FDA Considers the First Genetically Engineered Food Animal

Biotechnology Industry Organization

Consideration of the first genetically engineered food animals, the AquAdvantage salmon, by the U.S. Food and Drug Administration (FDA) continues.

This salmon has been genetically engineered to reach its market weight in half the time of conventionally raised salmon thus contributing to more sustainable aquaculture systems.

On December 21, 2012, the FDA released the long-awaited environmental assessment (EA) of the GE AquAdvantage salmon.

The FDA EA concluded that the salmon would have "no significant impact" on the environment. The agency also said the salmon was "as safe as food from conventional Atlantic salmon." The agency's draft environmental assessment is subject to a 60 day comment period.

BACKGROUND

VMAC Meeting

The FDA convened its Veterinary Medicine Advisory Committee (VMAC) on September 19-20, 2010, to consider the application by BIO member AquaBounty Technologies for its GE salmon.

The VMAC meeting is part of the rigorous regulatory process required to assess such technologies before being approved for commercialization. At this meeting, the Committee heard from independent experts about the product's safety, effectiveness, and environmental considerations and benefits; it also collected public testimony and examined 14 years of scientific evidence about the salmon.

At the VMAC meeting, BIO's Director of Animal Biotechnology David Edwards provided oral comments in support of the application.

FDA "Part 15" Meeting on Labeling

At this meeting, the FDA hosted discussion about whether their policies on labeling of food should be applied to food from the GE salmon.

FDA has have stated that their policies on food labeling are not up for debate. But discussion focused on whether food from the GE salmon will need to be labeled due to any material differences in the food from conventional versus GE salmon, which is the standard for mandatory labeling.

The law prohibits food labeling that is false and the law prohibits food labeling that is misleading, particularly in light of material facts about the product. The law allows voluntary labeling about production methods, so long as the labeling is not false or misleading. And the law requires that the label include a name that accurately describes the basic nature of the food. The FDA has reiterated these labeling regulations and BIO supports them.

FDA Regulatory Process

FDA has worked for over a decade to develop a robust system to determine the safety of food and drugs from genetically engineered (GE) animals.

The regulatory process for GE animals finalized by FDA in January 2009 ensures the products made available through genetic engineering go through a rigorous review process before being approved for the marketplace.

The FDA examines:

1. safety of the rDNA construct to the animal;
2. safety of the food from the animal;
3. environmental impact; and
4. the extent to which the producers of GE animals (referred to as "sponsors") have met the claims made for those GE animals (effectiveness).

The rubric for the approval of this genetically engineered product is the New Animal Drug Application (NADA) at the FDA through the Federal Food, Drug, and Cosmetic Act. The FDA's process for approval of the recombinant DNA construct in the animals is mandatory before going to market.

The first U.S. approval for a GE animal product came in February 2009 when the FDA approved ATryn®, a therapeutic protein derived from the milk of goats genetically engineered to produce recombinant antithrombin.

This would be the first U.S. approval of a product derived from a genetically engineered species targeted for human consumption. Other GE animals developed for food may follow, but the salmon is the first test of the system for a food application.

GENERAL TALKING POINTS

- A genetically engineered (GE) animal is one which has had a deliberate modification made to its genome. This technology allows scientists to precisely transfer a specific beneficial gene from one species to another.

- Research with GE animals such as goats, pigs, sheep, chicken, fish and cattle has yielded a variety of products that can advance human health, mitigate environmental impact, optimize animal welfare, improve state-of-the-art industrial products and provide sustainable food sources in agriculture and aquaculture.

- BIO and its members engaged in animal biotechnology support a strong and transparent federal regulatory system to oversee development and approval of all genetically engineered (GE) animals and the products derived from them.

- The regulatory process for GE animals finalized by FDA in January 2009 ensures the products made available through genetic engineering go through a rigorous review process before being approved for the marketplace.

- As the FDA considers its first GE food animal, we're hopeful that this process will pave the way for new technologies and their benefits currently in the pipeline.

- BIO supports the law and regulations administered by FDA and the U.S. Department of Agriculture (USDA) that require food labeling to be truthful and not misleading.

Key Points on AquaBounty and the GE AquAdvantage® Salmon

- AquaBounty Technologies (www.aquabounty.com) has been working for approximately 15 years towards FDA approval of the GE AquAdvantage® Salmon.

- AquAdvantage® Salmon include a gene from the Chinook salmon, which provides the fish with the potential to grow to market size in half the time of conventional salmon. In all other respects, AquAdvantage® Salmon are identical to other Atlantic salmon.

- The GE AquAdvantage® Salmon are safe for human consumption and are no different from conventional farmed salmon.

- These salmon are designed to be raised in contained, land-based growing facilities operated under strict FDA requirements. In addition, AquAdvantage® Salmon are sterile females - thus eliminating possibilities for cross-breeding.

- AquAdvantage® Salmon can be grown in contained facilities closer to population centers, including in the United States, positioning fresh seafood closer to market without the environmental costs of long distance transportation.

Key Facts on Salmon

- Consumption of salmon by Americans is growing, but the United States imports 90 percent of its salmon.

- Atlantic salmon comprises 64 percent of the salmon consumed in the United States.

- The United States currently imports 97 percent of its farm raised salmon –236,414 tons in 2007 (NOAA) at a cost of $1.6 billion, or $3.07 per pound.

- The domestic salmon farming industry disappeared for all intents and purposes in the 1990s in the face of environmental concerns and lower costs of production from foreign sources, notably Chile. Currently, most fresh imports are from Norway, Chile and Canada.

- Between 1989 and 2004, all salmon consumption in the United States increased from 130,000 mt to 300,000 mt.

- The domestic trade balance on salmon has gone from a positive $650m in 1989 to a negative $500m in 2005.)

FOR MORE INFORMATION

- **FDA** has posted The AquAdvantage Salmon Draft Environmental Assessment and FDA's Preliminary Finding of No Significant Impact of the AquAdvantage Salmon at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess

- **FDA** has posted information on the VMAC meeting at http://www.fda.gov/AdvisoryCommittees/Calendar/ucm223823.htm.

- **FDA**'s analysis and other summary documents related to the AquAdvantage Salmon are posted here: http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf

- **FDA**'s GE Animal Web Page is here: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm

- Visit **AquaBounty**'s Pressroom to get more information on the AquAdvantage Salmon: http://www.aquabounty.com/PressRoom/

- Visit **BIO**'s Online GE Animal Resource Center at http://bio.org/foodag/animal_biotech/#genetic.

- The potential benefits of GE animal technologies have been detailed in the report, *Genetically Engineered Animals and Public Health – Compelling Benefits for Health Care, Nutrition, the Environment and Animal Welfare*. For more information, visit BIO's GE Animals Web Resource Page at www.bio.org and visit FDA's GE Animals Web Resource Page at www.fda.gov/cvm/GEAnimals.htm.

- Technologies developed through animal biotechnology will be discussed in more detail at BIO's upcoming Livestock Biotech Summit, September 19-21, 2012 in Kansas City, Mo. Program details are posted online at www.bio.org/livestockbiotechsummit.