

# Update on Developments in Cloning and Genetically Engineered Animals

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Biotechnology Industry Organization

FASS Food Safety Symposium – Spring Meeting

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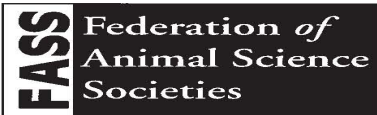
# What's Wrong With This Picture?



## Absolutely Nothing.

“The scientific evidence is absolutely, robustly clear. There is no food safety risk from the meat or milk of clones, or from their conventionally bred offspring.”

– **Terry Etherton, Ph.D.**  
Chair, Dairy and Animal Science, Penn State University. Member of the National Academy of Sciences panel that reviewed the safety of clones and their offspring in the food supply.



**The Food and Drug Administration said as much in its recent draft risk assessment. The National Academy of Sciences has twice agreed.**

**Now, America's leading animal scientists concur:**

**“Edible products from healthy cloned animals and the progeny of cloned animals pose no additional food consumption risks.”\***

**As the chief public voice for animal science in the United States, FASS represents more than 10,000 individual animal scientists. Our board of directors unanimously supports these findings.**

**In the words of NAS, “In summary, there is no current evidence that food products derived from somatic cell clones or their progeny present a food safety concern.”**

**We couldn't have said it better ourselves.**

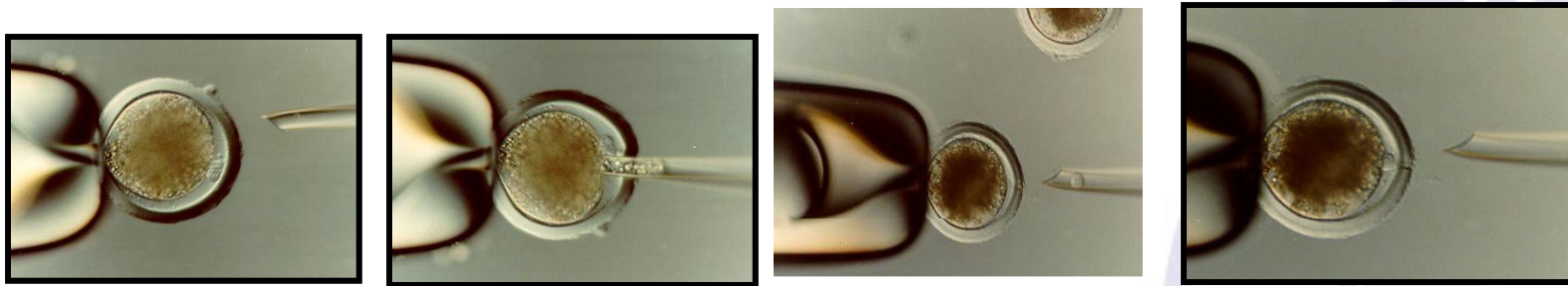
**\*Read the full scientists' letter and see an updated list of signatories at [www.fass.org/DefendScience](http://www.fass.org/DefendScience)**

**[www.fass.org/DefendScience](http://www.fass.org/DefendScience)**

- **Statement of Support for U.S. FDA Draft Risk Assessment on Livestock Cloning**
- We support and agree with the FDA's conclusion as stated in the science-based Draft Risk Assessment\* ....
- Signed,  
(326 signatures as of 9:14:33 AM CDT)

