

Comments of Consumers Union on  
Department of Health and Human Services (HHS) Food and Drug Administration (FDA)  
Draft Environmental Assessment and Preliminary Finding of No Significant  
Impact Concerning a Genetically Engineered Atlantic Salmon  
Docket No. FDA-2011-N-0899  
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Consumers Union<sup>1</sup> (CU) welcomes the opportunity to comment on the Food and Drug Administration (FDA) Draft Environmental Assessment and Preliminary Finding of No Significant Impact (FONSI) Concerning a Genetically Engineered (GE) Atlantic Salmon. For reasons articulated below, we strongly urge FDA not to approve the application for AquaBounty's AquAdvantage Salmon (AAS) at this time and should prepare a complete Environmental Impact Statement (EIS).

The present FDA Environmental Assessment (EA) suffers from a number of grave inadequacies. First, despite overwhelming evidence we have from many industries, from nuclear power to the airline industry, that the best and most conscientiously designed safety systems can and will inevitably at some point fail, FDA assumes that the containment systems for genetically engineered salmon will simply never fail. This allows FDA to conclude that growing GE salmon in Price Edward Island (PEI), Canada and in Panama, will never affect the environment of the United States. We believe that this is a fundamentally flawed conclusion, and that FDA must conduct a "failure mode analysis" as part of a full EIS on this GE salmon. The potential impact of the PEI facility in particular should consider the possibility that the GE salmon could escape and survive and that they or their offspring may be able to swim to waters off the coast of Maine, where there are populations of endangered Atlantic salmon. To assert that the GE salmon will never escape is wishful thinking on the part of FDA, not valid environmental impact analysis.

Second, the EA considers only that the GE salmon will be raised in two facilities, in Canada in Panama. However documents recently obtained by FOIA reveal that facilities within the United States are applying for permission to grow these GE salmon. It is a major omission from the current EA that the impact of these facilities is not considered. A full EIS must be conducted evaluating the potential impact of these facilities.

Under present drug law, companies must get permission for changes in production methods for drugs they sell. If a company changes its method of production for a drug, it must demonstrate that the change in production method hasn't changed the safety value

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<sup>1</sup> *Consumers Union, publisher of Consumer Reports, is an expert, independent nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. To achieve this mission, we test, inform, and protect. To maintain our independence and impartiality, Consumers Union accepts no outside advertising, no free test samples, and has no agenda other than the interests of consumers. Consumers Union supports itself through the sale of our information products and services, individual contributions, and a few noncommercial grants. Over 8 million people subscribe to Consumer Report or Consumer Reports online.*

of the resulting drug. In the case of the genetically engineered salmon, aka AquAdvantage Salmon (AAS), which is being evaluated by FDA as a new animal drug, this would mean that any decision to allow production or sales to any facility in the United States or elsewhere in the world should have to be evaluated but could be approved by FDA without any further public review or comment or environmental analysis. It is essential to review all proposed production sites now.

It is essential that this environmental assessment be done correctly. This decision, involving the first genetically engineered animal, is precedent setting. This will be the first GE food animal to be approved for human consumption and so will set the standard for the risk assessment of GE food animals that follow. We must set a high bar in terms of the scientific value/credibility of the environmental risk assessment. The scientific value of the draft EA is current inadequate due to the poor quality of the science in the EA and the fact that it ignores more up-to-date scientific methods for ecological risk assessment, e.g. failure mode analysis.

## **Detailed comments**

### **Physical, geographical and biological confinement systems are not 100% effective**

The draft EA'S Finding of No Significant Impact (FONSI) is based on the assumption that various confinement measures (e.g. physical, chemical, geographical, and biological) will ensure that no fish will escape into the environment in either Prince Edward Island (PEI) or Panama or, even if the fish do, they will die due to environmental conditions. We believe that a credible possibility exists that fish could escape at PEI and swim to Maine waters. Therefore, FDA must conduct a full EIS assessing this possibility.

