



# “Can process-based regulation of genetically-engineered animals keep pace with technology?”

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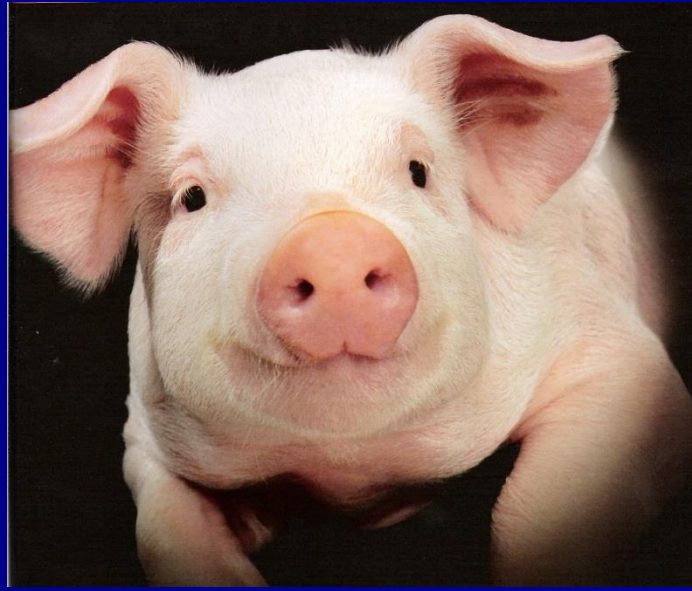
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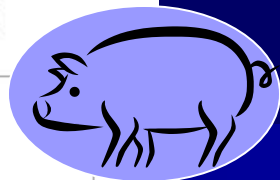
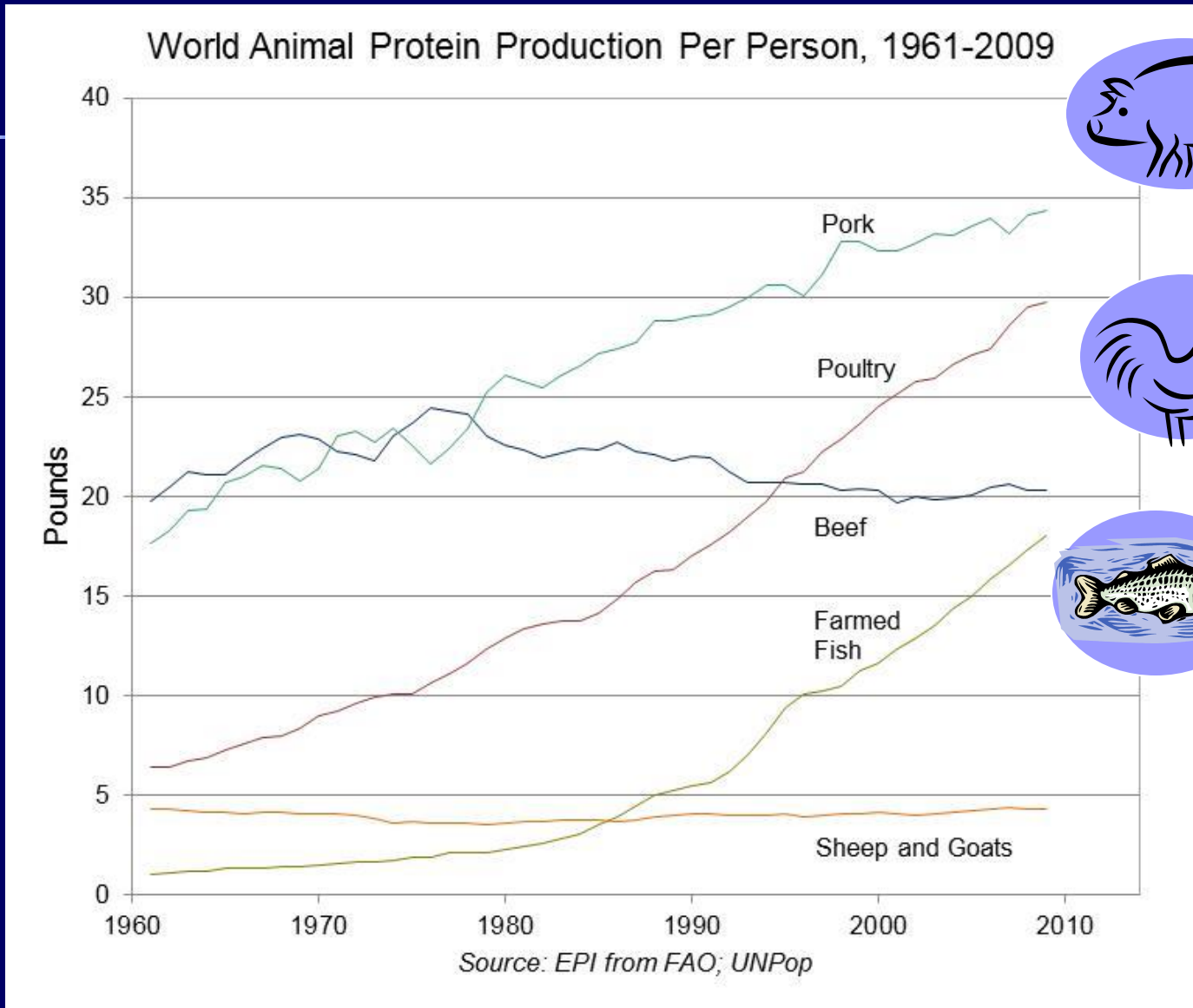


# Overview

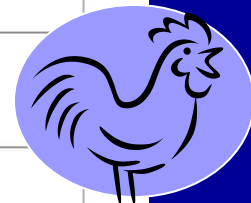


- The livestock revolution
- **What have animal breeders been up to?**
- Novel breeding technologies
- **The plant situation**
- The animal situation
- **The regulated article - product versus process**
- Regulating the future
- **A special TAC 2013-inspired limerick**

# World Animal Protein Production Per Person, 1961-2009



4 legs good



2 legs good



0 legs good

Rumen good (to consume roughage)



# POPULATION

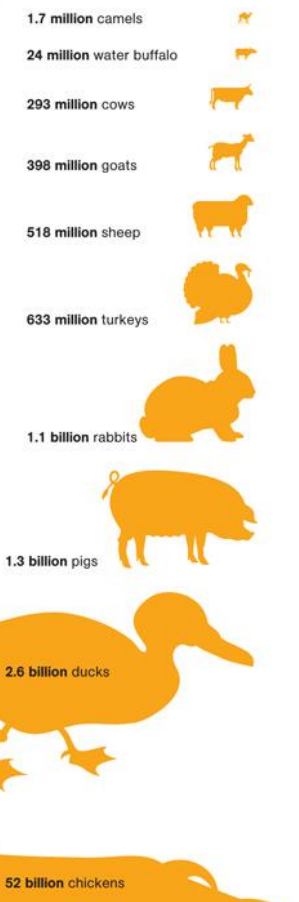
## Food for Thought

There will soon be seven billion humans on Earth, but how does that number compare to other species on the planet? We are certainly outnumbered by ants. Harvard biologist and ant expert Edward O. Wilson has estimated that there are a thousand trillion to ten thousand trillion ants at any one time.\* That would be about a million ants for every one of us. And doesn't it seem like that when they invade our kitchens?