# What is Cloning?

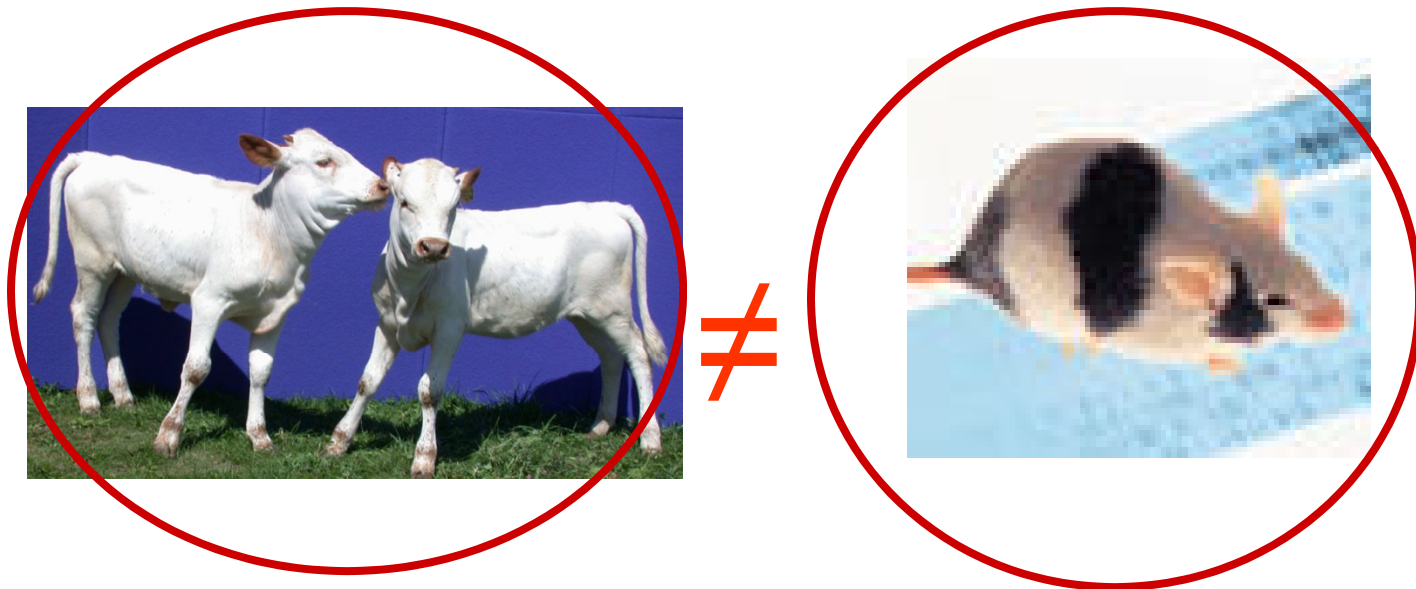
Cloning is simply an **assisted reproductive technology** which allows us to produce animals that are genetically identical to the single donor animal (identical twins separated in time). Offspring, which are not animal clones, will provide most of the food from the cloning process.



# What is Genetic Engineering?

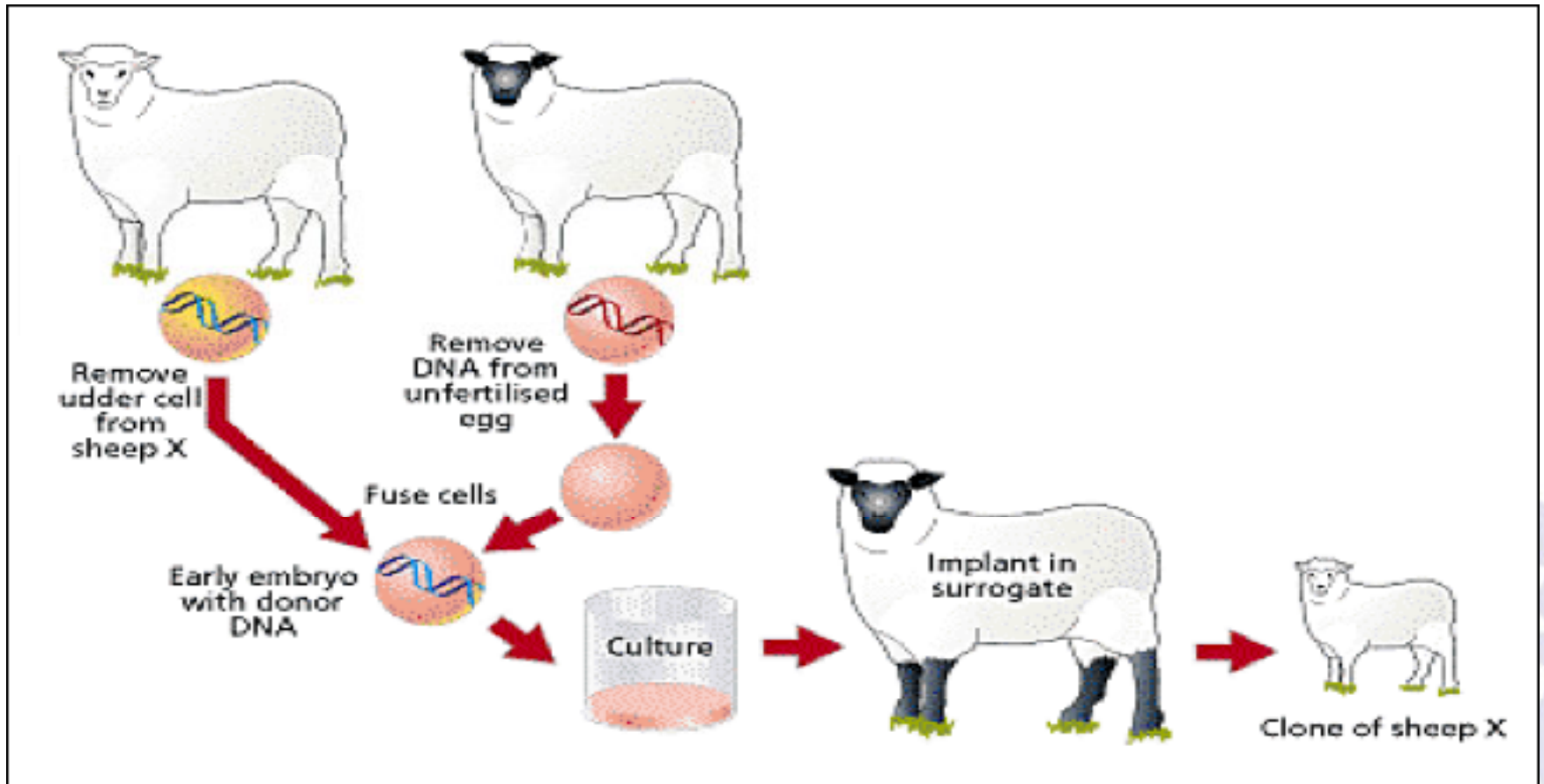
- Deliberate modification of the animal genome, in contrast to spontaneous mutation.
- Transgenesis, one method of GE, is moving one gene that expresses a desirable trait from the same species or another species into the genome of an agricultural animal, who will then express that desirable trait.

