cc: Alaska State House of Representatives



# UNITED FISHERMEN OF ALASKA

February 4, 2011

211 Fourth Street, Suite 110  
Juneau, Alaska 99801-1172  
(907) 586-2820  
(907) 463-2545 Fax  
E-Mail: [ufa@ufa-fish.org](mailto:ufa@ufa-fish.org)  
[www.ufa-fish.org](http://www.ufa-fish.org)

Representative Steve Thompson, Chairman  
House Special Committee on Fisheries  
Alaska State Legislature  
State Capitol, 120 Fourth Street  
Juneau, AK 99801-1182

Dear Chairman Thompson and Committee Members,

United Fishermen of Alaska supports bill HJR 8.

UFA is on record with the U.S Food and Drug Administration (FDA) in opposition to approval of genetically modified salmon for production and consumption in the U.S. However, if approved for production and consumption in this country., we have strongly requested that FDA regulations require that salmon or any other genetically modified seafood products be clearly labeled as such.

Alaska has world-leading sustainable fishery management practices and we have gone to great effort and expense to differentiate our seafood products in the marketplace. We are very concerned that, if genetically modified salmon is allowed to be sold in the U.S. at all or not labeled clearly if allowed, Alaska fishermen and coastal communities will suffer job losses and economic hardship due to consumer confusion about the wholesomeness of salmon in general.

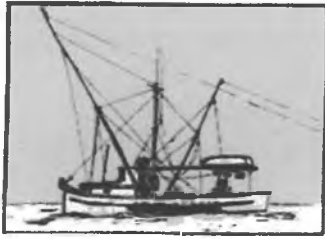
United Fishermen of Alaska represents 38 Alaska Commercial fishing organizations, and hundreds of individual fishermen and related businesses. We support HJR8 and thank you for your attention to this matter.

Sincerely,

Mark Vinsel  
Executive Director

#### MEMBER ORGANIZATIONS

Alaska Bering Sea Crabbers • Alaska Crab Coalition • Alaska Independent Fishermen's Marketing Association  
Alaska Independent Tendermen's Association • Alaska Longline Fishermen's Association • Alaska Scallop Association • Alaska Trollers Association  
Alaska Whitefish Trawlers Association • Aleutian Pribilof Islands Community Development Association • Armstrong Keta • At-Sea Processors Association  
Bristol Bay Reserve • Bristol Bay Regional Seafood Development Association • Cape Barnabas Inc. • Concerned Area "M" Fishermen  
Cook Inlet Aquaculture Association • Cordova District Fishermen United • Crab Group of Independent Harvesters • Douglas Island Pink and Chum  
Fishing Vessel Owners Association • Groundfish Forum • Kenai Peninsula Fishermen's Association • Kodiak Regional Aquaculture Association  
North Pacific Fisheries Association • Northern Southeast Regional Aquaculture Association • Petersburg Vessel Owners Association  
Prince William Sound Aquaculture Corporation • Purse Seine Vessel Owner Association • Seafood Producers Cooperative  
Southeast Alaska Herring Conservation Alliance • Southeast Alaska Fishermen's Alliance • Southeast Alaska Regional Dive Fishery Association  
Tribal Alaska Seafood Southern Southeast Regional Aquaculture Association • United Fishery Boats • United Commercial Drift Association  
United Southeast Alaska Fishermen's • United Fisheries Development Association



## **Alaska Trollers Association**

130 Seward #205  
Juneau, AK 99801  
(907) 586-9400 phone  
(907) 586-4473 fax

February 3, 2011

Representative Steve Thompson, Chairman  
House Fisheries Committee  
Alaska State Legislature  
Juneau, AK 99811

### **RE: HJR 8 Opposing Genetically Engineered Salmon**

Dear Representative Thompson and Committee Members:

The Alaska Trollers Association (ATA) strongly supports HJR 8, which encourages Congress to ban the sale of genetically engineered (GE) salmon in the United States; comply with consultation requirements, as defined in the Food and Drug Administration Amendments Act of 2007 (FDA); and, requires labeling should the nation allow the sale of GE salmon.

ATA represents hook and line commercial salmon fishermen. Our members take quite seriously the job of delivering a wholesome, high quality product to market and are firmly committed to sound science underpinning the decisions made regarding the food people eat. ATA is also concerned about the health of fishing communities, most of which have already suffered the negative impacts of seafood markets glutted with farmed fish.

ATA strongly opposes the genetic engineering of seafood and has called on FDA to deny approval of these engineered animals. To date, FDA has failed to conduct the appropriate studies to prove the claim that this product, and how it will be raised, will ultimately be safe for human health and the environment. Despite that fact, FDA has signaled that the product may be approved. Therefore we are also compelled to say that our members strongly support mandatory labeling to distinguish GE salmon if it ever should reach the marketplace. We are proud that Alaska has already taken action to support labeling for such products and we support strengthening and enforcing the existing law.

Fishermen are particularly alarmed by the cavalier approach the nation has taken on the issue of genetically engineered foodstuffs. FDA is treating the approval of genetically engineered salmon as if it were a drug. This has shrouded the process in secrecy, in part to protect the patent rights of the developers. The failure of our country to vision a transparent approval process and strict regulatory program for genetically engineered animals/foods is shameful and potentially harmful.

It is already well documented that when it comes to safe food production and GE, the jury is out amongst the scientific community. FDA's own veterinary advisory committee suggested that the science presented was incomplete, particularly if these fish will be raised outside of the two test farms studied and under full scale production scenarios. We can be certain this is the goal.

While FDA and industry backgrounders try to calm the public by explaining that these fish will be just like any other Atlantic salmon, that's simply not true. Once you allow an organism to be modified, it becomes different and the level of risk changes, period. FDA's own scientists pointed that out during the 1990s debate on FDA's policy on GE plants. GE salmon could pose enhanced allergy risks to consumers. This issue lacks robust study and is not well-understood by the consuming public.

Those of us in the seafood industry know far too well that there exists a great deal of confusion when it comes to the seafood market. Engineered salmon certainly aren't like any other salmon, yet the public could easily become confused about which fish are modified and which are not, and opt out of salmon altogether if they fear they are not safe. Our industry could bear a direct cost if this happens.

It appears that FDA and the nation are more than willing to place the burden of proving or disproving food safety on either a multi-national industry that stands to gain financially from GE salmon; or the smaller seafood industry that stands to lose by being overwhelmed by increased farmed production or consumer fears about salmon; or, perhaps even the public themselves if problems arise.

