

Alaska Trollers Association

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Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm 1061
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RE: Docket No. FDA-2010-N-0385 Labeling of AquAdvantage genetically engineered salmon

To Whom It May Concern:

The Alaska Trollers Association (ATA) represents hook and line salmon fishermen operating off the coast of Alaska, where our salmon resource is healthy and our fisheries are well-managed. Our members take quite seriously the job of delivering a wholesome, high quality product to market and are firmly committed to sound science underpinning the decisions made regarding the food people eat.

ATA strongly opposes the genetic engineering of seafood. For the record, ATA requests FDA reconsider its basis and rationale for approving GE animals for consumption and conduct the appropriate studies to prove the claim that this product, and how it will be raised, will ultimately be safe for human health and the environment.

FDA does not appear to have conducted the necessary science, and has not allowed the public access to adequate information, time, and forums to have meaningful input into the issue, yet all signals suggests that the product will be approved. Therefore we are also compelled to say that our members strongly support mandatory labeling to distinguish GE salmon if it ever should reach the marketplace.

Fishermen are particularly alarmed by the cavalier approach the nation has taken on the issue of genetically engineered foodstuffs. One quickly called hearing on the East Coast, during fishing season, where participation was limited – with small amounts of information released just days before the hearing -- does not amount to an acceptable public process.

The failure of our country to vision a transparent approval process and strict regulatory program for genetically engineered animals/foods is shameful. FDA's own published, non-binding, *Guidance for Industry Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* includes this qualifier:

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Does this mean that FDA has no intention of regulating the corporations who will hold valuable patents to GE animals that likely have a ready market worth untold amounts of money? As small businessmen who operate under significant international, national, and state regulatory burdens in

order to produce healthy food for the nation and world, it is our hope that FDA, and our nation's policymakers, will further clarify their intent in this regard.

In reading through FDA's documents it was interesting to see the emphasis on the need to prevent mislabeling of a product. We completely agree and believe that identifying GE salmon with a label would simply be a matter of truth in advertising.

How could an Atlantic salmon – essentially a sea-run trout – that is gene spliced with a true Pacific salmon and a non-salmonid -- be considered anything BUT genetically engineered? Once you allow it to be modified, it becomes different and the level of risk changes, period. Your own scientists pointed that out during the 1990s debate on FDA's policy on GE plants. It stands to reason that GE salmon should bear a label revealing the very basic fact that it is engineered, simply so the consumer can make an informed choice.

While FDA and industry backgrounders try to calm the public by explaining that these fish will be just like any other Atlantic salmon, that's simply not true. Wild Atlantic salmon are not genetically modified. Farmed Atlantic salmon are selectively bred, but not yet modified. Engineered salmon certainly aren't like any other salmon, yet the public could easily become confused about which fish are modified and which are not, and opt out of salmon altogether. Those of us in the seafood industry know far too well that there exists a great deal of confusion when it comes to the seafood market. Our industry could bear a direct cost if this happens.

Most importantly, how are you so certain that the salmon, chemically, is the same as wild Atlantic salmon, at the minutest levels? Where are the rigorous, published studies to back that up? What about over generations of breeding and under different conditions and production rules? Will biomarkers have any affect now, or in the future, on the composition of the fish (not to mention the health risk)?

It is already well documented that when it comes to safe food production and GE, the jury is out amongst the scientific community. FDA's own veterinary advisory committee suggested that the science presented was incomplete, particularly if these fish will be raised outside of the two test farms and under full scale production scenarios.

For many years, a variety of scientists – from federal agency staff, to academics, and farm and fisheries professionals – have questioned whether or not genetically modified animals and plants are safe. At minimum, questions regarding toxicity and allergens do not appear to have been thoroughly vetted and resolved. FDA's own regulations mandate that new substances be subjected to peer reviewed studies prior to determining them 'safe' (21 CFR Sec. 170.30 (a-b)). How can FDA move ahead without adequate science?

