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Jeffrey Shuren  
Associate Commissioner for Policy and Planning  
Food and Drug Administration  
7500 Standish Pl.  
Rockville, MD 20855

Re: Draft Comments on FDA GE Animal Guidance: Threats from GE Fish

Dear Mr. Shuren,

Please accept this letter from the undersigned conservation, fishing, and consumer organizations on the recent *FDA Draft Guidance on Regulating Genetically Engineered (GE) Animals*. The guidance outlines how the Food and Drug Administration (FDA) plans to use its authority under the New Animal Drug Provisions of the Federal Food Drug and Cosmetic Act (FFDCA) to oversee GE animals, including GE or transgenic fish. Already, species of transgenic fish are being developed around the world; there is at least one pending before FDA for approval, a GE Atlantic salmon designed to grow as much as 10 to 30 times faster than normal salmon.

#### *Overview*

We strongly urge FDA not to approve any applications for transgenic fish because of the foreseeable potential negative impacts to human health, the environment, and fishing communities. These significant impacts are summarized below.

#### *Impacts from GE fish*

We are very concerned about the potential toxicity, allergenicity, and diseases posed by the commercialization of transgenic fish. For example, there are concerns that foreign growth hormones in transgenetic fish may increase production of other compounds such as insulin in the fish.<sup>i</sup> Additionally, FDA has recognized that a transgene cannot be “turned off” once it is inserted in the organism, and therefore it will have effects that are uncontrollable.<sup>ii</sup> Depending on where transgenes are inserted, they could also “affect the expression of other genes by disabling them or turning them on at an inappropriate time.”<sup>iii</sup> Furthermore, FDA has acknowledged that “[t]he incidental insertion of drug resistance genes from bacterial plasmids introduces further uncertainties as to food

safety.”<sup>iv</sup> These uncertainties and unique food safety concerns must be assessed in appropriate scientific studies and mandatory pre-market safety review.<sup>v</sup>

Further, the genetic engineering of food, including transgenic fish, creates two separate and serious health risks involving allergenicity. The first is that genetic engineering can transfer allergens from foods, which people know they are allergic, to foods that they think are safe. A study in the *New England Journal of Medicine* showed that when a gene from a Brazil nut was engineered into soybeans, people allergic to nuts had serious reactions to the engineered product.<sup>vi</sup> At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem. These foods could also be creating new allergic responses. Each genetic “cassette” being engineered into a fish species may contain a number of novel proteins (in the form of altered genes, genes from bacteria and viruses, marker systems, and vectors) which may have never been part of the human diet. Each of these numerous novel proteins could create an allergic response in some consumers.<sup>vii</sup>

Inserting the same transgenic “cassette” into a different part of the animal’s genome may have different effects on the animal and its meat. Accordingly, if the FDA approves a GE animal, it should approve only a particular species (not all salmon or trout) with a GE change at a particular site in the animals’ genome. No other species, or any animal with the same GE construct in a different location, should be approved without an additional application and additional testing supporting the application. Any fish resulting from GE experiments before FDA approval should be destroyed and not consumed by humans or animals.

FDA must also develop and mandate specific testing protocols to determine whether the use of antibiotics to control diseases often found in aquacultured transgenic fish may impact human health. Transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities because transgenic fish are identified as “macro-mutants” with a reduced ability to survive.<sup>viii</sup> Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish. The most common method of distributing antibiotics to farmed fish is through fish feed. As a result, antibiotics enter the environment through uneaten fish feed and feces. It is predicted that 75% of most antibiotics are lost in the environment.<sup>ix</sup> Consequently, these antibiotics accumulate in wild fish and shellfish that feed on the food and feces of farmed fish.<sup>x</sup> By eating farmed fish treated with antibiotics or even wild fish exposed to the antibiotics, humans will be ingesting antibiotics that may be harmful.<sup>xi</sup> Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.<sup>xii</sup> Finally, the use of antibiotics in aquaculture also exacerbates the significant problem of antibiotic resistant bacteria. 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 FDA.