While FDA might not currently believe that GE salmon is markedly different, we have to wonder what other countries think, and why, since so many of them have strongly disagreed with the US on this and other policy questions swirling around GE foods. While current trade agreements and the tendency to lean towards agency discretion may be forcing the hand of the courts and nations, there is obviously no consensus amongst scientists on the matter of GE food and policy. In the court of public appeal, we suggest most people do believe GE salmon is different, and most aren't certain it's safe, therefore, if approved, it should be labeled.

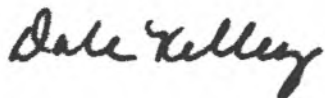
Labeling of GE foods boils down to one of the most fundamental of human needs and rights –access to wholesome foods and information about how they are produced. While the GE salmon may ultimately prove safe, there is no doubt that it is unlike any other salmon available today. It is a processed food 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.

Furthermore, there are many reasons beyond food safety that people may choose to avoid GE foods. Social, cultural, religious, and other factors all have a role in food selection. Respect for those choices can also be accomplished through labeling.

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 exists to underpin decisions with regard to what, if any, genetically engineered foods belong in the food chain and environment. We hope you will agree, and vote to support HJR8.

Thank you for considering ATA's point of view. Please let me know if I can answer questions on ATA's position or otherwise be of assistance as you work through this matter.

Best regards,

A handwritten signature in black ink that reads "Dale Kelley". The signature is written in a cursive, slightly slanted style.

Dale Kelley  
Executive Director

---

**From:** bobsal@gci.net  
**Sent:** Wednesday, February 02, 2011 12:45 PM  
**To:** Rep. Scott Kawasaki  
**Subject:** GMOs and Frankenfish  
**Categories:** GM Fish Bill

Dear Mr. Kawasaki,

This is in response to your note to me about my letter to the editor on GMOs.

Here are two great sites regarding GMOs, both involving Jeffrey Smith, an expert on the subject.

The discussion mainly revolves around the big chemical companies and seed involvement.

The results from seed modification is disastrous and there is no reason to believe messing around with the genetics of fish will have a different outcome.

The greed by both the chemical companies and our federal involvement has the potential for great harm to the world's people, not just American's.

On a different note from GMOs is the USDA Food Guidelines for the American Diet. Government involvement thirty to fifty years ago has lead to the increased health problems of cancer, diabetes, obesity and mental health problems. They still cannot see the forest for the trees, as to the problem, blaming the people, instead of the high carbohydrate and low-fat recommendations. This problem should be investigated by legislators as it would go a long way to solving the high expense of healthcare.

I am thankful for the interest by a legislator. Sincerely, Sally Stuart

<http://www.responsibletechnology.org>

The Institute for Responsible Technology (IRT)

The Institute for Responsible Technology is a world leader in educating policy makers and the public about genetically modified (GM) foods and crops. We investigate and report their risks and impact on health, environment, the economy, and agriculture, as well as the problems associated with current research, regulation, corporate practices, and reporting.

<http://www.seedsofdeception.com/Public/Home/index.cfm>

International bestselling author Jeffrey M. Smith is the leading spokesperson on the health dangers of Genetically Modified Organisms (GMOs). He documents how the world's most powerful Ag biotech companies bluff and mislead critics, and put the health of society at risk. At this site is a video well worth the time to watch.

There are a myriad links to good sites regarding how wrong the USDA Guidelines are. These are just a start to get your interest.

<http://www.hulu.com/watch/196879/fat-head> this movie explains in a humorous but accurate way how wrong the current recommendations are by the USDA.

Many bloggers have a scientific background and are up to date on the documented research, whereas, doctors seem to be indoctrinated in the low carb theory from medical school and not open minded.

<http://www.fathead-movie.com/index.php/2011/02/01/fat-kids-and-thermodynamics/> blog: by Tom

Naughton

<http://www.westonaprice.org/>

Sally Fallon

---

**From:** litsaofalaska@yahoo.com  
**Sent:** Friday, January 21, 2011 5:15 PM  
**To:** Rep Scott Kawasaki  
**Subject:** Please Introduce Bill to Label GMO Foods

**Categories:** GM Fish Bill

evangelia vlasakakis  
1601 hilton avenue  
fairbanks, AK 99701-4017

January 21, 2011

The Honorable Scott Kawasaki  
Alaska House of Representatives  
State Capitol  
Juneau, AK 99801-1182

Dear Representative Kawasaki:

Like most consumers, I want to avoid foods that contain genetically modified organisms, but they are not labeled.

In fact, the federal government does nothing to regulate, or guarantee the safety of, agricultural crops -- and now food animals -- that have been altered with foreign genes. There has never been a longitudinal scientifically rigorous health study on the impacts of eating genetically altered foods.

The little science there is shows that GMOs are more likely to trigger novel allergies, are less nutritious, sprayed with more herbicides, and contain elevated levels of hormones that correlate with common cancers. And, there's no doubt that the most common GMO foods are linked to epidemic levels of obesity and diet-related diseases. These include artery-clogging meat and milk products from animals fed GMO grains, trans fats from GMO vegetable oils, and high fructose (GMO) corn syrup.

Public health depends on labeling GMO foods so consumers can avoid them. Mandatory GMO labels are popular with consumers, consistently earning polling numbers politicians dream of.

I am hoping that you and your colleagues in the state legislature can help. Please stand up for consumers' right to know and truth in labeling by introducing a bill to label GMO foods this year.

I look forward to hearing from you on this important topic.

Sincerely,

evangelia vlasakakis

---

**From:** sltack63@hotmail.com  
**Sent:** Thursday, January 13, 2011 2:49 PM  
**To:** Rep. Scott Kawasaki  
**Subject:** Please Introduce Bill to Label GMO Foods

**Categories:** GM Fish Bill

Stephen Tack  
304 Noyes St.  
Fairbanks, AK 99701-3045

January 13, 2011

The Honorable Scott Kawasaki  
Alaska House of Representatives  
State Capitol  
Juneau, AK 99801-1182

Dear Representative Kawasaki:

Like most consumers, I want to avoid foods that contain genetically modified organisms, but they are not labeled.

In fact, the federal government does nothing to regulate, or guarantee the safety of, agricultural crops -- and now food animals -- that have been altered with foreign genes. There has never been a longitudinal scientifically rigorous health study on the impacts of eating genetically altered foods.

