Genetically Engineered Salmon

Fast-Growing Hype

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GENETICALLY ENGINEERED SALMON - FAST-GROWING HYPE

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Food & Water Europe monitors the practices of multinational corporations that impact our food and water. They work with grasroots organizations around the world to create a genuinely economically and environmentally viable future.

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Foreword by The Development Fund

Imagine a fish growing twice as fast with less use of feed and with less environmental impact! It would be just what is needed to feed the world. Or is reality somewhat more complicated? The genetically engineered salmon from the American company AquaBounty is a textbook example of the typical hype surrounding genetically modified organisms (GMOs). This briefing paper provides the simple facts about this fish, which demonstrates serious risks to consumer health, animal welfare, fishing economies and the environment. Even the claim about growth rates is questionable.

The AquaBounty salmon was the very first animal to be patented in Norway, after the patenting of plants and animals was first legalized in 2004. The Development Fund fights patents on plants and animals because they threaten food security. It is illegal to do further breeding using patented material. Patents are thus blocking the cumulative process breeding actually is. Furthermore, it is also illegal to do independent biosafety research on patented material.

Rather than a technological quick fix in order to meet the challenge of global hunger, there is a need to increase investment in sustainable agroecological agriculture, where the needs and priorities of small scale food providers are put in the driving seat. No GMO can replace the need for robust systems for continuous plant and animal breeding. Thus, the sustainable use and conservation of genetic resources for food and agriculture is a pivotal precondition for future food security. GMOs, such as the AquaBounty salmon, put this at risk.

This paper focuses on the regulatory processes of AquaBounty Salmon in North America. The company has yet not applied for approval in the EU and Norway, where different regulatory regimes are in place, e.g. if a GMO is approved in Europe, it must be labeled. The terms genetically engineered (GE) and genetically modified (GM) are used interchangeably in this report.

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Introduction

The U.S. Food and Drug Administration (FDA) has indicated that it is nearing regulatory approval of genetically engineered (GE) salmon, which would be the first GE animal allowed into the food supply—anywhere in the world.[1] AquaBounty Technologies, the creator of GE salmon, boasts that the fish's fast growth rate will increase food production, feed the world's hungry, reduce ecological pressure on wild salmon harvests, create jobs and diminish the carbon footprint of producing seafood.[2] However, the available science does not support these claims. Beyond GE salmon's uninspiring growth rates, the fish also demonstrates serious risks to consumer health, animal welfare, fishing economies and the environment. In addition, GE salmon may diminish the nutrition and taste of the fish, which is one of the most popular and important fish in many Western diets.[3] Unfortunately, the FDA's weak regulatory approach has failed to examine both the false promises and clear risks of AquaBounty's GE salmon, leaving consumers unprotected.

Regulating AquAdvantage Salmon

AquAdvantage salmon is the trade name of AquaBounty's GE Atlantic salmon, which contains genetic material from an eel-like fish and a Chinook salmon, designed to make the fish grow faster.[4] The company plans to produce salmon eggs at its facility in Prince Edward Island, Canada, then fly them to a facility in Panama for grow-out, then ship the final food product to the United States for consumption.[5]

«The risky nature of GE salmon combined with a lack of oversight greatly increases the likelihood of environmentally destructive GE salmon escapes.»

AquaBounty's elaborate production plan—involving shipping salmon from Canada to Panama to the United States—is designed, essentially, as a demonstration project for FDA approval.[6] Once approved, AquaBounty intends to sell eggs to third parties for their own production.[7] GE salmon will likely be grown in countries where regulatory oversight is weak and where the FDA will not have the resources or capacity to monitor. The risky nature of GE salmon combined with a lack of oversight greatly increases the likelihood of environmentally destructive GE salmon escapes.

