Wave of the Future: The Case For Genetically Modified Salmon

By “Coach Vance” Trefethen

Special Note: Be sure to check the latest news before running this case. The current laws governing GMO salmon could change at any time.

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GE Salmon are sterile, so they can’t breed with normal fish 14

They’re all sterile and they’re all female:  they can’t breed with each other, so they can’t establish an invasive population 14

The salmon are all female and all sterile 14

Conventional aquaculture salmon don’t survive in the wild, and neither would modified salmon 15

No escapes:  There is only 1 approved location in the world where they can be grown, and it is well protected (and it’s on land! in the highlands of Panama) 15

Even if a fish escaped, it would die on the way to the Pacific Ocean because the water is too warm 15

There are so many barriers that escape risk can be disregarded 16

“Human Health effects” / “Allergies” - Responses: 16

GE Salmon Safe to eat 16

No allergy problem:  Other fish currently on the market have a lot more allergens than GE salmon 16

No scientific consensus on what level of allergens would be a risk.  And people who are allergic will simply… not eat it. 17

The allergy risk of NON-Genetically Modified fish has never been studied, so no way to know if GM salmon have “more” allergy risk. 17

FDA Study:  modified salmon are not dangerous to humans 18

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The very first genetically modified animal food approved for sale in the United States was studied for 20 years, and the studies found no safety problems. You’d think selling it and eating it would be simple. But then Congress got involved, and nothing was simple any more. Please join my partner and me as we affirm that The United States federal government should substantially reform its agriculture and/or food safety policy in the United States.

OBSERVATION 1. We offer the following DEFINITIONS.

Policy: “a high-level overall plan embracing the general goals and acceptable procedures especially of a governmental body” (*Merriam Webster Online Dictionary, copyright 2016* [*http://www.merriam-webster.com/dictionary/policy*](http://www.merriam-webster.com/dictionary/policy))  
  
Substantial: “c :  [important](http://www.merriam-webster.com/dictionary/important), [essential](http://www.merriam-webster.com/dictionary/essential)” (*Merriam Webster Online Dictionary, copyright 2016* <http://www.merriam-webster.com/dictionary/substantial>*)*

OBSERVATION 2. INHERENCY, the structure of the Status Quo. Two key FACTS

FACT 1. Genetically engineered salmon finally approved

In November 2015, after 20 years of study, the Food & Drug Administration approved genetically engineered salmon

Michael Mezher 2016 (journalist) 29 Jan 2016 “FDA Baqns Import of Genetically Engineered Salmon” REGULATORY AFFAIRS PROFESSIONALS SOCIETY <http://www.raps.org/Regulatory-Focus/News/2016/01/29/24208/FDA-Bans-Import-of-Genetically-Engineered-Salmon/> (“GE” = genetically engineered)

In November, FDA approved AquaBounty Technologies' AquAdvantage salmon after two decades of deliberation. The genetically engineered salmon is modified to grow faster than non-GE Atlantic salmon and come to market in 18 months rather than the typical three years. "After rigorous scrutiny, FDA determined that food from AquAdvantage salmon is as safe and nutritious to eat as food from non-GE Atlantic salmon," [*said Dr. Bernadette Dunham*](http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM473976.pdf), director of the Center for Veterinary Medicine at FDA. As part of the approval, AquaBounty is only authorized to produce the salmon at two facilities, a breeding facility in Canada and a growing facility in Panama. The agency also conducted an environmental assessment to ensure there would be no significant environmental consequences of approving AquAdvantage salmon.