The little science there is shows that GMOs are more likely to trigger novel allergies, are less nutritious, sprayed with more herbicides, and contain elevated levels of hormones that correlate with common cancers. And, there's no doubt that the most common GMO foods are linked to epidemic levels of obesity and diet-related diseases. These include artery-clogging meat and milk products from animals fed GMO grains, trans fats from GMO vegetable oils, and high fructose (GMO) corn syrup.

Public health depends on labeling GMO foods so consumers can avoid them. Mandatory GMO labels are popular with consumers, consistently earning polling numbers politicians dream of.

I am hoping that you and your colleagues in the state legislature can help. Please stand up for consumers' right to know and truth in labeling by introducing a bill to label GMO foods this year.

I look forward to hearing from you on this important topic.

Sincerely,

Stephen Tack



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**Chris Wood**  
*Chief Executive Officer*

January 6, 2011

Representative Scott Kawasaki  
Alaska State Capitol  
Juneau, AK 99801

Dear Representative Kawasaki:

On behalf of Trout Unlimited's 140,000 members nationwide, I would like to thank you for formally opposing AquaBounty's proposal to produce and distribute genetically modified salmon in the U.S. We commend you on your leadership and for ensuring that Alaska's wild fish and fisheries are protected from potentially irreversible threats.

As you know, AquaBounty Technology's proposal to the U.S. Food and Drug Administration is concerning for multiple reasons. Trout Unlimited is particularly concerned about the Food and Drug Administration not properly investigating the potential environmental consequences to wild stocks when genetically modified fish escape into the wild. That is why we support your move to ban the production of genetically engineered fish in Alaska's waters as a way to ensure that Alaska's salmon fisheries are not compromised by this experimental technology. It is encouraging to see Alaska's lawmakers continue to make wild fish a priority and to protect this sustainable and renewable resource from harmful industries and actions.

Trout Unlimited has been working for several years with salmon retailers, restaurants and commercial fishermen to promote the sustainable harvest of wild salmon from places such as Alaska's Bristol Bay (see [www.whywild.org](http://www.whywild.org)). Our focus is on maintaining productive habitat that supports abundant salmon runs, sustainable fisheries, and healthy communities. Our work has helped build public awareness so that salmon consumers around the country can make informed choices that support our nation's sustainable salmon fisheries. Having genetically engineered salmon on grocery store shelves and restaurant menus without proper labeling would create confusion among salmon consumers, making it more difficult for them to make an educated decision. Lack of labeling could also discourage consumers who are opposed to genetically modified fish from buying salmon at all, thus impacting Alaska's salmon fishing industry and communities. Your proposed bill to require labeling of any genetically modified and farmed fish sold in Alaska will enable Alaskan consumers to continue making informed decisions when they purchase salmon and the ability to vote with their dollars for wild Alaska salmon.

**Alaska Fun Center**

1817 College Road  
Fairbanks, AK 99709

[www.alaskafuncenter.com](http://www.alaskafuncenter.com)

**Fax  
Transmission**

- Please call to confirm receipt
- Please respond by return fax
- Call only if transmission is incomplete

Date: 1/5

To: Scott Kawasaki

Fax number: 456-3346

From: Bill Larry

Our phone: (907) 452-3455

Our fax: (907) 451-8134

1 # of pages including cover page:

Notes:

Just wanted to clarify. I would like  
the "Bill" to state that Any genetic  
manipulation, adding chromosomes, genes  
or gene splicing will Not be allowed.  
We don't want to give Fight Game a  
way to manipulate or get around the  
intent of the "Bill".

Lets remember there are the guy who can't even  
get their filters to work at the new Fike. hatchery.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

December 6, 2010

Representative Scott Kawasaki  
Alaska State Legislature, Interior Delegation  
State Capitol, Room 428  
Juneau, AK 99801-1182

Dear Representative Kawasaki:

Thank you and Senators Joe Thomas, Albert Kookesh, and Joe Paskvan and Representatives Woodie Salmon, Mike Kelly, and David Guttenberg for the letter dated October 4 concerning AquAdvantage Salmon. We share your view that this product is of particular public interest. The Food and Drug Administration (FDA or the agency) is committed to a thorough review process that is transparent to the public and comprehensive in its attention to safety for humans, for animals, and for the environment.

FDA regulates genetically engineered (GE) animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act. Legally, the genetic material, or rDNA construct, used to engineer the salmon, meets the definition of a drug because it is intended to affect the structure or function of the animal. This regulatory pathway prohibits introducing food from the AquAdvantage Salmon into the United States without specific FDA approval. As part of the approval process, the producer of the GE salmon with the rDNA construct must meet safety standards not only for the animal, but also for the environment and for any food derived from the animal.

#### **Environmental Safety**

With regard to the environment, FDA's regulations implement the National Environmental Policy Act (NEPA), and require the agency to assess the environmental impact of an approval. For AquAdvantage Salmon, this requirement has meant evaluating the sponsor's plans for preventing the escape or breeding of the genetically engineered salmon by use of multiple, redundant systems of mechanical, biological, and geographical containment. These include the production of single sex, sterile populations of genetically engineered salmon by AquaBounty, and keeping them contained in inland tanks in areas unsuitable for survival outside the facility. With on-going consultation with sister agencies such as the National Oceanic and Atmospheric Administration, FDA will analyze the possibility of escape, survival, and breeding as part of its determination of the likelihood of any significant impact on the environment, including on populations of wild salmon. The specific conditions of use being considered by the agency are described in our briefing materials were made available to the public before the found at our Web site at:

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>.

If this application were to be approved, it would be approved only for the particular conditions of use specified in the application. If the sponsor wishes to make any changes in location, in containment systems, or in the genetic alteration, then a new application and environmental assessment will be required, and will be subject to the same rigorous safety standards.

### **Food Safety**

In addition to adherence to our statutory and regulatory requirements to demonstrate food safety as outlined in our guidance for industry, (<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf>), FDA's review is also consistent with internationally-adopted scientific consensus guidelines for the food safety assessment of foods from GE animals as outlined by the Codex Alimentarius, ([http://www.codexalimentarius.net/download/standards/11023/CXG\\_068e.pdf](http://www.codexalimentarius.net/download/standards/11023/CXG_068e.pdf)). FDA conducts on-site inspections to ensure (among other things) the accuracy of the data submitted pursuant to these studies. In addition to information from studies conducted by the sponsor, the agency reviews relevant studies from peer-reviewed journals. FDA reviewers use this combination of materials to reach an independent judgment on the safety of any changes caused by the genetic construct.