The FDA regulatory process is also severely weakened by the agency's decision to regulate GE animals as a veterinary drug rather than a food,[8] treating the new gene constructs as a veterinary drug. This regulatory approach severely limits the scope of the agency's risk-assessment on issues like food safety and allergies. For example, the agency has not conducted a single feeding study to assess health risks associated with eating GE salmon. Moreover, the FDA largely depended on veterinary scientists to review AquaBounty's application rather than those with a background in human nutrition, environmental science, or food science.[9]

The Science behind GE salmon

The FDA is basing its regulatory decision on scientific studies provided by AquaBounty, not independent science conducted by disinterested scientists. Not surprisingly, the data supplied by Aquabounty is biased, flawed, misleading and incomplete. Though rife with major errors, the data still suggests serious problems with the health and safety of GE salmon.

«Not surprisingly, the data supplied by Aquabounty is biased, flawed misleading and incomplete.»

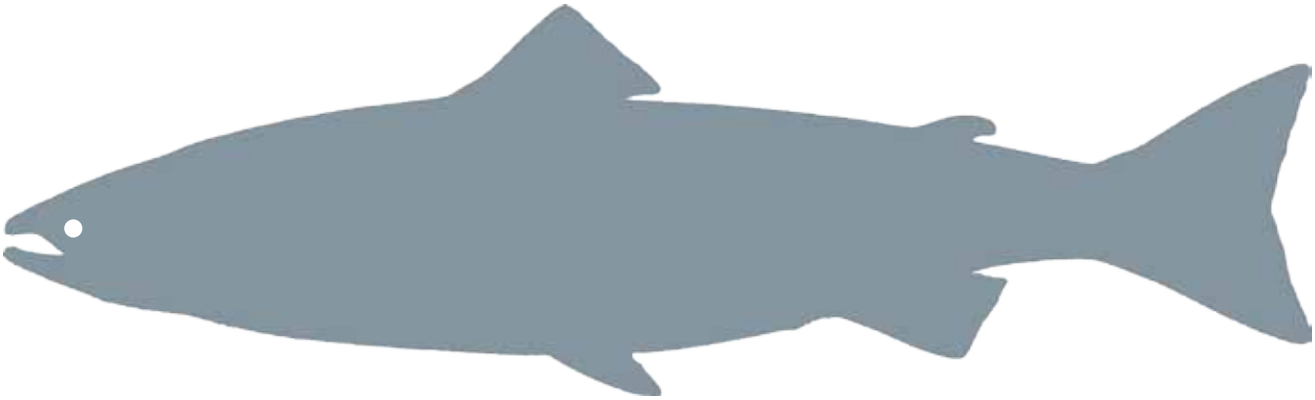
Independent scientists invited by the FDA to review the data called the overall data analysis lacking in rigor and poorly designed,[10] noted the insufficiently small sample sizes throughout the risk assessment,[11] highlighted the potential bias in several of the studies,[12] and criticized the agency's failure to fully investigate the gene insertion process.[13] One invited member—the only scientist with a background in fisheries (most of the members were large-mammal experts)—outright called for an entirely new and more rigorous risk-assessment by the FDA, called an Environmental Impact Statement.[14]

Scientists have been especially critical of the small sample sizes used by AquaBounty—often only six or seven GE fish were used in comparisons.[15] These small sample sizes meant that subsequent data analyses by the FDA did not find "statistically significant" differences between GE salmon and non-GE salmon, even when GE salmon, for example, manifested 40 percent higher levels of a hormone linked to cancer in humans.[16] The FDA, rather than insisting that AquaBounty re-conduct the studies using appropriate sample sizes, accepted AquaBounty's data and made far-reaching conclusions that there "are no food consumption risks" associated with GE salmon.[17]

Major deficiencies in the FDA's risk assessment—including gaps in data, missing studies, lack of transparency, dependence on industry-produced data and inconsistent regulatory coordination—have been highlighted in the scientific and legal community.[18]

Human Health Issues

The limited data that the FDA has released about the food safety and nutritional value of GE salmon show troubling results. GE salmon exhibited 40 percent higher levels of a hormone called insulin-like growth factor-1, which has been shown to increase the risk of certain cancers.[19] Also troublingly, the fish exhibited as much as 52 percent higher levels of "allergenic potency," which indicates possible allergic reactions from consumers.[20] This is especially relevant in light of evidence that other GE



«GE salmon exhibited 5 percent less protein but 58 percent greater total fat content compared to non-GE salmon.»

