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Introduction

Thank you Chairman Begich, Ranking Member Snowe and other members of the Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard for convening this hearing at such an important juncture, and for inviting me to testify. My name is George Leonard and I direct Ocean Conservancy's Aquaculture Program. I have a Ph.D. in marine ecology and evolutionary biology. For a decade I have worked to protect the long-term health of our oceans by identifying a viable, environmentally responsible seafood supply that is critical to America's economic strength.

A healthy ocean and a healthy seafood industry are critical to America's environmental and economic strength. Based on my assessment of the scientific literature and the current policy framework in the United States to regulate genetically engineered fish, we cannot yet conclude that the introduction of the first genetically engineered animal for human consumption – the AquAdvantage® farmed salmon – is safe for the environment. Furthermore, the existing federal regulatory structure and the current application before the Federal Food and Drug Administration (FDA) are incapable of asking and answering the broader suite of questions raised by the proliferation of genetically engineered fish farming and the range of engineered species that are likely to follow this potential first approval for GE salmon.

Genetically Engineered Salmon and the Future of Fish

The application from AquaBounty Technologies, Inc., for approval of its patented, genetically engineered farmed Atlantic salmon continues to be extraordinarily controversial. While there are numerous aspects of this specific proposal that warrant close scrutiny, much of the controversy, I believe, stems from the broader implications of approval. While the FDA, Congress, and the American public are right to pay close attention to the specific scientific and operational details of the proposed hatchery in Canada and the grow out facility in Panama, it is the broader ecological and societal consequences of the proliferation of genetically engineered salmon and other fish that are larger concerns and warrant careful scrutiny.

Chairman Begich and this Committee are to be commended for addressing this issue head-on and ensuring that these larger implications of genetically engineered (GE) fish are not ignored. What is at stake is no less than the future of fish, natural ecosystems, and our seafood supply. The issue is much larger than this single application from one private company. The critical question is whether society as a whole would be better off or worse from having this product on the market.[1] A more comprehensive

[1] Smith, M.D., Asche, F., Guttormsen, A. G., J. B. Wiener. 2010. Genetically Modified Salmon and Full Impact Assessment. Science 330:1052-1053.

analysis of the risks and benefits to our seafood supply, our current seafood industry, affected stakeholders, and natural ecosystems is desperately needed.

The specific controversy around GE salmon is embedded in a larger debate about how society hopes to procure fish protein. Unlike only three decades ago, our seafood supply is now dominated by farmed fish, with 50% of global seafood production coming from aquaculture.[2] Indeed, fish farming will play an important role in our future seafood choices. But aquaculture's reputation has suffered from the poor environmental and societal performance of some forms of farming, most notably the global shrimp and salmon industries.[3,4] Consumers and seafood businesses are increasingly making purchasing decisions based on the environmental impacts of their seafood choices, rewarding better environmental performance in the marketplace.[5] Without sufficient understanding of the risks, and public confidence in regulatory decision-making, adoption of GE technology has the potential to undermine a sustainable future for aquaculture, rather than secure it.

Rather than leaving the future of fish to a series of piecemeal decisions, beginning with the approval of AquAdvantage® farmed salmon, Congress should craft a broader, national vision for our future seafood supply that articulates the appropriate role of wild and farmed fish, including genetically engineered fish. Our nation's seafood future shouldn't be left to individual private companies or the FDA alone. Instead, it should be grounded in a public debate about the kinds of fish we wish to eat, involve decisions about which fish we will grow on farms and which we will catch in the wild, and be based on a clear-eyed analysis of the economic, environmental, and societal costs and benefits of doing so.

Chairman Begich and this Committee are to be commended for their role in starting the conversation.

Environmental Risks of Genetically Engineered Fish: Knowns and Unknowns

A decision to approve genetically engineered salmon should only be made with a full understanding of environmental risks and potential impacts that would accompany the broad adoption of this technology. Proponents of GE salmon have postulated that there is no risk of escapement, and that even if escapement does occur, there is no risk that GE salmon populations could take hold or otherwise reproduce with or negatively impact native, wild salmon populations or other components of the ecosystem. It would be irresponsible not to seriously question these assertions.

Given the stakes, we should take a more prudent approach. When considering approval of GE salmon and other GE fish, decision-makers should assume that there *will* be escapement. As explained in more detail below, history is replete with examples of fish and other animals that were never intended to get out, and yet they did. Given that history, it is only prudent to assume that GE fish will eventually escape from production facilities as the technology proliferates.

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[2] FAO Fisheries and Aquaculture Department. 2011. World aquaculture 2010. Technical Paper. No. 500/1. Rome, Food and Agriculture Organization.105 pp.

[3] Naylor, R. L., Goldburg, R. J., Mooney, H., Beveridge, M., Clay, J. Folke, C., Kautsky, N., Lubchenco, J., Primavera, J. and M. Williams. 1998. Nature's Subsidies to Shrimp and Salmon Farming. Science 282: 883-884.

[4] Ford J. S. and R. A. Myers. 2008. A Global Assessment of Salmon Aquaculture Impacts on Wild Salmonids. PLoS Biol 6(2): e33. doi:10.1371/journal.pbio.0060033.

[5] http://www.montereybayaquarium.org/cr/seafoodwatch.aspx

To be responsible, we must imagine the possible consequences if GE salmon compete and/or interbreed with wild salmon populations. What might those impacts be? What and whom will they affect? And what will the cost be to us as a nation? These are key questions about environmental and biological consequences and risks that must be asked and answered before any application for GE fish is approved. We must undertake an honest evaluation that includes an objective and clear-eyed view not only of the probability that an event might happen, but also of the magnitude and severity of the consequences of a range of potential, unintended outcomes. These are big questions with potentially significant consequences, and we must answer them before we commit to a course.

