Genetically Engineered (GE) Animals: Applications, Regulations, Implications, and Labeling

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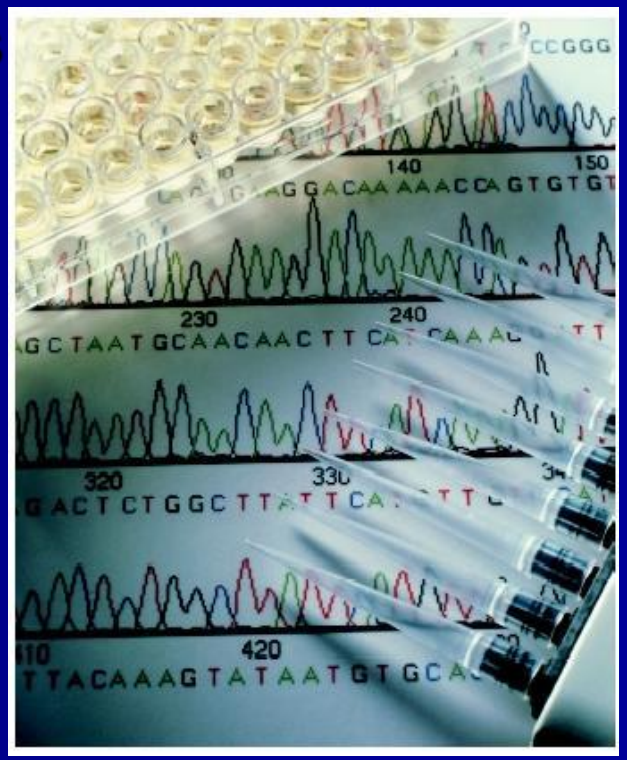
"The mission of the animal genomics and biotechnology extension program is to provide broad, science-based extension programming on the uses of animal biotechnologies in livestock production systems."



http://animalscience.ucdavis.edu/animalbiotech

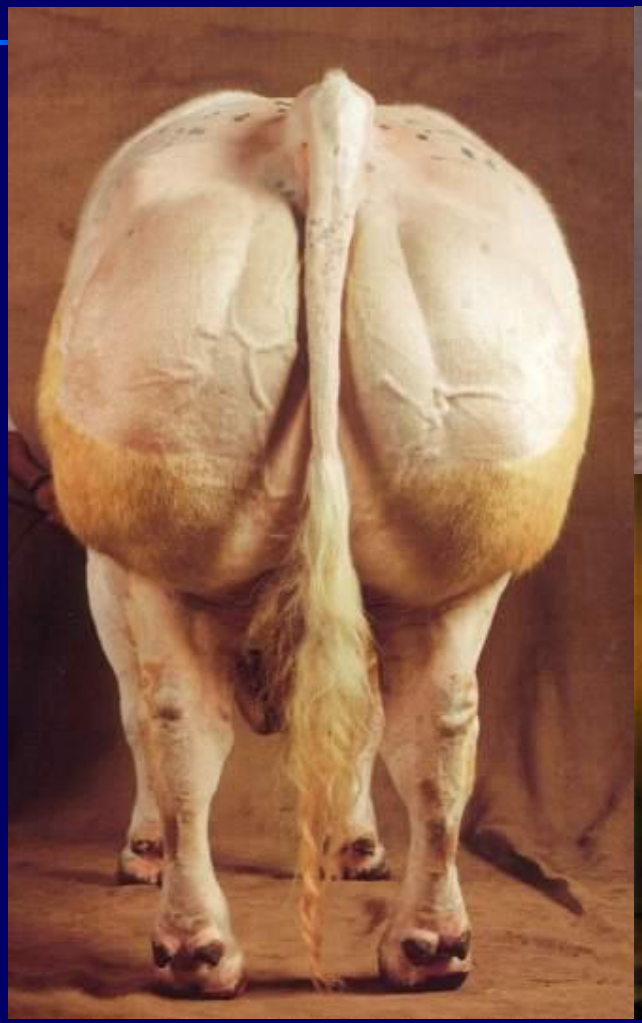
Overview

- Quick overview of genetic engineering (GE)?
- What are GE animals being used for?
- How are GE animals being regulated?
- The AquAdvantage GE salmon story
- Mandatory versus voluntary GE labeling
- California Proposition 37

Background

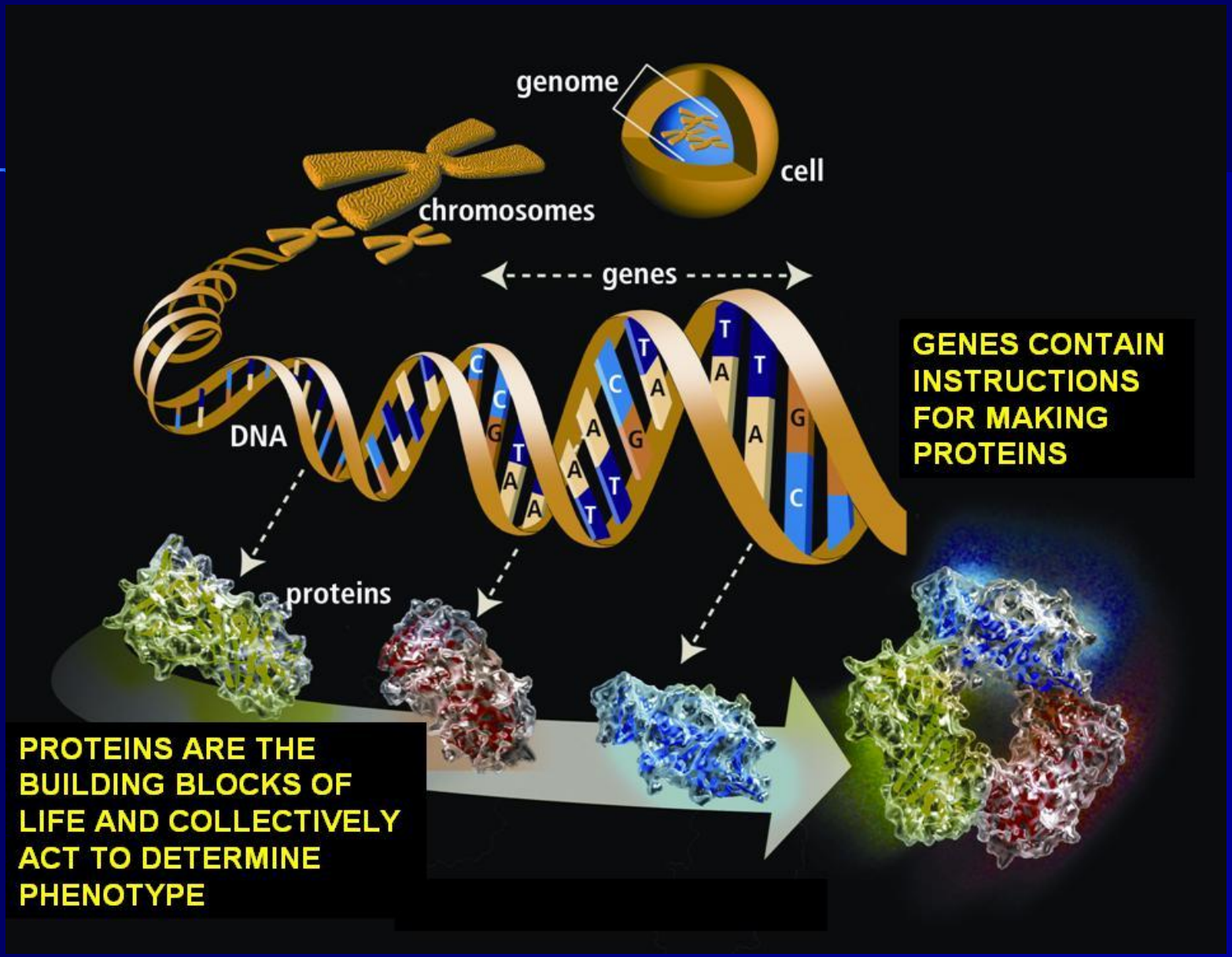
- The first genetically engineered (GE) or "transgenic" mice were produced almost 40 years ago (1974)
- Techniques have improved dramatically in the last 4 decades and it is now possible to precisely insert or replace genes in the genome of animals – enabling efficient "targeted transgenesis"
- This technology is being to develop biomedical models (e.g. millions of GE mice in US), and to produce biopharmaceuticals in animal products
- No GE animal currently approved for entry into the food supply

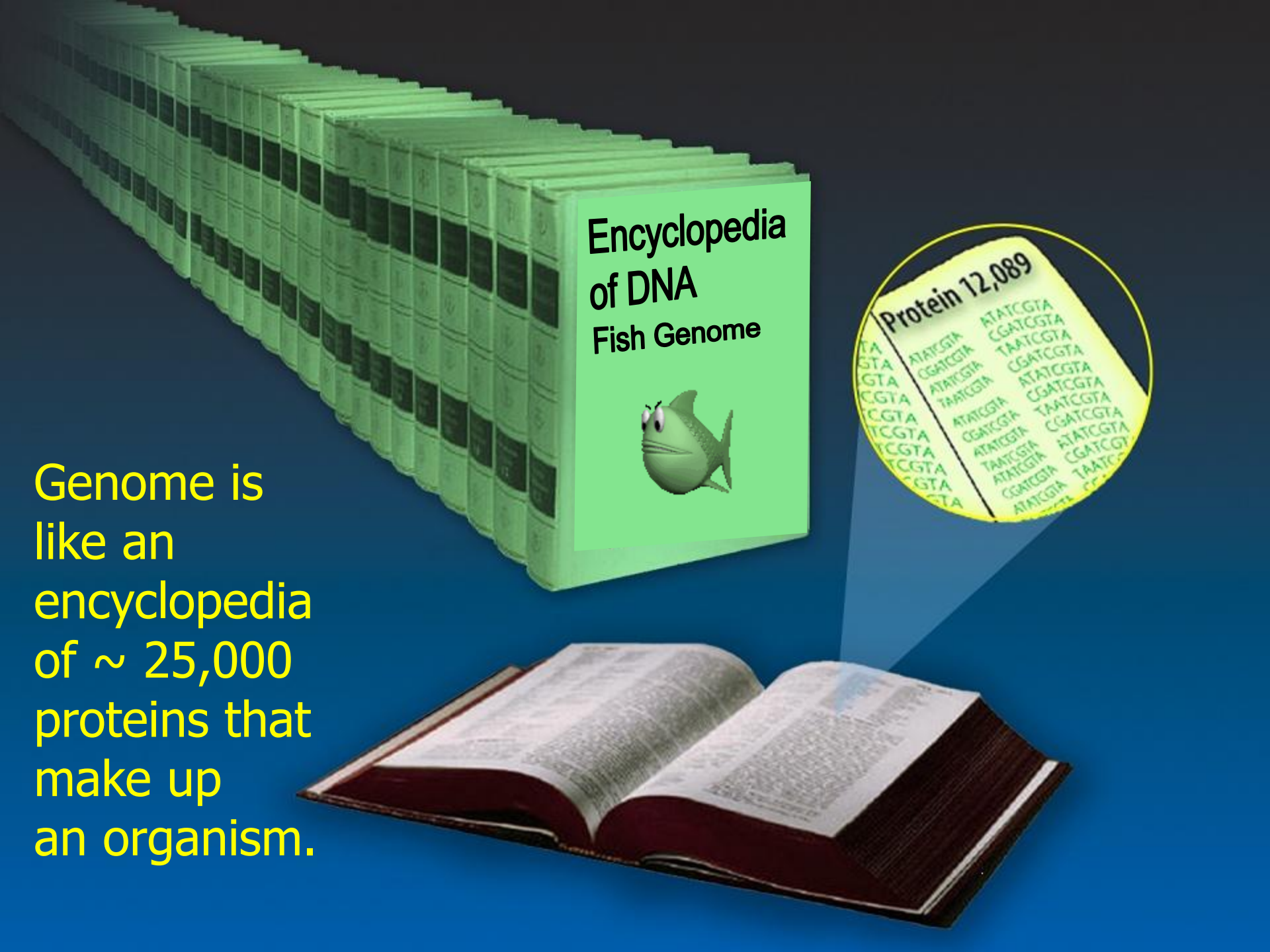
“Natural” genetic modifications selected by traditional animal breeders, such as the myostatin knockout, are in the food supply



