The science and politics of the AquAdvantage genetically engineered salmon

Alison Van Eenennaam, Ph.D.

Cooperative Extension Specialist

Animal Biotechnology and Genomics

Department of Animal Science

University of California, Davis

alvaneenennaam@ucdavis.edu

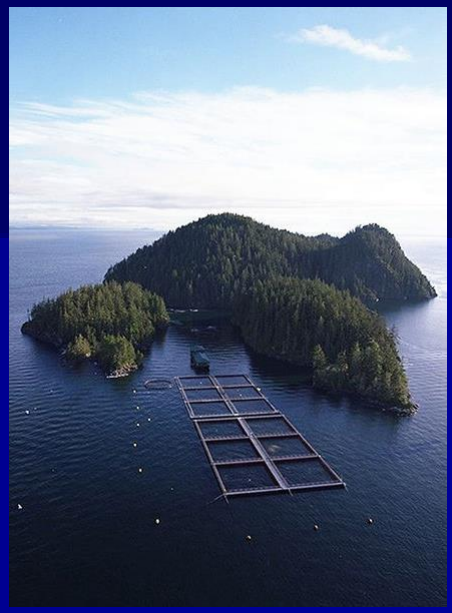
"The mission of the animal genomics and biotechnology extension program is to provide broad, science-based extension programming on the uses of animal biotechnologies in livestock production systems."

http://animalscience.ucdavis.edu/animalbiotech

Salmon

- 1996: World farmed salmon production (mostly Atlantic salmon) first exceeded wild salmon harvest
- Americans consume an average of about 0.28 MMT of salmon annually
  - ⅓ was wild Pacific salmon and ⅔ was imported, farmed Atlantic salmon
  - 99% of the Atlantic salmon consumed in the US is farmed – almost all from ocean pen aquaculture operations in Canada, Chile, Norway and Scotland
- Atlantic salmon can not interbreed with Pacific salmon – they are different species

There are three types of salmon aquaculture



- Sea cages or open net pens
- Sea ranching
  - salmon eggs are fertilized in hatcheries and grown until they are able to live independently, at which time they are released – either into streams or ocean
  - In 2008, the Alaska Department of Fish and Game reported that 146 million Pacific salmon were commercially harvested. Of this, 60 million salmon were identified as ocean ranched. Therefore ocean ranched salmon represented over 41% of the "wild-caught" Pacific salmon commercial catch in Alaska

    http://www.sf.adfg.state.ak.us/FedAidPDFs/fmr09-08.pdf
- Grow fish in inland tanks

More about recirculating-water land-based aquaculture systems

- A relatively new method of aquaculture involves growing fish in tanks in inland locations away from the native habitat of the fish.
- Fish spend their entire lives in these fully contained tanks.
- The tanks may hold either fresh or salt water (Atlantic salmon are able to spend their lives in fresh water, as many live in land-locked fresh water lakes). Temperature, oxygen levels, food delivery, and waste removal are monitored carefully.
- As the fish increase in size from the 100 gram smolt-size to more market sized animals, they are graded and moved into additional and/or larger tanks to ensure that the density of the animals is kept at appropriate levels. Fish are harvested directly from the tanks, processed, and sent to market.

October 2011
Davis, CA

Fast growing salmon

The founder female was generated in 1989 – 21 years ago

Nature Biotechnology 10:176 – 181. 1992

GROWTH ENHANCEMENT IN TRANSGENIC ATLANTIC SALMON BY THE USE OF AN "ALL FISH" CHIMERIC GROWTH HORMONE GENE CONSTRUCT

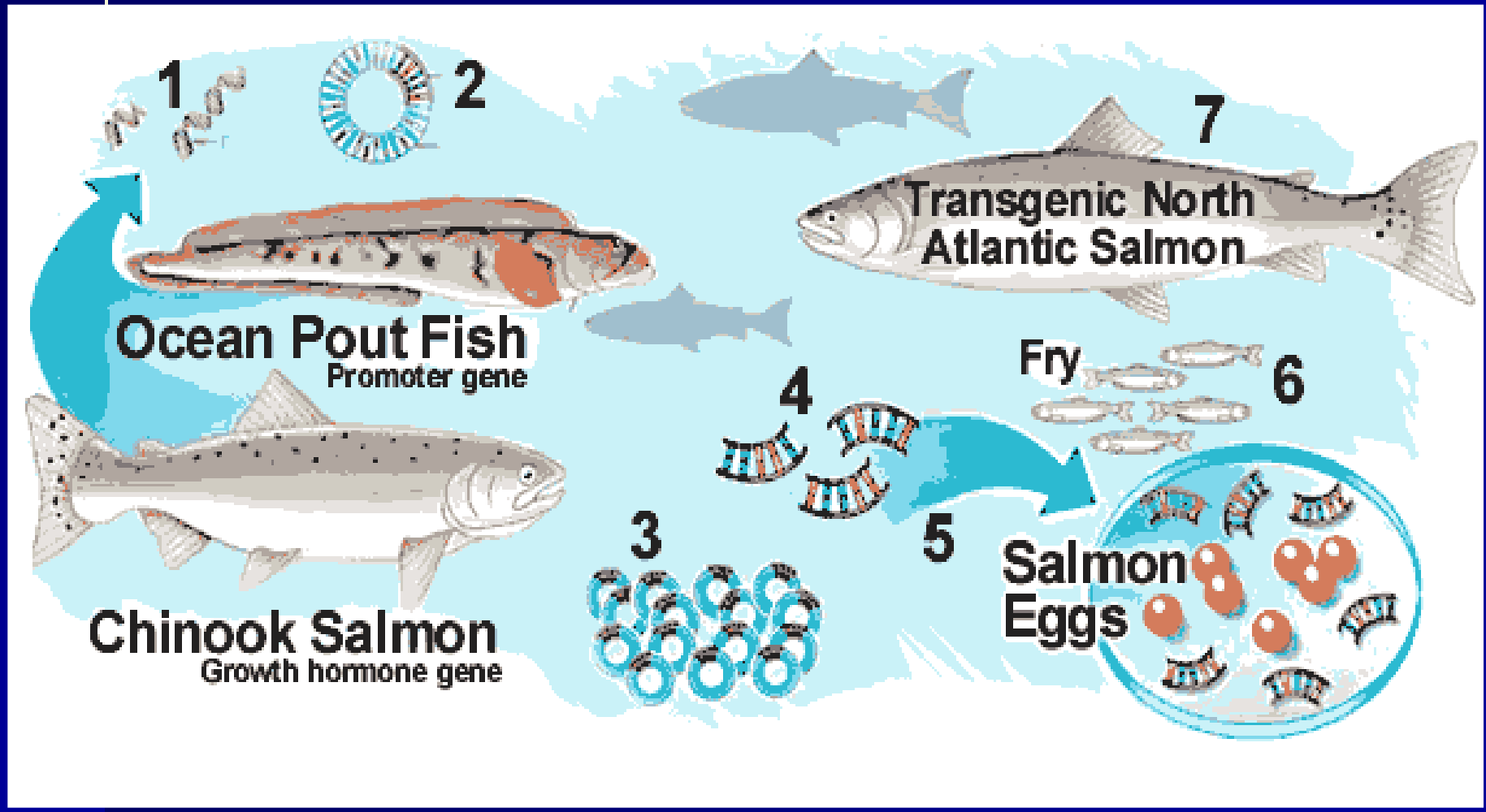
Shao Jun Du, Zhiyuan Gong, Garth L. Fletcher[1], Margaret A. Shears[1], Madonna J. King[1], David R. Idler[1] and Choy L. Hew*