Estimating animal populations, especially wild ones, is hard, but here's a look at one category of animals we can count: the ones we eat. —Nigel Holmes

**7 SEVEN BILLION**

## # animals killed for food 2009



\*And they're edible. Ants are a good source of protein and are considered a delicacy in many parts of the world.

# We are vastly outnumbered by chickens !!

1.3 billion pigs

2.6 billion ducks

52 billion chickens

- 59 million tons eggs
- 90 million tons meat





The 8-week old body weight of broiler (meat) chickens has increased from 0.81 kg to 3.14 kg over the period 1957 to 2001, and approximately 80% of this four-fold increase has been the result of genetic selection.

## 1957 vs. 2001 chickens

1957



2001



43

57

71

85 d.


Havenstein, G., Ferket, P. and Qureshi, M. (2003). Growth, livability, and feed conversion of 1957 versus 2001 broilers when fed representative 1957 and 2001 broiler diets. *Poultry Science* 82, 1500-1508.



# Fast growing salmon

*The founder female was generated in 1989 ~ a quarter century 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. Fletcher<sup>1</sup>, Margaret A. Shears<sup>1</sup>, Madonna J. King<sup>1</sup>, David R. Idler<sup>1</sup> 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. <sup>1</sup>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**



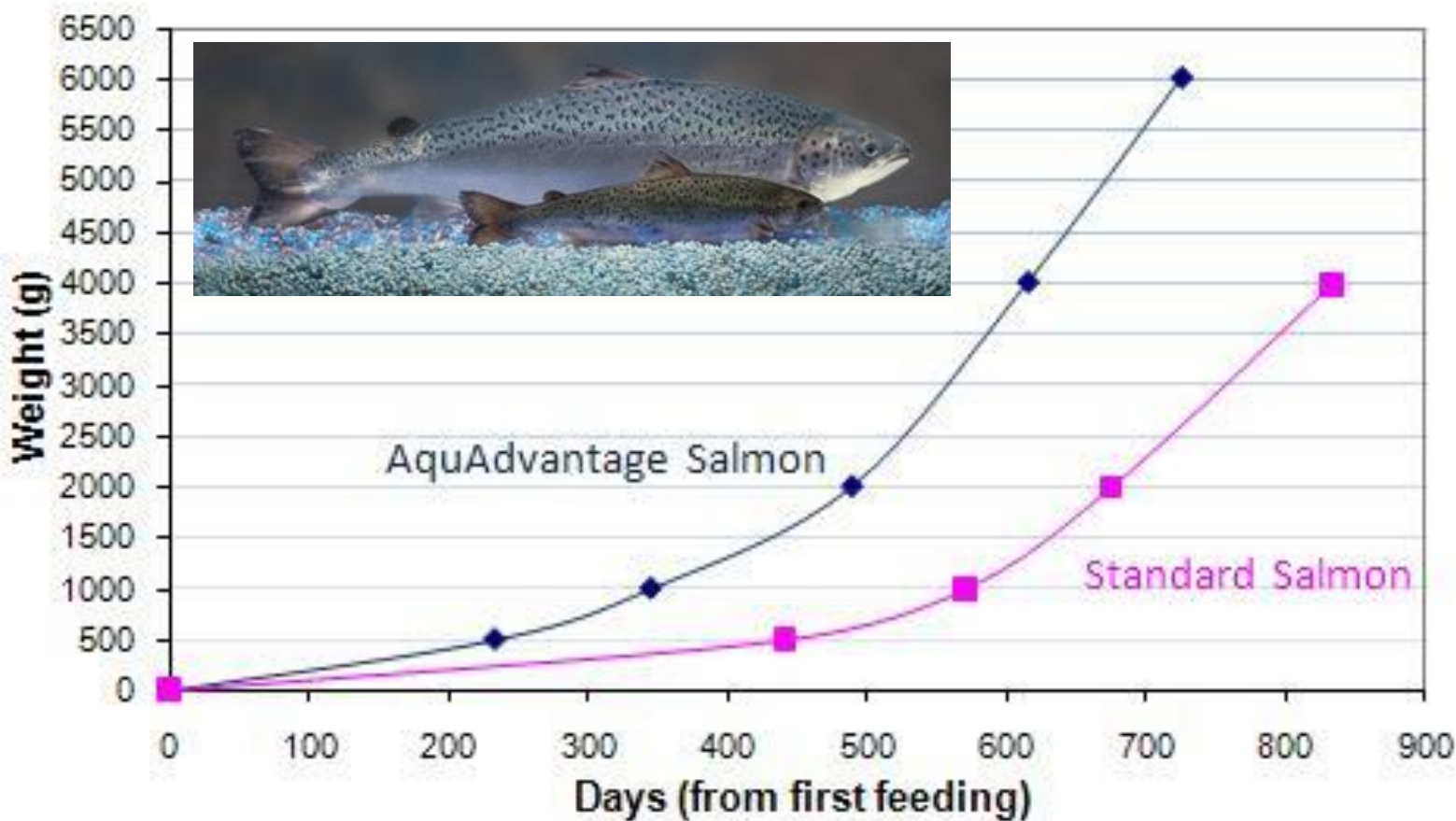




# Fish reach adult size in 16 to 18 months instead of 30 months



## Growth Curves (Growout)



# Timeline of AquAdvantage regulatory process

Year	Event
1989	<ul style="list-style-type: none"><li>• Founder AquAdvantage fish produced in Canada</li></ul>
1995	<ul style="list-style-type: none"><li>• FDA review of AquAdvantage salmon begins (INAD)</li></ul>
