Biotechnology Industry Organization

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Docket No. FDA-2011-0899
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: FDA-2011-0899: Draft Environmental Assessment and Preliminary Finding of No Significant Impact For a Genetically Engineered Atlantic Salmon; Availability

The Biotechnology Industry Organization (BIO) appreciates the opportunity to provide input on the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the AquAdvantage salmon application to 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. We have a strong commercial interest in FDA's application for the appropriate laws and principles for review of genetically engineered animals intended for the food supply. 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. As such, review of these technologies should take into account that they are just another extension of the application of technology to food production.

The issues addressed by these comments concern the release of the EA and the need for continued progress on the AquAdvantage application. Animal biotechnology is a tool that can positively impact human and animal health as well as sustainability for the environment. BIO's members are developing advances in agriculture to feed a growing population and are closely watching this application, as it impacts future applications and the ability of the U.S. to be a leader in innovation. Years of research, including publicly funded research, have concluded that this application of animal biotechnology is safe and can provide benefits to consumers, the environment, and job creation.

The proposed action of an approval for a New Animal Drug Application (NADA), under which this application is being reviewed, constitutes a "major Federal action" for which FDA is required to perform an environmental analysis under the National Environmental Policy Act (NEPA). This NADA approval includes a

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specific set of conditions for rearing and raising the AquAdvantage salmon, and significant changes to the conditions of use will require a further environmental analysis under an approval of a supplemental application to the FDA.

The very narrow conditions of use that would be approved in this application would lead to very little change to the environment, so the FONSI determination is entirely appropriate. This application may even lead to lowering the environmental impact of aquaculture with the ability to use less food to produce healthy salmon filets in highly controlled, land based systems that could also lead to less transportation impact on the environment. If development of this technology is allowed, it could lead to local supplies of fresh salmon being available more broadly.

Even with the narrow conditions of use, the EA describes in great detail the salient points for review. The multiple redundant containment measures that the sponsor, AquaBounty Technologies, has agreed to uphold include biological, chemical, and physical containment. There even exist natural ecological containment barriers (to migration) at the proposed production site. These measures will serve to keep this population distinct from other populations of salmon and ensure that the conditions of use are met. The effect of this particular DNA construct on the Atlantic salmon may even cause a reduced fitness, which is suitable for an aquaculture situation in which the fish is provided food by the farmer, but further enhances the environmental safety of the fish by making not as likely to survive in the wild.

Details on containment measures and environmental impact have not changed since the release of the AquaBounty EA in September 2010 in conjunction with the public meeting to give input on the application, a step that has been agreed to by animal biotechnology applicants to provide transparency in the application process. In the intervening 30 months, no new science has been brought forward that would change the opinion of the FDA from that time that the food derived through the use of this product is safe to consume, the DNA construct is safe for the fish, and the environment is not negatively impacted by the product and its conditions of use. It is now time move forward with a decision if we want to keep this technology in the U.S.

All of the necessary scientific steps have been completed and the charge of the FDA to evaluate safety and efficacy of the DNA construct on the intended animal is fulfilled. This evaluation has been thorough and the questions have been answered. It is past time to provide a decision and let the market determine whether it supports this innovation that increases healthy food in a sustainable manner. Even though this is sometimes called a new technology, in truth the AquAdvantage salmon was created 24 years ago. Over a decade has passed since the U.S. National Academies of Science used it as a case study for an application that could come out soon in the commercial realm. This regulatory pathway needs more certainty and a shorter path if we are to be able to realize the benefits of using these technologies.

Despite the lengthy regulatory timeline, opponents of the technology, who are less concerned with facts and more concerned with fear, have called for further unnecessary delays and reviews. The FDA has stated since 2001 that it would consult with the National Marine Fisheries Service and the Fish and Wildlife Service on this application, and these two agencies have reviewed the EA and not found any disagreement with it. Outside experts have also agreed with the conclusions of safety of the food, safety to the animals, and safety to the environment. Opponents of progress in agriculture will continue to rail against technology, but moving forward with safe technologies is how we will feed the world. This is a safe, sustainable technology.

The EA and FONSI are thorough and complete evaluations and conclusions of the environmental analysis for the AquAdvantage application. Publishing of these documents fulfills the last steps of review necessary for the application and should bring to a close the review. The science has spoken, and the FDA should now make the decision on approval of this application as soon as possible. Any social, ethical, or economic implications are for the market, and the market alone, to decide. We should use technology to better our health and our nutrition. This is an important opportunity to be able to do so.

Sincerely,

David Edwards, PhD
Director, Animal Biotechnology