HJR

5

<TARGET><BILL>HJR 5</BILL><SUBJECT>HJR
5</SUBJECT><COMM>SRES28</COMM></TARGET>

SENATE COMMITTEE REPORT

DATE: 2/21/13

FURTHER: RULES

DATE TURNED IN TO OFFICE: 3/15/13

Resources Committee considered CS FOR HOUSE JOINT RESOLUTION NO. 5(FSH)

HJR 5-OPPOSE GENETICALLY ENGINEERED SALMON

Opposing the United States Food and Drug Administration's preliminary finding relating to genetically engineered salmon; urging further examination of genetically engineered salmon; opposing AquaBounty's petition to produce genetically engineered salmon; and proposing, if AquaBounty's petition is approved, that its product should be labeled as "genetically modified."

and recommends:

[ ] be **replaced** with **SCS** _____ (_____) *[ ] Same Title [ ] Technical Title Change [ ] New Title/SCR No._____*

[ ] adopt **previous SCS** _____ (_____) *[ ] Same Title [ ] Technical Title Change [ ] New Title/SCR No._____*

[ ] attached amendment(s)

[ ] adopt _____Letter of Intent

[ ] further referral to _____Committee

Dept Abbr.	
ADM	LWF
CED	LAW
COR	LEG
CRT	MVA
EED	DNR
DEC	DPS
DFG	REV
GOV	DOT
DHS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
H.FSH			✓	

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
	MICCICHE	✓			
	BISHOP	✓			
	DYSON	✓			
	FAIRCLOUGH	✓			
	FRENCH	✓			
CHAIR:	GIESSEL	✓			

ALASKA STATE LEGISLATURE

REPRESENTATIVE GERAN TARR

February 26, 2013

To: Senator Cathy Giessel
Chairman Senate Resources Committee

From: Representative Geran Tarr

Re: Hearing Request for HJR 5

Please see the attached House Joint Resolution 5 and supporting documents. You will find the current version of HJR 5, letters of support, and documents with regards to genetically modified salmon.

We are requesting a hearing at the earliest possible convenience of the Senate Resources committee. Because of the deadline for the comment period with the Food and Drug Administration Regarding this issue, this is a time sensitive resolution.

Thank you for your time. Feel free to contact me or my aide, Monica Southworth, at 465-3424 with any questions, concerns, or comments about this resolution.

January-May: State Capitol • Juneau, AK 99801-1182 • (907) 465-3424 • Fax (907) 465-3793
June-December: 716 W. 4th Avenue • Anchorage, AK 99501• (907) 269-0144• Fax (907) 269-0148
Rep.Geran.Tarr@akleg.gov

ALASKA STATE LEGISLATURE

REPRESENTATIVE GERAN TARR

February 26, 2013

To: Senator Cathy Giessel
Chairman Senate Resources Committee

From: Representative Geran Tarr GT

Re: Hearing Request for HJR 5, Technology Request

For the hearing for House Joint Resolution 5, I will need the use of a computer for a power point presentation.

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ALASKA STATE LEGISLATURE

REPRESENTATIVE GERAN TARR

February 26, 2013

To: Senator Cathy Giessel

Chairman Senate Resources Committee

From: Representative Geran Tarr

Re: Hearing Request for HJR 5, Invited Testimony

Please see below for the list of invited testimony:

United Fisherman of Alaska: Julianne Curry 907-586-2820

Cordova District Fisherman United: Jerry McCune 907-424-3447

January-May: State Capitol • Juneau, AK 99801-1182 • (907) 465-3424 • Fax (907) 465-3793
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ALASKA STATE LEGISLATURE

REPRESENTATIVE GERAN TARR

Sponsor Statement
House Joint Resolution 5
Oppose Genetically Engineered Salmon

House Joint Resolution 5 (HJR 5) is a resolution from the 28th Alaska State Legislature opposing the United States Food and Drug Administration's preliminary finding in relation to genetically engineered salmon, and urging further examination of genetically engineered salmon before allowing them to be grown, harvested, and sold in the United States.

In December 2012, the FDA announced the genetically modified salmon grown by AquAdvantage in Canada and Panama pose no significant threat to salmon stocks in the wild even though they are notably more aggressive than their wild counter parts. According to scientists, "the FDA's environmental assessment of genetically modified salmon does not adequately consider the growing body of research on genetic and ecological risks and lacks basic quantitative information necessary to verify conclusions."

Alaska's fishing industry is valued at $1.5 billion annually, and $3.6 billion wholesale, according to the Alaska Department of Fish and Game. Some studies have shown that AquAdvantage fish could eliminate wild populations within 30 years and pose real environmental risks to the sustainability of the fish, and to the pocketbooks of Alaskans.

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, after escaping from neighboring fish farms in British Columbia. Many are infested with sea lice. They are considered an invasive species by Alaskans. The FDA is now considering allowing production of fish that could completely decimate wild salmon populations.

This resolution will send a clear message to the Federal government 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 ensuring the safety and well-being of Alaska's wild salmon.

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ALASKA STATE LEGISLATURE

REPRESENTATIVE GERAN TARR

Explanation of Changes

House Joint Resolution 5

Oppose Genetically Engineered Salmon

During the Fisheries committee hearing two changes were made. The first change was on page 1, line 13, replacing the words "less polluted" with "cleaner" and on page 3, line 8, replace the word "should" for "must."

Also on page 3, line 8 between the words "include" and "the" there was an insertion of as required by Alaska law"

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Fish Factor: FDA-approved Frankenfish fight continues

January 25th 2:46 pm | **Laine Welch** print email link

Fishing groups, consumers and health organizations are launching a final push to prevent genetically modified fish from getting the nod for American dinner plates.

During the holidays, the Food and Drug Administration issued its environmental assessment concluding that the fish, tweaked to grow at least three times faster than normal, will not have any significant impacts on the human environment and is unlikely to harm wild stocks. The FDA's environmental green light is the last step before AquaBounty, the creators of so called Frankenfish, can send the mutant to markets. The public has until February 26 to send comments to the FDA.

Alaska Senators Begich and Murkowski have written to the FDA asking for a 60 day extension to the comment deadline, citing the holiday timing and new transitions in Congress. Senators from Washington, Oregon and Maryland also signed on to the comment extension request. No word yet on if the request has been granted.

Meanwhile, Senator Begich said the agency is moving "full steam ahead with fine-tuning its Frankenfish regulations," and he is not optimistic that public opinion will sway the federal OK.

Indeed. Late last year the federal government

awarded a coveted $500,000 research grant from the National Institute of Food and Agriculture to

AquaBounty when the company disclosed it could run out of cash early this year. Over the past 16 years, Aqua Bounty has spent $67 million to genetically tweak its "AquaAdvantage" Atlantic salmon and navigate the permitting processes.

Senator Begich called the FDA's support of the mutant fish "totally misguided."

"I think the FDA is not equipped to understand the impacts this genetically engineered fish will have on the environment and ecosystem," he said in a recent teleconference.

That echoed earlier comments by Rep. Don Young and Senator Murkowski who called the FDA's actions "especially troubling since the agency is ignoring the opposition of fishing groups as well as more than 3,000 consumers and health organizations."

As of Friday there were 3,209 comments posted on the FDA regulation page - of the 15 pages of comments posted, not a single one spoke in support of the GM fish. The Alaska legislature and state fishing groups have come out strongly against Frankenfish as has the National Humane Society, Center for Food Safety, among others.

"Can they move forward even with so much opposition by so many diverse groups? The sad answer to this is probably," said Begich.

"Still I encourage more people to make comments. I think the more comments the agency gets on the official record may slow them down or prevent them from moving forward," he added.

According to AquaBounty documents, the company plans to grow the modified Atlantic salmon eggs at a lab in Prince Edward Island, fly them to Panama where they will be raised at inland fish farms, and then

shipped back for sale in the U.S. Prospective fish farmers are lined up

in South Dakota, West Virginia, Wisconsin and Ohio.

Meanwhile, Alaska's Congressional delegation intends to keep pressure on the FDA.

"We intend to reintroduce legislation that will deal with not allowing this product to come to market," Senator Begich said. "We will also deal with the labeling issue and some others. So if they think we are just going to roll over because they think they are a regulatory agency that just gives a check off and that's good enough, they are mistaken."

The Guardian newspaper in the UK quipped: If approved, the fish would be the world's first modified animal "to make its way into the food chain, clearing the way for an entire menagerie of redesigns, from fast-growing trout and tilapia to the "enviro-pig", genetically altered to produce less polluting poo."

Comments on Frankenfish can be sent to www.regulations.gov

Docket No. FDA-2011-N-0899.

Money for "Made in America"

Federal grants are available for Alaska companies that are getting pinched by competing imports.

"We look to assist firms that produce products or services made in America and in doing so, save and create as many U.S. jobs as possible," said Gary Kuhar, director of the nonprofit Northwest Trade Adjustment Assistance Center, an arm of the U.S. Dept. of Commerce Economic Development Administration.

If Alaska companies have lost sales or production to foreign competitors, they are eligible for up to $75,000 in matching grants for projects of their choice. Smaller companies, for example, can get up to $30,000 with a 25 percent match of $7,500 for the company and the grant covers the rest. Large companies have a 50/50 split with a maximum grant of $150,000.

The money can't be used to buy equipment or pay salaries, but it can cover consulting, training, website development and marketing.

"We do a lot in the marketing field," Kuhar said. "We help develop a marketing strategy and then help produce the tools needed to implement the strategy."

The TAA grants can help producers in manufacturing, agriculture, seafood and service firms such as fish brokerage companies. Co-ops and trade groups also may apply. Kuhar said his staff assists from the get go, from submitting applications and preparing and implementing projects through completion.

He added that the trade grants also are a tool for Alaska legislators.

"In some states we have very good success where the legislators refer clients to us. We are a tool to help their

constituents," Kuhar said. Learn more at www.nwtaac.org

Fish switch

Arni Thomson, one of Alaska's best known fishery advocates and policy wonk has joined the new Alaska Salmon Alliance as its first executive director. The ASA was formed in late 2011 to promote policies that protect fish and ensure long term fishing benefits at Cook Inlet. Its

membership includes Inlet fishing organizations, fishermen, and the region's four major processors.

Thomson is well known for his decade's long work at state and federal levels with Bering Sea crab fisheries and as recent president of United Fishermen of Alaska.

Thomson says the ASA will not focus on salmon fishing disputes between Cook Inlet user groups. Another focus is the loss of salmon habitat due to encroaching development and land uses.

"We want to stay out of allocative issues as much as possible. The objective is public education, communication and outreach to all user groups in the Cook Inlet salmon fisheries," he said in an interview.

The Alliance aims to make sure that the commercial fishing sector retains access to the resource. Both sport charters and Inlet setnetters were completely shut down last summer to protect king salmon returns, along with closures in the Mat Su drainage.

Thomson said at a recent meeting of a new Board of Fisheries task force "there was a serious effort by all the parties to start exchanging real proposals" and that "some interim solutions could be tested this summer."

