

FDA considering approval of genetically engineered salmon

Veterinarians, consumer advocates raise concerns over data

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Courtesy of AquaBounty Technologies

Both of these Atlantic salmon are 18 months old. The larger fish is an AquAdvantage salmon, which has been genetically modified to grow more quickly than conventionally spawned Atlantic salmon.

Some veterinarians and consumer advocates have recommended that the Food and Drug Administration require more data before deciding whether to allow a company to sell genetically engineered salmon in the U.S.

Several veterinarians who serve on the FDA Veterinary Medicine Advisory Committee, which is examining the issue, said in late September they found information gaps and flaws in some studies of the fish, but some expect and hope the salmon eventually will be sold in grocery stores. The FDA intends to regulate genetic modifications in food animals as drugs, because they are intended to alter the structure or function of the genetically altered animals.

AquaBounty Technologies produces the modified Atlantic salmon, also known as AquAdvantage salmon, by incorporating an rDNA construct with gene-coding sequences from ocean pout and Chinook salmon. The construct causes the modified fish to grow more rapidly, and company information states that the fish potentially grow to market weight in half the time of naturally spawned farmed salmon.

The company also asserts that the fish have about 10 percent improved feed conversion rates over other farmed salmon.

AquaBounty intends to breed the fish in a facility on Prince Edward Island in Canada and send fertilized eggs to a production facility in Panama, FDA information states. The broodstock in Canada and fish grown to market weight in Panama would be held in landlocked tanks.

The FDA has been considering public comments and suggestions from the VMAC, and the agency had no deadline for deciding whether to approve the product, spokeswoman Laura Alvey said. Prior to making its decision, the FDA also needs to determine whether to prepare an environmental impact statement or issue a finding of no significant impact.

The FDA is accepting public comments through Nov. 22 on label requirements for the salmon, should they be approved for sale, and on the safety and effectiveness of the rDNA construct.

Veterinarians see mix of flaws and potential

The agency asked VMAC members to assess whether the rDNA construct is safe for the salmon, whether eating the genetically modified salmon could harm humans, whether the modified salmon grow more quickly than their conventional counterparts, and whether the potential environmental impacts of production are mitigated by the conditions of use.

Dr. James D. McKean, a professor and extension swine veterinarian at Iowa State University and member of the VMAC, said the committee members indicated to the FDA that they received good preliminary data but that more information is probably needed. He saw problems with sample sizes and culling connected with some of the briefing materials supplied, and he noted that committee members raised concerns about whether studies performed at a Prince Edward Island hatchery can

provide a robust evaluation of commercial production conditions in Panama or other locations.

But Dr. McKean is confident that the fish are substantially the same as other Atlantic salmon, and he hopes they will be approved for sale.

"To the extent that FDA can show that these products are equivalent, then there will be a substantial part of the public that will accept that," Dr. McKean said. He noted that U.S. grocery stores already sell food from genetically modified plants, and he expects the public will gradually accept genetically modified animal products.

Dr. McKean also hopes the approval process for AquaAdvantage salmon will help the FDA improve determinations of data required and the approval process for future applications involving genetically modified animals.

Dr. Paul C. Stromberg, a committee member and a professor of veterinary pathology at The Ohio State University, also saw some flaws in data given to the committee, yet he saw reasonable evidence that the rDNA construct is safe for human consumption. But he expressed concern about some health problems, such as oral ulcers, seen in the salmon.

Dr. Craig Altier, a member of the committee and an associate professor at the Cornell University College of Veterinary Medicine, indicated flaws in some studies leave doubt about whether the constructs are safe for the fish. An important study of gross pathology, for instance, included only three to six fish per group examined, leaving doubt about the study's conclusion that the construct is safe.

A small number of abnormal fish were also culled prior to the start of two other studies, Dr. Altier said. While the FDA performed histologic analysis on most of the culled fish and found only small inflammatory changes that were regarded as normal and typical for Atlantic salmon, the fish did not have a chance to grow to the age of others in the study and possibly develop lesions seen on other fish, and their removal for abnormalities introduces additional uncertainty.

