



# Food Safety *Fact Sheet*

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## — GENETICALLY ENGINEERED FISH —

DESPITE A LACK of long-term food safety or environmental studies on the introduction of genetically engineered (GE) fish, the U.S. Food and Drug Administration (FDA) recently announced that they are in the process of approving the “AquAdvantage” Salmon—the first GE animal intended for human consumption—a GE Atlantic salmon produced by AquaBounty Technologies. At least 35 other species of GE fish are currently being developed around the world, including trout, catfish, tilapia, striped bass, flounder, and many species of salmon. These fish are being engineered for traits that allegedly will make them better suited for industrial aquaculture, such as faster growth, disease resistance, larger muscles, and temperature tolerance. The genes engineered in these experimental fish come from a variety of organisms, including other fish, coral, mice, bacteria, and even humans.



of fish and our marine environment. Each year, an estimated two million salmon escape from open-water net pens into the North Atlantic, outcompeting wild populations for resources and straining ecosystems.<sup>1</sup> The risk of transgenic contamination of wild stocks has been raised numerous times by members of the public, scientific community, and Congress. In one recent study, Canadian researchers concluded that if fertile male GE Atlantic

salmon (which the company uses to produce its female line of GE salmon) were to escape from captivity they could succeed in breeding and passing their genes into the wild.<sup>2</sup>

Further, research published in the Proceedings of the National Academy of Sciences concluded that a release of just sixty GE fish into a wild population of 60,000 could lead to the extinction of the wild population in less than 40 fish generations.<sup>3</sup> If FDA opens the approval door, GE fish will likely be among the millions of salmon that currently escape every year, resulting in the last blow to wild salmon stocks.

Anticipating the stark danger to our ocean environments and the fisheries that depend on them—and trying to avoid any analyses of those dangers—AquaBounty has claimed that they will only raise their fish in land-based facilities. As a result, FDA dramatically confined its analysis to two small land-based facilities. Regardless, even in land-based facilities, farmed salmon have the ability to escape into the wild, where they will be virtually impossible to recover. At present, the company’s breeding operation is on Prince Edward Island, where the Atlantic Salmon Federation’s surveys have found Atlantic salmon in 22 rivers.<sup>4</sup>

AquaBounty also says that it will only produce sterile females, but the evidence it submitted to FDA shows that it produces eggs that may be only 95% sterile.<sup>5</sup> Moreover, the company will need to keep stocks of fertile fish to produce additional offspring. If FDA permits companies to raise GE fish in “inland waters” this will present a novel threat to our nation’s lakes, rivers, and estuaries, many of which are already under attack by invasive fish species like the Asian carp and Northern snakehead. Thus even if grown in land-based facilities, the “farming” of GE fish raises serious environmental risks.

### GE SUPER-SALMON: COMING FOR DINNER?

The GE “AquAdvantage” salmon now in the final stages of FDA review is engineered with the growth hormone genes from a Chinook salmon (*Oncorhynchus tshawytscha*) and the DNA from the anti-freeze genes of an eelpout (*Zoarces americanus*). This engineering causes the production of the growth hormone year-round, creating a GE fish the company claims grows at twice the normal rate of natural salmon. The intended result is to allow industrial fish farms to increase their productivity: to crowd more salmon into net pens and still get high production rates.

In December 2012, FDA announced a public comment period on the FDA’s Environmental Assessment of the GE salmon (Docket No. FDA-2011-N-0899). The specific application seeks approval to manufacture its GE salmon eggs in Canada, ship the eggs to Panama to be grown and then sell the final fish product in the United States for human consumption. However, AquaBounty has stated on numerous occasions that it intends to sell its eggs to aquaculture companies world-wide once it secures FDA’s approval.

### GE FISH THREATEN THE ENVIRONMENT AND WILD SALMON

Genetically engineered fish pose serious risks to wild populations

But more fundamentally, AquaBounty's current claim is a thinly veiled smokescreen. AquaBounty has stated on record that its goal is to grow the GE fish in the U.S. and elsewhere in the world. A former executive of the company has already met with officials in the State of Maine seeking to grow these fish in Maine, one of the states with endangered Atlantic salmon.<sup>6</sup> Competing corporations will also no doubt race to produce GE fish in crowded open ocean facilities already in use for fish production. While FDA may purport to place initial restrictions on the farming of GE fish, it is likely merely a matter of time before FDA is pressured by corporations to replace conventional fish in open ocean farms with the GE variety, without even adequate analysis of potential impacts.