foods pose novel allergy risks to consumers. A New England Journal of Medicine study found that soybeans engineered with Brazil nut proteins caused allergic reactions for consumers with Brazil nut allergies.[21] Another study found that a harmless protein found in certain beans, which acts as a pest deterrent, became dangerous once it was transferred to a pea, causing allergy-related lung damage and skin problems in mice.[22]

On nutrition, an independent study found that traditional non-GE salmon contain 14 percent higher rates of beneficial omega fats.[23] In a compositional analysis submitted to the FDA by AquaBounty, GE salmon exhibited 5 percent less protein but 58 percent greater total fat content compared to non-GE salmon.[24] GE salmon also exhibits large differences in vitamin, mineral and amino acid levels compared to non-GE salmon, which the FDA did not rigorously investigate.[25]

Animal Welfare

Not only does GE salmon potentially pose a threat to human health, but it may also pose a threat to the health of the modified Atlantic salmon. Data submitted by AquaBounty shows that GE salmon suffered high rates of malformations and health problems, like jaw erosions and inflammation, which were not observed in non-GE salmon.[26]

«GE salmon suffered high rates of malformations and health problems»

A more complete understanding of animal welfare issues is not possible, however, because of major scientific errors and bias in AquaBounty's data collection. Before AquaBounty researchers physically examined salmon for health problems, they selectively killed off irregular fish, biasing the data set and severely compromising the integrity of the data.[27] The FDA acknowledged this major scientific error, [28] but never indicated that it would require AquaBounty to submit additional studies. The agency concluded it would address this serious issue through "post-approval safety surveillance"[29]—a dangerous wait-and-see attitude that will allow the fish to go to the marketplace before the FDA has made a scientific determination about the safety of the fish. This post-market regulatory approach also appears to treat consumers as guinea pigs.

Escape and Environment

When GE salmon escape from commercial facilities, their impact on wild salmon and biodiversity could be significant. Because fish move freely through bodies of water, escapees are essentially impossible to capture. This is especially the case for salmon, which spends part of its life in saltwater and part in freshwater.

Unfortunately, the FDA risk assessment scarcely examined the environmental problems associated with GE salmon. The agency has very little scientific expertise related to fisheries or environmental science and has failed to adequately and consistently consult with other government agencies with the necessary expertise.[30] Dartmouth University Professor Anne Kapucinski, a renown expert on environmental issues related to biotech fish, has noted major deficiencies in FDA's environmental review, citing three missing analyses: an uncertainty analysis, a quantitative failure-mode analysis and an analysis of the possible environmental impacts.[31]

Though the FDA did a cursory examination of the likelihood of GE salmon escaping, the agency did not examine the environmental consequences if salmon do escape. Many of Kapucinski's criticisms were echoed by the senior scientists at the United States Fish and Wildlife Service (a government agency) who have expressed grave concerns with the environmental implications of GE salmon.[32] These scientists called FDA's risk assessment "overly simplistic" and express having been excluded from the regulatory process, even though the FDA is required by law to consult with the agency.[33] This again casts doubt on how competently the FDA has conducted its regulatory review.

Also disconcerting, a news report in 2012 reported that AquaBounty may have already experienced an escape event of GE salmon at their experimental facility in Panama. A storm in 2008 caused a tree to fall on the facility, which caused a mechanical failure, which resulted in all GE salmon being "lost," according to the company.[34] The FDA never publicly acknowledged the existence of this major event, and has failed to publicly verify AquaBounty's claim in 2012 that the "lost" GE salmon actually suffocated rather than escaped.[35] AquaBounty's Panamanian facility is located in an area that routinely experiences severe weather and major flooding, suggesting the possibility of future natural disasters and more "lost" salmon.[36]

«Once GE salmon escape, they could out-compete wild salmon for food and even mates, quickly driving down wild populations.»

