The science and politics of the AquAdvantage genetically engineered salmon

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"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."

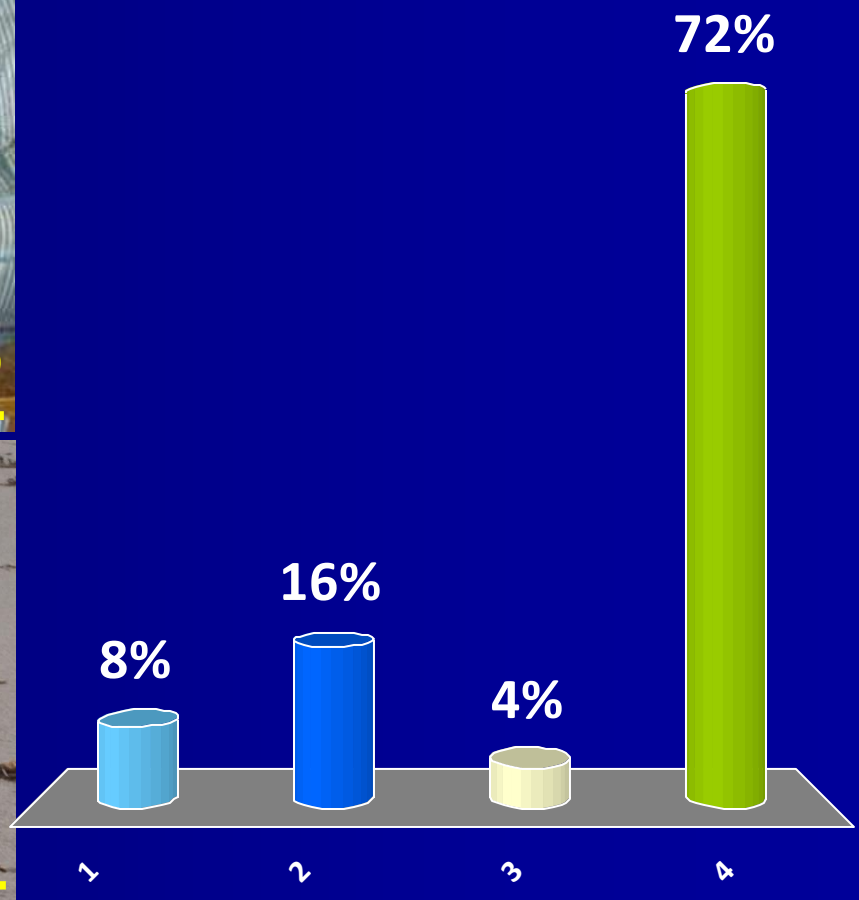
http://animalscience.ucdavis.edu/animalbiotech

Given this information……



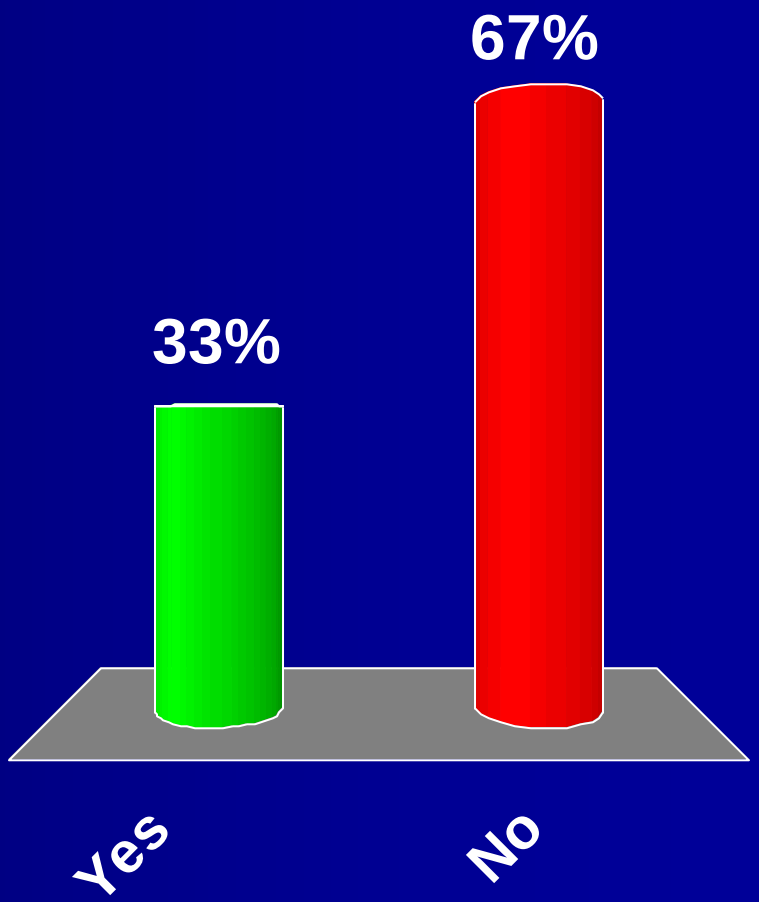



Which do you think is my dog?



Would you eat Frankenfish?