The two general categories of environmental impacts that should concern this committee are the effects on wild salmon, and the food web impacts on other species. As the members of the committee are well aware, wild salmon are already under considerable threat in many regions from a whole range of human activities, including coastal development, habitat loss, stream water diversions, net pen salmon aquaculture, and climate change.[6] Any additional impact from GE salmon could tip endangered or threatened populations over the edge, damaging currently healthy and commercially important salmon stocks and inhibiting recovery of those at low abundance. The mechanisms through which GE salmon escapement might damage wild salmon populations are four-fold: competition for food and habitat; pathogen or disease transmission; disruption of wild salmon reproductive behavior; and interbreeding with wild salmon. In assessing these issues, we should ask not only whether GE fish are more harmful than conventional farmed salmon, but more fundamentally, what harm can GE salmon cause and have we assessed and addressed these potential risks adequately?

Competition with wild salmon for food and habitat
Escaped GE salmon would be competitors for food,[7] habitat, and reproduction.[8] In experiments, growth-enhanced GE salmon dominated non-GE salmon for feed acquisition and exhibited strong agonistic and cannibalistic behavior when feed resources were inadequate.[9] A number of behavioral effects are reported in growth-enhanced GE fish that could affect wild populations, including significantly enhanced feeding motivation and reduced discrimination of prey choice. According to research from the Canadian Department of Fisheries and Oceans, a Coho salmon genetically engineered with a similar growth hormone gene as in the AquAdvantage® fish expressed aggressive behavior in hunting for food that even led to a collapse in wild salmon populations.[10] Studies found that GE Coho salmon are also more likely to take risks when feeding.[11] GE salmon also have greater thermal tolerance than wild fish, a trait which could give engineered fish an added advantage. GE salmon could thus potentially stress wild

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[6] Coates, P. A. 2006. Salmon. Reaktion Books Ltd. London. 216 pp.
[7] Devlin, R.H., J.I. Johnsson, D.E. Smailus, C.A. Biagi, E. Johnsson, and B.T. Bjornsson. 1999. Increased ability to compete for food by growth hormone transgenic coho salmon (*Oncorhynchus kisutch* Walbaum). Aquaculture Research 30: 1-4.
[8] Johnsson, J. I., and B. Bjornsson. 2001. Growth enhanced fish can be competitive in the wild. Functional Ecology 15 (5): 654-659.
[9] Devlin, R. H., M. D'Andrade, M. Uh, and C. A. Biagi. 2004. Population effects of growth hormone transgenic coho salmon depend on food availability and genotype by environment interactions. Proceedings of the National Academy of Sciences of the United States of America 101 (25): 9303.
[10] Muir, W. M. and R. D. Howard. 1999. Possible ecological risks of transgenic organism release when transgenes affect mating success; sexual selection and the Trojan gene hypothesis. Proceedings of the National Academy of Sciences.
[11] Sundström, L. F., Devlin, R. H., Johnsson, J. I. & Biagi, C. A. 2003 Vertical position reflects increased feeding motivation in growth hormone transgenic coho salmon (*Oncorhynchus kisutch*). Ethology 109: 701–712.

counterparts as they lay claim to new territory and habitat. Such an introduction could also push wild salmon into inferior habitats, which could further increase mortality.[12,13]

Pathogens and disease transmission

Unlike fish escapes, where a single large-scale release (or sustained, low level "leakage") would likely be required to have significant impacts, disease transmission from farmed to wild fish can cause severe mortality even from a small number of fish. There are few data, however, on any additional impact that GE salmon could have on disease transmission because no GE salmon have been introduced into commercial aquaculture to date. But some GE fish are known to have compromised immune systems, and it has been documented that triploid GE Coho salmon are more susceptible to disease.[14] This suggests that the introduction of transgenic salmon into commercial aquaculture could increase the number of infected fish and the degree of disease transfer into the marine environment, especially if GE fish are used in net pen grow-out systems. In addition, if escapes and interbreeding were to occur, the underlying genetics of GE fish with compromised immune systems would be introduced into the gene pool for wild fish.[15]

Disruption of wild salmon reproduction

Escaped GE salmon could also interfere with wild salmon breeding. For example, scientists have observed that spawning of wild females with farmed males occasionally results in poor egg fertilization when no wild males are involved.[16] When it comes to competition for spawning sites, later arriving fish may destroy a nest from an earlier spawn.[17] There is also some evidence that the hatchery environment produces more aggressive and more territorial fish.[18] While all these findings are for interactions between wild salmon and traditional, non-GE farmed salmon, similar concerns are likely to exist with GE salmon should they enter natural ecosystems.

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[12] McGinnity, P., C. Stone, J.B. Taggart, D. Cooke, D. Cotter, R. Hynes, C. McCamley, T. Cross, and A. Ferguson. 1997. Genetic impact of escaped farmed Atlantic salmon (*Salmo salar* L.) on native populations: use of DNA profiling to assess freshwater performance of wild, farmed, and hybrid progeny in a natural river environment. ICES Journal of Marine Science 54: 998-1008. McGinnity, P., P. Prodohl, A. Ferguson, R. Hynes, N. Maoiléidigh, N. Baker, D. Cotter, B. O'Hea, D. Cooke, and G. Rogan. 2003. Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farm salmon. Proceedings of the Royal Society of London. Series B: Biological Sciences 270: 2443.

[13] McGinnity, P., C. Stone, J.B. Taggart, D. Cooke, D. Cotter, R. Hynes, C. McCamley, T. Cross, and A. Ferguson. 1997. Genetic impact of escaped farmed Atlantic salmon (*Salmo salar* L.) on native populations: use of DNA profiling to assess freshwater performance of wild, farmed, and hybrid progeny in a natural river environment. ICES Journal of Marine Science 54: 998-1008. McGinnity, P., P. Prodohl, A. Ferguson, R. Hynes, N. Maoiléidigh, N. Baker, D. Cotter, B. O'Hea, D. Cooke, and G. Rogan. 2003. Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farm salmon. Proceedings of the Royal Society of London. Series B: Biological Sciences 270: 2443.

[14] Jhingan, E., R. H. Devlin, and G. K. Iwama. 2003. Disease resistance, stress response and effects of triploidy in growth hormone transgenic coho salmon. Journal of Fish Biology 63 (3): 806-823.

