Genetically Engineered Animals Tangled in Regulatory and Political Deadlock

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No genetically engineered animals have been approved for food production anywhere in the world

APPLICATION	Species	Gene	Approach
ENVIRONMENTAL			
Decreased P in manure	Swine	Phytase	Transgene expression
DISEASE RESISTANCE			
Mastitis resistance	Cattle	Lysostaphin	Transgene expression
Avian flu transmission	Chicken	Decoy protein	Transgene expression
PRODUCT QUALITY			
Increased ω-3 fatty acids in meat	Swine	n-3 fatty acid desaturase	Clone/Transgene expression
PRODUCTIVITY			
Enhanced growth rate	↑ fish species	Growth Hormone	Transgene expression

Fahrenkrug et al. 2010. Precision Genetics for Complex Objectives in Animal Agriculture. J. Anim Sci. 88(7):2530-9.

Enviropig™ (Low-phosphorus manure)

RESEARCH ARTICLE

Nature Biotechnology 19, 741–745 . 2001

Pigs expressing salivary phytase produce low-phosphorus manure

Serguei P. Golovan[1,2], Roy G. Meidinger[2], Ayodele Ajakaiye[3], Michael Cottrill[1], Miles Z. Wiederkehr[4], David J. Barney[4], Claire Plante[5], John W. Pollard[5], Ming Z. Fan[3], M. Anthony Hayes[6], Jesper Laursen[7,8], J. Peter Hjorth[7], Roger R. Hacker[3], John P. Phillips[2,*], and Cecil W. Forsberg[1,*]

To address the problem of manure-based environmental pollution in the pork industry, we have developed the phytase transgenic pig. The saliva of these pigs contains the enzyme phytase, which allows the pigs to digest the phosphorus in phytate, the most abundant source of phosphorus in the pig diet. Without this enzyme, phytate phosphorus passes undigested into manure to become the single most important manure pollutant of pork production. We show here that salivary phytase provides essentially complete digestion of dietary phytate phosphorus, relieves the requirement for inorganic phosphate supplements, and reduces fecal phosphorus output by up to 75%. These pigs offer a unique biological approach to the management of phosphorus nutrition and environmental pollution in the pork industry.

"reduces fecal phosphorus output by up to 75%"

www.uoguelph.ca/enviropig

Mastitis-resistant cows
(inflammation of mammary gland)

nature biotechnology

ARTICLES

Nature Biotechnology 23:445-451. 2005

Genetically enhanced cows resist intramammary *Staphylococcus aureus* infection

Robert J Wall[1], Anne M Powell[1], Max J Paape[2], David E Kerr[3], Douglas D Bannerman[2], Vernon G Pursel[1], Kevin D Wells[4], Neil Talbot[1] & Harold W Hawk[1]

Mastitis, the most consequential disease in dairy cattle, costs the US dairy industry billions of dollars annually. To test the feasibility of protecting animals through genetic engineering, transgenic cows secreting lysostaphin at concentrations ranging from 0.9 to 14 mg/ml in their milk were produced. *In vitro* assays demonstrated the milk's ability to kill *Staphylococcus aureus*. Intramammary infusions of *S. aureus* were administered to three transgenic and ten nontransgenic cows. Increases in milk somatic cells, elevated body temperatures and induced acute phase proteins, each indicative of infection, were observed in all of the nontransgenic cows but in none of the transgenic animals. Protection against *S. aureus* mastitis appears to be achievable with as little as 3 mg/ml of lysostaphin in milk. Our results indicate that genetic engineering can provide a viable tool for enhancing resistance to disease and improve the well-being of livestock.

http://www.nature.com/naturebiotechnology

Omega-3 Pigs
(Pigs cloned after genetically engineering cell)

BRIEF COMMUNICATIONS

nature biotechnology

Nature Biotechnology 24:435-436. 2006

Generation of cloned transgenic pigs rich in omega-3 fatty acids

Liangxue Lai[1,2,8], Jing X Kang[5,8], Rongfeng Li[1], Jingdong Wang[5], William T Witt[6], Hwan Yul Yong[1], Yanhong Hao[1], David M Wax[1], Clifton N Murphy[1], August Rieke[1], Melissa Samuel[1], Michael L Linville[3], Scott W Korte[4], Rhobert W Evans[7], Thomas E Starzl[6], Randall S Prather[1,2] & Yifan Dai[6]

Meat products are generally low in omega-3 (*n*-3) fatty acids, which are beneficial to human health. We describe the generation of cloned pigs that express a humanized *Caenorhabditis elegans* gene, fat-1, encoding an *n*-3 fatty acid desaturase. The hfat-1 transgenic pigs produce high levels of *n*-3 fatty acids from *n*-6 analogs, and their tissues have a significantly reduced ratio of *n*-6/*n*-3 fatty acids ($P < 0.001$).

