Sent via email to wilson.sharon@epa.gov

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Re: General Permits to Cover Aquaculture Facilities and Fish Processors in Idaho

Summary

Environmental Protection Agency ("EPA") must prohibit the discharge or release of non-native fish, including genetically engineered fish, into the waters of the United States. Specifically, in considering, denying, and/or granting the proposed general permits for aquaculture facilities and fish processors associated with aquaculture facilities, EPA should expressly consider transgenic fish a pollutant and prohibit their use. Additionally, all permits should require that permitted facilities implement practices to prevent fish escape and monitor and report escaped fish.

EPA's Legal Authority

The purpose of the Clean Water Act ("CWA") is to "restore and maintain the chemical, physical, and biological integrity of the nation's waters."[1] To achieve this purpose, the discharge of "any pollutant" into navigable waters is prohibited.[2] The only exemption is for facilities that obtain a national pollutant discharge elimination system ("NPDES") permit from EPA which limits the amount of pollutants that can be discharged from a facility and imposes other conditions such as monitoring and best management practices to protect the water quality.[3]

[1] 33 U.S.C. § 1251(a).
[2] 33 U.S.C. § 1311(a).
[3] *See* 33 U.S.C. § 1342 (A)(1)(2).

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Non-native fish and genetically engineered fish fit the category of "pollutants" under the CWA:

> The term "pollutant" means dredged spoil, solid waste, incinerator residue, sewage, garbage, sewage sludge, munitions, chemical wastes, *biological materials*, radioactive materials, heat, wrecked or discarded equipment, rock, sand, cellar dirt and industrial, municipal, and agricultural waste discharged into water.[4]

In *United States Public Interest Research Group v. Atlantic Salmon of Maine*, the court explained that "[f]ish that do not naturally occur in the water, such as non-North American salmon, fall within the term 'biological material' and are therefore pollutants under the Act."[5]

The Environmental Impacts of Genetically Engineered Fish

Genetically engineered fish can have many significant impacts on the environment. Many wild fish populations are declining and the U.S. waters that comprise their habitat are contaminated. In addition, non-native fish compete with wild fish for scarce resources, threaten the genetic integrity of wild fish, and transfer diseases and parasites to wild fish. Genetically engineered fish may harm native fish populations similarly to non-native fish. The National Academy of Sciences reported that "review of ecologic principles and empirical data suggests a considerable risk of ecologic hazards becoming realized should transgenic fish or shellfish enter natural ecosystems."[6]

At least 35 species of fish and shellfish have been genetically modified to enhance their growth such as carp, trout, salmon, catfish, loach, tilapia, pike and oysters.[7] For example, a genetically engineered Atlantic salmon contains a growth hormone gene from a Chinook salmon and an antifreeze-protein gene promoter from an ocean pout that keeps the growth hormone active.[8] These transgenes are injected into fertilized eggs. As a result, the engineered fish is designed to grow as much as 10 to 30 times faster than normal salmon.[9] Although these genetically engineered fish are not yet commercially farmed, they are poised to be introduced.

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[4] 33 U.S.C. § 1362(6). (emphasis added)

[5] 215 F. Supp. 2d 239, 247 (D. Me. 2002).

[6] National Academy of Sciences, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS 92 (2002).

[7] Center for Food Safety, The Catch with Seafood; Human Health Impacts of Drugs and Chemicals Used by the Aquaculture Industry, at 19, available at http://www.centerforfoodsafety.org/pubs/Aquaculture%20report%20FINAL%206.7.2005.PDF [hereinafter "The Catch with Seafood"]; see also Pew Initiative on Food and Biotechnology, Future Fish: Issues in Science and Regulation of Transgenic Fish 5 (Jan. 2003).

[8] The Catch with Seafood, supra note 7, at 19.

[9] Id.

Aquaculture of genetically engineered fish will exacerbate environmental problems. First and foremost, gene flow from transgenic fish into wild fish populations may cause a decline in the wild fish population and adverse impacts on species that rely on those wild fish for food or reproduction.[10] There will be a loss of genetic resources and biological diversity.

Additionally, transgenic fish are an exotic species that may become invasive in U.S. waters. Novel genetic characteristics may give transgenic fish a fitness advantage. Fish engineered for aquaculture are likely to grow rapidly. The result would be that they out-compete native fish for food, breeding sites, or prey upon wild fish.[11] Introduction of transgenic fish could reduce levels of biodiversity and cause the displacement and extinction of native populations.

Escaped farmed fish are also notorious for transmitting diseases and parasites to wild populations. EPA must place limitations on escaped fish from aquaculture facilities.

