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AquAdvantage Salmon

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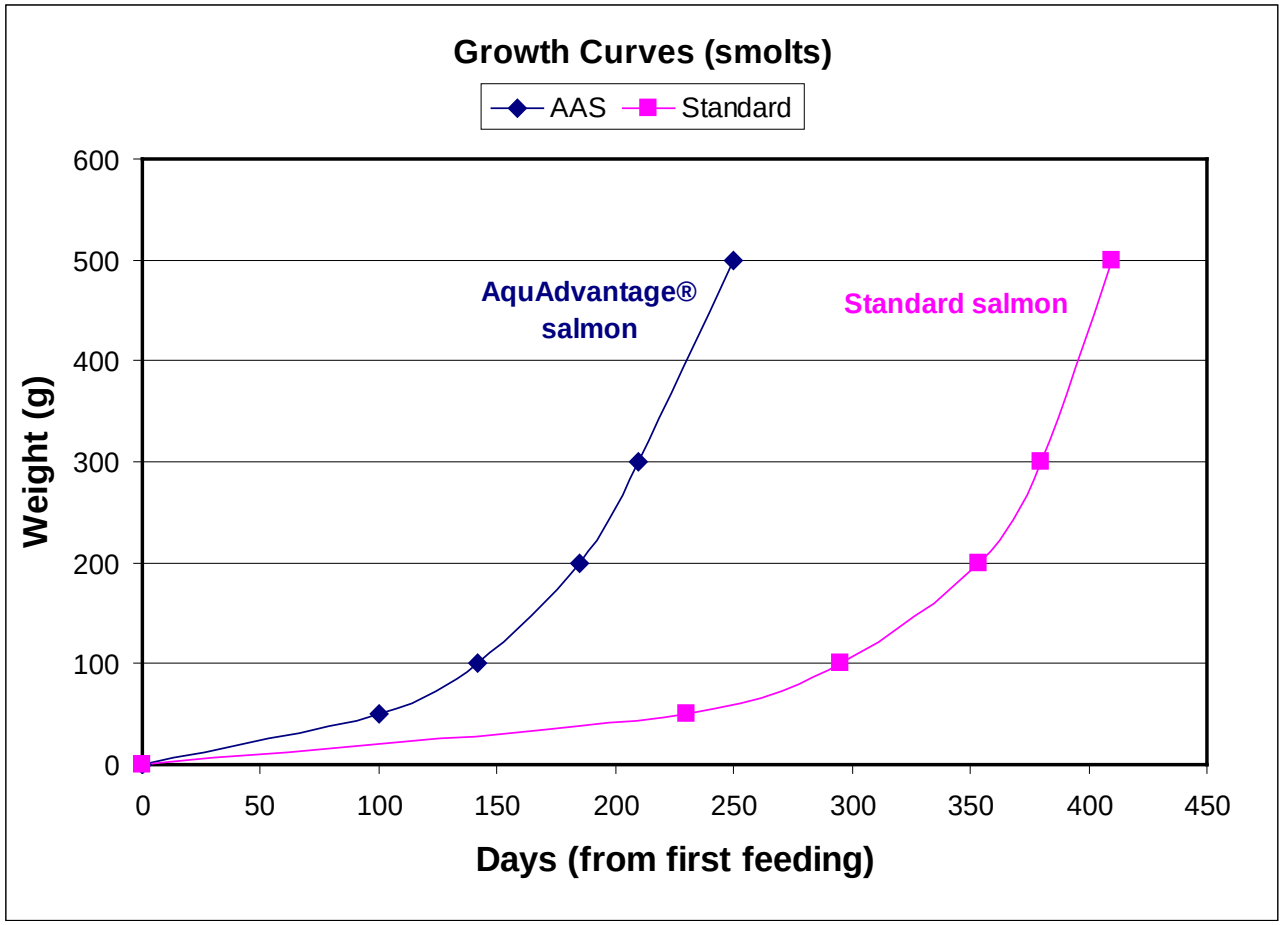
Gains in Growth – Smolts (AAS vs. Nontransgenics)



- Pooled growth data collected at ABT-PEI for year classes 2004-2006.
- Full sibs
- Triploid transgenics, diploid controls

- NOTE: these growth studies were carried out at an average annual temp. of 9-10° C.

