The regulation and politics of food from genetically engineered animals

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http://animalscience.ucdavis.edu/animalbiotech/
Although the public often say they disapprove of genetically-modified animals – many people live with one!
It is not the “natural” genetic modification of food animals that is of concern.....
It is the genetic engineering of food animals that is of concern – although in reality most are phenotypically rather unremarkable…….
Even though public perception may be something more like this!!
Outline

• The “livestock revolution”
• Extant genetically-engineered (GE) animals for agriculture
• US Regulatory approach
• Case study: AquAdvantage salmon
• Politics
Proportional increase in world head of livestock 1961-2004; data from FAO (2005)

- cattle and buffaloes (1961 = 1.03 billion)
- chickens (1961 = 3.89 billion)
- pigs (1961 = 0.46 billion)
- sheep and goats (1961 = 1.34 billion)

# Extant GE livestock applications

<table>
<thead>
<tr>
<th>ENVIRONMENTAL</th>
<th>Species</th>
<th>Gene</th>
<th>Approach</th>
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<tbody>
<tr>
<td>Decreased P in manure</td>
<td>Swine</td>
<td>Phytase</td>
<td>Transgene overexpression</td>
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## DISEASE RESISTANCE

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<td>Mastitis resistance</td>
<td>Cattle, Goat</td>
<td>Lysostaphin; Lysozyme</td>
<td>Transgene expression</td>
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<td>BSE resistance</td>
<td>Goat, Cattle</td>
<td>Prion</td>
<td>RNAi transgene; knockout</td>
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<td>Visna virus resistance</td>
<td>Sheep</td>
<td>Visna virus envelope gene</td>
<td>Transgene expression</td>
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<tr>
<td>Mastitis resistance</td>
<td>Goats</td>
<td>Lysozyme</td>
<td>Transgene expression</td>
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<td>Avian influenza</td>
<td>Chicken</td>
<td>Influenza decoy</td>
<td>Transgene expression</td>
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<tr>
<td>Bacterial resistance</td>
<td>Channel Catfish</td>
<td>Cecropin B gene</td>
<td>Transgene expression</td>
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## PRODUCT QUALITY

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<td>Increased ω-3 fatty acids in meat</td>
<td>Swine</td>
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<td>Clone/Transgene expression</td>
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<tr>
<td>Increase cheese yield from milk</td>
<td>Cattle</td>
<td>β-casein, κ-casein</td>
<td>Clone/Transgene expression</td>
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<th>Approach</th>
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<tr>
<td>Enhanced growth rate</td>
<td>Many fish species</td>
<td>Growth Hormone</td>
<td>Transgene expression</td>
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<tr>
<td>Enhanced milk production</td>
<td>Swine</td>
<td>α-lactalbumin</td>
<td>Transgene expression</td>
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<tr>
<td>Enhanced growth rate</td>
<td>Swine</td>
<td>Growth hormone</td>
<td>Transgene expression</td>
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<tr>
<td>Enhanced growth rate</td>
<td>Swine</td>
<td>Insulin-like-growth factor</td>
<td>Transgene expression</td>
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**Enviropig™** (Low-phosphorus manure)

Nature Biotechnology 19, 741–745. 2001

Pigs expressing salivary phytase produce low-phosphorus manure

Serguei P. Golovan1,2, Roy G. Meidinger2, Ayodele Ajakaiye3, Michael Cottrill1, Miles Z. Wiederkehr4, David J. Barney4, Claire Plante5, John W. Pollard5, Ming Z. Fan3, M. Anthony Hayes6, Jesper Laursen7,8, J. Peter Hjorth7, Roger R. Hacker3, John P. Phillips2,*, and Cecil W. Forsberg1,*

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)


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.
Suppression of Avian Influenza Transmission in Genetically Modified Chickens

Jon Lyall, Richard M. Irvine, Adrian Sherman, Trevelyan J. McKinley, Alejandro Núñez, Auriol Purdie, Linzy Outtrim, Ian H. Brown, Genevieve Rolleston-Smith, Helen Sang, Laurence Tiley

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 may occur directly or be facilitated by intermediate 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 possible (2). The diversity of viral antigenic subtypes...
Fast growing salmon

The founder female was generated in 1989 – 21 years ago


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
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).