The health benefits of long chain *n*-3 fatty acids, found mainly in fish oils, are well recognized. Meat products normally contain small amounts of *n*-3 fatty acids and large amounts of *n*-6 fatty acids[1]

University of Missouri/Massachusetts General Hospital and Harvard Medical School

GE Chickens That Don't Transmit Bird Flu

Breakthrough could prevent future bird flu epidemics

Suppression of Avian Influenza Transmission in Genetically Modified Chickens

Jon Lyall,[1] Richard M. Irvine,[2] Adrian Sherman,[3] Trevelyan J. McKinley,[1] Alejandro Núñez,[2] Auriol Purdie,[3]* Linzy Outtrim,[2] Ian H. Brown,[2] Genevieve Rolleston-Smith,[3] Helen Sang,[3]† Laurence Tiley[1]†‡

Infection of chickens with avian influenza virus poses a global threat to both poultry production and human health that is not adequately controlled by vaccination or by biosecurity measures. A novel alternative strategy is to develop chickens that are genetically resistant to infection. We generated transgenic chickens expressing a short-hairpin RNA designed to function as a decoy that inhibits and blocks influenza virus polymerase and hence interferes with virus propagation. Susceptibility to primary challenge with highly pathogenic avian influenza virus and onward transmission dynamics were determined. Although the transgenic birds succumbed to the initial experimental challenge, onward transmission to both transgenic and nontransgenic birds was prevented.

The diversity of avian influenza viruses (AIVs) and their propensity for interspecies transmission make them a global threat to animal and public health communities. Cross-species transmission of influenza viruses mediate host species that amplify and diversify virus populations, notably domestic chickens, ducks, and pigs (*1*). Although control of AIV infection in its wild aquatic bird reservoir is impractical, control of AIV in domesticated hosts is

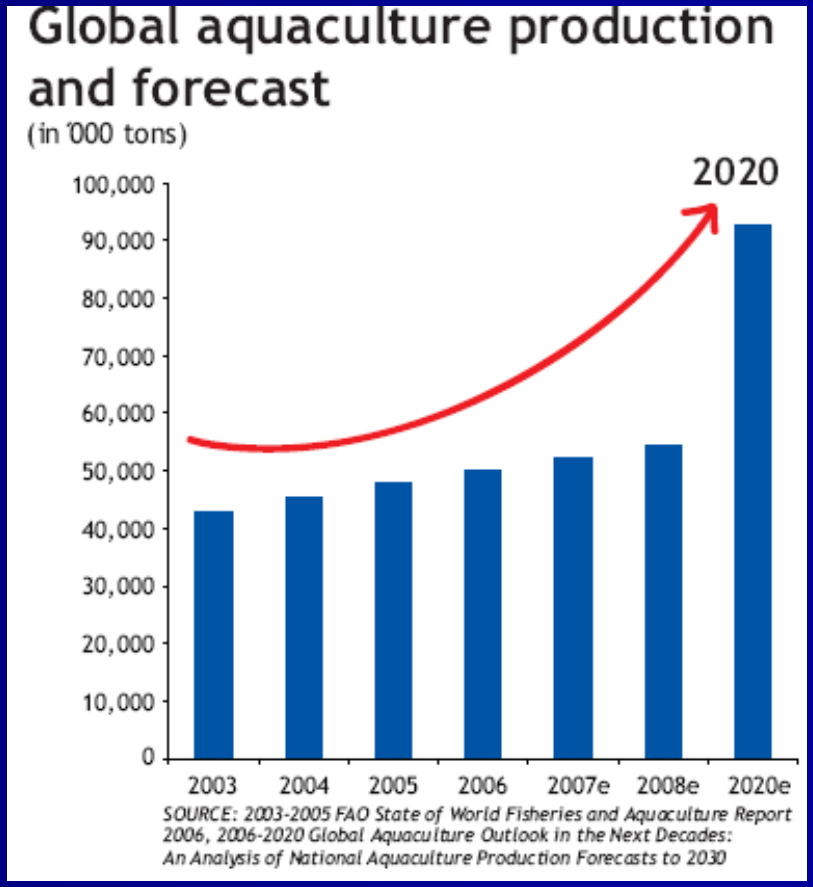
The diversity of viral antigenic sub-

Science 331:223-226. 2011 SCIENCE VOL 331 14 JANUARY 2011 223

http://www.roslin.ed.ac.uk/public-interest/gm-chickens

Moving onto FISH

- 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
- Aquaculture continues to grow more rapidly than all other animal food-producing sectors.
- Worldwide, the sector has grown at an average rate of 8.8 % per year since 1970, compared with only 1.2 % for capture fisheries