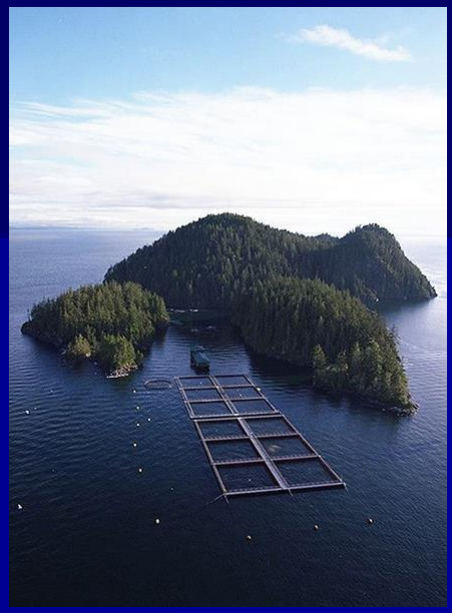
1. Yes
2. No



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

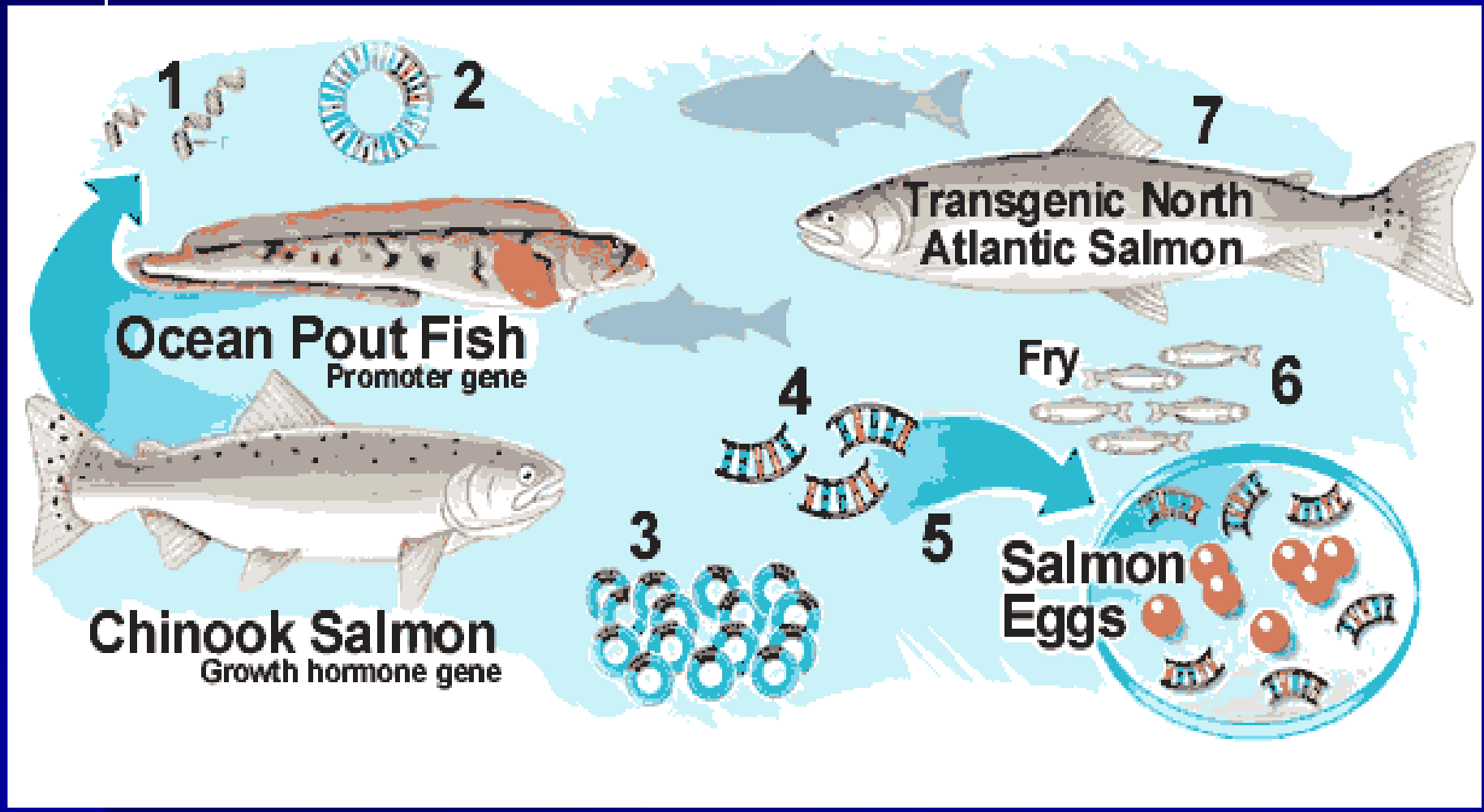
Shao Jun Du, Zhiyuan Gong, Garth L. Fletcher[1], Margaret A. Shears[1], Madonna J. King[1], David R. Idler[1] and Choy L. Hew*

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.

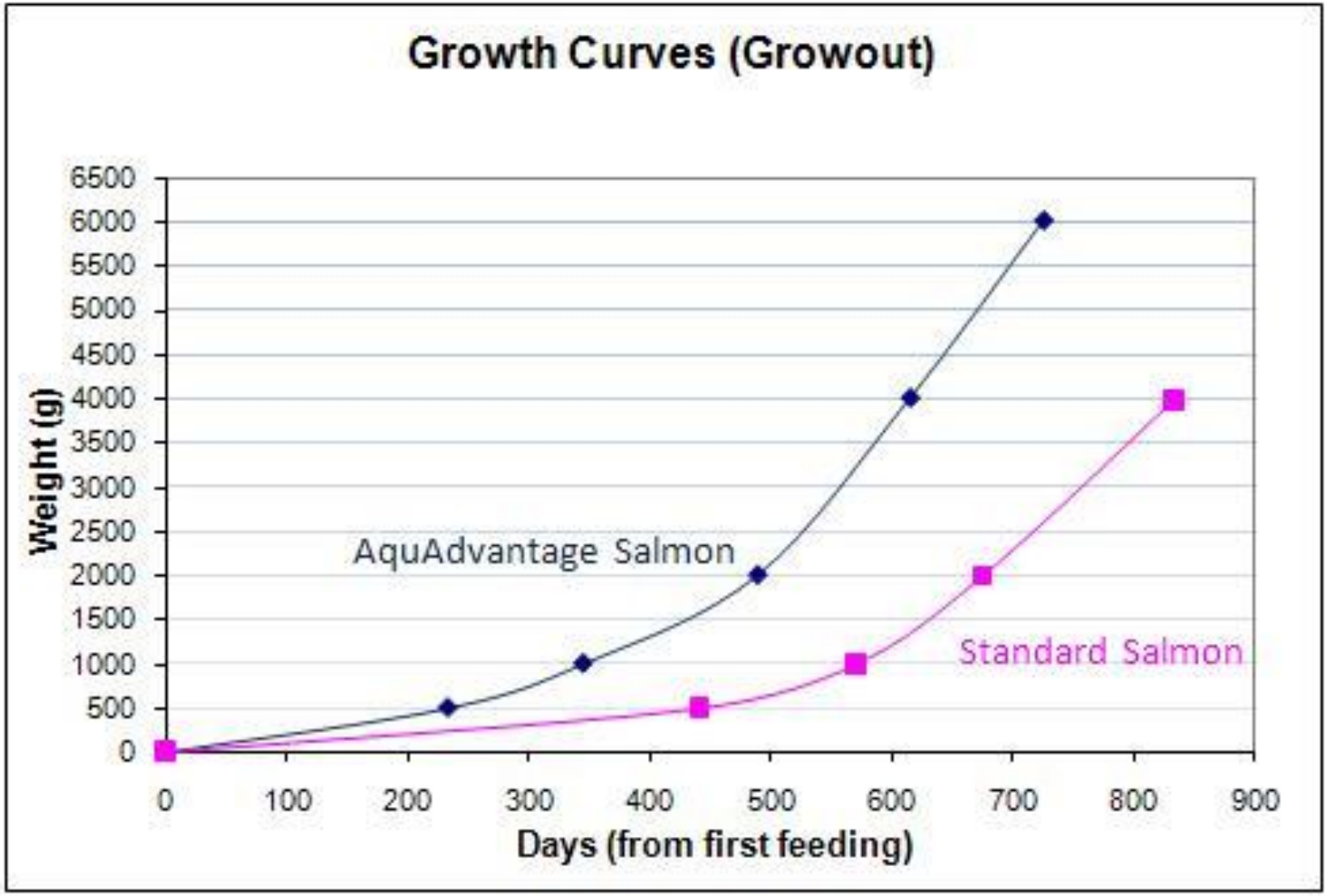
We have developed an "all fish" growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon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

