



# Technology on Trial: How Resistance to Innovation is Threatening the Global Food Supply

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*<http://animalscience.ucdavis.edu/animalbiotech/>*



# The case of the fast growing AquAdvantage salmon

*The founder female was generated in 1989 – 21 years ago*

Nature Biotechnology 10:176 – 181. **1992**



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## **GROWTH ENHANCEMENT IN TRANSGENIC ATLANTIC SALMON BY THE USE OF AN “ALL FISH” CHIMERIC GROWTH HORMONE GENE CONSTRUCT**

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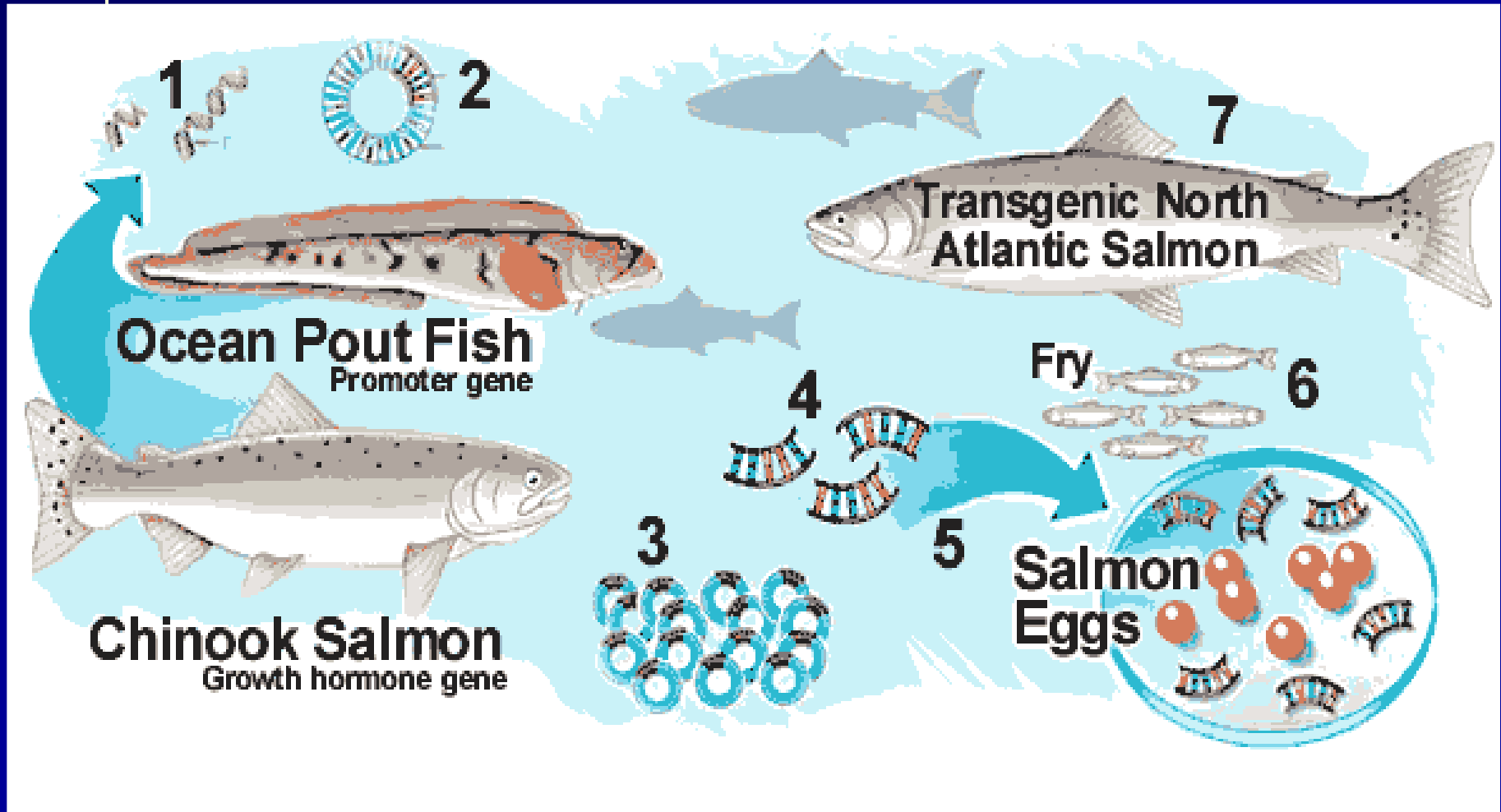
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We have developed an “all fish” growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon were generated. The presence of the transgene was



