Genetically Engineered Salmon

Deficient, Deformed, and Dangerous to You and the Environment

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In November 2015, the FDA approved GMO salmon based on AquaBounty's studies, failing to address the many scientific errors and concerns documented in this issue brief. According to AquaBounty, the first GMO salmon fillets should arrive in the United States in 2017 or 2018, though many leading U.S. grocers have publicly stated they do not intend to sell the product. FDA has said GMO salmon will not need a label, leaving consumers in the dark.

The Food and Drug Administration (FDA) has indicated that it will soon advance the regulatory application of genetically engineered (GE) salmon, which, if approved, would be the first such animal allowed into the U.S. food supply.[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 science behind GE salmon does not support the hype.

Beyond GE salmon's uninspiring growth rates, the fish demonstrates serious risks to consumer health, animal welfare, fishing economies and the environment. That's all on top of potentially diminishing the nutrition and taste of salmon, one of the most popular and important fish in the American diet.[3] Unfortunately, the FDA's flimsy regulatory approach has failed to examine both the false promises and clear risks of AquaBounty's GE salmon, leaving consumers unprotected.

The Biotech Push

Given the ambitions of the biotechnology industry, which claims that genetic engineering is essential to future food production and corporate profits, the FDA's approval of GE salmon would set an important precedent, paving the way for a deluge of new GE animals to enter the food supply. The FDA has also taken under consideration other proposals, like the Enviropig™, a GE pig engineered to have manure with less phosphorous and designed for use on environmentally damaging factory farms.[4]

The biotech industry spent nearly $550 million lobbying Congress between 1999 and 2009 to secure favorable rules, regulations and policies.[5] AquaBounty's main ally, the Biotechnology Industry Organization, spent around $8 million just in 2011 lobbying on issues including GE salmon.[6] The long-term intensive lobbying effort has allowed biotech companies to take control of the genetic content of much of the food produced in the United States, including almost all of the corn and

soybeans in production.[7] This irresponsible experiment on human health doesn't need an encore performance with animal agriculture.

Consumers clearly do not want to eat GE salmon. A 2010 *Reuters* poll found major consumer opposition to genetically engineered fish, and 93 percent of respondents said they would want it to be labeled.[8] The FDA has ignored consumer concerns while also setting an extremely low bar for AquaBounty's scientific submissions, accepting data from the company that is flawed, biased, misleading and incomplete. The FDA also failed to consult with other federal agencies that have expertise on environmental and fishery issues for much of the approval process.[9]

To make matters worse, the FDA is likely to allow this fish to be sold without labeling, leaving consumers without a way to avoid GE salmon if it reaches the market — or to make an informed choice about their diet.

A Biotech Solution in Search of a Problem

AquaBounty has radically altered Atlantic salmon by inserting genetic material from an eel-like fish and a chinook salmon, designed to make the fish grow faster.[10] AquaBounty promotes GE salmon in the media as being able to grow to harvest weight twice as fast as non-GE salmon,[11] recycling a narrative used throughout the biotech industry that GE food products dramatically increase production, needed to feed the world.[12] Just as biotech corn and soy have failed to live up to this hype,[13] so will AquaBounty's GE salmon.

In regulatory submissions to the FDA, AquaBounty made a far less robust claim about GE salmon's growth rate, saying only that GE salmon can reach a weight of 100 grams — one-fortieth of the normal harvest weight of salmon — more quickly than a non-GE salmon.[14] And it appears that the company was comparing GE salmon to a particularly slow-growing strain of salmon, which made GE salmon growth rates appear phenomenally fast by comparison.[15]

This bogus demonstration of GE salmon's growth rate has failed to impress the farmed-salmon industry, where commercial growers have used selective (non-GE) breeding techniques for decades to develop fast-growing salmon.[16] Two major commercial growers have said that their salmon grow as fast as or faster than GE salmon.[17] One salmon operation called GE salmon a "solution searching for a problem," noting the unimpressive growth rates.[18]

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.[19] Given the apparent commercial irrelevance of GE salmon, it is difficult to understand why the FDA has spent more than $1 million of taxpayer money reviewing this fish for regulatory approval.[20]

At What Cost?

Even if GE salmon could grow slightly faster than existing domesticated salmon, it would likely be much more expensive to produce. AquaBounty acknowledges that the price of GE salmon eggs will be higher than non-GE salmon eggs,[21] and also reports that the fish require up to five times more food and almost twice as much oxygen as non-GE salmon.[22] GE salmon also appear to exhibit higher rates of deformities,[23] which points to higher costs of production.