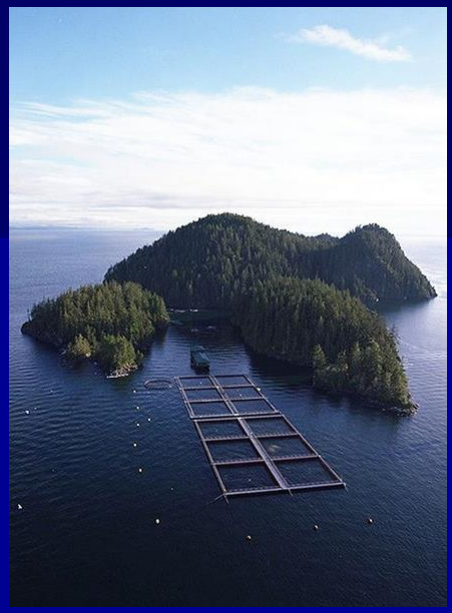


Salmon

- 1996: World farmed salmon production (mostly Atlantic salmon) exceeds wild salmon harvest.
- 99% of the Atlantic salmon consumed in the US is farmed – almost all from ocean pen aquaculture operations in Canada, Chile, Norway and Scotland
- During the years 2000-2004, Americans consumed an average of about 0.28 MMT of salmon annually
  - one-third was Pacific salmon and two-thirds was Atlantic salmon
  - one-third was wild and two-thirds was farmed
  - one-third was domestic production and two thirds was imported
- Atlantic salmon can not interbreed with Pacific salmon – they are different species

October 2011
Davis, CA

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.

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

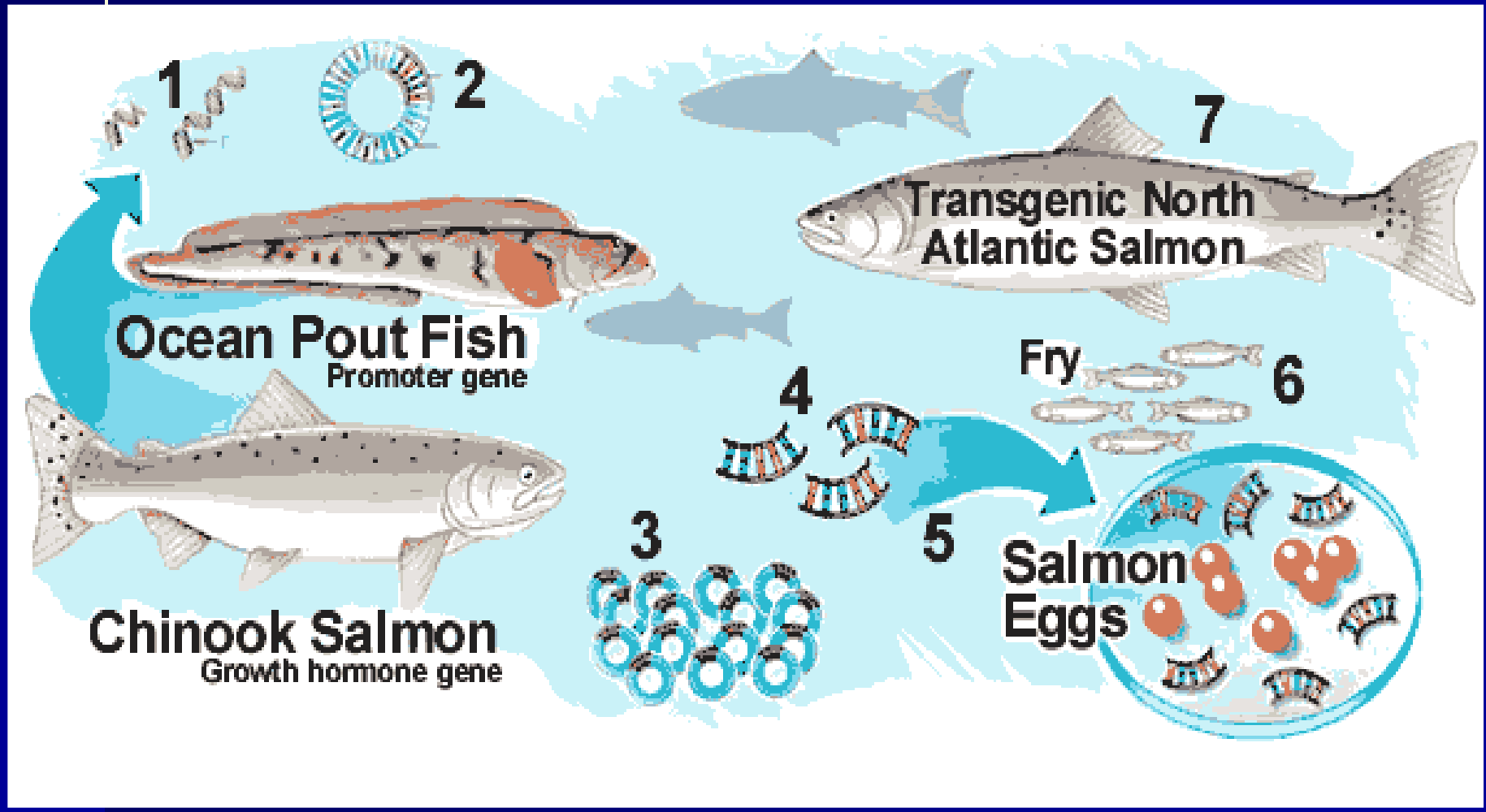
Shao Jun Du, Zhiyuan Gong, Garth L. Fletcher[1], Margaret A. Shears[1], Madonna J. King[1], David R. Idler[1] and Choy L. Hew*