Moreover, AquaBounty intends to sell GE salmon eggs to third parties for commercial production,[37] which may produce the fish in a variety of models, including the dominant industrial model of open-water net-pen aquaculture. The FDA, whose job it is to oversee future production, does not have the resources to comprehensively evaluate, audit or review the dozens or hundreds of new GE salmon facilities that may enter production. This lack of oversight creates additional likelihood of escape. An estimated 2 million farmed salmon escape into North Atlantic waters every year while millions of others escape into the Pacific.[38]

Once GE salmon escape, they could out-compete wild salmon for food and even mates, quickly driving down wild populations. A 2011 study of GE salmon mimicked an escape event and found that GE salmon would survive if released in the wild.[39] Even if salmon fail to survive or reproduce in the wild, their short-term presence could have myriad and insidious impacts on native fish populations and a variety of marine life, which the FDA did not examine.[40]

An additional concern about escaping GE salmon is the disease they could spread to wild populations. Farmed salmon currently in production, which are raised in stressful, densely crowded environments, have already been linked to the spread of disease, like infectious hematopoictic necrosis, sea lice and furunculosis.[41] In 2009, AquaBounty's Canadian facility tested positive for the lethal infectious salmon anemia virus (ISAV), which ravaged the company's fish stocks, leading the company to completely depopulate entire parts of the facility.[42] The company's struggles to contain this major outbreak, which appears to have happened only 12 months after AquaBounty's "lost" salmon in Panama, again calls into question competently the company can manage the many biosafety measures needed to raise GE salmon in a safe manner.

Scientists invited by the FDA to review AquaBounty's data in 2010 criticized the agency's failure to assess GE salmon's disease resistance, and it is unclear why the FDA did not inform these scientists or the public about the ISAV outbreak at that time, waiting two years to disclose this information.[43] Just as the agency has failed to meaningfully address the weather and natural disaster issues surrounding AquaBounty's "lost" salmon, so, too, has the agency failed to examine the critical issue of disease resistance in GE salmon.[44]

Lacking an understanding of disease resistance of GE salmon means the FDA cannot assess the volume of antibiotics that AquaBounty may use to commercially produce GE salmon. The over-application of antibiotics in animal agriculture has caused widespread antibiotic resistance that are of major concern to public health.

Sterility and Containment

Acknowledging the threat of escape, AquaBounty has attempted to render GE salmon sterile, which would prevent sexual reproduction in the event they are released into the wild. However, the company's regulatory submissions indicate that up to five percent of GE salmon will not be sterile.[45] If millions of GE salmon eggs are going to end up in commercial production, as industry cheerleaders contend,[46] this would mean hundreds of thousands of fertile GE salmon eggs will likely be production. As the company acknowledges, "No single containment measure can be assured of 100% effectiveness."[47]

Adding more doubt to AquaBounty's sterilization plan, in 2011 the USDA awarded the company a controversial $494,000 grant to improve its sterilization procedures for GE fish.[48] When asked at a U.S. Senate hearing whether this grant was an indication the current ineffectiveness of AquaBounty's current sterilization process, the company's president said the grant will be used for "next generation" of fish sterilization, which will strive for 100 percent sterilization.[49]

AquaBounty also has created a physical containment plan to prevent escape, claiming that the salmon will be grown in closed, in-land facilities like the facility it has in Panama.[50] However, most commercially raised salmon are grown in big nets in open water, notorious for salmon escapes. The company's largest investor, the biotech company Intrexon, has cited the potential of the company to contribute to "large-scale" and "global" aquaculture,[51] which would seem to translate to the dominant industrial model of net-pen aquaculture, which is prone to escapes. More than 330,000 salmon escaped from a large-scale sea-cage salmon farm in Scotland in a single event in 2011 because of bad weather.[52]

Even if GE salmon are grown in closed, in-land facilities, as AquaBounty promises, they could easily escape. Because fish eggs are miniscule in size, they would be easy to steal, by employees or intruders, a concern raised to the FDA by independent scientists.[53] Likewise, mechanical failure—due to things like power outages during storms—could result in escapes from closed facilities. Both of AquaBounty's facilities, in Canada and Panama, are located close to bodies of water that could support escaped GE salmon.[54]