Research Institute, The Hospital for Sick Children and Departments of Clinical Biochemistry and Biochemistry, University of Toronto, Toronto, Canada M5G 1L5. [1]Ocean Sciences Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada A1C 5S7. *Corresponding author.

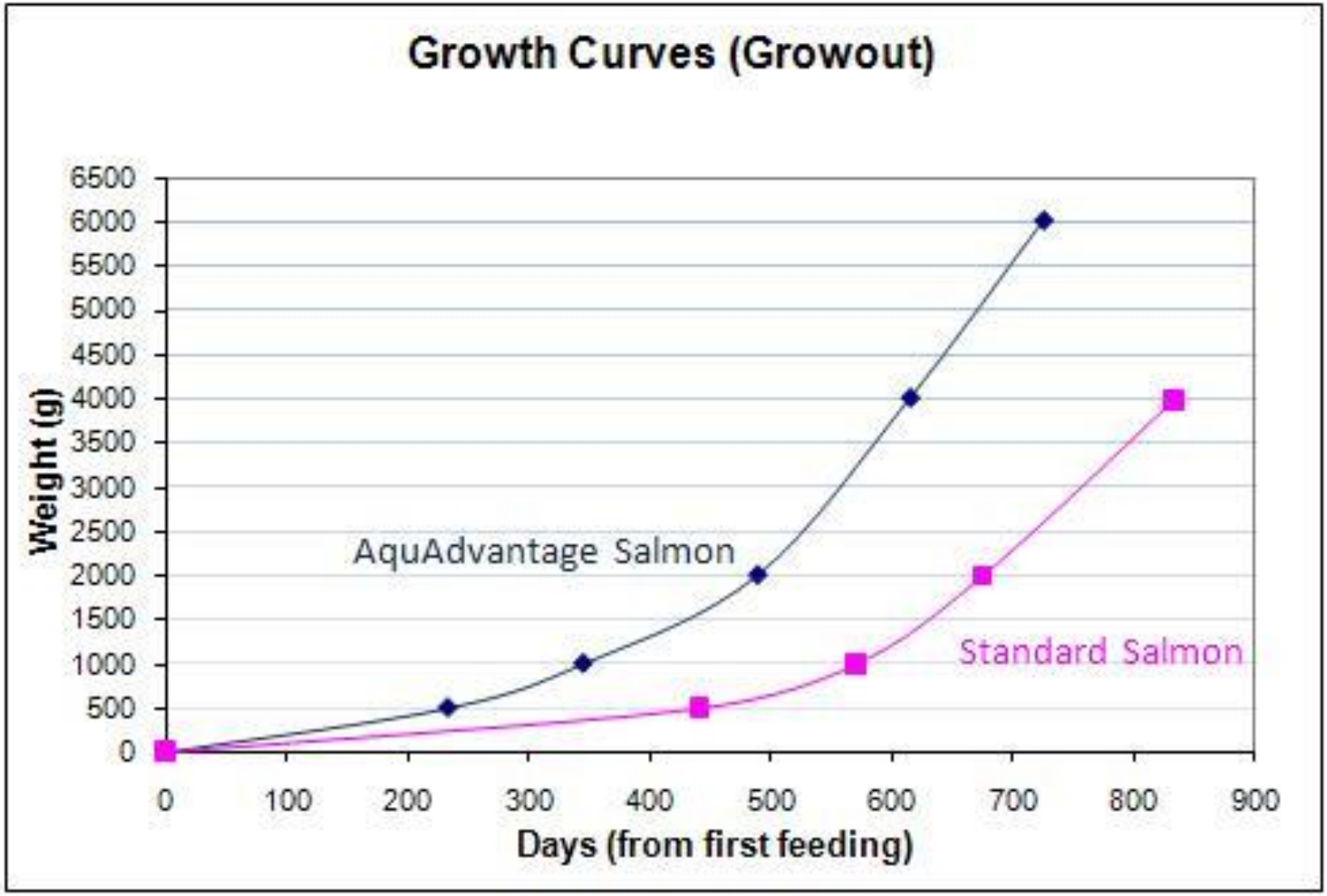
We have developed an "all fish" growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon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

University of Toronto/Memorial University of Newfoundland, Canada

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

In a letter to the FDA dated April 26, **1993**, AquaBounty Technologies (then A/F Protein) initiated discussions with the FDA seeking regulatory guidance for development and approval of a GE Atlantic salmon intended to grow faster than conventionally bred Atlantic salmon.

- In January 2009, the Food and Drug Administration issued a final guidance for industry on the regulation of genetically engineered (GE) animals (had 28,000 comments on draft!!)
- FDA plans to regulate GE animals under the new animal drug provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), and the National Environmental Policy Act (NEPA).

187

Guidance for Industry

Regulation of Genetically Engineered Animals

Containing Heritable Recombinant DNA Constructs

Final Guidance

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf

“New Animal Drug” approach

- The recombinant DNA (rDNA) construct is a new animal drug because it is “an article intended to alter the structure or function” of the animal.
- New animal drugs may be approved if they are shown to be safe and effective for the intended use.
- In a hierarchical risk-based multistep scientific review the agency examines the safety of the rDNA construct to the animal, the safety of food from the animal, and any environmental impacts posed, as well as the extent to which the performance claims made for the animal are met.

FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
January 15, 2009

Media Inquiries:
Michael Herndon, (301) 796-4673
Consumer Inquiries:
888-INFO-FDA

FDA Issues Final Guidance on Regulating Genetically Engineered Animals

En Español

The U.S. Food and Drug Administration today issued a final guidance for industry on the regulation of genetically engineered (GE) animals under the new animal drug provisions of the Federal Food, Drug and Cosmetic Act (FFDCA). The guidance, titled "The Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs," clarifies the FDA's statutory and regulatory authority, and provides recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law.