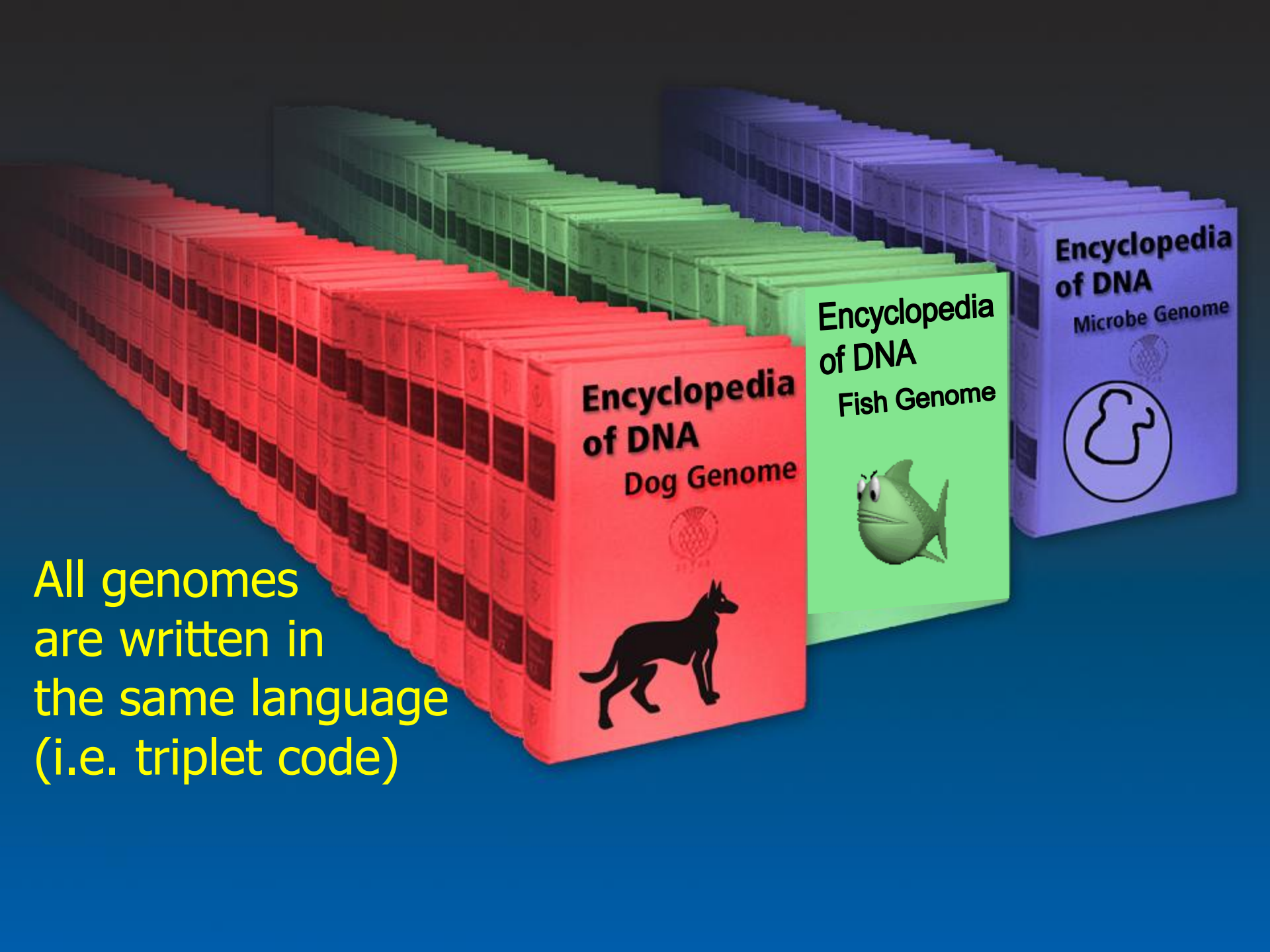
However genetic modifications made by the process of genetic engineering, aka genetically modified (GM or GMO) have not been approved for food purposes

The central dogma

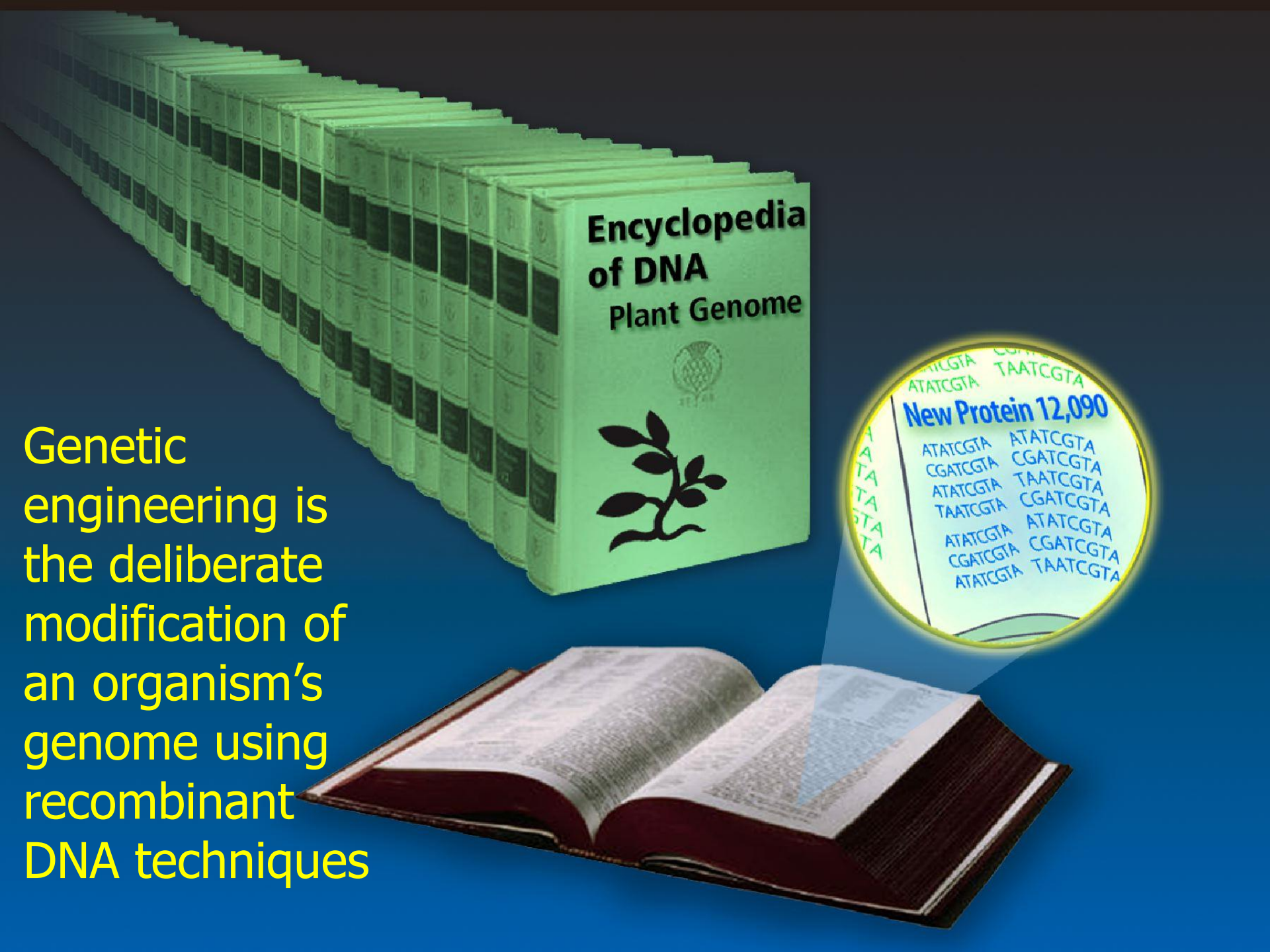




Genome is like an encyclopedia of ~ 25,000 proteins that make up an organism.