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AquAdvantage Salmon Product Definition

Product Identity:

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

Claim:

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

Conditions of Use:

These Atlantic salmon are produced as eyed-eggs for grow-out in FDA-approved, physically-contained fresh water culture facilities.

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AAS Regulatory Experience

Country	Regulatory Authority(ies)/ Statute
United States	FDA (CVM) ; FFD&CA / ESA, NEPA
Canada	Health Canada, Environment Canada, CFIA, and others / Novel Foods, New Substance Notification, CEPA
Panama	CNB, ANAM. ARAP, MIDA / variety of laws, Cartagena Protocol

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United States

The **Coordinated Framework for Regulation of Biotechnology**, proposed in 1984 by the White House Office of Science and Technology Policy and finalized in 1986, spells out the basic federal policy for regulating the development and introduction of products derived from biotechnology.

A key principle of the framework is that genetically engineered organisms would continue to be regulated according to their characteristics and unique features, and not according to their method of production. In other words, for example**, if a food product produced through biotechnology is substantially the same as one produced by more conventional means, that food is subject to no additional (or no different) regulatory processes.** The framework also maintains that new biotechnology products are regulated under existing federal statutory authorities and regulation.

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CVM / FDA

WILL TRANSGENIC FISH BE THE FIRST AG-BIOTECH FOOD-PRODUCING ANIMALS?

by John Matheson

FDA Veterinarian Newsletter May/June 1999 Volume XIV, No III

Genetically Engineered Animals

Introduction

Genetic engineering is a targeted and powerful method of introducing desirable traits into animals using recombinant DNA (rDNA) technology. DNA is the chemical inside the nucleus of a cell that carries the genetic instructions for making living organisms.

In January, 2009, the Food and Drug Administration issued a final guidance for industry on the regulation of genetically engineered (GE) animals. The guidance explains the process by which FDA is regulating GE animals and provides a set of recommendations to producers of GE animals to help them meet their obligations and responsibilities under the law. While the guidance is intended for industry, FDA believes it may also help the public gain a better understanding of this important and developing area.

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CONTAINS NON-BINDING RECOMMENDATIONS

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Guidance for Industry

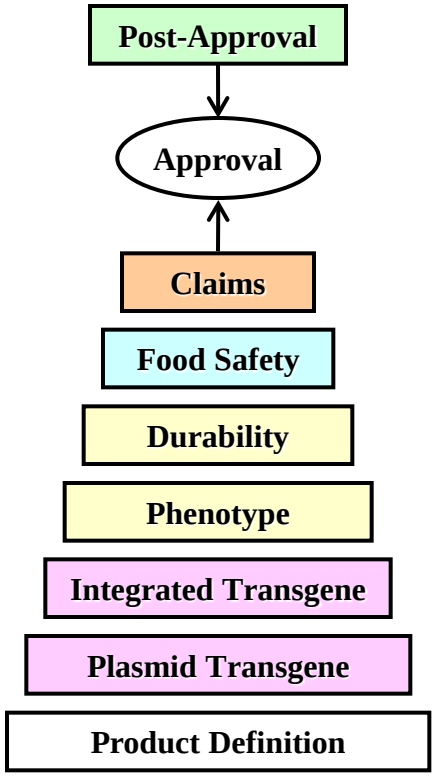
Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs

Final Guidance

For questions regarding this guidance document, contact Larisa Rudenko, Animal Biotechnology Staff, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, (240) 276-8247.

Additional copies of this guidance document may be requested from the Communications Staff, HFV-12, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at http://www.fda.gov/cvm.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine (CVM)
January 15, 2009



Regulate GE Animals using a Drug paradigm

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United States

The **National Environmental Policy Act** (**NEPA**) is a United States environmental law that established a U.S. national policy promoting the enhancement of the environment and also established the President's Council on Environmental Quality (CEQ).
NEPA's most significant effect was to set up procedural requirements for all federal government agencies to prepare Environmental Assessments (EAs) and Environmental Impact Statements (EISs). EAs and EISs contain statements of the environmental effects of proposed federal agency actions.[1] NEPA's procedural requirements apply to all federal agencies in the executive branch. NEPA does not apply to the President, to Congress, or to the federal courts.[2]

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United States

The **Endangered Species Act of 1973** (7 U.S.C. § 136, 16 U.S.C. § 1531 et seq. , **ESA**) is one of the dozens of United States environmental laws passed in the 1970s. Signed into law by President Richard Nixon on December 28, 1973, it was designed to protect critically imperiled species from extinction as a "consequence of economic growth and development untempered by adequate concern and conservation."