FDA also considers specific food safety issues, such as allergenicity. Because salmon are finfish, which as a group are among the eight most allergenic foods in the United States, the AquAdvantage Salmon would likely cause allergic reactions in anyone who is already allergic to conventionally bred salmon. FDA is looking closely at the biology of the GE salmon to determine if there is cause to believe the AquAdvantage Salmon would pose additional allergy issues for persons who at present eat salmon safely.

### **FDA's Review Process**

The AquAdvantage Salmon review has followed the procedure described in Guidance for Industry 187, "Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs," which was issued in final form in 2009 after public comment.

Key steps to date have included:

- Web publication of background documents on August 25, 2010. These documents contained detailed information on the review process, on the AquAdvantage Salmon, and on the ecology and biology of salmon in general. They presented a summary of all the information and data on which FDA relied for its analyses to date, and an explanation for the preliminary conclusions it would present to an advisory committee for discussion. See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm224089.htm> for these documents.

- FDA held a public Veterinary Medicine Advisory Committee (VMAC) meeting, on September 19-20, 2010. Members of the public were invited to provide written comments for the committee and to make oral presentations.
- FDA had a second meeting, on September 21, 2010, to offer the public a chance to engage in a focused discussion on requirements for food labeling and how they might apply to foods derived from AquaAdvantage Salmon in the event that the agency approves AquaBounty's application. Members of the public were invited to speak at the labeling meeting, and to submit written comments both before and after the meeting. Written comments were accepted for 60 days following the labeling meeting (until November 22).

FDA has not made a decision on the AquaAdvantage Salmon application. The agency's next steps entail a review of the VMAC meeting discussions and any new information brought to the agency's attention, as well as completion of the environmental review and analysis.

If FDA's environmental review results in a proposed finding of no significant impact (FONSI), the agency will publish a *Federal Register* notice to announce the availability of the environmental assessment and the FONSI, and invite public comment on these documents for 30 days.

If FDA decides to prepare an environmental impact statement (EIS), either initially or after reviewing public comment on a proposed FONSI, the public will have an opportunity to participate in the EIS development process. Either of these actions must be completed before the new animal drug application could be approved.

### **Food Labeling**

If FDA approves the AquaAdvantage Salmon, the agency will have to decide on the question of labeling food from the salmon. The September 21 meeting provided a chance for members of the public to learn about the relevant food labeling principles and federal court decisions. These were summarized in a background document available at:

<http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation.ucm222608.htm>.

FDA may require special labeling for "material" differences, such as nutritional content or range of uses (e.g., usability for frying). But as interpreted by the courts to date, the fact that a food comes from a GE source does not trigger mandatory food labeling absent a material change in the food itself. Food labels are geared to informing consumers about the attributes of the product, not about the production method. As a result, it has been held that consumer interest alone is not sufficient for FDA to force a manufacturer to put something on the label.

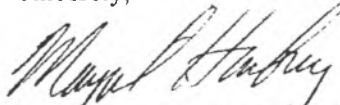
Manufacturers are free, however, to offer information to consumers provided it is truthful and not misleading. Therefore, if food from this salmon is permitted for sale in the United States, sellers will be free to label the foods as GE or non-GE to meet consumer demand, provided it is truthful and not misleading. This is similar to the system used for other foods, in which terms such as "natural" are used on voluntary basis to meet a growing consumer interest in the

Page 4 – Alaska State Legislature

information, whether or not the foods have attributes that could trigger a mandatory labeling requirement.

Thank you again for your interest in this matter. If you have any further questions or concerns, please let us know.

Sincerely,



Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs

Cc: Senator Joe Thomas, Alaska State Legislature, Interior Delegation  
Senator Albert Kookesh, Alaska State Legislature, Interior Delegation  
Senator Joe Paskvan, Alaska State Legislature, Interior Delegation  
Representative Woodie Salmon, Alaska State Legislature, Interior Delegation  
Representative Mike Kelly, Alaska State Legislature, Interior Delegation  
Representative David Guttenberg, Alaska State Legislature, Interior Delegation

COMMITTEE ON ARMED SERVICES  
COMMITTEE ON  
COMMERCE, SCIENCE, AND TRANSPORTATION

MARK BEGICH  
ALASKA

COMMITTEE ON VETERANS AFFAIRS  
COMMITTEE ON THE BUDGET

## United States Senate

WASHINGTON, DC 20510

November 17, 2010

The Editor  
*Time*  
Time & Life Building, Rockefeller Center  
New York, NY 10020-1393

Via email to: [letters@time.com](mailto:letters@time.com)

To the Editor:

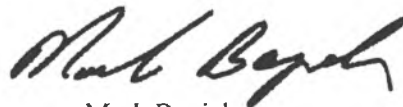
*Time*'s editors must have been watching too many mad scientist movies if they consider genetically-engineered salmon among the 50 best inventions of the year (Nov. 22, page 73).

Despite the supposed advantage of growing twice as fast as wild salmon, serious concerns remain about the environmental and human health impacts of these gene-spliced fish. There are glaring deficiencies in the Food and Drug Administration's closed-door review process and public opposition to eating these creatures is so strong proponents are fearful of labeling their product what it is: genetically-engineered.

Want more salmon? Here's a better idea: protect its natural habitat, maintain water quality and manage wild stocks for sustainability. That's what Alaska has done for over 50 years and now returns of wild salmon are at historically high levels. And wild salmon taste a lot better than anything you'll ever cook up in a laboratory.

Let's leave "Frankenfish" on the operating table and not the dinner table.