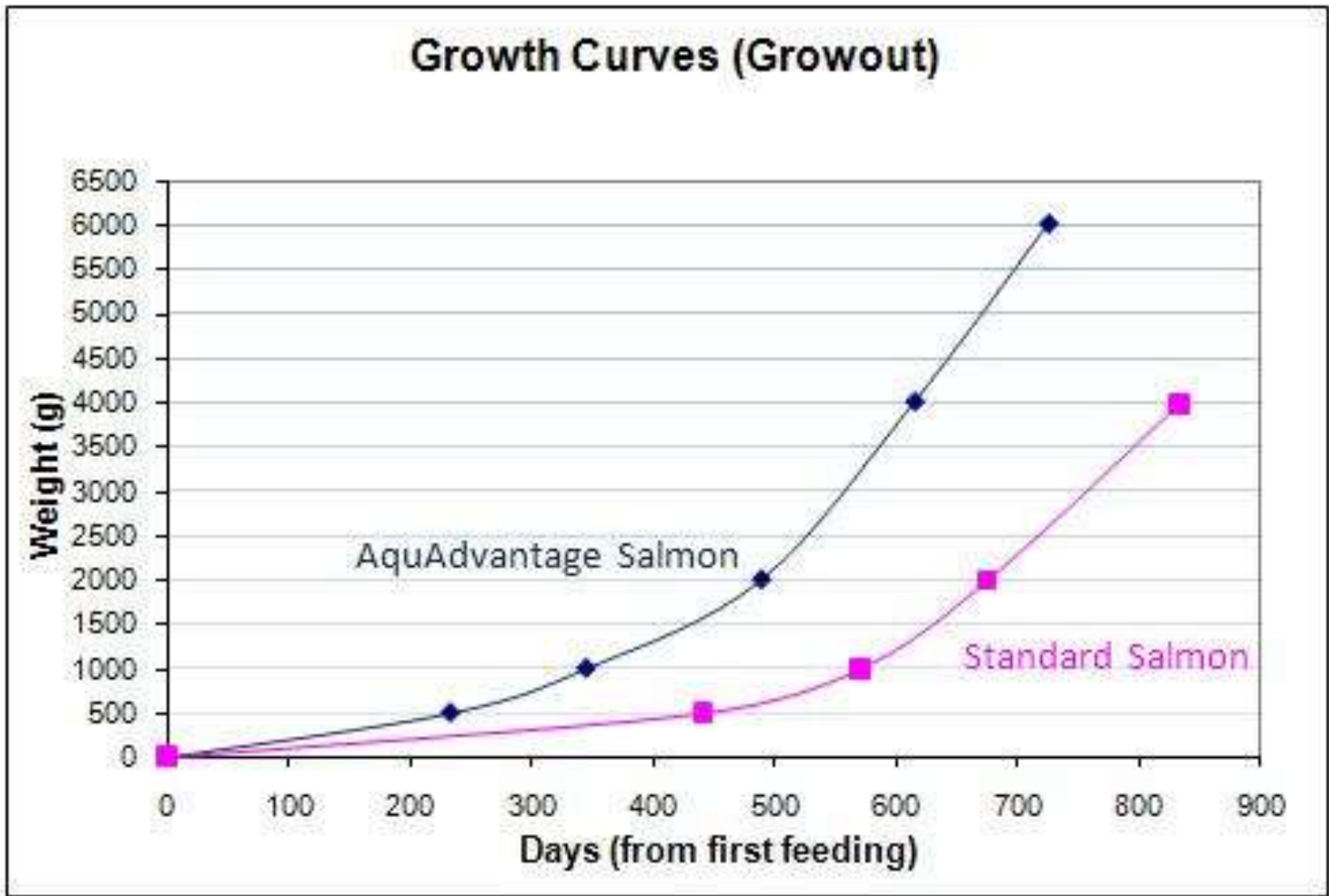


# What is the AquAdvantage salmon?





# Fish reach adult size in 16 to 18 months instead of 30 months





# Same-age siblings – one carrying a hemizygous copy of the transgene





# Retrieved from "AquAdvantage" image search on web Frankenfish





# Product Definition for the AquAdvantage Salmon

## Product Identity

Triploid hemizygous, all-female Atlantic salmon (*Salmo salar*) bearing a single copy of the  $\alpha$ -form of the opAFP-GHc2 rDNA construct at the  $\alpha$ -locus in the EO-1a lineage.

