



Animal Biotechnology: Background, Regulations, and Implications

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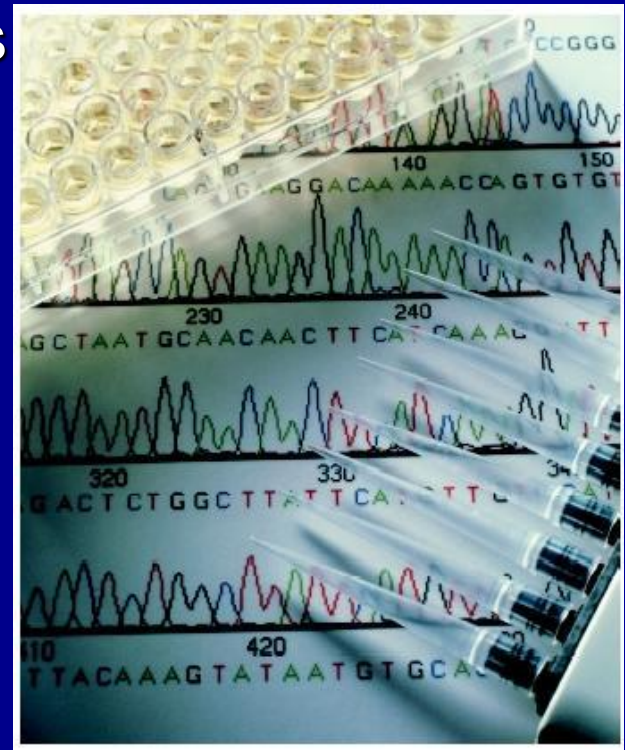
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"The mission of the animal genomics and biotechnology extension program is to provide broad, science-based extension programming on the uses of animal biotechnologies in livestock production systems."

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





What is Biotechnology ?



Biotechnology
Technology based on biology. The application of science and engineering to living organisms.





From the perspective of genetic improvement: What isn't biotechnology?

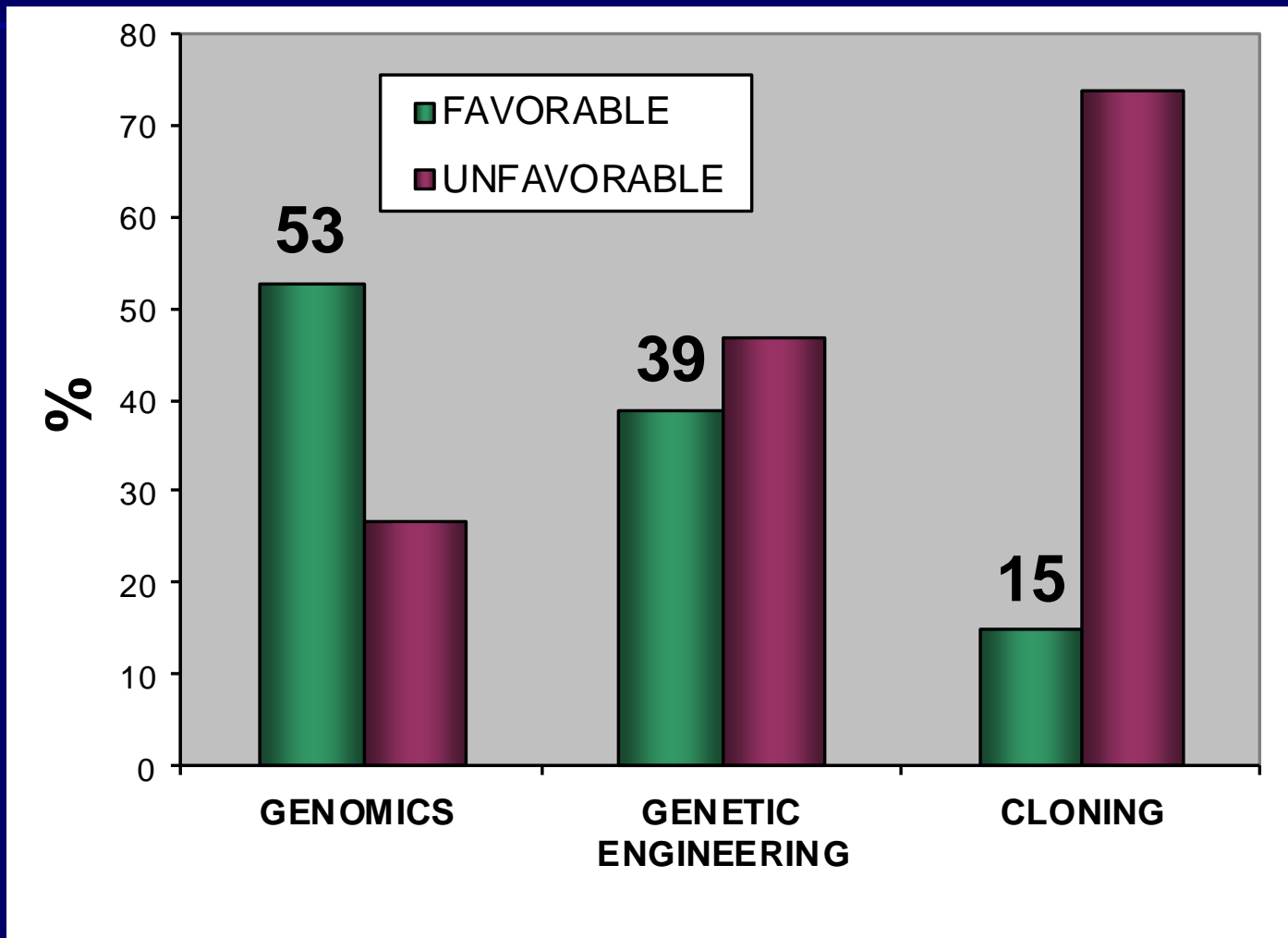
- Traditional breed development
- Selective breeding programs
- Cross breeding programs
- Artificial insemination
- Embryo transfer
- Genetic engineering
- Cloning
- Genome-enabled selection or genomics