Genetic engineering generally refers to the use of recombinant DNA (rDNA) techniques to introduce new characteristics or traits into an organism. When scientists splice together pieces of DNA and introduce a spliced DNA segment into an organism to give the organism new properties, it is called rDNA technology. The spliced piece of DNA is called the rDNA construct. A GE animal is one that contains an rDNA construct intended to give the animal new characteristics or traits.

"Genetic engineering is a cutting edge technology that holds substantial promise for improving the health and well being of people as well as animals. In this document, the agency has articulated a scientifically robust interpretation of statutory requirements," said Randall Lutter, Ph.D., deputy commissioner for policy. "This guidance will help the FDA efficiently review applications for products from GE animals to ensure their safety and efficacy."

The FDA released the draft guidance in September 2008 with a 60-day public comment period, and received about 28,000 comments. The agency has summarized and responded to these comments on the Web site listed below.

The FDA's Center for Veterinary Medicine (CVM) has been working with developers of GE animals on both early stage and more mature applications.

"At this time, it is our intent to hold public scientific advisory committee meetings prior to making decisions on GE animal-related applications" said Bernadette Dunham, D.V.M., Ph.D., director of CVM.

The FFDCA defines "articles (other than food) intended to affect the structure or any function of the body of man or other animals" as drugs. An rDNA construct that is in a GE animal and is intended to affect the animal's structure or function meets the definition of an animal drug, whether the animal is intended for food, or used to produce another substance. Developers of these animals must demonstrate that the construct and any new products expressed from the inserted construct are safe for the health of the GE animal and, if they are food animals, for food consumption.

The guidance also describes the manufacturer's responsibility in meeting the requirements for environmental review under the National Environmental Policy Act.

For more information:

- Genetically Engineered Animals

Date	Event
September 1995	AquaBounty submits Investigational New Animal Drug (INAD) 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 AquAdvantage salmon Held in Washington DC

Product Definition for the AquAdvantage Salmon

Product Identity

Triploid hemizygous, all-female Atlantic salmon (*Salmo salar*) bearing a single copy of the transgene.

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 safely 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 to prevent the accidental release of eggs and/or fish to nearby aquatic environments… 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.**

The public meeting held in Washington DC was intended to increase transparency, clarity, and public confidence in the GE animal regulatory process

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

Examples of claims made during the public meeting – not actually supported by what was in the data package that was made public by company to increase transparency

- **More Carcinogenic:** GMO salmon has 40% more IGF1, a hormone linked to prostate, breast and colon cancers in humans.
- **Less Nutritious:** GMO salmon has the lowest omega-3 to omega-6 ratio of any salmon.
- **More Allergenic:** GMO salmon have mean allergenic potencies that are 20% and 52% higher than normal salmon.
- **Likely To Change The Bacteria Of Your Gut:** Horizontal gene transfer, where the bacteria of the human gut takes up modified DNA from GMO foods during digestion, has been shown occur with soy and is likely to happen with GMO salmon, too.
- **All Messed Up:** GMO salmon has increased frequency of skeletal malformations like “humpback” spinal compression, increased prevalence of jaw erosions or “screamer disease,” and multisystemic, focal inflammation in its tissues.

http://organicconsumers.org/fish

More Carcinogenic: GMO salmon has 40% more IGF1, a hormone linked to prostate, breast and colon cancers in humans.

- Isoelectric focusing and 2-dimensional gels of protein extracts revealed no differences in patterns between the AquAdvantage salmon and control Atlantic salmon
- Analysis of **10 farmed control, 33 sponsor control and 30 genetically engineered salmon** revealed no statistically significant difference in the muscle/skin levels of growth hormone, insulin growth factor 1 (IGF1), estradiol, testosterone, triiodothytonine (T3), thyroxine (T4), or 11-keto testosterone
- Mean IGF1 levels (ng IGF1/g): 9.263 diploid GE (n=6) versus 8.892 control (n=7). Not significantly different, *P*=0.93, two-tailed t-test assuming unequal variances.
- REMAINDER WERE BELOW THRESHOLD OF DETECTION.

Pages 62-75, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

Alison Van Eenennaam , Ph.D., UC Davis

Table 18. IGF1 levels in Various Foods

Species	Source (tissue)	units	Range	Mean
Chinook salmon[1]	Plasma	ng/ml	5-35	-
Coho salmon[2]	Plasma	ng/ml	7-13	-
Coho salmon[3]	Plasma	ng/ml	10-15	-
Gilthead Bream[4]	Plasma	µg/L	36-100[5]	-
Bovine[6]	Raw milk	ng/ml	Intentionally Blank	5.6 ± 0.56
Bovine[6]	Pasteurized milk	ng/ml	Intentionally Blank	8.2 ± 0.35
Bovine[6]	Raw bulk milk	ng/ml	1.27-8.10	4.32 ± 1.09
Homo sapiens[6]	Milk	ng/ml	1 d post partum 17.6 2 d 12.8 3 d 6.8 6-8 wk 13-40	19
Chum salmon[7]	Plasma	ng/ml	Depends on maturity/sex/month: varies between 16.5 and 100	-
Rainbow trout (O.kiss)[8]	Plasma	ng/ml	Function of temperature/time Lowest value 11.2 Highest 33.6	-
Japanese beef cattle[9]	Plasma	ng/ml	Intentionally Blank	Preweaning 11.7± 3.6 Postweaning 50.5 ± 2.1

Mean IGF1 levels (ng IGF1/g) reported in briefing packet were 9.263 diploid GE (n=6) versus 8.892 sponsor control (n=7).

Page 69 & 71, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

Less Nutritious: GMO salmon has the lowest omega-3 to omega-6 ratio of any salmon.

