



# Genetically Engineered Salmon- Healthy for You, But Is It Healthy for the Earth?

by Gregory Jaffe

**P**ivate companies and academic scientists have been experimenting with genetically engineered (GE) animals for over 20 years. This past summer, the Food and Drug Administration (FDA) acknowledged that one of those animals – an engineered salmon – is on the verge of being approved for commercial production and entry into our food supply. How does the federal government ensure those animals are safe before they are marketed? Is the current regulatory process adequate and will it give consumers confidence in the safety of those products? This article discusses the federal government’s regulation of GE animals and the inadequacies in that process. While the current regulatory process does pro-

vide oversight, new legislation is needed to provide a comprehensive regulatory system that can address all food safety and environmental issues surrounding GE animals.

## Genetically Engineered Animals

Scientists produce an engineered animal by introducing a specific gene from one organism that codes for a desired trait or characteristic into an egg cell of a different animal in the laboratory. The new foreign DNA integrates into the animal’s DNA and becomes part of the animal and its progeny. Already, pet owners can purchase “glofish,” a zebra fish with an inserted gene that makes them glow different fluorescent colors. Medical patients with a rare clotting disorder are treated today with Atryn, a biologic manufactured by goats engineered with a human gene. The goat acts like a pharmaceutical factory, producing the biologically active molecule in its milk. The active molecule is then separated out from the milk and sold as a biologic.

AquaBounty’s AquAdvantage salmon, which was the subject of hearings at FDA in September 2010, is an Atlantic salmon which grows almost twice as fast as farm-raised salmon be-



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cause scientists added a growth hormone gene from a Chinook salmon and a promoter sequence from an ocean pout fish. The introduced DNA produces growth hormone in the fish year round, leading to the quicker growth. If adopted on a large scale, the company claims that the salmon would reduce producers' costs and benefit the environment by decreasing the amount of feed used and waste produced by fish-farming operations or it would also lower the cost of transporting the fish to market by growing them at local inland farms.

While AquaBounty espouses the potential benefits of its AquaAdvantage salmon if produced on a large scale, the application it submitted to FDA is quite limited. AquaBounty's application applies only to one egg production facility in Canada and one fish production facility in Panama with four inland tanks, not unrestricted sale of the GE salmon eggs to any salmon farmer. This will result in a relatively small amount of salmon which would then be exported to the United States for sale to consumers.

To prevent any potential impacts of the fish on the environment, AquaBounty has proposed multiple layers of biological, physical and geographical containment. Those redundant containment strategies include producing only female sterile fish that will be grown in secure facilities away from the ocean or other salmon populations. They also have picked facilities where an escaped egg or fish would encounter harsh conditions (such as water temperatures above or below which salmon can survive), greatly reducing the likelihood of survival and reproduction.

If AquaAdvantage salmon is approved for marketing in the United States, other GE animals may follow close behind. For example, next on the horizon may be the "enviropig," which has been engineered

to use phosphorus more efficiently than conventional pigs. This reduces the need to supplement the pig's feed with phytase. Additionally, the manure the pig produces is more environmentally friendly with less phosphorus that can affect nearby streams, lakes and ponds. Other GE animals currently in development include cattle resistant to mad cow disease and animals that could be used as factories to produce useful pharmaceuticals.

### The Federal Government's Regulation of GE Animals

The federal government regulates GE animals using FDA's legal authority to regulate "new animal drugs." According to the Federal Food Drug and Cosmetic Act, a new animal drug is "an article (other than food) intended to affect the structure or any function of the body of ... animals." FDA has stated that introduced foreign DNA meets the definition of a "new animal drug" and it is regulating that introduced DNA, not the animal itself, as the drug.