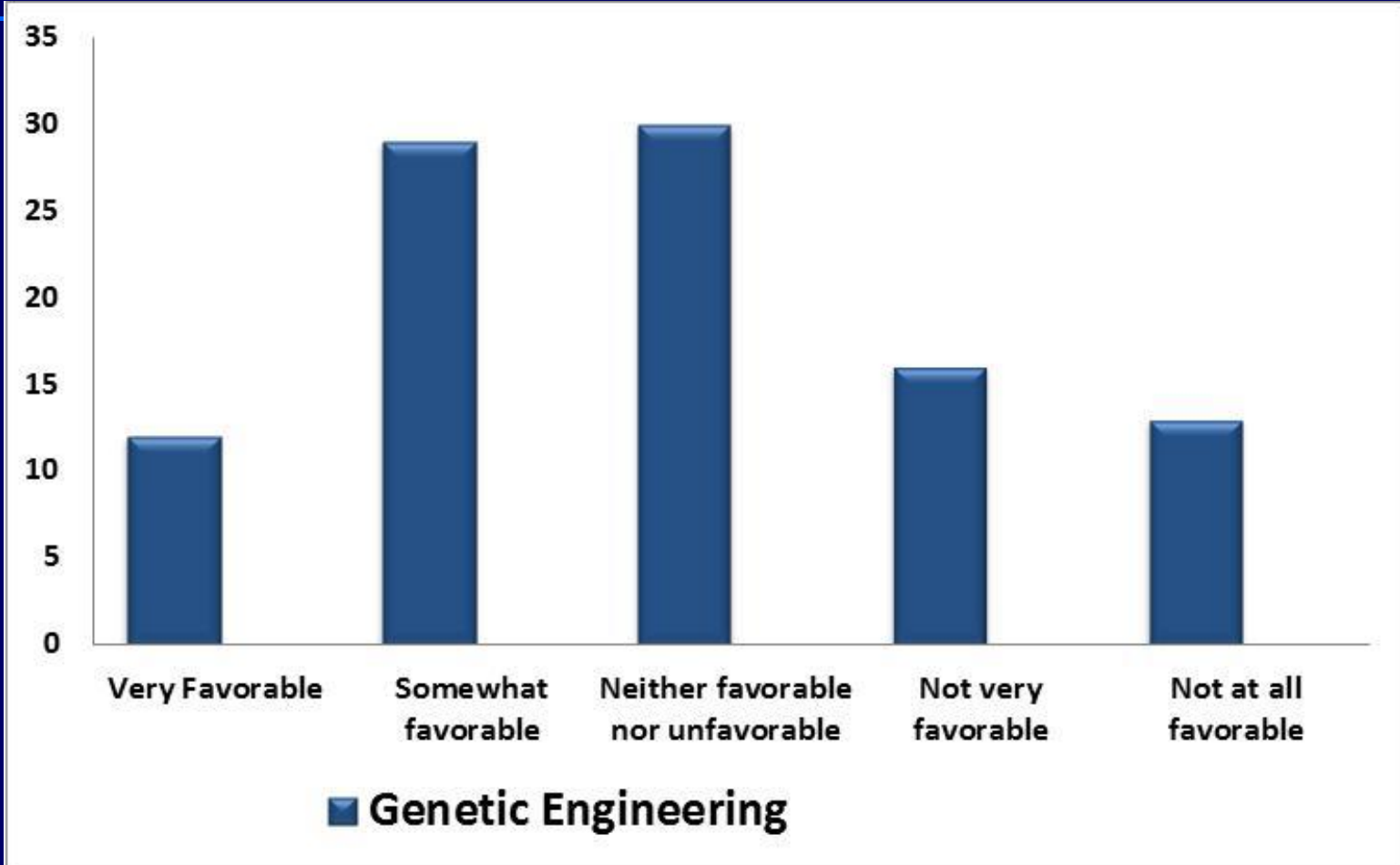
US Public Attitudes Towards Specific “Modern Animal Biotechnologies”