FACT 2. Salmon blocked again

Two months later, Congress voted to block genetically engineered salmon again due to false claims about safety

Vanessa Schipani 2016 (master’s degree candidate in history and philosophy of science at Utrecht Univ., Netherlands; B.S. degree in zoology; science journalist) “False Claims about ‘Frankenfish’” 23 Mar 2016 <http://www.factcheck.org/2016/03/false-claims-about-frankenfish/> (brackets added)

In January, the FDA also issued a [ban](http://www.accessdata.fda.gov/CMS_IA/importalert_1152.html) on the import and sale of GE salmon until the agency “publishes final labeling guidelines for informing consumers of such content,” the FDA said. The ban was [the result of](https://www.washingtonpost.com/news/to-your-health/wp/2016/01/29/fda-bans-imports-of-genetically-engineered-salmon-for-now/) language [Alaska Senator Lisa] Murkowski [introduced](http://www.murkowski.senate.gov/public/index.cfm/pressreleases?ContentRecord_id=BC5FB310-4726-4E5A-A28B-156D3ED64C94) into the 2016 fiscal budget, or omnibus, bill. False claims about GE salmon have come from politicians on both sides of the party divide. While Murkowski is a Republican, Rep. Jared Huffman, a Democrat from California, has [said](https://huffman.house.gov/media-center/press-releases/huffman-blasts-fda-approval-of-genetically-engineered-salmon), for example, that “by approving GE salmon, the FDA is allowing the release of a new hybrid animal that could pose a danger to our wild salmon populations, damage the ecosystems they live in, and undermine our domestic commercial fisheries.”

OBSERVATION 3. We have a PLAN

1. Congress votes for and the President signs a repeal of the ban on genetically engineered salmon
2. Plan takes effect the day after an Affirmative ballot
3. All Affirmative speeches may clarify

OBSERVATION 4. ADVANTAGES

ADVANTAGE 1.  Reduced heart disease

A.  The Link: Poor people would eat more fish.  Genetically Modified (GM) salmon would lower the price and motivate lower-income people to eat more fish - and that’s good for public health

Dr. Davide Menozzi, Prof. Cristina Mora, and Alberto Merigo 2012. (Menozzi - PhD in agricultural economics.  Mora - professor of agricultural economics, Univ. of Parma, Italy.  Merigo - researcher at Univ. of Parma, Italy)   AgBioForum - The Journal of Agrobiotechnology Management & Economics, Vol 15 No. 3 Article 4 “Genetically Modified Salmon for Dinner? Transgenic Salmon Marketing Scenarios”  <http://www.agbioforum.org/v15n3/v15n3a04-menozzi.htm>

Acceptance of GM salmon might increase if consumers identify more personal benefits than benefits to the business sector (Qin & Brown, 2006). Human health benefits from improved nutrition (higher n-3 fatty acid intake) may result from higher consumption of fish driven by a lower market price (Lutter & Tucker, 2002). In particular, the price reduction could stimulate fresh (GM) salmon consumption in low-income households susceptible to conditions linked to poor nutrition (Smith et al., 2010), thus, GM salmon consumption may have high marginal benefits to public health.

B.  The Impact:  Reduced deaths from heart disease.    N-3 Fatty Acids from fish reduce cardiovascular death.

Dr. J. L. Breslow 2006. (M.D.; Professor in the Laboratory of Biochemical Genetics and Metabolism, Rockefeller University) “n-3 fatty acids and cardiovascular disease”  AMERICAN JOURNAL OF CLINICAL NUTRITION, June 2006 <http://www.ncbi.nlm.nih.gov/pubmed/16841857>

The results of prospective cohort studies indicate that consuming fish or fish oil containing the n-3 fatty acids eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) is associated with decreased cardiovascular death, whereas consumption of the vegetable oil-derived n-3 fatty acid a-linolenic acid is not as effective. Randomized control trials (RCTs) in the context of secondary prevention also indicate that the consumption of EPA plus DHA is protective at doses <1 g/d. The therapeutic effect appears to be due to suppression of fatal arrhythmias rather than stabilization of atherosclerotic plaques. At doses >3 g/d, EPA plus DHA can improve cardiovascular disease risk factors, including decreasing plasma triacylglycerols, blood pressure, platelet aggregation, and inflammation, while improving vascular reactivity. Mainly on the basis of the results of RCTs, the American Heart Association recommends that everyone eat oily fish twice per week and that those with coronary heart disease eat 1 g/d of EPA plus DHA from oily fish or supplements.

