AQUABOUNTY

AquAdvantage Salmon

A Regulatory Odyssey

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ACCELERATED GROWTH ALLOWS AQUADVANTAGE© SALMON TO REACH HARVEST WEIGHT SOONER.

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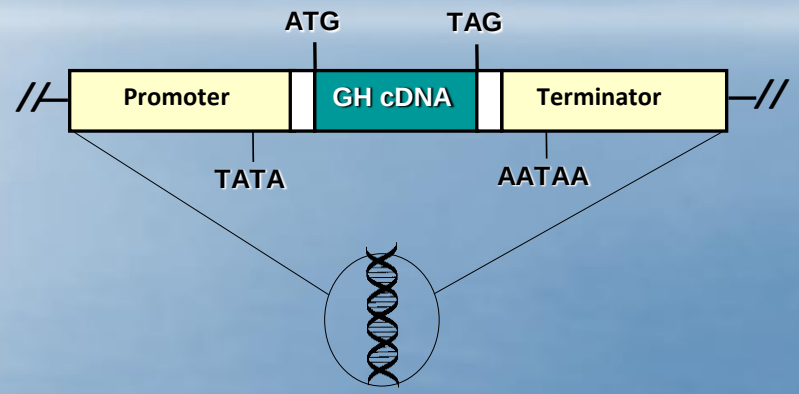
Genetics of AquAdvantage

Regulatory sequences from ocean pout AFP gene and coding domain from chinook salmon GH-1 cDNA



Transgene DNA Microinjection

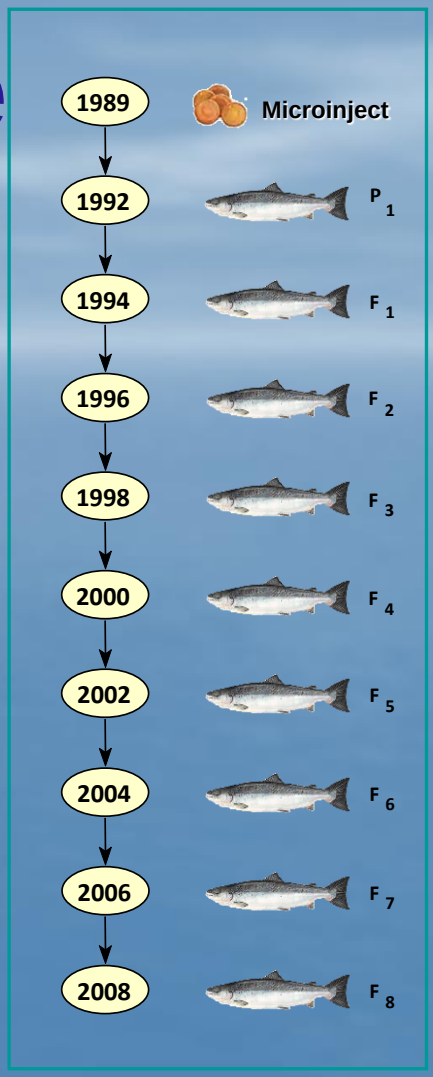
Milt

Fertilized Microinjected Eggs

Selection

Transgenic Founder

Non-transgenic Progeny



2016 F12

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Product Features + Benefits

FASTER GROWTH

- Reaches harvest weight in 16-18 months

BETTER FEED CONVERSION

- Operates with plant-based, sustainable feed
- Utilizes 25% less feed than non-transgenic siblings

SHORTER TRANSPORTATION DISTANCE

- Reduces cost and carbon footprint

LAND-BASED PRODUCTION

- Eliminates need for antibiotics or vaccines
- Poses no environmental risk to seas or wild fish

MADE IN THE U.S.A.

- Produced domestically by an American workforce

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AquAdvantage Chronology

- Founder fish established 1989
- INAD established 1995
- Guidance 187 issued February 2009
- All technical section complete letters received by firm 2010*
- VMAC September 2010
- EA released for public comment December 2012
- EA comment period closed April 2013
- NADA Approval November 19, 2015
- FDA Import Alert January 29, 2016
- Health Canada Approval March 2016

*except for “All Other Information” section

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CONTAINS NON-BINDING RECOMMENDATIONS

187

Guidance for Industry

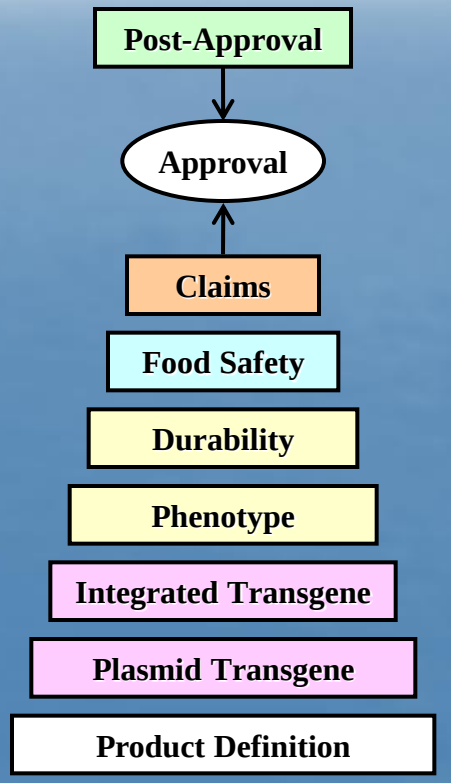
Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs

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



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WHATEVER HAPPENED TO THE "FRANKENFISH"?: THE FDA'S FOOT-DRAGGING ON TRANSGENIC SALMON

*Lars Noah**

Maine Law Review, Vol. 65, May 2013

Professor of Law, University of Florida; author of LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS (3d ed. 2012). As a longstanding vegetarian, my interest in this subject is solely theoretical.

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Food and Drug Law Institute Policy Forum 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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AquaBounty's Experience

What happened?

Science was the easiest part of the process
Regulatory paradigm was slow to develop
Regulatory Process was corrupted by political interference:

- ad hoc regulatory requirements
- Coordinated Framework "disconnect"
- Agency paralysis

What were the consequences?

AquaBounty forced into financial stress
Shareholders disenchanted
Innovation and investment suffocated
Industry innovation prevented / delayed
Economic benefits delayed or lost
American technology leadership threatened
Subjective regulatory policies –Activist agenda

For product applications dealing with new technology not raising clear moral, ethical or legal issues for our broader community, it is reasonable to empower appropriately trained and objective regulators to make decisions on safety and effectiveness of new product applications and appropriate that they be held accountable for their decisions. It is not reasonable to expose the process and the regulators to special interests *pro* or *con* with intent to impose their parochial economic or social views on the process. Science based regulation should be more than a campaign slogan.