The FDA appears to have ignored examining the dubious benefits of GE salmon, striving instead for a conclu-

sion that GE products are not unsafe. In the case of GE salmon, there are indications that the public will bear the costs of GE salmon — through damage to public health, the economy and the environment.

Manipulating Genes and Massaging Data

As part of its regulatory process, the FDA invited an advisory panel of scientists to review its risk assessment of GE salmon. This advisory committee found major errors in AquaBounty's science and the FDA's data analysis. Scientists were especially critical of the small sample sizes used by AquaBounty — often only six or seven GE fish were used in comparisons.[24]

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.[25] 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.[26]

Many advisory committee members criticized the science behind the FDA risk assessment. They called the overall data analysis lacking in rigor and poorly designed,[27] highlighted the small sample sizes throughout the risk assessment,[28] noted potential bias in the studies[29] and criticized the agency's failure to fully investigate the gene insertion process.[30] One invited member, the only scientist with a background in fisheries (most of the members were large-mammal experts), called outright for an entirely new and much more rigorous risk assessment by the FDA — known as an Environmental Impact Statement.[31]

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.[32] The science surrounding GE salmon is clearly insufficient as a basis for regulatory approval of the world's first transgenic animal and points to the need for more studies, more independence and more transparency.

GE Salmon's Impact on Human Health

The FDA has chosen to regulate GE animals as a veterinary drug rather than a food,[33] a decision that severely limits the scope of the agency's risk assessment. For example, the agency has not conducted a single feeding study to assess health risks associated with eating GE salmon. Moreover, most of the scientists invited by the FDA to review AquaBounty's application were from backgrounds in veterinary science or biotechnology — not human nutrition, environmental science or food science.[34]

The limited summaries of data that the FDA has released about the food safety 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.[35] Also troublingly, GE salmon exhibited as much as 52 percent higher levels of "allergenic potency," which indicates possible allergic reactions from consumers.[36]

This is especially relevant in light of evidence that other GE 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.[37] 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.[38]

On nutrition, an independent study of non-GE salmon found that their values of beneficial omega fats were 14 percent higher than those in GE salmon.[39] In a study performed by AquaBounty, GE salmon exhibited 5 percent less protein but 58 percent greater total fat content compared to non-GE salmon.[40] GE salmon exhibit large differences in vitamin, mineral and amino acid levels compared to non-GE salmon, which the FDA did not rigorously investigate.[41]

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, such as jaw erosions and inflammation, which were not observed in non-GE salmon.[42]

After physically examining GE salmon for abnormalities, AquaBounty frequently reported GE salmon exhibiting a greater rate of slight, moderate or severe irregularities.[43] The fish may experience higher rates of mortality as well, but unfortunately a more complete understanding of animal welfare issues is not possible because of major scientific errors and bias in AquaBounty's data collection.

Before AquaBounty researchers physically examined GE salmon for health problems, they selectively killed off irregular fish, biasing the data set and severely compromising the integrity of the data.[44] Although the FDA acknowledged this major scientific error, [45] the agency never indicated that it would require AquaBounty to submit additional studies. The agency concluded that it would address this serious issue through "post-approval safety surveillance."[46] This dangerous wait-and-see attitude also appears to treat consumers as guinea pigs for AquaBounty's lab experiment.

A molecular biologist from Cornell University who participated in the FDA advisory committee echoed a popular sentiment among the invited scientists: "I think that is not appropriate. I think that if there are uncertainties and there are admitted uncertainties, that they should be addressed prior to this fish being allowed on the market."[47] Another invited scientist said the FDA's proposed surveillance plan gave him "heartburn."[48]

Wild Salmon and the Environment

GE salmon can have unintended consequences that go beyond animal welfare and human health. When GE salmon escape from commercial facilities, their impact on wild salmon populations 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, in part because the agency has very little scientific expertise related to fisheries or environmental science. At a Senate hearing about the environmental safety of GE salmon, legislators and scientists roundly agreed that the FDA should be consulting with other federal agencies that have the necessary expertise in these areas, such as the National Oceanic and Atmospheric Administration.[49]

Dartmouth Professor Anne Kapucinski, a renowned expert on environmental issues related to biotech fish, has noted major deficiencies in the FDA's environmental review, citing three missing analyses: an uncertainty analysis, a quantitative failure-mode analysis and an analysis of the possible environmental impacts.[50] Although the FDA did a cursory examination of the