Fish watch

The nation's largest fishery opens on January 20 - Alaska pollock. This year's total catch from the Bering Sea and Gulf of Alaska is 1,387,146 metric tons or more than 3 billion pounds. Alaska pollock accounts for 30 percent of all U.S. seafood landings.

Fish bucks

American Seafoods Company is accepting applications for its Alaska community grant program. A total of $30,000 will be given out by the company's Community Advisory Board for projects addressing issues such as hunger, housing, safety, education, research, natural resources and cultural activities. Deadline to apply is Feb. 6; recipients will be selected

on Feb. 14th.

Request forms are available at www.americanseafoods.com, by contacting kim.lynch@americanseafoods.com or call 206-256-2659.

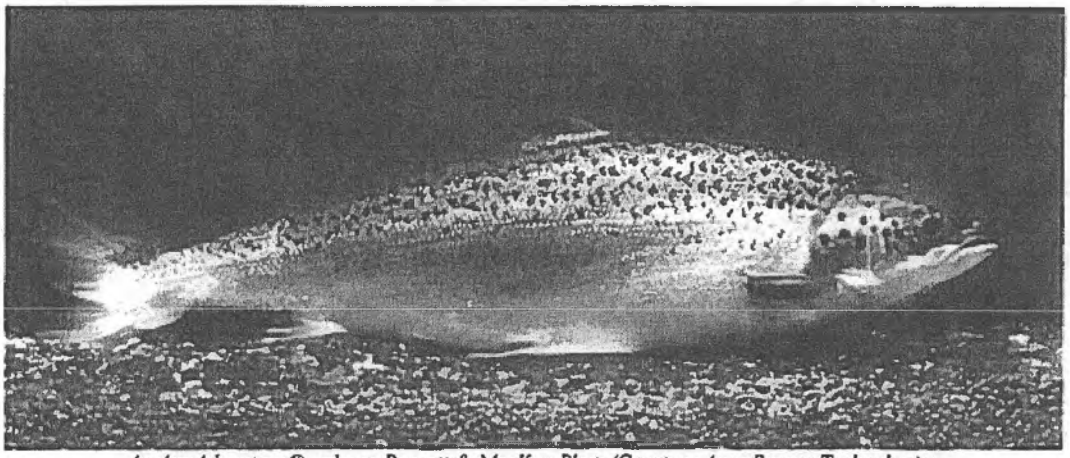
White House Ends Its Interference in Approval of Genetically Modified Salmon

By Jon Entine | Updated Friday, Dec. 21, 2012, at 2:03 PM ET
Updated Friday, Dec. 21, 2012, at 2:03 PM ET

Slate.com

White House Ends Its Interference in a Scientific Review

Leaks suggest politics blocked genetically modified salmon. Now the fish is on its way to approval.



An AquAdvantage® salmon Barrett & MacKay Photo/Courtesy AquaBounty Technologies.

Update, Dec. 21, 2012: On Wednesday, Slate and the Genetic Literacy Project published investigations into whether the White House was interfering in a scientific review process by the FDA. An environmental assessment of genetically modified salmon had cleared all internal regulatory hurdles and was due to be released in April, but the Obama administration put a hold on the release. Hours after the stories were published, according to FDA sources, the White House lifted its hold. Today, the FDA finally published the environmental assessment, one of the final stages in what could be the first federal approval of a genetically-modified animal in the United States.

The original article is below:

As president, Barack Obama promised to change "the posture of our federal government from being one of the most anti-science administrations in American history to one that embraces science and technology." To publicly guarantee that, the White House issued a science integrity memorandum in 2009 pledging, "Political officials should not suppress or alter scientific or technological findings and conclusions."

Except, it appears, when it comes to the fate of the first transgenic animal to be considered for federal approval—a genetically modified (GM) salmon developed by AquaBounty Technologies of Massachusetts. The so-called AquAdvantage salmon is a fish that has been modified to grow to market size in about half the usual time. It's raised in contained structures that eliminate many of the environmental effects that make farmed salmon unpopular with some environmentalists, including the generation of excess waste and the potential to spread disease or escape and compete with wild salmon.

The bioengineered salmon has been winding its way through a labyrinthine approval process for 17 years. And it's been in regulatory purgatory for more than two years since the Food and Drug Administration held public hearings—and promised a final determination within weeks.

As recently as last week, a spokeswoman for the Food and Drug Administration told me, "The application is still under review." But that's not the whole story.

The Genetic Literacy Project (GLP), which I direct, has learned that in April, the FDA completed its draft environmental assessment (EA), the final step in its scientific evaluation. The agency confirmed that the salmon is safe to eat and poses no serious environmental hazards. The approval document had made its way through every appropriate agency in an interagency review process coordinated by the Office of Science and Technology Policy (OSTP), which oversees the president's science policies and is empowered to enforce integrity guidelines.

But within days of the expected public release of the EA this spring, the application was frozen. The delay, sources within the government say, came after meetings with the White House, which was debating the political implications of approving the GM salmon, a move likely to infuriate a portion of its base.

The GLP has been leaked a confidential copy of the 159-page assessment, dated April 19, 2012, which had been circulated and approved—a summary of which we have been given permission to publish. It states that the Center for Veterinary Medicine, which has regulatory responsibility within the FDA, reached a "no effect" determination under the Endangered Species Act. That should have led to the publication of the EA in the Federal Register, paving the way for a public review period, which would have lasted 30 to 90 days. If the process had been followed, genetically modified salmon could have been on dinner tables by next year.

When asked about the holdup, FDA spokeswoman Siobhan DeLancey said, "I recommend you talk to the OMB or the White House. That's all I'm willing to say."

If, as FDA sources confirm, the scientific review is complete, the refusal to publish the draft EA in the Federal Register directly contradicts not only the president's directives, but also regulatory mandates ensuring the integrity of science at the Department of Health and Human Services, which oversees the FDA, and OSTP, which is under the executive branch.

"This shouldn't be happening," said Gregory Jaffe, director of biotechnology at the Center for Science in the Public Interest. Although cautious about biotechnology, Jaffe participated in a scientific review panel that unanimously endorsed the FDA's findings that the salmon was safe. "AquaBounty deserves regulatory due process," he added. "We need science-based decisions made in a timely fashion. The public deserves this, and there are questions whether that is what's going on in this case."

AquaBounty's fish is an Atlantic salmon with two added genetic elements: a Chinook salmon growth hormone gene and an on-off switch from the ocean pout, another edible fish. The modifications make the salmon grow through the winter, unlike conventional salmon. Only females are produced for consumption, and they are rendered sterile.

Americans consume 650 million pounds of salmon each year, with more than 530 million pounds of that imported. If allowed into the marketplace, the AquAdvantage salmon, as it is called, could lead to lower salmon prices and an increase in consumption of salmon, a heart-healthy food.

GM crops and animals are regulated under the 1986 Coordinated Framework. But while plants have a clear path to approval under guidance in place by 1992, animals must travel through regulatory no-man's land. The FDA has approved only one product, an anticoagulant derived from the milk of transgenic goats.

AquaBounty initiated its application to commercialize in 1995. By 2004, it had assembled its "data package," but its path to approval was never entirely clear. Finally in 2008, the Bush administration decided that transgenic animals intended for the dinner table would be regulated as animal drugs by the FDA's Center for Veterinary Medicine.

Anticipating environmental concerns, AquaBounty developed the salmon at a secure indoor facility in Prince Edward Island, Canada. A second facility was established in the mountains of Panama to evaluate whether the fish perform well under standard commercial conditions.

As part of its evaluation, the FDA inspected both facilities, determining the fish would be securely contained with multiple redundant systems that would prevent the salmon from escaping into the wild—one of the main concerns for people opposed to GMOs. The FDA concluded that even a catastrophic event at the Panamanian facility would not pose a threat. Lengthy expanses of warm, muddy water outside the facility would serve as a graveyard to any escaped cold-water fish. If some somehow made it to the ocean, they would die in the warm currents thousands of miles from their spawning grounds in the frigid waters of the North Atlantic.

There is no chance, independent scientists say, that released salmon would win a Darwinian war in open waters with wild salmon—the so-called Trojan gene effect. GMO opponents cite a 1999 study concluding that modified fish that grow extra large would have a competitive advantage, threatening extinction of conventional varieties. But AquaBounty engineered the salmon so it grows no larger than conventional fish. A co-author of that study, Bill Muir of Purdue University, who developed the risk assessment model for transgenic fish for the Department of Agriculture, studied the AquaBounty salmon and determined it has no fitness advantage—and now endorses it.

After years of reviews, in September 2010, the FDA released a long-awaited comprehensive guidance analysis that found the salmon environmentally benign and safe for human consumption. The agency concluded the AquAdvantage salmon is comparable to the traditional variety in every measurable way.

To underscore its commitment to transparency, the FDA's CVM convened a science advisory panel, which held public hearings a few weeks later. The scientists, including representatives from organizations skeptical of GMOs, unanimously reaffirmed the food safety report: AquaBounty salmon was materially identical to conventional salmon and posed no apparent environmental hazards.

The final step in the process—a "no effect" finding required under the Endangered Species Act—was expected within weeks, which would lead to its publication in the Federal Register and public hearings. Echoing one headline—"FDA to Approve GM Salmon Despite Strong Opposition"—everyone from the New York Times to anti-GMO activist groups was reporting that AquaBounty appeared to be on its way to producing the fish eggs that other companies could purchase to raise the quick-growing salmon.

Nothing has been released by the FDA since.

Friends of the Earth, Greenpeace, Union of Concerned Scientists, and other anti-GMO groups sent a letter to FDA Commissioner Margaret Hamburg demanding further review of whether wild salmon could face a competitive survival risk. AquaBounty's response noted the FDA's expert panel had already rejected those speculations.

Congressional politics then flared up. Forty members of Congress, most from the Pacific Northwest—whose salmon competes with Atlantic salmon—sent a letter to the FDA citing a supposed lack of transparency in the process. Whether because of the suddenly hostile political climate or renewed lobbying by opponents, the formal environmental assessment, which reporters had been told might be released any day, was never made public.

When rumors that approval was near surfaced again, in June 2011, a dozen members of the House, in a voice vote, approved a budget amendment prohibiting the FDA from approving the AquaBounty salmon. "Frankenfish is uncertain and unnecessary," said the bill's sponsor, Rep. Don Young, R-Alaska. "Should it receive approval as an animal drug, it clears the path to introduce it into the food supply; my amendment cuts them off before they can get that far." The Senate did not immediately take up the bill.

Critics cited the snail-like pace of approval as evidence that the AquaBounty application was in trouble. "If the FDA was so assured of the scientific merits of this application, they would have approved it by now," said Colin O'Neil of the Center for Food Safety. "The mere fact that it has taken this long tells me that jury is still out."