None of the various confinement measures are absolute. In terms of physical and chemical confinement, FDA offers no assurance that these multiple confinement methods will always be continuously working and achieving the desired result. FDA fails to consider that something could go wrong, either due to equipment malfunction, human error, or natural disaster (possibly exacerbated by climate change). We note further that AquBounty Technology (ABT) has had financial difficulties. In late 2012 a Russian businessman, Kakha Bendukidze, who had acquired 47.6% of the company's stock, sold his shares to the synthetic biology firm Intrexon.<sup>2</sup> FDA offers no assurances that this company, or future owners whoever they may be, will ensure that all the proper safeguards will be taken at all times at the facilities in Panama and PEI.

We further question whether FDA has the legal authority or sufficient resources to require these multiple confinement systems. As stated on page 74 of the draft EA, "both the production of eyed-eggs and the grow-out of the fish is to be conducted only in land-based facilities with redundant physical containment measures and with point-to-point

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<sup>2</sup> Pollack, A. 2012. Engineered fish moves a step closer to approval. *New York Times*, December 22, 2012. Pg. B1. At: <http://www.nytimes.com/2012/12/22/business/gene-altered-fish-moves-closer-to-federal-approval.html>

control of shipping and land-based materials transfer.” It is unclear whether FDA has any existing legal mechanism or practical inspection capabilities through which it could impose these claimed conditions.

Biological containment is also not foolproof. AquaBounty Technology likes to refer to AquaAdvantage Salmon (AAS) as “sterile all female population [that] ... cannot escape or reproduce in the wild.” However, the sterility is not 100%. The main sterility technique involves producing all females and then treating the eggs so that they become triploid. As FDA notes in the EA (pages 40-41), each batch of eggs must have no more than 5% diploid individuals. Thus, up to 5% of the eyed eggs could be diploid and still be allowed for sale. Since millions of eyed eggs will be sold, this could result in a significant number of fertile female AAS.

There is also the issue of “exceptional diploids.” Work done with coho salmon engineered with a growth hormone found that the process of press-shock induction of triploidy lead to an overall rate of 1.1% “exceptional diploids.”<sup>3</sup> These “exceptional” diploid fish contained the transgene but whether they are fertile and able to transmit the transgene to offspring isn’t known. Research needs to be done to see if “exceptional diploids” also occur in AAS and, if so, steps must be devised to detect such individuals and remove those eggs from grow-out.

If there is anything we should have learned from the experiences of the nuclear power industry, it is that even the best designed safety systems can sometimes unexpectedly fail. Given the potential lack of reliability of the multiple confinement systems, FDA should consider the possibility that these systems may at some point fail and so should consider the ecological and environmental consequences of release of AAS into nearby waters.

### **Inadequate science and unfounded assumptions in the environmental assessment**

The draft EA is insufficient in a number of respects. Not only are data missing, but there are numerous questionable assumptions made, and the most recent science is not included. In terms of the environmental effects looked at for the draft EA, FDA focused on an outdated list of issues from a 1991 publication.<sup>4</sup> There have been great strides made in methodologies for assessing the environmental risks of transgenic fish, with these newer methodologies systematically integrating information about the environment and fish’s genotype and phenotype to identify and prioritized hazards to focus on in the environmental risk assessment. Indeed, 2007 saw the publication of *Environmental Risk Assessment of Genetically Modified Organisms, Vol. 3: Methodologies for Transgenic Fish*<sup>5</sup>, the key document for this field. Unfortunately, FDA does not even reference this key document. A key notion is the need for a failure mode analysis, which is the state-of-

<sup>3</sup> Devlin RH, Sakhrani D, Tymchuk WE, Rise MA and B Goh. 2010. Occurrence of incomplete paternal-chromosome retention in GH-transgenic coho salmon being assessed for reproductive containment by pressure-shock-induced triploidy. *Aquaculture*, 304: 66-78.