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.

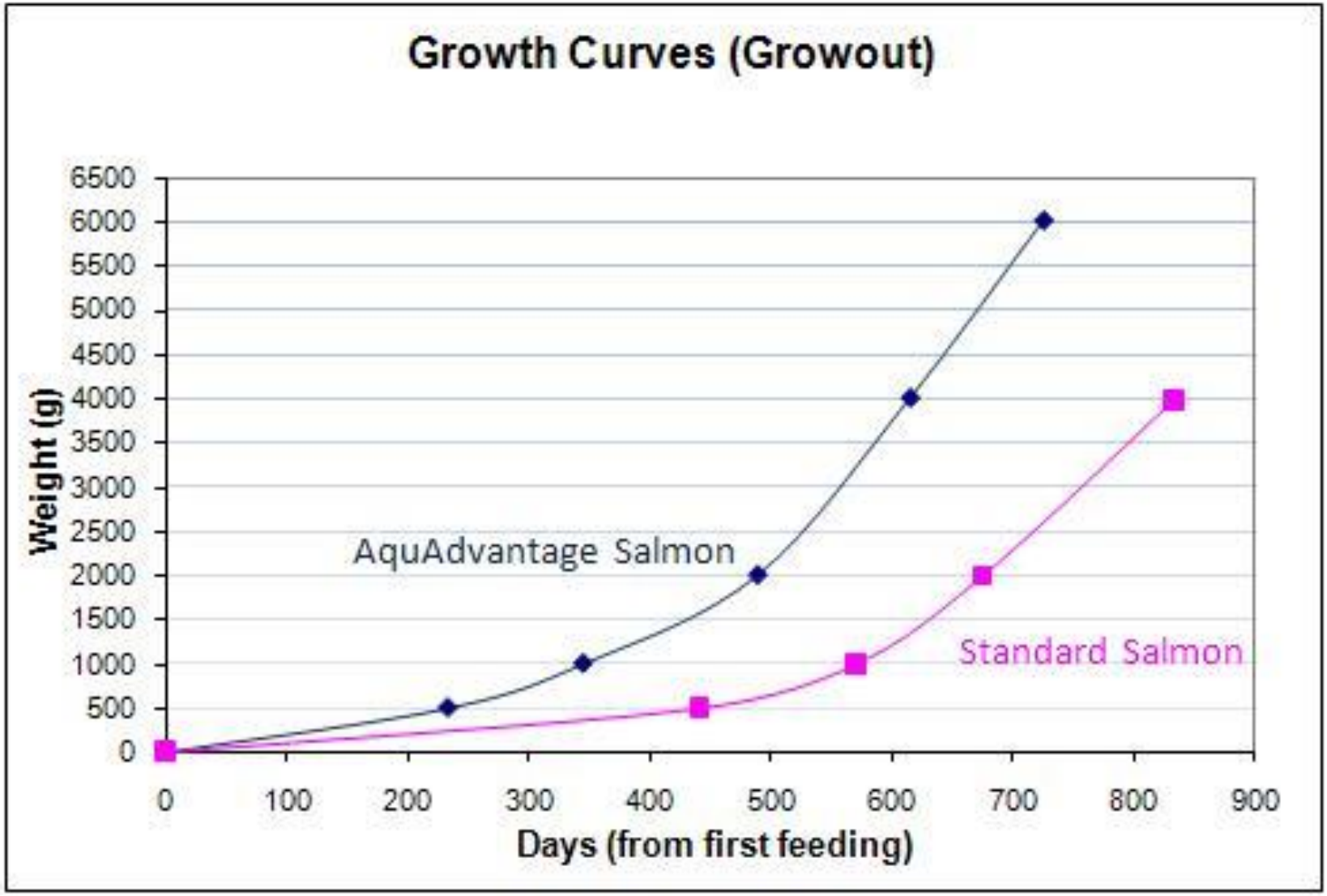
We have developed an "all fish" growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon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