# Clones v Genetically Engineered Animals



**Clones and genetically engineered animals occupy different “risk spaces”.**

# The Cloning Process





# Animal Clones



**Elite, Genetically Identical  
Angus Clones**





# Benefits of Cloning

- Cloning helps to rapidly and reliably spread the best genetics throughout a herd
  - Healthy animals produce healthy foods
  - Meets consumer demand for high-quality, consistency, and safe food
  - Meets demand for semen, embryos and/or offspring of best animals
  - Improve U.S. food supply and food exports
- The National Academies of Science concluded that animal clones would have “increased genetic merit for increased food production, disease resistance, and reproductive efficiency.”

# Cloning Status

- FASS and BIO conducted a survey
- Living today in U. S. are 570 cattle clones, few pigs and goats
  - Show ring purposes
  - Breeding animals
- Industry is abiding by voluntary moratorium on sales of clones in to the food supply
- Not aware of any offspring of clones in the food supply



# Safety of Food from Animal Clones

**On Jan. 15, 2008, FDA published the final risk assessment that concluded:**

- **Foods from livestock produced *via* cloning, and from their offspring, are as safe to eat as foods from conventionally-produced livestock.**
- **No unique health risks for clones and their offspring compared to conventionally-produced livestock.**
- **No labeling required**

# Safety of Food from Animal Clones

**USDA supports the science and the safety of the foods from clones and offspring. The USDA also will:**

**Facilitate the marketing of meat and milk from clones and their offspring; emphasized that offspring are safe.**

**•Will work closely with stakeholders to ensure a smooth and seamless transition.**

**•Encouraged industry to maintain their voluntary moratorium on sending food from animal clones into the food supply during the transition time.**

