

November 19, 2010

Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: (Docket No. FDA-2010-N-0385) Food Labeling; Labeling of Food Made From
AquAdvantage Salmon

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide input on the application of the food labeling laws and principles to food from the AquAdvantage salmon (also referred to as Aqua Bounty Technologies, Inc., or ABT, salmon) currently under consideration for approval by the U.S. Food and Drug Administration (FDA). BIO represents 1,100 member organizations that research, develop, and produce innovative health care, agricultural, industrial, and environmental technologies. Many of BIO's members are applying the science of biotechnology in animal agriculture applications to develop and produce products that will help feed the world. They therefore have a strong commercial interest in FDA's application of the appropriate laws and principles for the labeling of foods. The application of various technologies to animal agriculture is not something that is new; it has long allowed us to more efficiently and sustainably produce food and fiber for a growing population.

The issues addressed by these comments concern the application of FDA's labeling requirements to meat from an improved salmon. The questions related to the labeling of food made from AquAdvantage salmon are of importance to BIO, as they could also impact future applications that include food from other genetically engineered animals and plants, many of which are technologies being developed by BIO member organizations.

BIO strongly supports FDA's science-based labeling requirements that apply to all foods. To reiterate, these requirements include:

- No special label is required if a new food is substantially equivalent to its traditional counterpart in terms of safety, nutrition, taste, appearance, smell, and preparation methods.
- A label is required if the food is materially different from its traditional counterpart in nutritional or safety attributes, taste, appearance or smell, or in how its preparation methods may differ.
- Voluntary claims are allowed on food labels provided such labels are truthful, do not mislead consumers and are verifiable.



FDA is currently considering the application of these well-established legal principles to labeling of food derived from this improved growth-rate salmon. As reported in the briefing packet for the Veterinary Medical Advisory Committee meeting on September 19-20, 2010 distributed to the public, FDA concluded:

- “Food from AquAdvantage Salmon (triploid, monosex (all female) ABT salmon) is the same as food from other Atlantic salmon.”
- “We have found no biologically relevant difference between food from ABT salmon and conventional Atlantic salmon based on the criteria evaluated.”
- “No direct or indirect food consumption hazards were identified in AquAdvantage Salmon.”
- “Food from AquAdvantage Salmon (triploid, monosex (all female) ABT salmon) is as safe to eat as food from other Atlantic salmon.”

In addition, the FDA stated, “We therefore conclude the food from AquAdvantage Salmon (the triploid ABT salmon) that is the subject of this application is as safe as food from conventional Atlantic salmon, and that there is a reasonable certainty of no harm from the consumption of food from this animal. No animal feed consumption concerns were identified.”¹

According to these findings, FDA has concluded that salmon grown from AquAdvantage eggs are nutritionally and biologically the same as any other Atlantic salmon the consumer purchases; it is substantially equivalent to other Atlantic salmon.

FDA also determined that these salmon meet the standard of identity for Atlantic salmon established by FDA’s Reference Fish Encyclopedia², and noted no biologically relevant differences in either the gross composition (proximate analysis), or in any edible tissue component (e.g., amino acids, minerals, vitamins, fatty acids) between this salmon and a conventional salmon.³ Finally, FDA found that triploid AquAdvantage salmon “pose no additional allergenic risk than control Atlantic salmon.”⁴ Where no biologically relevant differences are found in the allergenicity of new products, a special label is not required to address allergenicity concerns.

¹

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf> at 62.

² Id. at 61.

³ Id. at 61-62.

⁴ Id. at 106.

As FDA has determined previously, and the courts have upheld, the mere fact of genetic engineering as part of a product's breeding history is not a material fact that warrants labeling. In other words, labeling is not required for the salmon meat just because genetic engineering was used in the breeding of these salmon. To require special labeling of foods that are indistinguishable based on breeding methods would mislead consumers by falsely implying material differences where none exist. The mandatory addition of immaterial product information on any product label also risks diverting consumer attention from material and important food label information, such as nutritional information.

FDA has examined the safety of these salmon under its authority to regulate new animal drugs, and must specifically approve this application before meat from these salmon may be placed on the market. This approval process, one of FDA's strictest review processes, requires FDA's consideration of extensive information characterizing the safety of the DNA insert to the fish, the safety of the fish for human consumption, and the impact on the environment by the conditions specified in the application. All of this information has been submitted for FDA review and approval here. FDA's review of these elements through the new animal drug process is at least as extensive as the review process followed for most new food ingredients that enter the market. Nevertheless, in all cases, FDA's food safety standard is the same, a "reasonable certainty of no harm." Once safety has been determined, the product may enter the market with only the labeling restrictions discussed above regarding potential material differences. Since FDA has concluded that AquAdvantage salmon meat is not materially different than other salmon meat, differential labeling is not needed, nor is it mandated by statute.

BIO supports any processor's right to voluntarily label a product as long as the claims are not false or misleading for consumers, and are verifiable. We appreciate that some producers want to label their products as "GE-free", but such labels cannot be false or misleading, whether implied or expressly labeled. For example, a label for Atlantic salmon cannot imply differential safety based on breeding methods. Assuming that FDA approves AquAdvantage salmon, that approval will include a determination that the GE salmon is as safe for the consumer as traditionally bred salmon. Any implication to the contrary would be misleading.

FDA has concluded that fillets from triploid, monosex AquAdvantage salmon are the same as those from other Atlantic salmon, with similar safety, allergenicity, and toxicity levels as compared to other farmed Atlantic salmon. Therefore, both of these products should be labeled the same. Again, we appreciate the opportunity to provide input on this important labeling issue.

Sincerely,

A handwritten signature in cursive script that reads "David Edwards". The signature is written in dark ink on a light-colored background.

David Edwards, Ph.D.
Director, Animal Biotechnology
Food & Agriculture Section