2001	<ul style="list-style-type: none"><li>• First regulatory study submitted by Aqua Bounty Technologies to U.S. FDA for a New Animal Drug Applications (NADA)</li></ul>
2009	<ul style="list-style-type: none"><li>• FDA guidance on how GE animals will be regulated</li><li>• FDA approval of first GE animal pharmaceutical</li><li>• Final AquAdvantage regulatory study submitted to FDA</li></ul>
2010	<ul style="list-style-type: none"><li>• FDA VMAC meeting on AquAdvantage salmon (9/20/10)</li></ul>
2011	<ul style="list-style-type: none"><li>• Political efforts to defund FDA, ban fish, delay approval</li></ul>
2012	<ul style="list-style-type: none"><li>• FDA released "FONSI" finding of environmental assessment</li></ul>
2013	<ul style="list-style-type: none"><li>• <b>AquaBounty Total R&amp;D investment &gt; \$60 million to develop and bring the AquAdvantage salmon through the regulatory approval process <i>thus far</i></b> (D. Frank, CFO, AquaBounty, pers. comm.)</li><li>• Still waiting for regulatory decision on AquAdvantage salmon</li><li>• Development of GE animal technology moving to other countries with more predictable policy environments</li></ul>

24+ years from discovery to application?





How can \$60+ million be warranted to bring a fast-growing fish to market, when conventional fish (and other animal) breeders routinely develop all manner of fast-growing animals that are associated with the same set of risks?

## 1957 vs. 2001 chickens

1957



2001



43

57

71

85 d.





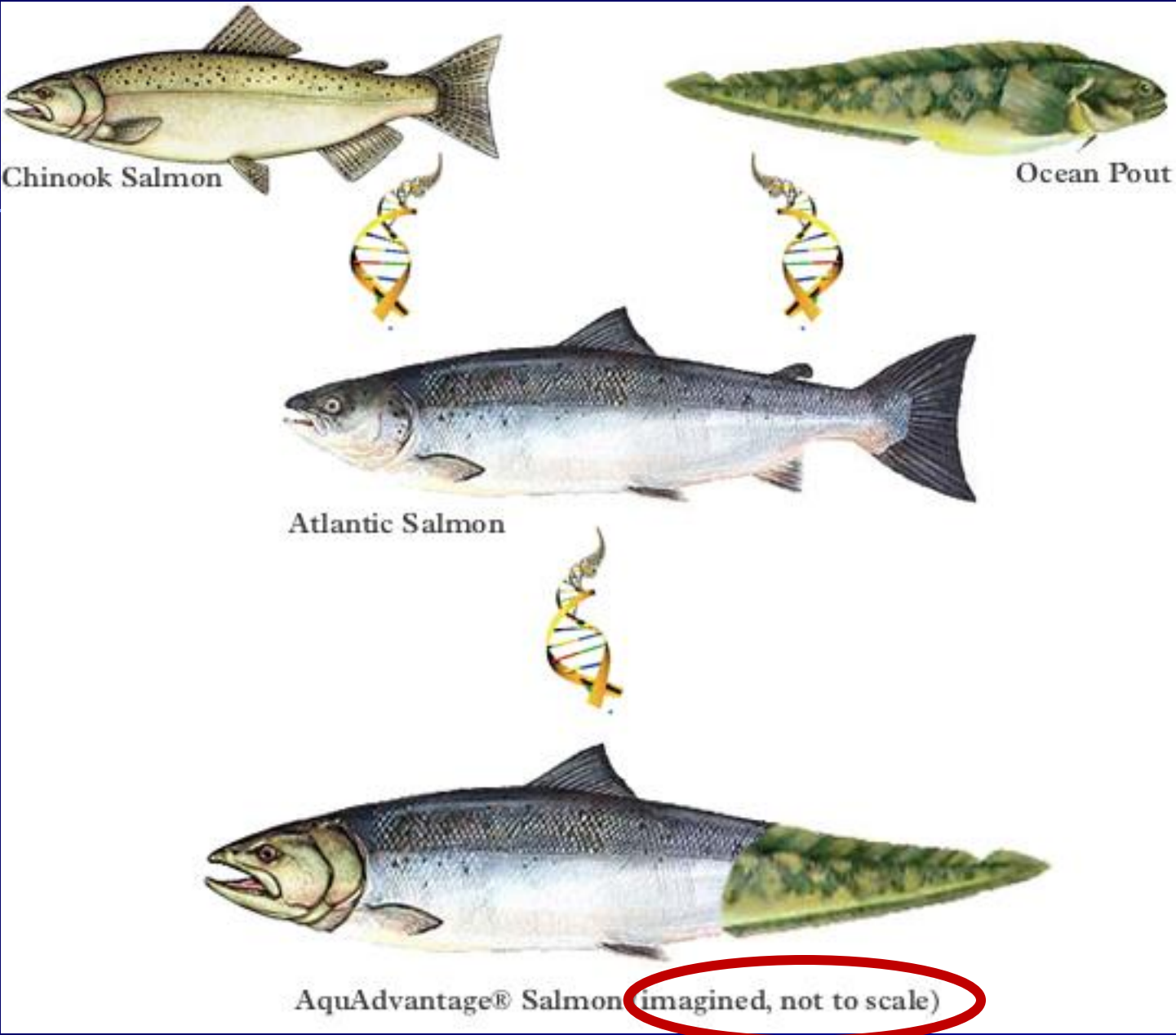
# “Public is concerned because salmon is first GM food animal”



[https://fbcdn-sphotos-f-a.akamaihd.net/hphotos-ak-ash3/p480x480/936235\\_497070347014003\\_426756402\\_n.jpg](https://fbcdn-sphotos-f-a.akamaihd.net/hphotos-ak-ash3/p480x480/936235_497070347014003_426756402_n.jpg)



