

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
USA



28 February 2012

Dear Sirs,

re: Docket No. FDA-2011-N-0899 Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon: Availability

I am writing on behalf of GM Freeze, a UK-based alliance of organisations opposed to the rapid development of GM crops, animals and food. We are calling for a moratorium until key questions relating to the safety of GM crops and animals, as well as the socio-economic and cultural impacts, are answered. We believe that people have the right to choose whether or not to purchase and consume GM food from any source, and therefore we support full labelling of all products using GM ingredients or derived from them, including products from animals reared on GM feed.

We object to the proposed licensing for food of AquaBounty's GM salmon and urge the US authorities to reject the application.

There are several reasons why we think that GM salmon should not be approved:

1. Ethical considerations

We object in principle to the genetic modification of animals. Using GM leads to the further commodification of animals for profit, and we object to extending the already problematic relationship people have with farm animals. We do not consider it to be ethical to treat animals in this way. The use of highly selective conventional animal breeding has already facilitated the rise of very intensive poultry and animal production units. These production systems demean other species and are unsustainable because of animal welfare, animal health, human disease, antibiotic resistance, waste management and feed supply problems.

We are concerned that animal welfare issues will arise with the GM salmon. These could include changes to biochemistry that could impact on the fish's ability to withstand disease, or they could impact upon its immune system, reproductive system or general metabolic pathways with unknown consequences for the health of the fish. We have not seen any evidence from AquaBounty that it has looked for such changes or assessed the risk they pose to the health and welfare of the GM fish.

2. Risks to the environment

AquaBounty admits that the "sterility" mechanism used in the GM salmon, based on production of triploid eggs, is not 100% effective, and we believe that it never will be. AquaBounty states that, "...[C]onditions used in the production facility can reliably produce batches of eggs that are on average 99.8% triploid (range: 98.9 to 100%)." If there was a release GM fish stock at any stage, two in 1,000 fish on average would be fully fertile, and as many as one in 100 could survive and breed.

Additionally AquaBounty provides no evidence that the sterile GM fish will not attempt to breed, which could disrupt reproduction in natural fish already struggling to survive.

AquaBounty's safety case appears to be based on the assumption that this faulty "sterility" mechanism, used in conjunction with biosecurity measures at hatcheries and production sites, will prevent the GM salmon becoming established in the environment. We do not accept that this is likely. Basic human error, or the breakdown of quality control systems, cannot be ruled out. Multiple failures of systems intended to protect people and the environment have occurred.

For instance BP blamed the Deepwater Horizon disaster in the Gulf of Mexico on “a complex and interlinked series of mechanical failures, human judgments, engineering design, operational implementation and team interfaces”.ⁱ Extreme weather events could also play a part in contributing to the escape of significant numbers of eggs, fry, fingerlings or adult fish at any stage in the AquaBounty production chain, including during transport between different facilities.

The aquaculture industry has a long history of escapes and survival of escaped fish in the wild. In the UK Pacific Humpbacked Salmon (a native of the Pacific Ocean region) have been caught in the River Camel in Southwest England, the River Tweed in Southern Scotland and off-shore near Montrose on the East coast of Scotland in recent years. These fish are believed to come from the White Sea in Northern Russia, where the species were introduced in the 1960s and then escaped to successfully breed in rivers in northern Norway, demonstrating that risk assessment should extend over large areas and long time periods. The impact of these escaped fish on these highly valued rivers, where several native salmonid species live and breed, is unknown. UK anglers are advised to kill any Pacific Salmon they catch and not return them to the river, but it is not clear if this will have any effect on the numbers and impact of the alien fish present.

The history of introductions of alien fish species in the UK (for example the Zander) illustrate that direct ecosystem impacts can often be delayed, can vary from location to location and that control measures are seldom 100% effective (especially if the escape is difficult to distinguish from native species, as would be the case with AquaBounty’s GM salmon).ⁱⁱ

The impact of escaped fast-growing GM salmon on freshwater ecosystems and native fish populations has not been adequately addressed by AquaBounty. These are extremely difficult to predict due to the lack of data, hence AquaBounty’s reliance on theoretical hypothesis. Given the faulty “sterility” system, the difficulty in identifying GM fish and the near impossibility of recapturing escapees, hypothesis is not enough.

Even the use of surrogate native species in experimental releases would not be an adequate approach to assess the risk because their behaviour and survival may be quite different from the GM fish in the wild. Even a short period of survival in the wild by a larger fast-growing GM fish might be sufficient to damage local breeding populations either through interference with breeding behaviour, competition for spawning sites, predation or general disturbance of the territories of native fish potentially making them more vulnerable to predators. These effects could be magnified if the GM fish survived for longer periods. AquaBounty has submitted no evidence on the behaviour of GM Atlantic salmon compared to native wild species. Gathering it would require either a full-scale release of GM salmon into the environments where escapes could occur or a series of very elaborate contained experiments that attempted to replicate condition in the wild. Neither is reliable or desirable.

An experimental release into the wild would be an entirely unacceptable risk because the fish would be impossible to recall. A contained experiment may not provide a true picture because key variables may be missing from the design. Deciding on the duration and size of such experiments would be very difficult because the impacts of escapes could be gradual or dependent on populations reaching a certain threshold.

We therefore conclude that it will very difficult to adequately establish a scientific judgment on the impact of fully fertile GM salmon or a sterile GM salmon on wild populations. The US regulatory authorities should therefore adopt a precautionary approach and reject the application to proceed with commercial production.

3. No market but expectation of serious economic damage

European opposition to any GM ingredient in food remains very high among the general public. The presence of GM salmon in the EU market would be strongly opposed. GM fish would have to carry normal compulsory GM labels, by which the GM fish could easily be identified, and we believe the potential for sales is extremely small. This could easily translate into reduced sales of other non-GM salmon, including both US exports, domestic UK salmon and UK salmon on sale in

the US (as the US is the largest market for UK salmon exports) as consumers fearing GM contamination are already indicating the safest option is to refuse to buy any salmon if the GM version is approved. This will have serious implications for the salmon industries on both sides of the Atlantic, and possibly beyond, and it is not warranted for a product with no informed market. Before approving GM salmon the US authorities should consider the adverse public reaction in the UK to GM tomato and soya-based food products in the late 1990s, which led retailers to withdraw products like Flavr Savr tomato puree and Batchelor's Beanfeast very soon after they were introduced. These strong public reactions against these products lead to the comprehensive ban UK supermarkets operate on all GM ingredients in own-brand products.

In summary we do not believe there is an ethical justification to genetically modifying salmon to grow faster, and we do not share AquaBounty's faith in its biosecurity systems. In addition the European market for GM salmon is likely to be very tiny, and the mere presence of GM salmon could have a knock-on effect on sales of other salmon, with serious implications for these industries.

We therefore respectfully request that the US FDA rejects the application.

Finally I confirm that GM Freeze is happy for our submission to be placed in the public domain.

Yours faithfully,



Pete Riley
Campaign Director

ⁱ See www.bp.com/sectiongenericarticle.do?categoryId=9034902&contentId=7064891.

ⁱⁱ Linford RSJ, undated. The impact of zander (*Stizostedion lucioperca* (L.)) in the United Kingdom and the future management of affected fisheries in the Anglian Region. <http://www.fao.org/docrep/009/ae997b/AE997B09.htm>