<sup>4</sup> Kapuscinski AR and EM Hallerman. 1991. Implications of transgenic fish into natural ecosystems. *Canadian Journal of Fisheries and Aquatic Sciences*, 48: 99107

<sup>5</sup> Kapuscinski AR, Hayes K, Li S and G Dana. 2007. *Environmental Risk Assessment of Genetically Modified Organisms, Vol. 3: Methodologies for Transgenic Fish*. CABI Publishing, UK. 304 pp.

the art for reducing environmental risks of many technologies. This failure mode analysis, which should be as quantitative as possible, could evaluate the multiple confinement methods to see how well each one of them actually works by themselves and collectively, and even suggest ways to improve any weaknesses found.<sup>6</sup> FDA must require an EIS and do an environmental risk assessment that uses the most scientifically accurate and up-to-date methodologies. **At a minimum, FDA must do a quantitative failure mode analysis of the multiple confinement methods.**

The EA makes a number of questionable assumptions to argue that the odds of survival of any escaped AAS are virtually zero. For example, FDA argues that even if AAS escape the Panama facility, they could not live as the temperature of the water in the nearby river is too high. FDA does not present any data to show that AAS cannot live at higher water temperatures, FDA simply assumes that “there is no *a priori* reason” for the AAS to have a higher temperature tolerance compared to non-GE salmon. FDA ignores a study published in 2010 that found that GE coho salmon (with an added growth hormone gene) grew faster at 18 °C than at 12 °C, whereas non-GE coho salmon did not.<sup>7</sup> According to the draft EA, the high-elevation portions of the Panamanian river near the grow-out facility have a water temperature range of 15 ° to 19 ° (Table 3, EA). This suggests that the AAS could show faster growth at higher temperatures, or be able to survive at these temperatures. The draft EA has no data on this topic. In addition, according to the US Fish and Wildlife Service scientist, there are rainbow trout in the river near the Panamanian facility, so the water conditions may be appropriate for AAS as well.

In terms of the PEI facility, where the brood stock are located, the EA asserts that even if AAS escape that facility the water is too cold and too salty for fry to survive. However, this area has in the past been wild salmon habitat. No data on cold or salt tolerance were presented for AAS.

A document obtained by Freedom of Information Act (FOIA), entitled, “Region 5 Fisheries Program Comments on FDA approval process for Aqua Bounty Technologies, Inc. (ABT)/AquAdvantage GMO salmon,” clearly shows US Fish and Wildlife Service scientists were concerned: “If the brood stock from the PEI facility were released either accidentally or with malicious intent, we do not feel enough evidence has been provided to conclude the risks to natural populations of Atlantic salmon in Canada and US are negligible. Additional experimentation needs to be conducted to verify that any escapees from the PEI facility will not be able to tolerate the brackish water in the vicinity of the facility. Also, the lack of information on the transport procedures from PEI to Panama is troublesome. It is during this stage of the operation that malicious activities could result in these fish being lost from the direct control of ABT.” This memo also raises the issue that populations of Atlantic salmon in Maine could be affected as well: “considerations

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<sup>6</sup> Pillay A and J Wang. 2003. Modified failure mode and effects analysis using approximate reasoning. *Reliability Engineering and System Safety* 79 (2003) 69–85.

<sup>7</sup> Löhmus M, Sundström LF, Björklund M and RH Devlin. 2010. Genotype-temperature interaction in the regulation of development, growth and morphometrics in wild-type, and growth-hormone transgenic coho salmon. *PLoS ONE* 5:e9980

about the potential implications to the listed Atlantic salmon stocks in Maine would need to be addressed, including the genetic issues, such as the threats such as introgression if escapes occurred.”

