



**AquAdvantage Salmon and
Other Current Issues in GMO Regulation
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- I am the Ocean and Coastal Law Fellow with the National Sea Grant Law Center and the University of Mississippi School of Law.
- As the NSGLC fellow, I research, publish, and present on legal and policy issues related to aquaculture, agriculture and food, and ocean and coastal matters.
- The National Sea Grant Law Center’s mission is to encourage a well-informed constituency by providing legal information and analysis to the Sea Grant Community, policy-makers, and the general public through a variety of products and services
- The NSGLC was established in 2002 to “coordinate and enhance Sea Grant’s activities in legal scholarship and outreach related to coastal and ocean law issues.”



Agricultural and Food Law Consortium

- National Agricultural Law Center at University of Arkansas provides non-advocacy agricultural law research and information services to the agricultural community.
<http://nationalaglawcenter.org/>
- Launched in 2014, the Consortium is a national, multi-institutional collaboration designed to enhance and expand the development and delivery of authoritative, timely, and objective agricultural and food law research and information.
 - Includes law related to land-based food, fiber, and energy production systems, as well as seafood and marine-based aquaculture.

**AquAdvantage Salmon and
Other Current Issues in GMO Regulation**

- AquAdvantage Salmon
- GMO Feed in Aquaculture
 - GMO Labeling
- The Regulatory Framework
- GMOs and other current Issues

AquAdvantage Salmon

<https://aquabounty.com>

Photo courtesy of AquaBounty Technologies, Inc.



Shown are two siblings of the same age, around 12 months. Both animals will reach the same market size, but the AAS will do so more quickly.

AquAdvantage Salmon



- On Nov 19, 2015, the U.S. Food and Drug Administration granted approval for the first genetically engineered (GE)/GMO animal to enter USA food supply.

Photo courtesy of AquaBounty Technologies, Inc.

AquAdvantage Salmon

- Corrections:
 - AAS salmon use 25% less feed to get to market size than non-GM Atlantic salmon
 - A study done by AquaBounty shows a reduction in the carbon footprint of AAS over farmed salmon by 23-25 times
 - <http://aquabounty.com/sustainable/>.

Photo courtesy of AquaBounty Technologies, Inc.

AquAdvantage[®] Salmon

- In their approval, the FDA's declined to impose labeling requirements; AquAdvantage Salmon was originally approved to be labeled as Atlantic salmon without reference to the genetic modifications.
- A consortium of environmental groups sued the FDA for approving the AquAdvantage salmon, "without considering or fully disclosing the environmental and other risks of this unprecedented decision."

AquAdvantage Salmon

- In January 2016, at the direction of Congress, the FDA banned the import and sale of AquAdvantage salmon until the agency develops and publishes labeling guidelines.
- In May 2016, Canada approved sale of AquAdvantage

GMO Feed in Aquaculture

- Although the controversy surrounding AquAdvantage salmon is most visible, it is limited to only one aquaculture operation.
- A potentially larger area of controversy for the aquaculture industry is the use of genetically modified (GM) ingredients in feed.

GMO Feed in Aquaculture

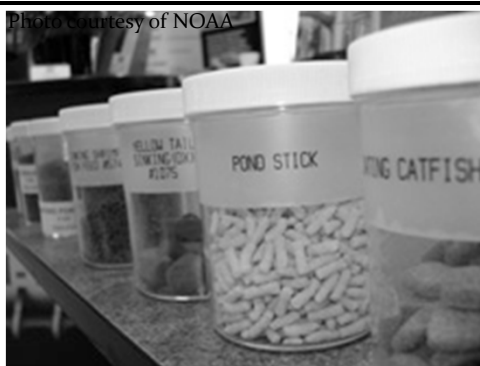


- Aquaculture has been recommended as a solution to the current seafood trade deficit.

- $\frac{3}{4}$ of the world's current capture fisheries are fully or overexploited

- One of the greatest challenges in the aquaculture industry is the issue of fish feed.