Table 28. Omega-3 and Omega-6 Fatty Acid Levels in ABT Salmon and Farmed Atlantic Salmon

Fatty Acid	Degree of saturation	Atlantic salmon							
		Aqua Bounty			Scientific literature				
		Farm raised	Sponsor control	ABT	Farmed[1]	Farmed[2]	Farmed[3]	Wild caught[4]	Farmed[4]
		Means (% of the wet weight)							
Oleic	18:1	2.88	2.011	3.299		0.465	1.05		
Linoleic¶	18:2	0.668	0.507	0.743	0.303	0.162	0.194	0.067	0.65
α-Linolenic§	18:3	0.178	0.131	0.232	0.066	0.031	0.103	0.05	0.181
γ-Linolenic¶	18:3	0.03	0.019	0.027				0.003	0.014
Arachidonic¶	20:4	0.084	0.055	0.092	0.037	0.025	0.029	0.03	0.091
Eicosenoic	20:1	0.913	0.455	0.534		0.144	0.275		
Eicosadienoic¶	20:2	0.053	0.039	0.059			0.029	0.017	0.063
Eicosatrienoic§	20:3	0.021	0.012	0.024				0.009	0.024
Eicosapentaenoic§	20:5	1.174	0.593	1.095	0.324	0.225	0.326	0.414	1.08
Docosapentaenoic§	22:5	0.436	0.266	0.5				0.12	0.519
Docosahexaenoic§	22:6	1.46	0.961	1.422	0.623	0.568	0.932	0.629	1.57
ω-3/ω-6 ratio		3.9	3.2	3.6				10.4	4.1

§ Omega - 3 fatty acids
¶ Omega - 6 fatty acids

Pages 95, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

Endogenous allergenicity – some foods are allergenic (e.g. nuts)

Natural variation exists in the allergenicity of available food crops due to differences in the genetics of commercial varieties, and interactions with the environment (Goodman et al., 2008)

- **In plants there is wide variation in IgE binding to different varieties of the same species[1]**
- **Apart from differences between varieties, natural variability in allergenicity can also occur due to harvest timing and storage conditions[2,3]**
- **Even between individual apples from a single cultivar and harvest, up to tenfold differences in allergenicity have been reported[4].**

1. Sten, E. *et al*. A comparative study of the allergenic potency of wild-type and glyphosate-tolerant gene-modified soybean cultivars. *APMIS* **112**, 21–28 (2004).
2. Sancho, A.I. *et al*. Maturity and storage influence on the apple (*Malus domestica*) allergen Mal d 3, a nonspecific lipid transfer protein. *J. Agric. Food Chem.* **54**, 5098–5104 (2006).
3. Sancho, A.I. *et al*. Effect of postharvest storage on the expression of the apple allergen Mal d 1. J. *Agric. Food Chem.* **54**, 5917–5923 (2006).
4. Marzban, G. *et al*. Localization and distribution of the major allergens in apple fruits. *Plant Sci.* **169**, 387–394 (2005).

Endogenous allergens in fish

- **The major allergens responsible for cross-reactivity among distinct species of fish and amphibians are parvalbumins. These proteins control calcium flow in the muscular sarcoplasm of the white meat and have a molecular weight of approximately 12 kD[1].**
- **Parvalbumins are resistant to thermal and enzymatic degradation.**
- **Parvalbumin (Sal s l) is the major allergen in the white muscle of Atlantic salmon[2]**
- **The Chinook salmon GH protein has no structural similarity to known allergens**

1. Wild LG, and S.B Lehrer. 2005. Fish and shellfish allergy. Current allergy and asthma reports. 5:74-49.
2. Lindstrom CD, van Do T, Hordvik I, *et al.* 1996. Cloning of two distinct cDNAs encoding parvalbumin, the major allergen of Atlantic salmon (Salmo salar). *Scand J Immunol* 44:335–344.

Important Variations in Parvalbumin Content in Common Fish Species: A Factor Possibly Contributing to Variable Allergenicity A. Kuehn, T. Scheuermann, C. Hilger, F. Hentges· 2010. *Int Arch Allergy Immunol* 2010;153:359-366 (DOI: 10.1159/000316346)

Table 1. Parvalbumin contents in raw fish, and commercially processed and cooked fish samples by quantitative ELISA

	Fish sample	Fish n	Extracts n	Parvalbumin mg/g	Parvalbumin %[1]
Herring	raw	2	12	3.8–5.7	3.3
	pickled	2	6	1.2–2.8	5.6
	cooked	2	12	3.0–4.4	16
Carp	raw	2	12	2.5–5.0	3.0
	cooked	2	12	2.1–4.0	15
Redfish	raw	3	18	2.0–3.0	2.2
	cooked	2	12	1.7–2.3	14
Trout	raw	6	36	2.0–2.5	1.3
	smoked	2	6	0.9–1.1	9.2
	cooked	2	12	1.7–2.0	11
Salmon	raw	2	12	1.9–2.5	1.2
	smoked	2	6	0.7–1.0	8.9
	cooked	2	12	1.5–1.9	9.5
Cod	raw	4	24	1.5–2.5	1.7
	cured	2	6	1.0–1.3	1.3
	cooked	2	12	1.3–1.9	7.2
Mackerel	raw	3	18	0.3–0.7	0.1
	smoked	2	6	0.08–0.15	2.3
	cooked	2	12	0.2–0.5	5.3
Tuna, white	raw	6	36	0.01–0.05	0.03
	cooked	2	12	0.01–0.03	0.2
Tuna, dark	raw	2	12	ND	–
Tuna	canned	2	6	ND	–

Two tissue samples were taken from each raw fish at different longitudinal body positions. ND = Not detected.
[1] Percentage per total soluble protein.

"The parvalbumin content of most commonly consumed fish species varies considerably. Differences range from several fold to one hundredfold. In raw fish, parvalbumin levels decreased significantly in the following order: herring > carp > redfish > salmon/trout > cod > mackerel > tuna. Differences in herring and tuna Parvalbumin levels were found to vary by a factor of 100".

"What level of change in endogenous allergens would be (un)acceptable?"

"*There is no consensus in the scientific and medical communities regarding the magnitude of the increase in endogenous allergens in an allergenic food that would present an additional risk to public health (Goodman et al., 2008), especially given that individuals that are allergic to a particular food would likely avoid that food* "

Page 97, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

"What level of change in endogenous allergens would be (un)acceptable?"

Because finfish are one of the major eight allergenic foods in the United States one potential indirect hazard that may result from the insertion of the AquAdvantage construct at the α- locus is an alteration in the endogenous levels of allergens in ABT salmon due to insertional mutagenesis. In particular, the question was asked whether the edible tissue from GE salmon is more allergenic than the non-GE comparator. This question was evaluated in the ABT submission discussed below.

Page 97, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

More Allergenic: GMO salmon have mean allergenic potencies that are 20% and 52% higher than normal salmon.

.

SUMMARY OF VMAC CHAIRMAN's REPORT

"There is currently lack of consensus in the scientific and medical literature relating the magnitude of increase in endogenous allergens in allergenic food that would present an additional risk to public health. An example of this is the natural variability in levels of the endogenous allergen, parvalbumin, in herring and tuna, which vary by a factor of 100 fold. Given that reliable predictors of risk of allergy when eating allergenic foods are currently elusive, *it cannot be concluded from the data submitted that AquAdvantage Salmon would be more or less allergenic than Atlantic Salmon*. Data and analysis on the introduced construct did not identify it as likely to produce a novel antigen."