ADVANTAGE 2.  Biotech jobs.  Our plan prevents offshoring US biotech jobs.

A.  The Link:  Companies will leave. Political interference means biotech companies will move offshore.

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  (Juma: Professor of the Practice of International Development and Director of the [Science, Technology, and Globalization Project](http://bcsia.ksg.harvard.edu/research.cfm?program=STPP&project=STG&pb_id=113&gma=27&gmi=45); co-chair of African Union's High-Level Panel on Science, Technology & Innovation) <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

Key GE animal innovations — including, but not limited to, the example of the AquAdvantage® salmon presented above — have languished in regulatory review from years to more than a decade. The VMAC public meeting regarding the GE salmon was itself nearly three years ago. The long wait is unnecessary and inappropriate. Regulatory inaction has the consequences of threatening not only these particular products, but animal biotechnology more generally. With many laudable products in the research and development and regulatory pipeline, it is not in society’s interest to give up on a promising set of technologies for lack of regulatory response. There is a need for regulatory milestones and enforceable response times. We suggest that regulatory authorities respond to proponents’ petitions and information packets within 180 days of receipt.  
V. IMPACT OF POLICY RECOMMENDATIONS  
By strengthening science-based regulatory evaluations of genetic engineering applications, the credibility of the FDA regulatory system will be preserved. Again, in the words of Dr. Calestous Juma: “It is imperative that the United  States stay the course it has set in not letting politics interfere with its science-based regulatory system that is truly the envy of the world.”  If the United States fails to provide a regulatory path to market for beneficial biotechnologies,research and development of these innovations will move to countries with more predictable policy environments.

B. The Impact: At least 200,000 high-paying jobs at risk

National Center on Education and the Economy 2006. (non-profit research organization; article written by Peter E. Carlson)  December 2006  Biotechnology Industry Trends, National Center on Education and the Economy  <http://www.jff.org/sites/default/files/publications/Biotech-IndustryTrends.pdf>

In 2004, the latest year for which figures are available, there were 1,444 US firms narrowly defined as engaged in biotechnology, employing close to 200,000 people. Other estimates, using a broader definition of “biotech,” put employment as high as 885,000.  Biotech jobs pay roughly $26,600 more than the overall national average private sector wage.

ADVANTAGE 3.  Two independent environmental benefits.

1. Reduce the environmental impact of traditional salmon farming

Dr. Ron L. Stotish 2011 (president and CEO of Aquabounty Technologies, maker of genetically engineered salmon) 15 Dec 2011 testimony before the US Senate U.S. Senate, Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard <https://www.gpo.gov/fdsys/pkg/CHRG-112shrg78022/html/CHRG-112shrg78022.htm>

Conventional aquaculture produces Atlantic salmon in sea cages, a practice that has a variety of environmental, ecological, and economic consequences. The availability of a more rapidly growing Atlantic salmon, for example, the AquAdvantage salmon, could facilitate land-based cultivation of this species, much like trout, catfish, and tilapia, reducing the cost and environmental impact of transportation, as well as reducing the environmental consequences of sea cage cultivation. In sum, the AquAdvantage salmon, when approved, would in all likelihood, approve the sustainability of salmon aquaculture, reduce imports, and create an opportunity for economic development in the United States.

1. Reduced depletion of wild-caught fish stocks

Alison L Van Eenennaam & William M Muir 2011. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University.) Transgenic salmon: a final leap to the grocery shelf?  NATURE BIOTECHNOLOGY Aug 2011    
<https://www.researchgate.net/publication/51552701_Transgenic_salmon_A_final_leap_to_the_grocery_shelf>

Wild-caught fish deplete the oceanic stocks and do not present a long-term, ecologically sustainable solution to rising global fish demand. One of the benefits associated with the development of GE fish for aquaculture may well be in helping to reduce recognized pressure on wild fish populations.