A biotech operation doing experimental work in New Zealand

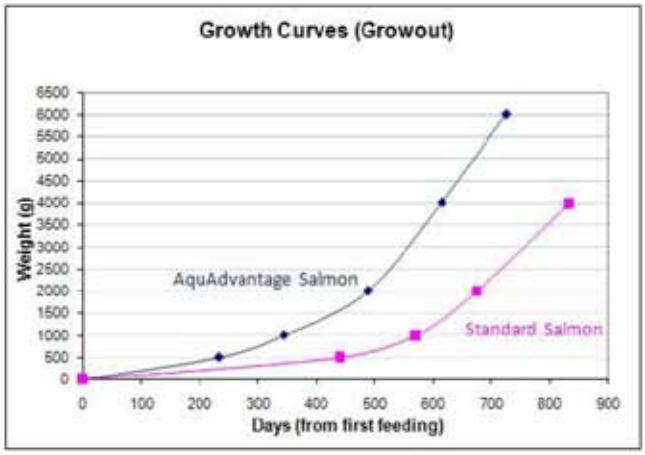
has already been suspected of accidentally releasing genetically modified salmon eggs into the wild.[55] And the FDA has still failed to publicly investigate the "lost" salmon at AquaBounty's Panamanian facility in 2008.[56]

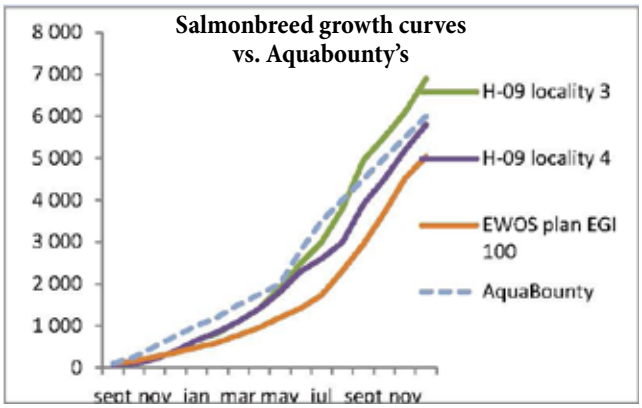
Purported Benefits and Industry Opposition

AquaBounty promotes GE salmon in the media as being able to grow to harvest weight twice as fast as non-GE salmon,[57] recycling a narrative used throughout the biotech industry that GE food products dramatically increase production, needed to feed the world.[58] Just as biotech corn and soy have failed to live up to this hype,[59] so will GE salmon.

GE salmon's purported growth rates has failed to impress the farmed-salmon industry, where commercial growers have used selective breeding (non-GE) techniques for decades to develop fast-growing salmon that can grow as fast or faster than AquaBounty purports GE salmon can grow.[60] Norwegian grower Salmobreed issued a press release showing that its own salmon grow as fast or faster than GE salmon purports to grow.[61] A senior scientist at Norway's NOFIMA institute has called AquaBounty's growth rates misleading.[62] Marine Harvest and Cermaq, both in Norway, which together produce 65 percent of the world supply of salmon, have also expressed opposition to GE salmon.[63]

No increased growth in GE salmon





SalmoBreed is questioning the growth curves used by AquaBounty. *Source: SalmoBreed newsletter november 2011*

In regulatory submissions to the FDA, AquaBounty appears to have compared GE salmon to a particularly slow-growing strain of salmon, which made GE salmon growth-rates appear phenomenally fast by comparison.[64] Not surprisingly, there has never been a head-to-head comparison between GE salmon and the fast-growing non-GE salmon already in commercial production in places like Norway.[65]

Nevertheless, AquaBounty uses its growth-rate claims to advertise GE salmon as a better and faster means of production, offering a more environmentally friendly production model than traditional salmon. But given the unimpressive growth rates, these beneficial claims are highly suspect.