Sincerely,



Mark Begich  
United States Senator

1000 E. 7th  
2101 STREET  
ANCHORAGE AK 99501  
907.271.5575

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907.336.6787

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907.225.2700

1000 SOUTH 144  
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WASHINGTON AK 99597  
907.225.1000



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**CORDOVA DISTRICT FISHERMEN UNITED  
RESOLUTION 2010-10-08**

**A RESOLUTION by the CORDOVA DISTRICT FISHERMEN UNITED (CDFU)  
BOARD of DIRECTORS OPPOSING GENETICALLY ENGINEERED ANIMALS  
INTENDED FOR HUMAN CONSUMPTION, SPECIFICALLY THE  
AQUADVANTAGE SALMON PRODUCED BY AQUABOUNTY TECHNOLOGIES  
(DOCKET NO. FDA-2010-N-0001).**

**WHEREAS**, the approval of genetically modified salmon, the first such hybrid to be considered for human consumption, is unprecedented, risky and a threat to the survival of wild species;

**WHEREAS**, the escape of genetically engineered farmed salmon into the wild carries the risk that genetic material from these fish will invade wild gene pools of native Pacific salmon populations;

**WHEREAS**, approving genetically engineered salmon is a sharp contradiction to the agreements the United States has signed with the North Atlantic Salmon Conservation Organization, where transgenic salmonids are considered a serious threat to wild salmon;

**WHEREAS**, the methodology of scientific research conducted by AquaBounty supporting the safety of consuming genetically engineered salmon is inadequate. Further independent research is necessary to demonstrate the long-term effects of human consumption of genetically engineered salmon;

**WHEREAS**, there was insufficient opportunity for the public to weigh in on this important issue;

**WHEREAS**, emphasis should be placed on protecting and maintaining the sustainability of wild salmon stocks as opposed to developing and introducing genetically engineered versions of wild foods into the consumer market;

**WHEREAS**, millions of farmed salmon have escaped from open-water net pens, outcompeting wild populations for resources and straining ecosystems. The 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;

**WHEREAS**, unlabeled GE salmon may force consumers to fear all types of salmon, further hindering an already strained wild fisheries industry.

**NOW THEREFORE BE IT RESOLVED** that Cordova District Fishermen United urges the FDA to delay approval of genetically engineered salmon until it can conduct independent, well-designed, long-term studies on the effects of consuming genetically engineered fish.

**NOW THEREFORE BE IT FURTHER RESOLVED** that Cordova District Fishermen United opposes the introduction of genetically engineered salmon into the marketplace.

**NOW THEREFORE BE IT FURTHER RESOLVED** that in the event of the approval of AquAdvantage GE salmon, Cordova District Fishermen United supports clear and mandatory labeling differentiating genetically engineered salmon from wild or farmed salmon enabling consumers to make informed purchasing decisions.

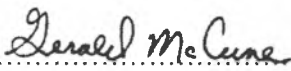
**NOW THEREFORE LET IT BE RESOLVED** that if approved by the FDA, genetically engineered salmon must be farmed in secure, self-contained, land-based facilities.

---

Adopted by the CDFU Board of Directors on October 8, 2010.

Signed: .....  .....

Rochelle van den Broek, Executive Director

Signed: .....  .....

Jerry McCune, President

# ALASKA STATE LEGISLATURE INTERIOR DELEGATION

Senator Joe Thomas  
Chairman  
(907) 465-2327  
Fax: (907) 465-5241  
Sen\_Joe\_Thomas@legis.state.ak.us  
Local office:  
1292 Sadler Way Ste. 308  
Fairbanks, AK 99701



**Delegation Members:**  
Senator Joe Thomas  
Senator Albert Kookesh  
Senator Joe Paskvan  
Senator John Coghil  
Representative Woodie Salmon  
Representative Mike Kelly  
Representative David Guttenberg  
Representative Scott Kawasaki  
Representative Jay Ramras  
Representative Tammie Wilson  
Representative John Harris

October 4, 2010

Margaret A. Hamburg, M.D.  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner,

The Interior Delegation of the Alaska Legislature is writing to convey our overwhelming opposition to the genetically engineered AquaAdvantage salmon proposed for marketing by AquaBounty. There are clear issues concerning the safety of consuming the AquaAdvantage salmon, the ability to contain the engineered fish, and the process by which this product is certified.

We feel there are too many unanswered questions concerning the potential dangers of this product. Our biggest concern is the potential damage to the population of wild salmon which is vital to the Alaska economy. The AquaAdvantage salmon could wreak havoc on local populations if any were to escape and intermingle with wild salmon. Interbreeding could devastate natural populations. AquaBounty assures that no genetically engineered fish could escape, and even if they did they could not breed, but these claims are not backed up by definitive scientific research. They admit that as many as five percent of the engineered salmon could be immune from the sterilization process. If AquaBounty sells modified salmon eggs to other commercial farms, which they currently plan to do, the risk of escape and destruction will only increase.

Additionally, the health hazards surrounding the AquaAdvantage salmon have not been fully investigated. Given that the FDA is currently not planning on labeling genetically engineered fish, this could pose a health hazard for consumers. People who want to avoid genetically modified salmon would have no way of knowing what they are buying, and many may choose to not purchase salmon at all. The testimony from Consumers Union states that studies were done using much smaller fish than those normally consumed, and that too few fish were in the samples. The data provided by AquaBounty was deemed incomplete by the Consumers Union. One study even showed a potential risk of allergic reaction triggered by the salmon. In short, the studies done by AquaBounty on their own product, upon which are you basing your decision, are inadequate.

The wild salmon fishing industry is vital to Alaska as a source of jobs, revenue and food. Genetically engineered salmon pose a grave threat to Alaska's economy, especially if the FDA does not require AquaBounty to label the fish as modified. If these fish are not labeled, a wary public may avoid salmon altogether, harming our economy.

A decision of this importance and with the potential health and economic impacts should only be made after all public concerns are satisfied beyond any doubt. We urge you to withhold your approval of this application. Thank you for your consideration of our concerns.

Sincerely,

Senator Joe Thomas, Chairman

Representative Woodie Salmon

Senator Albert Kookesh

Representative Mike Kelly



Senator Joe Paskvan Representative



David Guttenberg

Representative Scott Kawasaki

cc: The Honorable Barack Obama, President of the United States  
The Honorable Mark Begich, United States Senate  
The Honorable Lisa Murkowski, United States Senate  
The Honorable Don Young, United States House of Representatives  
Bernadette M. Dunham, D.V.M., Ph.D., Director, Center for Veterinary Medicine, Food and Drug Administration  
Aleta Sindelar, Center for Veterinary Medicine (HFV-3), Food and Drug Administration



UNITED STATES DEPARTMENT OF COMMERCE  
National Oceanic and Atmospheric Administration  
NATIONAL MARINE FISHERIES SERVICE  
NORTHEAST REGION  
One Blackburn Drive  
Gloucester, MA 01930-2298

NOV 19 2003

Christine Godfrey  
Chief, Regulatory Branch  
Construction/ Operations Division  
New England District, Corps of Engineers  
696 Virginia Road  
Concord, Massachusetts 01742-2751

Ref: Transmittal of Final Biological Opinion and Response to Comments on Draft  
F/NER/2002/00936

Dear Ms. Godfrey:

Enclosed is a biological opinion (Opinion) issued by the National Marine Fisheries Service (NOAA Fisheries) on the U.S. Army Corps of Engineers (ACOE) proposed continuation and modification of existing permits authorizing the installation and maintenance of net pens to raise finfish off the coast of Maine. The NOAA Fisheries national Section 7 tracking number is F/NER/2002/00936.