All genomes
are written in
the same language
(i.e. triplet code)



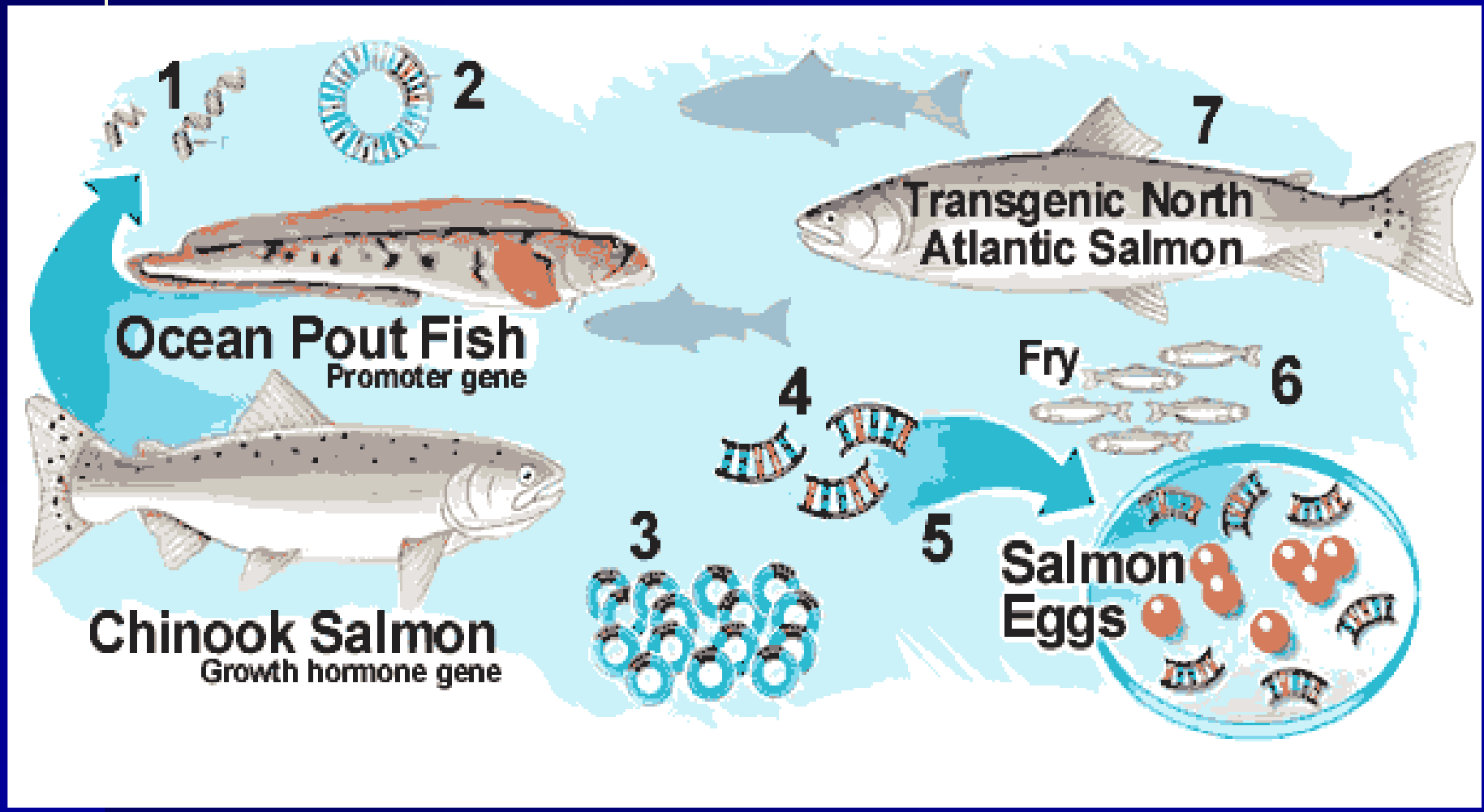
Genetic engineering is the deliberate modification of an organism's genome using recombinant DNA techniques

AquAdvantage salmon: "All-fish" GE construct

Ocean pout: promoter/ "on switch" from the antifreeze gene

Chinook salmon: growth hormone coding sequence

Ocean pout: downstream 3' regulatory sequences



Pharma and industrial applications of GE (or a combination of cloning & GE)

Products derived from transgenic goats and rabbit milk have gained approval by the regulatory bodies. The first product from a transgenic farm animal to become a registered drug was Antithrombin III (ATryn®) from GTC-Biotherapeutics, USA, produced in the mammary gland of transgenic goats. ATryn® was approved for treatment of heparin resistant patients undergoing cardiopulmonary bypass by the European Medicines Agency (EMEA) in 2006, and by the FDA in 2009.

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FDA Grants First-Ever U.S. Approval of GE Animal Product Printer Friendly

For Immediate Release
2/6/2009

Contact:
Contact Karen Batra
202-449-6382

WASHINGTON, D.C. (Friday, February 06, 2009) - Advances in human health care from the genetic engineering of animals are now being realized in the United States. The U.S. Food and Drug Administration (FDA) announced today the first approval of a product derived from a genetically engineered (GE) animal.

ATryn®, a recombinant form of human antithrombin developed by GTC Biotherapeutics, was approved by the FDA for the prevention of peri-operative and peri-partum thromboembolic events in hereditary antithrombin deficient patients. It is not indicated for treatment of thromboembolic events in hereditary antithrombin deficient patients. ATryn® is the first ever transgenically produced therapeutic protein and the first recombinant antithrombin approved in the United States.

Along with the approval of ATryn®, the FDA's Center for Veterinary Medicine also approved GTC's New Animal Drug Application, the first of its kind to regulate GE animals. This is now required for a recombinant technology used to develop transgenic animals, such as the goats that produce recombinant antithrombin. GTC has granted OVATION the right to market ATryn® in the United States and pursue further clinical development.

February 2009, First GE Animal Product

www.gtc-bio.com

Subsequently, human recombinant C1 plasma protease inhibitor (RUCONEST or RHUCIN)® from Pharming BV in the Netherlands, produced in transgenic rabbit milk, was approved for treatment of patients with hereditary angiooedema. The enzyme α-glucosidase (Pharming BV) from transgenic rabbit milk has orphan drug status and has been successfully used for treatment of Pompe's disease.

It is estimated that currently more than twelve milk derived recombinant proteins are in different phases of clinical testing.

Pharming Plans Submission Rhucin BLA To Us FDA End 2010

Published : Wednesday, August 25, 2010

PHARMING Biotech company Pharming Group NV ("Pharming" or "the Company") (NYSE Euronext: PHARM) announced that it intends to submit the Biologic License Application (BLA) to the US Food and Drug Administration (FDA) to obtain marketing approval for Rhucin® for the treatment of acute angioedema attacks in patients with Hereditary Angioedema (HAE). Following pre-BLA discussions with the FDA, Pharming is preparing the BLA dossier for submission towards the end of this year but no later than January 2011.

FDA turns down 'incomplete' Rhucin dossier

Article | 1 March 2011

Print This ShareThis

Dutch biotechnology company Pharming and its marketing partner Santarus have suffered a setback in their bid to bring hereditary angioedema treatment Rhucin (conestat alfa) to the US market.

The US Food and Drug Administration (FDA) issued a "refusal to file" indicating that the Biologics License Application filed by the companies "was not sufficiently complete to enable a critical medical review."

www.pharming.com

The production of recombinant proteins in the mammary gland of transgenic animals for use as antidote for organophosphorus compounds used as insecticides in agriculture and chemical warfare has also been demonstrated . Butyrylcholinesterase is a potent prophylactic agent against these compounds, of which high amounts have been produced in the mammary glands of transgenic mice and goats .

PNAS PNAS PNAS

Recombinant human butyrylcholinesterase from milk of transgenic animals to protect against organophosphate poisoning

Yue-Jin Huang*†, Yue Huang*, Hernan Baldassarre*, Bin Wang*‡, Anthoula Lazaris*§, Martin Leduc*¶, Annie S. Bilodeau*, Annie Bellemare*, Mélanie Côté*, Peter Herskovits*, Madjid Touati*, Carl Turcotte*, Loredana Valeanu*, Nicolas Lemée*, Harvey Wilgus*, Isabelle Bégin*, Bhim Bhatia*, Khalid Rao*, Nathalie Neveu*, Eric Brochu*, Janice Pierson*, Duncan K. Hockley*, Douglas M. Cerasoli‖, David E. Lenz‖, Costas N. Karatzas*,**, and Solomon Langermann*

*PharmAthene Canada, Inc., 7150 Alexander-Fleming, Montreal, QC, Canada H4S 2C8; and ‖United States Army Medical Research Institute of Chemical Defense, 3100 Ricketts Point Road, Aberdeen Proving Ground, MD 21010-5400

Edited by R. Michael Roberts, University of Missouri, Columbia, MO, and approved June 22, 2007 (received for review March 23, 2007)

Dangerous organophosphorus (OP) compounds have been used as insecticides in agriculture and in chemical warfare. Because exposure to OP could create a danger for humans in the future, butyrylcholinesterase (BChE) has been developed for prophylaxis to these chemicals. Because it is impractical to obtain sufficient quantities of plasma BChE to treat humans exposed to OP agents, the production of recombinant BChE (rBChE) in milk of transgenic animals was investigated. Transgenic mice and goats were generated with human BChE cDNA under control of the goat β-casein promoter. Milk from transgenic animals contained 0.1–5 g/liter of active rBChE. The plasma half-life of PEGylated, goat-derived, purified rBChE in guinea pigs was 7-fold longer than non-PEGylated dimers. The rBChE from transgenic mice was inhibited by nerve agents at a 1:1 molar ratio. Transgenic goats produced active rBChE in milk sufficient for prophylaxis of humans at risk for exposure to OP agents.

sufficient quantities of rBChE with a residence time similar to native huBChE that would allow development of the enzyme as an agent for prophylaxis against OP poisoning.

The production of recombinant proteins by the mammary gland of transgenic animals is well established (13, 14). A variety of recombinant human proteins, including immunoglobins, growth hormone, and clotting factors have been expressed by the mammary gland and secreted in the milk of transgenic animals (13). This article describes the production of functional rBChE in the milk of transgenic mice and goats and the characterization of the recombinant protein. These studies illustrate the feasibility of producing large quantities of rBChE in transgenic animals for prophylaxis or treatment of humans exposed to OP agents.

