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Testimony to the US Senate Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard Oversight Hearing on the Environmental Risks of Genetically Engineered Fish

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I wish to thank Chairman Begich, Ranking Member Snowe, and Members of the Oceans, Fisheries, and Coast Guard Subcommittee for convening this hearing and for inviting me to share my perspectives and experiences on the environmental risks and consequences to marine and freshwater ecosystems from the release of manipulated (or GE) fish genomes.

During the past 25+ years, I have had a number of relevant experiences both on the scientific side and the administrative side that have shaped my perspectives on and overall approach to this specific issue and one related to it. First, as a population geneticist serving several state agencies and universities, the scope of my students' and my own work has focused on the uses and ecological-genetic consequences from the intentional and inadvertent release of propagated fishes on populations in recipient ecosystems. As such we have examined species ranging from Pacific salmonids to American shad to largemouth bass. Second, I've also served several agencies including as Coordinator of the National Fisheries Program with the US Geological Survey (in the Reston Headquarters) and Assistant Program Leader for Fisheries with the USDA-Forest Service (in the DC Headquarters), and Director for Ecology and Conservation Sciences with the Illinois state Department of Natural Resources. Third, I served as a resource scientist with Trout Unlimited, a non-governmental conservation organization, where my focus was on the scientific underpinnings of conserving salmonid biodiversity. Finally, I served on the Northwest Power and Conservation Council's Independent Scientific Review Panel (ISRP) where we review the scientific rigor of the Columbia basin's fish and wildlife program – where maintaining the integrity of Pacific salmon gene pools is a central focus for projects reviewed by the ISRP. In short, each of these and other direct experiences has contributed and given shape to the perspectives I offer today.

I intend to focus my comments narrowly on the potential hazards from the release or escapement of genetically engineered (GE) salmon on the biological diversity and full range of ecosystem services in recipient environments[1]. I ultimately defer to others on issues related to product-labeling, food safety, or applications of gene transfer in fishes used as models in medical research. The heart of the matter before us today is whether a proposed New Animal Drug Application (NADA) for commercial production of a genetically engineered, growth-enhanced salmon and associated reviews has sufficiently weighed the potential consequences if a group of these modified individuals were to escape or be released into an adjacent ecosystem. In light of this narrow focus, it is worth stating explicitly and up front, the importance that the precedence this specific case brings to other future applications.

To begin, as a fish conservation geneticist, I am familiar with the ecological consequences from the release (or escape) of fish with genomes that have been modified either from conventional and transgenic pathways. It is important to state upfront that, to my knowledge, there are no documented or studied cases of genetically engineered Atlantic salmon escaping into the wild, even though we have laboratory studies from Canada on growth and reproductive performance. Therefore, we must rely on information on analogous releases of altered information. At the most general level, there are essentially two broad categories of concern that genetically modified salmon represent to marine or inland ecosystems -1) impacts due to ecological interactions (such as predation, competition, and transmission of diseases); and 2) impacts directly from interbreeding or indirectly through husbandry practices.

In terms of ecological impacts posed by potential escape of genetically engineered fish, the release of a novel top-predator or more efficient competitor is expected to have cascading effects throughout a local food web. While we might be able to make some rather wide predictions about the size and shape of potential disruptions, our ability to precisely hone in on the scale of these impacts ultimately depends on quality of previously-gathered information and the appropriate expertise brought to bear on the issue – in short, a formal Uncertainty Analysis. Moreover, our understanding several ecological attributes of released individuals are key to more accurately predicting impacts, such the number escaped, their behavioral dominance, reproductive capacity, the overall persistence (through time) of the escaped fishes, as well as how these attributes are expressed in different local ecosystems. One needs only to consider the recent emergence of non-native species such as sea lamprey in the upper Great Lakes, northern snakeheads in the mid-Atlantic region, lionfish in the Caribbean, or the various Asian carp species in the Mississippi River basin to comprehend the enormity of ecological effects on local biota from release of new predators or competitors. Ultimately, in the case of a genetically modified salmon escaping into the wild, the full extent of its ecological impact will be determined not only by the characteristics of the salmon itself, but also on the ecosystem into which it escapes. For example, an already-stressed habitat and biotic community is more likely to be impacted than one that is pristine and resilient.