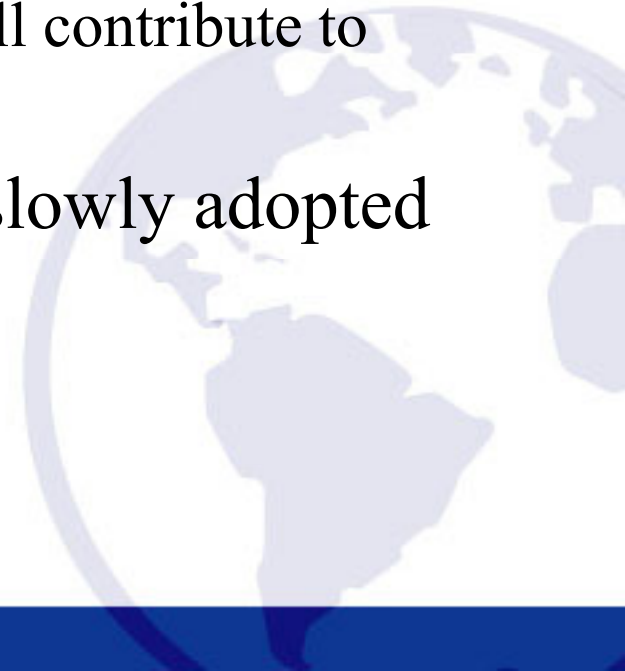
# Transition Period

- Smooth transition is the goal
- USDA is educating international markets
- USDA is initiating an economic analysis by Economic Research Service
- USDA has held discussions with stakeholders
- Industry is initiating the Supply Chain Management Program and working with USDA



# Transition Period

- Key---Marketing of offspring may proceed so clones will begin to used in breeding programs
  - Sexually produced offspring are not clones.
  - Consumers will likely never eat food from a cloned animal
  - It will 3-5 years before offspring will contribute to the food supply
- Cloning technology will now be slowly adopted





# Transition Period

- Supply Chain Management program is the core of the transition period
  - From clones produced today, it will 3-5 years before offspring will contribute to the food supply
  - SCM allows for ‘no-clone’ food supply lines
  - Provides choice in the world’s food supply
  - Supports smooth trade transactions
- Cloning coalition will continue to work on SCM and on public awareness



# Supply Chain Management Program

- Food industry initiated, over 20 groups
  - Allows tracking of cloned animals
  - Provides choice in the food supply
  - Beef, pork and dairy
- Not a safety or health issue
- Allows potential marketing/purchasing claims to be met
- ViaGen and Transova Genetics announced the program on December 19 and recently that AgInfoLink will manage the registry



# Supply Chain Management Program

- Education and identification program
- Cloned animals only
- Specifics
  - Client education
  - Animal identification and registry
  - Affidavits
  - Marketing incentive



# Supply Chain Management Program

- Participation of all technology providers is essential
- Inviting participation by other cloning companies and academia, researchers
- Have been in discussions with third major tech provider but no decision
- Education in collaboration with FASS
  - Scientist education
  - Via institutional animal care and use committees, possibly partnering with AAALAC



# Supply Chain Management Program

- Participation of all clone owners is important
- ViaGen and Transova are inviting participation by past clients
- Offering to register their clone
- Offering the incentive payment without the upfront cost
- Providing educational material



# Supply Chain Management Program

- BIO continues to lead the animal agriculture cloning coalition
- Assure SCM is working across the food chain
- Assure beef, dairy and pork industries are covered
- Address public awareness challenges particularly with the food industry





# Public Awareness

- Food industry initiated – the coalition
  - Food retailer survey was conducted
  - They appreciated a united effort by national organizations was taking the lead on providing materials
- Consumer tool kit was developed
- Kit has recently been refreshed and may be found at <http://bio.org/foodag/animals/>
- Links and materials at [www.clonesafety.org](http://www.clonesafety.org)



# USDA and the National Organic Program

- NOSB has recommended but BIO opposes exclusion of animal clones and offspring from the NOP because it is not legal according to the Organic Foods Production Act
- It will be impossible for organic livestock producers to comply with a standard to exclude offspring.
- Only possible to exclude clones if using the SCM Program.
- USDA considering an ANPR to open for public comment.

# Challenges

- Labeling is only possible through use of the SCM Program and for clones only
- Media has been balanced with respect to acceptance by consumers; mis-information on “cloned food”, labeling
- Food retailers are studying; a few have stated they will not use food from clones in their products
- Activists spread mis-information particularly about animal welfare and offspring

# Labeling 'Debate'

- Capitol Hill – Calls for hearings on the FDA risk assessment and on labeling
  - Degette – RA process
  - Mikulski and DeLauro- Labeling
- States – Seven labeling bills have been re-introduced- CA, IA, KY, MD, NJ, TN
- There are 13 bills pending in 10 states- additionally IL, MA, NY, WA.