University of Toronto/Memorial University of Newfoundland, Canada

What is the AquAdvantage salmon?

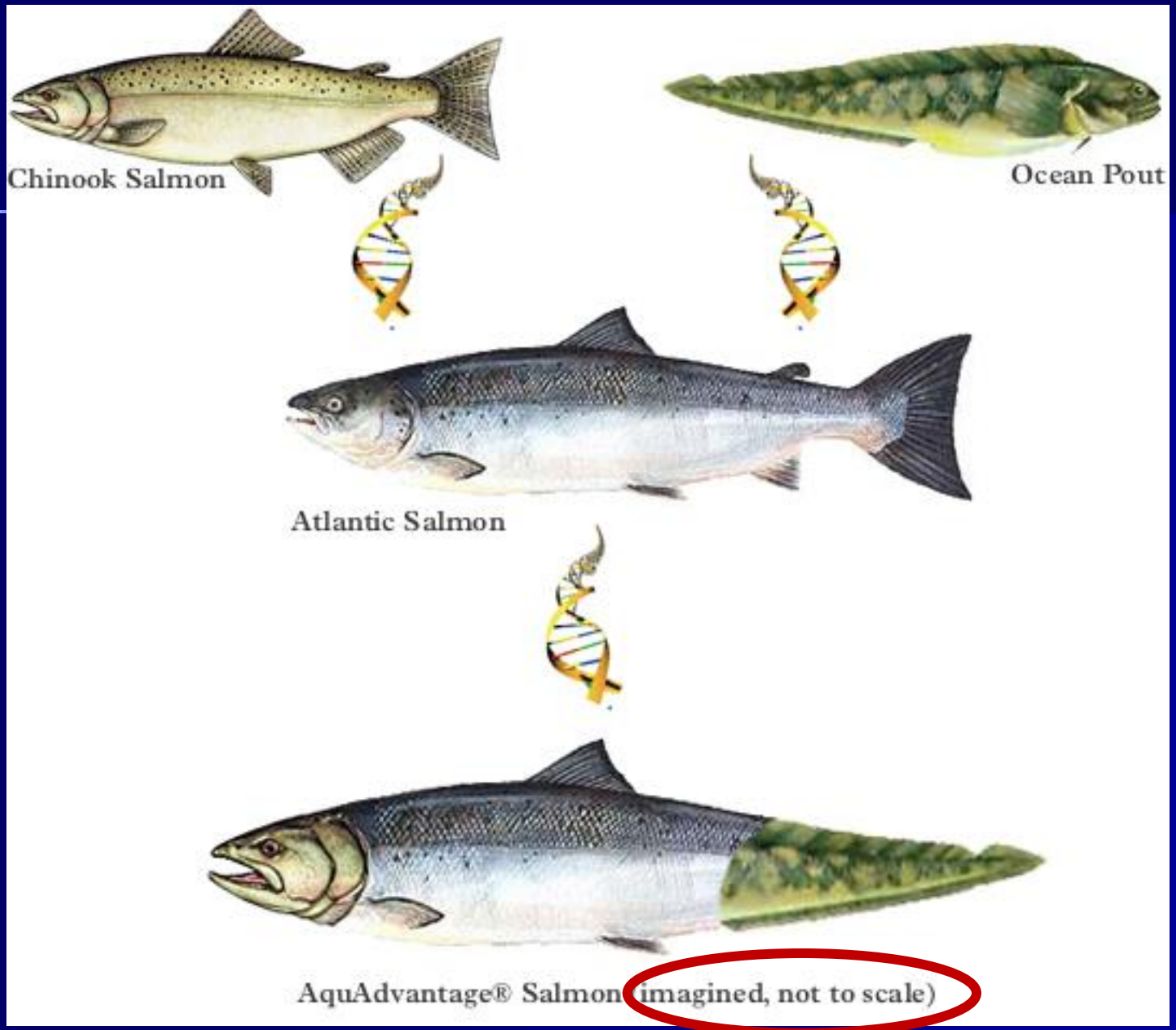


Fish reach adult size in 16 to 18 months instead of 30 months



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

Retrieved from "AquAdvantage" image search on web



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).