[15] De Eyto, E., P. McGinnity, S. Consuegra, J. Coughlan, J. Tufto, K. Farrell, H. J. Megens, W. Jordan, T. Cross, and R. J. M. Stet. 2007. Natural selection acts on Atlantic salmon major histocompatibility (MH) variability in the wild. Proceedings of the Royal Society B: Biological Sciences 274: 861.

[16] Fleming, I., K. Hindar, I. Mjølnerød, B. Jonsson, T. Balstad and A. Lamberg. 2000. Lifetime success and interactions of farm salmon invading a native population. Proceedings of the Royal Society B: Biological Sciences 267: 1517-1523.

[17] Naylor, R., K. Hindar, I. Fleming, R. Goldburg, S. Williams, J. Volpe, F. Whoriskey, J. Eagle, D. Kelso and M. Mangel. 2005. Fugitive salmon: assessing the risks of escaped fish from net-pen aquaculture. Bioscience 55: 427–38.

[18] Sundström, L. F., M. Löhmus, and J. I. Johnsson. 2003. Investment in territorial defense depends on rearing environment in brown trout (*Salmo trutta*). Behavioral Ecology and Sociobiology 54: 249-255.

Interbreeding with wild salmon

Given the complexity of how novel genes function in different environments, considerable concern remains over how GE fish may impact wild populations. Wild fish have been optimally selected over many generations for various life history characteristics such as growth rate, age and size at sexual maturity and clutch size. If escaped GE salmon and wild salmon interbreed successfully, it could have dire consequences for the survival of wild fish. If gene complexes from GE salmon take hold in wild populations, wild fish populations could have reduced survival and reproduction. In addressing the risk of GE fish generally, Muir and Howard (2002) stated: "If the population is struggling for existence prior to an introduction event, the induced genetic load may be sufficient to drive the population to extinction."[19] One mechanism by which this might occur is the Trojan gene hypothesis. First postulated in 1999,[20] this hypothesis suggests that GE fish possess a mating advantage that drives the engineered gene into wild populations; but the resulting GE offspring have reduced viability, which eventually drives the wild population to extinction. There is scientific uncertainty as to whether the Trojan gene effect will manifest in AquAdvantage® GE salmon. The theory's relevance should not be dismissed outright, as other studies note that behavior, genetics, and other factors can alter the likelihood of such effects. This suggests that an in-depth risk assessment is crucial before GE fish are approved.[21]

Two very recent studies have shown that escaped GE salmon will not die out quickly and, when fertile, can reproduce and pass on genes to future generations.[22] Particularly in situations where the rate of non-GE farmed salmon escapement is close to the reproductive rate of wild fish, the genetic consequences of such ongoing interbreeding could lead to an "extinction vortex," where an increase in presence of GE fish would lead to a decrease in genetic variance and adaptive potential.[23]

In addition, considerable scientific uncertainty remains regarding the evolutionary success of GE offspring in the wild; it is difficult to predict how offspring containing the engineered gene would evolve over several generations. Natural selection could either increase or decrease offspring fitness in the wild, and both could have potential impacts on the conservation of wild salmon populations.[24] A great deal more remains to be learned about the effects of GE fish on wild fish. Until a larger body of research is available, caution is crucial.

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[19] Muir, W. M. and R. D. Howard. 2002. Methods to assess ecological risks of transgenic fish releases. Genetically Engineered Organisms: Assessing Environmental and Human Health Effects. D. K. Letourneau and B. E. Burrows. Boca Raton, FL, CRC Press: 355-383, p. 358.

[20] Muir, W. M. and R. D. Howard. 1999. Possible ecological risks of transgenic organism release when transgenes affect mating success; sexual selection and the Trojan gene hypothesis. Proceedings of the National Academy of Sciences. 96:13853-13856.

[21] Ahrens, R.N.M. and Devlin, R.H. 2010. Standing genetic variation and compensatory evolution in transgenic organisms: A growth-enhanced salmon simulation. Transgenic Research 20(3):583-597.

[22] Moreau, D.T. R., I. A Fleming, G. L. Fletcher and J.A. Brown. 2011a. Growth hormone transgenesis does not influence territorial dominance or growth and survival of first-feeding Atlantic salmon *Salmo salar* in food-limited stream microcosms. Journal of Fish Biology 78:726-740. Moreau, D.T. R., Corrine Conway, and I.A. Fleming. 2011b. Reproductive performance of alternative male phenotypes of growth hormone transgenic Atlantic salmon (*Salmo salar*). Evolutionary Applications 4(6): 736-748.

[23] McGinnity, P., P. Prodohl, A. Ferguson, R. Hynes, N. Maoiléidigh, N. Baker, D. Cotter, B. O'Hea, D. Cooke, and G. Rogan. 2003. Fitness reduction and potential extinction of wild populations of Atlantic salmon, *Salmo salar*, as a result of interactions with escaped farm salmon. Proceedings of the Royal Society of London. Series B: Biological Sciences 270: 2443.

[24] Kapuscinski, A.R., Hayes, K.R., Li, S., and G. Dana, 2007. Environmental Risk Assessment of Genetically Modified Organisms: Methodologies for Transgenic Fish. Vol. 3. CABI International, Oxfordshire.

In sum, GE salmon could potentially damage already-struggling wild salmon populations through competition for food and habitat, pathogen and disease transmission, disruption of reproduction, and interbreeding. If such impacts come to pass, they could have real-world and far-reaching impacts on people, industries, and the environment. Congress should ensure that key questions are answered before GE salmon are approved for commercial production:

- If wild salmon populations are damaged by GE salmon, how will this affect commercial and recreational wild salmon fisheries in Alaska and along the West Coast?
- How might it impact our ongoing efforts to recover wild Atlantic salmon in Maine and throughout New England?
- How would it impact our existing international salmon management agreements with Canada under the Pacific Salmon Treaty?
- What implications would a further-weakening of Endangered Species Act-listed salmon stocks have on other sectors of our economy that are already impacted by ESA restrictions, such as the Columbia River hydropower system, the use of agricultural pesticides, and flood-control structures along salmon-inhabited rivers?
- Would damage done by GE salmon roll back the positive impact of billions of dollars of federal taxpayer money that has been invested in helping protect, replenish, and restore wild salmon populations?