Add to that the complication of farmed GE salmon, which may be fed some combination of GE foods and be subjected to a variety of pharmaceuticals and pesticides during the culture phase. Many of these farms, including the two GE test farms, aren't even in the US and all countries and states are likely to be governed by a variety of conflicting laws. How will modified animals respond to various foods, chemicals, and conditions? How can FDA be sure it and other agencies can foresee, monitor, and control any changes in toxicity, or the development of new metabolites that may result from genetic engineering of animals across generations? Will inspections of foreign and domestically farmed seafood have to be increased to monitor such issues? There is a raft of potential dangers to the environment should these fish escape, and even if they don't, since no one has analyzed or discussed with the public the impact of large, production scale closed containment. Where will the funding for this, and more, come from?

Who will be doing the necessary research, monitoring, and enforcement – FDA? And, where are the appropriate human and environmental and economic risk analyses? Previous statements from FDA give us little hope and make us wonder what other agency, if any, will take on this role? In 1998 FDA stated that it had, *...not found it necessary to conduct comprehensive scientific reviews of foods derived from bioengineered plants*. Your policies haven't changed much since that time. FDA has also claimed that it has no public process obligation under NEPA for this issue, nor does it have labeling authority, since it is not regulating GE salmon. So, who is in charge of exploring this issue in a more meaningful, scientific, and bioethical way? Why should the animal be approved before that's done?

It appears that FDA and the nation are more than willing to place the burden of proving or disproving food safety on either a multi-national industry that stands to gain financially from GE salmon; or the small seafood industry that stands to lose by being overwhelmed by increased farmed production or consumer fears about salmon; or perhaps even the end consumer themselves.

Labeling of GE foods boils down to one of the most fundamental of human needs and rights –access to wholesome foods and information about how they are produced. While the GE salmon may ultimately prove safe and wholesome, there is no doubt that it is unlike any other salmon available today. It is a processed food at its most basic level, and should be labeled accordingly, particularly when no independent science exists to prove that it is safe. Such a label is not misleading, nor is it in any way false, it is simply telling the consumer the truth about a type of food that until just a few years ago was inconceivable. People should have the right to choose!

While FDA might not currently believe that GE salmon is markedly different, we have to wonder what other countries might think, and why, since so many of them have strongly disagreed with the US on this and other policy questions swirling around GE foods. While current trade agreements and the tendency to lean towards agency discretion may be forcing the hand of the courts and nations, there is obviously no consensus amongst scientists on the matter of GE food and policy. In the court of public appeal, we suggest most people do believe GE salmon is different, and most aren't certain it's safe, therefore, it should be labeled.

Furthermore, there are many reasons beyond food safety that people may choose to avoid GE foods. Social, cultural, religious, and other factors all have a role in food selection. Respect for those choices can also be accomplished through labeling.

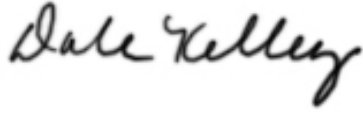
While the use of genetic engineering may be appropriate and beneficial for a variety of purposes, such as medical advancement, it does not appear that the science exists to underpin decisions with regard to what, if any, genetically engineered foods belong in the food chain and environment.

Additionally, a clearly articulated set of publicly negotiated policies, along with relevant statutory, regulatory, research, monitoring, enforcement, and remediation programs do not even appear to be in development.

Until such time as the public is adequately brought into the debate; appropriate, peer reviewed, science shows genetically engineered salmon to be safe for human health and the environment; and, the appropriate statutory and regulatory sideboards are in place, ATA does not believe FDA should issue its approval for GE seafood products. If FDA goes against what appears to be the will of a vast majority of Americans, then labeling of any GE seafood product should be mandatory.

Thank you for considering ATA's point of view. Please let me know if I can answer questions on ATA's position or be of assistance to FDA as you work through this matter.

Best regards,

A handwritten signature in cursive script that reads "Dale Kelley". The signature is written in dark ink and is positioned above the printed name and title.

Dale Kelley
Executive Director