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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

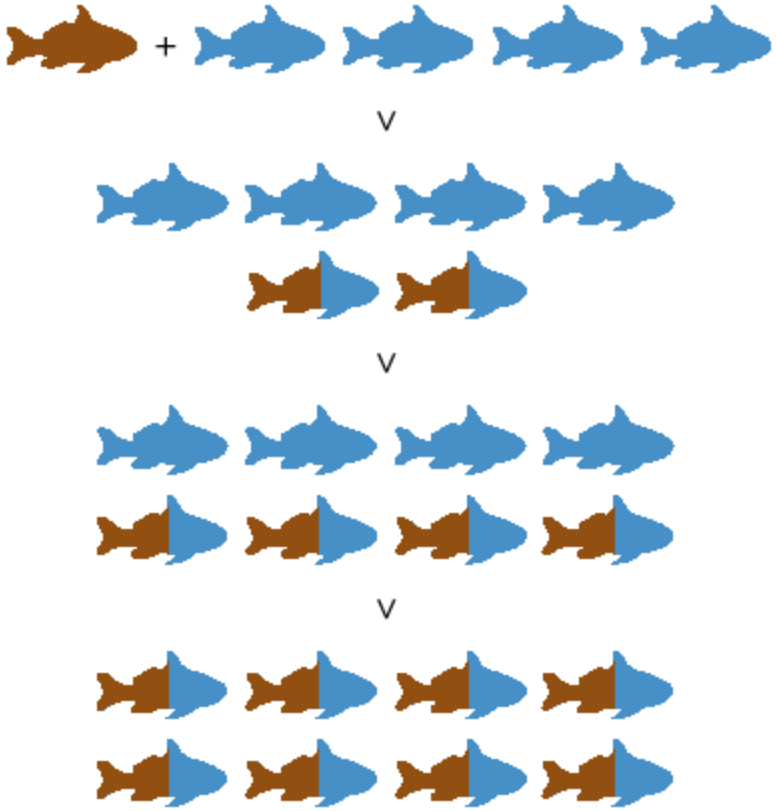
Environmental Safety: What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?