VMAC Chairman's report:
http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230467.pdf

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

This letter was signed by 11 Senators, and a similar one was signed by 29 members of Congress

Higher levels of insulinlike growth factor!

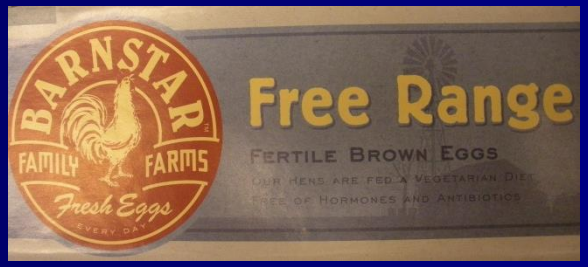
My reflections on the process

The VMAC participated in a candid, transparent discussion of the data. While such scientific discussions are rarely entertaining enough to make the nightly news, I consider that there was a sincere attempt to fairly and impartially evaluate the data presented

Unfortunately others used this important occasion to unfairly misrepresent the data. There is little benefit to society if attempts to increase public participation and transparency in the regulatory process provide an unfettered opportunity to demonize technology and undermine the science-based regulatory review process.

In my opinion, this process seriously jeopardized the future of genetically-engineered animals in the United States, both for food and pharmaceutical applications, with global implications.

Voluntary labeling is allowed if it is not false or misleading



Fish case at my local supermarket


SALMON COHO FILLET COLOR ADDED
FRESH
FARM-RAISED PRODUCT OF CANADA
269310 91510
SAFE HANDLING INSTRUCTIONS
THIS PRODUCT WAS PREPARED FROM INSPECTED AND PASSED MEAT AND/OR POULTRY. SOME FOOD PRODUCTS MAY CONTAIN BACTERIA THAT COULD CAUSE ILLNESS IF THE PRODUCT IS MISHANDLED OR COOKED IMPROPERLY. FOR YOUR PROTECTION, FOLLOW THESE SAFE HANDLING INSTRUCTIONS.
KEEP REFRIGERATED OR FROZEN. THAW IN REFRIGERATOR OR MICROWAVE.
KEEP RAW MEAT AND POULTRY SEPARATE FROM OTHER FOODS. WASH WORKING SURFACES (INCLUDING CUTTING BOARDS), UTENSILS, AND HANDS AFTER TOUCHING RAW MEAT OR POULTRY
COOK THOROUGHLY
KEEP HOT FOODS HOT. REFRIGERATE LEFTOVERS IMMEDIATELY OR DISCARD.
238767 91090
SAFEWAY
Tare 0.06 lb
Store No. 1205
Sell By Sep 19, 10
Net Wt/Ct 1.01 lb
Unit Price $9.99/lb
Total Price $10.09
P 12:
Safeway Inc. Pleasanton, CA 94588
CLUB PRICE $7.99/lb
YOU SAVE $2.02
WITH CARD YOU PAY $8.07
EAFOOD for
BAKING

Country of Origin Labeling (COOL) is a labeling law that requires retailers to notify their customers with information regarding the source of certain foods – including fish and shellfish.

SALMON COHO FILLET COLOR ADDED
FRESH
FARM-RAISED PRODUCT OF CANADA

COD TRUE FILLET FRESH
WILD PRODUCT OF USA

SHRIMP RAW 21-25 CT SHELL ON
W/SALT FROZEN / DEFROSTED
FARM-RAISED PRODUCT OF THAILAND

CATFISH FILLET PREVIOUSLY FROZEN
FARM-RAISED PRODUCT OF USA

ATLANTIC SALMON FILLET
FRESH
FARM-RAISED PRODUCT OF CANADA AND PANAMA

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

Transgenic salmon: a final leap to the grocery shelf?

Nature Biotechnology (2011) **29**: 706–710.

Alison L Van Eenennaam & William M Muir

Despite being caught up in regulatory proceedings for 15 years or more, AquAdvantage 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 AquAdvantage 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, AquAdvantage 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

AquaBounty Technologies

Less than 2 weeks after the meeting, more than 40 members of Congress signed letters requesting FDA halt the approval of the 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.

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 AquAdvantage salmon
June 15th 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 (AK) and Lynn Woolsey (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*."

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 AquAdvantage salmon
June 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 (AK) and Lynn Woolsey (CA).
July 2011	Eight senators urge FDA Commissioner Margaret A. Hamburg, MD, to stop her agency from further considering approving the GE salmon. The letter expresses concerns about potential threats to public and environmental health and economic harm for wild salmon producers. The letter also indicates that the Senate could concur with a measure passed by the House of Representatives

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

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 AquAdvantage salmon
June 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 (AK) and Lynn Woolsey (CA).
July 2011	Eight senators urge FDA Commissioner Margaret A. Hamburg, MD, to stop her agency from further considering approving the GE salmon. The letter expresses concerns about potential threats to public and environmental health and economic harm for wild salmon producers. The letter also indicates that the Senate could concur with a measure passed by the House of Representatives
December 15, 2011	The Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard is holding a hearing to examine potential environmental risks of genetically engineered (GE) fish. Testifying were: - Dr. Ron Stotish, president and CEO AquaBounty Technologies, Inc. - Dr. John Epifanio, Illinois Natural History Survey - Paul Greenberg, journalist and author of "Four Fish" - Dr. George Leonard, Aquaculture Program Director Ocean Conservancy

The 12/15/11 hearing was led by a man who has dubbed this bio-engineered creation the "frankenfish"—U.S. Sen. Mark Begich (D-Alaska) chairman of the Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard. Begich has been a staunch opponent of the gene-altered salmon and has even introduced legislation to stop it.

U.S. senator and ranking committee member Olympia Snowe (R-Maine) further commented on the regulatory limits of the FDA in its ability to effectively evaluate environmental concerns.

"*The FDA is using an approval process originally created to approve new animal drugs that the agency has interpreted to include genetically engineered or modified fish,"* said Snowe. *"This is an outdated and inadequate approach to evaluating a technology of this magnitude*."

Snowe called on the FDA to halt its approval until the agency establishes a "transparent and comprehensive review process for genetically engineered animals."

