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September 9, 2010

Center for Veterinary Medicine (HFV3)
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

RE: **Docket No. FDA-2010-N-0001 and Docket No. FDA-2010-N-0385**, VMAC
Meeting on approval of AquAdvantage genetically engineered salmon; Labeling
of AquAdvantage genetically engineered salmon

The undersigned members of the food industry, including chefs, restaurants, grocers, and food companies urge the Food and Drug Administration (FDA) *not to approve genetically engineered (GE), AquAdvantage salmon for commercial use.*

This transgenic salmon is the first GE animal intended for food, yet the human health impacts of eating these GE fish are completely unknown. These GE fish also pose unacceptable risks to wild salmon and the marine environment. GE salmon must not be approved until and unless further study indicates that it is safe for consumers, native salmon populations, and the environment. Additionally, we are alarmed that the FDA may not require labeling of GE salmon should it be approved. Mandatory labeling is the only way to protect the public's right to know about these unprecedented and material changes to our food.

As food providers, we are the first line of defense for consumers. We are expected to provide the highest quality food possible, and to respond to consumers' desires. *In sum, we advocate sustainable, safe, and nutritious food and therefore have no desire to purchase, sell, or serve GE salmon.*

Greater Use of Antibiotics

Some of our concerns include the potential toxicity, allergenic effects, and diseases posed by the commercialization of transgenic fish. While data on human health impacts of GE fish is sparse, especially because the FDA has yet to share the data it has reviewed, there is cause for serious concern. For example, the routine use of antibiotics to control diseases often found in farm-raised fish can impact human health. Some research

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suggests that transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities¹. Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish. Already farmed salmon are given more antibiotics by weight than any other livestock. Eating farmed fish treated with antibiotics could be harmful to humans. Indeed, some antibiotics are toxic and can even cause fatal allergic reactions².

Additionally, the use of antibiotics in aquaculture also exacerbates the significant problem of antibiotic resistance in humans (as well as animals). The potential human health concerns connected with the use of antibiotics in aquaculture, including the unique role transgenic fish may play in exacerbating such use, must be fully assessed by the FDA.

Effects on Wild Salmon Population

We are also concerned that GE fish pose serious risks to wild populations of fish, and to consumers who rely on them for healthy nutrition. Each year millions of farmed salmon escape from net pens and outcompete wild populations for resources and straining ecosystems. Even in land-based facilities salmon have the ability to escape and will be virtually impossible to recover. We believe any approval of GE salmon would represent a serious threat to the survival of native salmon populations, many of which have already suffered severe declines related to salmon farms and other man-made impacts.

Escaped GE salmon can pose an additional threat – genetic pollution resulting from what scientists call the “Trojan gene” effect. Research published in the *Proceedings of the National Academy of Sciences* notes that a release of only 60 GE fish into a wild population of 60,000 would lead to the extinction of the wild population in less than 40 fish generations.

Labeling Issue

As already noted, we are greatly concerned that the FDA may not require the labeling of GE salmon if it is approved for the consumer market. It is totally unacceptable for GE fish not to be labeled if approved for commercial use. Our customers tell us that sustainable, safe seafood is of utmost importance to them and in order for us to maintain our professional and personal integrity, it is vital that we have full information on foods that we sell and/or serve. Should the FDA approve GE salmon despite our strong opposition, we unequivocally demand that such fish be labeled.

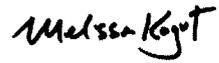
We know there is a great appetite for salmon, but the solution is not to “farm” GE versions; *the solution is to work to bring our wild salmon populations back.*

¹ William Muir et al . Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis, 96 PNAS 13853-13856, at 13853 (Nov. 23, 1999).

² Rebecca Goldberg and Tracy Triplett. *Murky Waters: The Environmental Effects of Aquaculture in the U.S.* (p 44). Environmental Defense Fund (1997).

We strongly oppose FDA approval of GE salmon. Should FDA decide to approve the AquAdvantage GE salmon despite overwhelming consumer opposition and potential threats to the environment, human health, and native salmon populations, we urge that clear, mandatory labeling be unconditional.

Sincerely,

A handwritten signature in black ink that reads "Melissa Kogut". The signature is written in a cursive, slightly slanted style.

Melissa Kogut
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