# Retrieved from "AquAdvantage" image search on web





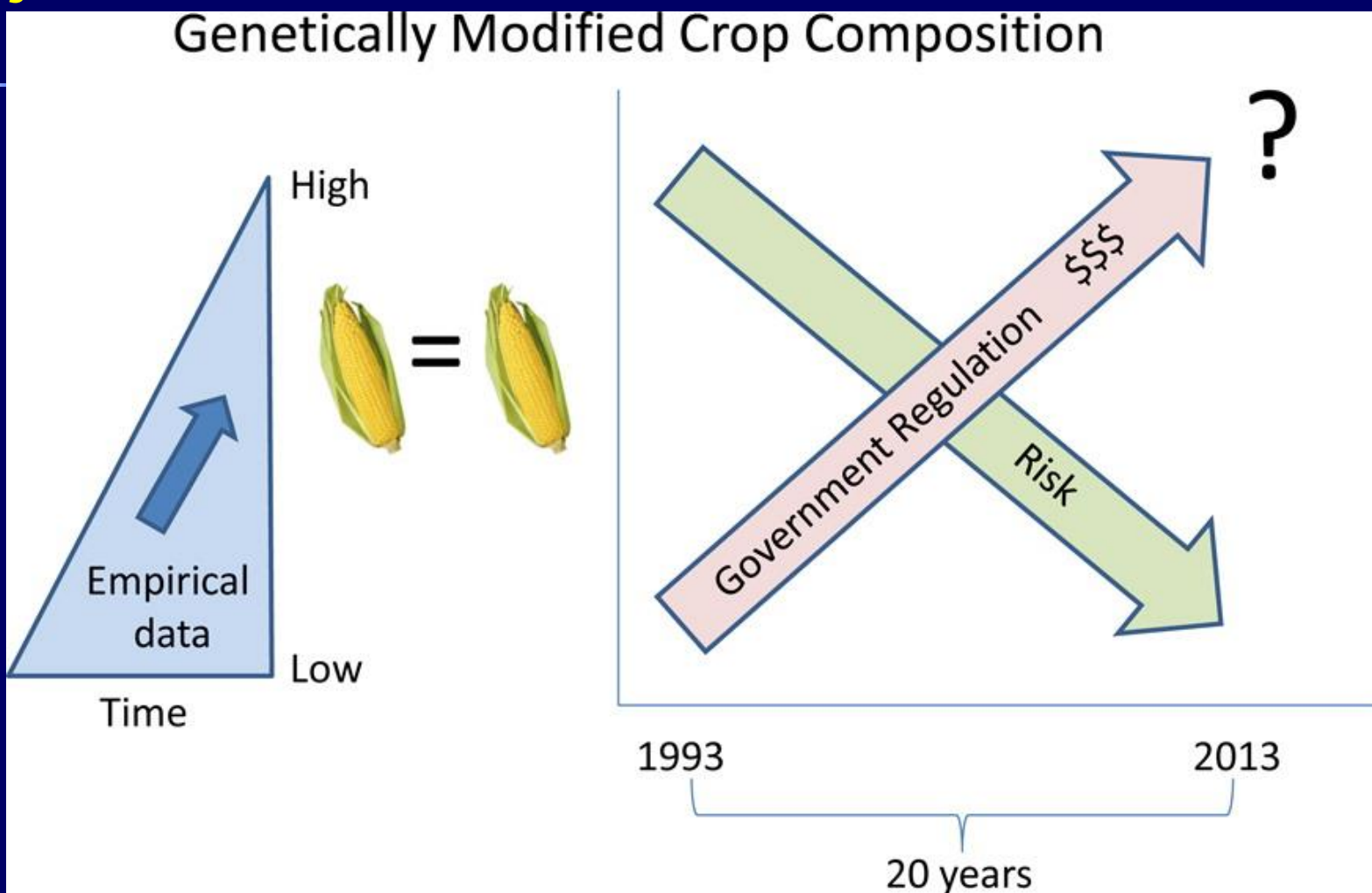
# My basic question is this



- The first genetically engineered (GE) crops came to the market in ~1995
- In 2012 **17.3 million** farmers grew GE crop varieties on > 170 million hectares, and of these > 90% (15 million) were small, resource-poor farmers in developing countries
- Humans and livestock have consumed billions of meals without a single case of harm attributable to the GE nature of the materials consumed
- Currently products developed through the process of GE are singled out and uniquely required to go through regulatory approval
- These regulatory policies add years and millions of dollars to the cost of developing GE crops and animals

***Is this level of scrutiny aligned to science-based risks associated with this technology, or is this overabundance of precaution making the deployment of this valuable technology beyond the means of all but the largest, multinational corporations, to the detriment of food security globally?***

# GE process-based “equivalence” studies uniquely required for GE plants can no longer justified on the basis of scientific uncertainty



Herman RA, Price WD. 2013. **Unintended Compositional Changes in Genetically Modified (GM) Crops: 20 Years of Research.** J Agric Food Chem. 2013 Feb 25.

Van Eenennaam 8/14/2013

Animal Biotechnology and Genomics Education



# There is no scientific case for a blanket approval of all uses of GE. But equally there is no scientific case for contrived safety testing

There is always the issue of novel proteins or compounds with no history of safe use. These will always have to be tested for toxicity and allergenicity— be they introduced by GE or conventional breeding techniques.

The bulk of safety testing and expense is to detect “unintended” changes specifically resulting from GE

It is continued testing using ever more-expensive techniques including emerging “omics” for these “**unexpected**” **unintended effects of GE** that is scientifically dubious as the **biological relevance** of a “statistically significant” compositional change is unclear – especially in the absence of data for conventional food.





# Unintended effects have not materialized

It seems more scientifically defensible to be able to state that certain likely effects (e.g. novel allergens and toxins, positional insertion effects) have been assessed and found absent, than to admit that one did not know quite what to look for – but found it absent nevertheless

*“Skeptics who remain fearful sometimes respond that “absence of evidence is not the same thing as evidence of absence”. Yet if you look for something for 15 years and fail to find it, that must surely be accepted as evidence of absence. It is not proof that risks are absent, but proving that something is absent (proving a negative) is always logically impossible\*”*

\* Paarlberg, R. 2010. **GMO foods and crops: Africa's choice**. *New Biotechnology* 27:609-613



# The only time I EVER laughed reading a “GMO biosafety research” paper



“Historically, risks to the environment presented by crop plants are low. In these projects, we think what we need to do is to collect scientific data and understand the scientific basis for safe use of GMO products..... *We are not trying to prove how risky it may be by strange imagination or by inventing some special phenomena that do not occur in nature.*”

Jia S, Peng Y. 2002. **GMO biosafety research in China.** Environ Biosafety Res. 2002 1(1):5-8.