(International Food Information Council Survey of US, 2005)





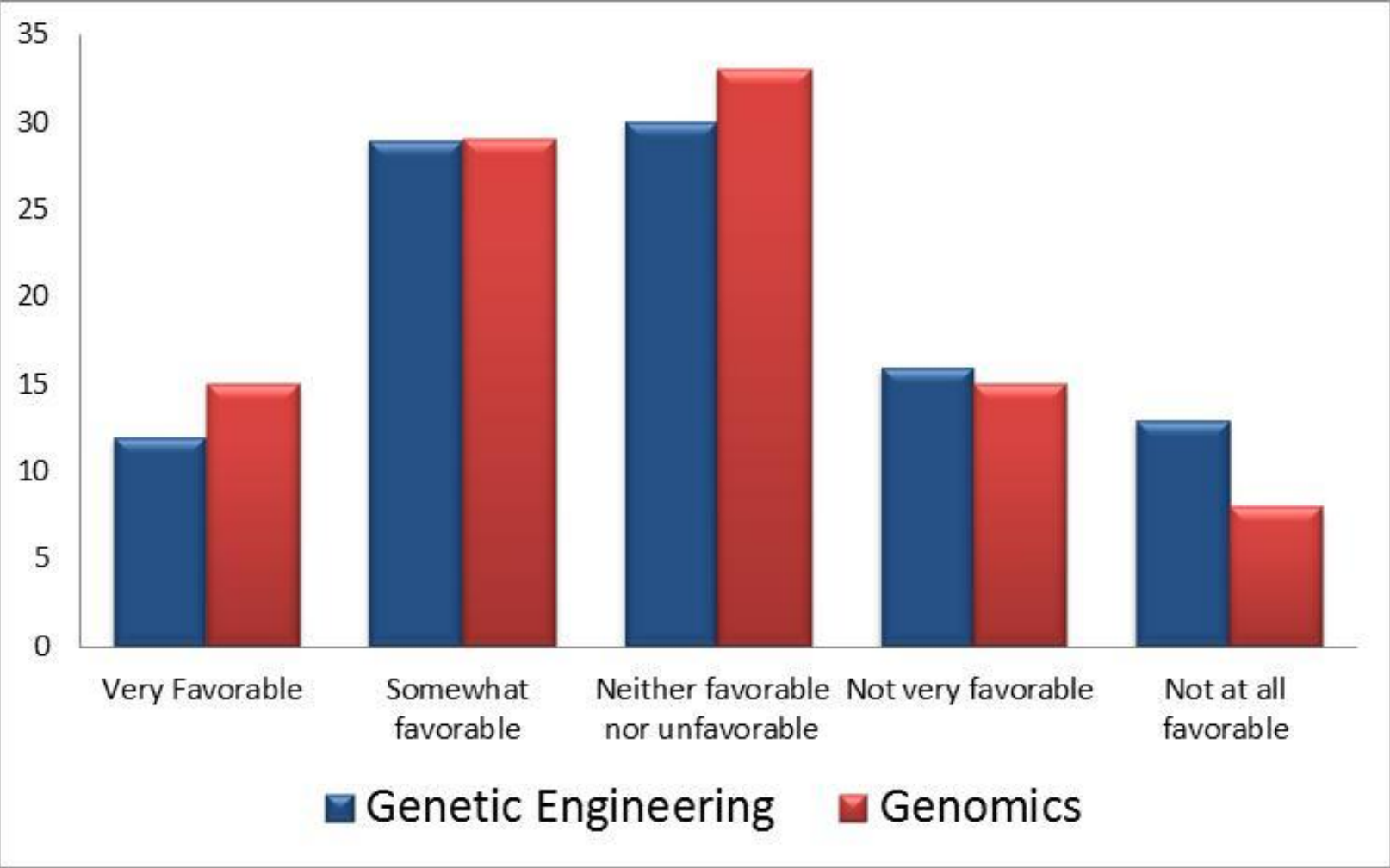
Genetic engineering is a form of animal biotechnology that allows for the transfer of beneficial traits from one animal to another in a precise way that allows for improved nutritional content or less environmental impact. *What is your overall impression of genetic engineering in animals?* **(IFIC, 2012)**