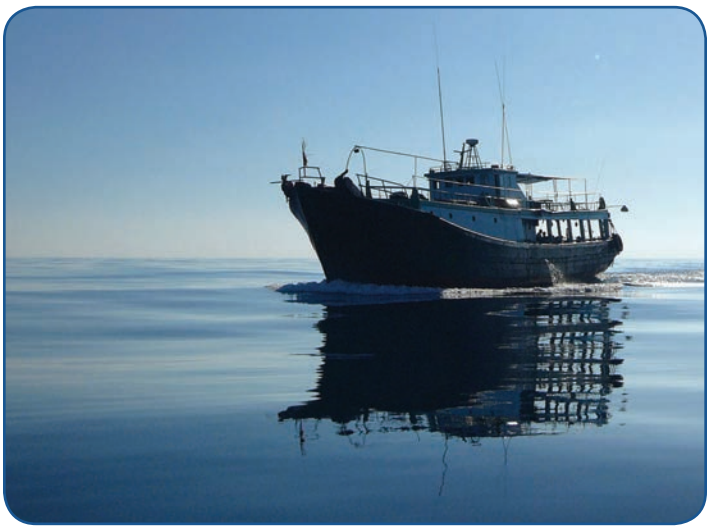
likelihood of GE salmon escaping, the agency did not examine the environmental consequences if salmon do escape. Many of Kapucinski's criticisms were echoed by senior scientists at the U.S. Fish and Wildlife Service, who expressed grave concerns about the environmental implications of GE salmon.[51]

In documents released through a Freedom of Information Act request, Fish and Wildlife Service scientists called the FDA's risk assessment "overly simplistic" and expressed having been excluded from the regulatory process, even though the FDA is required by law to consult with the agency.[52] This again casts doubt on how competently the FDA has conducted its regulatory review.

More troubling, a news report in 2012 reported that AquaBounty may have already experienced an escape event of GE salmon at its experimental facility in Panama. A storm in 2008 caused a tree to fall on the facility, which caused a mechanical failure, resulting in all GE salmon being "lost," according to the company.[53] The FDA never publicly acknowledged the existence of this major event, and has failed to publicly verify AquaBounty's 2012 claim that the "lost" GE salmon actually suffocated rather than escaped.[54] 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.[55]

AquaBounty intends to sell its GE salmon genetics to third parties for commercial production,[56] 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.[57]

Once GE salmon escape, they could outcompete 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.[58] Even if salmon fail to survive long enough to reproduce, their short-term presence in the wild could have myriad and insidious impacts on native fish populations and a variety of marine life, which the FDA did not examine.[59]



An additional concern about escaping GE salmon is the disease that they could spread to wild populations. Farmed salmon currently in production, which are raised in stressful, densely crowded environments, already have been linked to the spread of diseases, such as infectious hematopoictic necrosis, sea lice and furunculosis.[60]

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 parts of the facility.[61] The company's struggles to contain this outbreak, which appears to have happened only 12 months after AquaBounty's "lost" salmon in Panama, again calls into question how the company will manage the many biosafety measures needed to raise GE salmon.

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.[62] 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.[63]

Lacking an understanding of disease resistance of GE salmon means that 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 is of major concern to public health, and the FDA should not be approving new products that could further drive this dangerous trend.

Externalizing Risk

AquaBounty, meanwhile, has taken a more cavalier approach to potential GE fish escapes. In the mid-1990s, the company's research manager authored a risk assessment that included a hypothetical scenario involving the "usual number of fish escaping." The company claimed that such an escape could have a beneficial effect on employment by giving Aboriginal Canadians work as fishing guides for the trophy-sized GE fish.[64]

The biotech industry has a long history of failing to live up to promises to keep GE products contained, which has resulted in major economic damages to U.S. food producers.[65] At least one farmer has proven in court that his land was contaminated with biotech crops he did not plant.[66] In another example, U.S. rice growers lost an estimated $1.2 billion in revenue in 2006 after an experimental GE rice was accidentally co-mingled with non-GE rice stocks,[67] prompting trade partners to ban or restrict imports.[68]

Biotechnology companies do not have a track record of responsible stewardship and control of their genetically engineered organisms. GE salmon could be particularly damaging not only to wild fish populations but to the entire fishing industry. A reduction in wild stocks due to GE salmon escapes would hurt the fishing industry and could serve to consolidate fish production in corporate-owned fish farms. The fishing industry could suffer, too, if non-GE salmon became contaminated with GE traits. This and other threats have prompted members of Congress to support legislation banning or restricting GE salmon.[69] Notably, these legislators include the entire delegation of Alaska, where wild salmon fishing is an important part of the economy.[70]