In fact, by summer 2011, by all reports, the FDA had yet again reaffirmed its finding that the salmon was ready for approval. The draft environmental assessment was prepared and circulated under an interagency review process coordinated by the president's Office of Science and Technology Policy. The two other agencies responsible for assessing the application under the Endangered Species Act, Fish and Wildlife, and the National Marine Fisheries Service, signed off on the "no effect" determination.

The review even went to the OMB at the Executive Office, which under normal circumstances would have no input on individual applications. Its authority is usually limited to reviewing new regulations. However I've been told that, because of the politicized nature of this case, the White House wanted to be involved. According to Talking Points Memo and my sources, OMB signed off on release of the EA that summer.

The approval was derailed when anti-GMO organizations circulated a report that the salmon at AquaBounty's Canadian facility had tested positive for a salmon virus two years previously. The company had reported the incident to Canadian authorities but not to the FDA—which reportedly did

not make officials happy. The FDA immediately put a hold on the release of the draft EA. It took months before the agency determined the incident had been isolated and had nothing to do with AquaBounty's technology.

While that controversy was being addressed, Food and Water Watch, Consumers Union, and the Center for Food Safety submitted a formal petition in February 2012, demanding the FDA reclassify AquaBounty's AquAdvantage salmon and its components as a food additive, setting up the possibility of a different regulatory regime that would have resulted in the process starting over at square one. The FDA stood firm, reaffirming its commitment to the evaluation by the CVM.

Finally, on April 19, 2012, the FDA circulated a draft EA that was an almost exact copy of what had been approved months before. The "approval of the AquaAdvantage Salmon," the document states, "... will not jeopardize the continued existence of the United States populations of threatened or endangered Atlantic salmon, or result in the destruction or adverse modification of their critical habitat."

For AquaBounty, the end again seemed in sight.

"It's a lengthy process, especially when you are dealing with a first-in-kind product that cuts across many dimensions," the FDA's Hamburg told the New York Times. A revised environmental assessment, she said, would be issued "very soon"—in a matter of days, weeks at most.

Then the gears of government and communication between the federal officials and AquaBounty shut down completely.

Late spring was a challenging time at the White House. The GOP primaries had just wrapped up, and Republicans were coalescing around Mitt Romney, who appeared to be a formidable candidate. The president's popularity remained lackluster. A late June Newsweek/Daily Beast poll showed that 54 percent of Americans thought Obama was doing a poor job—one of the lowest approval ratings of his presidency.

The main concern, politicos mused at the time, was a lack of enthusiasm by his political base, whose turnout would be critical if Obama hoped to squeeze out a victory during distressed economic times. Environmental activists were particularly ambivalent. They were upset about the president's unwillingness to block the Keystone pipeline and shale gas exploration using hydraulic fracturing.

And some of them were incensed about what they considered weak-kneed regulatory oversight by the FDA on chemicals and GMOs, which they believed had gotten a pass during the Bush administration. In late March, the FDA, citing "sound science," rejected a petition by the Natural Resources Defense Council to introduce tough restrictions on bisphenol A (BPA), a controversial plastic additive. "The FDA is out-of-step with scientific and medical research," the NRDC wrote in a blistering rebuke. "The agency has failed to protect our health and safety."

The last thing the Obama re-election effort needed was a messy dustup over the first genetically modified animal. But that was brewing. Union of Concerned Scientists' Margaret Mellon, a foe of bioengineering, had already publicly warned of "a firestorm of negative response" if the FDA approved the salmon.

With political opposition bubbling in Congress and anti-GMO activists mobilizing in cyberspace, AquaBounty's president and CEO, Ronald Stotish, encountered FDA Secretary Hamburg at an industry event in Boston.

"You've been great," he quoted her as saying. "You've been patient and taken the high road." She pointedly did not repeat her statement of a month before that the publication of the EA would be coming any day now.

Her comment set off alarm bells within the industry. Was there a new holdup? Stotish and Jim Greenwood, president of the biotech industry trade group BIO, met on July 11 with HHS Secretary Kathleen Sibelius' senior adviser Andrea Palm. Palm is known as a "fixer"—she coordinates policy with politics, often working directly with Valerie Jarrett, the president's most trusted adviser. Sources say the White House had been hearing regularly from anti-GMO organizations.

Palm professed to have no knowledge of the salmon controversy, according to people in the meeting. Palm promised to get back to them within a week. Five months later, dozens of calls and emails have gone unreturned. I've fared no better; Palm did not respond to my request for a statement.

Sources within the FDA have repeatedly asserted that the scientific review process is complete and the agency is not the source of the holdup. The media office says the application itself has not been formally approved. DeLancey referred me to the executive branch, to the White House and OMB. The OMB referred me back to the FDA. The White House declined to respond to requests for comment.

The regulatory foot-dragging sparked a letter sent to the White House in late September from more than 50 scientists and interested parties concerned about the delay.

"There is much more at stake here than just a fish," the letter asserted. "The inexplicable regulatory bottleneck that has been encountered by the AquAdvantage salmon suggests that the FDA's science-based regulatory review process for the products of animal biotechnology has no predictable timeline and is holding up the development of an industry that promotes economic growth, innovation, competitiveness, and job creation in the United States."

China has launched an $800 million public-private investment into transgenic animals, and genetically modified animals are being developed in India, New Zealand, and across Latin America, including in Cuba. But North America has become a dead zone.

James Murray, an animal scientist at the University of California–Davis has developed goats that make milk with diarrhea-preventing lysozyme, a bacteria-fighting protein that could save children's lives. With no government or private money on the horizon, he's set up his lab in Brazil, a more biotech-friendly locale. "When you don't have a regulatory pathway forward and the government doesn't support research in this area, what company will invest in this field?" he asked. "None. The AquaBounty situation is just confirmation of a hopelessly politicized process."

The future of animal genetics is so dire, universities are killing off courses. "My program started off doing genetic engineering," said Alison Van Eenennaam, a University of California–Davis animal scientist who co-authored a scathing article for Nature Biotechnology on the broken approval process.

"I couldn't get any government funding for my work in this area, so I shut the program down. Why would I train graduate students for jobs that won't exist?"

A question remains whether the White House or FDA could face legal challenges for intervening in a scientific evaluation process that is supposed to be insulated from politics. The Federal Food, Drug & Cosmetic Act requires that the Health and Human Services secretary approve the AquaBounty application within six months after compliance with Section 512. The company holds letters from earlier this year from the FDA advising that every major component of its application has been successfully addressed.

The FDA, apparently caught in the political crossfire, appears to be in violation of its own scientific integrity guidelines, adopted last February. Scientists and staffers involved in the process say they have been instructed not to discuss the application. Key provisions of the guidelines require the agency to shield its staff from "political influence" and to allow the "FDA staff to communicate their personal scientific or policy views to the public, even when those views differ from official Agency opinions."

The FDA has referred any questions about the logjam to the White House. The chief spokesperson for the OSTP, which is empowered by the executive branch to ensure that scientists are insulated from political concerns, has not responded to requests for comment.

"I think the credibility of our regulatory process is destroyed if someone at the White House or even at the FDA can essentially, arbitrarily pocket veto an application," said Stotish.

But that's what's going on, say those monitoring science policy—even those critical of the AquaBounty salmon. The Union of Concerned Scientists, which has campaigned against bioengineering, expressed its concern that the science approval process is being compromised by politics.

"If the statutes say the decision is supposed to be made based on science, and promptly, the government should follow that," Francesca Grifo, who helped craft UCS's scientific Integrity reports, told me. "Despite what the President might have said about scientific integrity, we've seen White House interference on what should be science regulatory decisions. They have a legal responsibility to follow their own guidelines."

`FDA Moves Forward on Genetically Engineered Salmon

(*Beyond Pesticides*, January 3, 2012) On December 21, just as everyone was gearing up for the holidays, the U.S. Food and Drug Administration (FDA) announced its release of a Draft Environmental Assessment (EA) and Preliminary Finding of No Significant Impact on the genetically engineered (GE) AquaBounty AquaAdvantage salmon. The FDA action is widely viewed as confirmation that the Obama Administration is prepared to approve shortly the first GE animal intended for human consumption in the face of widespread opposition from the public.

"It is extremely disappointing that the Obama Administration continues to push approval of this dangerous and unnecessary product," said Andrew Kimbrell, executive director for Center for Food Safety. "The GE salmon has no socially redeeming value; it's bad for the consumer, bad for the salmon industry and bad for the environment. FDA's decision is premature and misguided."

AquaBounty claims that the company's process for raising GE fish is safer than traditional aquaculture, yet documents released by the Canadian government show that a new strain of Infectious Salmon Anaemia, the deadly fish flu which has been devastating fish stocks around the world, contaminated their Canadian production site. This information was not included in the FDA's review and hidden from the public. Many additional long standing concerns regarding impacts to wild species and the environment raised during a Senate hearing last year remain unanswered in the latest FDA review documents.

In order to create the transgenic fish, Aquabounty genetically engineered an Atlantic salmon by inserting a Chinook salmon growth-hormone gene, as well as a gene sequence from an ocean pout. The company claims this engineering causes the GE salmon to undergo an increase in growth rate that allows the fish to reach market size in half the normal time. Consumer groups Center for Food Safety, Food & Water Watch and Consumers Union submitted a formal petition to the agency in February 2012 to classify and evaluate the GE salmon as a food additive.

The FDA decision ignores calls from more than 40 members of the U.S. Congress who have repeatedly urged FDA to conduct more rigorous review of environmental and health safety, and halt any approval process until concerns over risks, transparency and oversight have been fully satisfied. The public filed nearly 400,000 comments demanding FDA reject this application. Additionally, more than 300 environmental, consumer, health and animal welfare organizations, salmon and fishing groups and associations, food companies, chefs and restaurants filed joint statements with FDA opposing approval.

"We need a robust regulatory system that puts environmental, human health, economic and animal welfare risks first," said Mr. Kimbrell. "Putting a GE animal on the path to consumer use without proper safeguards and with no mandatory labeling requirement proves that the system FDA has in place gives us none of that."

Cordova District Fishermen United
PO Box 939 | 509 First Street | Cordova, AK 99574
phone. (907) 424 3447 | fax. (907) 424 3430
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February 8, 2013

Rep. Paul Seaton
House Fisheries Committee
State Capitol Room 102
Juneau, AK 99801
f. 465.3472

RE: HJR 5 - "A Resolution opposing the US FDA's preliminary finding relating to genetically engineered salmon"

Dear Chairman Seaton and Committee Members:

I am writing on behalf of the Cordova District Fishermen United Board of directors and our membership to express our support of HJR 5 and proposed position of statewide opposition to the US Food and Drug Administration's (FDA) preliminary approval of Aquabounty's New Animal Drug Application (NADA) for genetically engineered salmon.

As one of Alaska's oldest fishing organizations, CDFU represents over 800 fishermen and their families in the Prince William Sound region, each with tremendous investment in their fishing operations and a commitment to the continued sustainability and productivity of Alaska's wild salmon runs.

