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My name is Alison Van Eenennaam. I am a Cooperative Extension Specialist at the University of California, Davis specializing in Animal Biotechnology and Genomics. My training includes a Bachelor of Agricultural Science from The University of Melbourne in Australia, and both a MS and Ph.D. in Genetics from UC Davis. I am a past-member of the national USDA "Advisory Committee on Biotechnology and 21st Century Agriculture (AC 21)", and in September, 2010 served as a subject matter expert on the FDA Center for Veterinary Medicine's Veterinary Medicine Advisory Committee (VMAC) that was responsible for reviewing the data package associated with the AquAdvantage genetically engineered salmon. Thank you for the opportunity of allowing me to testify here today.

I am here today to speak on House Bill 2530 which seeks to prohibit the importation, transportation, farming, cultivation, incubation or spawning of genetically engineered (GE) fish into the State of Oregon. It also prohibits the farming of Atlantic salmon that may come into contact with native anadromous fish except those spawned by the State Department of Fish and Wildlife. The stated purpose of this emergency bill is that it is necessary to preserve the "public peace, health, and safety." I will also comment on an accompanying bill House Bill 3177 that requires signage in area where genetically engineered fish are sold except in restaurants. This bill states that the State Department of Agriculture rules shall not be more restrictive than "the laws and rules of the federal Food and Drug Administration" and shall give appropriate consideration to the opinions of recognized experts and governmental agencies. The stated purpose of this bill is that it is also necessary to immediately preserve the "public peace, health, and safety."

### Prohibition of (live) Genetically Engineered (GE) Fish in Oregon

The global demand for fish and fishery products is predicted to continue to increase in the years to come—from 133 million tons in 1999 to 2001 to 183 million metric tons by the year 2015. Taking into account indications that capture fisheries are close to or have already reached their potential, the world is looking toward aquaculture and its technologies to fulfill the expanding food demands: by 2020, aquaculture is expected to supply 41% of the global food fish production (compared to 3.9% in 1970 and 29.9% in 2002). A major focus of research in the aquaculture industry is on the use of biotechnology to increase food availability and reduce production costs, specifically through the precise and careful rearrangement of the genes and chromosomes of cultivated species. Examples include transgenic fish species (Atlantic, coho, and chinook salmon, rainbow and cutthroat trout, tilapia, striped bass, mud loach, channel catfish, common carp, Indian major carp, goldfish, Japanese medaka, northern pike, red and silver sea bream, walleye, and zebrafish) engineered to produce select traits including increased growth rates, feed conversion efficiency, disease resistance, cold tolerance, and improved metabolism of land-based plants (Reviewed by Rasmussen and Morrissey, 2007).

Prior to commercialization all GE animals, including fish, are subject to a mandatory premarket regulatory review on a case-by-case basis (i.e. each species/transgene combination would be examined separately) by the U.S. Food and Drug Administration (reviewed by CAST, 2011). In a multistep scientific review process described by the FDA (2009), the agency examines the safety of the rDNA construct to the animal, the safety of food from the animal, and any environmental impacts posed, as well as the extent to which the performance claims made for the animal are met. If the GE animal is intended as a source of food, the FDA assesses whether or not the composition of edible tissues differs and whether or not its products pose more allergenicity risk than non-GE counterparts. To meet the requirements of the National Environmental Policy Act (NEPA), the FDA evaluates an environmental assessment of the GE animal and of conditions proposed for raising it. The data requirements for demonstrating environmental safety of GE animals focus on the rDNA construct, host organism, production system, physical and biological confinement measures, and receiving environment.

To date only one GE animal application for food purposes, the GE fast-growing AquAdvantage salmon, has reached the final steps at the FDA. Under the proposed conditions of use in the application to the FDA the fish would be bred in a FDA-inspected broodstock facility in Canada; and then fertilized, triploid eggs will be shipped only to a FDA inspected grow-out facility in the highlands of Panama, where they will be raised to market size in freshwater inland tanks. There are multiple, redundant containment measures in place at these two FDA-inspected facilities. To raise these fish anywhere else, including Oregon, the company would have to submit another application to the FDA.