GMO Feed in Aquaculture



- Fishmeal and oil have an excellent balance of the roughly 40 essential nutrients needed by all animals.
 - Additionally, fishmeal is a natural source of high-quality protein.

GMO Feed in Aquaculture

- Relying on large populations of wild fish to grow farmed fish can make aquaculture inefficient and increase the cost of production.
- Relying on fishmeal and fish oil can be a challenge to aquaculture production and industry growth.
- One possible alternative is the inclusion of soy products to replace the reliance on fishmeal and oil in aquaculture feed.

GMO Feed in Aquaculture

- There is significant investments being made in aquafeeds to remove the reliance on fishmeal and oil.
- Companies including Cargill, Monsanto, and Dow Chemical have developed genetically engineered oilseeds, such as soybeans and canola, as sources of long chain omega-3 fatty acids
- However, nearly all soy and the vast majority of U.S. produced corn are grown from genetically engineered seed, which are then utilized as aquaculture feed.

GMO Feed in Aquaculture

- In aquaculture operations (besides cage produced aquaculture) uneaten feed flows into the natural environment.
 - The GMO products then enters the environment and the diets of other marine creatures.
- The larger issue is human consumption of GMO fed animals.
- Federal agencies in the U.S. have stated that GMO animal feed is considered to be the “substantial equivalence” to non-GMO other feed.

GMO Feed in Aquaculture: Main Issues

- Many European consumers are uncomfortable consuming GMO fed animals and the majority of fish feed used in Europe is free from GMO ingredients.
- Consequently, the use of GM feeds could interfere with the ability of aquaculture producers to access some European markets.
- The use of GM feeds could interfere with the ability of aquaculture producers to or obtain organic certifications, if USDA standards for aquaculture are approved in the future..

GMO Feed in Aquaculture: Future Outlook

- Due to rising global demand, large aquaculture feed producers are working to develop and market non-GMO fish feed.
- Cargill Chairman & CEO David MacLennan has said that Cargill is actively working on developing non-GMO supply chains for aquaculture feed due to consumer demand.
- Cargill, and other aquaculture feed producers, are betting that in the near future, consumers will be willing to pay a premium for non-GMO products.



Current Legal Issues Involving GMOs
Professor Ross H. Pifer

Mandatory GMO Labeling **California Proposition 37**

- **November 6, 2012 General Election**
- **The California Right to Know Genetically Engineered Food Act**
 - **“Commencing July 1, 2014, any food offered for retail sale in California is misbranded if it is or may have been entirely or partially produced with genetic engineering and that fact is not disclosed.”**

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Mandatory GMO Labeling **California Proposition 37**

- **Results:**
 - **Yes – 6,088,714 (48.59%)**
 - **No – 6,442,371 (51.41%)**
- **Who really won?**

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Mandatory GMO Labeling **Vermont Act 120**

- **Signed into law on May 8, 2014**
- **Scheduled to become effective on July 1, 2016**
- **Labeling required if food is “entirely or partially produced with genetic engineering.”**
- **Label must indicate “produced with genetic engineering”, “partially produced with genetic engineering”, or “may be produced with genetic engineering.”**

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GMO Labeling Update **Federal Legislative Activity (2015)**

- **Genetically Engineered Food Right-to-Know Act (S. 511, H.R. 913)**
 - Would impose mandatory labeling requirements
- **Safe and Accurate Food Labeling Act (H.R. 1599)**
 - Would impose standards on voluntary labeling

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Federal Legislation **National Bioengineered Food Disclosure Standard**

- **July 29, 2016 – Senate Bill 764 signed into law as Public Law 114-216**
- **Establishes National Mandatory Bioengineered Food Disclosure Standard**
- **Provides for Federal Preemption of state labeling or disclosure requirements**

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Federal Legislation

National Bioengineered Food Disclosure Standard

- **Within 2 years of enactment, USDA shall develop standards.**
- **Within 1 year of enactment, USDA shall conduct study to identify technological challenges to disclosure methods.**