We are extremely concerned with the ramifications that approval of GE salmon may have on Alaska's fishing industry. And are appreciative of the authors' recognition of the deficiencies in the FDA process to adequately assess the broader implications of approving GE salmon based on the limited scope considered in the preliminary EA and FONSI. We also support the state's proposed commitment to pursue mandatory product labeling should federal approval of this product be granted.

Thank you for your thorough consideration of HJR 5.

Sincerely,

Alexis Cooper
Executive Director

CC: Rep. Tarr

CITY AND BOROUGH OF YAKUTAT
RESOLUTION 10-165

A RESOLUTION OPPOSING THE APPLICATION FROM AQUABOUNTY TECHNOLOGIES, INC. TO THE US FOOD AND DRUG ADMINISTRATION (FDA) TO APPROVE AND MARKET GENETICALLY ENGINEERED ATLANTIC SALMON (SALMON SALAR) IN THE UNITED STATES AND ABROAD

WHEREAS, Aqua Bounty Technologies, Inc. has submitted an application to the FDA for approval of the "Aqua Advantage Salmon", a genetically engineered Atlantic salmon, for commercial production, human consumption and marketing in the United States; and

WHEREAS, this is the first genetically engineered animal, land or water, intended to be used as food within the United States; and

WHEREAS, the Aqua Advantage salmon is a combination of three species of fish; and

WHEREAS, the fertilization and incubation of the genetically engineered eggs will occur on Prince Edward Island, Canada adjacent to existing Atlantic salmon runs, human error may result in unintentional release into the wild, or become attractive for cage grow out; and

WHEREAS, the existing Atlantic salmon runs are severely depleted and already altered genetically between European and North American strains from crossbreeding of existing pen stock and subsequent escape; and

WHEREAS, we believe there are already problems with "Round Up Ready" canola and BT corn regarding genetic drift and pesticide resistance; and

WHEREAS, a massive marketing campaign restored the economic viability of wild salmon fisheries in Alaska after the surge in cage reared salmon supply; and

WHEREAS, the City and Borough of Yakutat has the highest per capita commercial fishing permit holder population in the State of Alaska and is highly dependant on salmon fishing to maintain the local economy

NOW, THEREFORE BE IT RESOLVED, the City and Borough of Yakutat , by this resolution, does not support the approval of any genetically engineered salmon under the FDA application process for sale or production in the United States and abroad.

BE IT FURTHER RESOLVED THAT if approval moves forward the words "Genetically Modified" be obviously displayed on all shipping , packing and retail labeling ensuring the American Consumer can make the distinction between wild salmon and genetically engineered salmon.

PASSED AND APPROVED THIS 4 DAY OF Nov 2010.

CITY AND BOROUGH OF YAKUTAT, ALASKA

MAYOR

ATTEST:

BOROUGH CLERK

CITY AND BOROUGH OF YAKUTAT CORPORATE SEAL ALASKA SEPTEMBER 22, 1992

THE CENTER FOR
FOOD SAFETY

October 25, 2010

ECONOMIC CONCERNS AND IMPACTS RELATING TO GE SALMON

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 AquAdvantage Salmon (AA Salmon) produced by Aqua Bounty Technologies. FDA convened two separate public meetings in September to discuss the GE fish, yet absent from FDA's meetings and materials are any discussions about potential economic impacts that would result from GE salmon approval or the unintended escape of GE salmon. Below is a summary of the major concerns:

Market Contamination

The AA Salmon application under consideration by FDA stipulates that the GE eggs will be grown in a land-based facility on Prince Edward Island, Canada, and then shipped to a land-based facility in Panama where they will be grown-out and processed for shipment to the U.S. and the international market. If GE salmon are approved, there exists significant potential for GE contamination of processed seafood as well as the likelihood for GE salmon to be sold as non-GE due to either human or tracking error. The international seafood market already suffers from deficient regulation and any tracking measures beyond the Country-of-Origin Labeling (COOL) requirements will be very difficult. FDA officials acknowledged during the public meetings that the Agency currently inspects only a small amount of fish imported to the US, making the risk of global market contamination a vital concern.

As demonstrated by the StarLink contamination fiasco, biological contamination of non-GE foods can have tremendous consequences for producers and markets. StarLink was a variety of GE corn was not approved for human consumption due to concerns that it could cause allergic reactions. However, wide swaths of corn acreages were contaminated by StarLink, which lead to the recall of tens of millions of supermarket items. The event was further complicated by the slow and deplorable investigation by the FDA. In 2003, a group of farmers was awarded a $110 million settlement due to the loss of foreign markets resulting from the StarLink contamination.[i]

Market Confusion or Rejection

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. 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.[ii] A 2008 Consumer Reports poll found that 95 percent of respondents said they thought food from genetically engineered animals should be labeled.[iii]

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Email: info@centerforfoodsafety.org | www.centerforfoodsafety.org | www.ge-fish.org

A number of fishing associations as well as salmon farming companies have already voiced their opposition to the use of transgenic salmon including the Bristol Bay Regional Seafood Development Association, the Pacific Coast Federation of Fishermen's Association, International Salmon Farmers Association, the Irish Salmon Growers Association, the New Brunswick Salmon Growers' Association, Alaska Trollers Association, the Gloucester Fishermen's Wives Association, the Massachusetts Fishermen Partnership, Inc, Cooke Aquaculture, Inc, Marine Harvest ASA, Canadian Aquaculture Industry Alliance, Scottish Salmon Producers Organization, California Fisheries Network, SalmonAid, North Atlantic Marine Alliance, the Rhode Island Fishermen's Alliance, and many others. AquaBounty conducted trials of genetically engineered salmon in both New Zealand and Scotland that were halted by government regulators in New Zealand and public outcry in Scotland. Salmon producers worry that since AquaBounty has approached Chilean salmon farmers about growing its salmon once it is approved in the US, Chile, the second largest farmed salmon producer in the world, could become a major source of this GE fish.

Effect on Wild Stocks and Fisheries

Millions of farmed salmon have escaped from open-water net pens, competing with wild species for resources and placing an increased pressure on ecosystems.[iv] 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. States that have commercial salmon fishing are Alaska, California, Oregon and Washington. Species of commercially fished salmon are: Chum, Pink (Humpback), Sockeye (Red), Coho (Silver), Chinook (King). Each state has different regulations on which species can be fished commercially; for example, in Alaska you can fish for all five species of salmon. In the Northeastern United States, wild Atlantic salmon is on the endangered species list and commercial fishing is prohibited. In both restricted and commercial fisheries, GE salmon would pose serious risks to 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.

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.[v] 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.[vi] 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.[vii] 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.

The American Sportfishing Association (ASA), the trade association representing the sportfishing industry, released economic information indicating that a full recovery of California's Central Valley Chinook salmon runs can potentially provide $5.7 billion in new economic activity for the state and the creation of 94,000 new jobs. It is estimated that the current shutdown of the salmon fishery due to pollution and degradation of habitats is costing California $1.4 billion in lost economic activity and 23,000 jobs in both the commercial and recreational saltwater fishing sectors.[viii] As ASA suggests, reinvestment in wild fisheries could generate thousands of new jobs and billions of dollars in revenue. Investments to restore native Atlantic salmon fisheries in the Northeast are being made and through strong support there could be a similar creation of new jobs and additional revenue.

Conclusion

In moving forward, it is critical that economic impacts associated with the production and sale of GE salmon are fully addressed. In the recent Supreme Court case *Monsanto v. Geertson Farms*, the Court recognized that the threat of transgenic contamination is harmful and onerous to organic and conventional farmers and that the injury allows them to challenge future biotech crop commercializations in court. Given the serious potential economic consequences, not to mention potential environmental and human health risks associated with the GE salmon, FDA must complete an Environmental Impact Statement (EIS) to consider the range of foreseeable economic impacts of this novel fish.

Please contact Bill Wenzel, Policy Advisor for the Center for Food Safety (bwenzel@icta.org) or Colin O'Neil, Regulatory Policy Analyst for the Center for Food Safety (colin@icta.org)with any questions:
(ph) 202-547-9359 | (fax) 202-547-9429

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[i] Paul E. (2003, February 7). Biotech firms pay $110 million to settle StarLink lawsuit. *Associated Press. Available at* http://ipm.osu.edu/trans/023_071.htm.

[ii] Lake Research Partners, Commissioned by Food and Water Watch. 9/20/10 http://documents.foodandwaterwatch.org/release-FWW-Omnibus.pdf

[iii] Consumer Reports. 11/11/08 http://www.greenerchoices.org/pdf/foodpoll2008.pdf

[iv] 1 According to the Ministry of Agriculture and Lands (BCMAL)in Canada, the agency responsible for tracking industry-reported farmed salmon escapes, over 1.5 million farmed salmon escaped into BC waters between 1987 and 2008 (http://www.al.gov.bc.ca/fisheries/escape/escape_reports.htm); This is also referenced in a report by World Wildlife Federation [Eva B. Thorstad, Ian A. Fleming, Philip McGinnity, Doris Soto, Vidar Wennevik & Fred Whoriskey (January 2008). Incidence and Impacts of Escaped Farmed Atlantic Salmon in Nature, Technical Report to the Salmon Aquaculture Dialogue. World Wildlife Federation, p.5.

[v] 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.

[vi] 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

[vii] 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]

[viii] See "Economic Data Supports Efforts to Recover California's Salmon Fisheries" (August 2009) Commisioned by the American Sportfishing Association and produced by Southwick Associates.

FDA Quietly Pushes Through Genetically Modified Salmon Over Christmas Break

Anthony Gucciardi
Infowars.com
December 27, 2012

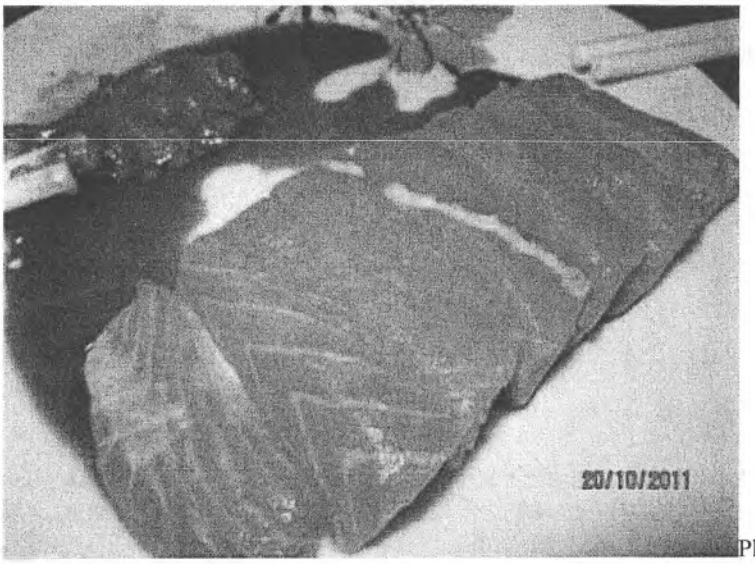

Photo by K.b.cheng, via Wikimedia Commons

While you were likely resting or enjoying time with friends and family over the Christmas break, the United States Food and Drug Administration was hard at work **ramming through genetically modified salmon** towards the final acceptance process. Despite the frankenfish actually being blocked by Congress last year over serious health and environmental concerns, the FDA is making a massive push to release the genetically modified salmon into the world as the FDA-backed biotech giant and creator of the fish AquaAdvantage screams for profits.