Beyond these direct impacts of GE salmon, we must remember that wild salmon are a major component of the marine food web. A major blow to wild salmon could reverberate throughout the system in unexpected ways. In particular, wild salmon populations damaged by the effects of GE salmon could have implications on their predators through a reduction in wild salmon availability as prey for higher trophic levels.

For example, if the effects of GE salmon impair wild salmon, how would it affect Puget Sound's iconic and endangered Southern Resident Orca population? Members of this cetacean population have been observed in an emaciated state, and the population struggles with high levels of contaminants – especially among young and newborn whales.[25] If GE salmon trigger a further collapse in the availability of wild salmon prey in the Puget Sound or somehow add to toxicity loads, it is reasonable to expect that this could further imperil Puget Sound's endangered orcas. The same question could – and should - be asked of Cook Inlet beluga whales in Alaska, another population that relies heavily on wild salmon as prey and whose endangered status has caused great consternation in surrounding communities.[26] Given the central role of salmon in marine and terrestrial food webs,[27,28] impacts could also extend to a long list of other predator species such as bald eagles, river otters, and bears.

We know a great deal about the importance of wild salmon and healthy ecosystems. We know a great deal less about the risks and potential consequences to wild salmon and healthy ecosystems from commercial-scale production of GE salmon. The process of approving GE salmon should not proceed

[25] http://www.nwr.noaa.gov/marine-mammals/whales-dolphins-porpoise/killer-whales/esa-status/

[26] http://www.defenders.org/wildlife_and_habitat/wildlife/beluga_whale.php; http://www.biologicaldiversity.org/species/mammals/Cook_Inlet_beluga_whale/index.html

[27] Hocking, M. D., and J. D. Reynolds. 2011. Impacts of salmon on riparian plant diversity. Science. 331:1609-1612.

[28] Gende, S. M., Edwards, R. T., Willson, M. F., and M. S. Wipfli. 2002. Pacific salmon in aquatic and terrestrial ecosystems. BioScience 52:917-928.

without rigorous and objective assessment of those risks and consequences. Thus far, the FDA has not only failed to provide answers to these questions, the agency has failed to even ask the questions at all.

Ecological Consequences of Management Decisions in the Face of Imperfect Information

As the Committee ponders the range of questions that must be answered before GE salmon are allowed in commercial aquaculture, it is worth examining a few examples of other fish species that were intentionally deployed for what appeared good reasons at the time, but that only later became recognized as poor management decisions. While these examples are not related to genetic engineering, they do highlight the dire consequences that can occur when novel species are moved outside their natural habitats. They are "object lessons" in the need for a precautionary approach when potential impacts could be dire.

The United Nations has acknowledged that invasive species are "one of the greatest threats to biodiversity, and to the ecological and economic well-being of society and the planet[29]." The peer-reviewed literature is replete with examples of plants and animals, both intentionally released and accidentally escaped, that have caused extreme ecological harm.[30] One study has estimated that 50,000 non-indigenous species are now present in the U.S., causing major environmental damage that totals nearly $137 U.S. billion annually.[31]

In many cases, species have been introduced with little concern or evaluation of potential ecological consequences, under the belief that transporting or otherwise using species outside their natural habitat provided societal benefits. Plants have been used as erosion or predator control, while other species have been intentionally released to provide new hunting and fishing opportunities.[32] In an extraordinarily large number of cases, this has resulted in ecological harm.

In studying these examples, scientists have found that the behavior of exotic species is often puzzling. Introduced species often defy efforts to predict if and when they become established, whether they will spread, and what their impacts will be in new habitats. Resource managers have learned that it is much easier and less costly to prevent an introduction of a species than to remove it once it has been established.[33] In the absence of sufficient information, the precautionary approach is to refrain from deploying a species when there is an unacceptable risk of escape and harm. In all cases, a hefty dose of caution and skepticism is warranted. This is especially true for genetically engineered species, which can be thought of as special case of non-indigenous species, where the engineered gene could interact with the genetic makeup of wild populations in novel and difficult to predict ways.[34]

With the growth of aquaculture globally, a number of aquatic species have been distributed well beyond their natural borders and grown in non-indigenous environments. While never intended to be released,

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[29] Convention on Biological Diversity. 2009. The international day for biological diversity. http://www.cbd.int/idb/2009

[30] Vitousek, P.M., C. M. D'Antonio, L.L. Loope, and R. Westbrooks. 1996. Biological invasions as global environmental change. American Scientist 84: 468-478.

[31] Pimental, D., L. Lach, R. Zuniga, and D. Morrison. 2000. Environmental and economic costs of non-indigenous species in the United States. . BioScience 50:53–65.

32 Davis, M.A. 2009. Invasion Biology. Oxford University Press. Oxford, UK. 243 pp.

33 Volpe, John. 2001. Super un-Natural: Atlantic salmon in BC waters. David Suzuki Foundation. 31 pp.

[34] Ahrens, R.N.M. and R. H. Devlin. 2010. Background: genotype effects on transgenes in populations: a growth-enhanced salmon simulation. Transgenic Research. DOI 10.1007/s11248-010-9443-0.

many have escaped, validating the now famous quote from Jeffrey Goldblum in *Jurassic Park* that "life often finds a way." Furthermore, the "law of unintended consequences" often governs the fate of species when people utilize them in ways that fail to recognize or account for the species' natural history or their potential ecological role in new habitats.

Several examples illustrate the dire consequences for natural ecosystems of management decisions made without sufficient understanding of ecological risk.