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.

"New Animal Drug" approach

- Because of the requirements set forth in the National Environmental Protection Act (NEPA) and FDA environmental impact regulations, the agency typically must prepare an environmental assessment (EA) for each New Animal Drug Application (NADA)
- FDA has to consider the possible effects on the human environment and possible risk mitigation strategies that may arise from the specific conditions of use that are the subject of the NADA.
- There will be a 60 day comment period following the release of the FDA's Environmental Assessment
- 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.

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.

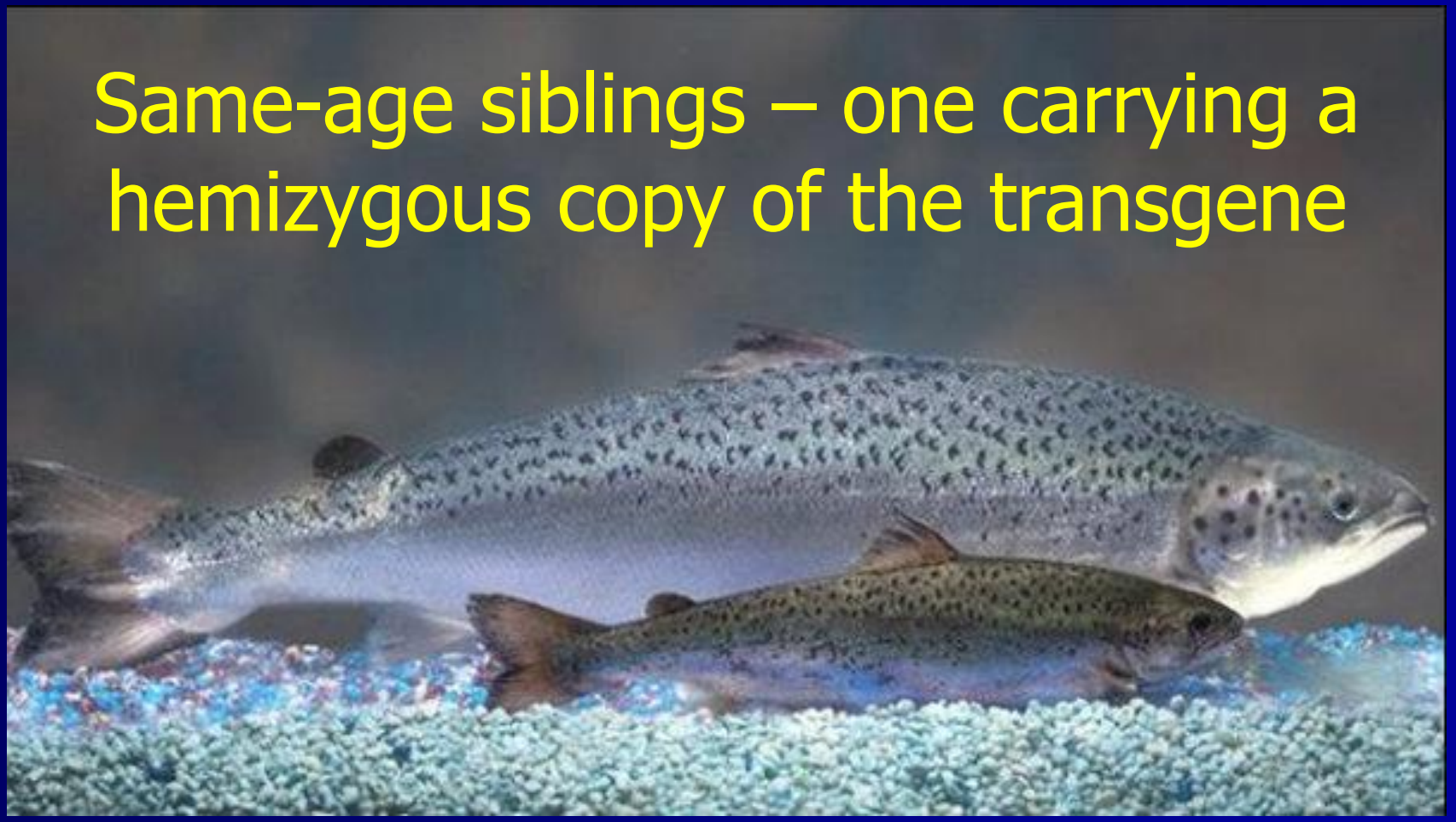
The guidance also describes the manufacturer's responsibility in meeting the requirements for environmental review under the National Environmental Policy Act.