These fish of course threaten the very genetic integrity of the food chain when considering the fact that they will ultimately be unleashed into waters with other salmon and likely even the ocean at large. The AquaAdvantage genetically modified salmon have been engineered through genetic manipulation to grow double the size and weight of the average salmon. Hitting 24 inches instead of 13 and weighing in at 6.6 pounds instead of 2.8, the GM fish contains both a gene from another salmon known as the Pacific Chinook as well as an eel-like fish.

This unnatural genetic infusion allows the fish to generate a growth hormone 24/7, making it a massively mutated ball of growth hormones and disease.

Genetically Modified Salmon Threaten Genetic Stability of Food Chain

In the event that awareness is not spread and Congress allows the FDA to approve AquaAdvantage' GM salmon, it will become the first approved GM animal for growth and human consumption.

Modified salmon will mate with regular breeds, creating hybrid mutations that may likely never be tracked. Hybrid families that may continue to repopulate for generations, all containing modified genes. After being consumed by predators like sharks or others, the sharks are then affected by the genetically modified fish through the development of various health conditions. In mice trials alone it was found that eating GMOs triggered mass tumors and early death in the animals — **and that's just crops. Genetically modified crops are concerning enough, but are much less complex than animals.**

The fact of the matter is that **no one truly knows the long term effects of GM crops, let alone GM animals.** But hey, why not test it out on the public? After all, who cares? It's not like the FDA will do anything to Monsanto despite the numerous studies linking GMOs to disease. Instead, they just say it's pseudo science and that only FDA-backed 'science' is worth anything. Forget the fact that the only lifelong rat study done on GMOs found it led to tumor development.

So what can we do?

There are a number of methods here, but first and foremost the word needs to be spread far and wide that genetically modified salmon is being pushed through by the FDA. People despise GM products on average, with 90 plus percent in favor of at least labeling. In addition, there is a petition going around to send to politicians to ask them to stop this approval as they did in 2011.

Ultimately, it comes down to opposition. If enough people know this is coming and are very upset about it, they will have trouble ramming it through. That's why they announce these things over Christmas weekend. They don't want anyone to even hear about it — they want to make it harder to popularize since hardly anyone saw it.

We can beat this as we did back in 2011, and the FDA knows it. Their dirty tactics are not effective in the technological age in which the transfer of information is more powerful than ever. Share this news and spread the word. Block genetically modified salmon from getting put on your dinner table without any labels.

This article first appeared on Anthony Gucciardi's health site NaturalSociety.com.

AK First State to Require Labeling of GM Fish

May 31, 2005

Alaska has become the first state to enact a law requiring the labeling of certain genetically modified food. NCEL participant, State Senator Kim Elton, sponsored the bill, SB25, which was signed into law on May 19, 2005. The new law requires genetically modified fish or fish product to be conspicuously labeled as genetically modified. According to the Center for Food Safety, Senator Elton's legislation is the first such law passed in the country requiring labeling of genetically engineered food.

Senator Elton and NCEL participant Representative Beth Kerttula also worked to pass a resolution, HJR15, opposing open ocean fish farming and urging Congress to prohibit the issuance of any license to permit fish farming in federal waters. The National Oceanic and Atmospheric Administration, part of the Department of Commerce, is currently working on legislation to help foster ocean fish farming in federal waters (3 to 200 miles offshore), regulations that could have a far-reaching effect on the Alaska seafood industry. Alaska state law prohibits finfish farming.

In 2001, Maryland NCEL participant Delegate Dan Morhaim sponsored HB189, which was enacted, banning for at least five years the raising of genetically modified fish unless they are in ponds or lakes that do not connect to other state waterways. Growers also must ensure that the fish cannot escape. To view the Maryland law, use this link: .

California, Oregon and Washington have similar bans on genetically modified fish from being raised in state waterways. Michigan, Minnesota, Mississippi, and Wisconsin also regulate transgenic fish. The attached chart provides a summary and links to genetically modified fish regulations around the country. If you have an update to the list, please notify NCEL.

February 1, 2013

Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

RE: SUPPORT HJR 5, OPPOSING GENETICALLY MODIFIED SALMON

Dear Chairman Seaton and Fisheries Committee Members,

The Petersburg Vessel Owners Association (PVOA) is a diverse group of over 100 commercial fishermen and businesses based in Alaska. Our members provide millions of meals to the public annually by participating in a variety of fisheries statewide with our foremost interest being the commercial halibut and sablefish fisheries managed by the North Pacific Fishery Management Council. PVOA appreciates the opportunity to comment on HJR 5.

PVOA supports the passage of HJR 5. PVOA is already on record with the Food and Drug Administration opposing the development and marketing of GE Salmon. Alaska leads the world in sustainable fishery management practices and the Alaska seafood industry has gone to great effort and expense to differentiate our seafood products in the marketplace. **We oppose allowing genetically engineered (GE) salmon to be sold in the U.S. at all.** However, if GE salmon, or any GE salmon products are allowed to be sold in the U.S. then those products must be clearly and distinctly labeled as being genetically modified. We are particularly concerned that if GE salmon is allowed to be sold in the U.S. Alaska fishermen and coastal communities will suffer job losses and economic hardship due to consumer confusion about the origins and wholesomeness of salmon in general.

Thank you for the opportunity to comment on this resolution. If we can provide further information or answer any questions as you make this important decision, please feel free to contact us.

Sincerely,

Brian Lynch
Executive Director

Southeast Alaska Fishermen's Alliance
9369 North Douglas Highway
Juneau, AK 99801
Phone: 907-586-6652 Email: seafa@gci.net
Fax: 907-523-1168 Website: http://www.seafa.org

February 5, 2013

Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

RE: Support HJR 5

Representative Paul Seaton, Chair and Fisheries Committee Members,

Southeast Alaska Fishermen's Alliance (SEAFA) supports HJR 5, a resolution that opposes FDA's preliminary finding relating to Genetically engineered salmon and if approved that the end product should be labeled.

We urge speedy passage of this resolution so that it may be submitted by the Feb. 24 comment deadline published in the federal register.

We also urge the Alaska State Legislature to consider if a final approval is given to Aquabounty to require mandatory labeling in the State of Alaska.

Thank you for this opportunity to testify on this legislation. If you have any questions about our testimony or points raised in the testimony, please contact the office, we would be glad to provide additional information.

Sincerely,

Kathy Hansen
Executive Director

HAINES BOROUGH
RESOLUTION No. 10-11-247 **Adopted**

A Resolution of the Haines Borough Assembly, opposing an application from Aquabounty Technologies, Inc. to the U.S Food and Drug Administration (FDA) to approve and market genetically engineered Atlantic Salmon in the United States.

WHEREAS, AquaBounty Technologies, Inc. has submitted an application to the U.S. Food and Drug Administration (FDA) for approval of the "AquAdvantage Salmon," a genetically engineered Atlantic salmon for human consumption in the United States; and

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

WHEREAS, the "AquAdvantage Salmon" was bred by inserting a recombinant DNA construct (also called a transgene) comprised of a Pacific Chinook salmon growth hormone gene and an Ocean Pout antifreeze protein gene into fertilized eggs of wild Atlantic salmon; and

WHEREAS, the breeding of six subsequent generations led to an "AquAdvantage Atlantic Salmon" line which bears a single copy of the integrated transgene; and

WHEREAS, the brood stock used in spawning of "AquAdvantage Salmon" are females containing two copies of the transgene that have been scientifically sex-reversed for breeding purposes, therefore labeled neomales, which are then crossed with female Atlantic salmon that do not possess the transgene to produce eggs containing a single copy of the transgene; and

WHEREAS, the fish that develop from these eggs have an enhanced growth rate compared to non-transgenic Atlantic salmon; and

WHEREAS, AquaBounty proposes fertilization and incubation to the eyed-egg stage on Prince Edward Island, Canada; shipment of the eyed-eggs to Panama; grow-out and processing of fish in Panama; and shipment of processed fish to the United States for retail sale; and

WHEREAS, the development of "AquAdvantage Salmon" has been ongoing for approximately 15 years, yet the product has not been the subject of thorough scientific research and testing to ensure its consumption is safe in the long term; and

WHEREAS, many salmon consumers purchase the product for its widely recognized health benefits, this lack of safe consumption testing could weaken consumer confidence in all salmon products; and

WHEREAS, Alaska's wild seafood industry, which is extremely important to the economy of the Haines Borough, could be severely impacted by the introduction of genetically engineered salmon,

NOW, THEREFORE BE IT RESOLVED that the Haines Borough opposes approval of genetically engineered salmon for release in the wild and for human consumption in the United States based on strong economic, environmental, and human health concerns.

BE IT FURTHER RESOLVED that Haines Borough calls upon the FDA to not approve the application from AquaBounty Technologies, Inc. to market and sell genetically engineered Atlantic salmon for human consumption in the United States.

Adopted by a duly-constituted quorum of the Haines Borough Assembly on this 30th day of November, 2010.

Janice Hill, Borough Mayor

Attest:

Julie Cozzi, Borough Clerk

HAINES BOROUGH INCORPORATED SEAL OCTOBER 17 2002 STATE OF ALASKA

UNITED FISHERMEN OF ALASKA

Mailing Address: PO Box 20229, Juneau AK 99802-0229
Physical Address: 410 Calhoun Ave Ste 101, Juneau AK 99801
Phone: (907)586-2820 **Fax:** (907) 463-2545
Email: ufa@ufa-fish.org **Website:** www.ufa-fish.org

February 1, 2013

Representative Paul Seaton, Chairman
House Special Committee on Fisheries
Alaska State Legislature
State Capitol
Juneau, AK 99801-1182

RE: SUPPORT HJR 5, OPPOSING GENETICALLY MODIFIED SALMON

Dear Chairman Seaton and Committee Members,

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 leads the world in 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, 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 34 Alaska Commercial fishing organizations, and hundreds of individual fishermen and related businesses. We support HJR 5 and we applaud the State Legislature for your dedication to Alaska's fisheries and position in the global marketplace.

Sincerely,

Julianne Curry
Executive Director

MEMBER ORGANIZATIONS
Alaska Bering Sea Crabbers • 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 • Cape Barnabas Inc. • Concerned Area "M" Fishermen • Cook Inlet Aquaculture Association • Cordova District Fishermen United
Douglas Island Pink and Chum • 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 Fisherman's Alliance • Southeast Alaska Regional Dive Fisheries Association
Southeast Alaska Seiners • Southern Southeast Regional Aquaculture Association • United Catcher Boats • United Cook Inlet Drift Association
United Southeast Alaska Gillnetters • Valdez Fisheries Development Association

International Seafoods of Alaska, Inc.

