Scientists react to FDA approval of genetically engineered salmon

On November 19, the U.S. Food and Drug Administration approved a genetically engineered AquAdvantage salmon, produced by Aquabounty Technologies, for human consumption. The salmon is farmed in on-land aquaculture facilities and has been modified to grow faster than conventional salmon. This is the first time a genetically engineered animal has been approved for human consumption.

Familiar GMO <u>critics claim consumers won't want to eat it and that it poses an environmental risk.</u> In contrast, most independent scientists welcomed the FDA's decision as it brings a resolution to a regulatory and review process that took a staggering 20 years.

The GLP offers a broad selection of reactions from fishery and biotechnology scientists. You can read the complete quotes and declared interest statements from the scientists here, at the site of GLP's sister organization, GENeS (Genetic Expert News Service).

Garth Fletcher, Professor Emeritus and Head of the Department of Ocean Sciences, Memorial University of Newfoundland

This is exciting news both for AquaBounty and for me. It has been a long time coming, but many years of hard work have finally come to fruition. This product started out in 1989 when two academic faculty members at Memorial University of Newfoundland (myself and Choy Hew) decided see if we could enhance the growth rates of Atlantic salmon. Early in 1990 we realized that our work had been successful when we observed growth rates that greatly exceeded everyone's expectations. At that time NSERC (Natural Science and Engineering Research Council of Canada), which funded the project, had started promoting the idea that academics should get involved in transferring research discoveries to the private sector. Fortunately for us we met up with Elliot Entis, the CEO of a start-up biotech company, who agreed to licence the invention from our respective universities. This brought in the necessary funds to complete the years of research required to document that the product was safe to eat and safe for the environment.

This approval is good news for all academic researchers interested in genetic modification of animals being bred for human consumption. The pioneering efforts of AquaBounty working with FDA regulatory authorities has demonstrated that with care, good science, and patience, innovative research in this somewhat controversial field can be taken from the laboratory bench to the market place.

William Muir, Professor Genetics, Department of Animal Sciences, Purdue University

I view the announcement of the FDA to approve the AquaBounty GE salmon for production in

land based system as a huge win-win for the environment, consumers, and the process! The scientific review is clear, there is no credible evidence that these fish are a risk to either human health or the environment. In contrast, the current practice of using wild caught salmon as a food source is not sustainable, our oceans are over fished. This development provides a safe and sustainable alternative. Further, this opens the door for the use of biotechnology as a tool to improve US food production in other species and in other ways to help feed a growing population. This GE technology has been on hold for over a decade waiting for confirmation that the process works, i.e. that the FDA can regulate product of biotechnology through use a rigorous scientific method or be constrained by political considerations. The answer is now clear, the process works, and all sectors will benefit.

Alison Van Eenennaam, Animal Geneticist in the Department of Animal Science at the University of California, Davis

Five years ago FDA scientists determined that the food from AquAdvantage salmon was 'as safe as food from conventional salmon' and that the proposed physical, biological and genetic confinement of the fish in the highlands of Panama posed minimal environmental risk. The unexplained five year delay in the FDA's regulatory decision regarding the AquAdvantage was unprecedented and today's decision is long overdue.

Eric Hallerman, Professor of Fish Conservation, Virginia Polytechnic Institute and State University (Virginia Tech)

This approval follows extensive review of food safety and environmental safety under the authority of the U.S. Food, Drug and Cosmetics Act. The action allows pilot-scale production at these specific facilities, which will be critical for quantifying the economics of production and the efficacy of confinement. Yet, the significance of the action is that it marks the first approval globally for production of genetically modified animals for purposes of food production and sale.

Today's action is significant for another reason, as FDA also announced draft guidance on the voluntary labelling of food derived from the product. Much controversy has focused on whether and how foods derived from biotechnology should be labelled. While studies have shown that salmon products derived from the AquAdvantage salmon are no different from those derived from conventional production, some consumers have argued for a 'right to know' how food products were produced.

J. Andrew DeWoody, Professor of Genetics and University Faculty Scholar, Purdue University

I see no reason to worry about human health effects and apparently neither does the FDA. However, I've always had concerns about the potential environmental effects should these GE fish escape into the wild because of their potential impact on native gene pools. That said, I was pleased to learn that the GE fish will be sterile, landlocked, and surrounded by multiple physical barriers. The onus now falls on AquaBounty to maintain their physical facilities and on regulatory agencies to continually monitor the integrity of these safety measures into the

foreseeable future, because U.S. waters have been negatively impacted by other species (such as carp) that escaped from containment ponds.