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.**

Gene Flow - The Spread Scenario



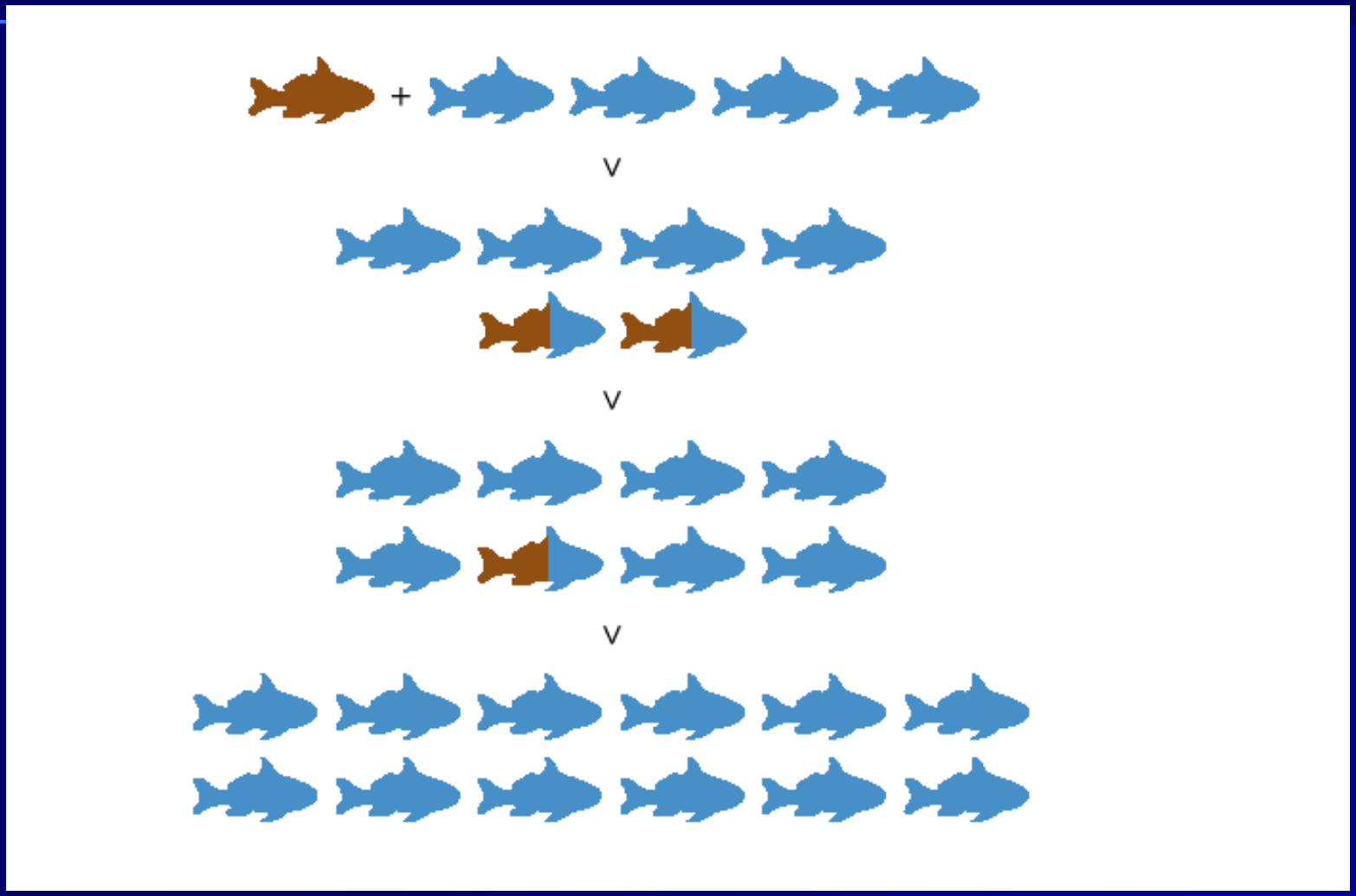
fish carrying "wild" or "native" genes

fish carrying transgenic DNA

> *movement from one generation to the next and the related gene flow*

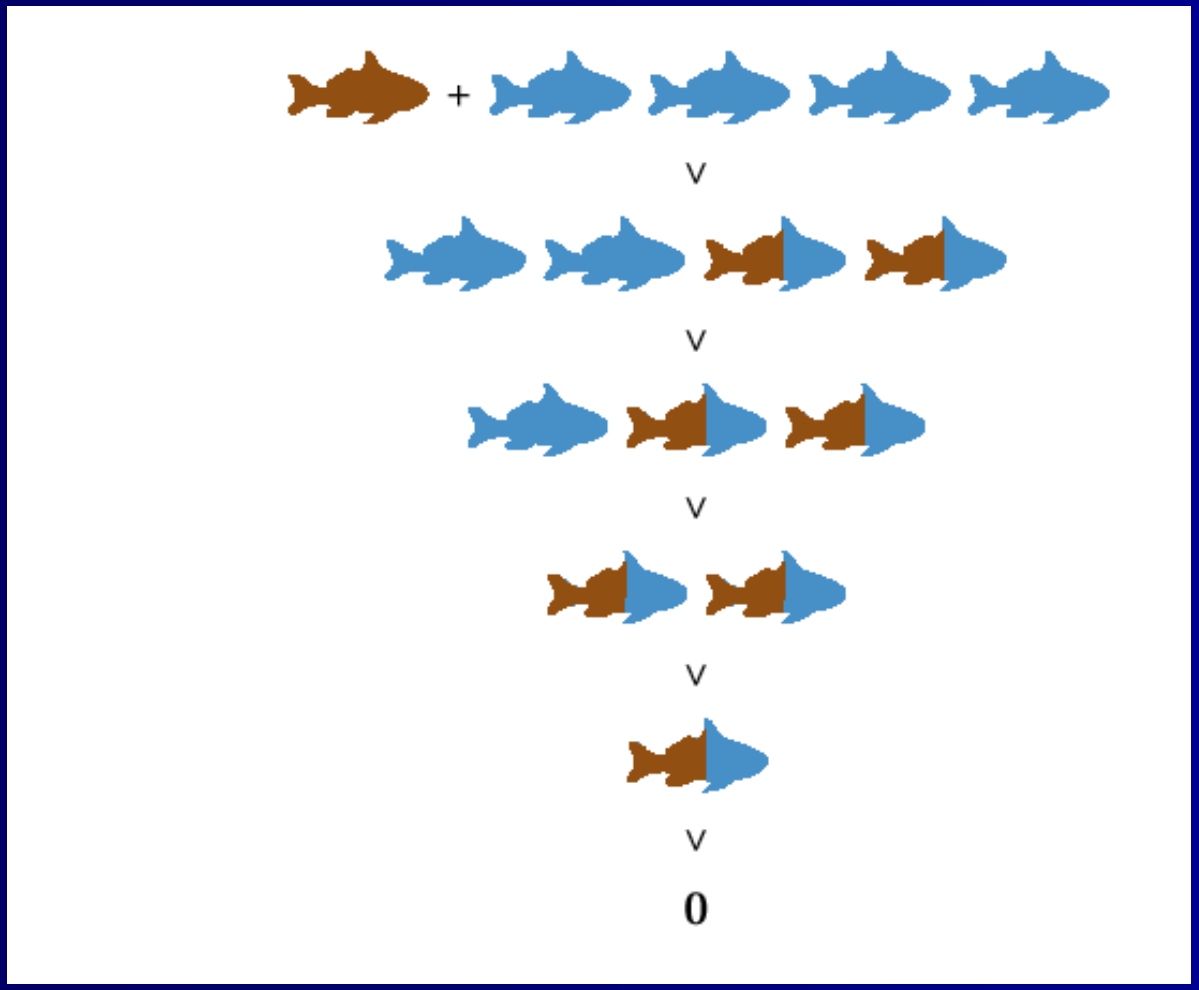
PEW 2003. Future Fish: Issues in Science and Regulation of Transgenic Fish

Gene Flow - The Purge Scenario



PEW 2003. Future Fish: Issues in Science and Regulation of Transgenic Fish

Gene Flow - The Trojan gene effect (Muir and Howard, 1999)



Occurs when there is a conflict of mating success with viability fitness; e.g. increased mating success with decreased juvenile viability.

PEW 2003. Future Fish: Issues in Science and Regulation of Transgenic Fish

Net Fitness Model: An Approach for Predicting the Outcome of Natural Selection

Two Step Process

- Estimation of Net Fitness Components for Alternative Genotypes
- Incorporate Parameters Into A Model that
  - Predicts the Change in Gene Frequency
  - Predicts Change in Population Size

Muir and Howard (2001) Fitness components and ecological risk of transgenic release: a model using Japanese medaka (Oryzias latipes) American Naturalist 158: 1-16

Net Fitness Components

Muir Howard (1999); extended (2001)

1. **Juvenile viability** (chances of surviving to sexual maturity)
2. **Age** (at sexual maturity)
3. **Mating success** (success at securing mates)
4. **Fecundity** (number of eggs produced by a female)
5. **Fertility** (number of eggs successfully fertilized by male sperm)
6. **Adult viability** (chances of surviving to procreate)

Muir WM and Howard RD (1999) Possible ecological risks of transgenic organism release when transgenes affect mating success: sexual selection and the Trojan gene hypothesis. Proc Natl Acad Sci 96: 13853–13856.

Muir WM and Howard RD (2001) Fitness components and ecological risk of transgenic release: a model using Japanese Medaka (Oryzias latipes). Am Natur 158: 1–16.

