

September 28, 2010

WASHINGTON, D.C. (September 28, 2010) -- Congressman Peter DeFazio (D-OR), Dennis Kucinich (D-OH), Mike Thompson (D-CA) led 23 Members of Congress in asking the U.S. Food and Drug Administration (FDA) to halt the approval process of AquaBounty genetically engineered (GE) salmon in a letter to FDA Commissioner, Margaret Hamburg.

The letter asserts that the FDA should not approve the first GE animal intended for human consumption because of a flawed review process. GE fish pose serious risks to wild populations of fish since millions of farmed fish have escaped into the wild.

The House letter lays out four serious concerns to the FDA: the review method being used is seriously deficient; there is a lack of data on whether the GE salmon is safe to eat; irreversible environmental effects are likely; and the FDA is sidestepping its responsibility to consumers by not requiring a label.

“The FDA’s hastily completed approval process puts American consumers and the environment at risk. GE salmon could be devastating to fishing and coastal communities, our food source, and already depleted wild salmon populations. The FDA should put the interests and safety of American families and our ocean resources above special interests,” DeFazio said.

“We cannot allow the FDA to rush to rubber stamp the approval of a genetically engineered animal before we know what will happen. The risks for our health and for the environment are enormous and irreversible. And once these GE animals are out there, there is no going back,” said Kucinich, who has introduced right to know legislation that would provide a consumer oriented framework for GE plants and animals that includes labeling for GE foods.

“FDA’s move to approve GE salmon threatens fishing families across the country, native wild salmon, as well as the millions of federal and state dollars invested to restore salmon populations,” said Thompson. “Given the current lack of information, threats to human health, the environment and the livelihood of hard working fishing families, it would be irresponsible for the FDA to approve GE salmon.”

The letter calls on the FDA to suspend the approval of GE salmon until the agency thoroughly examines and addresses the serious flaws with FDA's approval process and includes greater public input and scientific data.

[Click here to see a list of organizations supporting the DeFazio/Kucinich/Thompson letter](#)

The full text of the letter is below:

Commissioner Margaret Hamburg, M.D.

U.S. Food and Drug Administration

10903 New Hampshire Ave.

Silver Spring, MD 20993

Dear Commissioner Hamburg:

We have serious concerns regarding the recent Food and Drug Administration (FDA) process for review and possible approval of the AquaBounty Technologies' genetically engineered (GE) 'AquAdvantage' salmon for sale to consumers. The FDA approval process is inadequate and sets a dangerous precedent: the environmental review is flawed, and the consumer's right to know is ignored.

The Approval Process is Inadequate

The FDA's decision on whether to approve the first GE animal for human consumption will have far-reaching consequences and will influence other pending GE applications awaiting FDA approval. However, the FDA currently has no adequate means to assess the AquaAdvantage salmon as a GE animal intended as a human food product. Rather than developing an appropriate evaluation method, the FDA is currently proceeding to approve the GE fish using its process for reviewing a new drug meant for animals.

While AquaBounty filed a New Animal Drug application for AquaAdvantage salmon with FDA in 2001, the Environmental Assessment compiled by AquaBounty for the FDA is inherently flawed and does not take into account the full and broad range of impacts the approval of the GE salmon could have on the environment. The FDA should have initiated a full Environmental Impact Statement (EIS) and consulted with other federal agencies responsible for managing federally listed Endangered Species.

The FDA's decision not to disclose to the public any data relating to environmental, food safety, or efficacy concerns until 10 working days before the public Veterinary Medicine Advisory Committee meeting strongly contradicts the agency's claim of commitment to transparency. The public's skepticism of the FDA's review process for the gene-spliced salmon is magnified by the fact that according to the FDA's 'Advisory Committees' website, it is commonplace to schedule meetings at least two months after their announcement in the Federal Register. However, in this case, the public was given less than a one month notice.