With that background, it is unclear to me as a scientist what "the public peace, health, and safety dangers" are that necessitate the immediate banning GE fish as a group. GE fish are not a recognized taxonomic category, nor a category of animals for which there is any credible scientific evidence to demonstrate a universal threat. There is already a federal regulatory process in place to evaluate both health and environmental risks associated with any GE animal application. If the AquAdvantage salmon application is approved, live AquAdvantage salmon could not be imported into or grown out in Orgeon under the proposed conditions of use. Arbitrarily banning technology can have unanticipated effects in terms of forestalling future applications that may be highly beneficial and well-aligned with food safety and security goals. Example might include disease resistant fish, and fish with improved metabolism of land-based plants with the potential to reduce aquaculture's reliance on fish meal and fish oil-based feed.

#### 2. Banning of Atlantic Salmon Farming

A report was posted on Oregonlive on 3/18/13which suggested that banning the farming of Atlantic salmon stems from concern that farmed Atlantic salmon could escape into the wild (<a href="http://www.oregonlive.com/politics/index.ssf/2013/03/oregon\_could\_ban\_genetically\_e.html">http://www.oregonlive.com/politics/index.ssf/2013/03/oregon\_could\_ban\_genetically\_e.html</a>. As a scientist there are a few comments I would like to make about this concern—based on the literature and experience of Washington, California and British Columbia.

A comprehensive report by the Northwest Fisheries Science Center of the NOAA National Marine Fisheries Service looked at the "the potential impacts of Atlantic salmon culture on the Puget Sound chinook salmon and Hood Canal summer-run chum salmon" in Washington State. The executive summary of this report (Waknitz et al., 2002) stated:

"For several parameters, the risks associated with escaped Atlantic salmon are low, in particular:

- The expectation that Atlantic salmon will increase current disease incidence in wild and hatchery salmon is low.
- The risk that escaped Atlantic salmon will compete with wild salmon for food or habitat is low, considering their well-known inability to succeed away from their historic range.
- The risk that salmon farms will adversely impact Essential Fish Habitat is low, especially when compared to other commonly accepted activities that also occur in nearshore marine environments.

For other parameters, there appears to be little risk associated with escaped Atlantic salmon, in particular:

- There is little risk that escaped Atlantic salmon will hybridize with Pacific salmon.
- There is little risk that Atlantic salmon will colonize habitats in the Puget Sound chinook salmon and Hood Canal summer-run chum salmon ESUs.
- There is little risk that escaped Atlantic salmon will prey on Pacific salmon.
- There is little risk that existing stocks of Atlantic salmon will be a vector for the introduction of an exotic pathogen into Washington State.
- There is little risk that the development of antibiotic-resistant bacteria in net-pen salmon farms or Atlantic salmon freshwater hatcheries will impact native salmonids, as similar antibiotic resistance often observed in Pacific salmon hatcheries has not been shown to have a negative impact on wild salmon."

## Important excerpts from that report include:

"No genetic compatibility between Atlantic salmon (genus Salmo) and wild Pacific salmon (genus Oncorhynchus) has been reported in the Pacific Northwest or elsewhere. Similarly, under controlled and protected laboratory conditions, where survival of hybrid offspring should be optimized, genetically viable hybrids between Atlantic and Pacific salmonid species have been impossible to produce. (Waknitz et al., 2002)."

"In the past century, there have been numerous attempts in the United States and elsewhere to establish Atlantic salmon outside their native range. At least 170 attempts occurred in 34 different states where Atlantic salmon were not native, including Washington, Oregon, and California (MacCrimmon and Gots 1979). None of these efforts was successful. No reproduction by Atlantic salmon was verified after introductions in the waters of these states (MacCrimmon and Gots 1979, Alverson and Ruggerone 1997, Dill and Cordone 1997). In California, attempts to establish Atlantic salmon populations have been discontinued because the expectation of successful introductions is "so remote that it does not warrant the effort or expense of an attempt" (Dill and Cordone 1997)."