## Claim

Significantly more of these Atlantic salmon grow to at least 100 g within 2700 deg C days than their comparators.

## Limitations for Use

These Atlantic salmon are produced as eyed-eggs for grow-out only in the FDA-approved physically-contained fresh water culture facility.





## Food/Feed Safety: Does food or feed from the GE animal pose any risk to humans or animals consuming edible products from GE animals compared with the appropriate non-transgenic comparators?

Conclusion of food/feed safety evaluations:

*"We therefore conclude the food from AquAdvantage Salmon (the **triploid** ABT salmon) that is the subject of this application is as safe as food from conventional Atlantic salmon, and that there is a reasonably certainty of no harm from the consumption of food from this animal. No animal feed consumption concerns were identified".*

Page 62, AquAdvantage Briefing packet. <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>



# Environmental Safety: What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?

## *Where will the AquAdvantage Salmon be raised?*

If approved, the AquAdvantage Salmon will be raised **in inland tanks**. They will not be raised in ocean net pens. Any change would require a new application and approval.

There are multiple and redundant physical and mechanical barriers in place in the water systems at the PEI egg production and Panama grow-out facilities to prevent the accidental release of eggs and/or fish to nearby aquatic environments. These barriers have been designed specifically to prevent the escape of different life stages of AquAdvantage Salmon. Both facilities have a minimum of three to five mechanical barriers in place for all internal flow streams which release water to the environment. Standards and has been verified by an FDA inspection or site visit. Therefore, the likelihood is considered very low that AquAdvantage Salmon will escape from confinement at these sites.







# Summary of advantages of land-based (inland tank) SUSTAINABLE aquaculture



- Shorter production time – 16-18 months versus 30 months
- Shorter time to harvest diminishes the risk of disease and resultant use of chemotherapeutics/antibiotics
- Culture in a land based, contained (e.g recirculating) system reduces spread of disease in the environment (and wild salmon populations)
- Lower Food Conversion Ratio (i.e. LESS lbs feed eaten per lb product produced) - feed is major cost of animal production!
- Does not spawn during growout (more energy available for growth AKA less energy wasted on reproduction!).
- Land based salmon culture systems can be located adjacent to major markets, reducing freight costs and the associated environmental impact i.e. locally-grown “locivovre” source of fish



Date	Event
September 1995	AquaBounty submits Investigational New Animal Drug application with FDA for fast-growing salmon with intent to commercialize
September 2010	Public Veterinary Medicine Advisory Committee meeting to consider data on safety and efficacy of AquaAdvantage salmon Held in Washington DC





“There is little benefit to society if attempts to increase public participation in the regulatory process are used as an opportunity to demonize technology.”



**Wenonah Hauter of Food and Water Watch carries a box with public comments opposing FDA approval of genetically-engineered salmon.**



# Frankenfood, Coming Soon to a Store Near You?

Published September 20, 2010 | FoxNews.com

Print Email Share Comments (0) Recommend 799 Text Size



Reuters/Barrett & McKay Photo/AquaBounty Technologies

A genetically engineered AquAdvantage Salmon (background) is compared to an Atlantic salmon of the same age (foreground). The U.S. Food and Drug Administration will hold a two-day meeting starting September 19 to discuss whether to approve the altered fish for U.S. consumers to eat.

WASHINGTON – Watch for a new section between "frozen foods" and "organic" in your supermarket: genetically engineered. That is, if the government approves the so-called "frankenfoods" for sale.

The Food and Drug Administration Monday began a two-day look at the issue Monday, focusing on genetically modified salmon, which would be the first such food approved for human consumption.

The agency has already said the salmon, which grow twice as fast as conventional ones, are safe to eat. But salmon act as a genetic gatekeeper in this case: Approve them and open the door for a variety of other genetically engineered animals, including an environmentally friendly pig that is being developed in Canada or cattle that are resistant to mad cow disease.

"For future applications out there the sky's the limit," said David Edwards of the Biotechnology Industry Association. "If you can imagine it, scientists can try to do it."

SFS 10/12/2011

# Industry Fights Altered Salmon

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By ALICIA MUNDY And BILL TOMSON

The fishing industry and politicians from commercial-fishing states are mobilizing against a possible Food and Drug Administration approval of genetically modified salmon for the American dinner table.