The Opinion is submitted in accordance with section 7 of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 *et seq.*). This Opinion concludes that the proposed continuation and modification of existing permits authorizing the installation and maintenance of fish pens in the state of Maine (including incorporation of the special conditions to protect the Gulf of Maine Distinct Population Segment (DPS) of Atlantic salmon) may adversely affect but is not likely to jeopardize the continued existence of the endangered Atlantic salmon within the DPS. Please note that any changes to the proposed action, including any changes to the special conditions proposed to protect wild Atlantic salmon, may change the conclusion in this Opinion and would warrant further Section 7 consultation. No other federally-listed species is likely to be affected by the proposed action.

While the ACOE's proposed permit modifications do contain conditions for the protection of wild Atlantic salmon, the incorporation of these conditions does not eliminate the potential for the permitted activities to result in "take" of Atlantic salmon within the DPS; therefore, an Incidental Take Statement (ITS) has been issued with this Opinion. The anticipated incidental take from the existing aquaculture industry's marine sites that were the subject of this consultation (42 sites) is the detection at weirs or traps of up to 21 escaped fish per year, based on a three year rolling average. If the ITS is exceeded, consultation must be reinitiated. To validate the ITS, the ACOE must implement the non-discretionary Reasonable and Prudent Measures contained therein. Discretionary Conservation Recommendations are also included with this Opinion.

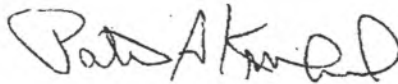


Reinitiation of this consultation is required if: (1) the amount or extent of taking specified in the ITS is exceeded; (2) new information reveals effects of these actions may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) project activities are subsequently modified in a manner that causes an effect to the listed species that was not considered in this Opinion; (4) significant changes to the proposed action are made that may change the conclusion in this Opinion; or (5) a new species is listed or critical habitat designated that may be affected by the identified actions. If any one of the conditions requiring reinitiation of consultation is triggered, the ACOE should contact NOAA Fisheries. Alternatively, NOAA Fisheries may provide written advice to the ACOE relative to the need to reinitiate consultation. Requests for reinitiation must be in writing and must contain sufficient information to record the nature of the change in the action or its effects and the rationale for any modifications.

### Conclusion

NOAA Fisheries greatly appreciate your cooperation during this Section 7 consultation. If you have any questions concerning this Opinion, please contact Jessica Anthony of my staff at (978) 281-9328 ext 6532. We look forward to working with you in the future to ensure compliance with permit conditions and protection of the Atlantic salmon DPS.

Sincerely,



Patricia A. Kurkul  
Regional Administrator

cc:

Jessica Anthony - NOAA Fisheries  
Rick Bennett - USFWS  
Wende Mahaney - USFWS

JANUARY 28, 2011

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## FDA ignored FWS and NOAA biological opinions on GMO salmon?

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Documents released in October indicate the U.S. Fish and Wildlife Service and NOAA's National Marine Fisheries Service issued biological opinions that growing genetically modified salmon in marine net pens would pose a threat to wild Atlantic salmon protected under the Endangered Species Act and should be prohibited. A FOIA request by the Center for Food Safety, a non-profit group which says its mission is "to protect human health and the environment by curbing the use of harmful food production technologies and by promoting organic and other forms of sustainable agriculture," resulted in the release of biological opinions issued by the agencies in 2003 and 2001, as well supplemental documents. The documents indicate that the FDA was aware of the opinions as it conducted recent hearings over AquaBounty's genetically modified AquAdvantage salmon. Read more of the non-profit's statement concerning the documents, and find links to the documents themselves, here.

### Read more of the Dispatch

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# The Washington Post

## FDA rules won't require labeling of genetically modified salmon

Advertisement

By Lyndsey Layton  
Saturday, September 18, 2010; 11:20 PM

As the Food and Drug Administration considers whether to approve genetically modified salmon, one thing seems certain: Shoppers staring at fillets in the seafood department will find it tough to pick out the conventional fish from the one created with genes from another species.

Despite a growing public demand for more information about how food is produced, that won't happen with the salmon because of idiosyncracies embedded in federal regulations.

The FDA says it cannot require a label on the genetically modified food once it determines that the altered fish is not "materially" different from other salmon - something agency scientists have said is true.

Perhaps more surprising, conventional food makers say the FDA has made it difficult for them to boast that their products do not contain genetically modified ingredients.

The labeling question has emerged as the FDA determines whether to approve the fish, an Atlantic salmon known as AquAdvantage that grows twice as fast as its natural counterpart. The decision carries great weight because, while genetically modified agriculture has been permitted for years and engineered crops are widely used in processed foods, this would be the first modified animal allowed for human consumption in the United States. The AquAdvantage salmon has been given a gene from the ocean pout, an eel-like fish, and a growth hormone from a Chinook salmon.

### 'The public wants to know'

Consumer advocates say they worry about labeling for genetically engineered beef, pork and other fish, which are lining up behind the salmon for federal approval.

"The public wants to know and the public has a right to know," said Marion Nestle, a professor in the Nutrition, Food Studies and Public Health Department at New York University. "I think the agency has discretion, but it's under enormous political pressure to approve [the salmon] without labeling."

The debate will be taken up this week, with an advisory committee meeting Sunday and Monday on whether to allow the modified fish, and a separate panel meeting Tuesday on whether the fish should be labeled. The panels will offer recommendations to the FDA commissioner, who will decide both matters.

The biotechnology industry is opposed to mandatory labeling, saying it will only bewilder a public that is not well informed about genetic engineering.

"Extra labeling only confuses the consumer," said David Edwards, director of animal biotechnology at the Biotechnology Industry Organization. "It differentiates products that are not different. As we stick more labels on products that don't really tell us anything more, it makes it harder for consumers to make their choices."

The FDA defends its approach, saying it is simply following the law, which prohibits misleading labels on food. And the fact that a food, in this case salmon, is produced through a different process, is not sufficient to require a label.

The controversy comes at a time when Americans seem to want to know more about their food - where it is

grown, how it is produced and what it contains. Books criticizing industrial agriculture have become bestsellers, farmers markets are expanding and organic food is among the fastest-growing segments of the food industry.