<http://www.foodinsight.org/Resources/Detail.aspx?topic=2012ConsumerPerceptionsOfTechnologySurvey>



Genomics is a way of evaluating the genetic makeup of farm animals to help make breeding decisions that will result in producing better offspring for improved meat, milk, and egg quality. *What is your overall impression of animal genomics?* (IFIC, 2012)



<http://www.foodinsight.org/Resources/Detail.aspx?topic=2012ConsumerPerceptionsofTechnologySurvey>



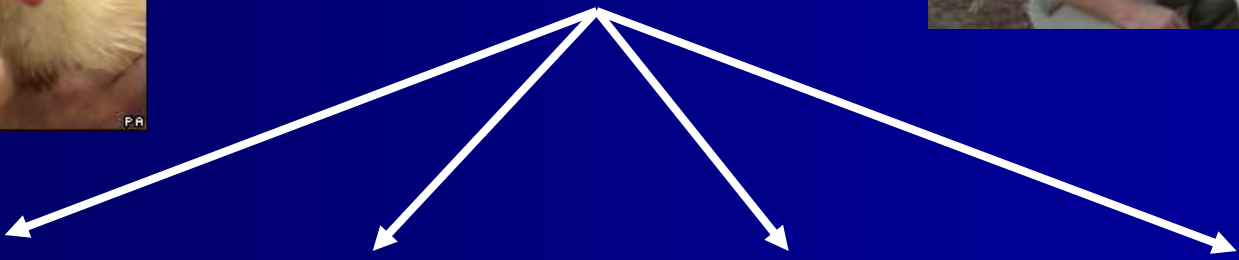
rDNA
gene construct



embryo



transgenic animal



Research

- disease models

Biomedical

- pharmaceuticals
- xenotransplantation

Industrial

Agriculture

- none on market to date



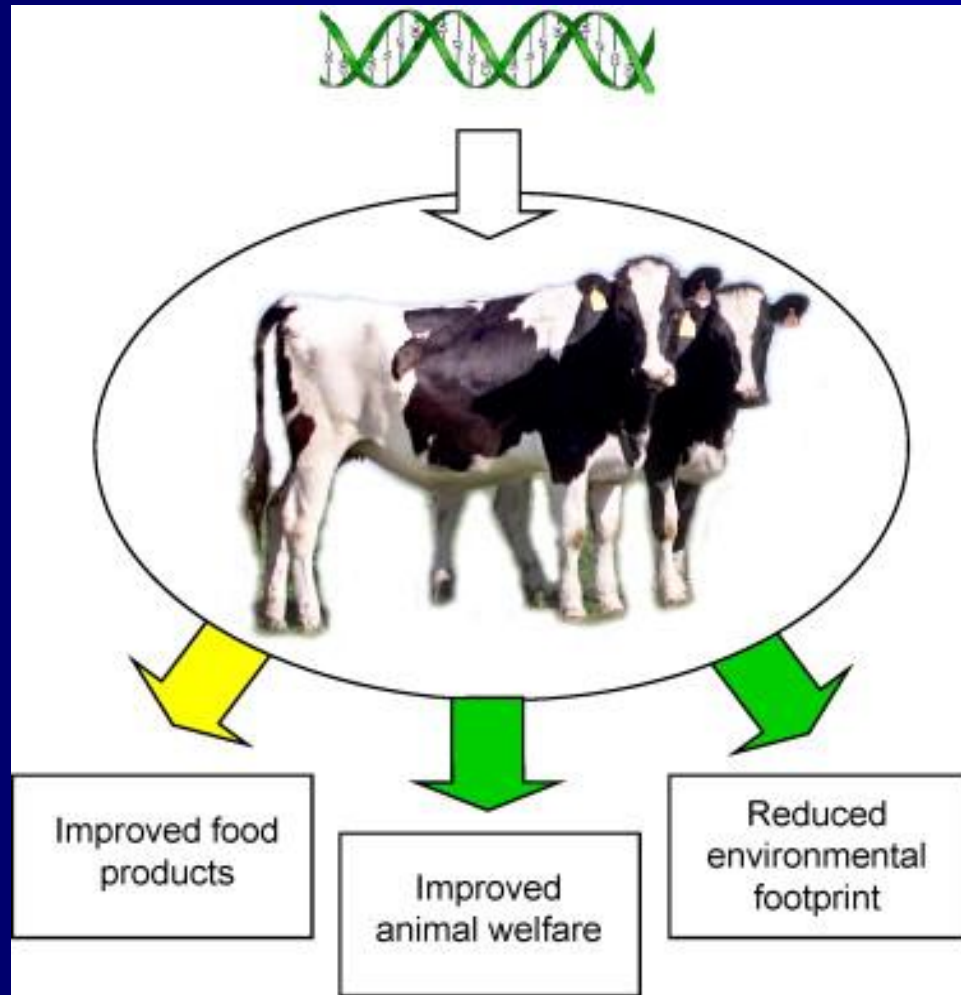
Timeline of genetically engineered (GE) animals in US