<u>Mark Abrahams</u>, Dean of Science & Professor, Department of Biology / Ocean Sciences, Memorial University of Newfoundland:

In my opinion, the review process undertaken by the FDA has been extremely thorough so I think it reasonable to assume that the conclusions they have drawn and the recommendations they have made are well supported by the evidence. From that perspective there is no evidence that these fish pose a risk to human health but time will tell whether they will be accepted by consumers.

Rex Dunham, Professor, School of Fisheries, Aquaculture and Aquatic Sciences, Auburn University

This ruling is important to make aquaculture more productive and efficient. Technologies such as this are important as the population of our planet continues to grow, and requires more protein with increasing demand for fish. It is important to be able to increase production and efficiency using as small a footprint as possible, and genetic engineering is an important tool to accomplish this. From an economic standpoint, it is inevitable that other countries will implement this technology and it is important for the US and North America to remain competitive. This is actually another food safety positive for Americans as little of our imported fish is inspected and often contains unhealthy compounds. Utilizing technologies that reduce imports increases the food safety for Americans.

Environmentally, I also feel that this is positive, as proper implementation of this technology will help reduce the pressure on wild populations of fish. Companion technologies will eventually and actually help us to protect natural populations from domesticated fish in general as well as exotic species, hybrids and transgenics, making aquaculture more environmentally friendly. It is important to proceed cautiously and responsibly, so the sterilization is an important aspect. The available good scientific data indicates that growth hormone transgenic fish would not be competitive in the natural environment. However, they should be sterilized, as AquaBounty is implementing, to ensure another layer of safety.

Mart Gross, Professor, Department of Ecology and Evolutionary Biology, University of Toronto

I believe this is a historic decision for the future of human agriculture.

First, it recognizes that the GMO technology used with the Atlantic salmon is part of the 10,000 year practice of genetic manipulation including artificial selection and artificial hybridization that has made food abundant and sustained a growing human population. It signals that GMO production is about as natural as anything else done in agriculture to develop improved strains.

...the decision shows that the important pressure from environmental groups to meet ecological concerns can be incorporated into decision making, and that there is a role for concern about the environment in deciding how and when modern technology will be applied in agriculture. Thus the efforts of many environmentalists have been successful: the decision was delayed until more information about environmental impact was analyzed and significant environmental protections were incorporated. I believe that it is unlikely that wild fish populations are at risk if enforcement of the rules is followed.

Finally, in the Anthropocene the use of GMO production has its place and the FDA's decision recognizes and supports the use of science for human progression.

Additional reactions from scientists in the United Kingdom are available from the Science Media Centre. A selection is provided below. Please see the <u>website</u> for full quotes and declared interest statements from the scientists.

Bruce Whitelaw, Professor of Animal Biotechnology, Roslin Institute at the University of Edinburgh

The announcement today that the first transgenic animal can enter our food chain has been a long time coming. AquaBounty have successfully navigated through a wealth of challenges – political, financial, regulatory, scientific – all under acute public scrutiny, to arrive at this point. Now it is up to the market to determine how successful this product will be and what contribution it will make to our society. In addition, this announcement signals that such products can be produced safely in our environment and are considered likely to contribute to society's needs. Many will watch in keen anticipation for further successes with genetic engineering technologies.

<u>Prof. Helen Sang</u>, Personal Chair in Vertebrate Molecular Development, Roslin Institute at the University of Edinburgh

AquaBounty has been the first company to attempt to commercialise a genetically-modified animal for food. They developed a form of salmon that grows faster and is much more efficient in the conversion of feed to protein, compared to conventional salmon. The company has provided extensive information for evaluation of the safety of the salmon as a food and of the potential environmental risks. These data have been made freely available and scrutinised by regulators and external groups. It is very encouraging to see that the process of evaluating risks has at last been completed and that the use of genetic modification for breed

improvement can be progressed after careful evaluation of risks. Genetic modification technologies provide additional tools for breed improvement that have potential to contribute to sustainable and efficient production of animals for food, an increasing challenge for society.