# FDLI'S FOOD *and* DRUG POLICY FORUM

VOLUME 3 // JULY 24, 2013

## ISSUE 12

**\*Is FDA Ready to Regulate  
the World's First Biotech  
Food Animal?**

**Tim Schwab**  
Senior Researcher  
Food & Water Watch

## ISSUE 13

**\*Is Unaccountable Regulatory  
Delay and Political Interference  
Undermining the FDA  
and Hurting American  
Competitiveness?**

*A Response to Tim Schwab's 'Is FDA Ready  
to Regulate the World's First Biotech  
Food Animal?'*

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AquAdvantage regulatory delay has been occasioned by factors including: the use of a process-based risk assessment arbitrarily triggered by the use of rDNA rather than the novel phenotype and attributes of the product; misrepresentation and questionable interpretation of data by special interest groups; a risk assessment paradigm that does not consider the known risks associated with existing production systems; continued political interference; lack of predefined timeline



- Focus risk assessments on those **unique risks** associated with the GE animal application and evaluate them in relation to known risks associated with existing production systems.
- Require **hypothesis-driven studies** for regulatory evaluation detailing the biologically relevant issue(s) based upon the novel traits or phenotype(s) associated with the species/gene/insertion event combination.
- Following submission of all pre-defined required data, impose **finite response times** for agency decisions at each point in the evaluation process to provide developers and investors with a predictable regulatory timeline for GE animals.

Van Eenennaam, A.L., W. M. Muir, and E. A. Hallerman. 2013. Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?: A Response to Tim Schwab's 'Is FDA Ready to Regulate the World's First Biotech Food Animal'? The Food and Drug Law Institute (FDLI) Food and Drug Policy Forum. Volume 3(13).



# What does the future look like

The European Commission (EC) has asked the EFSA Panel on Genetically Modified Organisms (GMO) to deliver a scientific opinion on whether there is a need for new guidance or whether the existing guidance on risk assessment should to be updated or further elaborated, in anticipation of the placing of products on the market through the application of:

- zinc finger nuclease technology
- oligonucleotide-directed mutagenesis
- cisgenesis (comprising cisgenesis and intragenesis)
- grafting onto a GE rootstock
- reverse breeding
- RNA-dependent DNA methylation via RNAi/siRNA
- **agro-infiltration**
- **synthetic biology**





# What are we talking about?



- **Zinc-finger nuclease (ZFN) technology** - involves the use of an engineered zinc finger nuclease to introduce site-specific mutations into the plant genome. Depending on the type of ZFN technology deployed, mutations can either be restricted to one or a few nucleotides or involve the insertion of a new piece of DNA.
- **Oligo-directed mutagenesis (ODM)** - involves the use of synthetic oligonucleotides to introduce small, site-specific mutations into the plant genome.
- **Cisgenesis and intragenesis** - involve transferring a new gene into the genome of a plant using gene technology. In both cases the gene is derived from either the same or a cross-compatible species.
- **GM rootstock grafting** - involves grafting the vegetative part of a non-GM plant (the scion) onto the rootstock of a GM plant to create a chimeric plant that shares a single vascular system.
- **Reverse breeding** - a novel plant breeding technique that involves suppressing meiotic recombination in order to recreate homozygous parental lines that, once hybridised, reconstitute the composition of an elite heterozygous plant without the need for backcrossing or selection.



# Food standards New Zealand/Australia

<http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx>



## REGULATED AS GM FOOD

- food produced using cisgenesis/ intragenesis
- food produced using zinc-finger nuclease technology (where it is used for targeted gene addition or replacement)
- food produced using GM rootstock grafting may contain novel GM material and/or have altered characteristics as a result of the genetic modification to the rootstock and should therefore be regarded as GM food

## NOT GM FOOD

- food produced using oligo-directed mutagenesis and zinc-finger nuclease technology, where the techniques are used to introduce small, site-specific mutations involving only one or a few nucleotides, would be similar to food produced using traditional mutagenic techniques and should therefore **not be regarded as GM food**
- food produced using seed production technology should not be regarded as GM food, as a genetic separation exists between an early GM ancestor and the non-GM parents of the final food-producing line, which does not contain the genetic modification





# EU plans to regulate cisgenic and intragenic as GMOs

- The EFSA GMO Panel considers that the *Guidance for risk assessment of food and feed from genetically modified plants* (EFSA, 2011) and the *Guidance on the environmental risk assessment of genetically modified plants* (EFSA, 2010) are applicable for the evaluation of food and feed products derived from cisgenic and intragenic plants and for performing an environmental risk assessment and do not need to be developed further.
- It can be envisaged that on a case-by-case basis less event specific data are needed for the risk assessment. For example relevant information might already be available regarding the nature of the cisgenic/intragenic traits and/or plant products, experience with the donor and/or recipient plants and the history of safe use and/or consumption

EFSA Panel on Genetically Modified Organisms (GMO); Scientific opinion addressing the safety assessment of plants developed through cisgenesis and intragenesis. *EFSA Journal* 2012;10(2):2561. [33 pp.]





# USDA APHIS does not regulate GE unless process used is a plant pest or product is a plant pest



USDA was approached by a plant breeder concerning the regulatory status of a grapevine transformed by an **'ingenic or cisgenic'** approach (which corresponds to the definition of intragenesis used in this paper). The plant which carries a grapevine-derived anthocyanin regulatory gene and grapevine-derived regulatory elements is not considered to be a regulated article under the Plant Pest Act (letter from 2012).

Basically if it does not contain DNA from a plant pest and the plant itself is not a pest then it does not fall under APHIS

- Innate potatoes – still doing FDA premarket consultation



EFSA [http://www.aphis.usda.gov/biotechnology/reg\\_loi.shtml](http://www.aphis.usda.gov/biotechnology/reg_loi.shtml)



# GE plants are regulated by at least two and for specific applications, namely GE plants that express pesticides (called plant-incorporated protectants), by three agencies in the US



- **The USDA regulates the environmental release of certain GE organisms, which are, or are believed to be, plant pests under the Plant Protection Act.** GE plants are regarded as a plant pest when genes from plant pests are introduced. As transgenic approaches frequently use *Agrobacterium* as a vector and/or genes from soil bacteria (e.g. antibiotic resistance genes) or viral promoter sequences (e.g. 35S promoter from cauliflower mosaic virus), most GE plants to date have fallen under this definition and consequently under the oversight of USDA.
- **EPA regulates biopesticides, including Bt toxins, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).** If a crop is genetically engineered to carry a gene for a Bt toxin, EPA requires the developer to verify that the toxin is safe for the environment and conduct a food-safety analysis to ensure that the foreign protein is not allergenic.
- **FDA is responsible for regulating the safety of GE crops that are eaten by humans or animals.** According to a policy established in 1992, FDA considers most GE crops as “substantially equivalent” to non-GM crops. In such cases, GM crops are designated as “Generally Recognized as Safe” under the Federal Food, Drug, and Cosmetic Act (FFDCA) and do not require pre-market approval. If, however, the insertion of a transgene into a food crop results in the expression of foreign proteins that differ significantly in structure, function, or quality from natural plant proteins and are potentially harmful to human health, FDA reserves the authority to apply more stringent provisions of FFDCA requiring the mandatory pre-market approval of food additives, whether or not they are the products of biotechnology. In 1997, FDA established a “**voluntary**” consultation process with GM crop developers to review the determination of “substantial equivalence” before the crop is marketed, such as assessing the toxicity and allergenicity of the gene product and the plant itself. If the data in the food-safety assessment are satisfactory, FDA notifies the developer that marketing of the crop may proceed.