"Putting unlabeled, genetically altered salmon in the marketplace is simply irresponsible, and the FDA needs to strongly consider what impacts this will have before they approve this Frankenfish," Sen. Lisa Murkowski, a Republican from Alaska, said Thursday.



View Full Image

Associated Press

Icy Bay crewmen remove sockeye salmon from their net in July. Commercial fisheries are fighting the introduction of genetically altered salmon.

They cited concerns about "human health and environmental risks" from the AquAdvantage salmon.

The resistance could raise difficulties for the FDA, whose scientists have said the AquAdvantage Atlantic salmon developed by AquaBounty Technologies Inc. is safe for human consumption. AquAdvantage contains a growth-hormone gene from another salmon that helps it grow twice as fast as conventional farmed fish.

A coalition that includes Pacific Coast trollers, Atlantic fishing companies and organic-yogurt maker Stonyfield Farm says the genetically altered salmon might threaten their livelihoods by spreading unease about salmon and other foods.

"This stuff is not healthy for people, and it's not like our fresh fish," said Angela Sanfilippo, president of the Gloucester Fishermen's Wives Association of Massachusetts.

Ms. Sanfilippo's group and others have joined with 39 lawmakers who wrote to the FDA this week asking the agency to stop its approval process for the genetically modified salmon.

Animal Biotechnology and Genomics Education



**In September 2010, more than 40 members of Congress sent letters requesting FDA halt the approval of the long-shelved AquaBounty transgenic salmon.**

***"The FDA's hastily completed approval process puts American consumers and the environment at risk. GE salmon could be devastating to fishing and coastal communities, our food source, and already depleted wild salmon populations. The FDA should put the interests and safety of American families and our ocean resources above special interests"***

**Rep. DeFazio (D-OR) September 2010.**





# Fish facts

- In 2006 the world consumed 110.6 million metric tons of fish with ~ half coming from aquaculture
- Need to increase another 28.8 MMT by 2030
- Fish represent less than 8 percent of total U.S. consumption of meat, poultry and fish in 2001, salmon represented just 1 percent.
- Since 2001, salmon has ranked third among fish species consumed in the United States, after shrimp and canned tuna and accounted for about 14 percent of U.S. fish consumption.





# Salmon facts

- 1996: World farmed salmon production exceeds wild salmon harvest.
- In US the breakdown of salmon consumption
  - 1/3 was Pacific salmon and 2/3 is Atlantic salmon
  - 1/3 is wild and 2/3 is farmed
  - 1/3 is domestic production and 2/3 is imported
- 99% of the Atlantic salmon consumed in the US is farmed – almost all from aquaculture operations in Canada, Chile, Norway and Scotland
- Atlantic salmon do not interbreed with Pacific salmon i.e. can not harm Pacific salmon populations

**Review of Potential Impacts of Atlantic Salmon Culture on Puget Sound Chinook Salmon and Hood Canal Summer-Run Chum Salmon Evolutionarily Significant Units. 2002. NOAA Technical Memorandum NMFS-NWFSC-53**



# Average Annual U.S. Salmon Consumption, 2000-2004

(1000 metric tons, import and processing weight basis)



	Pacific	Atlantic	Total
Total	105	180	284
Canned	47	0	47
Frozen	36	24	60
Fresh	22	156	178
Domestic	81	10	91
Imported	24	170	193
Wild	97	2	99
Farmed	7	178	185

	Pacific	Atlantic	Total
Total	100%	100%	100%
Canned	45%	0%	16%
Frozen	34%	13%	21%
Fresh	21%	87%	63%
Domestic	77%	6%	32%
Imported	23%	94%	68%
Wild	93%	1%	35%
Farmed	7%	99%	65%

October 2011  
Davis, CA





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September 2010	Public Veterinary Medicine Advisory Committee meeting to consider data on safety and efficacy of AquAdvantage salmon
June 15 <sup>th</sup> 2011	House of Representatives passed a voice vote amendment that prohibit use of FDA funds to approve any application for approval of genetically engineered salmon. Offered by Reps. Don Young (R-AK) and Lynn Woolsey (D-CA).

Young argued that the modified fish are unnatural and their production could create competition for his state's fishing industry. In a statement, Young said he had deep concern about the salmon, which he dubbed "Frankenfish."

"Frankenfish is uncertain and unnecessary," Young said. "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. Any approval of genetically modified salmon could seriously threaten wild salmon populations as they grow twice as fast and require much more food."