The FDA itself is part of a new effort to improve nutrition information on processed foods.

In the European Union and Japan, it is nearly impossible to find genetically modified foods, largely because laws require labeling, said William K. Hallman, director of the Food Policy Institute at Rutgers University. "No one wants to carry products with such a label," he said. "The food companies figure that consumers won't buy it."

There is nothing to stop salmon producers or food makers in the United States from voluntarily labeling their products as genetically engineered - except a fear of rejection in the marketplace, Hallman said. "I don't know of a single company that does that," he said.

The FDA maintains it can only require labeling if a genetically engineered food is somehow different from the conventional version - if it has an unusual texture, taste, nutritional component or allergen, for example.

Although some consumer advocates maintain there are important differences, the agency's scientists have already said they see no "biologically relevant" variations between the AquAdvantage salmon and traditional salmon.

Consumers could be certain of getting the non-modified version if they bought salmon labeled as "wild," but most salmon consumed in this country is farmed.

Ever since the FDA approved the first genetically altered material for use in food in 1992, when Monsanto developed a synthetic hormone injected into cows to increase milk production, the agency has held that it cannot require food producers to label products as genetically engineered.

In the intervening years, the use of genetically engineered crops has skyrocketed; 93 percent of this year's soybean crop is genetically engineered, according to the U.S. Agriculture Department.

Byproducts of those crops - soy lecithin, for example - are found in thousands of processed foods from chocolate bars to breakfast cereal; none is labeled as containing genetically modified ingredients.

#### **No 'Hormone Free' either**

The labeling matter is further complicated because the FDA has maintained a tough stance for food makers who don't use genetically engineered ingredients and want to promote their products as an alternative. The agency allows manufacturers to label their products as not genetically engineered as long as those labels are accurate and do not imply that the products are therefore more healthful.

The agency warned the dairy industry in 1994 that it could not use "Hormone Free" labeling on milk from cows that are not given engineered hormones, because all milk contains some hormones.

It has sent a flurry of enforcement letters to food makers, including B&G Foods, which was told it could not use the phrase "GMO-free" on its Polaner All Fruit strawberry spread label because GMO refers to genetically modified organisms and strawberries are produce, not organisms.

It told the maker of Spectrum Canola Oil that it could not use a label that included a red circle with a line through it and the words "GMO," saying the symbol suggested that there was something wrong with genetically engineered food.

"This to me raises questions about whose interest the FDA is protecting," said Rep. Dennis J. Kucinich (D-Ohio), who has introduced legislation that would require labeling for genetically engineered food. "They are clearly protecting industry and not the public."

One state with a sizable salmon fishing industry - Alaska - passed a law in 2005 that requires labeling of any genetically engineered fish sold there.

"One side of the argument says let's give consumers sovereignty over their food choices," Hallman said. "The other says we've done the science on this and it's no different, so if we put a label on it, we're implying it's somehow risky and that's like government imposed false advertising."

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# Bloomberg Businessweek

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AQUACULTURE September 23, 2010, 5:00PM EST

## This Genetically Altered Salmon Is No Fish Story

Inching toward FDA approval, AquaBounty's mega-fish stir critics

By Molly Peterson

For 15 years, AquaBounty Technologies has tried to win U.S. approval to sell a genetically modified salmon that can reach full size up to twice as fast as its naturally occurring brethren. Now the effort by the Waltham (Mass.) company may be drawing to a close. U.S. Food and Drug Administration advisers last week held what may be the agency's final hearing on whether AquaBounty's salmon is safe to eat.

The FDA hasn't set the timing of a final decision. Its staff, though, has already agreed that the meat from the altered fish is safe and has no biologically relevant differences from that of the naturally occurring variety. So AquaBounty's fish finally may be headed for American kitchens. FDA approval could make the salmon the first in a series of animals with mix-and-match DNA that have the potential to change the U.S. food chain.

AquaBounty's Atlantic salmon contain a growth gene implanted from another variety of salmon that's activated by DNA from an eel-like creature called the ocean pout. The altered fish can grow to "market weight" of as much as 13 pounds in two or three years, compared with three to four years required for natural salmon, says Chief Executive Officer Ronald L. Stotish.

The company would sell its AquAdvantage brand salmon eggs to fish farms isolated from the ocean that then could see their catch reach supermarkets in about two years. Stotish says the enhanced fish could "increase the availability of a high-quality product that is indistinguishable from the traditional food."

Not everyone is firing up their grills just yet. Groups opposed to genetically modified foods on Sept. 16 held a protest in Washington. "Today it's a fish that we're talking about. But very soon it will be genetically engineered pigs, chicken, and our beloved cows," Ben & Jerry's CEO Jostein Solheim told protesters.

Critics say they're particularly miffed that the FDA is reviewing AquaBounty's altered fish as a veterinary drug rather than creating a new review process for gene-altered foods. FDA spokeswoman Siobhan DeLancey says the genetic material used in the AquaBounty fish meets the statutory definition of a veterinary drug because it alters the structure and function of the animal. She says veterinary drug approval is stringent: "The review of the AquAdvantage salmon, conducted under that process, includes a rigorous analysis of food safety and application of a stringent safety standard: 'reasonable certainty of no harm'."

The FDA's decision, critics say, allows some testing data reviewed by regulators to be kept confidential, as trade secrets. "They're obviously using this veterinary designation to keep the data confidential," says Wenonah Hauter, executive director of Food & Water Watch, an environmental and food-safety group in Washington. "I think they're afraid of the public reaction."

Alaska Senators Mark Begich and Lisa Murkowski, whose state harvested 163 million commercial salmon last year, are also against AquAdvantage. "Let's call this genetically engineered fish for what it is: Frankenfish."

Begich said in a statement. "Approval of genetically modified salmon, the first such hybrid to be considered for human consumption, is unprecedented, risky, and a threat to the survival of wild species."

The modified fish, all female, are sterile, so they can't reproduce with regular salmon, Stotish says. "People who take the time to look" at the regulatory data "will satisfy themselves that the FDA has taken a very cautious, very robust regulatory approach," he says.

Stotish says 97 percent of the total tonnage of salmon now consumed in the U.S. is imported. Almost 427,000 tons, valued at \$1.39 billion, was imported last year from countries led by Chile, Canada, and Norway, according to Agriculture Dept. data. Although he says it's too early to project the sales potential of AquaAdvantage eggs, Stotish says the fast-growing salmon could help domestic fisheries gain a larger share of the market.