Life stages: Atlantic salmon

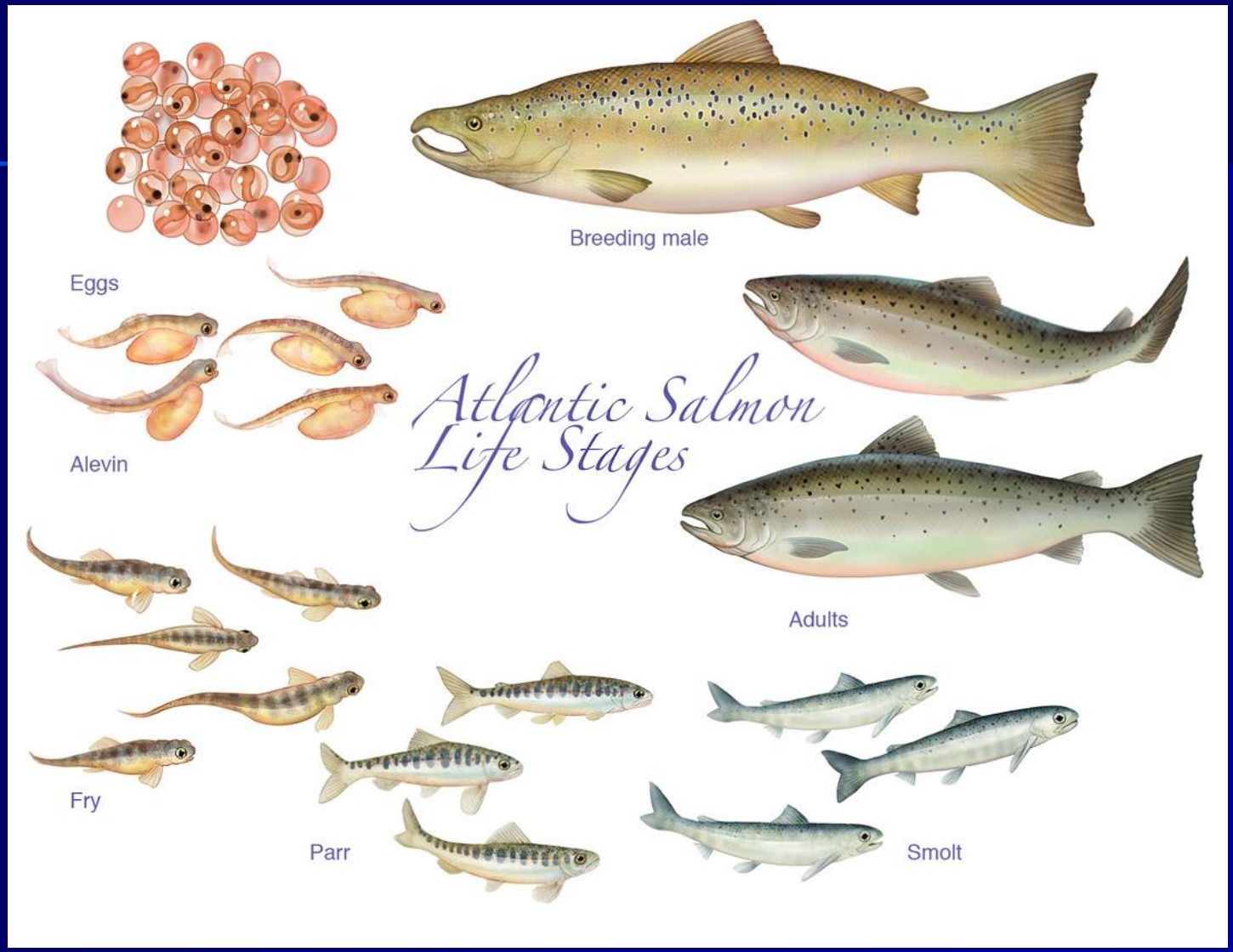


Image from http://harmon-murals.blogspot.com/2011/01/life-cycle-of-atlantic-salmon-for-new.html

Environmental risk assessment parameters for growth hormone Atlantic salmon, Salmo salar

- In 2005, Eric Hallerman (PD) , E. McLean, J. Brown, I. Fleming, and G. Fletcher were awarded a USDA Biotechnology Risk Assessment Grant (2005-39454-16417)

United States Department of Agriculture
National Institute of Food and Agriculture

OBJECTIVES included:

- Quantifying key aspects of the survival and reproductive components of fitness of GH transgenic Atlantic salmon in near-natural systems, including survival fitness (early viability, territoriality and anti-predation behavior) and reproductive fitness (age at maturation and mating success)
- To utilize empirical data to predict the net fitness of GH transgenic salmon and transgene fate in near-natural ecosystems.

Early viability: Juvenile fitness testing

Territorial dominance, growth and survival of first-feeding

- In stream environments with limited food, the transgene did not influence the growth or survival at high or low fry densities.
- Transgenic and non-transgenic individuals were equally likely to be dominant.
- No differences were found between GH-transgenic and non-transgenic *S. salar* fry in any of the fitness-related phenotypic traits measured.

Moreau, D. T. R., I. A. Fleming, G. L. Fletcher, and J. A. Brown. 2011. Growth hormone transgenesis does not influence territorial dominance or growth and survival of first-feeding Atlantic salmon Salmo salar L. in food-limited stream microcosms. Journal of Fish Biology 78:726–740.

Reproductive Fitness testing

Three stocks:

- Wild Atlantic salmon: Exploits River, Newfoundland
- Transgenic line: AquaBounty Farms AquAdvantage salmon line – raised in captivity
- Immature and mature parr derived from 2004 crosses of wild Exploits River salmon

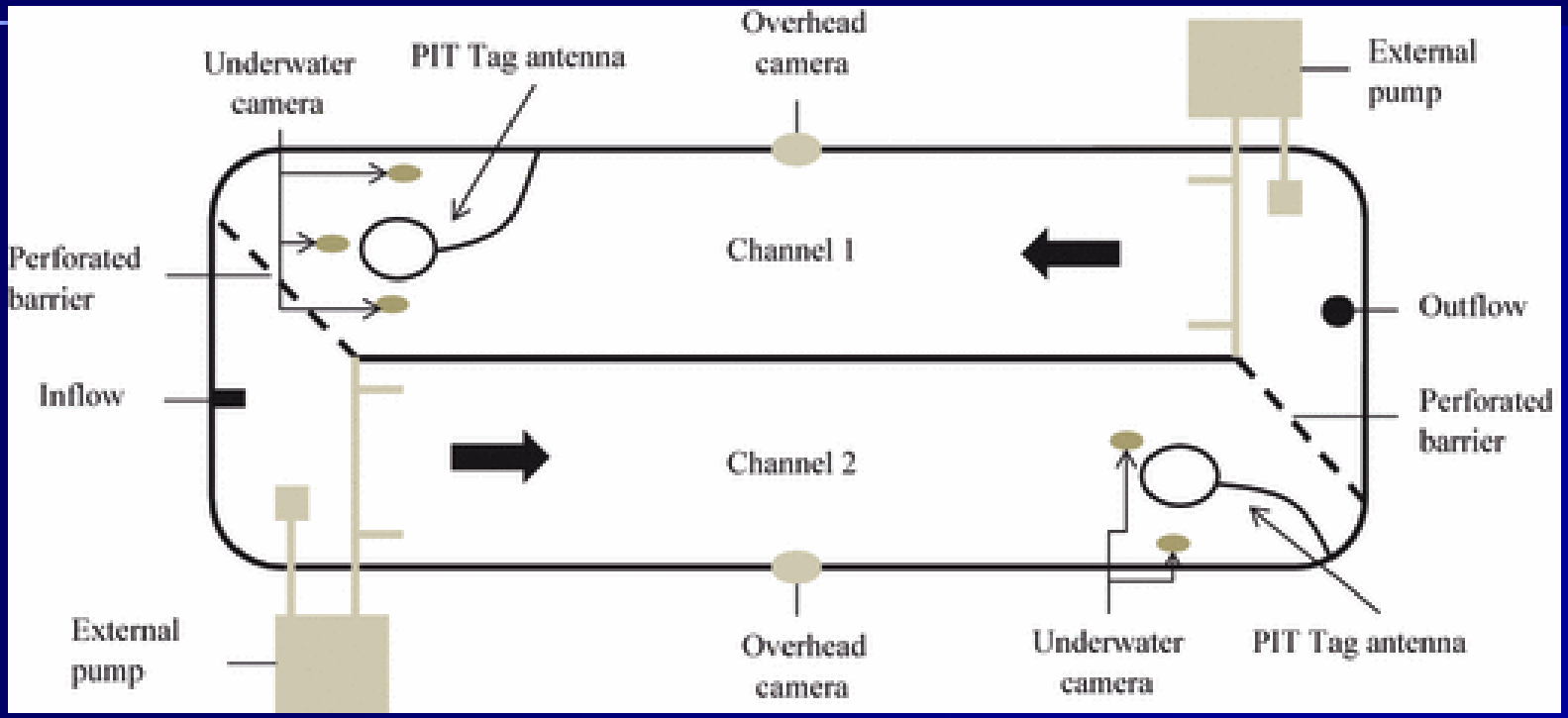
Moreau, D. T. R., C. Conway, I. A. Fleming. 2011. Reproductive performance of alternative male phenotypes of growth hormone transgenic Atlantic salmon (Salmo salar). Evolutionary Applications. http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1752-4571/earlyview