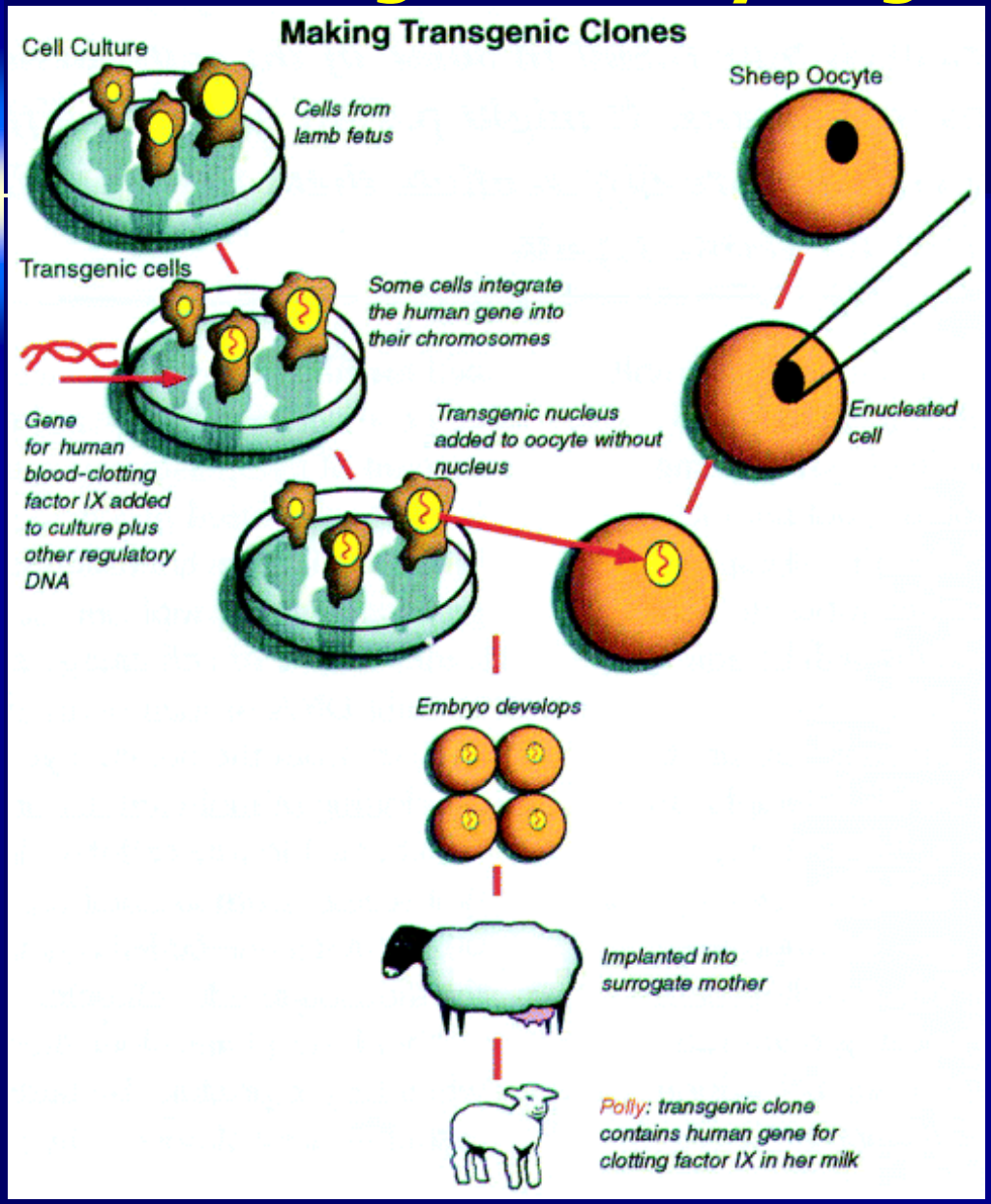
APPLIED BIOLOGICAL SCIENCES

Results

Generation of rBChE Transgenic Animals. A DNA expression vector,

Huang Y, Huang Y, Baldassarre H, Wang B, Lazaris A, Leduc M, Bilodeau A, Bellemare A, Côté M, Herskovits P, Touati M, Turcotte C, Valeanu L, Lemée N, Wilgus H, Bégin I, Bhatia B, Rao K, Neveu N, Brochu E, Pierson J, Hockley D, Cerasoli D, Lenz D, Karatzas C, Langerman S, 2007: Recombinant human butyrylcholinesterase from milk of transgenic animals to protect against organophosphate poisoning. PNAS104, 13603–13608

Somatic cell nuclear transfer (SCNT) cloning of genetically engineered cells



Polly – clotting factor IX milk

Schnieke AE, Kind AJ, Ritchie WA et al. (1997) Human factor IX transgenic sheep produced by transfer of nuclei from transfected fetal fibroblasts. Science 278: 2130–2133.

Cloned transchromosomic calves producing human immunoglobulin

Yoshimi Kuroiwa[1], Poothappillai Kasinathan[2], Yoon J. Choi[3], Rizwan Naeem[4], Kazuma Tomizuka[1], Eddie J. Sullivan[2], Jason G. Knott[2], Anae Duteau[3], Richard A. Goldsby[3], Barbara A. Osborne[5], Isao Ishida[1*], and James M. Robl[2*]

Published online: 12 August 2002, doi:10.1038/nbt727

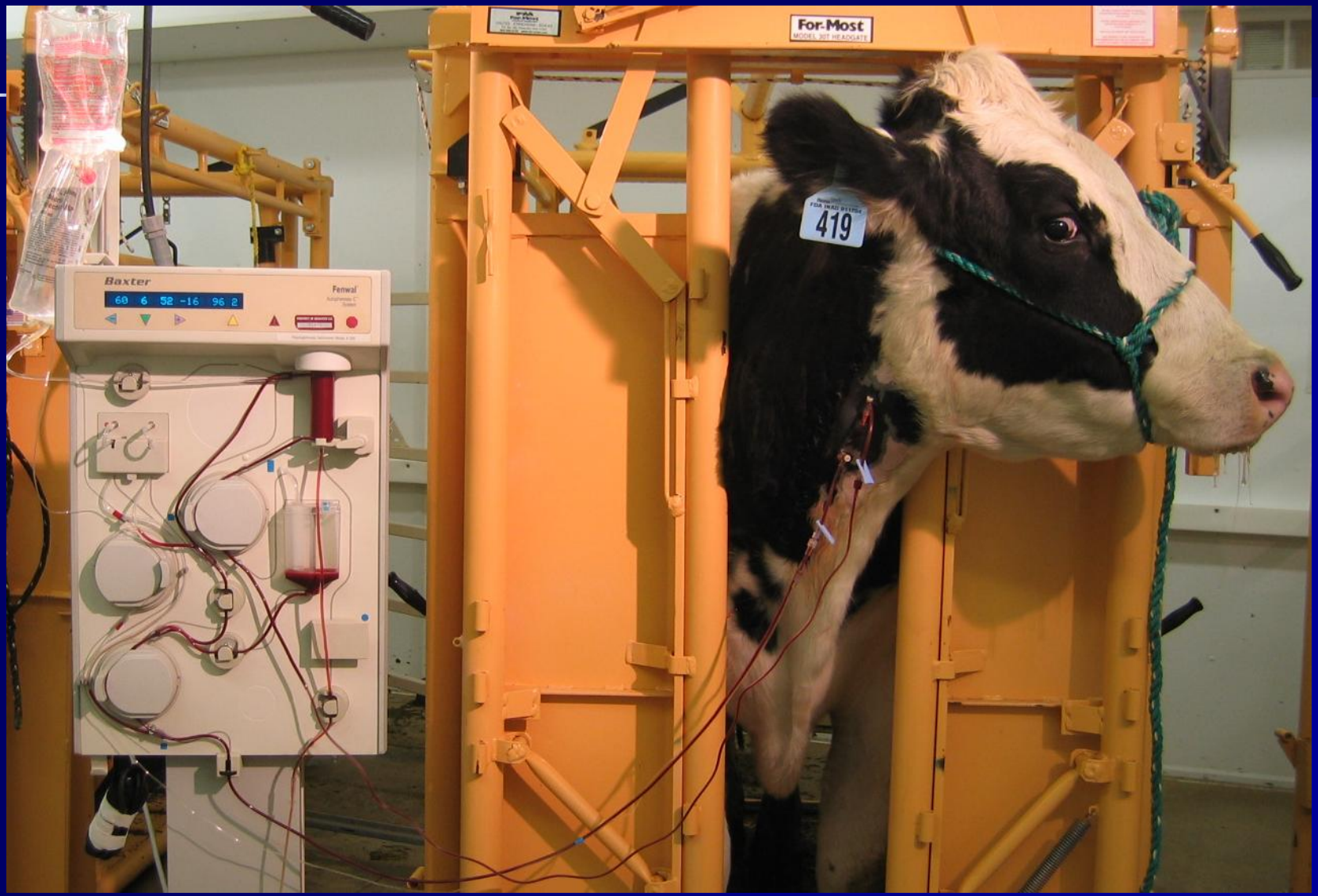
Human polyclonal antibodies (hPABs) are useful therapeutics, but because they are available only from human donors, their supply and application is limited. To address this need, we prepared a human artificial chromosome (HAC) vector containing the entire unrearranged sequences of the human immunoglobulin (h*Ig*) heavy-chain (*H*) and lambda (*λ*) light-chain loci. The HAC vector was introduced into bovine primary fetal fibroblasts using a microcell-mediated chromosome transfer (MMCT) approach. Primary selection was carried out, and the cells were used to produce cloned bovine fetuses. Secondary selection was done on the regenerated fetal cell lines, which were then used to produce four healthy transchromosomic (Tc) calves. The HAC was retained at a high rate (78–100% of cells) in calves and the h*Ig* loci underwent rearrangement and expressed diversified transcripts. Human immunoglobulin proteins were detected in the blood of newborn calves. The production of Tc calves is an important step in the development of a system for producing therapeutic hPABs.

http://www.nature.com/naturebiotechnology

Transchromosomal cattle carry a human artificial chromosome harboring the entire sequence of the human Major Histocompatability Complex . These animals were cloned from bovine fibroblasts after transfection with the additional chromosome.

www.hematech.com

Plasmapheresis to extract polyclonal antibodies from the blood of cloned, transchromosomic, knockout cattle carrying human immunoglobulin



Xenotransplantation 2010: 17: 48–60
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doi: 10.1111/j.1399-3089.2009.00564.x

XENOTRANSPLANTATION

Pigs as organ donors

Structural characterization of α1,3-galactosyltransferase knockout pig heart and kidney glycolipids and their reactivity with human and baboon antibodies

Diswall M, Ångström J, Karlsson H, Phelps CJ, Ayares D, Teneberg S, Breimer ME. Structural characterization of α1,3-galactosyltransferase knockout pig heart and kidney glycolipids and their reactivity with human and baboon antibodies.
Xenotransplantation 2010; 17: 48–60. © 2010 John Wiley & Sons A/S.

Mette Diswall,[1] Jonas Ångström,[1] Hasse Karlsson,[2] Carol J. Phelps,[3] David Ayares,[3] Susann Teneberg,[2] and Michael E. Breimer,[1]

[1]Department of Surgery, Institute of Clinical

www.revivicor.com

Genetically engineered food animals

No genetically engineered animals have been approved for food production

No genetically engineered animals have been approved for food production

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-

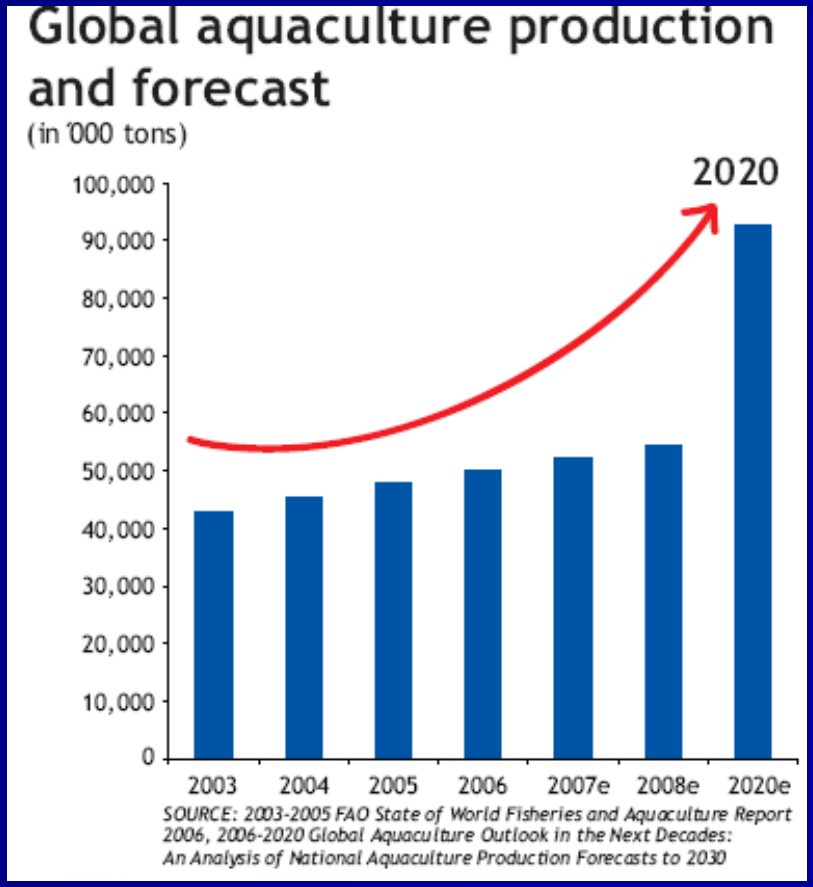
Science 331:223-226. 2011 SCIENCE VOL 331 14 JANUARY 2011 223