Atlantic salmon

Salmon farming began in the mid 1970s on the western coast of British Columbia, Canada, largely in response to a growing global market for farmed salmon and a provincial government focused on the economic benefits that a new seafood industry could bring to struggling coastal communities. From 1972 to 1985, salmon farms grew from zero to 185 coastal farm sites.[35] This expansion was driven by national legislation that encouraged foreign investment, combined with a weak and poorly coordinated regulatory regime in Canada. Critics have raised numerous concerns about farmed salmon, including disruption of natural ecosystems, spread of disease like sea lice and infectious salmon anemia, harm to wild salmon stocks, and pollution from feed, chemicals and waste. My comments, however, address only one main issue: regulators were repeatedly proven wrong when they made assumptions about whether farmed salmon could escape and be viable in the wild.

Starting in the mid 1980s, federal regulators and the salmon farming industry made a series of assurances related to farmed Atlantic salmon impacts that were based on a combination of invalid assumptions, wishful thinking, and willful ignorance.[36] Long after the industry had already become entrenched, a body of research showed each of these statements to be patently false.

Particularly germane to genetically-engineered salmon and other GE fish, these assurances – in chronological order - were:

- Fish escapes are rare;
- Escapes are inevitable but fish can not survive;
- Escaped fish can survive, but they don't ascend rivers;
- Some escaped fish are found in rivers, but they can't spawn in those habitats;
- Escaped fish in rivers are likely to spawn, but their progeny are not viable; and finally
- Multi-year classes of escaped fish are not a threat to native wild salmon populations.[37]

In hindsight, all of these assurances turned out to be false when they were empirically tested. Over a period of years, information was gleaned through observations made by fishermen, concerned citizens, and a large body of empirical research (in the laboratory and in the field) by Dr. John Volpe. But by 1997, when Atlantic salmon had already been in the natural environment in British Columbia for over a decade, government regulators still had not seen fit to conduct a proper environmental analysis to evaluate the potential spawning performance of aquaculture-reared Atlantic salmon compared to native Pacific salmon. From the beginning of the industry's development, government officials and federal

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[35] Keller B. C. and R. M. Leslie. 1996. Sea-silver: Inside British Columbia's salmon farming industry. Horsdal and Shubart Publishers Ltd., Victoria. .

[36] Volpe, John. 2001. Super un-Natural: Atlantic salmon in BC waters. David Suzuki Foundation. 31 pp.

[37] Ibid.

scientists had been silent on the need to estimate this risk. And throughout the period, the aquaculture industry had portrayed the risk as essentially non-existent, a portrayal revealed to be false once the correct questions were asked and answered.

In contemplating this issue in 2001, Volpe concluded that the only answer to the question of the potential ecological consequences of the BC salmon farming industry should have been "we don't know," given the high levels of uncertainty regarding the impacts of ocean farming of salmon. In evaluating the effectiveness of Canadian regulators, Volpe concluded that to safeguard common resources, the government must ensure there is a rational evaluation of the industry with a full accounting, not only of benefits, but also of risks.[38] The same is equally true in the United States with respect to the proposed deployment of genetically engineered salmon and the other genetically engineered fish that are sure to follow.

Nile tilapia

Today, tilapia is likely the world's most widely distributed non-indigenous fish species—having invaded every tropical and subtropical environment to which they have gained access.[39] Since the 1980s, almost all of the worldwide introductions of tilapia have been for new aquaculture developments.[40] Over this time, there has been a shift from growing Mozambique tilapia (*Oreochromis mossambicus*) toward growing Nile tilapia (*Oreochromis niloticus*) in aquaculture.[41] Nile tilapia now dominate global tilapia aquaculture, accounting for 72% or 474,000 metric tons of production in 1995.[42] Throughout the world, cases of tilapia introductions are the result of both intentional release and unintentional escape. Regardless of mechanism, this has resulted in the decline of native fish and alteration of natural benthic communities globally. [43, 44]

The United States is no exception. In the U.S., Nile tilapia has been used for aquaculture since 1974, and while it was never intended to be released, it has become introduced into open waters through escape or release from fish farms.[45] Reports of Nile tilapia in the wild have come from the states of Arizona, Illinois, Massachusetts, Georgia, and the Gulf of Mexico, including Texas, Mississippi, Alabama, and Florida.[46] Studies suggest that Nile tilapia can invade coastal areas beyond their initial point of introduction by finding areas of thermal refuge from cold winter temperatures which would otherwise limit their survival. In particular, thermal gradients within a power plant cooling pond have provided

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[38] Ibid.

[39] Costa-Pierce, Barry A. "Rapid evolution of an established feral tilapia (*Oreochromis* spp.): the need to incorporate invasion science into regulatory structure." Biological Invasions 5 (2003): 71-84

[40] Ibid.

[41] Ibid.

[42] FAO (Food and Agriculture Organization of the United Nations) (1997) Review of the state of world aquaculture. FAO Fisheries Circular. No 886, Rev 1. Inland Water Resources and Aquaculture Service, Fishery Resources Division, Rome, 163 p

[43] "*Oreochromis* spp. (fish)." Global Invasive Species Database. 9 Dec. 2011. <http://www.issg.org/database/species/ecology.asp?si=813&fr=1&sts=sss.>

[44] Canonico, Gabrielle C., Angela Arthington, Jeffrey K. McCrary, and Michele L. Thieme. . "The effects of introduced tilapias on native biodiversity." Aquatic Conservation: Marine and Freshwater Ecosystems 15 (2005): 463-483.

[45] "*Oreochromis niloticus* Factsheet." United States Geological Survey. 9 Dec. 2011. <http://nas.er.usgs.gov/queries/factsheet.aspx?SpeciesID=468>.

[46] Ibid.

Nile tilapia with the warm habitat needed for successful invasion and establishment.[47] Studies have also shown that the fish's reproduction is not hampered by the salinity of typical ocean seawater.[48]

In coastal Mississippi in particular, Nile tilapia was deployed in the state through aquaculture and has since established breeding populations.[49] The environmental conditions in coastal southeastern Mississippi appear to provide a high quality environment for the survival of released Nile tilapia.[50] This species of tilapia can spawn year-round. Fish as small as 80 millimeters in total length carry mature eggs, showing that this exotic species can survive and become established in our present ocean landscape.