Quantify Male Reproductive Fitness: Anadromous (i.e. large, fighter) males

Part 1:

- Anadromous adult transgenic and control males
- Competing for access to breeding females.
- Transgenic males were captive-reared and the control males were wild
- Replicated (n = 11 replicate trials)
  - 2 large anadromous males – 1 transgenic, 1 control
  - 1 breeding female
  - 5 mature male parr - nontransgenic
  - 10 immature parr - nontransgenic

An illustration of the fully-contained naturalized stream mesocosm (1.25 × 7.8 × 0.25 m per channel)



This was used to compare the reproductive performance of growth hormone transgenic and nontransgenic Atlantic salmon males, both as anadromous fish and precocial parr.

Behavioral data - a combination of video observation and passive integrated transponder tag detection - Thick arrows indicate the direction of water flow.

Darek T. R. Moreau, Corinne Conway, Ian A. Fleming. 2011. Reproductive performance of alternative male phenotypes of growth hormone transgenic Atlantic salmon (*Salmo salar*).

Results: Anadromous Males

- Transgenic anadromous males (i.e. large, fighter males), reared to maturity in captivity, were behaviorally out-competed by the wild control males
  - Nest fidelity
  - Quivering frequency
  - Spawn participation

- Parentage analyses were deemed unnecessary because the behavioral results from the anadromous male experiments “made it unnecessary to assess breeding success at the genetic level”.

Moreau, D. T. R., C. Conway, I. A. Fleming. 2011. Reproductive performance of alternative male phenotypes of growth hormone transgenic Atlantic salmon (Salmo salar). Evolutionary Applications. http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)1752-4571/earlyview

Quantify Male Reproductive Fitness: Precocially mature parr (aka: sneaker males)

Part 2:

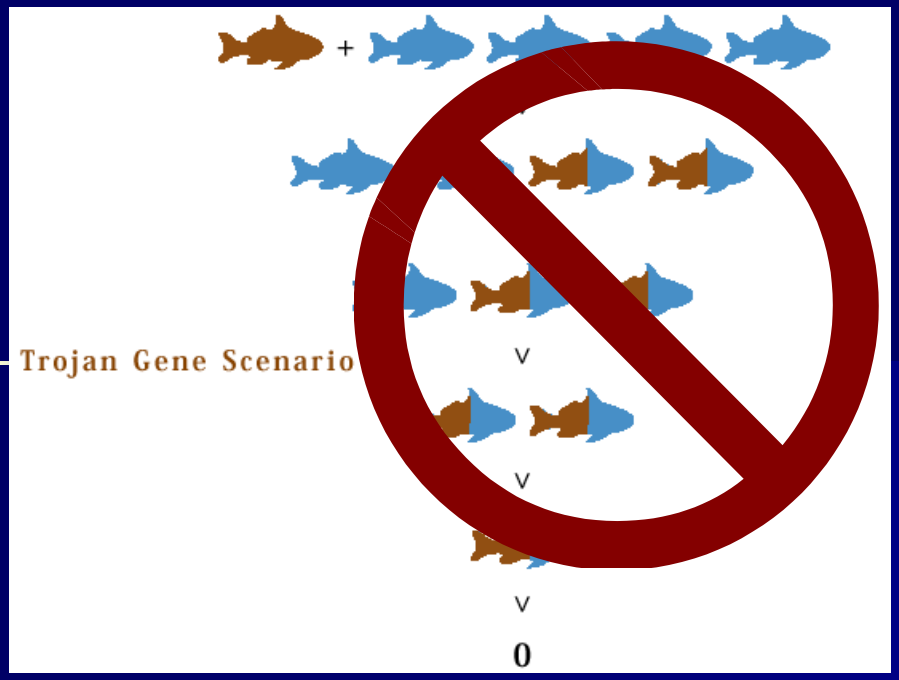
- Compared early-maturing transgenic and control parr for access to breeding females
- Both transgenic and control mature male parr were captive-reared
- Replicated (n = 11)
  - 1 large anadromous male
  - 1 breeding female
  - 2 mature parr (1 transgenic, 1 control)
  - 4 immature parr