Guidance for Industry

Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs

Final Guidance

“New Animal Drug” approach

- The recombinant DNA (rDNA) construct is a new animal drug because it is “an article intended to alter the structure or function” of the animal.
- New animal drugs may be approved if they are shown to be safe and effective for the intended use.
- In a hierarchical risk-based multistep scientific review the agency examines the safety of the rDNA construct to the animal, the safety of food from the animal, and any environmental impacts posed, as well as the extent to which the performance claims made for the animal are met.
FDA NEWS RELEASE

FOR IMMEDIATE RELEASE
January 15, 2009

FDA Issues Final Guidance on Regulating Genetically Engineered Animals

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 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
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<td>September 2010</td>
<td>Public Veterinary Medicine Advisory Committee meeting to consider data on safety and efficacy of AquAdvantage salmon Held in Washington DC</td>
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What is the AquAdvantage salmon?
Tg(opAFP-GHc2)/EO-1αAb
Fish reach adult size in 16 to 18 months instead of 30 months.
Same-age siblings – one carrying a hemizygous copy of the transgene
Retrieved from “AquAdvantage” image search on web

Frankenfish
Product Definition for the AquAdvantage Salmon

Product Identity
Triploid hemizygous, all-female Atlantic salmon (*Salmo salar*) bearing a single copy of the $\alpha$-form of the opAFP-GHc2 rDNA construct at the $\alpha$-locus in the EO-1$\alpha$ lineage.

Claim
Significantly more of these Atlantic salmon grow to at least 100 g within 2700 deg C days than their comparators.

Limitations for Use
These Atlantic salmon are produced as eyed-eggs for grow-out only in the FDA-approved physically-contained fresh water culture facility.
Food/Feed Safety: Does food or feed from the GE animal pose any risk to humans or animals consuming edible products from GE animals compared with the appropriate non-transgenic comparators?

Conclusion of food/feed safety 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*”.

Environmental Safety: What is the likelihood that AquAdvantage Salmon will escape the conditions of confinement?

Where will the AquAdvantage Salmon be raised?

If approved, the AquAdvantage Salmon will be raised in inland tanks. They will not be raised in ocean net pens. Any change would require a new application and approval.

There are multiple and redundant physical and mechanical barriers in place in the water systems at the PEI egg production and Panama grow-out facilities to prevent the accidental release of eggs and/or fish to nearby aquatic environments. These barriers have been designed specifically to prevent the escape of different life stages of AquAdvantage Salmon. Both facilities have 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.
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 ocean ranched salmon represented over 41% of the “wild-caught” commercial catch in Alaska

http://www.sf.adfg.state.ak.us/FedAidPDFs/fmr09-08.pdf

- **Grow fish in inland tanks**
Summary of advantages of land-based (inland tank) aquacultural systems

- Shorter production time – 16-18 months versus 30 months
- Shorter time to harvest diminishes the risk of disease and resultant use of chemotherapeutics/antibiotics
- Culture in a land based, contained (e.g. recirculating) system reduces spread of disease in the environment (and wild salmon populations)
- Lower Food Conversion Ratio (i.e. LESS lbs feed eaten per lb product produced) - feed is major cost of animal production!
- Does not spawn during growout (more energy available for growth AKA less energy wasted on reproduction!).
- Land based salmon culture systems can be located adjacent to major markets, reducing freight costs and the associated environmental impact i.e. locally-grown “locivovre” source of fish
The public 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.

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.
Examples of claims made during the public meeting – not actually supported by what was in the data package that was made public by company to increase transparency

- **More Allergenic**: GMO salmon have mean allergenic potencies that are 20% and 52% higher than normal salmon.
- **More Carcinogenic**: GMO salmon has 40% more IGF1, a hormone linked to prostate, breast and colon cancers in humans.
- **Less Nutritious**: GMO salmon has the lowest omega-3 to omega-6 ratio of any salmon.
- **Likely To Change The Bacteria Of Your Gut**: Horizontal gene transfer, where the bacteria of the human gut takes up modified DNA from GMO foods during digestion, has been shown occur with soy and is likely to happen with GMO salmon, too.
- **All Messed Up**: GMO salmon has increased frequency of skeletal malformations like “humpback” spinal compression, increased prevalence of jaw erosions or “screamer disease,” and multisystemic, focal inflammation in its tissues.

[http://organicconsumers.org/fish](http://organicconsumers.org/fish)
“There is little benefit to society if attempts to increase public participation in the regulatory process are used as an opportunity to vilify technology.”

Transgenic salmon: a final leap to the grocery shelf?

Alison I. 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...
Frankenfood, Coming Soon to a Store Near You?

Published September 20, 2010 | FoxNews.com

A genetically engineered AquaAdvantage Salmon (background) is compared to an Atlantic salmon of the same age (foreground). The U.S. Food and Drug Administration will hold a two-day meeting starting September 19 to discuss whether to approve the altered fish for U.S. consumers to eat.

WASHINGTON – Watch for a new section between “frozen foods” and “organic” in your supermarket: genetically engineered. That is, if the government approves the so-called ”frankenfoods“ for sale.

The Food and Drug Administration Monday began a two-day look at the issue Monday, focusing on genetically modified salmon, which would be the first such food approved for human consumption.

