For oral presentation on September 20, 2010:
US FDA VMAC on AquaBounty GE salmon application
Docket No. FDA–2010–N–0001

Members of the Veterinary Medical Advisory Committee,

My name is Dr. David Edwards, and I am the Director of Animal Biotechnology for the Biotechnology Industry Organization (BIO). We represent 1,100 member organizations that research, develop and produce innovative health care, agricultural, industrial, and environmental technologies. The application of technology to animal agriculture is not something that is new; it has allowed us to more efficiently and sustainably produce food and fiber for a growing population. The application being considered today is an extension of technology that precisely applies our genomic knowledge to improve the rearing of salmon and the production of a high quality food.

The process of bringing this application through the regulatory system is based upon the rigorous process at the U.S. Food and Drug Administration (FDA) for approval of a new animal drug, which BIO supports as the most effective way to determine both the safety and efficacy of the recombinant DNA construct in the target animal and the safety of the food harvested from the animal for human consumption and enjoyment. Many products of BIO's member organizations go through reviews at the FDA, and we appreciate and support the rigor of the process that was followed, allowing for the application of existing FDA product requirements to the review of genetically engineered salmon. FDA's statutory authority under the Federal Food, Drug, and Cosmetic Act to evaluate articles intended to alter the structure or function of the body of an animal has allowed FDA to create a science-based method to evaluate these DNA constructs. FDA has assumed this responsibility by undertaking its own extensive and exhaustive review of the data in this application, as well as by assembling outside experts on the subject matter to review the application through the public process currently taking place. As a government agency in charge of protecting public health, the FDA performs this review process for all of us, for the public at large. The FDA requires scientific data to validate each step of the review in a process outlined in the FDA Guidance 187: *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs*. This process was finalized in January 2009 after extensive review of the underlying statutory authority, the existing and anticipated products poised to undergo the process, and many public comments. The FDA's regulatory process sets forth a cautious and scientifically sound approach to the application of

well-established legal and scientific requirements to this new technology, illustrating why the FDA maintains its position as the world leader in science-based reviews of products affecting human and animal health.

The technical advances in agriculture discovered by researchers have reduced environmental impacts of agriculture while continuing to feed a growing population. The use of these technologies and, specifically, the approval of this biotechnology in the U.S., would benefit American aquaculture and lead to more jobs being created here in the United States. Domestic production in approved, well-regulated facilities increases food safety and lessens the impact of trade disruptions on the available aquaculture supply.

FDA participated in the Codex Alimentarius Commission's *ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology and its Working Group that developed and adopted guidelines for assessing food safety of foods from recombinant DNA animals. Codex standards are recognized as international food safety benchmarks and act as models for governments in the establishment of their own food safety policies. The information needed to establish food safety for food from GE animals under a New Animal Drug Application is consistent with that described in the Codex Guideline. Many other products from animal biotechnology have and will benefit consumers. Many of these products are in development and will undergo the same rigorous, science-based review by the FDA. BIO appreciates the opportunity to comment and looks forward to biotechnology helping to Heal, Fuel, and Feed the World.

Thank you.

David Edwards, PhD
Director, Animal Biotechnology
Biotechnology Industry Organization