Year	Event
1980	<ul style="list-style-type: none">Genetically engineered (GE) mice
1985	<ul style="list-style-type: none">GE livestock and fish first created
1997	<ul style="list-style-type: none">Hello Dolly – Adult somatic cell nuclear (SCNT) cloning in UK
2008	<ul style="list-style-type: none">FDA issues risk assessment on clones in the food supply
2009	<ul style="list-style-type: none">FDA guidance on how GE animals will be regulated using new animal drug approachFDA approval of first GE animal – a goat producing a human pharmaceutical drug in its milk



Genetically engineered animals for agricultural applications







Animal welfare: Mastitis-resistant (inflammation of mammary gland) dairy cows



ARTICLES

nature
biotechnology

Nature Biotechnology 23:445-451. **2005**

Genetically enhanced cows resist intramammary *Staphylococcus aureus* infection

Robert J Wall¹, Anne M Powell¹, Max J Paape², David E Kerr³, Douglas D Bannerman², Vernon G Pursel¹, Kevin D Wells⁴, Neil Talbot¹ & Harold W Hawk¹

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>

www.ars.usda.gov



Fast growing salmon

The founder female was generated in 1989 – 24 years ago

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



© 1992 Nature Publishing Group <http://www.nature.com/naturebiotechnology>

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. Fletcher¹, Margaret A. Shears¹, Madonna J. King¹, David R. Idler¹ 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. ¹Ocean Sciences Centre, Memorial University of Newfoundland, St. John's, Newfoundland, Canada A1C 5S7. *Corresponding author.

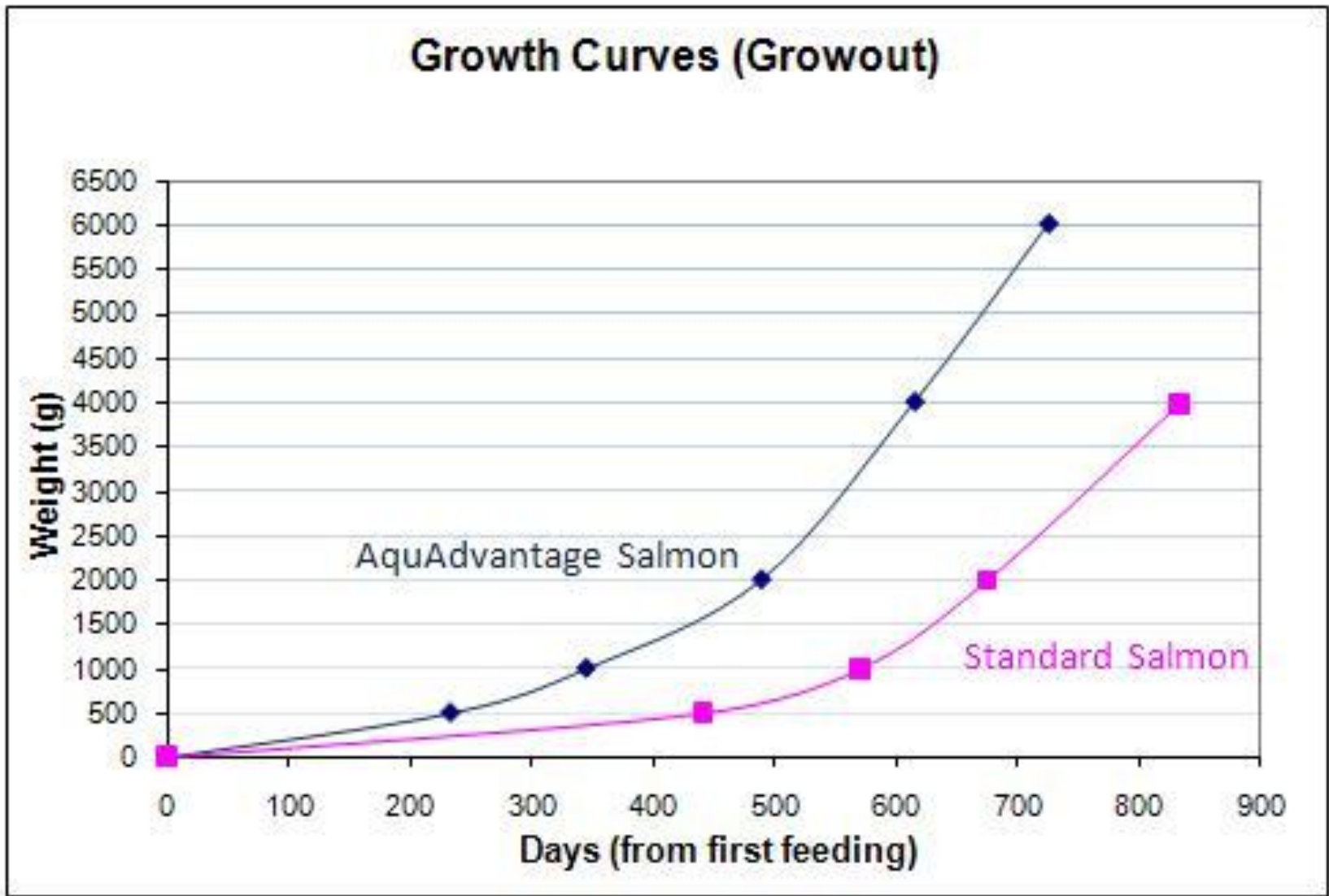
We have developed an “all fish” growth hormone (GH) chimeric gene construct by using an antifreeze protein gene (AFP) promoter from ocean pout linked to a chinook salmon GH cDNA clone. After microinjection into fertilized, nonactivated Atlantic salmon eggs via the micropyle, transgenic Atlantic salmon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