# The Science and Regulation of Food from Genetically Engineered Animals

Authors:

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West Lafayette, Indiana

**June 20, 2011 Washington Roll-out of the CAST report to House Committee on Agriculture, including the lead staffer for Cong. Don Young (R-AK, sponsor of the amendment cutting FDA funds for oversight of GE salmon)**





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The letter was signed by Sens. Daniel Akaka (HI), Mark Begich (AK), Maria Cantwell (WA), Jeff Merkley (OR), Barbara Mikulski (MD), Lisa Murkowski (AK), Patty Murray (WA), and Jon Tester (MT).



**Van Eenennaam, A.L. and W.M. Muir. 2011. Transgenic salmon: a final leap to the grocery shelf? Nature Biotechnology. 29: 706–710.**



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**Transgenic salmon: a final leap to the grocery shelf?**

Alison L. Van Eenennaam & William M. Muir

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*Nature Biotechnology* 29, 706–710 (2011) | doi:10.1038/nbt.1938  
Published online: 05 August 2011

Despite being caught up in regulatory proceedings for 15 years or more, AquaAdvantage salmon, the first animal genetically engineered (GE) for food purposes, continues to raise concerns. Are any of these concerns scientifically justified?

The tortuous passage of AquaAdvantage salmon through the US regulatory system provides a stark reminder of the adage that sometimes it is good not to be first. A fast-growing transgenic fish containing a gene encoding Chinook salmon growth hormone under the control of an antifreeze protein promoter and terminator from ocean pout, AquaAdvantage salmon has been subjected to one of the most prolonged, if not exhaustive, regulatory assessments in history. This process culminated last September with a meeting of the Veterinary Medicine Advisory Committee (VMAC) as well as a public hearing, together with the release of a comprehensive health and safety briefing and an environmental assessment package on the transgenic animal developed by AquaBounty Technologies of Waltham, Massachusetts.

Despite VMAC's determination that AquaAdvantage salmon is "as safe as food from conventional Atlantic salmon," critics continue to raise concerns relating to its allergenicity, levels of insulin-like growth factor 1 (IGF-1) and composition of polyunsaturated fatty acids as well as the potential impacts of the fish on the environment. In the following article, we briefly trace the twists and turns taken by AquaAdvantage salmon through the US regulatory regime. We then address each of the remaining 'regulatory' concerns, which have been raised as justifications for delaying approval of this



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**Scientist defends genetically engineered salmon**



**UNITED STATES**  
**Tuesday, August 09, 2011, 02:00 (GMT + 9)**

A Purdue University scientist is urging US officials to make progress on the decision of whether genetically engineered (GE) salmon would be allowed for US consumption.

The scientist made the case that not doing so may hinder scientific efforts to bolster food production.

William Muir, a professor of animal sciences, said that the data made available by the [US Food and Drug Administration \(FDA\)](#) points to [AquaBounty Technologies's](#) AquaAdvantage (AA) salmon posing little real risk to the environment or human health.

"Once the assessment has been completed and the agency concludes from the weight of evidence that risks of harm, either to the environment or to consumers, is negligible, the next step, which is to allow production and sale of the product, needs to be taken," Muir said.

Muir and Alison L Van Eenennaam, an animal genomics and biotechnology Extension specialist at the University of California Davis, urged FDA approval in a peer-reviewed commentary in the online version of the journal *Nature Biotechnology*.

August 9, 2011



# **Animal Agriculture Coalition (see below) sent leaders in the House and Senate a letter defending the use of a science-based review process to evaluate genetically engineered products (August 2011).**



American Association of Bovine Practitioners

American Association of Swine Veterinarians

American Association of Veterinary Laboratory Diagnosticians

American Farm Bureau Federation

American Feed Industry Association

American Horse Council

American Meat Institute

American Rabbit Breeders Association

American Sheep Industry Association

American Society of Animal Science

American Veal Association

American Veterinary Medical Association

Animal Agriculture Alliance

Animal Health Institute

Association of American Veterinary Medical Colleges

Association of Veterinary Biologics Companies

Biotechnology Industry Organization

Catfish Farmers of America

Council for Agricultural Science and Technology

Federation of Animal Science Societies

Holstein Association USA, Inc.