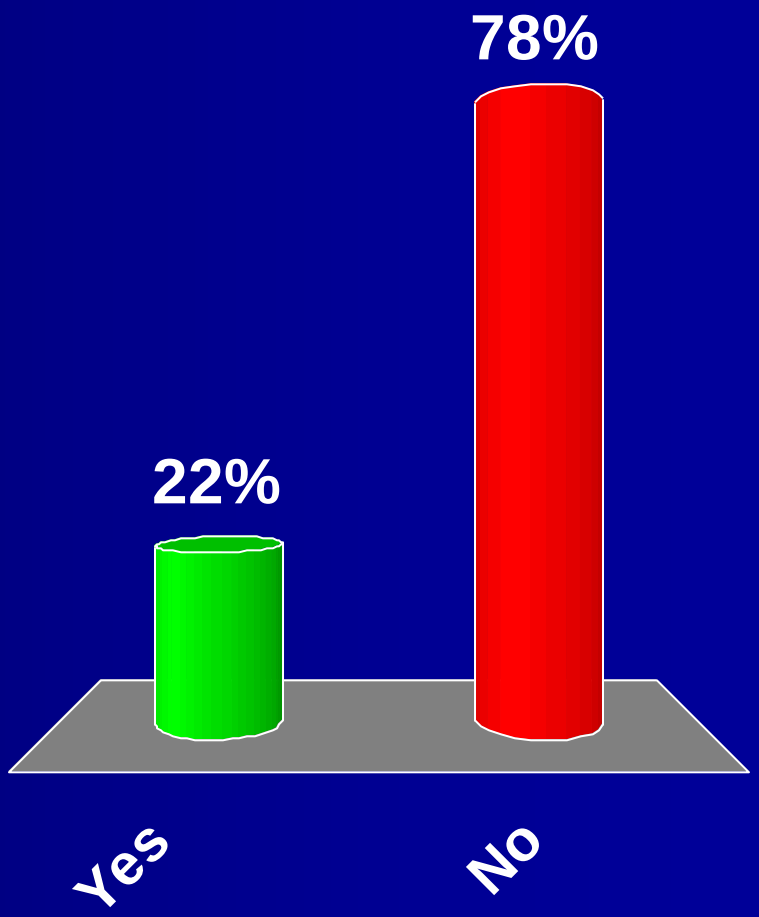
"*The FDA has a procedure that is not designed for this type of product in its public review*," said Sen. Begich. "*It's a different ballgame*."

"*I know Dr. Stotish has struggled through years of review, but Congress has had very little conversation about this*," said Begich in his closing comments. "***I will tell you as chair of this subcommittee and someone who comes from a state that produces 60 percent of the wild stock of this country: we are going to be interested in this***."

http://www.theepochtimes.com/n2/united-states/battle-to-put-genetically-engineered-fish-on-dinner-tables-161957.html

Would you eat Frankenfish?

Results from general public audience at UCD College of Agriculture and Environmental Sciences breakfast 11/05/2011



1. Yes
2. No

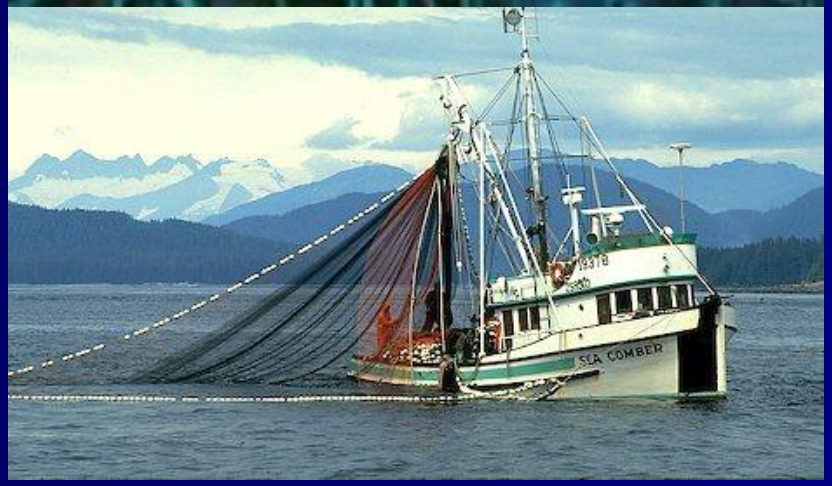
CASE STUDY: SALMON

Which type of salmon would you buy?

Summary of potential advantages of land-based (inland tank) AquAdvantage 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 system reduces spread of disease in the environment (and wild salmon populations)
- 15% improvement in food conversion ratio (i.e. produce more lbs product per lb feed) –feed is major cost of fish production!
- Does not spawn during growout (more energy available for growth AKA less energy wasted on reproduction!).
- Land based salmon culture systems ***could*** be located on land adjacent to major markets, reducing freight and the associated environmental impact i.e. locally-grown "**locivovre**" source of fish

1. Wild-caught: $17.99/lb Pacific salmon



2. Farm-raised: $6.99/lb net pen imported from Norway/Scotland/Canada

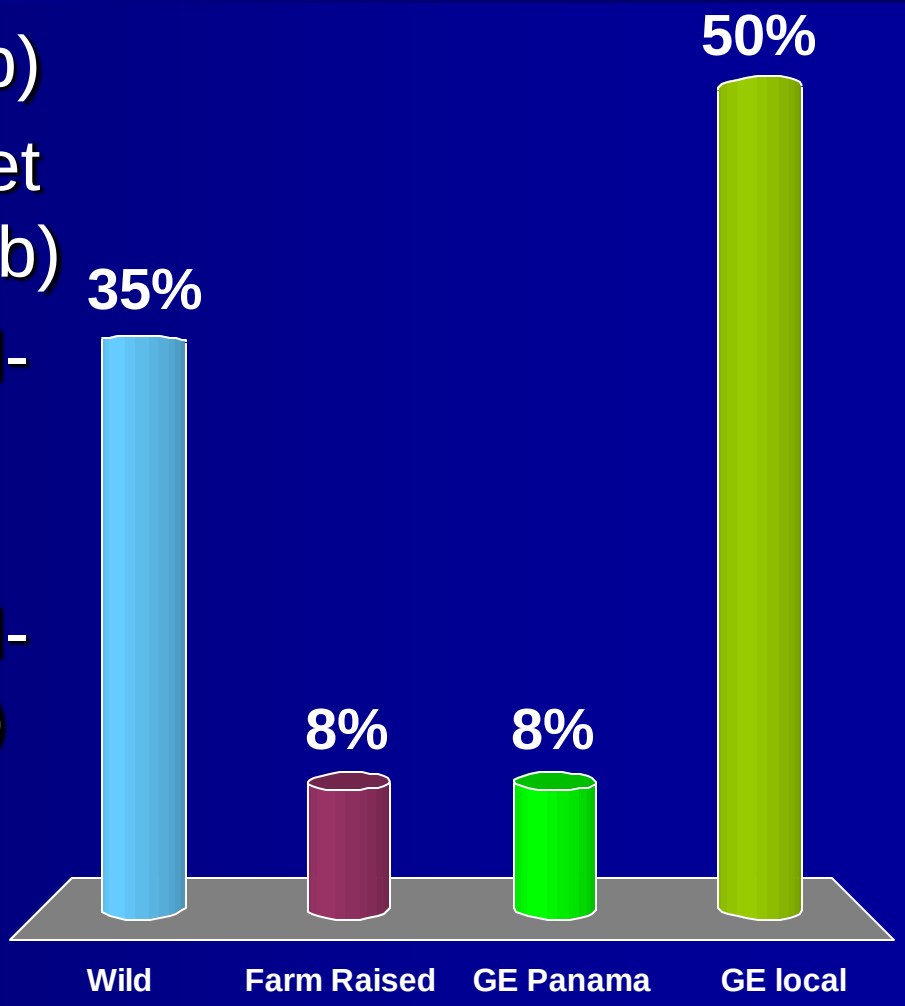
3. Farm-raised: $6.99/lb land-based GE AquAdvantage Atlantic triploid, female salmon raised in Panama