ADVANTAGE 4.  New technologies.

Salmon approval would stop blocking the development of additional new technologies that would benefit mankind

Alison L Van Eenennaam & William M Muir 2011. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University.) Transgenic salmon: a final leap to the grocery shelf?  NATURE BIOTECHNOLOGY Aug 2011    
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The current regulatory approach in the United States, coupled with the unpredictable time frame, has stymied commercial investment in the development of GE animals for agricultural applications. The abuse of good-faith attempts to increase transparency and enable public participation in the GE animal regulatory process, coupled with political efforts to prohibit the FDA from regulating GE AquAdvantage salmon as it approaches the close of its protracted regulatory journey, are unlikely to have reassured potential investors. There is little benefit to society if attempts to increase public participation in the regulatory process are used as an opportunity to vilify technology. This outcome may jeopardize future access to improved genetic lines resulting from new technological developments (e.g., disease-resistant GE animals), with negative consequences on food security and other broadly supported societal goals, including improved human and animal health.

2A Evidence: Genetically Modified Salmon

INHERENCY

After earlier finding it was safe to eat , FDA banned GMO salmon in Jan. 2016 because Congress told them to

Michael Mezher 2016 (journalist) 29 Jan 2016 “FDA Bans Import of Genetically Engineered Salmon” REGULATORY AFFAIRS PROFESSIONALS SOCIETY <http://www.raps.org/Regulatory-Focus/News/2016/01/29/24208/FDA-Bans-Import-of-Genetically-Engineered-Salmon/>

The US Food and Drug Administration (FDA) has issued an alert banning the import of genetically engineered (GE) salmon, months after approving the first such animal as safe to eat. The import alert helps the agency comply with the FY 2016 omnibus spending bill President Obama signed into law in December. The law ordered FDA to block imports of GE salmon until the agency issues final guidance requiring food derived from GE salmon to be labeled as such.

Legal details: Page 106 of the Dec 2015 budget act passed by Congress blocks sale of GMO salmon

WASHINGTON POST 2015. (journalist Brady Dennis) “FDA must develop plan to label genetically engineered salmon, Congress says” 17 Dec 2015 <https://www.washingtonpost.com/news/to-your-health/wp/2015/12/17/congress-to-fda-no-genetically-engineered-salmon-in-supermarkets-unless-it-is-labeled/>

In two paragraphs on page 106, lawmakers instructed the Food and Drug Administration to forbid the sale of genetically engineered salmon until the agency puts in place labeling guidelines and "a program to disclose to consumers" whether a fish has been genetically altered. The language comes just a month after FDA made salmon the first genetically modified animal approved for human consumption and represents a victory for advocates who have long opposed such foods from reaching Americans' dinner plates. At the very least, they say, consumers ought to know what they are buying.

Alaska politicians oppose ALL farmed salmon (genetically modified or not) because they compete with Alaskan salmon

Craig Medred 2012. (journalist)  21 Dec 2012 Feds pronounce genetically modified salmon OK; Murkowski says balderdash” ALASKA DISPATCH (Alaska newspaper) <http://www.alaskadispatch.com/article/feds-pronounce-genetically-modified-salmon-ok-murkowski-says-balderdash> (brackets added)

[Alaska Senator Lisa] Murkowski, backed by Alaska fishing organizations, has repeatedly tried to stop such approval by tying the agency up in red tape. She previously tried, but failed, to get the Senate to require the National Oceanic and Atmospheric Administration (NOAA) be intimately involved in the process. She said again and again she thought a more thorough scientific review of the biotechnology was in order. But she sort of let slip on Friday that the demand for better science was really more of a smokescreen for efforts to simply kill the idea. In a video released by her office outlining her renewed opposition, she stated flatly, "I just don't believe that these fish should be approved." That view is shared by many Alaska fishermen, especially commercial fishermen who fear genetically modified salmon could provide yet more competition for Alaska wild salmon in markets already dominated by farmed fish. As technology has improved, fish farmers in Norway, Canada and Chile, in particular, have begun to dominate the markets.  
No Alaskan fish farmers  
Alaska produces no farmed fish. The 49th state's politically powerful commercial fishing industry convinced lawmakers to ban salmon farming in Alaska in 1989. "They didn’t want economic competition from farmed fish,'' University of Alaska Anchorage economics professor Gunnar Knapp noted a decade ago in a study on "Implications of Aquaculture for Wild Fisheries: The Case of Alaska Wild Salmon."