# USDA opinions on regulation of gene editing in plants



Letters from USDA APHIS to companies who contacted them concerning the regulatory status of crops produced by site-specific mutagenesis are published on USDA web site

A letter from **2004** states that under the current regulations, **USDA has no authority to regulate products created by mutagenesis techniques such as Oligonucleotide-Directed Mutagenesis**

Concerning plants derived by meganuclease techniques (letter from **2011**), USDA concluded that plants containing targeted gene deletions will not, in most cases, be regulated articles under the Plant Protection Act, unless the engineered plant is already a plant pest or if the meganuclease is delivered into the plant using a plant pest.

For applications where template DNA molecules are used APHIS will consider case-by-case enquiries regarding the regulatory status of the plants. Similar conclusions were drawn for plants produced by zinc finger nuclease technology with or without template DNA molecules (letters from **2010** and **2012**).

Maria Lusser, Howard V. Davies, 2013 Comparative regulatory approaches for groups of new plant breeding techniques, *New Biotechnology* 30, issue 5, 25 June 2013, pages 437-446



# USDA APHIS does not regulate null segregants (rDNA excised) unless process used or product is a plant pest

USDA was contacted by plant breeders concerning the regulatory status of 'null-segregant' (negative segregant) lines derived from genetically modified early flowering parents (plums) and parents (sorghum) transformed by an RNAi transgene to down-regulate the expression of a native plant gene. In letters from 2011 and 2012 USDA replied that they do not consider the described 'null segregant' lines to be regulated articles.



EFSA [http://www.aphis.usda.gov/biotechnology/reg\\_loi.shtml](http://www.aphis.usda.gov/biotechnology/reg_loi.shtml)

Van Eenennaam 8/14/2013



# Enough about plants – what about animals – what is regulated article? *It depends.....*



In 2008 the Codex developed a science-based guideline “Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals (GL68-2008)<sup>2</sup>” which provides internationally-recognized recommendations for assessing the nutrition and safety of food from GE animals. In that document a “*Recombinant-DNA Animal*” is defined as an animal in which the genetic material has been changed through *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles.

The Food and Drug Administration’s Center for Veterinary Medicine (CVM) evaluates GE animals under the new animal drug provisions of the Federal Food Drug and Cosmetic Act (FFDCA). The act defines drugs as “articles (other than food) intended to affect the structure or any function of the body of man or other animals.” The rDNA construct in the resulting GE animal is thus a regulated article that meets the drug definition; the GE animal itself is not a drug. The FDA defines “genetically engineered (GE) animals” as those animals modified by rDNA techniques, including the entire lineage of animals that contain the modification, and regulates based on the use of rDNA techniques. All GE animals are captured under these provisions, regardless of their intended use. **Thus although the review is product based, the process used to produce the genetic change that results in the product (e.g. rDNA versus traditional breeding) has implications for triggering regulatory oversight.**



# Enough about plants – what about animals – what is regulated article? *It depends.....*



The Cartagena Protocol definition of ‘living modified organisms’ resulting from modern biotechnology’. This means that the Law covers living organisms produced by (a) **modern biotechnology** such as recombinant DNA technology including self cloning and/or recombinant DNA techniques using genetic material (host, vector and foreign genes) derived from an organism between which natural gene exchange is possible (‘natural occurrence’) and (b) techniques for fusing of cells of organisms belonging to different taxonomic families (‘fusion techniques beyond taxonomic family’).

EU definition of GMO (included in Directive 2001/18/EC) is defined as an ‘**organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination**’. The Annexes of the Directive include techniques of genetic modification, including recombinant nucleic acid techniques recombinant nucleic acid techniques involving the formation of new combinations of genetic material ii) direct introduction into an organism of heritable material prepared outside the organism and iii) cell fusion, and techniques **not considered to result in a genetic modification** such as *in vitro* fertilisation, natural processes like conjugation, transduction, transformation and polyploidy induction and techniques of genetic modification yielding organisms to be excluded from the Directive including, for example, **mutagenesis**.



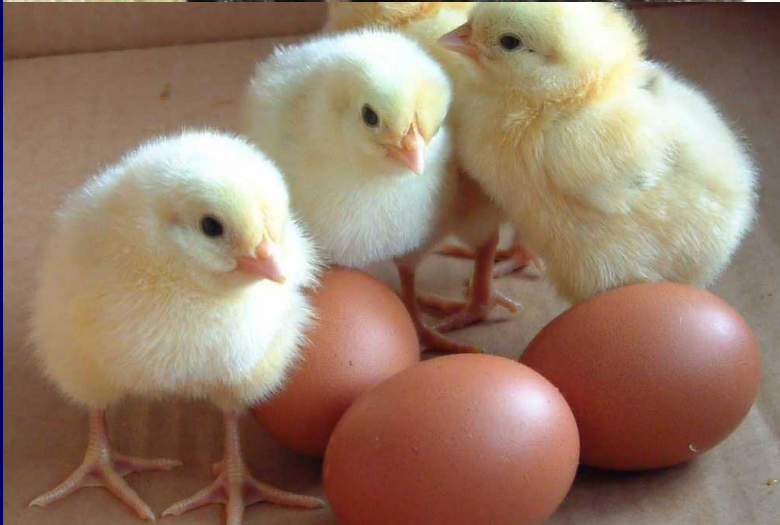
# Example where rDNA was used to make an intragenic fast growing Atlantic salmon with an Atlantic growth hormone promoter expressing an Atlantic growth hormone gene; and the same phenotype made by selecting a naturally-occurring gene duplication mutant



Attribute	GE salmon	Gene duplication salmon
Fast growth?	YES	YES
Possible environmental impacts if escape and interbreed with native salmon?	YES	YES
Possible differential levels of growth hormone expression?	YES	YES
Regulated	Yes in the U.S.; EU, New Zealand, and Australia	NO
Regulatory costs	>\$USD 60 million?	\$0



Some animal biotechnology applications, including GE animals, would seem to align with many sustainability goals including improving animal well-being – will they be permitted to do so given current regulatory policy?