4. Farm-raised: $6.99/lb land-based GE AquAdvantage triploid, female Atlantic salmon locally-grown in land-based tanks

Which type of salmon would you buy?

Results from general public Audience at UCD College of Agriculture and Environmental Sciences breakfast 11/05/2011

1. Wild-caught ($17.99/lb)
2. Farm-raised, ocean net pen, imported ($6.99/lb)
3. Farm-raised, GE, land-based, imported ($6.99/lb)
4. Farm-raised, GE, land-based, local ($6.99/lb)

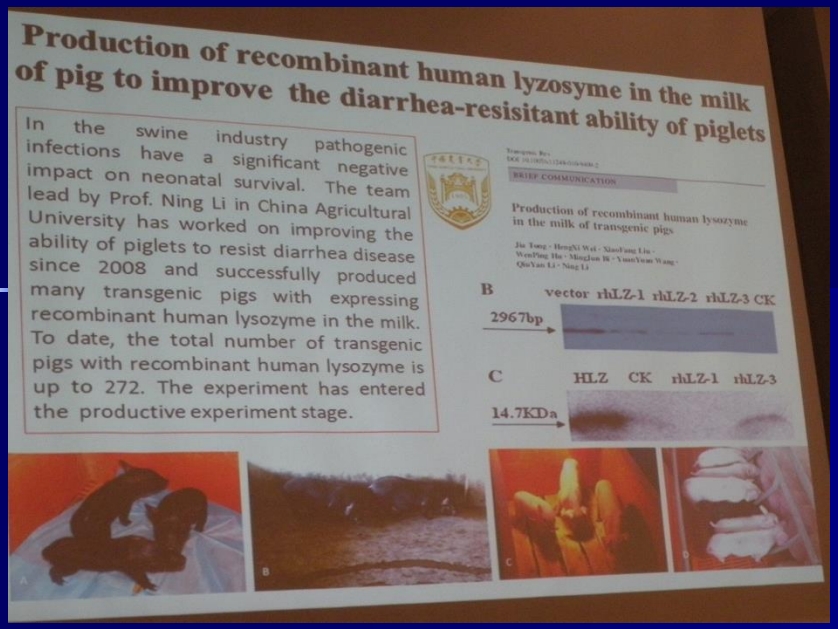


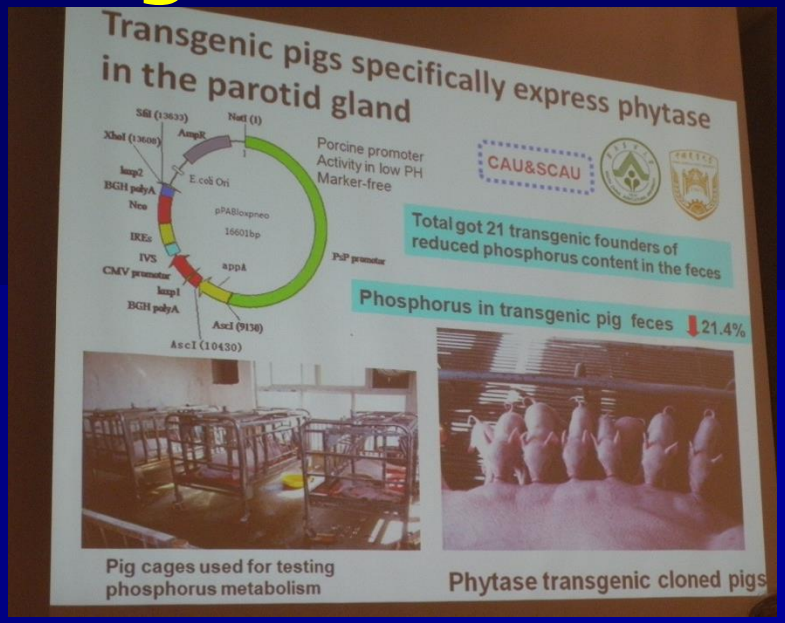
Dr. Calestous Juma, Harvard's Kennedy School of Government, at a 6/23/11 hearing to examine the benefits of agricultural biotechnology held by the House Agriculture Committee's Subcommittee on Rural Development, Research, Biotechnology, and Foreign Agriculture

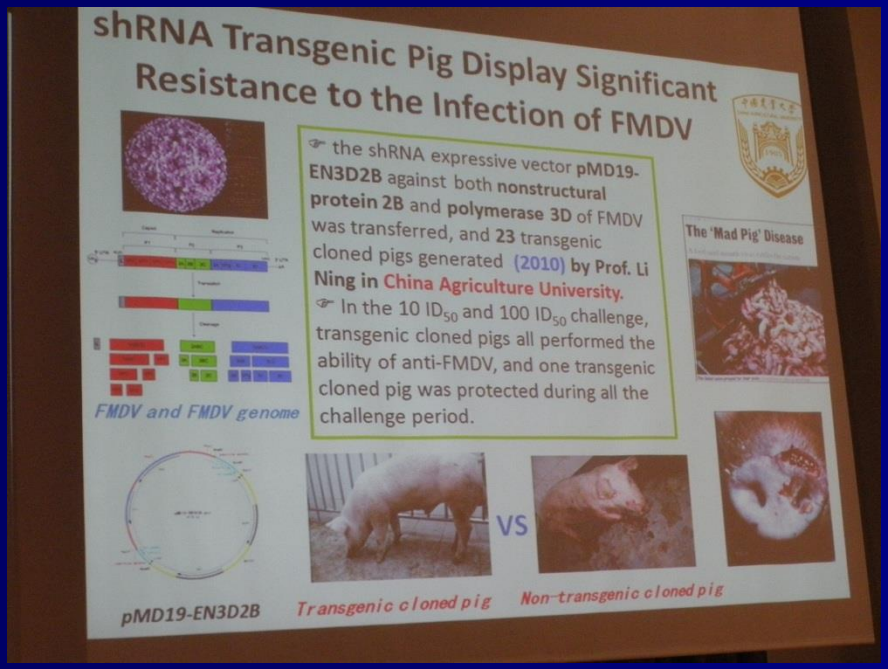
*". . It is not this particular fish that is at stake. It is the principle behind the amendment (*to prohibit use of FDA funds to evaluate any application for approval of genetically engineered salmon*) and its wider ramifications. It sends the message to the rest of the world that the science-based regulatory oversight as embodied in the FDA review process is subject to political intervention.*