For more information:

- Genetically Engineered Animals

"Increase transparency, clarity, and public confidence in the GE animal regulatory process"

Date	Event
September 1995	AquaBounty submits Investigational New Animal Drug application with FDA for fast-growing salmon with intent to commercialize



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.**

Did the public meeting achieve its stated goal of increasing 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 Allergenic:** GMO salmon have mean allergenic potencies that are 20% and 52% higher than normal salmon.
- **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.
- **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

"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 FDA 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
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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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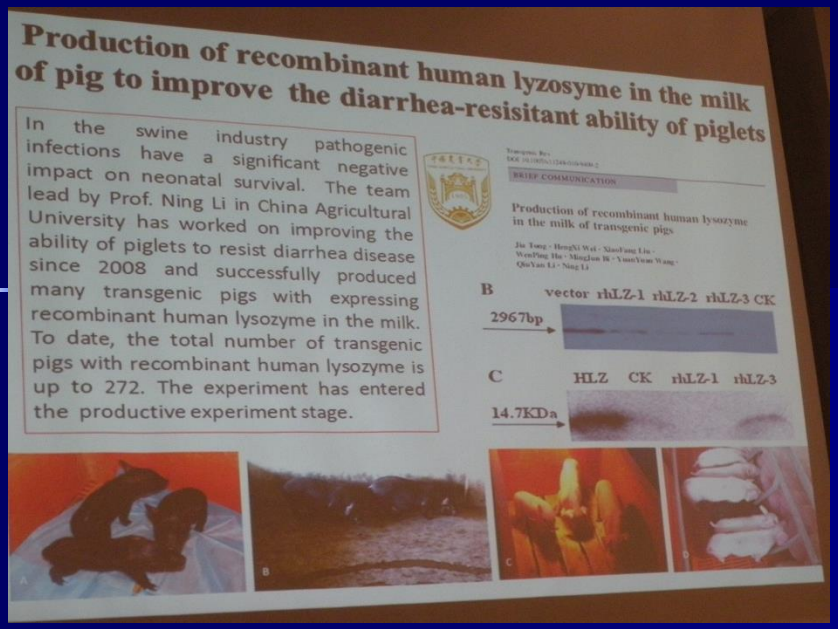
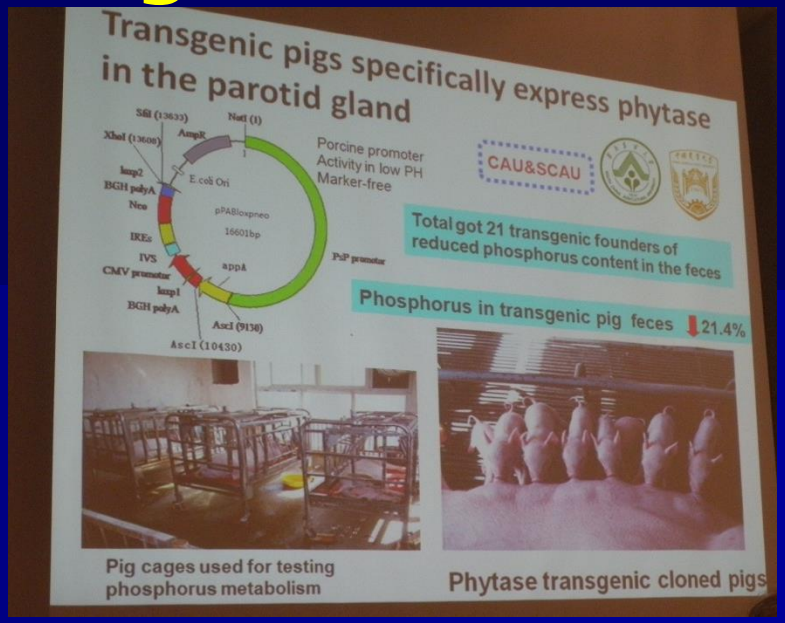
December 15, 2011	The Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard held hearing to examine potential environmental risks of genetically engineered (GE) fish.
Feb 7, 2012	The Center for Food Safety and two other consumer advocacy groups petitioned the FDA to begin a new safety 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**,