The agency has already said the salmon, which grow twice as fast as conventional ones, are safe to eat. But salmon act as a genetic gatekeeper in this case. Approve them and open the door for a variety of other genetically engineered animals, including an environmentally friendly pig that is being developed in Canada or cattle that are resistant to mad cow disease.

“For future applications out there the sky’s the limit,” said David Edwards of the Biotechnology Industry Association. “If you can imagine it, scientists can try to do it.”

Industry Fights Altered Salmon

By ALICIA MUNDY And BILL TOMSON

The fishing industry and politicians from commercial-fishing states are mobilizing against a possible Food and Drug Administration approval of genetically modified salmon for the American dinner table.

“Putting unlabeled, genetically altered salmon in the marketplace is simply irresponsible, and the FDA needs to strongly consider what impacts this will have before they approve this Frankenfish,” Sen. Lisa Murkowski, a Republican from Alaska, said Thursday.

The resistance could raise difficulties for the FDA, whose scientists have said the AquaAdvantage Atlantic salmon developed by AquaBounty Technologies Inc. is safe for human consumption. AquaAdvantage contains a growth-hormone gene from another salmon that helps it grow twice as fast as conventional farmed fish.

A coalition that includes Pacific Coast trollers, Atlantic fishing companies and organic-yogurt maker Stonyfield Farm says the genetically altered salmon might threaten their livelihoods by spreading unease about salmon and other foods.

“This stuff is not healthy for people, and it’s not like our fresh fish,” said Angela Sanfilippo, president of the Gloucester Fishermen’s Wives Association of Massachusetts.

Icy Bay crewmen remove sockeye salmon from their net in July. Commercial fisheries are fighting the introduction of genetically altered salmon.

They cited concerns about “human health and environmental risks” from the AquaAdvantage salmon.
Less than 2 weeks after the 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"

Will farmed GE Atlantic salmon devastate depleted wild salmon populations?

- 99% of the Atlantic salmon consumed in the US is farmed—from ocean net pen aquaculture operations in Canada, Chile, Norway and Scotland.
- 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.

Overview of U.S. Salmon Consumption. Chapter 8. The Great Salmon Run
By Gunnar Knapp and Cathy Roheim and James Anderson of the Department of Environmental and Natural Resources at the University of Rhode Island.
http://www.iser.uaa.alaska.edu/Publications/greatsalmonrun/SalmonReport_Ch_8.pdf
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Young argued that the modified fish are unnatural and their production could create competition for his state's fishing industry. In a statement, Young said he had deep concern about the salmon, which he dubbed "Frankenfish."

"Frankenfish is uncertain and unnecessary," Young said. "Should it receive approval as an animal drug, it clears the path to introduce it into the food supply. My amendment cuts them off before they can get that far. Any approval of genetically modified salmon could seriously threaten wild salmon populations as they grow twice as fast and require much more food."
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<td>July 2011</td>
<td>Eight senators urge FDA Commissioner Margaret A. Hamburg, MD, to stop her agency from further considering approving the GE salmon. The letter expresses concerns about potential threats to public and environmental health and economic harm for wild salmon producers. The letter also indicates that the Senate could concur with a measure passed by the House of Representatives</td>
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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).
"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"
Chinese work on transgenic animals

Production of recombinant human lysozyme in the milk of pig to improve the diarrhea-resistant ability of piglets

In the swine industry, pathogenic infections have a significant negative impact on neonatal survival. The team, led by Prof. Ning Li in China Agricultural University, has worked on improving the ability of piglets to resist diarrhea disease since 2008 and successfully produced many transgenic pigs with expressing recombinant human lysozyme in the milk. To date, the total number of transgenic pigs with recombinant human lysozyme is up to 272. The experiment has entered the productive experiment stage.

Transgenic pigs specifically express phytase in the parotid gland

Total got 21 transgenic founders of reduced phosphorus content in the feed.

Phosphorus in transgenic pig faces, 21.4%.

Pig cages used for testing phosphorus metabolism.

Phytase transgenic cloned pigs.

shRNA Transgenic Pig Display Significant Resistance to the Infection of FMDV

In the shRNA expressive vector pMD19-EN3D2B against both nonstructural protein 2B and polymerase 3D of FMDV, the shRNA was transferred, and 23 transgenic cloned pigs generated in 2010 by Prof. Li Ning in China Agriculture University. In the 10 ID50 and 100 ID50 challenge, transgenic cloned pigs all performed the ability of anti-FMDV, and one transgenic cloned pig was protected during all the challenge period.

sfat-1 Transgenic Cattle increased the Omega-3 fatty acids in dairy and beef

Prof. Guangpeng Li group from Inner Mongolia University generated sfat-1 transgenic dairy cattle and beef cattle in 2009 and 2010. These cattle were supposed to increase the omega-3 fatty acids of beef or milk.