SOLVENCY

More Advocacy

Canadian government approved Aquadvantage salmon, safe for sale and consumption

PR Newswire 2016. “AquaBounty's AquAdvantage Salmon approved by Health Canada” 19 May 2016 <http://www.prnewswire.com/news-releases/aquabountys-aquadvantage-salmon-approved-by-health-canada-300271876.html>

Ronald L. Stotish, Ph.D., Chief Executive Officer of AquaBounty, commented: "We are pleased to receive the approvals of the various authorities of Canada which means we can produce, sell and eat our AquAdvantage Salmon in Canada. We thank the scientists in the Ministries of Health, Food Inspection and Fisheries of the Canadian Government for carrying out their assessments diligently and confirming the safety of our salmon for both the consumer and the environment.

“More Study Needed” Responses

Salmon had the longest and most exhaustive assessment in history

Alison L Van Eenennaam & William M Muir 2011. ( Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University.) Transgenic salmon: a final leap to the grocery shelf?  NATURE BIOTECHNOLOGY Aug 2011    
<https://www.researchgate.net/publication/51552701_Transgenic_salmon_A_final_leap_to_the_grocery_shelf>

A fast-growing transgenic fish containing a gene encoding Chinook salmon growth hormone under the control of an antifreeze protein promoter and terminator from ocean pout, AquAdvantage salmon has been subjected to one of the most prolonged, if not exhaustive, regulatory assessments in history. This process culminated last September with a meeting of the Veterinary Medicine Advisory Committee (VMAC) as well as a public hearing, together with the release of a comprehensive health and safety briefing and an environmental assessment package on the transgenic animal developed by AquaBounty Technologies of Waltham, Massachusetts.

How much more is needed?  They already produced a 171-page health & safety briefing, 84-page environmental assessment, plus independent review by veterinarians and scientists.

Alison L Van Eenennaam & William M Muir 2011. ( Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University.) Transgenic salmon: a final leap to the grocery shelf?  NATURE BIOTECHNOLOGY Aug 2011    
<https://www.researchgate.net/publication/51552701_Transgenic_salmon_A_final_leap_to_the_grocery_shelf>

Included in this final guidance was the FDA’s stated intent to increase the transparency of its deliberations and actions by holding public advisory committee meeting hearings before approving any GE animal. And in an unprecedented move toward increased transparency, the FDA made the 171-page briefing package summarizing all of the health and safety data on the AquAdvantage salmon and the 84-page environmental assessment publicly available approximately two weeks before the public VMAC meeting in September 2010. This committee, appointed by the FDA and charged with providing scientific advice to the agency, consisted of independent veterinarians and scientists with expertise on the subject matter.

No standards and vagueness.

NEG never gives a timeline or standards for specifically what else would have to be done to prove the salmon are safe.  We challenge them to prove with evidence which part of the 171-page safety study is incomplete, and which part of the 84-page environmental assessment needs further study.