- Naturally polled cattle
- Trypanosome resistance
- Sex selection for ♀ in dairy and egg industries





# Use of rDNA to introduce a site specific polled mutation into Holstein cattle versus repeated backcrossing from Angus into Holstein to obtain the same phenotype through introgression of the polled mutation into Holstein germplasm



Attribute	Polled Holstein through rDNA	Polled Holstein through introgression
No horns	YES	YES
Mutation uniquely detectable	NO	NO
Food safety concerns associated with phenotype	NO	NO
# generations taken to achieve polled >15/16 Holstein	ONE (FAST)	MANY (SLOW)
Linkage drag?	NO	YES
Improved animal welfare	YES	YES
Regulated?	Depends on definition of regulated article	NO
Likely to happen	Not if costs >\$60 million	NO



**Now is an opportune time to review the current process-based regulatory framework where the trigger for regulatory review is the process used to make the modified animal, rather than the unique characteristics and attributes of the resulting animal.**



*“More sophisticated gene editing and knockout techniques have been developed in the 25 years since the founder AquAdvantage® fish was made using pronuclear microinjection. These techniques result in genetic modifications that do not fit the classic definition of “transgenic” or GE, although they are produced through human intervention using rDNA. Use of these techniques will challenge the definition of “regulated article,” as the resulting animals will not harbor rDNA constructs nor any foreign DNA .....*

*To complicate the regulatory oversight and segregation of these animals further, there will likely be no molecular approach to detect and uniquely identify genetic changes made by these approaches. This undetectability issue highlights one of the problems associated with arbitrarily regulating a process (i.e., rDNA), rather than the novelty of the product. If the process changes over time, then process-based regulations become obsolete in that they apply specifically to a process that has been superseded by an improved approach. **The techniques and processes being used to make genetic modifications in animal genomes comprise a rapidly evolving field, and the line between animal breeding and genetic modification is becoming increasingly blurred.”***



# Process versus product? A shift in EU attitude?

“A recent EFSA review of its risk assessment processes for GMOs (Waigmann *et al.* 2012. Special issue: Risk assessment of Genetically Modified Organisms (GMOs). EFSA Journal 10(10):s1008.), suggests that process-based regulation is not inevitable, however.

In the context of the ‘product vs process’ debate, it was remarked that “***Given the fast development of new breeding/production technologies applied to organisms, which may need a revision of current regulatory definitions of genetic modification, EFSA is prepared to investigate risk assessment strategies for modified organisms, based on the characteristics of obtained products rather than based on the applied breeding/production technology.***” If followed through, this could signal the beginning of a major shift in European regulatory systems as applied to GM and related technologies.”

Bruce A, Castle D, Gibbs C, Tait J, Whitelaw CB. 2013. Novel GM animal technologies and their governance. Transgenic Res. Aug;22(4):681-95. doi: 10.1007/s11248-013-9724-5. Epub 2013 Jun 19. PubMed PMID: 23780762.



# It is time to reconnect the GE animal regulatory framework to regulate risk rather than process?



- “Difficult regulatory regimes for GE animals produce, to varying degrees, a negative, reinforcing cycle of regulatory inertia, lack of investment, policy ambivalence, lack of research funding and lack of commercial products.”
- “Increasingly sophisticated and discriminating innovation in the methods available for producing GE animals raises questions about the current state of development of regulatory regime in the EU and USA; about the appropriateness of regulations that have been derived in the context of previous generations of GE technology; and about the relevance of regulatory systems developed for GE crops and micro-organisms to GE animals.”

Bruce A, Castle D, Gibbs C, Tait J, Whitelaw CB. 2013. Novel GM animal technologies and their governance. *Transgenic Res.* Aug;22(4):681-95. doi: 10.1007/s11248-013-9724-5. Epub 2013 Jun 19. PubMed PMID: 23780762.