Ultimately, the data the FDA provided to the public on food safety is altogether deficient because it is produced by the very corporation seeking approval for its product; not by the FDA or an independent body. Among the most egregious flaws with the data released is that the sample sizes in the company-provided studies on changes in the morphology of the new GE salmon as well as possible allergic reactions, were only 12. These small sample sizes are completely inadequate to use as a basis for a substantive evaluation of the full range of potential health and safety ramifications of releasing these fish for human consumption, especially since they are likely to be raised in a large-scale commercial setting by the tens of thousands and elevated levels of PCBs and dioxin are already documented in farm raised fish.

The GE Salmon Raise Significant Environmental Concerns

Genetically engineered fish could pose serious risks to wild populations of fish such as the Atlantic salmon, as well as the Coho and Chinook salmon (numerous species of which are currently listed under the Endangered Species Act of 1973). Approval of this GE salmon, especially in light of plans to raise them at an egg hatchery facility on Prince Edward Island, Canada, could jeopardize all remaining wild Atlantic salmon populations. Despite AquaBounty's claims that its AquaAdvantage salmon poses "less risk" to wild salmon populations due to induced sterility, the company acknowledges that 5% of its fish could remain fertile and would therefore be able to mate with wild populations.

We believe any approval of GE salmon could represent a serious threat to the survival of native salmon populations. Each year, millions of farmed salmon escape from open-water net pens, outcompeting wild populations for resources and straining ecosystems. For example, a GE salmon that grows twice as fast as natural salmon would reach full size more quickly and easily outcompete natural salmon for food, territory, and reproductive access. Even if grown in contained, land-based facilities, the "farming" of fish raises serious environmental and economic risks, and even indoor ponds typically recirculate water into the environment, providing an escape route for fish or eggs. Research published in the Proceedings of the National Academy of Sciences notes that a release of just sixty GE fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations.

The FDA must not ignore the lessons from GE crops. Unintended genetic contamination of conventional soybean crops by GE soybeans has been well-documented. The spread and breeding of different varieties of GE canola into areas far from where they were experimentally planted has also been proven. It would now be nearly impossible to eradicate the GE varieties of the crops because of their uncontrollable proliferation. During the approval process, the seed manufacturer offered unenforceable assurances of seed containment that are similar to those being offered by AquaBounty. We must learn from our mistakes instead of repeating them.

We object to a federal agency ignoring major environmental issues by exporting the questionable process overseas. According to the application submitted to the FDA, AquaBounty will raise the engineered eggs in a facility on Prince Edward Island in Canada, and then ship those fish to a land-based facility in Panama where the fish will be grown and processed before being shipped worldwide for commercial sale. We are troubled by reports that the FDA plans to approve the fish if they are raised outside the U.S., effectively encouraging AquaBounty to dump expected environmental problems onto other countries. Doing so sidesteps the FDA's responsibility to protect public health.

The FDA's Stance on Labeling Undermines Consumer Choice

If the FDA chooses to ignore the advice of scientific experts and the will of the public by choosing to approve the genetically altered salmon for public consumption, it must reverse its position that the GE salmon is not “materially” different from natural salmon and require that the product bear a label. A label should not be a substitute for comprehensive risk assessment as Americans have the right to know what they are eating, especially when there are so many unanswered questions about the health effects of consumption and about the impact on the natural salmon species. An informed consumer is the last line of defense against the virtually unchecked ability by the sellers and producers to manipulate the market. The buyer cannot beware if the buyer is not informed.

The FDA’s process for review and potential approval of the first genetically engineered animal to be mass-marketed to American consumers has so far raised many more troubling questions than answers. We strongly urge you to immediately suspend your approval process until you thoroughly examine and address the very serious flaws with your process including the need for greater public input and independent scientific data.

Sincerely,

Peter DeFazio

Dennis Kucinich

Mike Thompson

George Miller

Peter Welch

Lynn Woolsey

Jackie Speier

Barbara Lee

Sam Farr

Jerrold Nadler

John Garamendi

James Moran

David Wu

Maurice Hinchey

Earl Blumenauer

Betty McCollum

Madeleine Bordallo

Raul Grijalva

Dennis Moore

Donna Christensen

Lloyd Doggett

Lois Capps

Louise Slaughter