A/T “FDA doesn’t have the scientific expertise “ - They consult with other agencies

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

The FDA spends much of its time responding to unfounded criticisms and recommendations. For example, some have claimed that the FDA does not have the appropriate expertise to evaluate GE fish and that the agency is going forward with the evaluation of the AquAdvantage® salmon without consulting with other federal agencies. However, Appendix D of the publicly-available AquAdvantage® EA35 clearly states that this consultation occurred, as it reads: “The two federal agencies responsible for administering the ESA, the National Marine Fisheries Service (NMFS) of the National Oceanic and Atmospheric Administration (Department of Commerce) and the U.S. Fish and Wildlife Service (FWS) of the Department of Interior, have been provided with this ‘no effect’ determination and underlying information in support of it, provided within the attached draft EA. Both of these agencies have either concurred with, or indicated no disagreement with, FDA’s ‘no effect’ determination.”

ADVANTAGES

Heart Disease Reduction

Salmon contains omega-3 fatty acids. Recommended by the American Heart Association

American Heart Association. Last Updated 2015.  (non-profit; nation’s oldest, largest voluntary organization devoted to fighting cardiovascular diseases and stroke) last updated 15 Oct 2015 “Fish and Omega-3 Fatty Acids”

Fish is a good source of protein and, unlike fatty meat products, it’s not high in saturated fat. Fish is also a good source of omega-3 fatty acids. Omega-3 fatty acids benefit the heart of healthy people, and those at high risk of — or who have — cardiovascular disease. Research has shown that omega-3 fatty acids decrease risk of arrhythmias (abnormal heartbeats), which can lead to sudden death.  Omega-3 fatty acids also decrease triglyceride levels, slow growth rate of atherosclerotic plaque, and lower blood pressure (slightly).   
Go fish  
The American Heart Association recommends eating fish (particularly fatty fish) at least two times (two servings) a week. Each serving is 3.5 ounce cooked, or about ¾ cup of flaked fish. Fatty fish like salmon, mackerel, herring, lake trout, sardines and albacore tuna are high in omega-3 fatty acids.

Biotech jobs

Note: In case anyone is wondering, since the fish are conceived in Canada and raised in Panama, how would it affect jobs in the US? The answer is that the company with the scientists doing all of this is based in Massachusetts.

Political intervention in salmon research hurts our credibility: the US could lose its leadership in agricultural biotech

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

In April 1993, A/F Protein, later renamed AquaBounty, made its first formal approach to the U.S. Food and Drug Administration (FDA) for guidance on an appropriate path for regulatory approval of the AquAdvantage® salmon, culminating in the formal submission of an investigational new animal drug (INAD) application for the AquAdvantage® on September 14, 1995. In 2009, AquaBounty submitted the last required regulatory study to the FDA.  As of June 2013, no statement has been issued regarding approval or otherwise of pilot-scale production of this first GE food animal. This protracted regulatory review is undermining the credibility of the FDA’s science-based regulatory system. In the words of Dr. Calestous Juma, at Harvard’s Kennedy School of Government: “It sends the message to the rest of the world that the science-based regulatory oversight as embodied in the FDA review process is subject to political intervention. Furthermore, it signals to the world that the United States may cede its leadership position in the agricultural use of biotechnology.”

Failure to approve salmon will send biotech scientists overseas, or shut down such research altogether

EMILY ANTHES. New York Times 2013. ( Anthes has a master’s degree in science writing from MIT and a bachelor’s degree in the history of science and medicine from Yale.) “Don’t be afraid of Genetic Modification” 10 March 2010 <http://www.nytimes.com/2013/03/10/opinion/sunday/dont-be-afraid-of-genetic-modification.html?pagewanted=1>

WE should all be rooting for the agency to do the right thing and approve the AquAdvantage salmon. It’s a healthy and relatively cheap food source that, as global demand for fish increases, can take some pressure off our wild fish stocks. But most important, a rejection will have a chilling effect on biotechnological innovation in this country. Some scientists may move abroad, to China, Argentina, India or another nation where the political climate is more favorable. (Indeed, some have already done so — researchers at the University of California, Davis, who have developed goats whose modified milk could be used to treat and prevent childhood diarrhea, are moving much of their operation to Brazil.) Others may decide not to pursue such research at all. If a company that has done everything right can’t get its product approved, who else will be foolish enough to embark upon this kind of research? Who will finance it?