Consumer Opposition

Hundreds of thousands of consumers in the United States have formally objected to FDA's review of GE salmon, submitting comments that criticize the agency's regulatory process, express concern over the safety of the salmon as a food, and insist that the fish be labeled.[66] These comments are bolstered by several consumer surveys, which have revealed overwhelming opposition to the approval of GE salmon. A Reuters survey found that almost two-thirds (65 percent) of consumers would not eat GE fish and 93 percent of consumers want it labeled.[67] This mirrors the results of a poll commissioned by Food & Water Watch, which found that 78 percent of consumers oppose GE salmon.[68] Even an online poll from the conservative Wall Street Journal found that 60 percent of its readers would not eat GE salmon.[69]

Loudly, clearly and consistently, consumers have voiced their opinion that they see GE salmon as a fish with potential food safety and environmental risks, which deserves better regulation and mandatory labeling if the FDA does approve it.

And How Does it Taste?

Completely absent from the FDA's review of GE salmon is an analysis of its consumer and industry desirability— its taste, smell, texture, quality and costs of production. The commercial success of meat products, including salmon, depend on their having marketable characteristics associated with taste, smell and texture.[70] Given the large differences in the fat, protein and nutritional content of GE salmon, it is unclear why the FDA did not examine such characteristics.

Lobbying and Political Influence

As AquaBounty's poor data has inspired many critics, the company's false promises have also inspired several angel investors. The synthetic biology company, Intrexon, acquired a close to half of the company's stock in November 2012.[71] Intrexon is run by the former CEOs of Monsanto and Pfizer,[72] and the company's vice-president is a 20-year veteran from Monsanto who worked on the company's highly controversial biotech product recombinant bovine growth hormone (rBGH).[73]

Intrexon bought all of the shares controlled by Kahka Bendukidze,[74] a former economics minister from the Republic of Georgia who made his fortunes in Russia and who today maintains several investments in biotechnology and aquaculture.[75] Bendukidze

injected a million dollars into AquaBounty in 2011 to keep the company afloat and, in return, the company spun off its research arm into a separate organization called the Center for Aquaculture Technologies, which Bendukidze purchased for one dollar.[76] This spin-off included AquaBounty's egg-production facility in Prince Edward Island.[77] The restructuring of the company was designed to reduce the operating costs of AquaBounty because the company was facing financial difficulties while awaiting FDA regulatory approval.[78]

Because GE salmon would be the first-ever GE animal to enter the food supply, the stakes of FDA approval go beyond AquaBounty. The biotechnology industry as a whole has a tremendous interest in seeing GE salmon approved and setting a low bar for future GE animal applications with the FDA. And the influence the wider biotechnology industry has over policy and regulation cannot be understated. Biotech corporations spent nearly $550 million in campaign contributions and lobbying expenditures in the last decade in an effort to secure favorable rules, regulations and policies.[79]

AquaBounty has also found a major ally in the Biotechnology Industry Organization (BIO), a powerful American trade organization that represents the interests of biotech companies. BIO spent close to $8 million lobbying Congress in 2011 on issues including GE salmon.[80]

Labeling

In the United States, the FDA has, thus far, declared that all GE food products are similar enough to non-GE food products that they do not need to be labeled. Though the FDA has said it will make a separate labeling decision on GE salmon, which will set a precedent for all GE animals entering the food supply, it seems almost certain that the agency will allow the product to be sold without a label.

The economic consequences of such a labeling decision by the FDA could be great for non-GE salmon producers. Consumers may react to the FDA's decision by choosing to avoid salmon altogether, hurting markets for wild salmon and traditional non-GE salmon.

Patenting

It is unclear the entire scope of AquaBounty's patent regime surrounding GE salmon, but when the company went public on the London Stock Exchange in 2006, it reported having obtained a "worldwide exclusive licence" to the patent over GE salmon.[81] The company reported that this would enable its production of GE salmon in the United States, Spain, France, Great Britain, Netherlands, Canada, Chile, Japan and Australia.[82] As of its 2006 filing with the London Stock Exchange, AquaBounty reported that the patent over GE salmon was still pending in Norway.[83] The company also claimed that a patent had been issued or was pending in Chile.[84]

«BIO spent close to $8 million lobbying Congress in 2011 on issues including GE salmon.»