Kodiak • Egegik • Seattle

February 1, 2013
Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

Chairman Seaton and Fisheries Committee Members,

We are a seafood processor in Kodiak, Alaska. We process wild caught Salmon, which is imperative to our local community. As a member of the seafood industry, our company has a vested interest in the health of the wild salmon stocks. GE salmon run the risk of escaping into the wild and harming wild salmon populations. We have seen, with farmed salmon, that despite measures taken, they cannot be controlled and kept out of the wild salmon stock, and often are infected with sea lice.

GE salmon will also threaten the jobs of Alaskan fisherman and coastal communities that thrive off of the commercial fishing industry. The fishing industry in the state of Alaska is the largest source of private sector employment and is valued at $505 million.

It is important the FDA and the Federal Government hear our concerns, and adequately assess the threat that GE salmon pose to our state.

Thank you for the opportunity to voice our support for House Joint Resolution 5.

Sincerely,

Ted Kishimoto
Vice President
International Seafoods of Alaska, Inc.

☑ 517 Shelikof Street
P.O. Box 2997
Kodiak, AK 99615-2997, USA
TEL: 907 / 486-4768
FAX: 907 / 486-4885

KODIAK SEAFOOD

☐ 2360 West Commodore Way
Seattle, WA 98199-1285, USA
TEL: 206 / 284-4830
FAX: 206 / 286-5920

February 8, 2013

Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

Chairman Seaton and Fisheries Committee Members,

My name is Sara Pozonsky and I co-own Wild Alaskan Salmon Company, an online Alaskan seafood store (www.SEABEEF.com). I am also the producer of a documentary called A Fishy Tale, which exposes the devastating environmental and health impacts of farmed fish. You can learn more about the film at www.afishytalemovie.com.

I grew up commercial fishing with my father, Chuck Crapuchettes, out in the Bristol Bay as well as in the Cook Inlet and fell in love with Alaska and our fisheries at a young age. I have a huge interest in keeping our marine environment pristine, and especially the health of our wild salmon stocks. I am so concerned about the risks of farmed salmon, and now Frankenfish, that I have privately funded a documentary to try to spread awareness about this devastating industry and practice.

We are told that GE salmon (Frankenfish) are sterile and, even if they escape, they will not harm our wild salmon populations. However, since we have no prior history with this genetically modified salmon, we do not know how much trust we can put into that claim. In fact, of the GE salmon tested, it is noted that up to 5 percent of the fish could be fertile even though they're engineered to be sterile females.[1] We have seen with farmed salmon, that they cannot be controlled and kept out of the wild salmon stock, and have devastated the wild salmon fisheries that surround them. In addition, the amount of pollution that fish farms produce is devastating to the ocean floors and kills all marine life and organisms living there. In fact, NASA space photos reveal that ocean dead zones are found most everywhere open-net fish farms are located.

Also of great concern, is that Monsanto, THE fish feed producer for GE salmon, is spending an absurd amount of money lobbying Congress protecting their interests and have also made sizeable donations to Congressman re-election campaigns. According to OpenSecrets.org data, Monsanto spent almost 6 million dollars in lobbyist efforts in 2012, more than any other agribusiness firm except the tobacco company Altria. [2]

It makes it almost impossible to compete against that kind of power. The money spent by any environmental coalition or concerned person trying to combat Monsanto pales in comparison. It makes it all the more important that Alaska, and all concerned private citizens around the world, join in this important battle by adding their voice to the opposition of GE salmon.

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[1] Genetically Engineered Salmon Nears FDA Approval - http://abcnews.go.com/Health/genetically-modified-frankenfish-nears-fda-approval-debate-heats/story?id=18078157&page=2

[2] Monsanto Co - http://www.opensecrets.org/lobby/clientsum.php?id=D000000211&year=2012

All farmed fish threatens the jobs of Alaskan fisherman and coastal communities that thrive off of the commercial fishing industry. Alaskans need to be vigilant and on guard, making sure that even if the federal government allows GE salmon to be sold, that no fish farm be allowed to operate in Alaska.

Alaskan fishermen have taken great pride in the fact that our government has outlawed fin-fish farms. However, federal waters run well into some of our most pristine commercial fishing waters, and any fish farm located in those waters would devastate those local fisheries. Alaskans do not have control over what the federal government does in federal waters. It would take someone only one visit to British Columbia in Canada to see the economic and environmental devastation fish farms have caused to their once vibrant wild salmon fishery and community.

The health risks of consuming GE salmon are unknown. The health risks of consuming any farmed fish have always been alarming and called into question. We know that the environmental impacts of farmed salmon have also been devastating, and we should expect nothing less from these genetically modified GE salmon. The escape of GE salmon could be devastating to wild fisheries as has been demonstrated by the current farmed fish industry. Prior to approval, the FDA must do its own independent and credible research – not base its findings on the studies given to them by the makers of GE salmon.

And finally, the labeling of GE salmon, and all farmed salmon, must be required. Just as alcohol and cigarette companies are required to put health warnings on their labels, the federal government should require these same health warnings to be on all farmed salmon, especially salmon that has been genetically modified.

It is important the FDA and the Federal Government hear our concerns, and adequately assess the economic threat that GE salmon poses to Alaska.

Thank you for the opportunity to voice my support for House Joint Resolution 5.

Sincerely,

Sara Pozonsky, Owner
Wild Alaskan Salmon Company

Producer, A Fishy Tale

February 8, 2013

Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

Chairman Seaton and Fisheries Committee Members,

PLEASE READ!!!!!!!!!!!!!!!!!!!

Pickled Willys is the only salmon pickling plant in Alaska. Located in Kodiak, our products are sold largely on the basis of the quality of our fish and its health claims. Organic vinegar, sustainable fish and made in Alaska. Genetically engineered salmon, should it get into our waters, (and it will) WOULD KILL OUR PRODUCT AND OUR BUSINESS. I plead with you not to allow this to happen. Retired from the medical field in high risk pregnancy, working with genetics every day I understand what this is about. Genetically engineered salmon once in our system will never be reversed or contained. This is a decision that will impact our salmon in Alaska and other areas for the life of our plant. This should not and can't happen. If the FDA lets this go ahead than they should provide me (or the company who lets it escape) with the means to show my salmon is not GE. This should come at no cost to me.

Genetically engineering life always comes with a consequence and I don't want it to be Alaska.

As a member of the seafood industry, our company has a vested interest in the health of the wild salmon stocks. GE salmon run the risk of escaping into the wild and harming wild salmon populations. We have seen, with farmed salmon, that despite measures taken, they cannot be controlled and kept out of the wild salmon stock, and often are infected with sea lice.

GE salmon will also threaten the jobs of Alaskan fisherman and coastal communities that thrive off of the commercial fishing industry. The fishing industry in the state of Alaska is the largest source of private sector employment and is valued at $505 million.

It is important the FDA and the Federal Government hear our concerns, and adequately assess the threat that GE salmon pose to our state.

Thank you for the opportunity to voice our support for House Joint Resolution 5.

Sincerely,

Barbara Hughes
Co/owner
Pickled Willys LLC
907-512-7635

ALASKA GLACIER SEAFOODS INC
"Alaska's Finest"

February 6, 2013

Alaska State Legislature
House Fisheries Committee
Representative Paul Seaton, Chair
State Capitol
Juneau, AK 99811

Chairman Seaton and Fisheries Committee Members,

Alaska Glacier Seafoods is a family owned seafood company with approximately 135 employees seasonally in Juneau, Alaska. We have been operating since 1996 and have become extremely dependent on the strong stocks of our wild fisheries.

As a member of the seafood industry, our company has a vested interest in the health of the wild salmon stocks. GE salmon run the risk of escaping into the wild and harming wild salmon populations. We have seen, with farmed salmon, that despite measures taken, they cannot be controlled and kept out of the wild salmon stock, and often are infected with sea lice.

GE salmon will also threaten the jobs of Alaskan fisherman and coastal communities that thrive off of the commercial fishing industry. The fishing industry in the state of Alaska is the largest source of private sector employment and is valued at $505 million.

It is important the FDA and the Federal Government hear our concerns, and adequately assess the threat that GE salmon pose to our state.

Thank you for the opportunity to voice our support for House Joint Resolution 5.

Sincerely,

Michael J Erickson Sr.
President
Alaska Glacier Seafoods

P.O. BOX 34363 • JUNEAU, ALASKA 99803 • (907) 790-3590 • Fax: (907) 790-4286

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.

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 States Senate

WASHINGTON, DC 20510

January 11, 2013

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

Re: Docket No. FDA-2011-N-0899

Dear Dr. Hamburg:

We, the undersigned United States Senators, request a 60-day extension to the public comment period for the U.S. Food and Drug Administration's (FDA) draft Environmental Assessment (EA) and preliminary Finding of No Significant Impact (FONSI) concerning genetically engineered Atlantic salmon.

While the AquaBounty Technologies proposal has been under consideration for some 15 years, the surprise publication of the draft EA and FONSI on Dec. 26, 2012, came in the midst of the holiday season when the public was more concerned with family matters than reviewing a 144-page, highly-technical scientific document.

Publication of the FDA's findings also came just days before the new Congress was sworn in. Many incoming members from affected states will be preoccupied with organizational issues during the next few months that will preclude them from giving adequate attention to a precedent-setting decision that could lead to approval of the first genetically engineered animal for human consumption.

We continue to have serious concerns about the AquaBounty proposal and the FDA review process that would regulate a proposed food product as if it were a new animal drug. The FDA review narrowly applies only to a limited set of production and rearing facilities, and fails to consider the implications of the broader application of this technology which assuredly would occur should the FDA's final approval be granted.

Congress has and will continue to raise these and other concerns about this controversial and unsustainable seafood product, including the potential escape of these engineered fish into U.S. waters. Legislation will be introduced in the 113th Congress to seek a more comprehensive environmental review of this and other genetically engineered fish, and require labeling of any such products sold in the U.S. so consumers are aware of what is on their dinner plates.

An extension of the public comment period regarding approval of the first genetically engineered animal for human consumption is necessary and appropriate. A 60-day extension to afford better public review of this draft action is minimal when compared to lengthy review process already afforded this proposal.

Thank you for consideration of this request.

Sincerely,

Mark Begich
United States Senator

Patty Murray
United States Senator

Ron Wyden
United States Senator

Barbara Mikulski
United States Senator

Lisa Murkowski
United States Senator

Maria Cantwell
United States Senator

Jeff Merkley
United States Senator

United States Senate

WASHINGTON, DC 20510

September 28, 2010

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hamburg:

We the undersigned members of the United States Senate request you halt all proceedings related to the U.S. Food and Drug Administration (FDA) approval of the first genetically engineered (GE) animal for human consumption – a hybrid salmon produced by AquaBounty Technologies. There are a number of serious concerns with the current approval process and many potential human health and environmental risks that are associated with producing GE fish have not been fully or openly reviewed. Critical information has been kept from the public and consequently, only FDA and AquaBounty know important details about the approval process for this GE salmon, or the product itself. Accordingly, we urge you to discontinue the FDA's approval process of the GE salmon at this time to protect consumers, fishing and coastal communities, and the environment.