The Act is administered by two federal agencies, the United States Fish and Wildlife Service (FWS) and the National Oceanic and Atmospheric Administration (NOAA).

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CVM Review Process

- Technology Description, Product Definition Meetings : 1995-2009
- Negotiation of requirements within overall regulatory paradigm
- Protocol Development and negotiation
- Conduct and reporting of studies
- Effective Compliance platform, site inspections
- Submission of reports
- Follow up on reviews
- Interactive process, cyclical by review level
- "Sign-off" by technical section, "Phased Review"

- Public hearings : September 19-21, 2010
- EA released for comment : December 29, 2012
- Public Comment period EA closed : April 26, 2013

Elective

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"Elective" US Regulatory Steps

Veterinary Medical Advisory Committee : 9/20/10

- Standing Committee supplemented by additional experts
- Committee supplied summaries of CVM reviews in advance
- Committee supplied opposition comments in advance
- Presentations by invited experts and sponsor
- CVM presentations / Question format by technical section
- Discussion by VMAC
- Comments from Public
- Chairman's Report Released : 10/14/10

Environmental Assessment

released : 12/29/12

Public comment period closed : April 26, 2013

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CFSAN Part 15 Hearing

Public discussion of label requirement possibilities

- September 21, 2010, one day after VMAC
- Presentation by Sponsor
- Comments from Public
- Questions from CFSAN participants

- No action unless/until approval

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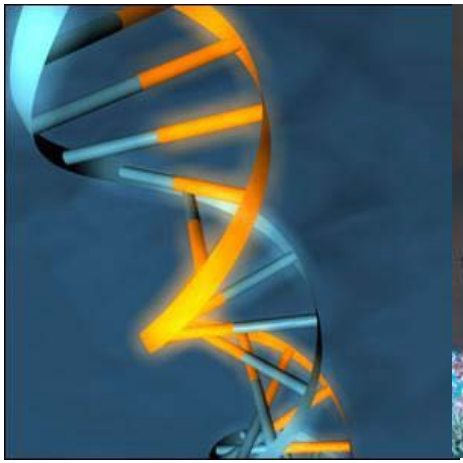

The Science and Regulation of Food from Genetically Engineered Animals

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Conclusion from CAST Report, June 20, 2011

Despite the FDA's attempts to increase transparency and public participation in the regulatory process**, opposition to the GE salmon from environmental and consumer groups, food safety advocates, and commercial and recreational fisheries associations remains. The current regulatory approach, coupled with the prolonged and unpredictable time frame, has resulted in an inhibitory effect on commercial investment in the development of GE animals for agricultural applications with ramifications for U.S. agriculture and food security.**

Note added August 2014: This circumstance does not appear to have changed.

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Van Eenennaam, Muir, and Hallerman, FDLI Policy Forum July 24, 2013

We recommend that the FDA and other federal agencies:

•Maintain and strengthen a science-based regulatory review system for the evaluation of GE animals and continue formal consultation with all agencies with relevant expertise.

•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.

•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.

•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.

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US History

- CVM science based review process works
- VMAC process was a disaster and has been discontinued
- Transparency exercise a fiasco and showcase for hypocrisy
- Activist groups well organized, funded, and connected
- Activist groups not held to any standards of integrity or honesty
- Anti-technology groups manipulate legal/political system to block new technology and have hijacked the risk assessment process
- Public apathy and lack of understanding
- Limited engagement of broader scientific community
- Cynical political interference in regulatory process

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Status Report

Regulatory Paradigm for Genetically Engineered Animals

What have we learned ?

- CVM science based review process unproductive
  - Political interference in regulatory process
  - Economic and ideological opponents
- Canadian review process appears to have integrity
- Panamanian process appears to be developing
- Brazil appears to offer hope
- Anti-Technology lobby well funded and connected
  - Not troubled by facts when opposing an application
  - Participation in risk assessment process, e.g. BCH

It's not just about the science

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"This is the lesson: never give in, never give in, never, never, never, never—in nothing, great or small, large or petty—never give in except to convictions of honour and good sense.

Sir Winston Churchill —*HarrowSchool, 29 October 1941*