Tilapia provides a second cautionary tale of the consequences of growing a fish known to pose ecological risks beyond its native range. Even with the best of intentions, fish can and do escape.

Asian carp

Asian carp is a third example of a non-indigenous fish species that has spiraled out of control. . The carp now infesting the Mississippi River Basin and threatening the fisheries of the Great Lakes were introduced both intentionally by the government and unintentionally through escapes from fish farms. In the late 1970s and early 1980s, the Environmental Protection Agency and state Fish and Game programs carried out research using bighead and silver carp to clean sewage ponds and to consume undesirable aquatic vegetation. At the time, carp were touted as an innovative breakthrough to control water pollution because the fish were a cheaper, more wholesome form of biological control than that provided by traditional chemical treatments.[51]

Yet today, we know the dire consequences of the decision to introduce this highly invasive fish. The once-desirable fish are now spreading northward, especially up and throughout the Mississippi River Basin. A growing body of evidence shows that Asian carp compete with native species for both food and habitat, may spread disease to native wild fish, and negatively affect water quality.[52]

It is not just biologists who know the dangers posed by non-indigenous carp; recreational fishermen have experienced these dangers first hand. Not only do the fish that recreational anglers seek compete with carp for food, but fishermen can be personally injured in pursuit of their catch. Enormous silver carp – weighing up to 100 pounds – can jump out of the water and have been known to injure anglers

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[47] McDonald, Jennifer L., Mark S. Peterson, and William T. Slack. . "Morphology, density, and spatial patterning of reproductive bowers in an established alien population of Nile tilapia, *Oreochromis niloticus*." Journal of Freshwater Ecology 22.3 (2007): 461-468.

[48] Schofield, Pamela, Mark S. Peterson, Michael R. Lowe, Nancy J. Brown-Peterson, and William T. Slack. "Survival, growth and reproduction of non-indigenous Nile tilapia, *Oreochromis niloticus* (Linnaeus 1758). I. Physiological capabilities in various temperatures and salinities." Marine and Freshwater Research 62.5 (2011): 439-449.

[49] McDonald, Jennifer L., Mark S. Peterson, and William T. Slack. . "Morphology, density, and spatial patterning of reproductive bowers in an established alien population of Nile tilapia, *Oreochromis niloticus*." Journal of Freshwater Ecology 22.3 (2007): 461-468.

[50] Peterson, Mark S., William T. Slack, and Christa M. Woodley. "The occurrence of non-indigenous Nile tilapia, *Oreochromis niloticus* (Linnaeus) in coastal Mississippi, USA: ties to aquaculture and thermal effluent." Wetlands 25.1 (2005): 112-121.

[51] See Myths, Dangers, U.S. Failures: The Truth About Asian Carp, 6 Part Series, Detroit Free Press (July 20, 2011).

[52] See, e.g., Laird, C. A., and L. M. Page (1996) (The silver carp has the potential to cause enormous damage to native species because it feeds on plankton required by larval fish and native mussels); A.J. Bocek et al. (1992) (Silver carp is an effective carrier of Salmonella typhimurium, and it can transport diseases to new areas).

sitting in their boats.[53] Now, millions of federal and state dollars are being spent to try to stop Asian carp from spreading into additional lakes and waterways. But this effort may be doomed to failure; just last week DNA from the invasive silver carp was found in the Mississippi River above the Coon Rapids Dam, further north than it has ever been discovered, raising the prospect that the fish may be headed to Minnesota's most popular recreational lakes.[54]

Like tilapia and salmon, Asian carp provides an example of the law of unintended consequences. With all these fish, important questions should have been asked before they were introduced and ultimately escaped.

Regulation of Genetically Engineered Fish: FDA Approval Process Is Inadequate

Given these cautionary tales and the environmental perils associated with the potential escape of GE salmon and other GE fishes, it is critical that the United States has in place a regulatory process that can anticipate, evaluate, and guard against these concerns. I have little confidence that the process led by the Food and Drug Administration is up to the task.

Under the 1986 Coordinated Framework for the Regulation of Biotechnology ("Coordinated Framework"), genetically engineered organisms (GEOs) are regulated according to the concept of "product, not process." This means that, federal agencies evaluate GEOs as products like any other – "substantially equivalent" to their non-engineered analogues – not as a special category distinguished by their development using the process of recombinant DNA technology.[55] The Coordinated Framework assumes that the existing agencies, using existing authority, have the ability and expertise to review commercialization applications.

There are a number of problems with this approach. First, existing statutes have generally been designed to address situations where harm or risk has already been quantified, not situations where there remains a high degree of scientific uncertainty, such as is the case for genetic engineering technology. The "new animal" drug laws currently being used to regulate GE animals, for example, were written well before GE animals were ever conceptualized as a possible food source and are woefully outdated. Second, the theory of substantial equivalence is predicated on an assumption of safety; that is, it starts from a position of assumed safety, the burden of proof falls on the public to show harm.[56] Third, an agency with expertise in one area relevant to a permit application may not be best suited to evaluate the other potential effects a GEO may have when it is commercially released. This potential for problems in regulating transgenic fish and livestock under the Coordinated Framework Early was recognized as early as 1990.[57]

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[53] Injurious Wildlife Species: Silver Carp and Largescale Silver Carp, Federal Register: July 10, 2007 (volume 72, number 131).

[54] http://www.startribune.com/local/135259173.html?page=1&c=y

[55] In fact, however, there are exceptions to this policy: the most notable, perhaps, is the USDA decision to regulate GE crops as plant pests based on their incorporation of a pesticide but also on their being genetically engineered (see Marden 2003: 769).

[56] Kelso, Dennis Doyle Takahashi. "Genetically Engineered Salmon, Ecological Risk, and Environmental Policy." *Bulletin of Marine Science* 74, no. 3 (2004): 509-28.