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
- *“At this time it is our intent to hold public scientific advisory board meetings prior to making decisions on GE animal applications.”*





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







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.

10. Frankenfish Aren't Animals, They're "Animal Drugs"

1 of 11

Obama's FDA is regulating genetically engineered salmon, a genetically modified organism (GMO) that is the first of its kind, not as an animal, but as an animal drug.





“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?

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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 VMAC meeting, more than 40 members of Congress signed letters requesting FDA halt the approval of the Aqua Bounty 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"

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





Paradoxically it often seems that the arguments for and against GE animals for food purposes overlap

- Groups opposed to the technology argue that the risks GE animals pose to food safety, animal health, and the environment are too great to allow the technology to move forward.
- Proponents of the technology see the potential benefits for GE animals to produce safer food, improve animal health, and reduced environmental impact as too great to forgo the use of this technology in animal agriculture production systems.





Timeline of GE animals for agricultural applications in US



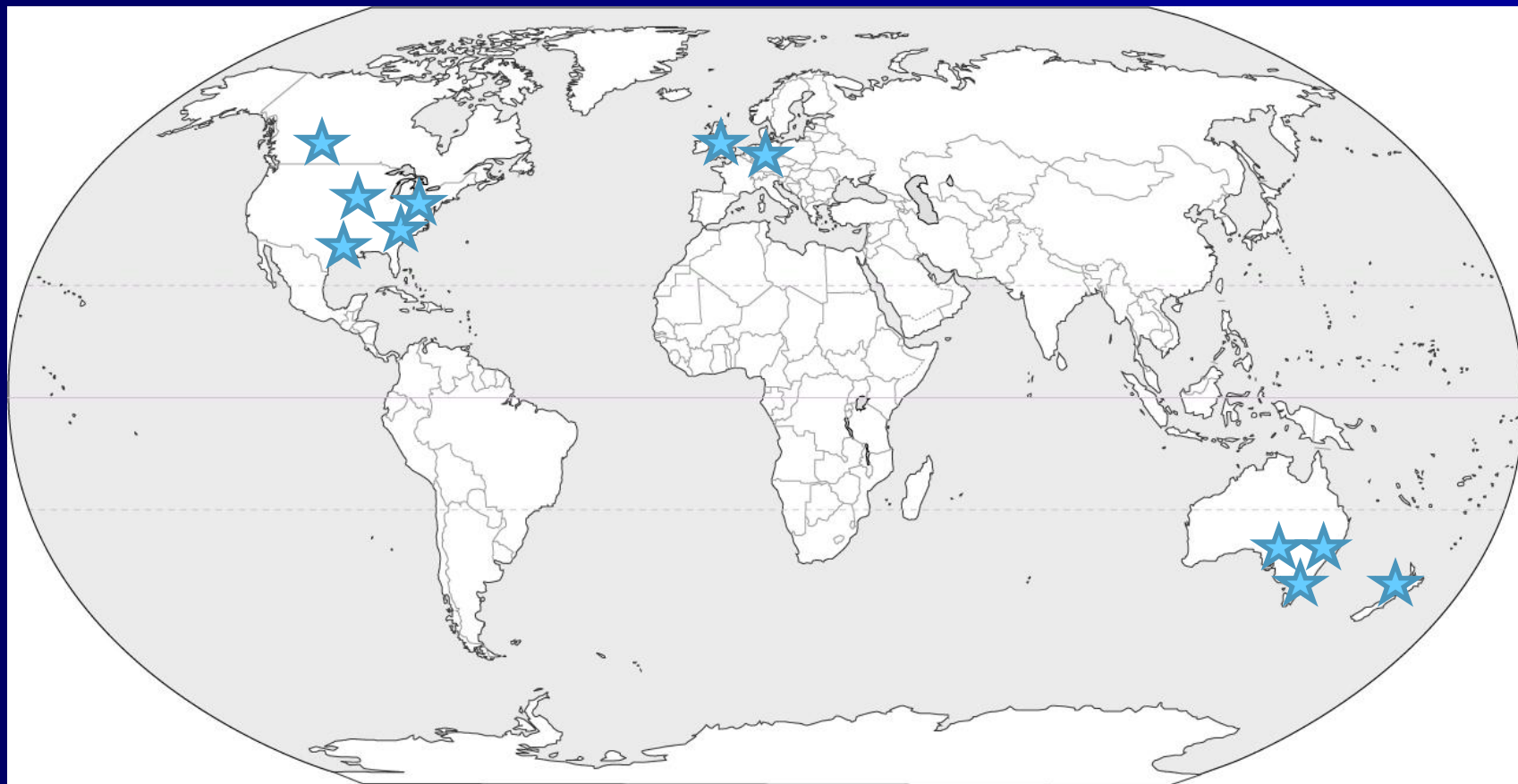
25+... years from discovery to application

Year	Event
1985	<ul style="list-style-type: none">• GE livestock and fish first created
1995	<ul style="list-style-type: none">• FDA review of AquAdvantage salmon begins
2001	<ul style="list-style-type: none">• First regulatory study submitted by Aqua Bounty Technologies to U.S. FDA for a New Animal Drug Applications
2008	<ul style="list-style-type: none">• FDA issues risk assessment on clones in the food supply
