



Franciscan Action Network

Transforming the World in the Spirit of St. Francis and St. Clare

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Docket No. FDA-2010-N-0385
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam,

Inspired by the witness of Saints Francis and Clare of Assisi, Franciscans are committed to the care of all members of creation, with special regard for the dignity of the human person at every stage of life. Given these values, the Franciscan Action Network (FAN), comprised of 47 institutional members and 4,000 individual members, has grave concerns about the FDA's pending approval of genetically engineered AquAdvantage salmon. **FAN opposes the approval of this salmon at this time; in the case of FDA approval, FAN strongly urges clear, mandatory labeling of all uses of this salmon.**

In 2008, the FDA released Draft Guidance for Industry #187: Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs via the Docket's Division. In the report, the FDA admits that the "moral, ethical, and socioeconomic issues outlined above do not fall within the scope of the guidance. It is FDA's intent, however, that the regulatory approach described in the guidance will provide a predictable science-based framework that will ensure the safety and safe use of GE animals." The report also states that the majority of comments submitted oppose genetically modified food.

The moral, ethical, and socioeconomic issues must be addressed before the FDA rules on AquAdvantage salmon. On moral grounds, the FDA must consider that a majority of the public opposes genetically modified food. Of ethical concern, the FDA Center for Veterinary Medicine rejected the analysis of the data on AquAdvantage salmon. The sample size used for the analysis was too small for accurate conclusions as it pertained to malformations from the additional DNA material from a different salmonoid species. The genetically engineered fish could have a higher rate of jaw erosion and increased prevalence of focal inflammation. It is unethical to approve the AquAdvantage Salmon without verifying accurately that the fish will not be exposed to higher rates of serious malformations due to genetic alterations of the species. In socioeconomic terms, the FDA has failed to address the potential impact of AquAdvantage salmon on the small salmon fishing businesses that are part of the culture in the North West, especially the Native American community that is already impoverished.

The FDA must also address all environmental impacts to the highest degree possible. FDA approval of AquAdvantage salmon could lead to major environmental issues in Canada and Panama. The United States must stop outsourcing its environmental impacts to other countries with less stringent environmental laws. This is an injustice to the impoverished of the world that do not have the power to engage corporations that degrade the environment.

Several items of environmental concern include:

- 1) The egg manufacturing site on Prince Edward Island uses high levels of chlorine to kill any eggs that might escape from filters. The high levels of chlorine in the water must be treated prior to the discharge of water into nearby waterways. The environmental impacts would be great in the case of inadequate water treatment.
- 2) At the grow-out site in Panama, nitrite levels and other potential contaminants must be removed adequately from the effluent and treated in an area where these contaminants cannot reenter nearby water bodies.
- 3) If approved, all measures should be taken to prohibit escape of the genetically modified salmon. Our ecosystems are filled with plants, animals and insects that have escaped their containments even when preventative measures meet U.S. standards. Our ecosystems are bombarded with invasive species, as well as decreased water, air, and soil quality; an additional threat such as from the AquAdvantage salmon puts these ecosystems in danger. If the genetically modified salmon escape in waters where they could prosper, ecological impacts would be great and would include decrease in biodiversity and instability of the food chain. If some genetically modified salmon escaped that were not triploid, the devastation to the salmon populations would be grave to the health of the ecosystem as well as to the multi-million dollar salmon industry.

In addition, genetically engineered Atlantic salmon should be regarded as materially different from farm-raised Atlantic salmon. There is some doubt that an AquAdvantage salmon and a farm-raised Atlantic salmon are identical other than growth rates. The complexity of the biology of a living creature necessitates an adequate study to verify that the nutritional levels and proteins that cause allergic reactions would be the same in both the AquAdvantage salmon and farm-raised Atlantic salmon.

In light of the above concerns, proper labeling of the AquAdvantage salmon in the event of approval should be required. With a majority of individuals opposed to genetically modified foods, the sale of the fish without labeling is unjust. Allowing the AquAdvantage salmon into the market for human consumption before knowing the full extent of the effects on human health is not ethical. Human persons should never be guinea pigs without their knowledge and informed consent. Genetically engineered salmon is not the same as farm-raised Atlantic salmon and should be treated accordingly. Many persons oppose genetically modified foods for religious reasons. Failure to label genetically modified food violates religious freedom, particularly in relation to kosher foods.

Due to the moral, ethical, socioeconomic, environmental, and human health concerns associated with the AquAdvantage salmon, FAN opposes approval of the AquAdvantage salmon at this time, urges the FDA to complete further analysis, and demands labeling of any genetically engineered animals that do receive FDA approval.

Thank you for your consideration.

Sincerely,

Fr. Larry Janezic, OFM
Interim Executive Director
Franciscan Action Network

Sr. Caryn Crook, OSF
Action Commissioner
Franciscan Action Network