Congressional action on GE salmon threatens the development of the biotech industry in general

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

It should be noted that wild Pacific salmon are marketed as such in order to obtain a premium price relative to cultured Atlantic salmon. It should be further noted that no Atlantic salmon (Salmo salar) has ever successfully mated with any of the Pacific salmon species (Oncorhynchus spp.), and so fears that sterile, female Atlantic salmon housed in a contained facility in the highlands of Panama will escape, migrate to the ocean, and then traverse thousands of miles across tropical seas and interbreed with wild Alaskan Pacific salmon are scientifically unfounded. Whether or not this was the intent, these repeated calls for ever more regulatory review and further studies, and threats of congressional action regarding GE salmon, have had the consequence of threatening the development of targeted products and animal biotechnology more generally.

Political interference motivates genetic research to move offshore to countries that have better policies

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

Against this background, relative to commercialization of GE crops, GE animals are associated with disproportionately high regulatory delay and considerable uncertainty. Regulatory uncertainty makes their commercialization in the United States prohibitively expensive and is moving development of this technology offshore to countries with more predictable policy environments.

Example of canceled research: The ENVIROPIG

EMILY ANTHES. New York Times 2013. ( Anthes has a master’s degree in science writing from MIT and a bachelor’s degree in the history of science and medicine from Yale.) “Don’t be afraid of Genetic Modification” 10 March 2010 <http://www.nytimes.com/2013/03/10/opinion/sunday/dont-be-afraid-of-genetic-modification.html?pagewanted=1>

Then there’s the Enviropig, a swine that has been genetically modified to excrete less phosphorus. Phosphorus in animal waste is a major cause of water pollution, and as the world’s appetite for meat increases, it’s becoming a more urgent problem. The first Enviropig, created by scientists at the University of Guelph, in Canada, was born in 1999, and researchers applied to both the F.D.A. and Health Canada for permission to sell the pigs as food. But last spring, while the applications were still pending, the scientists lost their funding from Ontario Pork, an association of Canadian hog farmers, and couldn’t find another industry partner. (It’s hard to blame investors for their reluctance, given the public sentiment in Canada and the United States, as well as the uncertain regulatory landscape.) The pigs were euthanized in May.

Impact:  Lost jobs.  It’s hard to replace high-tech jobs that go overseas.

Linda Levine 2011. (Specialist in Labor Economics with Congressional Research Service) 21 Jan 2011 “Offshoring (or Offshore Outsourcing) and Job Loss Among U.S. Workers”  <http://forbes.house.gov/uploadedfiles/crs_-_offshoring_and_job_loss_among_u_s__workers.pdf>

The loss of U.S. jobs to offshoring has led people to ask what field is going to be the next generator of jobs for U.S. workers, and more particularly, of “good” jobs. Because the question is not easily answered, it may exacerbate people’s anxiety. The job-generating candidates that have been put forth, such as nanotechnology and biotechnology, may not provide as many new jobs as are thought to be moving abroad; further, life sciences jobs have themselves begun to be sent overseas.

Environmental Protection

Status Quo uses more risky aquaculture salmon because we’re afraid of using the less risky GE salmon

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

All technologies pose both risks and benefits. However, regulatory evaluation as currently practiced for GE animals emphasizes risk assessment regarding the GE animal and fails to evaluate the use of GE animals in relation to known risks associated with existing production systems. Fertile, fast growing salmon produced via conventional breeding programs and raised in ocean net pens can escape into the ocean and must surely have an elevated risk profile relative to the AquAdvantage® salmon application. Focusing solely on risks associated with the GE approach has the unintended consequence of distorting public perception regarding animal biotechnology, even in cases where the likely benefits clearly outweigh the risks in a balanced analysis. Environmental risk assessments should be based upon probability of long-term exposure. Exposure results not only from escape or release into natural environments, but also from the ability of the transgene to spread in the receiving population (i.e., expression of the transgene must confer a net positive fitness advantage). The net fitness of an organism is based on critical life-history characteristics common to all organisms; these include relative viability and reproductive success. Sterile and contained animals do not present a long-term environmental risk of ecological or genetic harm becoming realized.