As part of the environmental consequence assessment (EA, section 7, pp 65 and following), the EA puts forth several other unsupported assertions about why escaped fish would not survive. First, FDA assumes that AAS are the most fit in the environment that they were developed/evolved in and will be less fit in a new environment, e.g. the wild. This assumption ignores the fact that fish often do better in new environments as evidenced by the growing crisis of successful establishment of alien aquatic species.<sup>8</sup> The EA also assumes that AAS are so domesticated and dependent on artificial food that they wouldn't be able to survive in the wild. The EA offers no data to back up this assertion. It also ignores the fact that GE coho salmon do as well or better than wild-type coho salmon under most food-limited conditions.<sup>9</sup>

Finally, the EA fails to consider the growing body of research on the genetic and ecological risks of transgenic fish. This growing body of research has been excellently summarized by the submission of Drs. Anne Kapuscinski and Fredrik Sundström to this docket.<sup>10</sup> We strongly concur with the recommendation of Drs. Kapuscinski and Sundström that FDA “require a science-driven environmental risk assessment that treats the complexity and uncertainty directly and honestly, using the most current methodologies,” and following 7 ecological risk assessment steps they lay out.<sup>11</sup> In sum, given the inadequate science and narrow scope of this draft EA FONSI, and the criticisms of outside scientists and of the Region 5 Fisheries Program, we urge FDA to not accept the EA FONSI, but, rather to require a science-driven EIS that uses up-to-date assessment methodologies.

### **EA fails to consider all likely grow-out locations, including US sites**

Documents obtained by Freedom of Information Act (FOIA) and released on April 25, 2013 reveal that a number of companies have already applied to US Fish and Wildlife Service for permits to import eyed eggs of AAS but have not told the FDA about that.<sup>12</sup> In one email, an employee of the National Oceanic and Atmospheric Administration notes that ABT “can sell eggs they produce to companies anywhere in the country for those companies to grow out. **There have been requests from several companies to**

<sup>8</sup> Casal CMV. 2006. Global documentation of fish introductions: the growing crisis and recommendations for action. *Biological Invasions*, 8: 3-11.

<sup>9</sup> Sundström LF and RH Devlin. 2010. Increased intrinsic growth rate is advantageous even under ecologically stressful conditions in coho salmon (*Oncorhynchus kisutch*). *Evolutionary Ecology* 25: 447-460. At:

<sup>10</sup> Kapuscinski A and F Sundström. 2013. Comments on Docket No. FDA-2011-N-08 Draft Environmental Assessment for AquAdvantage Salmon and Preliminary Finding of No Significant Impact, Dated 4 May 2012. At:

[http://www.dartmouth.edu/~ark/images/stories/kapuscinski\\_sundstrom\\_comments\\_2012draftea\\_aas.pdf](http://www.dartmouth.edu/~ark/images/stories/kapuscinski_sundstrom_comments_2012draftea_aas.pdf)

<sup>11</sup> Pg. 9 in IBID.

<sup>12</sup> Center for Food Safety. 2013. Press Release. Nearly 1.5 Million Objections to Genetically Engineered Salmon Filed with FDA. At: <http://www.centerforfoodsafety.org/press-releases/2121/nearly-15-million-objections-to-genetically-engineered-salmon-filed-with-fda>

**USFWS (they regulate importing salmon to the US) to import those eggs, though AquaAdvantage [sic] has not discussed this with FDA.” bold added.**

For example, in one of the FOIA documents released on April 25, Joseph Moran, USFWS official, sent an email in 2011 noting that “We received a call yesterday that a private West Virginia aquaculture facility (Wilson Mill Farms) may submit a request under Title 50 to import as many as 80,000 genetically-modified salmon eggs ... to accomplish grow-out field testing.”

Since FDA appears unaware of these plans to raise AAS in the USA, it has not evaluated whether AquaBounty has taken any steps to ensure that any company that it sells eyed eggs to will agree to all the biological, chemical and geographical confinement measures. Would ABT sell eyed eggs to a company that planned to grow the AAS in open net pens? Although FDA maintains that AAS should only be grown on land-based facilities, how can they ensure this if they don’t know to whom ABT is selling their eyed eggs?

Even if FDA is informed of additional grow-out facilities, there is the question of whether FDA has the staff, resources and sufficient overseas jurisdiction for adequate surveillance of diverse US and foreign hatcheries and grow-out facilities as sales of the AAS proliferate.

### **Conclusion**

We believe that FDA must prepare a full EIS with the best most up-to-date science for ecological risk assessment that considers all possible grow-out locations, including ones in the USA, and that includes a thorough failure mode analysis.