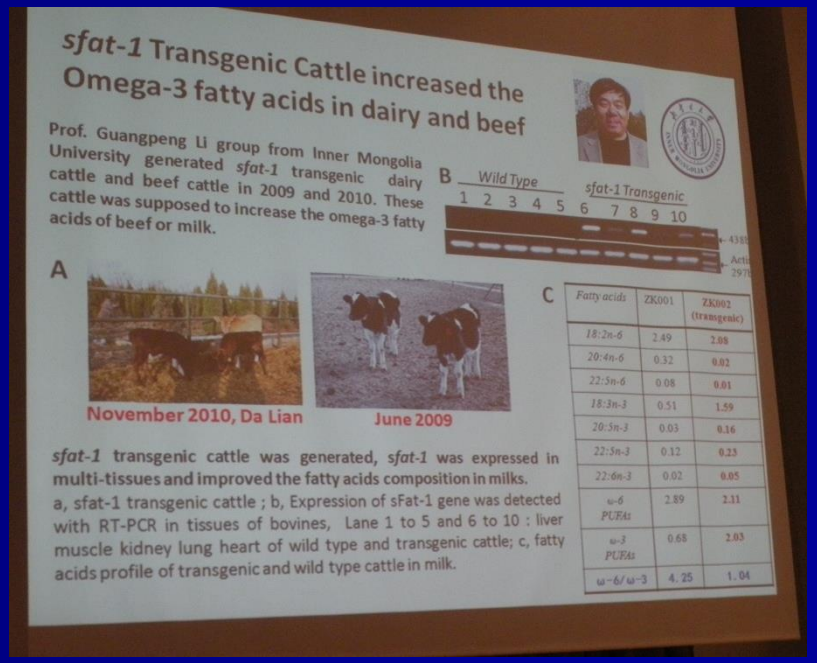
Furthermore, it signals to the world that the United States may cede its leadership position in the agricultural use of biotechnology. . . I believe it is imperative that the United States stay the course it has set in not letting politics interfere with its science-based regulatory system"

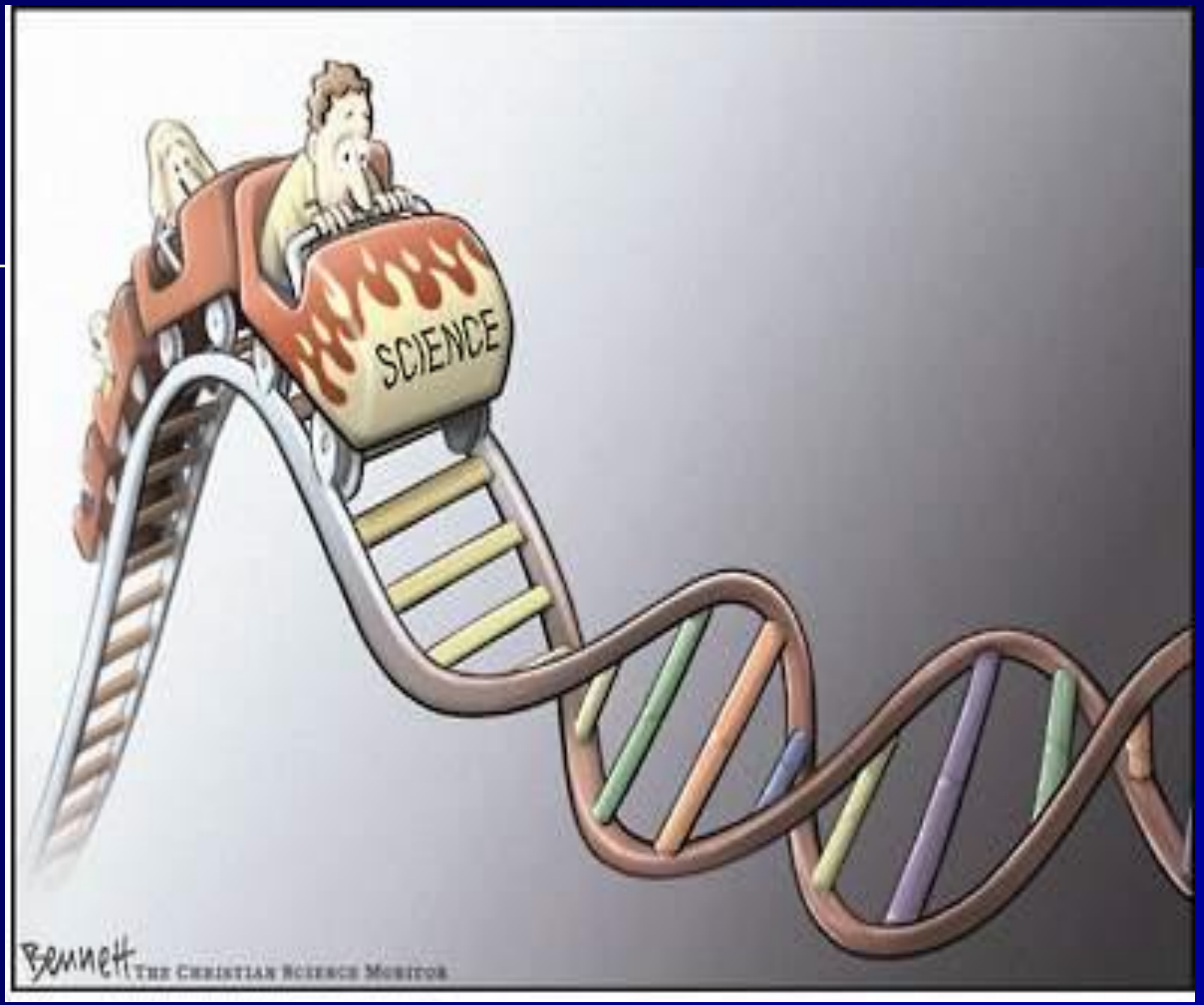
Chinese work on transgenic animals










SCIENCE
Bennett
The Christian Science Monitor