To approve a new animal drug, FDA must address the following areas in its review and analysis of an application. First, it must determine whether the drug is safe for the health of the animal. For the AquaAdvantage salmon, this involves determining whether the salmon's health is adversely affected by the introduced gene and the growth hormone it produces. Second, FDA must determine that food from the GE animal is safe for humans or other animals to eat. In other words, FDA must apply the "reasonable certainty of no harm" standard to filets that would come from the AquaAdvantage salmon. Also, it must determine that the drug is efficacious, or that it does what it is intended to do. For the AquaAdvantage salmon, this would mean determining that the fish grows significantly faster than other farm raised Atlantic salmon.

Finally, FDA must meet its obligations under the National Environmental Policy Act (NEPA) to assess the environmental impacts of any major federal action, which includes the approval of a new animal drug. NEPA is a procedural statute which requires FDA to assess the environmental impacts of the AquaAdvantage salmon and then work with the sponsor to mitigate any potential impacts. NEPA, however, does not provide FDA with any legal authority to deny its approval of a GE animal based on any actual or potential impacts that may be identified by the NEPA analysis.

FDA's regulation of GE animals as set forth above has some significant strengths. The "new animal drug" approval process provides FDA with mandatory pre-market authority so that the sponsor cannot market the drug until FDA has approved it. It requires FDA to determine that the drug is safe for the animal and that there is a reasonable certainty of no harm to humans or animals if they eat anything from the animal that has received the drug. Therefore, FDA must make certain scientific findings before any consumer will eat food from a GE animal.

While FDA is reviewing and approving a GE animal, however, the public may not know what is going on or have the opportunity to provide its input into FDA's decision. Congress imposed on FDA strong confidentiality provisions surrounding animal drugs, which shroud the approval process in secrecy, greatly limit access to information and prevent public participation. FDA and AquaBounty have been in discussions for over 10 years, but the public got its first look at some safety data and FDA's analysis at the eleventh hour of the decision process only because FDA convened a public meeting of its Vet-

erinary Medicine Advisory Committee (VMAC). While FDA's release of its AquAdvantage salmon analysis through a VMAC meeting was a creative way to make the FDA animal drug regulatory process for GE animals significantly more transparent and participatory than what has occurred for other animal drugs, it did not result in a full release of all safety data nor did it provide the public with a formal opportunity to provide comments to FDA on its proposed decision. In fact, Senator Mark Begich (D-Alaska) and ten of his colleagues sent FDA Commissioner Hamburg a letter on September 28, 2010, identifying numerous problems with FDA's regulatory process, specifically citing the lack of transparency and opportunity for public participation.

While FDA has the expertise to address food-safety questions, it has less expertise to analyze environmental concerns presented by GE animals. A National Academy of Science report from 2002 described environmental issues as the "greatest science-based concerns" associated with GE animals due to the inability to identify all potential problems early on and the difficulty of solving problems after they arise. For instance, might an engineered salmon escape from confinement and disrupt native fish populations? The Environmental Protection Agency, the Fish and Wildlife Service and other federal agencies with expertise and experience with environmental assessments have been surprisingly silent about any role they might have in regulating GE animals. A strong regulatory system that safeguards the environment should draw on the expertise of agencies other than FDA to ensure that if an engineered animal is commercialized, the potential environmental risks have been analyzed by those within the government with the most expertise in that area. While FDA

is required to assess the environmental impact of a GE animal, it has no authority to deny approval if that animal could have a significant impact on the environment. Some other agencies, however, may have the legal authority to prevent the release of a GE animal which might harm the environment.

### Congress Needs to Act

Congress should step in and provide FDA with adequate authority to ensure the safety of all engineered animals through a transparent and participatory regulatory process. FDA needs authority to both analyze and address the full range of environmental concerns that GE animals might pose, including the power to deny an application if it could result in significant environmental impacts and to "recall" those animals if problems arise after commercialization. FDA should be directed to consult with other agencies with expertise in assessing environmental risks of animals. Also, Congress should eliminate the confidentiality requirements so safety data and FDA's analysis can be reviewed by outside experts before granting any approvals. Additionally, Congress should require that FDA provide a formal public comment opportunity before any decisions are completed. Senator Richard Durbin's Genetically Engineered Foods Act, which was introduced in 2004, would do all that, and Congress should take it up again next year.