[57] Kapuscinski, Anne R. and Eric M. Hallerman, "Transgenic Fish and Public Policy: Anticipating Environmental Impacts of Transgenic Fish," *Fisheries* 12 (1990), p. 3.

Pursuant to the Food, Drug, and Cosmetic Act of 1938 (FDCA), the Food and Drug Administration (FDA) is responsible for regulating food additives, food, and animal drugs. Within the Coordinated Framework, FDA regulates GE animals under the concept of "new animal drugs."[58] The transgene, or recombinant DNA (rDNA) construct, used to produce a GE fish is considered the "new animal drug" under the agency's New Animal Drug Application process.[59] It is important to recognize that the actual *drug* being regulated is the rDNA construct itself in the resulting fish. The fish itself is not a drug. Yet under this system, approval of the GE drug equates to approval of the GE fish itself. If approved, therefore, the AquAdvantage Salmon® would be the first genetically engineered animal approved for human consumption.

FDA's authority was designed to provide the agency with oversight of traditional pharmaceutical drugs. Applying the new animal drug application process to GE salmon intended for interstate commerce and human consumption raises a host of problems. FDA's existing process does not ensure adequate protections for the environment, such as environmental analyses and public participation requirements.[60] Because of concerns about trade secrets, the process is open to public comment only *after* the approval of the new animal drug application, and thus, approval of the GE fish has been made.[61] Unlike applications led by USDA or EPA, FDA's approval process occurs almost entirely behind closed doors, making it nearly impossible for the public to participate meaningfully in an agency decision that could lead to devastating and irreversible ecological harm. While this process might protect confidential business information, it fails to adequately and transparently examine potentially far-reaching and serious consequences and environmental risks from GE salmon.

FDA's existing regulatory process was simply not designed to address the complex issues involved in developing genetically engineered fish for human consumption. Because the FDA's focus is on food and drug safety, the agency does not have the expertise or experience to adequately identify and analyze the environmental risks and consequences of GE salmon and other fish. In addition, the FDA approval process lacks adequate public participation, adequate consideration of the full range of environmental hazards, and the opportunity for sufficient input from other federal agencies with expertise in fisheries and environmental risk.

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[58] 21 U.S.C. §§ 301 - 399a.

[59] The New Animal Drug Application (NADA) process, as required pursuant to 21 U.S.C. § 360ccc, is detailed in an FDA guidance policy document: Guidance for Industry #187, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* (January 5, 2009).

[60] *See, e.g.*, 21 C.F.R. § 514.11(b)-(c) (stating that FDA will not disclose to the public the existence of a NADA file before approval has been published in the Federal Register, unless it has previously been publicly disclosed or acknowledged); 21 C.F.R. § 25.50(b) (asserting that "unless the existence of applications for…animal drugs…has been made publicly available, the release of the environmental document before approval of…animal drugs…is inconsistent with statutory requirements imposed on FDA"). In the case of the current GE salmon application, FDA has hosted a public hearing and has stated that it will seek public comment on the final environmental analysis documents required by the National Environmental Policy Act (NEPA) before publishing a final determination. . However, such opportunities are not presently required by law and therefore may not be afforded each time the Agency is considering approval of a GE food animal application.

[61] FDA provided an opportunity for public comment in September 2010 before final approval of GE salmon, likely because the agency sensed this decision would be highly controversial; FDA, however, is not legally required to be similarly forthright when new entities seek approval from the agency for additional species or culturing conditions.

As a result of these inadequacies, FDA's review process does not address the far-reaching environmental risks to fisheries and natural ecosystems. Among other issues[62], the current process fails to adequately consider threats to wild salmon populations, threats to commercial and recreational salmon fisheries, threats to fisheries targeting other species that interact with salmon, threats to marine and terrestrial food webs in which salmon are embedded, and threats to recovery efforts for salmon stocks listed as endangered or threatened under the Endangered Species Act.

Other federal agencies with relevant expertise must play a stronger leadership role in the approval and regulation of GE fish. These include the National Marine Fisheries Service (NMFS), the U.S. Fish and Wildlife Service (USFWS), and the Environmental Protection Agency (EPA). NMFS and FWS have scientific expertise backed by extensive ecosystem research, and have expertise in conservation and protection of the natural resources that could ultimately be affected by GE salmon and other GE fish. EPA has knowledge and experience in the oversight and management of threats to water and watersheds. At a minimum, FDA should be required to consult these agencies during all stages of development and approval of GE salmon. Furthermore, if FDA is to remain the lead agency, FDA should be required not only to consult with these agencies, but also to either heed their advice or provide adequate rationale for any decisions to the contrary.

Concerns over the FDA approval process were brought to the attention of FDA in September 2010 in a letter from eleven U.S. Senators, including Senator Begich.[63] The letter requested that FDA halt the GE salmon approval process, citing concerns over unknown impacts to human health and environmental risks. These concerns are valid, and FDA is ill-equipped to deal with the environmental and biological consequences and risks associated with the farming of genetically engineered fish.

Congressional Oversight and the Need for Reform

Our nation is faced with the prospect of approving genetically engineered salmon and future GE fish under statutes that were not designed for that purpose, by a federal agency that doesn't have the appropriate expertise to address environmental risk, and through a process that doesn't account for many of the major possible stakeholder impacts. This is not a judgment on the FDA or its many dedicated and capable public servants; we have tremendous respect for the FDA and its employees. But like all federal agencies, the FDA has a specific perspective shaped by a particular set of statutes.

As its name implies, the FDA is charged with addressing issues of drug efficacy and safety, not matters of fisheries science, marine ecology, and evolutionary biology. So when faced with an application for an animal such as GE salmon, the FDA is structured to ask questions that reflect the laws that govern and shape the FDA – not those that govern, for example, the National Marine Fisheries Service. In the case of GE salmon—and the other GE fish that are sure to follow—an initial approval under the FDA's limited perspective falls far short of what is needed. It does not adequately reflect the full suite of public policy considerations, and it clearly does not reflect the body of concerns being expressed by citizens throughout Alaska, Maine, and other states across this nation. As representatives of the citizenry at large, then, it is the job of members of Congress to step in and ensure that the tough questions are asked and answered.