2009	<ul style="list-style-type: none">• FDA guidance on how GE animals will be regulated• FDA approval of first GE animal pharmaceutical• Final AquAdvantage regulatory study submitted to FDA
2010	<ul style="list-style-type: none">• FDA VMAC meeting on AquAdvantage salmon (9/20/10)
2011	<ul style="list-style-type: none">• Political efforts to prevent FDA from regulating GE salmon
2012	<ul style="list-style-type: none">• Still waiting for regulatory decision on AquAdvantage salmon• Delayed approvals decreasing investment in GE ag animals <p>Use of GE animals for food actively pursued in other countries</p>



Sites working on GE livestock for food – 1985

North America, Europe and Australasia





Sites working on GE livestock for food - 2012

Asia and South America are moving forward with this technology in their animal agriculture





How should society decide/draw the line as to which (bio)technologies should be adopted, regulated, and/or forbidden for (developed world) animal agriculture?

PRODUCTION

- ✿ Bovine somatotropin
- ✿ Beta-agonists
- ✿ Implants
- ✿ Ionophores
- ✿ Genetically engineered feed (i.e. GM corn, soy)
- ✿ Antibiotics
- ✿ Cages/feedlots
- ✿ Vaccines
- ✿ Castration/dehorning

GENETIC

- ✿ Cloning
- ✿ Genetic engineering
- ✿ Targeted gene knockouts
e.g. myostatin, prion protein
- ✿ Genomic selection
- ✿ Embryo transfer
- ✿ Artificial insemination
- ✿ Estrus synchronization
- ✿ Crossbreeding
- ✿ Selective breeding programs





AUSTRALIA

3 Nov 2012 Last updated 16:11 EST

A- A+

search term

SEARCH

Groups set sights on factory farming

22 Oct 2012



Updated Tuesday, 23 October

Coles has announced it will speed up its plans to implement a sow stall-free policy on its Australian fresh pork and small goods, as well as imported pork products.

The move comes as animal rights groups launch a major blitz on factory farming.

The supermarket chain had originally benchmarked 2014 as the date from which all Coles branded pork, including ham and bacon produced in Australia and overseas, would be sourced from pigs not confined in sow stalls.

However, it has announced this morning that it will reach that goal twelve months early, by the start of 2013.