# Parting thoughts

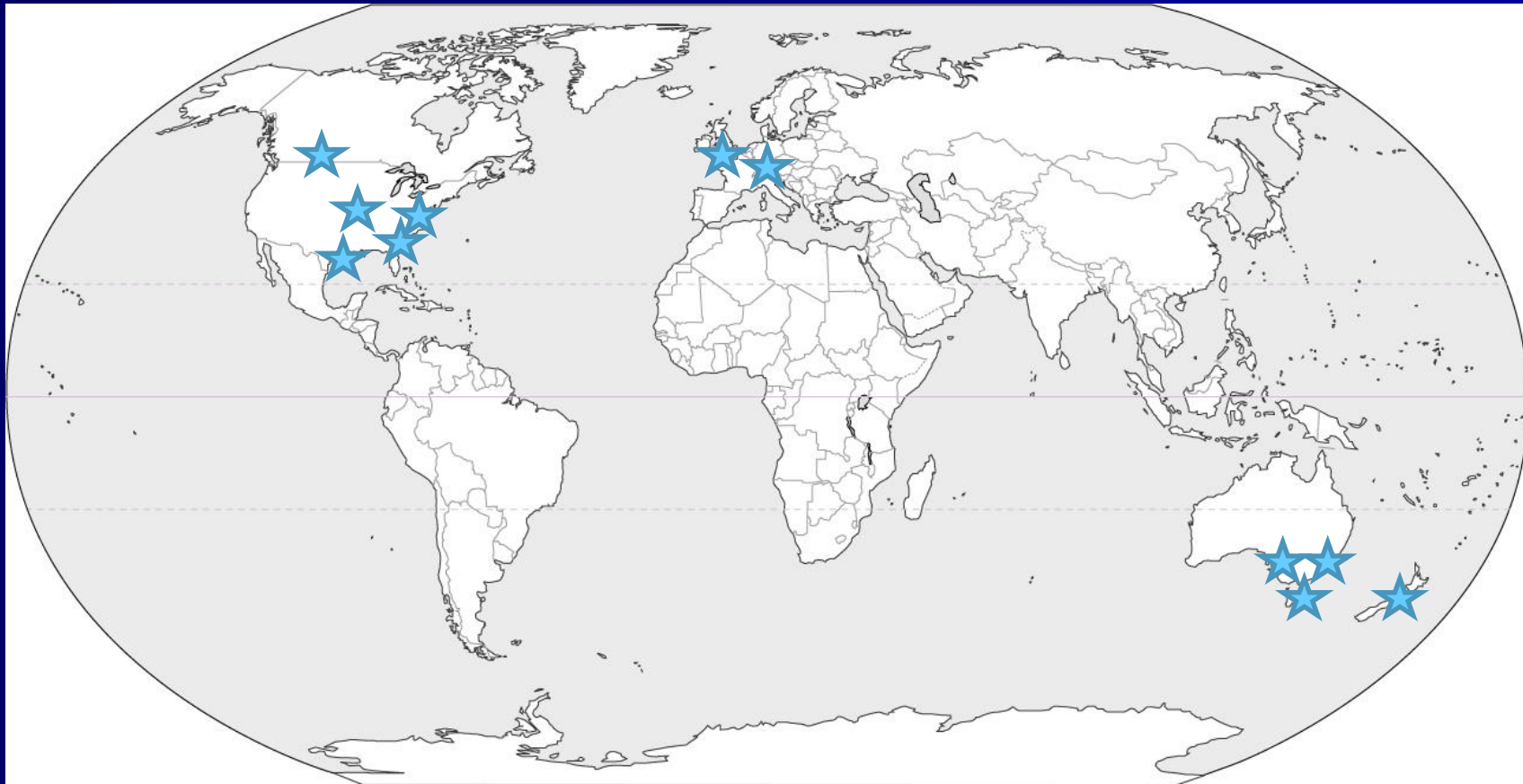


- Regulatory processes should be consistent across products that have equivalent levels of risk. Regulations based on how products are made are inconsistent with science-based risk assessment unless there is something inherently risky about the process, as compared to existing methods
- The trigger for regulatory review should be the novelty of the introduced trait (regardless of how or when it was derived), and *not* the process used to introduce the trait
- GE animal regulatory burdens are disproportionately high and are associated with unaccountable delay and considerable uncertainty. These regulatory burdens are not justified by scientific evidence or experience
- While regulation to ensure the safety of new technologies is necessary, in a world facing burgeoning demands on agriculture from population growth, economic growth, and climate change, overregulation is an indulgence that global food security can ill afford



# Sites working on GE livestock for food – 1985

## North America, Europe and Australasia

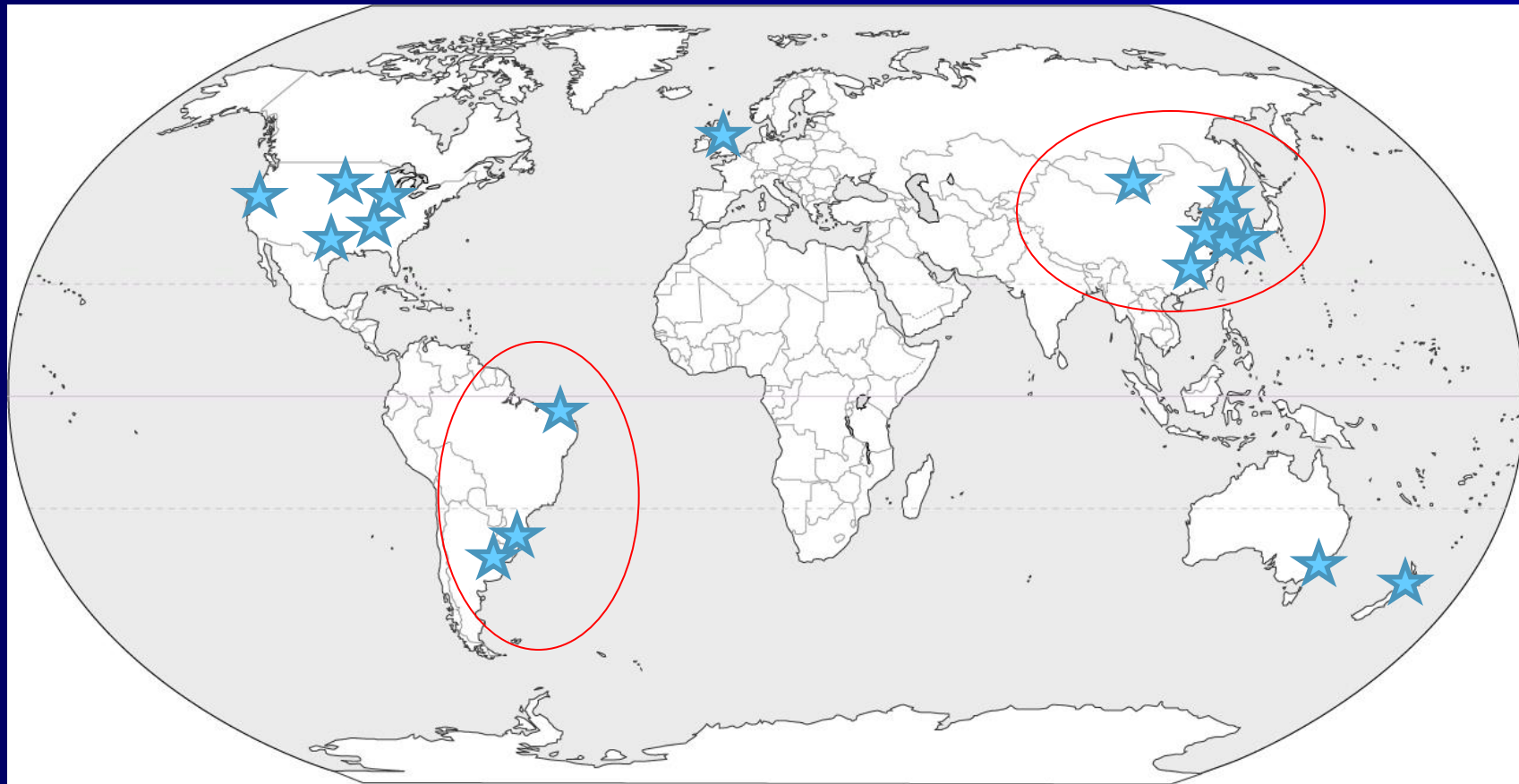


Graphic developed by Dr. J. Murray, UC Davis



# Sites working on GE livestock for food - 2012

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



Graphic developed by Dr. J. Murray, UC Davis



***“I now say that the world has the technology — either available or well advanced in the research pipeline — to feed on a sustainable basis a population of 10 billion people. The more pertinent question today is whether farmers and ranchers will be permitted to use this new technology? While the affluent nations can certainly afford to adopt ultra low-risk positions, and pay more for food produced by the so-called ‘organic’ methods, the one billion chronically undernourished people of the low income, food-deficit nations cannot.”***

**Norman Borlaug**





# A limerick inspired by TAC '13



**A genetic engineer once lived in a cottage  
Enduring an undoubted absence of frottage  
When magically appeared an animal  
With a glutus so inconceivably maximal  
That it inspired an odd sort of dotage**