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

“If there is an approach to engineer resistance to influenza in poultry and therefore lessen the risk of an avian influenza epidemic, such as the one in 1918 that killed more than 20 million people, is there an ethical obligation to use such disease-resistant 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


August 2012
Davis, CA
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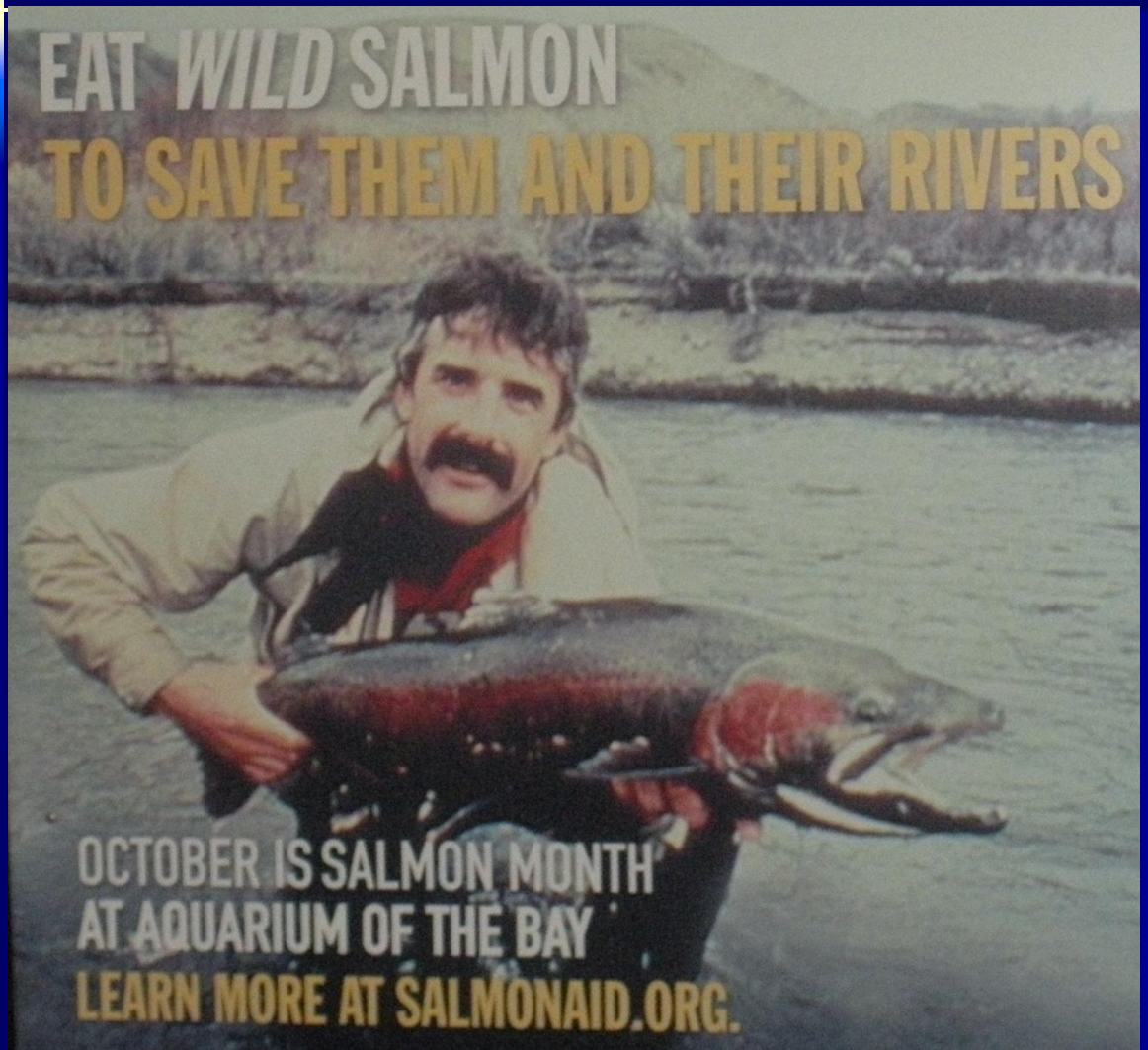
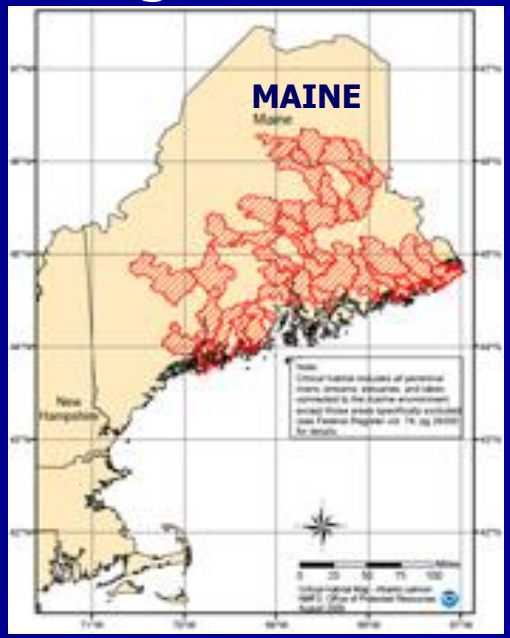
CLUB CARD SPECIAL
9.99 LB
WILD
Product of USA
Wild Sockeye
Salmon Fillets
Fresh
High in Omega-3
9.99 LB
CLUB CARD SPECIAL
$14.99 LB

If you are eating US wild salmon, it is most likely Pacific salmon

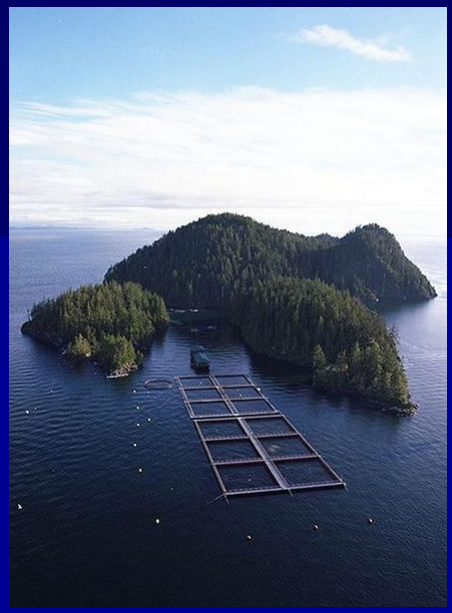


Atlantic salmon are genus ***Salmo***



Atlantic Salmon (*Salmo salar*) Critical Habitat

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 “sustainable” aquacultural production which involves growing fish in inland tanks away from oceans and rivers.
- Fish are harvested directly from the inland tanks, processed, and sent to market – no exposure to rivers or oceans.
- Temperature, O_2, food delivery, and waste removal are monitored carefully to optimize growth and efficiency.
- No opportunity for disease transmission to/from, or interbreeding with wild fish populations.
- Improved feed conversion efficiency as compared to wild fish as they expend no effort or energy searching for food.
- **Land based salmon culture systems *could* be located in cities adjacent to major markets, reducing freight i.e. potential for US-grown (locivovre) source of fish protein.**

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

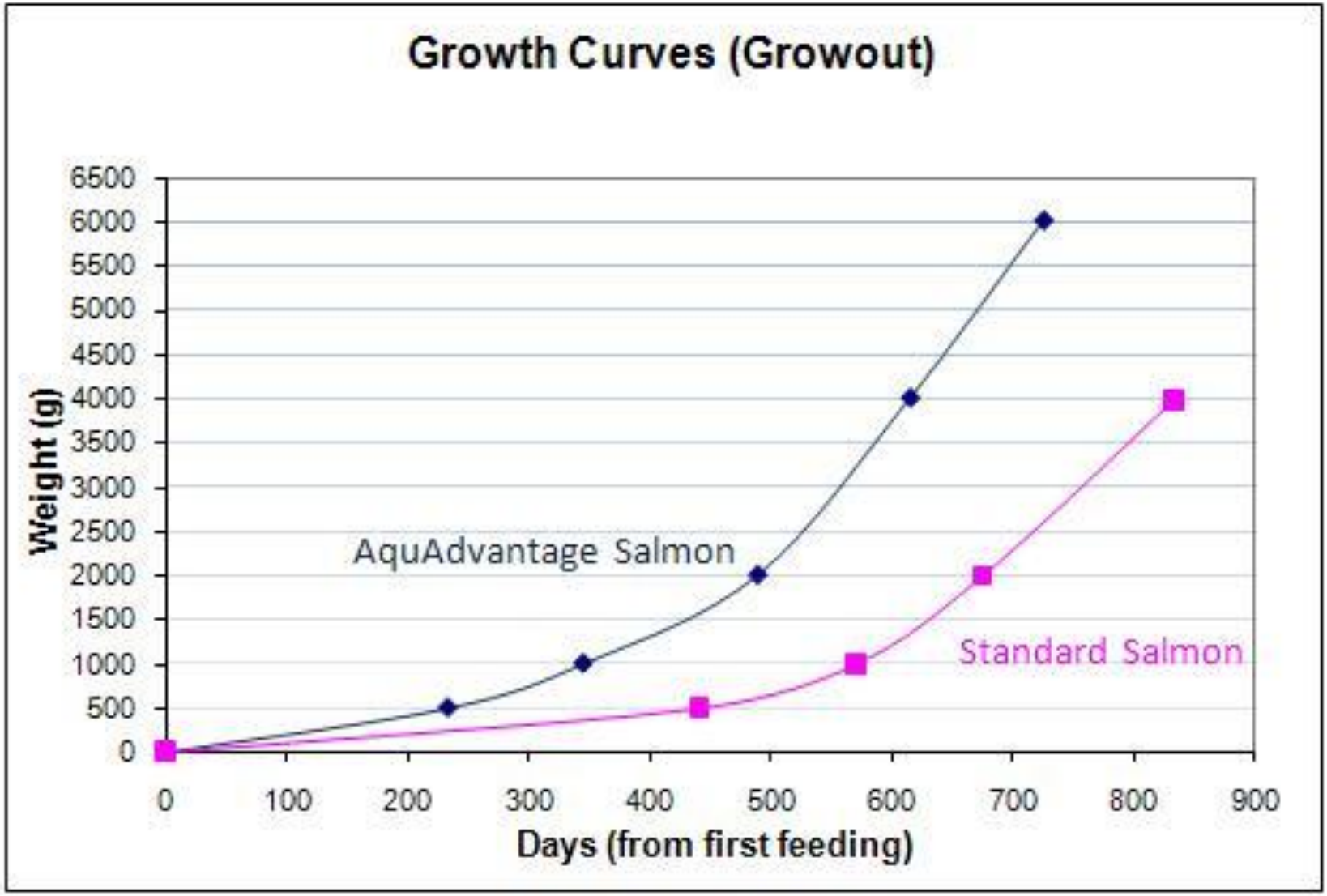
Shao Jun Du, Zhiyuan Gong, Garth L. Fletcher[1], Margaret A. Shears[1], Madonna J. King[1], David R. Idler[1] and Choy L. Hew*

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

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).