The genetically engineered salmon eggs are produced at an AquaBounty facility in Prince Edward Island, Canada, and the fish are grown to market weight at an AquaBounty farm in Panama. If the FDA approves the aquaculture company's salmon, another company would sell the Panama-grown fish in the U.S., Stotish told reporters at a Sept. 20 FDA advisory panel meeting. He declined to identify the company because the product hasn't been approved yet. "AquaBounty does not plan to be in the fish business," he said. "We're a technology company."

***The bottom line:*** Although genetically modified crops have been used for 20 years, AquaBounty's gene-altered salmon is facing fierce scrutiny and protests.

*Peterson is a reporter for Bloomberg News.*

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# Canadian 'Frankenfish' Named One of 2010 Top Inventions

## FDA could soon approve genetically modified salmon, lawsuit threatened

By Joan Delaney  
Epoch Times Staff

*Last Updated:* Dec 30, 2010

*Created:* Dec 30, 2010



Salmon wait to be processed at a fish factory in Chile. A controversial fast-growing genetically engineered salmon developed in Canada could soon be approved for sale in the U.S. (Francisco Negroni/AFP/Getty Images)

Administration (FDA) to sell the salmon in the U.S. If it gets the green light, the salmon, called AquAdvantage, will be the first GE animal ever approved for human consumption.

AquaBounty engineered Atlantic salmon to grow faster by inserting a growth hormone from Chinook salmon and genetic material from the eel-like ocean pout, which can survive in extremely cold waters. The technology was developed by scientists at Newfoundland's Memorial University.

“The problem is that salmon make bad farm animals; it takes 3 lb. (1.36 kilos) of feed to grow 1

A controversial fast-growing genetically engineered salmon developed in Canada has been named one of the 50 best inventions of 2010 in the online version of Time Magazine.

U.S. biotech company AquaBounty Technologies Inc.'s GE salmon—dubbed “Frankenfish” by environmentalists—could soon be approved for sale in the U.S.

AquaBounty plans to produce the GE salmon eggs at its facility on Prince Edward Island, then ship them to Panama to be grown and processed in controlled facilities.

The company is currently seeking approval from the Food and Drug

lb. (.45 kilo) of salmon," Time said. "AquAdvantage Atlantic salmon can grow twice as fast, making them easier to farm."

But opposition to the transgenic salmon—from environmental and consumer groups, food safety advocates, and commercial and recreational fisheries associations, among others—has been growing on both sides of the border.

Just last week, the U.S. chapter of Trout Unlimited said it is prepared to take legal action if the FDA approves AquAdvantage for sale.

Trout Unlimited  
CEO  
Chris Wood

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says the FDA is not equipped to estimate the environmental risk posed by GE animals and doesn't have any fisheries scientists—"and that's who we need looking at this now."

"We are not a litigious organization, but we are just so profoundly concerned that while the FDA may have done a great job in terms of looking at the potential impacts on human health of genetically modified salmon, the FDA is patently unqualified to be able to look at the potential environmental effects of allowing these fish to be brought to market."

### 'Enviropig' Next?

The FDA declared in September that the genetically altered salmon are safe to eat and "are not expected to have a significant impact" on the environment.

AquaBounty has said there will be tight regulations around marketing the salmon. But that's not enough, says Wood.

"Once these get on the market and other countries get a hold of them and other companies get a hold of them, there's no guarantees and there's no assurances or safeguards that they won't be released into the environment, either inadvertently or intentionally.

"We want to see the affects of that almost inevitability very carefully studied and researched before the government makes a decision."

Biotech opponents in Canada fear that if AquaBounty's salmon is approved for the U.S. market, Canadians will be the next to find unlabelled GE salmon on their store shelves—followed by the GE "Enviropig" engineered by scientists at the University of Guelph. The university has asked Health Canada to approve Enviropig for human consumption.

A coalition representing fisheries and oceans conservation, environmental, and social justice groups—60 organizations in all—is working to block the GE salmon completely in Canada.

The coalition has released a statement of

*The consequences of an accident are so huge that the risks are just*

"categorical objection" to the raising of GE fish and fish eggs and has called on Environment Minister John Baird to take action to prevent the eggs from being produced in Canada.

*too big to consider releasing this GE salmon.* —Lucy Sharratt

Lucy Sharratt of the Canadian Biotechnology Action Network calls the technology dangerous and says the GE salmon pose a "profound threat" to wild fish if they escape.

"There's always going to be a risk, and the consequences of an accident are so huge that the risks are just too big to consider releasing this GE salmon. Consumers don't want it. Even the aquaculture industry doesn't want it. So it's not wanted and yet it represents a huge risk to an endangered wild fish population."

### Minimal Risk of Escape

AquaBounty, which does not yet have permission from Environment Canada to commercially produce its salmon eggs in P.E.I., says the likelihood of escape is minimal due to stringent containment measures at its land-based facilities in both P.E.I. and Panama.

If an accidental escape did occur, "environmental conditions at the facilities are such that survival of the organisms would be highly unlikely," the company said in its Environmental Risk Assessment.

"We believe the economic and environmental benefits of our salmon will very effectively help to meet the demand for food from the growing world population," said Ronald Stotish, president and CEO of AquaBounty, in an August press release.

Ruth Salmon, spokeswoman for the Canadian Aquaculture Industry Alliance, says the aquaculture industry doesn't support producing genetically engineered salmon for human consumption.

"We have done quite a bit of research and the market doesn't want [GE salmon], our customers don't want it," Salmon told the Vancouver Sun.

"The aquaculture industry knows that if genetically engineered salmon are approved, consumers will start rejecting farmed salmon as a means of avoiding genetically engineered salmon," says Sharratt.

"There's [Related Articles](#)

going to be a huge consumer backlash

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and it's the aquaculture industry that's going to feel that when consumers stop buying farmed salmon."

A U.S. survey conducted in September found that, overall, 78 percent of adults believe the FDA

should not approve GE salmon for human consumption, compared to 16 percent who want to see it approved.

A group of 12 U.S. organizations, including the Union of Concerned Scientists, Greenpeace, and the Ocean Conservancy, has sent a letter to President Barack Obama and the FDA demanding that the agency conduct a rigorous environmental impact study before deciding whether to approve the GE salmon.

**REPRESENTATIVE PAUL SEATON, Co-CHAIRMAN**  
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