# International

- Initial questions have now quieted
- Several countries have risk assessments with same conclusions of safety-
  - EU (EFSA), France, NZ, Japan
  - Japan is completing another risk assessment
  - CN and AR are initiating risk assessments; AU is evaluating
- Scientific groups providing guidelines-
  - International Embryo Transfer Society, World Animal Health Organization (OIE) and Federation of Animal Science Societies

# Cloning Final Remarks

- Cloning allows farmers and ranchers to produce healthier offspring for healthful meat and milk
- The science is clear, the technology is safe, SCM has started during transition
- Cloning is being adopted slowly and will be entering the marketplace in the next few years





# Benefits of Genetic Engineering

- Advancing human health
- Softer environmental footprint
- Enhancing food quality and safety and improving animal health
- Improving industrial products



# Genetic Engineering - Industry Status

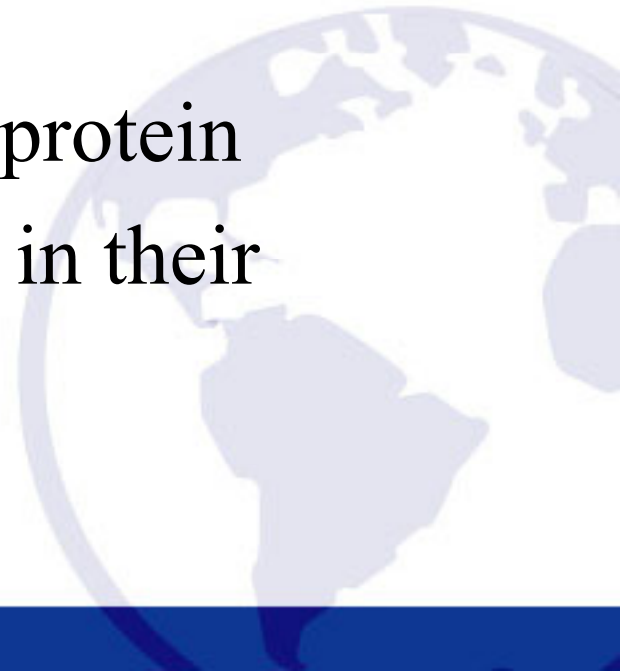
- One approved product in the world from a genetically engineered animal.
- One product, the GloFish, is allowed to be commercially marketed in the United States
- There are over 100 approved biotechnology-derived vaccines, biologics and diagnostics for animal health



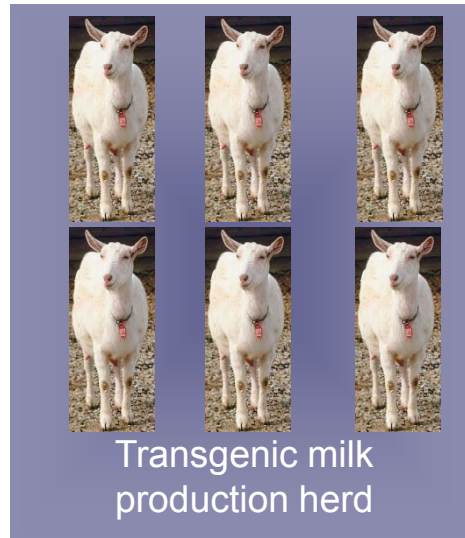
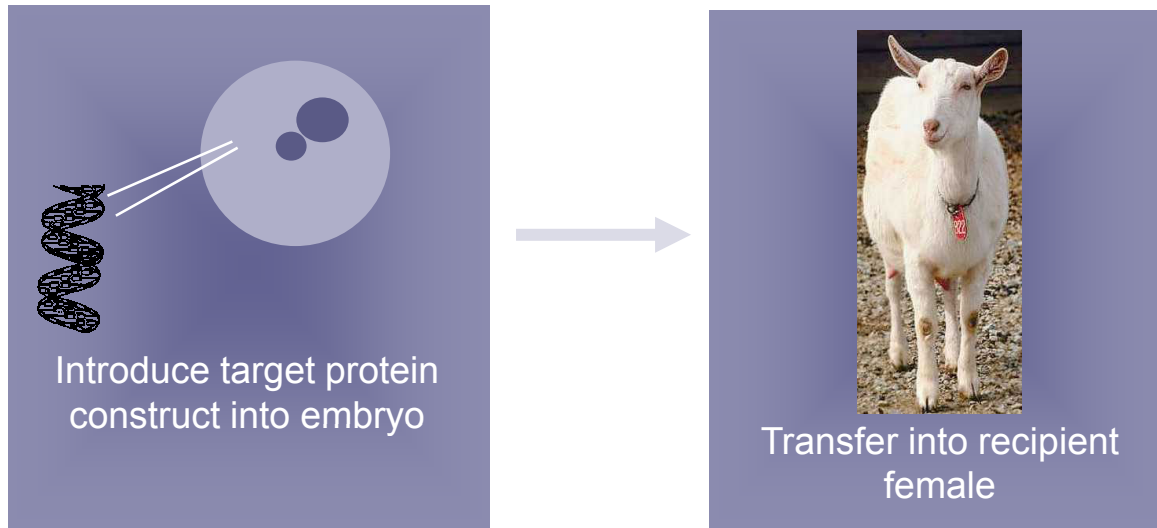
# European Commission Approves First Protein Produced by a Genetically Engineered Animal