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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

- "Drugs are …articles…intended to affect the structure or function of the body of man or other animals"
- The expression product of the new construct (e.g. growth hormone) is also considered to be the new animal drug
- Application process requires that the developer demonstrate that no harm comes to individuals who use the drug under prescribed conditions

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 (VMAC) meeting to consider data on safety and efficacy of AquAdvantage salmon Held in Washington DC

180 page VMAC Briefing Packet on AquAdvantage Salmon – made publicly-available before meeting

In the seven-step regulatory process described by FDA, the agency examines the safety of the recombinant DNA (rDNA) construct to the animal, the safety of food from the animal and any environmental impacts posed (collectively the 'safety' issues), as well as the extent to which the performance claims made for the animal are met ('efficacy').

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

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.

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 physically-contained fresh water culture facility. 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."***

Page 129, AquAdvantage Briefing packet. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

Addressing Risk: Definitions

Risk Assessment in the Federal Government: Managing the Process (1983). Committee on the Institutional Means for Assessment of Risks to Public Health, National Research Council (aka "The Red Book").

- **Harm** = Undesirable Outcome
  Example: Species Extinction, Displacement, or Disruption
- **Hazard** = Item that may bring about Harm given exposure
  Example: GE Organism Escapes Into the Environment and Spreads
- **Risk** = P(Harm results from Hazard)
  = P(Harm/Exposure) * P(Exposure)

Note: In This Context EXPOSURE results from escape and GE Spread

Implications For Risk Assessment

Risk = **Prob(Harm/ Exposure) x Prob(Escape) x Prob(Transgene Spreads/Escape)**

If the probability of any link in the chain is close to zero, then the product is close to zero

Methods to minimize risk:

Prob (Escape): Managed by Physical Containment
P(Spread/Escape): Managed by Biological Containment or Sterility (or may be limited by Natural Selection itself)

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

The public VMAC 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 VMAC 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
- Proxinal analysis of **>70** fish (10 farmed fish, 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

"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 VMAC 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.

http://ge-fish.org/2010/09/29/thirty-eight-representatives-and-senators-call-on-fda-to-halt-ge-salmon-approval

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!

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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."

http://donyoung.house.gov/news/documentprint.aspx?DocumentID=247046

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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 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 U.S. Sen. Mark Begich (AK) chairman of the Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard. Begich who has dubbed the salmon "Frankenfish" 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 (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

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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

- There has been no formal comment or response from FDA or any other government body on the status of the application, or why it has not been acted upon in the 2 years following September 2010 VMAC meeting and VMAC report
- Procedurally, the next step is for the FDA to release an Environmental Assessment (EA) 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.
- This would trigger 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.

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."

"Transgenic Animals: Developments regarding transgenic animals since 2007 including risk assessment and status-quo in respect of cloned animals." German ministry report authored in February 2012.

"To get the whole picture especially concerning future developments a thorough screening of ongoing activities has to focus on South American and Asian countries, which are economically and geopolitically of increasing importance. Quite some scientific research and development of transgenic animals is going on e.g. in ***China, India, Argentina, Brazil, or Singapore****". Page 43 of the report at the URL below*

http://www.bmg.gv.at/cms/home/attachments/3/5/3/CH1050/CMS1331298442672/transgenicanimals_druckversion_170212.pdf.

CA PROPOSITION 37: GENETICALLY ENGINEERED FOODS LABELING INITIATIVE requires the words "Genetically Engineered" must appear on front package or label

- Requires labeling on raw or processed food offered for sale to consumers if made from plants or animals with genetic material changed in specified ways (e.g. genetically engineered)
- Prohibits the use of terms such as "natural," "naturally made," "naturally grown," and "all natural" in the labeling and advertising of GE foods. Given the way the measure is written, there is a possibility that these restrictions would be interpreted by the courts to apply to some processed foods regardless of whether they are GE."
- Excludes certain food products from the above labeling requirements. For example, alcoholic beverages, organic foods, and restaurant food and other prepared foods intended to be eaten immediately would not have to be labeled. Animal products—such as beef or chicken—that were not directly produced through genetic engineering would also be exempted, regardless of whether the animal had been fed GE crops.

Legislative Analyst's Office http://www.lao.ca.gov/ballot/2012/37_11_2012.aspx

Litigation to Enforce Prop. 37

Violations of the measure could be prosecuted by state, local, or private parties. It allows the court to award these parties all reasonable costs incurred in investigating and prosecuting the action. In addition, the measure specifies that consumers could sue for violations of the measure's requirements under the state Consumer Legal Remedies Act, which allows consumers to sue without needing to demonstrate that any specific damage occurred as a result of the alleged violation.

Summary prepared by CA Attorney General
http://vig.cdn.sos.ca.gov/2012/general/pdf/37-title-summ-analysis.pdf

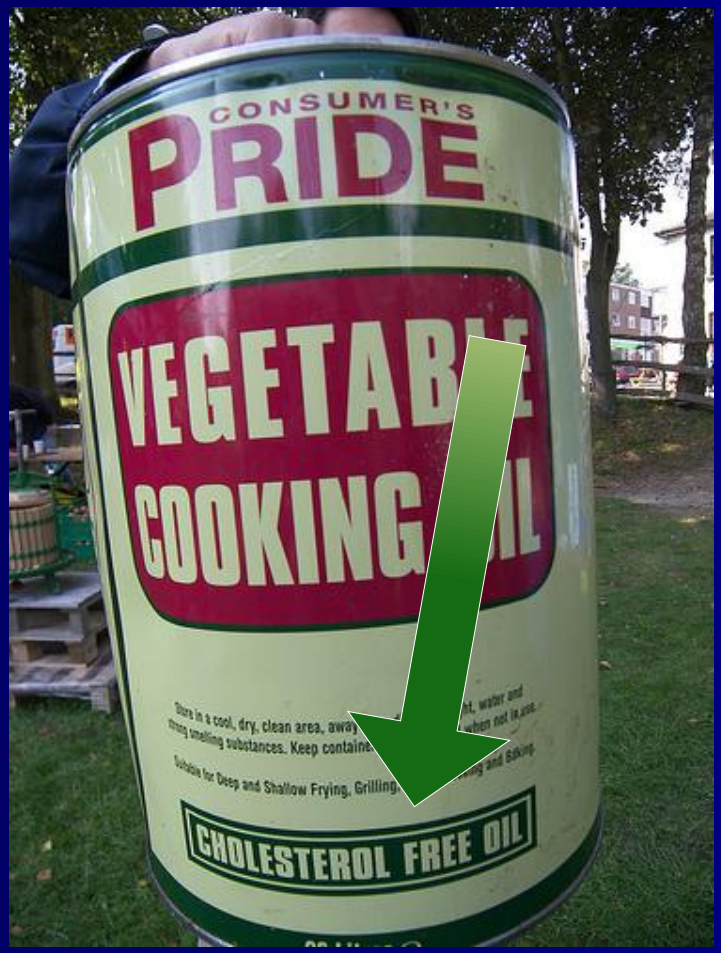
Background of U.S. food labeling

The principles of food labeling in the U.S. are the same, whether or not the food is made from a GE source (plant or animal).

1. Labels cannot be false
2. Labels cannot be misleading
3. Label must describe basic nature of the food (e.g. fish)
4. FDA cannot require labels include information about production methods if there is no material difference in the products due solely to the production process
5. Voluntary labeling is allowed if not false or misleading

Source: http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm

Voluntary labeling is allowed if it is not false or misleading

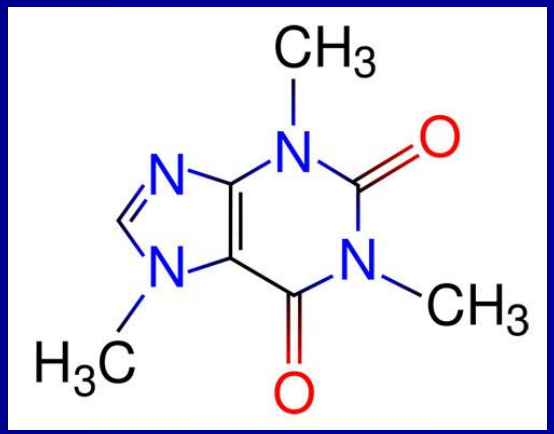


Non-misleading

"Cholesterol-free oil"

– Such claims are forbiden in the USA because they imply other vegetable oils have cholesterol, when in fact, none do.

Although some labels do exist that are both false and misleading!!



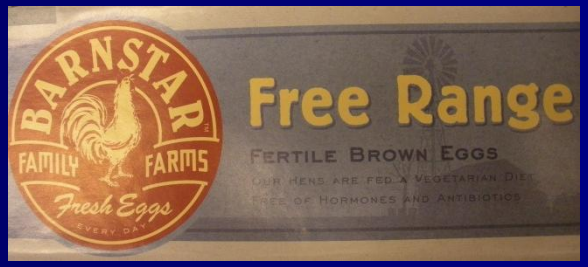
CAFFEINE!!!

FDA cannot **mandate** that labels include information about production methods if there is no material difference in the products

FDA cannot require additional labeling about production methods unless it is necessary to ensure that the labeling is not false or misleading. Another way of stating this point is that FDA cannot require labeling based solely on differences in the production process if the resulting products are not materially different due solely to the production process.

http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm#Background

Voluntary production method labeling



rBST Labeling: Voluntary labeling stating the milk is from cows not treated with r-BST must also have a disclaimer of similar font next to it stating the FDA has found no significant difference between milk from treated and untreated cows.

Legal opinion regarding mandatory production method labeling

The Second U.S. Circuit Court of Appeals ruled that a labeling mandate grounded in consumer perception, rather than in a product's measurable characteristics, raises serious constitutional concerns – namely, that it violates commercial free speech. The court held that food labeling cannot be mandated merely because some people would like to have the information, and ruled mandatory rBST labeling unconstitutional because they forced producers to make involuntary statements contrary to their views when there was no material reason to do so.