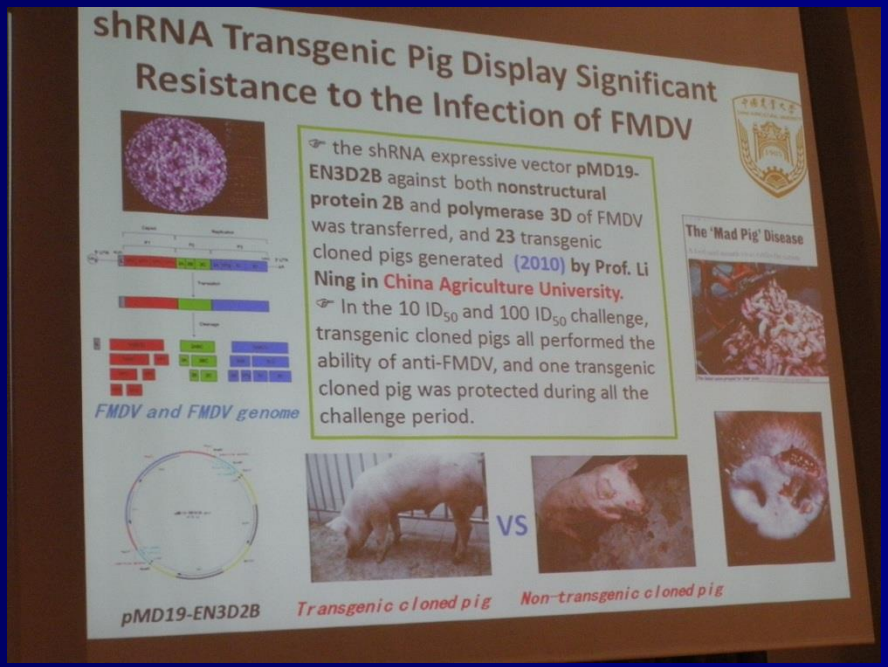
Current Situation of AquAdvantage Application

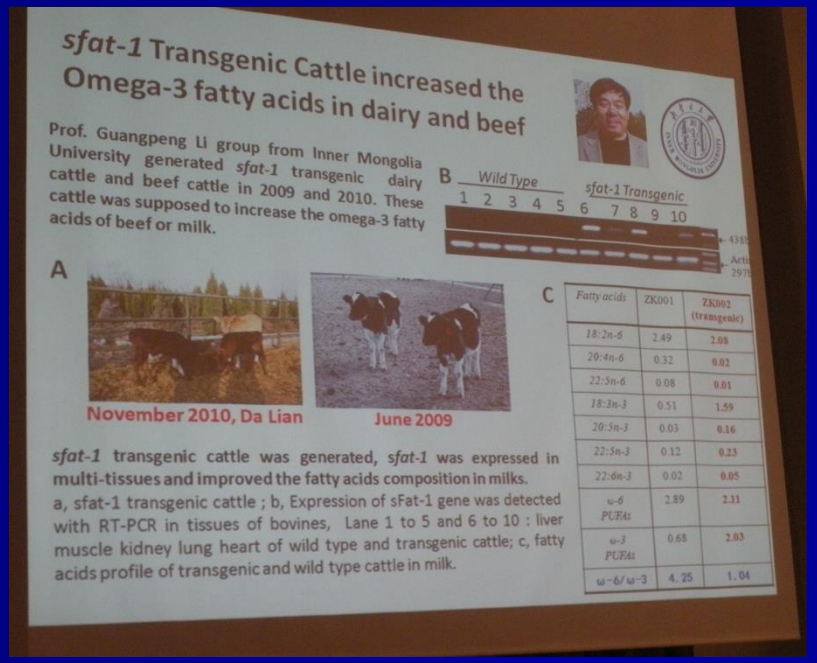
- No formal comment/response from FDA following September 2010 VMAC meeting
- The next step is for the FDA to release an Environmental Assessment given the proposed conditions of use which will either be associated with a “finding of no significant impact” (FONSI), or a finding of significant environmental 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