The company also reported in 2006 an agreement with Oxford Insect Technologies (Oxitec) to eventually patent a "molecular sterility system."[85] Oxitec is currently doing controversial work testing GE mosquitoes, designed to reduce malaria and dengue fever through population reduction of mosquitoes.[86]

AquaBounty has filed an Australian patent for "maternally induced sterility in animals" that uses transgenics to achieve 100 percent sterility, according to the company's claims.[87] AquaBounty's sister company, A/F Protein,[88] holds a patent for "determination of genomic sex in salmonids."[89]

The patent in Europe was filed in 1992 on "transgenic fish comprising a promoter and a fish growth hormones gene sequence", but since 20 years have passed, the patent has now expired.[90] Also the patent in Norway has expired. The US patent is still valid until August 2013.

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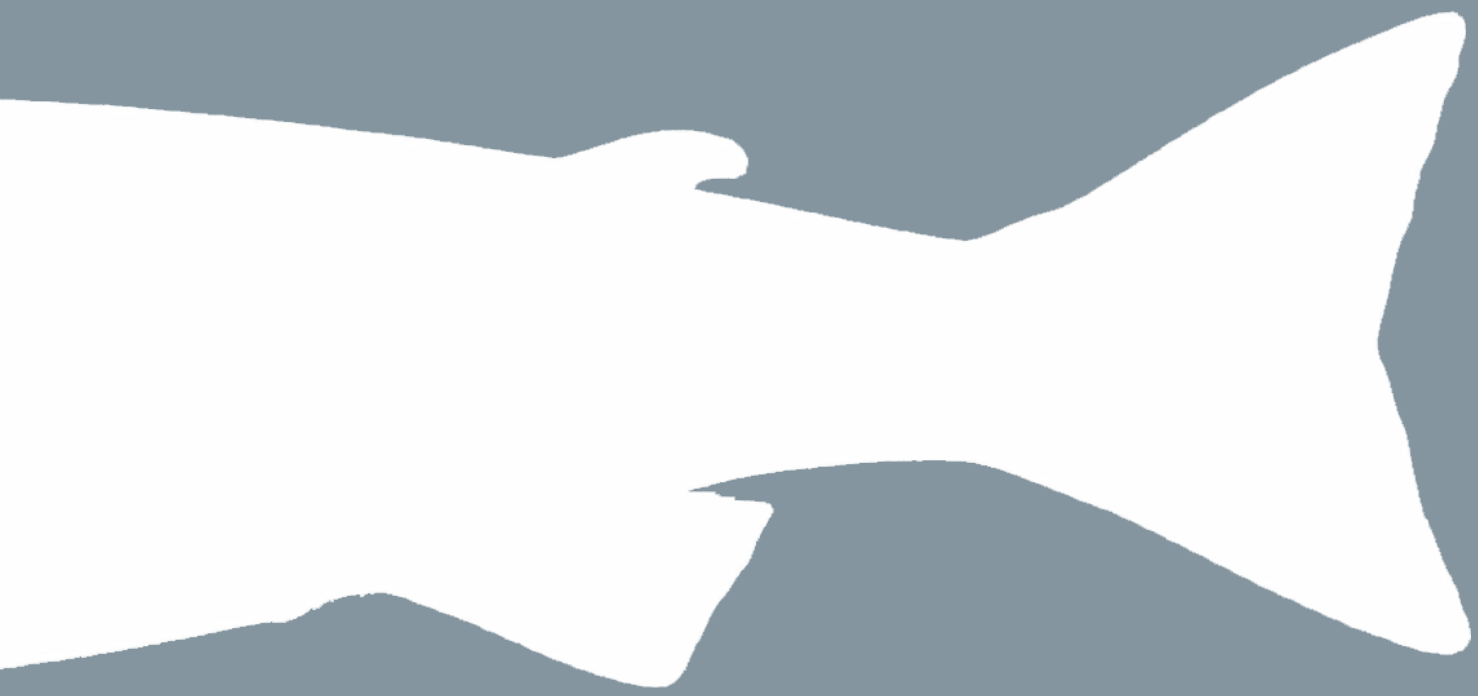
«Beyond GE salmon's uninspiring growth rates, the fish also demonstrates serious risks to consumer health, animal welfare, fishing economies and the environment.»



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