In addition to these novel issues of food safety, the commercial introduction of transgenic fish poses significant and unprecedented potential risks to the environment. Although FDA has experience and authority to regulate food and drugs, the agency does not have

expertise in areas such as marine ecology. It is undisputed that, if allowed to be farmed in open water net pens, GE fish will escape. On average, 15% of farmed fish escape.<sup>xiii</sup> Unintended releases of transgenic fish into the world's waters may cause significant impacts to the environment and endangered species. Studies show that transgenic fish are more aggressive, eat more food, and will attract more mates than wild fish.<sup>xiv</sup> As a result, scientists predict that transgenic fish will cause some species to become extinct within only a few generations.<sup>xv</sup> Other research indicates that transgenic fish are less careful about avoiding predators and may not be able to endure the arduous migratory process.<sup>xvi</sup> As a result, transgenic fish would produce less fit offspring yet obtain a disproportionate share of the mates. Accordingly, species extinction may occur because of transgenic fish that slip out of ocean pens into the wild. There are 139 listed species of fish protected under the Endangered Species Act, including Atlantic salmon.<sup>xvii</sup> Allowing transgenic fish in ocean pens may significantly increase this number of listed species or cause the extinction of those already in danger. By out-competing wild fish and other endangered species for resources and habitat, transgenic fish will likely seriously disrupt ecosystems. Even if transgenic fish are required to be sterile, the reliability of the sterilization is not guaranteed for every fish.<sup>xviii</sup> These foreseeable, significant environmental impacts must be exhaustively and transparently studied, in compliance with the National Environmental Policy Act (NEPA) and the ESA, before the potential approval of the unprecedented growing of these animals in the wild. This would require the agency secure a Biological Opinion and draft an Environmental Impact Statement before the approval of any application for a transgenic fish.

Other unpredictable and egregious environmental consequences are also likely to occur as a result of the accidental introduction of these non-native species into the aquatic environment. Repeatedly, non-native organisms have caused harmful ecological disruptions. Introduction of diseases, increased pollution, and superior competition for wild fish for food and habitat are some of the ecological disruptions likely to be caused by transgenic fish. FDA must study all potential indirect and cumulative impacts to the environment.

FDA must also examine the intertwined foreseeable and significant potential socioeconomic impacts to fishing communities and businesses. Many families, from the coast of Alaska to the Gulf of Mexico, depend on healthy wild fish stocks and their habitat for their livelihoods. Their way of life will be threatened by the farming of GE fish.

### *Conclusion*

Even with these foreseeable negative impacts, we are concerned that FDA has recently ignored the interests of the public. Should FDA decide to unjustifiably allow the use of GE animals, we urge FDA to adopt the most rigorous and transparent pre-market regulatory review process it can. This would require that FDA work with other agencies to sponsor new legislation, which would enable the federal government to better address the novel health and environmental issues presented by GE animals such as transgenic

fish. Such legislation should ban the use of transgenics in open systems from which they could escape into the environment. Public scrutiny for and during any potential approvals in closed systems should be paramount. Potential conflicts of interests of reviewers must be fully disclosed.

In the absence of new legislation or in the interim, potential transgenic fish producers must be required to complete a New Animal Drug Application (NADA) and demonstrate the safety and effectiveness of these fish. Any such demonstration of safety must be shown through substantial evidence that is made available to the public, unlike in animal drug tests. The FDA approval of cloning with scant evidence (the largest study of the safety of milk from cloned cows included samples from only 16 animals) makes all the more important that the FDA demonstrate that it is actually applying tests at least as stringent as those for other animal ‘drugs’ and is not inventing a new weaker standard for GE animals or failing to take a hard look at their impacts. Moreover the agency must act to fully inform the public by requiring the mandatory labeling of all transgenic fish of species likely to be consumed by humans, their pets, or other food fish, poultry and livestock. In addition, any GE fish intended as food must also be regulated by FDA as food additives to fully analyze questions of food safety. In the case of the GE salmon, genes from other species never before found in salmon will be in every cell of the animal. FDA must develop and mandate specific testing protocols to determine whether there are toxicity, allergenicity, mutagenicity and other unintended and unique effects from GE fish that may affect human health. These tests should be conducted through at least four generations of animals to determine whether there are unintended effects passed down to subsequent generations.