The AVMA Policy "Creation and Use of Genetically Modified Animals" indicates AVMA leaders have not seen a need to restrict genetic research or modification as long as the integrity of the environment and the modified animals' health and well-being remains preferential to human values and needs. Having DNA sequences for animals presents "a remarkable opportunity as well as a profound responsibility to utilize this knowledge and technology in a fashion that will preserve, if not improve, the health and well being of animals, while at the same time enhancing their appeal and value to humans."

Consumer advocate: data don't show safety

Michael Hansen, PhD, senior scientist for Consumers Union, thinks numerous information gaps and flaws in AquaBounty's studies of its salmon mean that the data are insufficient to show whether the salmon are safe for human consumption. He was among people who spoke during a comment period before the VMAC, and he recounted some of his concerns in a subsequent interview with JAVMA.

Dr. Hansen said study problems included use of tests of growth hormone concentrations that were too insensitive to detect the hormone, an insufficient range of allergenicity tests, an absence of data on fish raised under the actual husbandry conditions the company proposes to use, analyses of fish at well below market weights, and insufficiently sensitive tests for amino acid sequences connected with allergies. He does not think the data meet the standard for a new animal drug application.

For example, Dr. Hansen thinks AquaBounty also should have used mass spectrometry rather than western blot tests to discover subtle changes in the salmon that could cause allergic reactions. He cited as evidence a study by Australian and U.S. scientists involving transgenic peas that contained a bean alpha-amylase inhibitor and caused allergic reactions in mice that ate the modified peas, even though the mice didn't develop such reactions when fed conventional beans or peas. Western blot analysis did not show differences in the inhibitor, but mass spectrometry did, he said.

Dr. Hansen also pointed to an allergenic potency study involving the AquaAdvantage fish which, even with a sample size of only six fish per group, showed a significant increase in allergenic potency among engineered diploids. He thinks the lack of a significant increase in potency among engineered triploids could have been due to the small sample size.

Dr. Stromberg noted that members of the public had also expressed concerns over growth hormone concentrations in AquaBounty's Atlantic salmon, but he thinks those concerns are misplaced.

"Whatever growth hormone there is in the fish, there is scientific evidence that indicates that the growth hormone would be digested and denatured in the stomach and wouldn't be absorbed as growth hormone," he said. "And if it were, the fish growth hormone is so significantly structurally different than mammalian growth hormone that the mammalian receptor wouldn't bind it."

Escape risks

Margaret Mellon, PhD, JD, senior scientist and director of the Food and Environment program for the Union of Concerned Scientists, does not think the FDA is adequately assessing potential environmental issues. She said that, while two facilities are being considered by the FDA in connection with AquaBounty's application, she expects AquaBounty will eventually sell transgenic eggs to facilities around the world. She believes a more realistic view of environmental risk would have considered the likelihood of release from facilities not as well contained as the two controlled by AquaBounty.

Only remnants of the world's wild Atlantic salmon population remain, and competition could further endanger those fish, Dr. Mellon said.

The FDA concluded that the fish are extremely unlikely to escape the physical containment measures at either facility. The agency also noted that eggs and young salmon would be unlikely to survive the high salinity and low temperatures of waters off Prince Edward Island, and young and adult salmon would be unlikely to survive the high temperatures in the lower reaches of the watershed near the Panama facility.

While FDA documents state that up to five percent of a given batch of eggs sold for grow-out could be fertile (i.e., nontriploid) fish, the company expects that, on average, more than 99 percent of the eggs will be sterile female triploids with greatly reduced fertility in comparison with female diploids. Dr. Altier said that, short of a catastrophic failure at one of the facilities, it was unlikely that a large number of fish would escape. But he stressed that rigorous security would be needed to guard the valuable, fertile broodstock fish at the Prince Edward Island facility.

Dr. Stromberg expects that, provided AquaBounty can supply the additional studies requested, approval of the AquaAdvantage salmon will set a precedent for genetically modified food animals.

"We have built our society on technology; we are an adventurous, forward-looking people; and we are risk-takers," Dr. Stromberg said. "And given the perceived risks, harms, and hazards and given the potential positive benefit from this, will we ultimately take this risk and do this?" ❖

—Greg Cirra

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