## GE FISH THREATEN HUMAN HEALTH

The human health impacts of eating these GE fish are completely unknown. While data on human health impacts of GE fish is sparse, some recent studies have provided cause for serious concern. For example, the routine use of antibiotics to control diseases often found in farm-raised fish may already be impacting human health. Some research has suggested that transgenic fish may be susceptible to more diseases than fish currently grown in aquaculture facilities.<sup>7</sup> Consequently, the amount of antibiotics given to transgenic fish may be higher than the amount currently given to farmed fish; farmed salmon are already given more antibiotics than any other livestock by weight. By eating farmed fish treated with antibiotics, humans will be ingesting antibiotics that may be harmful. Indeed, some antibiotics are toxic and can even cause fatal allergic reactions.<sup>8</sup> The use of antibiotics in aquaculture further exacerbates the significant problem of antibiotic resistant bacteria.

The potential human health concerns connected with the use of antibiotics in aquaculture, including the unique role transgenic fish may play in escalating these concerns, must be fully assessed by FDA. FDA reviews noted that increased prevalence of focal inflammation in various tissues in the salmon is most likely due to the presence of the AquaAdvantage genetic engineering. These findings suggest that the AquaAdvantage salmon may require more antibiotics.

The importance of thorough human health and environmental studies cannot be overstated because the AquaBounty transgenic salmon is the first-ever GE animal intended for human consumption. This animal should not be approved for human consumption until and unless further study indicates that they are safe for consumers, native salmon populations and the environment.

## NO FEDERAL LAWS SPECIFICALLY GOVERN THE REGULATION OF GE ANIMALS

Unfortunately, there are no U.S. laws specifically governing the

regulation of GE animals. Instead, FDA has decided to "regulate" GE fish and any other future GE animals as "new animal drugs." To receive FDA approval to commercialize a GE fish, producers must complete a New Animal Drug Application (NADA) and demonstrate the efficacy of the fish and genetic construct. There are numerous major weaknesses in such an approach, including lack of transparency, improper scope of review, lack of appropriate agency expertise, and lack of public participation. To date, the Center has taken a number of steps to attempt to address this regulatory disparity.

- As far back as 2001, the Center for Food Safety, on behalf of a coalition of over 60 organizational partners, filed legal petitions with the FDA and other regulatory agencies demanding a moratorium on the domestic marketing and importation of GE fish until and unless FDA adequately addresses impacts to the environment, native fish populations, and threats to food safety, and requires labeling of any GE fish in the marketplace.

- In 2011, the Center, Earthjustice, Ocean Conservancy, Friends of the Earth, Food & Water Watch, Center for International Environmental Law, and Greenpeace filed a legal petition demanding FDA complete a thorough environmental impact statement assessing the full range of potential environmental and ecological risks associated with the AquaBounty GE salmon, and calling on the agency to fix the flaws in its regulatory process for GE animals.<sup>9</sup>

- Later in 2011 Center for Food Safety filed a legal petition with FDA to require the labeling of all GE foods, including any GE fish. So far over 1 million of you have written to FDA in support of that petition.

**FDA's decision to go ahead with this approval process is misguided and dangerous.** We all know there is a great appetite for salmon, but the solution is not to factory farm genetically engineered salmon; the solution is to work to bring our wild salmon populations—and the ecosystems they depend upon—back to sustainability. Instead, the approval of these dangerous transgenic fish will only exacerbate the problems facing our ocean ecosystems.

The Center for Food Safety strongly opposes the commercialization of genetically engineered fish and is urging FDA not to approve AquaBounty's GE salmon. Should FDA decide to approve the AquaAdvantage GE salmon despite our opposition, clear, mandatory labeling is an absolute must to allow consumers to make informed purchasing decisions.

## WHAT YOU CAN DO: GET INVOLVED!

Visit our campaign website, [www.ge-fish.org](http://www.ge-fish.org), to get involved! Individuals can send comments to FDA, download campaign materials, or send a letter to Congress.

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6. October 6, 2010 email from Robert Stratton, of Maine government to Fish and Wildlife Services employees regarding Joe McGonigle former VP of AquaBounty. Email obtained by Food and Water Watch using Freedom of Information Act request.  
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