## August 2, 2006

- A milestone
- Medical application
- ATryn, a human anti-clotting protein
- Produced by transgenic goats in their milk



# Platform Technology





# Regulatory Framework

- In the U.S., GE animals and their products will undergo a rigorous federal regulatory process, coordinated among agencies and include
  - Human safety
  - Target animal safety and health of the animal
  - Environmental safety
  - Safety of protein product

# BIO Policy on Regulatory Process for Genetically Engineered Food Animals

- BIO supports a coordinated U. S. government regulatory framework that is science-based.
- FDA and USDA are primary departments.



# BIO Policy on Regulatory Process for Genetically Engineered Food Animals

- BIO supports the application by the FDA of the New Animal Drug provision, defined in the Federal Food, Drug and Cosmetic Act, to genetically engineered food animals
- BIO supports development of science-based and appropriate, non-duplicative regulatory oversight by the USDA





# BIO Policy on Regulatory Process for Genetically Engineered Food Animals

- Publication of a process is essential; enhances investor confidence
- Facilitates approvals and commercialization
- Improves public transparency
- Enhances consumer acceptance and credibility



# International Activity Impacting Animal Biotechnology

- International R&D is active. Work to define risk assessment guidelines and a regulatory framework has begun
- Codex Alimentarius Commission– food safety
- FAO/WHO – food safety
- Organization for Economic Cooperation and Development – food safety, other
- World Animal Health Organization (OIE) –animal health
- Cartagena Protocol on Biosafety – environmental impact



# GE Animal Regulatory Status

- Two primary departments that have statutory authority are FDA and USDA
- BIO supports
  - DHHS, FDA draft guidance is in interagency clearance at OMB
  - USDA considering an Advance Notice of Proposed Rulemaking
- Discussions include need for coordination of regulatory review



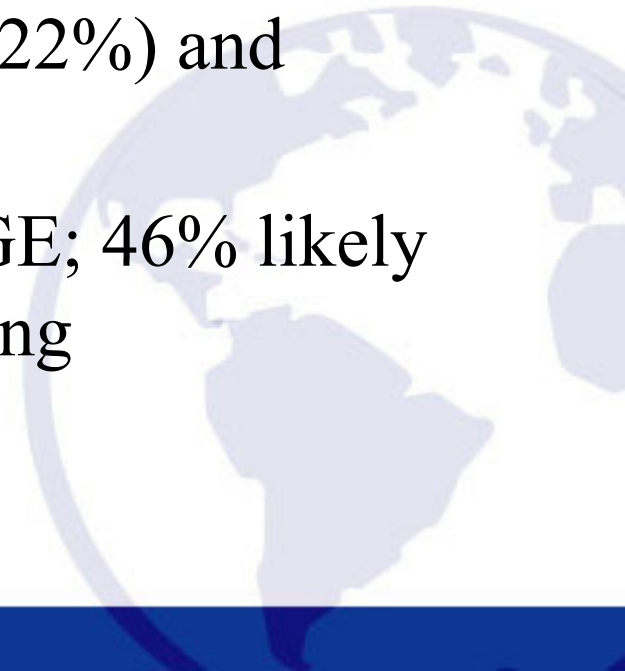
# GE Animal Challenges

- Education and stewardship are key strategic thrusts
- BIO has commissioned a white paper on benefits of genetic engineering of agricultural animals
- Will continue interaction with stakeholders and media
- Will provide fact based information, transparently
- Domestic and international