Another level of complexity and potential disturbance emerges where modified fishes can escape into an ecosystem where the species' wild relatives occur. Here, we face additional risks

[1] The foundation for these comments can be made available to the Subcommittee staff if desired, and ultimately may be found in the nation's leading professional and technically peer-reviewed journals by numerous research groups, including my own, as well as a number of reviews by the National Academy of Sciences.

stemming from the interbreeding. Based on three or more decades of study on salmon and other species, the fisheries genetics community has discovered that even very subtle genetic differences between previously isolated breeding groups can seriously disrupt survival and reproduction in future generations. In the case of genetic engineering (or, transgenesis), we have a case where a single gene (or a single construct of a few genes) is introduced into a genome in a way that is essentially a human-directed mutation. Such a mutation is expected and designed to have a major effect on the physiology, anatomy, or behavior of the host genome – the very reason the genetic engineering is undertaken. Whereas in nature the vast majority of random mutations are not expected to alter populations because they are generally deleterious and quickly removed from a population, human-mediated mutations may have lingering effects because they are designed for traits that are not subjected to natural selection in the wild.

To be sure, many of the long-practiced, classical modes of gene pool and genome manipulation have proven to be problematic – we should expect no exception to this pattern from transgenesis. For example, some recent work by scientists in Oregon have observed that release of steelhead, a Pacific salmonid domesticated but a few generations, are less fit than their wild counterparts. Moreover, the interbreeding between these domesticated and wild fish has conveyed an impact by lowering the overall reproductive capacity of the supplemented population. As another example, a study conducted in my home state of Illinois examined the impacts of interbreeding and moving largemouth bass from the northern and southern extremes of the state into each other's range. Here, even though the populations exhibited very subtle genetic-level differences between northern and southern populations, their interbred offspring had much reduced survival and reproductive rates regardless of the location they were released into.

One consistent pattern through the documented cases of this kind interbreeding penalty in bass, salmon, or other species is a failure to adequately predict the full scope of the impacts beforehand. In short, by failing to consider the consequences of even these classical modes of genome manipulations, we risk unintended environmental effects. Ultimately, the newer approaches carry similar and additional risks unless adequate safeguards are rigorously carried out. While the New Animal Drug Application for Genetically Engineered salmon includes precautions for physical containment to prevent escapement and for reproductive sterility should escape occur, it is critical to consider that no established safeguard has proven foolproof nor eliminates all risk classes simultaneously or completely.

In closing, I offer several observations and recommendations for the Subcommittee to consider as it further deliberates the issues before it.

1) Salmon exhibit a complex suite of life-histories that will benefit from specific experience and expertise in the ecology and genetics of the species in question. Certainly, FDA has experience with food and drug science, whereas other agencies in the federal and state sphere are more versed in salmon biology and the unique qualities of the environments

they generally occupy (especially, NOAA-Fisheries for marine ecosystems, and Fish and Wildlife Service and the states for inland ecosystems).

2) Whereas containment and engineered sterility may, in fact, reduce the probability of escape or reproduction (triploidy has proven an imperfect method of mass sterilization), these do not completely remove risks of escape, reproduction, or ecological interference. A robust and formal risk assessment is warranted. Such assessments will benefit from formal uncertainty analyses. Moreover, it would be prudent to treat any transgenic modification of fishes as a controlled experiment that is a) actively monitored for impacts after approval and that can be b) terminated should the need arise without lingering environmental effect. More specific and detailed recommendations may be found in a 2004 National Academy of Sciences report entitled, “Biological confinement of genetically engineered organisms”.

3) While I recognize the confidentiality requirements of trade secrets laws that are intended to safeguard proprietary information from potential competitors about food and drug products, a fuller transparency and debate of the science behind environmental risk-reviews differs in a couple material ways. First, it promotes bringing the brightest minds and best ideas to bear on the issues. Second, it more adequately protects fisheries and fish biodiversity that are managed in trust by public resource agencies.

As a final thought, I contend we need to consider the scientific issues surrounding the risks of Genetically Engineered salmon and other fishes based on the appropriate and full-range of scientific fields to shape the policy discussions. Based on analogous concerns and risks from release of fishes genetically altered in more traditional or conventional ways (rather than with more recent molecular and cellular biology based approaches), the risks appear to all too real, albeit to an insufficiently understood extent. Ultimately, the environmental concerns surrounding release or escape have been debated and summarized by various experts and groups including no less than three separate Panels from the National Academy of Sciences entitled “Animal Biotechnology: Science Based Concerns” (2002); “Biological Confinement of Genetically Engineered Organisms” (2004); and, “Genetically Engineered Organisms, Wildlife and Habitats” (2008). I trust the Subcommittee will encourage continued examination of these concerns by the lead and consulting agencies.

Mr. Chairman, Thank you, again, for the opportunity to share these views. I would be happy to address any questions you or the Members might have.