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USDA AMS Activity

National Bioengineered Food Disclosure Standard

- **9/1/16 – Request issued for information on study design**
- **10/19/16 – Request issued for proposals to conduct study**
- **For more information:**
 - **www.ams.usda.gov/rules-regulations/gmo**

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GMO Labeling Update **Process Verified Program**

- **Voluntary program administered by USDA AMS**
- **Allows companies to make marketing claims and use “USDA Process Verified” shield**
- **Includes auditing requirement**

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Process Verified Program **Examples**

- **Birds are never given antibiotics**
- **Raised by independent farmers**
- **Raised cage free**
- **Traceable from birth through harvest and fabrication**

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Process Verified Program SunOpta

- **May 1, 2015 – Dear Employees letter from Sec. Vilsack**
 - **Leading company requested verification**
 - **AMS worked with company to develop verification processes**
 - **“[O]ther companies are already lining up to take advantage of this service.”**

SunOpta
Process Verified Non-GMO/GE Program
HOPE, MN: SOYBEANS & CORN

NON-GMO/GE PROCESS VERIFIED

SunOpta's Hope, MN location is the first facility to receive certification for our non-GMO/GE program through the USDA's Process Verified Program (PVP). The program makes it possible to label our food-grade soybeans and corn as non-GMO/GE.

SunOpta has a long history in identity preserved grains and has been utilizing programs to trace desirable characteristics since 1978 - long before GMO/GEs were even introduced! Throughout the years we've traced characteristics such as protein levels, oil content and non-GMO/GEs throughout the supply chain to verify that our customer's product fits their exact specifications.

SunOpta's Hope facility became USDA PVP certified non-GMO/GE for a number of reasons:

- Soybeans & Corn have high potential for unintended presence of GMO/GE materials.
- We value consumer education and want to help reinforce the right messaging by focusing on commodities where GMO/GE varieties exist.
- We utilize a robust program and verification by a USDA program further enhances this. We believe it's important to test every inbound delivery to assure proper storage and handling in our facility.

We plan to implement the program at other SunOpta facilities across our vertically integrated platform to the benefit of our customers.

For more information, please contact us at grains@sunopta.com or visit our website at www.sunopta.com.

USDA PROCESS VERIFIED
<http://processverified.usda.gov/>

99.1% VERIFIED NON-GMO/GE

www.sunopta.com



Regulatory Framework for GMOs General Principles

- **Coordinated Framework for Regulation of Biotechnology (1986)**
 - **Established by White House Office of Science and Technology Policy**
 - **Provides foundation for existing regulatory framework**



Regulatory Framework for GMOs **General Principles**

- **Coordinated Framework for Regulation of Biotechnology (1986)**
 - Biotechnology poses no unique risks
 - Products of biotechnology, not the process, should be regulated
 - Regulation based upon verifiable scientific risks
 - Existing statutes are sufficient to regulate GM products

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Updating the Framework **Office of Science and Technology Policy**

- **July 2, 2015 blog post**
 - Improving Transparency and Ensuring Continued Safety in Biotechnology
- **July 2, 2015 memo to FDA, EPA, and USDA**
 - Modernizing the Regulatory System for Biotechnology Products
 - Update Coordinated Framework within one year

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Updating the Framework **Tasks for Biotechnology Working Group**

- Clarify biotechnology product areas for each agency
- Clarify regulatory role of each agency
- Clarify standard for communication and coordination
- Clarify mechanism and timeline for updating Coordinated Framework

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Updating the Framework **Completed / Ongoing Tasks**

- Jan. 4, 2017 – 2017 Update to the Coordinated Framework for the Regulation of Biotechnology
- Sept. 2016 – National Strategy for Modernizing the Regulatory System for Biotechnology Products
- Ongoing – National Academy of Sciences study on future biotechnology products

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Regulatory Framework for GMOs **APHIS Rulemaking**

- **Jan. 19, 2017 – APHIS issues Proposed Rule on Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms**
 - Represents first comprehensive regulatory revision since 1987
 - Comment period closes on June 19, 2017.

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