Source: International Dairy Foods Association vs. Amestoy 92 F.3d 67 (1996)
http://www.public.iastate.edu/~jwcwolf/Papers/IDFA_Amestoy.pdf

Voluntary labels have provided the US consumer with a wide range of production method choices - including GM free

USDA ORGANIC

CERTIFIED HUMANE RAISED & HANDLED

NO rBST

OUR COWS ARE NOT TREATED WITH THE GROWTH HORMONE rBST

GMO

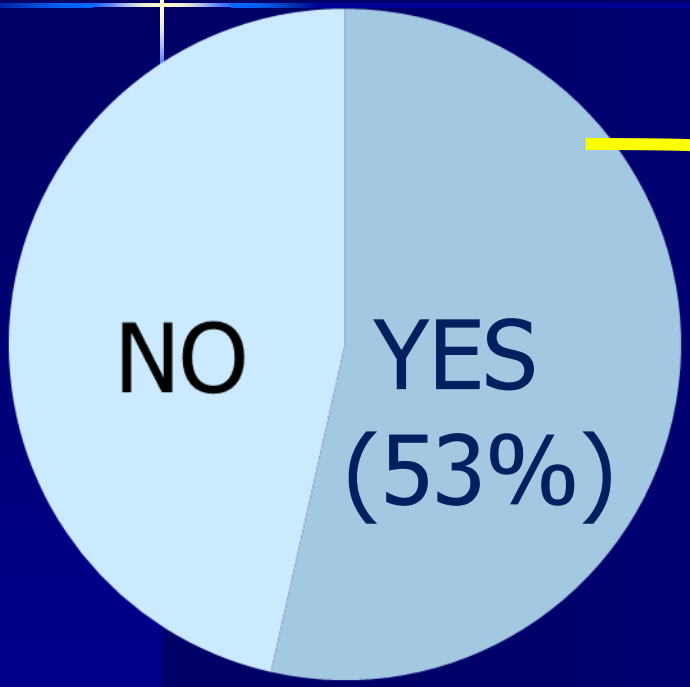
DEMETER CERTIFIED BIODYNAMIC®

CERTIFIED NATURALLY GROWN

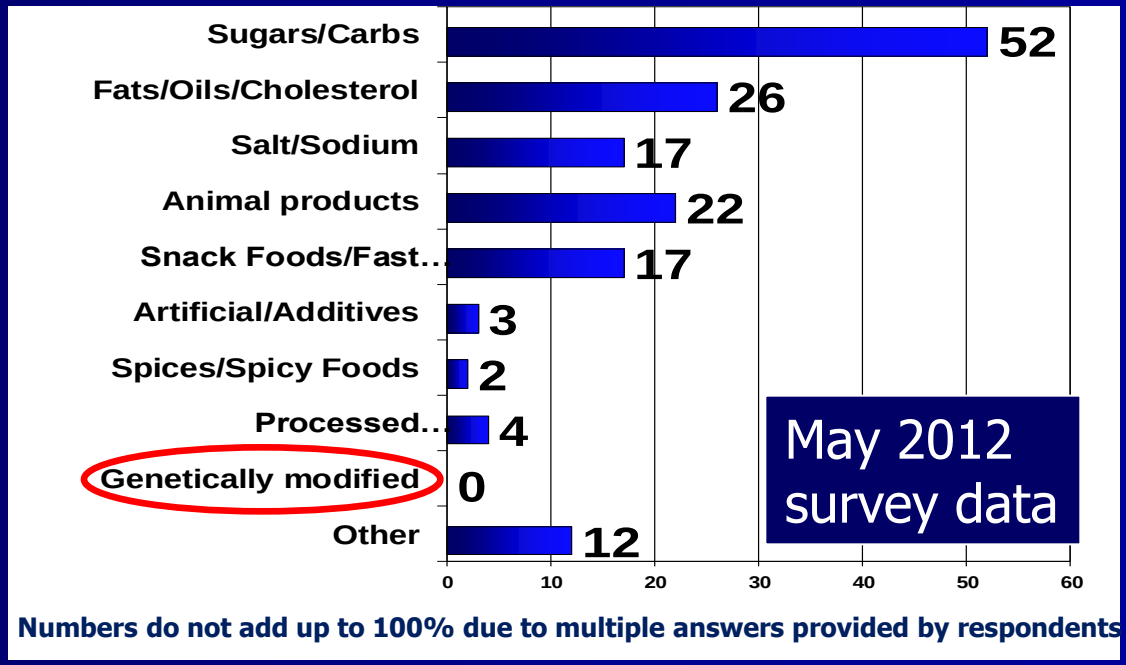
Three main arguments for mandatory GE labeling

1. **Public opinion**: Polls show an overwhelming majority of people support mandatory labeling of GE foods
2. **Consumer choice**: People should have a choice in what types of products they purchase and consume
3. **Right to know**: People have the right to know what is in their food

Thinking about your diet over the past few months, are there any foods or ingredients that you have avoided or eaten less of?? (n=750)

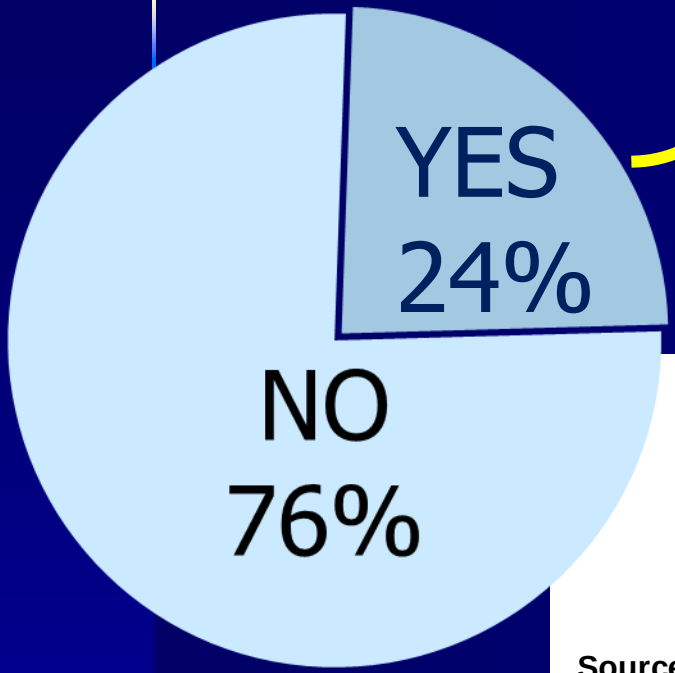


What foods or ingredients have you avoided? [OPEN ENDED]

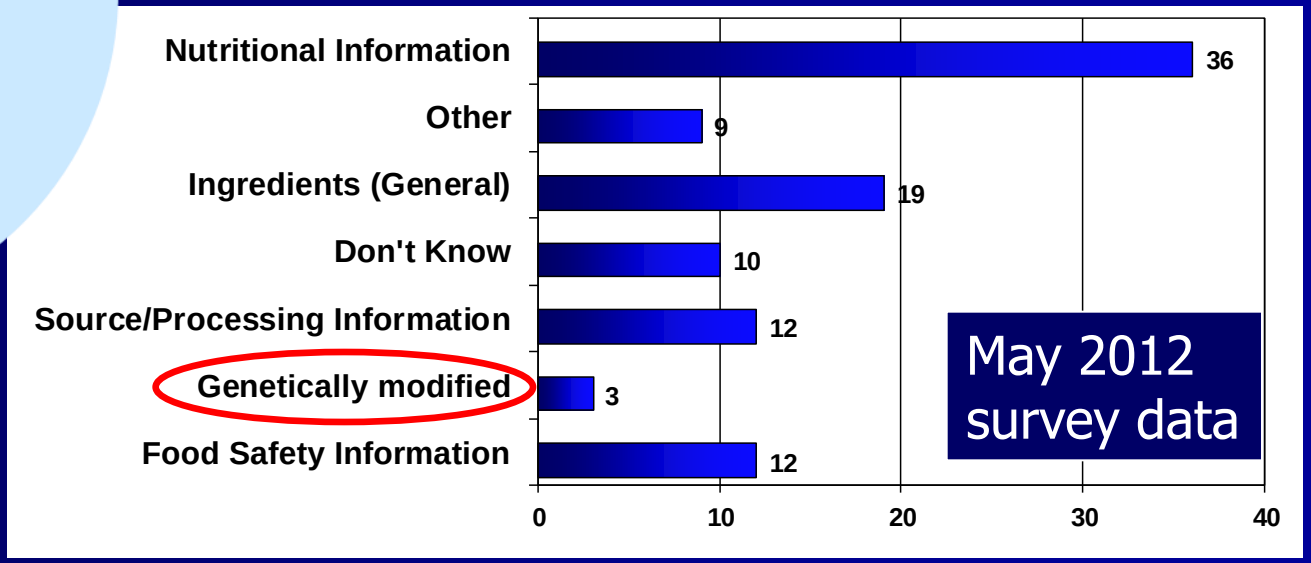


http://www.foodinsight.org/Content/5519/IFIC%202012%20Food%20Technology%20Survey-US%20Topline%20Summary.pdf

Can you think of any information that is not currently included on food labels that you would like to see on food labels? (n=750)



What types of information would that be? [OPEN ENDED]



IFIC International Food Information Council Foundation

http://www.foodinsight.org/Content/5519/IFIC%202012%20Food%20Technology%20Survey-US%20Topline%20Summary.pdf

1. Public opinion pros and cons

- **Pro**: Polls show an overwhelming majority of people support mandatory labeling of GE foods
- **Con:** Majority (99%) of consumers don't ask for mandatory labeling of GE (unless specifically prompted by the interviewer)
- Imposes identity preservation costs on the entire food supply chain and transfers costs of labeling onto all consumers – including majority who are not concerned about GE

Does mandatory labeling provide choice?

- Experience with mandatory labeling in the European Union, Japan, and New Zealand has not resulted in consumer choice. Rather, retailers have eliminated GE products from their shelves to avoid being targeted by NGOs
- "*A real concern is that mandatory labeling could force GE foods out of the market. Mandatory labeling in Europe virtually eliminated any ability to choose GE foods, because there were fewer than 10 acknowledged GE products."*

Gary E. Marchant, Guy Cardineau, and Thomas Redick. 2010. Thwarting Consumer Choice: The Case Against Mandatory Labeling for Genetically Modified Foods. Rowman and Littlefield Publishing Group.

Is labeling being sought to provide consumer choice?

"Following the launch of the European labeling requirement, Greenpeace announced it would summon thousands of volunteers across Europe to police grocery stores and ensure they were not stocking food with GM labels"

Gary E. Marchant, Guy Cardineau, and Thomas Redick. 2010. Thwarting Consumer Choice: The Case Against Mandatory Labeling for Genetically Modified Foods.

"Proponents of mandatory GM labeling make no secret that mandatory labeling is not their final goal."

Klintman, M. (2002), 'The Genetically Modified (GM) Food Labelling Controversy: Ideological and Epistemic Crossovers', Social Studies of Science, Vol.32, No.1, pp.71–91.