These environmental impacts may also affect protected and sensitive species. Declining habitat for wild fish species and the environmental concerns above pose risks to species listed as threatened or endangered under the Endangered Species Act. Furthermore, changes in biological diversity of U.S. waters may have indirect impacts on birds and other wildlife.

The Human Health Impacts of Genetically Engineered Fish

In addition to the significant environmental impacts, the novel nature of genetically engineered fish creates significant human health hazards, such as allergenicity, toxicity, and other unintended effects.

The National Academy of Sciences looked at the human health impacts of consuming genetically engineered animals and found that novel genes may trigger severe allergic reactions in some people.[12] Additionally, FDA recognizes that the transgene cannot be "turned off" once it is inserted in the organism, and this may lead to uncontrolled expression.[13] Over-expression of an existing protein leads to higher levels of exposure to that protein. As toxicity to humans may be determined by either the nature or the quantity of a substance, a higher concentration of a protein may create toxic results for some people.[14] Depending on where transgenes are inserted, they may also

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[10] Pew Initiative on Food and Biotechnology, supra note 7, at 23.
[11] Id. at 25-26; see also Mary Liz Brenninkmeyer, The Ones that Got Away: Regulating Escaped Fish and other Pollutants from Salmon Fish Farms, 27 B.C. ENVTL. AFF. L. REV. 75, 83 (1999).
[12] Nat'l Acad. of Sci., Animal Biotechnology: Science Based Concerns, 70 (2002).
[13] John Matheson, Food & Drug Admin., Will Transgenic Fish Be the First Ag-Biotech Food-Producing Animals?, 9 FDA Veterinarian (May/June 1999), available at http://www.fda.gov/cvm/index/fdavet/1999/may.html#transgenics.
[14] See AquaBounty, Faster Growing Salmon Could Give Growers Competitive Edge (adapted from Prince Edward Island Dep't of Fisheries & Env't, AQUACULTURE REVIEW (1997)), available at http://www.aquabounty.com/peidof.htm.

"affect the expression of other genes by disabling them or turning them on at an inappropriate time."[15]

Furthermore, the foreign growth hormone genetically inserted into salmon may increase production of other compounds such as insulin in the fish.[16] FDA also acknowledges that "[t]he incidental insertion of drug resistance genes from bacterial plasmids introduces further uncertainties as to food safety."[17] Thus, genetically engineered fish pose many potential food safety and human health problems as well as environmental harms.

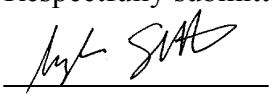
Conclusion

In light of its duty to prohibit pollutants from entering U.S. waters, EPA must regulate non-native fish as pollutants under the CWA. The permits contemplated for aquaculture operations in Idaho do not sufficiently address the environmental and human health risks presented by genetically engineered fish. Previously, EPA has established NDPES permits with prohibitions on the use of transgenic salmonids.[18] EPA should also require the following conditions in these Idaho aquaculture permits and other general aquaculture permits:

- Prohibit the use of genetically engineered fish;
- Require technologies that completely prevent the escape of non-native fish from aquaculture facilities; and
- Require monitoring and reporting of escaped fish within 24 hours.

Because the research shows that transgenic fish are likely to disrupt the ecosystem, EPA should not risk allowing these fish to escape.

Respectfully submitted,



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[15] See, e.g., Zhang P., Institute of Oceanology, Chinese Academy of Sciences, Genetic Manipulation of Olive Flounder (discussing the fast-growing transgenic flounder and the all-female flounder), available at http://www.imbc.gr/biblio_serv/aquachallenge/zhang.html (last visited Oct. 4, 2004); A/F Protein Inc., Winter Flouder (discussing use of the flounder's antifreeze protein in other organisms), available at http://www.afprotein.com/flounder.htm (last visited Oct. 1, 2004).

[16] Richard Howard, Genetically Modified Male Mating Advantage and the Trojan Gene Effect in a Fish, ISB News Report (Apr. 2004) (discussing salmon growth hormone gene (sGH) driven by a metallothionine (Mt) promoter), available at http://www.gene.ch/genet/2004/Apr/msg00028.html.

[17] Andrew Pollack, Gene-Altering Revolution Nears the Pet Store: Glow-in-the-Dark Fish, N.Y. TIMES, Nov. 22, 2003, available at http://www.nytimes.com/2003/11/22/science/22FISH.html.

[18] Letter from Steph J. Silva, Director, EPA's Maine Program to Erick Swanson, Acadia Aquaculture LLC 20 (Feb. 21, 2002) (approving NPDES Permit No. ME0036234).