Five-Percent Uncertainty

Acknowledging the threat of escape, AquaBounty has attempted to render GE salmon sterile, which would prevent sexual reproduction in the event that the fish are released into the wild. However, the company's regulatory submissions indicate that up to 5 percent of GE salmon will not be sterile.[71] If millions of GE salmon eggs are going to end up in commercial production, as industry cheerleaders contend,[72] this would mean hundreds of thousands of fertile GE salmon eggs will likely be in production. As the company acknowledges, "No single containment measure can be assured of 100% effectiveness."[73]

Adding more doubt to AquaBounty's sterilization plan, in 2011 the U.S. Department of Agriculture (USDA) awarded the company a controversial $494,000 grant to improve its sterilization procedures for GE fish.[74] When asked at a U.S. Senate hearing whether this grant was an indication of the ineffectiveness of AquaBounty's current sterilization process, the company's president said that the grant will be used for the "next generation" of fish sterilization, which will strive for 100-percent sterilization.[75]

AquaBounty also has created a physical containment plan to prevent escape, claiming that the salmon will be grown in closed, inland facilities.[76] 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,[77] which would seem to translate to the dominant industrial model of net pen aquaculture. More than 330,000 salmon escaped from a large-scale sea-cage salmon farm in Scotland in single event in 2011 because of bad weather.[78]

Even if GE salmon are grown in closed, inland 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.[79] Both of AquaBounty's facilities, in Canada and Panama, are located very close to bodies of water that could support escaped GE salmon.[80]

Likewise, mechanical failure — due to things like power outages during storms — could result in escapes from closed facilities. A biotech operation doing experimental work in New Zealand has already been suspected of accidentally releasing genetically modified salmon eggs into the wild.[81] And the FDA has still failed to publicly investigate the "lost" salmon at AquaBounty's Panamanian facility.[82]

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, depends on their having marketable characteristics associated with taste, smell and texture.[83] 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.

High-Powered Investors

As AquaBounty continues to collect critics, it has also inspired several angel investors. The synthetic biology company, Intrexon, acquired close to half of the company's stock in November 2012.[84] Intrexon's board of directors includes the former CEOs of Monsanto and Pfizer,[85] and one of the company's senior vice presidents is a 20-year veteran from Monsanto who worked on the company's highly controversial biotech product, recombinant bovine growth hormone (rBGH).[86]

Like GE salmon, rBGH received very minimal FDA review despite major food safety concerns, specifically including high levels of IGF-1. Most western nations don't allow the use of rBGH, and a host of private companies like Kroger, Walmart and Starbucks eventually took the extraordinary measure of independently banning rBGH use from their own products.[87] With former Monsanto executives now looking to take the lead on GE salmon, there is grave concern that they will be able to muscle the product through regulatory approval and sell it without a label.

Conclusion

Peddling potentially dangerous products of dubious value to the marketplace, AquaBounty appears to be the biotech industry's sacrificial lamb — securing regulatory approval of a product that will likely be a market failure, but that will pave the way for other bioengineered food animals.

The FDA, meanwhile, is pushing forward despite widespread criticism over the agency's lack of rigor, independence and transparency in analyzing GE salmon. Consumers have said they don't want to eat it, and salmon growers say they don't want to produce it, but the FDA continues to add to the more than $1 million tab it has racked up reviewing GE salmon. Meanwhile, the USDA and other government agencies have handed over another $2.4 million in taxpayer-funded research grants to keep the company afloat while it faces bankruptcy.[88]

AquaBounty has clearly not demonstrated that GE salmon is safe for consumers or the environment or the fishing industry. The FDA's unwillingness to step up to the plate and protect consumers has compelled dozens of legislators to support legislation opposing GE salmon or to require the FDA to conduct additional studies.[89] But because FDA Commissioner Margaret Hamburg insists that the agency will soon be moving ahead with AquaBounty's regulatory application for GE salmon, the FDA needs to hear your voice.

Take Action!

Tell the FDA not to allow GE salmon into the food supply. Go to www.foodandwaterwatch.org to take action.

Or, contact the FDA at:

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

1-888-INFO-FDA

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Food & Water Watch works to ensure the food, water and fish we consume is safe, accessible and sustainable. So we can all enjoy and trust in what we eat and drink, we help people take charge of where their food comes from, keep clean, affordable, public tap water flowing freely to our homes, protect the environmental quality of oceans, force government to do its job protecting citizens, and educate about the importance of keeping shared resources under public control.