Livestock Exporters Association of the USA

Livestock Marketing Association

National Aquaculture Association

National Association of Federal Veterinarians

National Cattlemen's Beef Association

**(NCBA)**

National Chicken Council

National Dairy Herd Improvement Association

National Farmers Union



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August 2011	Three Massachusetts representatives write to Commissioner Hamburg to urge her to let the FDA continue its scientific investigation. The representatives' letter states that the FDA has spent 15 years working with AquaBounty to collect health, safety, and environmental data; sought consultation and expertise from other federal agencies; and evaluated the safety and effectiveness of the genetic modification.



## Senators offer amendments to ag appropriations bill

WASHINGTON — Amendments to keep the Food and Drug Administration from approving “Frankenfish” genetically modified salmon and to stop the Agriculture Department from cutting back on the use of potatoes and other starchy vegetables in the school lunch program are among those that might be offered on the Senate floor if the Senate version of the fiscal year 2012 Agriculture appropriations bill comes up there as an independent piece of legislation.

By: Jerry Hagstrom, Special to Agweek

September 12, 2011

Sen. Dianne Feinstein, D-Calif., told Murkowski, “I don’t like genetically modified anything,” but added that this situation had “caught us cold” and that she would prefer to “do due diligence” before voting on the amendment.

<http://www.agweek.com/event/article/id/19068>

September 13, 2011

Alison- Senator Feinstein has asked me to prepare a substantive briefing for her of the potential impacts of the AquaBounty Salmon on California. Generally, she has questions regarding the process used to approve the fish (treating it as an animal drug) and is concerned about the environmental impacts as well.

Would you be available to speak on this subject?

Devin Rhinerson

Office Of Senator Dianne Feinstein



# Chinese work on transgenic animals



## Production of recombinant human lysozyme in the milk of pig to improve the diarrhea-resistance ability of piglets

In the swine industry pathogenic infections have a significant negative impact on neonatal survival. The team lead by Prof. Ning Li in China Agricultural University has worked on improving the ability of piglets to resist diarrhea disease since 2008 and successfully produced many transgenic pigs with expressing recombinant human lysozyme in the milk. To date, the total number of transgenic pigs with recombinant human lysozyme is up to 272. The experiment has entered the productive experiment stage.

**Production of transgenic pigs**

Production of transgenic pigs involves the insertion of the human lysozyme gene into the pig genome. The process includes the construction of a recombinant plasmid vector, followed by microinjection into pig embryos and subsequent selection of transgenic piglets.

**Transgenic piglets**

Transgenic piglets are born with the human lysozyme gene integrated into their genome. They are raised in a controlled environment to ensure the successful expression of the recombinant human lysozyme in their milk.

## Transgenic pigs specifically express phytase in the parotid gland

CAU & SCAU

Total got 21 transgenic founders of reduced phosphorus content in the feces

Phosphorus in transgenic pig feces 21.4%

**Phytase transgenic cloned pigs**

Phytase transgenic cloned pigs are produced by inserting the phytase gene into the pig genome. These pigs are used to study the effects of phytase on phosphorus metabolism and to improve the efficiency of phosphorus utilization in swine.

## shRNA Transgenic Pig Display Significant Resistance to the Infection of FMDV

the shRNA expressive vector pMD19-EN3D2B against both nonstructural protein 2B and polymerase 3D of FMDV was transferred, and 23 transgenic cloned pigs generated (2010) by Prof. Li Ning in China Agriculture University.

In the 10 ID<sub>50</sub> and 100 ID<sub>50</sub> challenge, transgenic cloned pigs all performed the ability of anti-FMDV, and one transgenic cloned pig was protected during all the challenge period.

**shRNA Transgenic Pig**

shRNA transgenic pigs are produced by inserting the shRNA vector into the pig genome. These pigs are used to study the effects of shRNA on FMDV infection and to improve the resistance of swine to FMDV.

## sfat-1 Transgenic Cattle increased the Omega-3 fatty acids in dairy and beef

Prof. Guangpeng Li group from Inner Mongolia University generated sfat-1 transgenic dairy cattle and beef cattle in 2009 and 2010. These cattle was supposed to increase the omega-3 fatty acids of beef or milk.

**sfat-1 Transgenic Cattle**

sfat-1 transgenic cattle are produced by inserting the sfat-1 gene into the cattle genome. These cattle are used to study the effects of sfat-1 on fatty acid composition and to improve the quality of dairy and beef products.

Fatty acid	Wild type					sfat-1 Transgenic				
	1	2	3	4	5	6	7	8	9	
18:2n-6	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	0.08	
20:4n-6	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
22:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
24:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
26:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
28:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
30:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
32:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
34:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
36:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
38:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	
40:6n-3	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	