AquaBounty's GE product is a transgenic Atlantic salmon egg, in which genes from an ocean pout have been inserted into the genes of Chinook salmon, and then inserted into an Atlantic salmon. The egg is meant to produce a fish that grows to full size twice as fast as a normal Atlantic salmon. The eggs are intended for sale to aquaculture companies which will grow them to market-sized fish to be sold for human consumption.

One of the most serious concerns regarding AquaBounty's application is the FDA has no adequate process to review a GE animal intended as a human food product. FDA is considering this GE fish through its process for reviewing a new drug to be used by animals, not for creation of a new animal, especially one intended for human consumption. Clearly, this is inappropriate. Creation of a new genetically engineered species should not be treated as an animal drug issue but undergo formal evaluation by FDA's Center for Food Safety and Applied Nutrition to review the product's potential health effects on humans.

Such a limited review of the first GE animal for human consumption is wholly inadequate to review potential public safety concerns associated and recklessly and needlessly endangers consumer health. A recent *New York Times* article reported, "the engineered salmon have slightly higher levels of insulinlike growth factor," and "some

studies suggest that high levels of [this] insulinlike hormone in the bloodstream are associated with greater cancer risk."

The FDA's review process lacks transparency. It has been nearly impossible for the public to obtain clear information about the FDA's process or particulars about the fish itself. According to existing regulations, FDA is not required to release important details regarding AquaBounty's GE salmon as this is considered a "trade secret." Even though the proposal has been pending for nearly a decade, the FDA only recently released some information on the matter barely two weeks before public hearings began on Sunday, September 19. FDA should have made public all information regarding the salmon well in advance of any hearings to encourage full and knowledgeable public participation. To have facilitated broader public participation, hearings on such a contentious issue should not have been held in Rockville, Maryland, but rather in a more central location and with outreach to regions dependent on wild salmon production.

There are serious concerns about damage to the environment if FDA approves AquaBounty's GE salmon. While the current application only covers the grow-out of GE salmon at a land-based facility, we believe that any approval must also include a thorough review of the possible devastating effects were fish farmers to grow GE fish in open water net pens and cages. Such a review is essential given the threats posed by escaped fish, fish waste, other pollutants, and infectious diseases that could spread to the natural environment.

AquaBounty claims its eggs will produce reproductively sterile fish to help prevent any escaped fish from interbreeding with wild fish. However, the company's own data suggests 5 percent of its eggs may not be sterile and it plans to produce millions of eggs. Studies suggest that an invasion of transgenic fish that escape into a natural fish population could lead to the extinction of both wild and transgenic fish in that region even if they are sterilized. Concerns include competition for habitat and food, abnormal behaviors of farmed fish and their interactions with wildlife and uncertainty regarding all potential impacts. Finally, we are concerned about the dangerous precedent that this ruling could set, as companies will likely seek FDA approval for other genetically engineered products such as GE tilapia and GE trout.

Given the inappropriate approval process, the lack of transparency for over ten years regarding this particular application, and the myriad of potential human health and ecological risks associated with production and consumption of GE animals, we believe the AquaBounty salmon should not be approved for human consumption. We strongly urge you to stop the approval process immediately to allow for review and examination

of the various concerns associated with genetically engineered animals, openly and with meaningful public input.

Sincerely,

Mark Begich

Lisa A. Murkowski

Patty Murray

Bernard Sanders

Maria Cantwell

Ron Wyden

Patrick J. Leahy

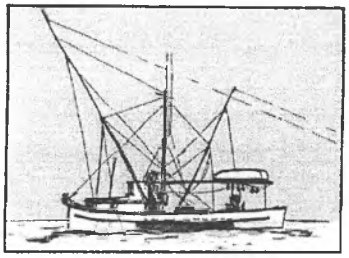
Kirsten E. Gillibrand

Barbara A. Mikulski

Jeff Merkley

Jon Tester

Cc: Kathleen Sebelius, Secretary of Health and Human Services
Michael, M. Landa, J.D., Acting Director, Center for Food Safety and Applied Nutrition
Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research



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 end 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

Dale Kelley
Executive Director

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907-465-3500
fax: 907-465-3532

Governor Sean Parnell
STATE OF ALASKA

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Governor@alaska.gov

September 23, 2010

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg,

The State of Alaska wishes to express its strong concern regarding AquaBounty's application to market genetically engineered Atlantic salmon. Due to the significant potential threats genetically engineered salmon pose to the environment, consumer health, and the wild seafood industry, we urge you to withhold approval of this application. Furthermore, we question whether the application has received sufficient scientific and public scrutiny, and are troubled by the lack of transparency that has marked the review process.

Like many, we fear genetically engineered salmon could jeopardize the health of wild salmon stocks if released into the wild. Genetically engineered salmon could spread disease, cross-breed with wild salmon, and out-compete them for food and mates. The U.S. Fish and Wildlife Service and National Oceanic and Atmospheric Administration (NOAA), in a joint letter to the FDA in 2001, and the National Academy of Sciences in a 2002 study, have recognized these concerns and warned the Food and Drug Administration (FDA) about the potential dangers associated with escaped genetically engineered fish.

While AquaBounty proposes containment measures to reduce the chance of genetically engineered salmon escapes, these measures would not eliminate the risk. That risk would grow if AquaBounty supplies genetically engineered salmon eggs to a network of commercial farms, as the company intends. Alaskans are well aware that fish farming containment measures are not fail-safe. Commercial fishermen in Alaska have caught hundreds of Atlantic salmon, escaped from fish farms in Canada and the state of Washington.

We urge you to honor a provision introduced by the late Senator Ted Stevens and Senator Lisa Murkowski, which became law as part of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85). The provision requires the FDA Commissioner "to consult with the Assistant Administrator of the National Marine Fisheries Service of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks." This statutory language was intended to ensure NOAA played a role in the FDA's approval process for genetically engineered seafood products. To our knowledge, no such report has been produced for AquaBounty's genetically engineered salmon.

Before genetically engineered salmon are allowed into the U.S. food supply, more rigorous scientific research is necessary to ensure its long-term consumption is safe for a large cross-section of the population, including sensitive populations such as young children and expectant mothers. As you know, salmon is widely recognized for its health benefits, and many consumers purchase salmon for this reason. Allowing a company to sell a genetically engineered product that has not been the subject of sufficient long-term testing would undermine consumer confidence in all salmon products, as well as the health benefits of salmon consumption.

Genetically engineered salmon could also erode the strength of the wild seafood industry, especially if appropriate labeling is not mandated. For Alaska, the results could be devastating. Alaska's salmon industry is critically important to the state's economy, and is the primary source of employment and revenue in many of our coastal villages. Farmed salmon has already threatened the position of Alaska's wild salmon in the seafood market. Alaska salmon, however, regained its status thanks to significant investments in infrastructure, product quality, and marketing. Marketers focused on distinguishing the health benefits and taste properties of Alaska salmon. Studies still show, however, that consumers struggle to distinguish seafood in the marketplace. Adding genetically engineered salmon to the store shelf could further complicate the efforts of consumers seeking healthy, wild seafood products.

The State of Alaska is also disturbed by the process employed by FDA to review AquaBounty's application. The environmental and public health implications associated with genetically engineered salmon and the significance of approving the first genetically modified animal for consumption in the U.S. warrant the highest level of public participation and transparency. The studies and data submitted to the FDA for consideration of AquaBounty's product were not made available to the public for review and comment until very recently, leaving consumers in the dark about the effects of genetically engineered salmon. We urge you to conduct a more public and transparent process.

Concurrent with the decision on approval of AquaBounty's application, we understand that the FDA is also considering the issue of product labeling for genetically engineered fish. The State of Alaska does not support approval of genetically engineered salmon for sale. If, despite significant environmental and human health concerns, the FDA approves such an application, it should also require that genetically engineered salmon sold in the United States be clearly labeled "genetically modified," so consumers can make an informed choice. This label should be prominently displayed on the front of the package in a contrasting color, and a minimum print size should be required. Alaska statutes require the conspicuous labeling of such products sold in the state.

I appreciate your consideration of Alaska's position on this important issue.

Sincerely,

Sean Parnell
Governor

cc: The Honorable Lisa Murkowski, United States Senate
The Honorable Mark Begich, 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

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December 14, 2011

The Honorable Mark Begich
Chairman
U.S. Senate Subcommittee on Oceans,
Atmosphere, Fisheries, and Coast Guard
420A Hart Senate Office Building
Washington, DC 20510

The Honorable Olympia Snowe
Ranking Member
U.S. Senate Subcommittee on Oceans,
Atmosphere, Fisheries, and Coast Guard
227 Hart Senate Office Building
Washington, DC 20510

Re: Environmental Risks of Genetically Engineered Fish

Dear Chairman Begich and Ranking Member Snowe,

I commend the subcommittee for its attention to the environmental risks associated with genetically engineered fish. My administration continues to have strong concerns regarding AquaBounty's application to market genetically engineered Atlantic salmon. Due to the significant potential threats genetically engineered salmon pose to the environment, consumer health, and the wild seafood industry, we have urged the United States Food and Drug Administration (FDA) to withhold approval of this application. Furthermore, we question whether the application has received sufficient scientific and public scrutiny, and are troubled by the lack of transparency that has marked the review process.

Threat to Wild Salmon Stocks

Like many, we fear genetically engineered salmon could jeopardize the health of wild salmon stocks if released into the wild. Genetically engineered salmon could spread disease, cross-breed with wild salmon, and out-compete them for food and mates. The United States Fish and Wildlife Service (FWS) and National Oceanic and Atmospheric Administration (NOAA) have recognized these risks, and warned the FDA about the potential dangers associated with escaped genetically engineered fish in a joint letter to the FDA in 2001, and the National Academy of Sciences in a 2002 study.

While AquaBounty proposes containment measures to reduce the chance of genetically engineered salmon escapes, these measures would not eliminate the risk. That risk would grow if AquaBounty supplies genetically engineered salmon eggs to a network of commercial farms, as the company intends. Alaskans are well aware that fish farming containment measures are not fail-safe. Commercial fishermen in Alaska have caught hundreds of Atlantic salmon, escaped from fish farms in Canada and the state of Washington.

Insufficient Consultation with National Marine Fisheries Service (NMFS)

We have urged the FDA to honor a provision authored by the late Senator Ted Stevens and Senator Lisa Murkowski, which became law as part of the Food and Drug Administration Amendments Act of 2007 (P.L. 110-85). The provision requires the Commissioner of FDA "to consult with the Assistant Administrator of the NMFS of the National Oceanic and Atmospheric Administration to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks." This statutory language was intended to ensure NOAA played a role in the FDA's approval process for genetically engineered seafood products. We are not convinced that this statutory obligation has been fully met.