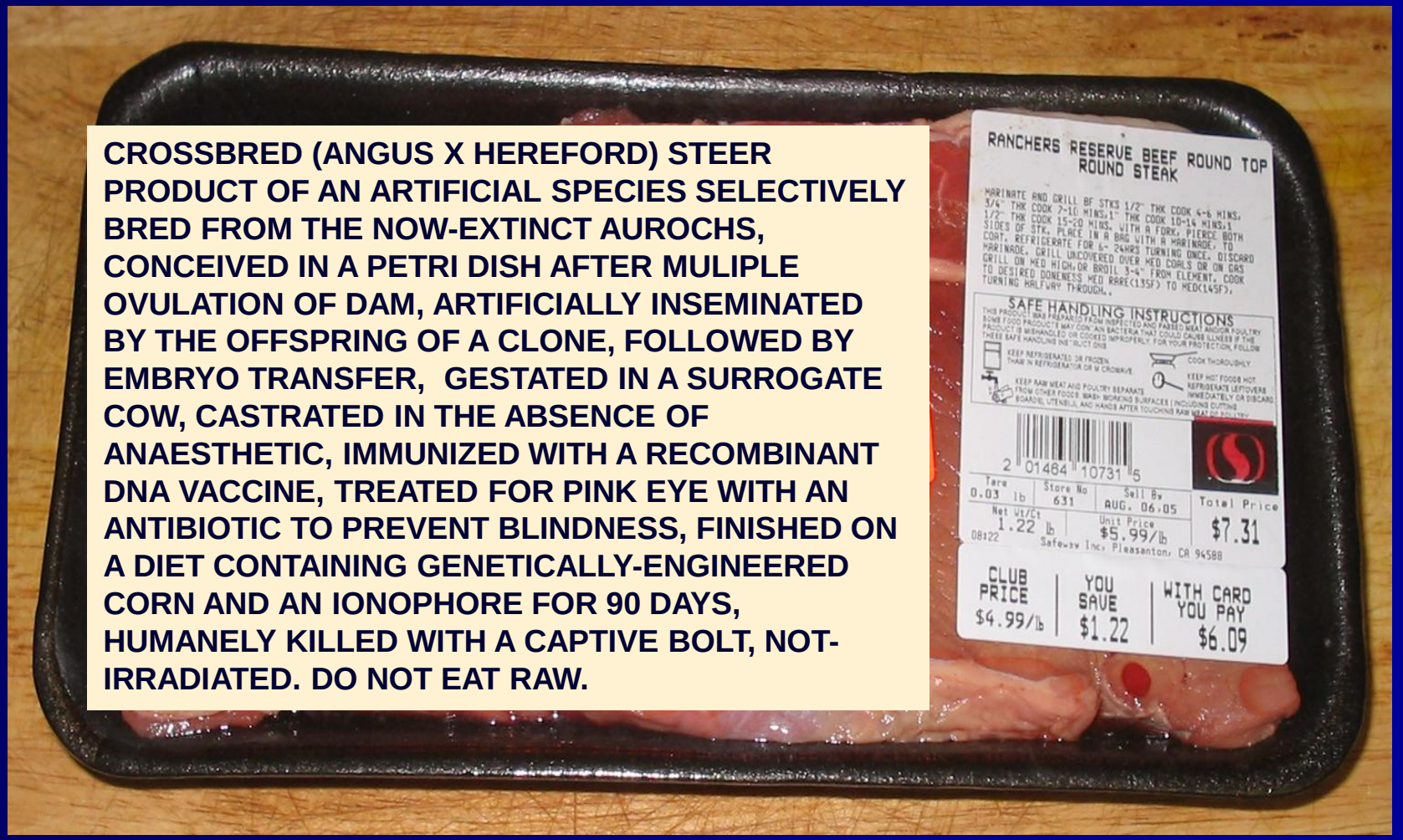
"Personally, I believe GM foods must be banned entirely, but labeling is the most efficient way to achieve this. Since 85 percent of the public will refuse to buy foods they know to be genetically modified, this will effectively eliminate them from the market just the way it was done in Europe."

Dr. Mercola, http://vtdigger.org/2012/04/17/wanzek-genetically-modified-food-is-perfectly-healthy/

2. Consumer choice pros and cons

- **Pro**: People should have a choice in what types of products they purchase and consume
- **Con**: Implementation of mandatory labeling has not resulted in consumer choice. In fact it has been used as a weapon to scare consumers and demonize GE food and prevent the availability of that option to consumers
- What information does labeling as “Genetically Engineered” provide to enable informed choice – GE for WHAT and how does the product differ?

Should there be mandatory "right to know" labeling about all aspects of the food production process?



3. Right to know pros and cons

- **Pro**: People have the right to know what is in their food
- **Con**: Singles out GE technology for right to know, not other production methods.
  "*There is no prima facie case that consumers have a right to know everything through mandated labels or at any cost*."

Kalaitzandonakes, N., 2004. "Another look at Biotech Regulation" Regulation. 27(1):44-50.

FDA Public Hearing on the Labeling of Food Made from the AquAdvantage Salmon, September 21st, 2010

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

COOL label would be quite distinct for a farmed Atlantic salmon grown in Panama

Public testimony from Food and Water Watch

"We are not willing to settle for making other labels do double duty. We're not going to settle for country of origin labeling being used as code for how we're somehow supposed to educate people which countries are producing genetically engineered salmon this year. That is not acceptable. That's not a label that discloses what we need".

Patricia Lovera , Food and Water Watch, Washington, D.C.
http://stopgefish.files.wordpress.com/2011/02/transcript-of-labeling-hearing-fda-2010-n-0385-0339.pdf

Public testimony from Food and Water Watch

Question from FDA panel: ***I would like for you, if you could, to elaborate a little more on really what the messaging is in terms of how to use the food, what specific attributes may be changed in the food if the food says genetically engineered. I mean, through your presentation you mentioned things like allergens. … But if the food simply says, genetically engineered, how does that convey that to a consumer?***

MS. LOVERA: "Well, we've heard a lot about education, and I assume that the industry is going to be trying to educate or market this product in a way"

http://stopgefish.files.wordpress.com/2011/02/transcript-of-labeling-hearing-fda-2010-n-0385-0339.pdf

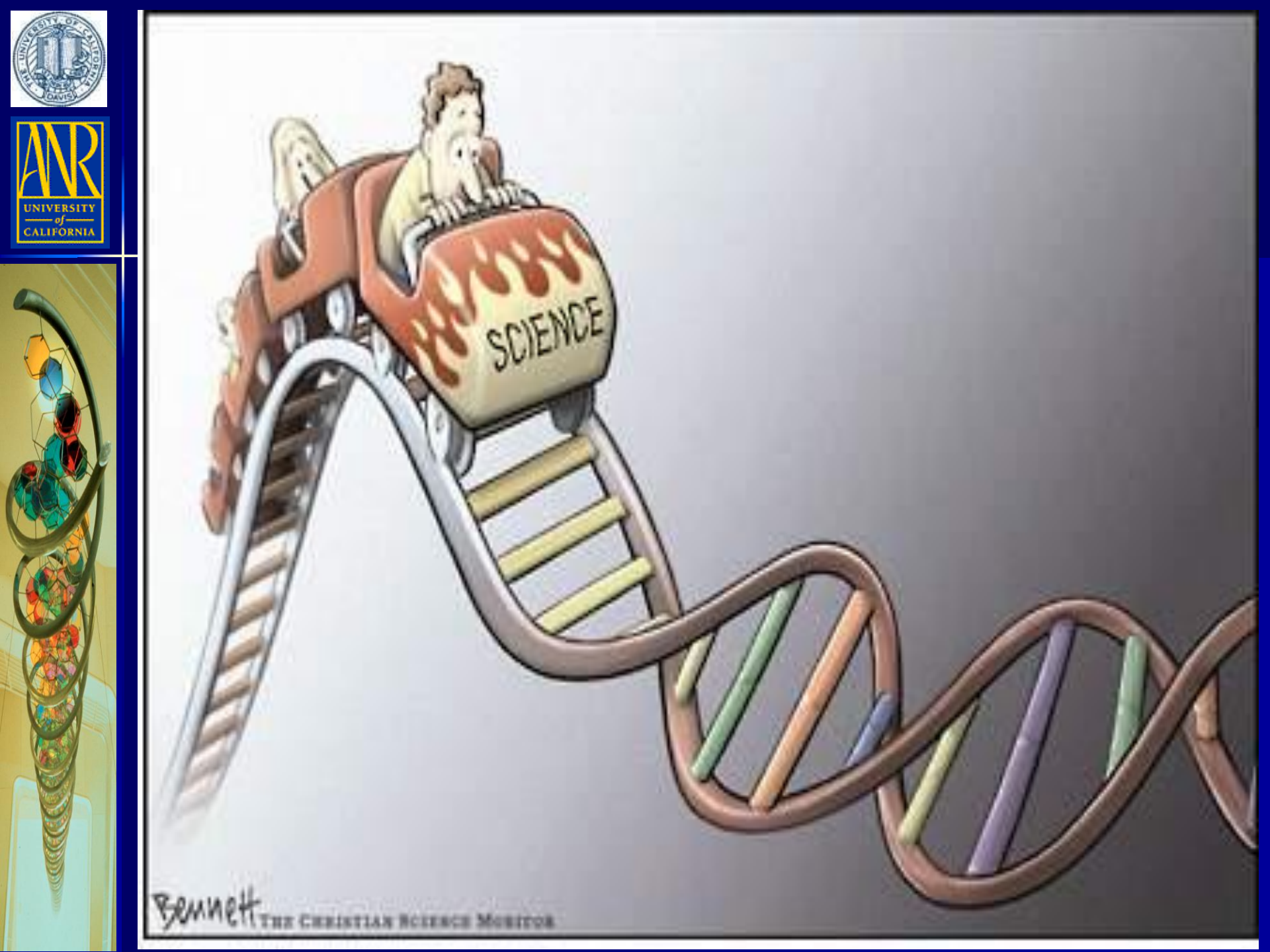
Public testimony from Center for Science in the Public Interest

"There are many production methods for food products and many production methods for salmon. Identifying this production method without requiring all the other production methods to be identified would needlessly discriminate against genetic engineering and not provide the consumer with information about the "material" differences in this particular salmon… Providing information without education about what that information means is not particularly helpful to the consumer."

Greg Jaffe, Center for Science in the Public Interest, Washington, D.C.
http://cspinet.org/new/pdf/salmon_labeling_presentation.pdf

Labeling Conclusions

- Mandatory GE labeling is not a simple matter of putting some additional ink on a package
- There are several reasons put forward for mandatory labeling which can be argued either way
    1. Public opinion/depends on question
    2. Consumer choice/lack of choice
    3. Right to know/scope of methods to include
- Labeling GM is not a food safety issue and developers are understandably wary of the additional costs of supply chain segregation, lawsuits, and having their brand and or retail outlets targeted by opponents.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Bennett
The Christian Science Monitor