Results: Mature Male Parr

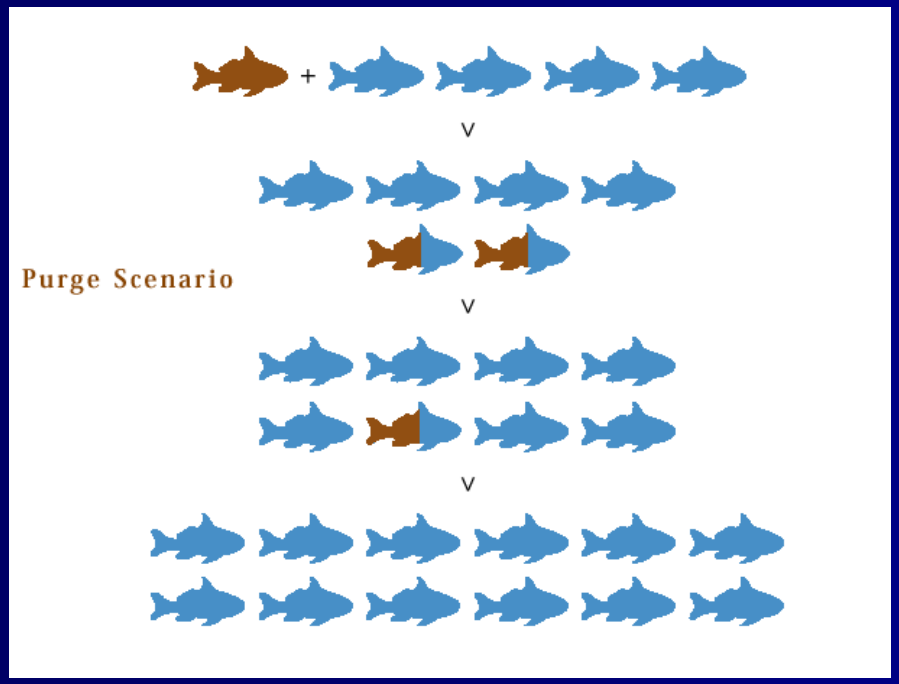
- Large anadromous males sired dominated parr in fertilization success
- Transgenic male parr (i.e. precocially mature, sneaker males) were inferior competitors to wild-type parr in terms of nest fidelity and spawn participation
- Control parr had higher overall fertilization success than transgenic parr
- Offspring fathered by control were present in more trials (n=5) than transgenic parr (n=1).

Summary: Estimates of Components of Net Fitness

- **Juvenile viability**: No differences were found between GH-transgenic and non-transgenic *S. salar* fry in any of the fitness-related phenotypic traits measured in first-feeding Atlantic salmon
- **Mating success**: Transgenic males displayed REDUCED reproductive performance relative to control males.



REMEMBER: The trojan gene scenario is predicted to occur if the trait both increases male mating success AND lowers transgenic viability



Collectively these data suggest the purge scenario is the more likely fate for the AquAdvantage growth hormone transgene i.e. it would be purged by natural selection IF FERTILE MALES ESCAPED

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

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

"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

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."

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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).

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December 15, 2011	The Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard held 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

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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.
July 2011	Eight senators (AK, WA, OR) urge FDA Commissioner Margaret A. Hamburg, MD, to stop her agency from further considering approving the GE salmon.
December 15, 2011	The Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard held hearing to examine potential environmental risks of genetically engineered (GE) fish.
Feb 7, 2012	The Center for Food Safety and two other consumer advocacy groups petitioned the FDA to begin a new safety review. That set in motion a process that requires the FDA to respond to the request before it makes any decision about approving the fish. When the FDA did a safety review two years ago, it did so as if the fish were a new animal drug, with the review for safety conducted by the FDA's Veterinary Medicine Advisory Committee. **Instead, the fish should be reviewed as a food additive, which offers a more rigorous and transparent process**,

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
- 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

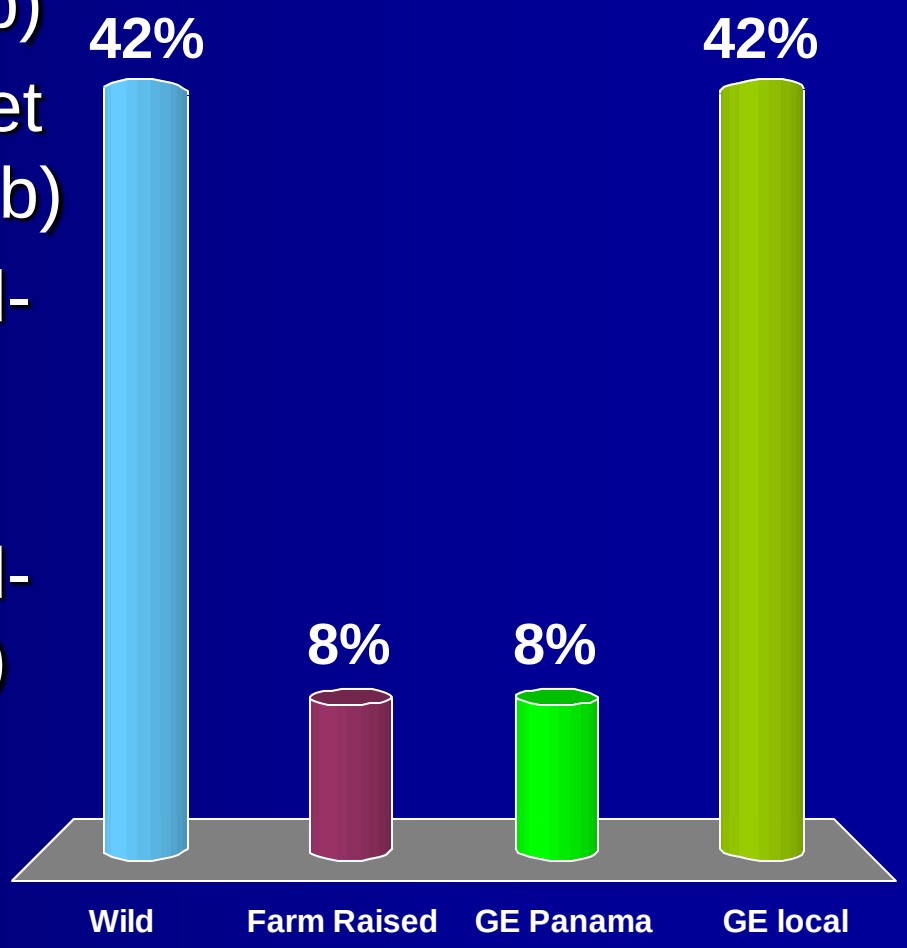
2. Farm-raised: $6.99/lb net pen imported from Norway/Scotland/Canada

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?

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)



Current Situation of AquAdvantage Application

- No formal comment/response from FDA following September 2010 VMAC meeting
- The next step is for the FDA to release an Environmental Assessment given the proposed conditions of use which will either be associated with a “finding of no significant impact” (FONSI), or a finding of significant environmental impact.
- There will be a 60 day comment period following the release of the FDA’s Environmental Assessment (EA)
- In the event that the EA results in a finding that a significant environmental impact may result, an Environmental Impact Statement (EIS) may need to be prepared.
- The wait continues…..in the US

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