Threat to Human Health and Consumer Confidence in Salmon

Before genetically engineered salmon is allowed into the United States' food supply, more rigorous scientific research is necessary to ensure its long-term consumption is safe for a large cross section of the population, including sensitive populations such as young children and expectant mothers. As you know, salmon is widely recognized for its health benefits, and many consumers purchase salmon for this reason. Allowing a company to sell a genetically engineered product that has not been the subject of sufficient long-term testing would undermine consumer confidence in all salmon products as well as the health benefits of salmon consumption.

Economic Impact on Wild Seafood Industry

Genetically engineered salmon could also erode the strength of the wild seafood industry, especially if appropriate labeling is not mandated. For Alaska, the results could be devastating. Alaska's salmon industry is critically important to the state's economy, and is the primary source of employment and revenue in many of our coastal villages. Farmed salmon has already threatened the position of Alaska's wild salmon in the seafood market. Alaska salmon, however, regained its status thanks to significant investments in infrastructure, product quality, and marketing. Marketers focused on distinguishing the health benefits and taste properties of Alaska salmon. Studies still show, however, that consumers struggle to distinguish seafood in the marketplace. Adding genetically engineered salmon to the store shelf could further complicate the efforts of consumers seeking healthy, wild seafood products.

Lack of Public Participation and Transparency

In addition, my administration is disturbed by the process employed by the FDA to review AquaBounty's application. The environmental and public health implications associated with genetically engineered salmon and the significance of approving the first genetically modified animal for consumption in the United States warrants the highest level of public participation and transparency. We do not believe that FDA's review process for veterinary drugs allows for a sufficiently public and transparent process.

Lack of Genetically Engineered Labeling

FDA's statements that suggest it may not be able to require labeling for AquaBounty's genetically engineered salmon is also troubling. The State of Alaska does not support approval of genetically engineered salmon for sale. If, despite significant environmental and human health concerns, the FDA approves such an application, genetically engineered salmon sold in the United States should

be clearly labeled "genetically modified," so consumers can make an informed choice. This label should be prominently displayed on the front of the package in a contrasting color, and a minimum print size should be required. Alaska statutes require the conspicuous labeling of such products sold in the state.

For the reasons mentioned above, I support legislation to prevent the FDA's approval of genetically engineered salmon for human consumption and to require appropriate labeling for any genetically engineered seafood products.

I appreciate your consideration of Alaska's position on this important issue and respectfully request that this letter be included in the hearing record.

Sincerely,

Sean Parnell
Governor

cc: The Honorable John Rockefeller, Chairman, United States Senate Committee on Commerce, Science, and Transportation
The Honorable Kay Bailey Hutchison, Ranking Member, United States Senate Committee on Commerce, Science, and Transportation
The Honorable Lisa Murkowski, United States Senate
The Honorable Don Young, United States House of Representatives
The Honorable Cora Campbell, Commissioner, Alaska Department of Fish and Game
The Honorable Larry Hartig, Commissioner, Alaska Department of Environmental Conservation

February 1, 2013
Representative Paul Seaton, Chairman
House Special Committee on Fisheries
Alaska State Legislature
State Capitol
Juneau, AK 99801-1182
RE: HJR 5 Oppose FDA Approval of GE Salmon

Mr. Chairman,

My name is Steve Merritt and I am a commercial fisherman living in Craig, Alaska. I strongly support HJR 5, 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.

The FDA has been allowed to conduct its analyses of GE salmon under a cloak of secrecy, in order to protect the patent rights of the companies involved. Of significant concern is that fact that this review is being conducted under the rules governing animal drugs – not food for human consumption. If this bogus analyses is allowed to prevail the implications for the future approval of basic cyanide as a food source, seems possible, as long as it passes the animal drug rules. The irrationality of approving a product heading for human consumption using rules that govern animal drugs can be called one thing. Stupid!!

Only one public hearing was held, by the FDA's veterinary committee, and participation was limited to a handful of people. Note that FDA only requested comments on labeling – not the question of whether or not GE salmon should be approved for human consumption. Ironically, FDA has no authority to label anything, leading to the question, Why even opened that comment period? This irrational dodging of the main issue is suggestive of only one thing. Corruption.!! It appears the FDA has been bought by Aquabounty so to sneak this GE salmon approval through no matter what the cost to consumer's safety. Is there nothing left in the back bone of the FDA's bureaucracy that is of any moral, ethical fiber? Any scientific rational thinking left? Has the US government fallen so far in the direction of squalidness, that it ignores this agency's blatant misconduct?

I ask you to uses your legislative powers and support HJR 5 in hopes to bring the FDA back in line and make that agency a respectable representative of the US government..
FDA has failed to adequately evaluate the impact of this designer fish on either humans or the environment. The agency must evaluate this product as a human food source – not a drug – and the data and FDA's analyses should undergo rigorous peer review. A full Environmental Impact Statement and consultation under the Endangered Species Act, on both the East and West Coasts. In addition, FDA, or another appropriate agency, should be given direction and authority to ensure that all life stages and final product forms of this creature are prominently labeled so an educated choice can be made by US consumers. A concept that founded this country!!

Sincerely, Steve Merritt

Steve Merritt
Box 1138
Craig, Alaska 99921

SEAGO
SouthEast **Alaska** Guides Organization

Rep. Geran Tarr
State Capitol, Rm. 114
Juneau, AK 99801

March 7, 2013

Dear Representative Tarr:

On behalf of the members and Board of Directors of the Southeast Alaska Guides Organization (SEAGO) which represents charter fishing operators, lodge owners and guided sport anglers throughout Southeast Alaska, I am offering this letter of support for your resolution CSHJR 5(FSH) "Oppose Genetically Engineered Salmon". This is consistent with our earlier position supporting Sen. Murkowski's amendment introduced in 2012 (S.AMDT.2108) to S.3187 – Food and Drug Administration Safety and Innovation Act.

SEAGO has no position on genetically engineered fish, generally. We acknowledge that there may be merit to the use of this technology as a means to help alleviate current and future global food shortages. However, we are concerned about how these fish may ultimately impact Alaska's wild fish stocks.

I'm sure you are aware of how important commercial, charter/recreational and subsistence fishing is to our state. Not only do hundreds of thousands of Alaskans feed their families on our abundant fish resources but thousands more Alaskans depend on our fisheries for their livelihoods and dozens of coastal communities rely heavily on the economic contributions these industries make.

For the last ten years or more, the Alaska Seafood Marketing Institute has spent thousands of hours and millions of dollars promoting Alaska's seafood products. As their promotional materials correctly assert, "Wild-caught Alaska salmon, whitefish varieties and shellfish mature at a natural pace, and swim freely in the pristine waters off Alaska's rugged 34,000-mile coastline." They go on further point out perhaps the single most important factor that distinguishes Alaska's seafood from that of any other throughout the world, "The superior flavor and texture of Alaska seafood is prized around the world."

Clearly, that natural process and the north Pacific marine environment is what makes Alaska seafood so highly sought after, globally. Furthermore, recreational anglers come from all areas of the world for the experience of the incredible fight associated with reeling in a wild Alaska Chinook.

News stories from the week of May 14th, 2012, throughout the Pacific Northwest are a testament to ASMI's assertions. The Seattle Times and the Anchorage Daily News, among others, heralded the arrival of the first shipments of Copper River King Salmon to restaurants in both cities.

Alaska seafood is a national treasure and one that significantly contributes to Alaska's economy.

To that end, SEAGO strongly supports your resolution

Southeast Alaska Guides Organization (SEAGO)
907.244.4909
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http://www.seagoalaska.org

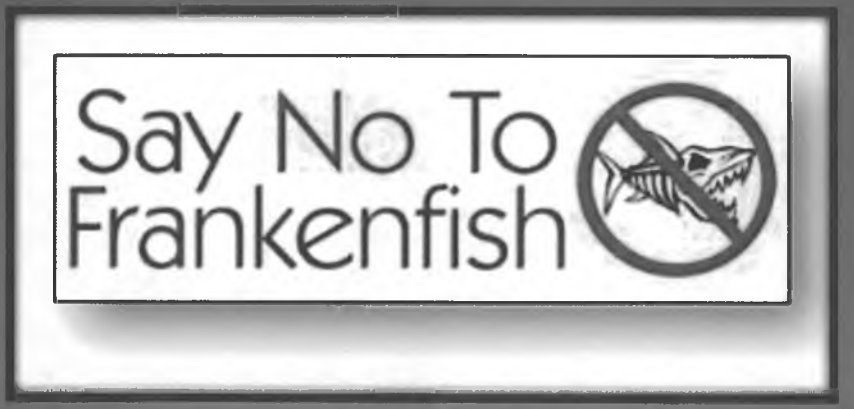
We remain concerned that despite best efforts to guarantee the sterility of these fish or separation of from wild fish through bioconfinement, that any escapement could jeopardize the health of the wild fish population either through competition or genetic compromise due to interbreeding.

We sincerely appreciate your efforts to provide adequate protections for Alaska's fisheries.

Sincerely,

Heath E. Hilyard, Executive Director
Southeast Alaska Guides Organization (SEAGO)

HJR 5: No to GM Salmon



Significance of this decision

- Final stage of approval
- First time FDA would approve a genetically modified (GM) organism for human consumption

What is GM salmon?

- Genetically modified using fast growing Atlantic salmon and DNA from two other species of fish
  - Ocean pout (an eel like fish)
  - Chinook salmon (King)

How does it work?

- Chinook DNA makes the GE fish grow bigger faster
- Ocean pout DNA makes it grow year-round

- The DNA of the top fish has been genetically engineered to continually produce growth hormones for its entire life
- GM salmon grow to full size twice as fast

Need for Action

- December 2012 announcement by FDA that genetically modified salmon pose no significant threat (FONSI)
- Comments being accepted until February 25, 2013
- Legislature would join Governor Parnell, Senators Mark Begich and Lisa Murkowski, and Representative Don Young in opposing this application

Concerns about GM salmon

- Possible effects of GM salmon
  - Threat to wild salmon
  - Risks to human health
  - Risk to state's economy

Threat to Wild Salmon

- Escapement poses a threat
- Reports from Alaska fisherman that they have caught farmed Atlantic salmon that was reared in Washington and British Columbia
- Risks were recognized by the USFWS and NOAA

Threat to Wild Salmon

- GM salmon can spread disease
- More aggressive, can out compete wild salmon
- Cross breed with wild fish

Risks to Human Health

- People who eat the GMO salmon will be eating the foreign DNA, along with the growth hormones.
- The FDA has not conducted sufficient long term safety testing to determine that genetically engineered salmon is safe to eat and that long- term consumption does not pose health risks
- Vulnerable populations: children and expectant mothers.

Risk to State's Economy

- Look back to introduction of farmed salmon
- Significant investments in marketing and branding for health benefits
- Could undermine confidence in Alaska wild salmon
- Second largest private sector employer with over 70,000 jobs

Let's speak in one
UNIFIED ALASKAN VOICE!

Questions?