Since 1991, 14 Biological Status Reviews have been published by NMFS as part of its federal obligation under the Endangered Species Act (ESA). These reviews are individual scientific studies of the current status of all anadromous salmonid populations on the west coast of the United States. These are generally regarded as the most complete scientific reviews of their kind ever published. They form the basis for National Marine Fisheries Service (NMFS) actions concerning ESA listing determinations, as well as the scientific basis for NMFS testimony for

litigation and courtroom challenges to proposed and implemented listings under ESA. In these reviews, experienced federal scientists have identified many factors which have adverse effects on the Pacific salmonids of the west coast. ... "Atlantic salmon farms have not been identified as the cause of any adverse effects in any of the 14 reviews conducted to-date, which cover 58 separate evolutionarily significant units (ESUs) for Pacific salmon species, or factors in the decline of west coast populations of chinook salmon or steelhead." (Waknitz et al., 2003)

#### 3. Mandatory signage in areas where genetically engineered fish are sold

This bill states that the State Department of Agriculture rules shall not be more restrictive than "the laws and rules of the federal Food and Drug Administration" The FDA cannot require that labels include information about production methods if there is no material difference in the products due solely to the production process. The National Research Council (NRC, 2002) found that foods from GE animals, as a class, do not present different or greater safety concerns than their conventional counterparts. Nor has the FDA found that, as a class, GE animals differ materially in nutritional value, organoleptic properties, or functional characteristics. Therefore, the FDA does not consider the fact that a food was made using GE, in and of itself, to be a material difference. Voluntary labeling is allowed if the label is neither false nor misleading.

As the most likely first GE fish on the market is likely to be the AquAdvantage salmon, what does the data and "the opinions of recognized experts and governmental agencies" say regarding the safety of this fish? The entire evaluation package including all of the compositional studies on the AquAdvantage salmon is available online (FDA 2010). The unanimous conclusion of the FDA scientists after examining all of the data and information summarized in the AquAdvantage salmon briefing packet was that the food from AquAdvantage salmon "is as safe as food from conventional Atlantic salmon, and that there is a reasonable certainty of no harm from the consumption of food from this animal".

The stated purpose of this emergency bill to provide signage where GE salmon is sold is to immediately preserve the "public peace, health, and safety." Labeling GE is not a food safety issue. The World Health Organization, the National Academy of Sciences, American Medical Association and more than 300 independent medical studies on the health and safety of GE foods have reached the same determination that foods made using GE ingredients are safe, and in fact are substantially equivalent to conventional alternatives.

It seems quite likely that the public will perceive the mandatory signage to be a warning suggesting that GE fish are inherently unsafe. Developers and grocery stores are understandably wary of having their brand targeted by activists and opponents, as happened in Europe where process-based GE labeling is mandatory. Voluntary process-based labeling (e.g. Kosher, Organic, GMO free, free range) provides consumer choice in the U.S. market place. Mandatory food labeling should be reserved for food safety and correctly identifying material differences in the nutrient content or some other material attribute of the food. I would also note that given the requirements of Country of Origin Labeling (COOL) act, packages of AquAdvantage salmon would be required to be labeled with the unique identifier "Farm Raised Atlantic Salmon, Product of Canada and Panama" at the point of sale.

I will finish with a quote from Greg Jaffe, from Center for Science in the Public Interest (CSPI) from a paper he gave at the FDA hearing on the labeling of food from AquAdvantage salmon held in Washington DC in 2010 (http://cspinet.org/new/pdf/salmon\_labeling\_presentation.pdf)

"CSPI believes it is very important that the language required on the label be neutral and informative. FDA should not require that the label include the words "genetically engineered." As mentioned earlier, there are many production methods for food products and many production methods for salmon. Identifying this production method without requiring all the other production methods to be identified would needlessly discriminate against genetic engineering and not provide the consumer with information about the "material" differences in this particular salmon. In addition, whatever label information is required, it will be important that FDA, the salmon industry, the sponsor and other food chain participants educate consumers about the label and the information it conveys. Providing information without education about what that information means is not particularly helpful to the consumer"

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