# Public Acceptance – 2007 IFIC Poll

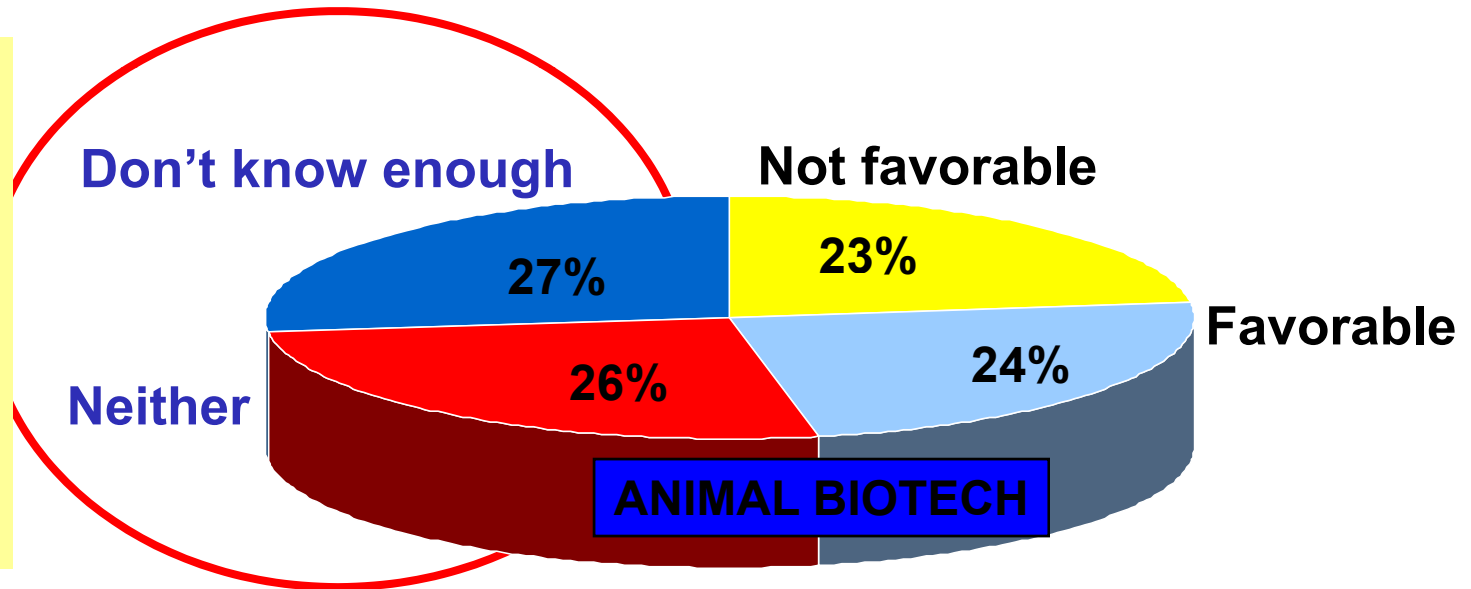
- Increased favorability of animal biotechnology (24% vs 19%)
- Plant biotechnology favorability was higher (33% vs 32%)
- Impressions of favorability - No change for GE (35%); improvement for cloning (22%) and offspring (25%)
- Purchase intent – 61% likely for GE; 46% likely for cloning; 49% likely for offspring



# Attitudes are “soft” (unformed)

What is your overall impression of **using animal biotechnology with animals that produce food products, such as meat, milk, and eggs?**  
Would you say...

53% say they have neither a favorable or unfavorable opinion, don't know enough



# GE Animals Final Remarks

- Consumer acceptance will be a challenge
- Genetic engineering holds compelling promise
- We support a coordinated regulatory process that leads to approval of products across the spectrum of animal biotechnology
- We look forward to working with FASS toward improving future foods



# Information Sources

- **BIO**
  - <http://bio.org/foodag/animals/>
- **Clone Safety**
  - [www.clonesafety.org](http://www.clonesafety.org)
- **FDA**
  - <http://www.fda.gov/cvm/CloneRiskAssessment.htm>
- **International Food Information Council (IFIC)**
  - <http://www.ific.org/research/biotechres.cfm>
- **University of Maryland Center for Food, Nutrition and Agricultural Policy (CFNAP)**
  - [http://cfnap.umd.edu/Topline\\_of\\_Animal\\_Cloning\\_121406.pdf](http://cfnap.umd.edu/Topline_of_Animal_Cloning_121406.pdf)



*Bio*<sup>®</sup>

**BIOTECHNOLOGY**  

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**INDUSTRY ORGANIZATION**

# February 1997 - Hello Dolly!