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[62] Center for Food Safety v. Vilsack, No. C 09-00484 JSW (N.D. Cal.) (2009), on sugar beets, found that the USDA had improperly failed to consider environmental and economic impacts of GE sugar beets before approving its commercialization.

[63] Letter to Commissioner Margaret Hamburg, Commissioner of Food and Drugs, FDA (Sept. 28, 2010).

Given the potential far-reaching consequences of genetically engineered fish, it is appropriate for Congress to use the full force of both its legislative and oversight powers to tackle this issue. Given the shortcomings of existing laws and regulations described above, it is essential that Congress take legislative action to ensure that genetically engineered salmon and other GE fish are not approved unless and until the full suite of environmental risks are thoroughly understood. And until the day comes when new legislation is enacted into law, Congress should use its oversight authority to rigorously scrutinize the FDA approval process, examine the environmental risks, evaluate the adequacy of the science being used in decision-making, and bring to light the possible consequences if worst-case scenarios should come to pass.

When Congress pursues both oversight and legislation, it should endeavor to achieve the four following overarching objectives:

First, Congress should demand more science and a modern, science-driven environmental risk assessment that treats complexity and uncertainty directly and objectively, using the most current methodologies[64] before GE salmon and other GE fish are given approval. Possible approval of GE salmon and other GE fish raises a whole host of new scientific questions that have not yet been answered. Merely sweeping scientific uncertainty under the rug is not an option. A comprehensive risk assessment – including a quantitative "failure analysis" would entail formulating a problem statement; identifying and prioritizing all possible risks; defining measurable assessment endpoints; estimating exposure, likelihood, and severity of consequences; identifying and appropriately treating uncertainties; and using this information to characterize the overall risk.[65] Congress should communicate to the executive branch that it expects the tough scientific questions to be dealt with *before* GE salmon are approved – not after. In so doing, the government should not rely solely on data from applicant companies without independent verification.

Second, Congress should demand that the appropriate federal and state agencies with the necessary expertise be provided a substantive role in assessing the environmental risks of GE salmon and other GE fish. FDA simply lacks the scientific expertise to identify and sufficiently analyze the full range of possible impacts from genetically engineered salmon. Other federal agencies such as NOAA, the National Marine Fisheries Service, the U.S. Fish and Wildlife Service, and the EPA are far better equipped with the scientific experts and institutional history to identify the impacts and assess the risks. It may even be appropriate to provide an agency such as the National Marine Fisheries Service with veto power over FDA approval if the agency concludes there is sufficient risk to wild fisheries or natural ecosystems. Other federal bodies, such as the Regional Fishery Management Councils, could also provide valuable perspective given their emphasis on sustainable fisheries. Finally, state natural resource agencies should be involved, to take advantage of their decades of on-the-ground experience in salmon management and restoration.

Third, Congress should demand a far more inclusive and transparent approval process. Worst-case escapement and interbreeding scenarios for GE salmon could have major impacts across a wide group of

[64] Burgman, M. 2005. Risks and Decisions for Conservation and Environmental Management. Cambridge University Press. Cambridge, UK. 488 pp.

[65] Kapuscinski, A. R., Hayes, K., Li, S., and G. Dana, eds. 200. Environmental Risk Assessment of Genetically Modified Organisms, Vol. 3: Methodologies for Transgenic Fish, CABI Publishing, UK. 304 pp.

stakeholders and industries. The ramifications for the public interest are of an entirely different scale and nature than those typical for drug approval. Stakeholder engagement should begin early in the process, during the problem definition phase of the risk assessment; such an approach is now considered the "state of the art" in addressing environmental risk, resulting in questions being asked and answered that are directly relevant to stakeholder concerns.[66] The current FDA process that provides for public input only *after* an approval is made is unacceptable and not in the public interest. While FDA is not presently required to provide more transparency or comprehensive public participation, the policy realities of GE fish demand that the government hold itself to a far higher standard than what is currently required of the FDA.

Finally, Congress should adopt a highly conservative, precautionary approach toward a future seafood supply that potentially entails genetically engineered fish. Given the uncertainty that surrounds GE salmon and other GE fish at this juncture, Ocean Conservancy is supportive of efforts to issue a ban or moratorium against GE salmon unless and until the scientific evidence demonstrates that GE salmon can be produced with little or no risk to wild fish and the marine environment. In this regard, we support Senator Begich's legislation, S.1717, to ban interstate commerce of genetically engineered salmon. Senator Begich's bill is a prudent step, given the considerable risks and public policy implications of allowing the production of first genetically engineered fish for human consumption.

Conclusion

Chairman Begich's decision to hold this hearing is a very important step toward achieving a better understanding of the full suite of environmental risks posed by GE salmon. I commend the Chairman for holding this hearing, and Ocean Conservancy encourages future actions to pursue rigorous Congressional oversight on this topic.

The environmental risks posed by GE salmon specifically, and GE fish in general, are real. How Congress and the Food and Drug Administration address the application for the first genetically engineered animal destined for human consumption will set a precedent for all applications for GE fish that follow it. While science cannot predict with certainty what the outcomes will be if engineered fish escape into natural ecosystems, given what is at stake, considerable caution is warranted.

Congress should take legislative action to ensure that the full suite of environmental risks is thoroughly understood before we proceed. A modern, science-driven environmental risk assessment must be applied to this issue, and stakeholder engagement and transparency must be at the heart of the process. Congress should ensure that the federal agencies with environmental protection as their core mission – most notably the National Marine Fisheries Service – play a substantive role in fully assessing these risks. In short, Congress should ensure that the hard questions are asked and answered. If those questions cannot be satisfactorily addressed, we should not risk our oceans and our seafood supply to a future with genetically engineered fish.

[66] Kapuscinski, Anne. Professor of Sustainability Science, Dartmouth College, Hanover, NH. Personal communication, December 10, 2011.