Chinese work on transgenic animals





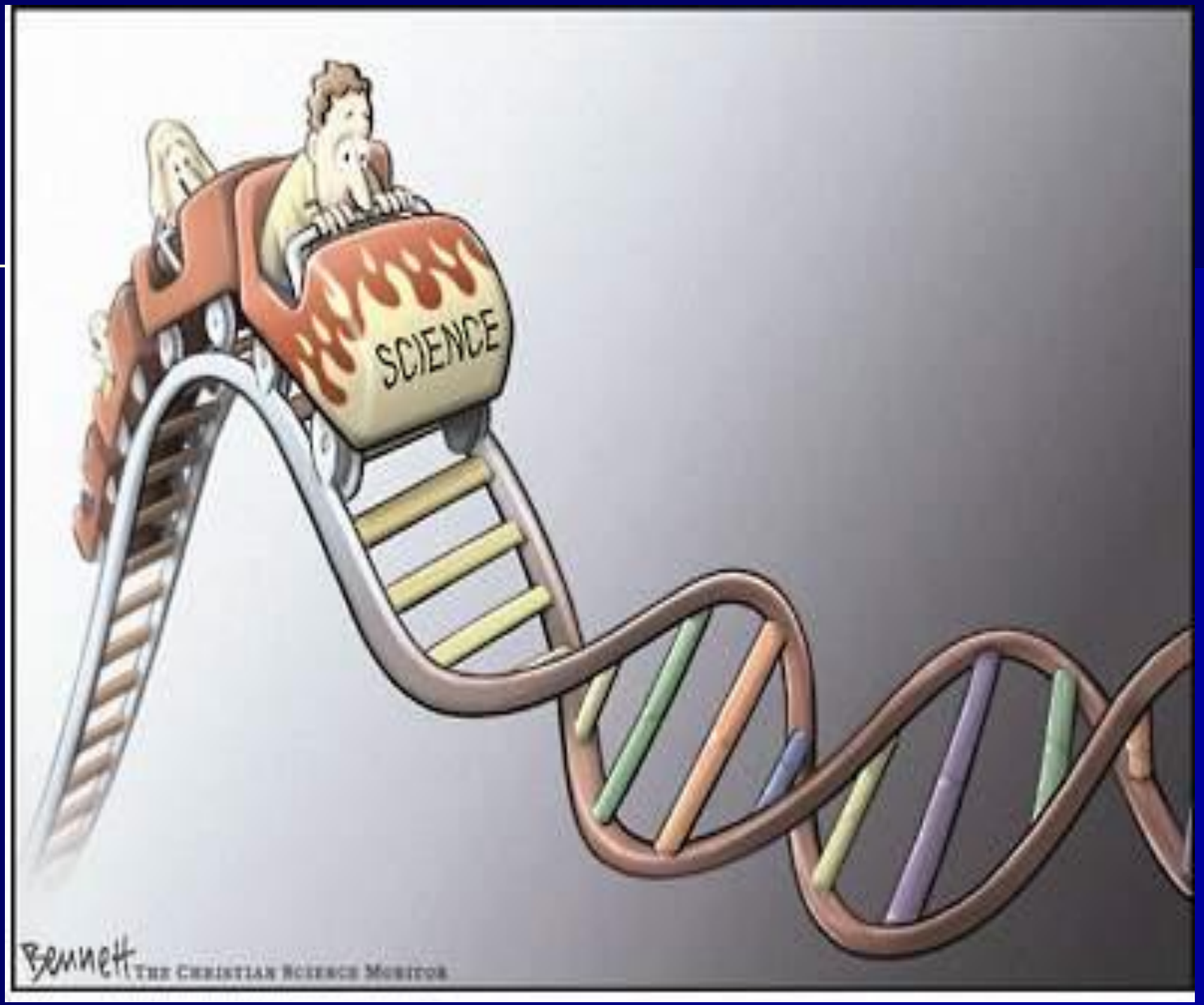




Dr. Calestous Juma, Harvard's Kennedy School of Government, at a 6/23/11 hearing to examine the benefits of agricultural biotechnology held by the House Agriculture Committee's Subcommittee on Rural Development, Research, Biotechnology, and Foreign Agriculture

". . 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 that is truly the envy of the world."


SCIENCE
Bennett
The Christian Science Monitor