In the meantime, the public should take comfort in the fact that if FDA goes forward and approves the AquAdvantage salmon, the data and analysis released last month indicate that the filets are just as safe to eat as filets from any other salmon and that there are no significant adverse impacts on the salmon from the introduced gene. The proposed conditions for rearing those fish – in two facilities with

redundant layers of physical, biological and geographical containment – also make it extremely unlikely that the salmon would escape the facilities, reproduce and impact other salmon or the environment.

### Labeling of Food from the AquAdvantage Salmon

If FDA approves the AquAdvantage salmon as a new animal drug, it will need to decide whether or not to require any special labeling for food derived from those fish. In addition to requiring that all food labels be truthful and not misleading, FDA has stated that it can only require a mandatory label if the engineered salmon is "materially" different from a non-engineered salmon. FDA has determined that the fact that a food was made using genetic engineering is not a material difference that requires a special label and that it cannot require labeling based solely on the food's method of production. Even if there is a material difference between the AquAdvantage salmon and other Atlantic salmon, the required label would identify the "material" difference to the consumer but not the fact that the fish was genetically engineered. For example, FDA has required GE soybeans with a higher concentration of oleic acid to be labeled as "high oleic acid soybeans" but not "genetically engineered high oleic acid soybeans."

Based on current data released by FDA about the AquAdvantage salmon, FDA is unlikely to require mandatory labeling of AquAdvantage filets. Those fish do not differ from other Atlantic salmon in any way that falls within FDA's current understanding of a "material" difference. The data suggests they are the same as other Atlantic salmon except for the inserted gene. For consumers, the filets from AquAdvantage salmon will have the same nutritional properties, taste and

preparation instructions as any other salmon filet.

Independent of the scientific and legal arguments surrounding whether a mandatory label should be required for AquaAdvantage salmon, the reality is that some consumers will want to know if their salmon has been engineered. Some may want to know that information in order to avoid eating those filets and others may want to know so that they can support the product. It is important that consumers who want information about their food and its production methods be able to get that information. Therefore, FDA should help AquaBounty and the food chain companies who bring salmon to grocery stores put in place a voluntary labeling scheme for AquaAdvantage salmon that results in information for the consumer at the point of purchase. Such a scheme probably would not use the term “genetically engineered” but would brand the product in the marketplace – it would be a positive label for the company, such as “AquaBounty Salmon” or “Panamanian Inland Salmon” to

identify this salmon at the grocery store. The label might promote the purported benefits of the products, such as calling it “fast-growing salmon” or “environmentally friendly salmon,” as long as those benefits are supported by sufficient evidence. While FDA would not be able to require such a label, it could work with AquaBounty to come up with a truthful and non-misleading voluntary label. Then AquaBounty could use contracts to ensure the label was affixed throughout the food chain (similar to the way that a meat producer of Angus beef might make sure that their product is differentiated at the supermarket).

Another area where FDA can be helpful regarding voluntary labeling is in “absence” claims. An “absence” label claim would allow a grocery store to identify on the label that its salmon was not engineered. However, this information would need to be provided in a truthful and non-misleading fashion. FDA should provide specific guidance about what language would be acceptable in advance so that such claims are uniform and meet all legal

requirements. They should also identify the documentation and evidence that would be sufficient to verify the claim that the salmon was not engineered.

## Conclusion

GE animals, like GE crops (which encompassed over 80 percent of U.S. corn, soybeans, cotton and sugar beets in 2010), may become a significant part of American agriculture. But without regulatory procedures that are thorough and transparent, consumers will question the safety of GE animals, handicapping a technology that has potentially beneficial applications for farmers, consumers and the environment. Before the government becomes too invested in the existing flawed regulatory process, Congress should pass legislation that allows safe, beneficial products to reach the marketplace while protecting consumers and the environment. Without a regulatory process that is both thorough and transparent, there is no chance that American consumers will—or should—have confidence in the safety or environmental-harmlessness of these animals. ▲