Not approving any transgenic fish is our preferred alternative and, we believe, the only justified conclusion. However, if the agency does succumb to pressure to approve use of transgenic fish, it should **at a minimum** not approve transgenetic fish if they are going to be used in net pens or other structures, such as cages, where fish can escape and disease can threaten the environment, wild fish populations and those communities that depend on them. Instead, if FDA feels it must approve any transgenic fish, approval should only be granted for fish that are grown in enclosed land based recirculating systems. These systems are highly controllable and because these systems are enclosed and on land, the concerns that transgenic fish will escape or cause environmental damage is virtually eliminated, as long as effluent is recovered and treated. FDA should carefully evaluate and closely monitor this alternative as well.

We urge FDA and other federal agencies with jurisdiction over this subject to ban the farming of GE fish in open water systems because of their foreseeable dangers to health, the environment and fishing communities. In addition, FDA must establish a rigorous and transparent regulatory framework that requires mandatory pre-market safety testing, full pre-market environmental review of all impacts, and mandatory labeling of all transgenic fish should commercialization occur.

Sincerely,

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<sup>i</sup> Carol Kaesuk Yook, Altered Salmon Leading Way To Dinner Plates, but Rules Lag, N.Y. Times, May 1, 2000, at A1, A20; See Royal Society of Canada, Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, 89 (Jan. 2001)(explaining that the growth hormone can affect the production of insulin and catecholamines and the size of the pituitary gland of transgenic coho salmon is reported to be reduced by 50- 83%).

<sup>ii</sup> FDA,14 FDA Veterinarian, 1, 11 (May/June 1999), *available at* <http://www.fda.gov/cvm/fda/infores/fdavet/1999/may.htm>.

<sup>iii</sup> Id.; Elements of Precaution, supra note 1, at 87-89 (explaining that unintended genetic changes in fish is the rule rather than the exception and includes changes in enzyme activity, gross anatomy, behavior and hormonal activity).

<sup>iv</sup> Id.

<sup>v</sup> See 40 C.F.R. § 1508.27(b)(2)(5).

<sup>vi</sup> Nordlee, Julie A., MS; *et al.* Identification Of A Brazil-Nut Allergen in Transgenic Soybeans, 334 New Eng. J. Med. 726-728 (1996).

<sup>vii</sup> Hansen, Michael, Ph.D. & Jean Halloran, Jeopardizing the Future? Genetic Engineering, Food and the Environment, PAN AP Safe Food Campaign (1998).

<sup>viii</sup> 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).

<sup>ix</sup> Rebecca Goldberg and Tracy Triplett, Murky Waters: Environmental Effects of Aquaculture in the U.S., Environmental Defense Fund at 44 (1997) [hereinafter "Murky Waters"].

<sup>x</sup> Id.

<sup>xi</sup> Id.

<sup>xii</sup> Id.

<sup>xiii</sup> Eric Hallerman & Anne Kapuscinski, Ecological Implications of Using Transgenic Fishes in Aquaculture, 194 ICES Mar. Sci. Symp. 56, 59 (1992)

<sup>xiv</sup> William M. Muir and Richard D. Howard, Possible ecological risks of transgenic organism release when transgenes affect mating success: Sexual selection and the Trojan gene hypothesis, 96 PNAS 13853-13856 (Nov. 23, 1999)[hereinafter "Trojan gene hypothesis"].

<sup>xv</sup> Id.

<sup>xvi</sup> RH Devlin, *et al.* Increased ability to compete for food by growth hormone-transgenic coho salmon *Oncorhynchus kisutch*, 30 Aquaculture Research 479-482 (1999)

<sup>xvii</sup> See <http://www.fws.gov/endangered/wildlife.html#Species>

<sup>xviii</sup> See generally, Anne Kapuscinski and Eric Hallerman, Transgenic Fish and Public Policy: Anticipating Environmental Impacts of Transgenic Fish, 15 Fisheries 2-11 (Jan - Feb 1990).