"Few Australians are aware that the majority of pork, chicken and egg products are produced in factory farms, or of the conditions and treatment these animals are forced to endure," Ms White (*from Animals Australia*) said.

"Factory farming in terms of numbers of animals involved and duration of suffering is by far the greatest animal welfare issue in this country, and one that only continues because the spotlight has not been shone on it."



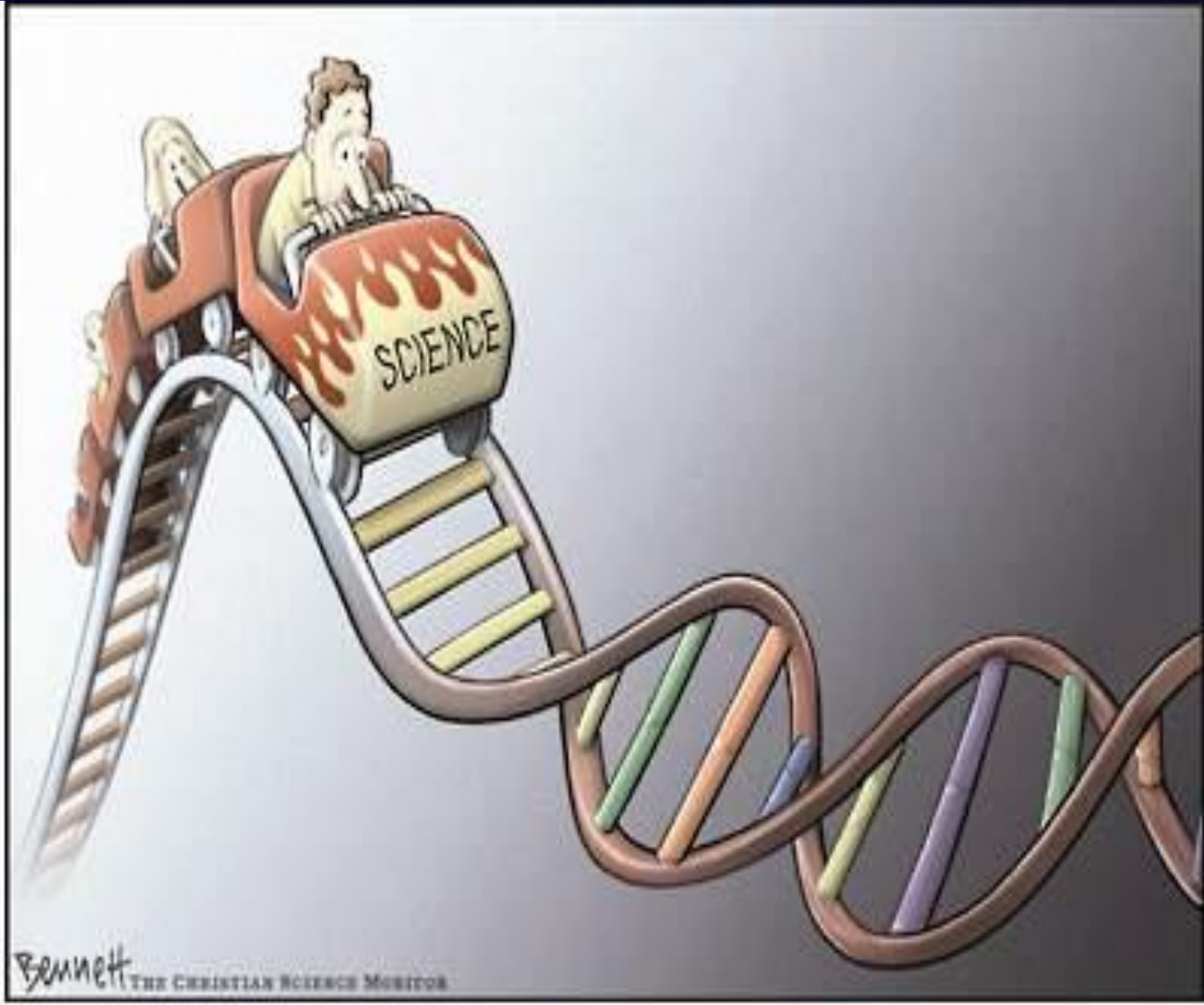
CHAMPION BREED
AT...



North Dakota General Election November 6, 2012 Constitutional Amendment Referendum

“The right of farmers and ranchers to engage in modern farming and ranching practices shall be forever guaranteed in this state. No law shall be enacted which abridges the right of farmers and ranchers to employ agricultural technology, modern livestock production and ranching practices.”





Bennett
THE CHRISTIAN SCIENCE MONITOR