Using on-shore raised GE salmon would allow us to reduce multiple hazards of aquaculture regular salmon

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The “risk-only” analysis is entrenched in the current GE animal regulatory review results in an inherently unlevel playing field. No technology could survive a risk-only analysis, as all technologies are associated with both risks and benefits. The biosafety considerations associated with GE animals have to be compared to the full range of risks associated with existing alternative approaches and the risks of inaction. Risks from GE animals should be compared to those of conventional production. For example, Atlantic salmon are commonly produced in floating net-pens. Hazards presented by conventional production include: (1) local eutrophication due to nutrient enrichment from decomposition of uneaten feed and animal wastes, (2) transmission of parasites and pathogens among cultured and wild fish populations, and (3) interbreeding of cultured and wild populations, leading to outbreeding depression and demographic decline of wild populations. A shift to greater fish production in on-shore facilities presents the option of reducing these environmental impacts.

Technological Innovation

Stopping the salmon will close the door on new technologies that could save lives and the environment

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The F.D.A. must make sure that other promising genetically modified animals don’t come to the same end. Of course every application needs to be painstakingly evaluated, and not every modified animal should be approved. But in cases like AquaBounty’s, where all the available evidence indicates that the animals are safe, we shouldn’t let political calculations or unfounded fears keep these products off the market. If we do that, we’ll be closing the door on innovations that could help us face the public health and environmental threats of the future, saving countless animals — and perhaps ourselves.

DISAVANTAGE RESPONSES

“Public Opposition”

Science is not a democracy. Voting on scientific conclusions undermines regulatory institutions that could have benefited society

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

Regulatory decisions and timelines should not be swayed by a tally of public comments on issues unrelated to the science-based evaluation received during a comment period, or the ability of special interest groups to effect congressional interference in regulatory decision making, even if it is presented in the context of agency oversight. In the recent words of Arjo and colleagues: “Regulatory bodies exist to provide objective assessments. They comprise experts on the topic with the authority to establish regulations that ensure society benefits from scientific discoveries, rather than coming to harm. Therefore plurality of opinion not supported by relevant data and propelled by democracy in science undermines the very institutions put in place to ensure the proper use of science and technology for the benefit of society.”

“Disrupting the ecosystem by escaping and breeding with wild salmon” - Responses:

Salmon are raised in Panama, 100 kilometers (62 miles) from the ocean on a 1800 meter (~5800 ft) mountain.

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

There is only one proposed FDA approved site for commercial growout of AquAdvantage Salmon anywhere in the world, a site in the highlands of Panama. The site is located more than 100 km from the Pacific Ocean, at an elevation of approximately 1800 meters. The site is equipped with a total of 21 individual containment measures, which maintain the salmon in confinement (Table 1; Draft EA for AquAdvantage Salmon, CVM, 2010). Physical containment to prevent the escape of fish at the grow-out facility is provided by the use of screens wherever water flows out of the system. There are a minimum of 11 sequential physical barriers in place between the fish tanks and the nearest natural body of water (a river), confining AAS to the site; seven of these barriers are positioned posterior to the outflow from the grow-out tanks. In addition, netting prevents the fish from being actively removed from containment by predators or passively removed in the event of any overflow of the water level. The multiple, redundant containment measures consist of tanks, screens, filters, stand-pipes, containment boxes, netting, and sedimentation ponds (Figure 2; Draft EA for AquAdvantage Salmon, CVM, 2010), making it virtually impossible for the salmon to leave the confines of the culture system and enter the environment.

No threat to Alaska.  These sterile fish are going to migrate to Alaska from Panama and breed with a different species of fish they aren’t compatible with? Really?

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

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GE Salmon are sterile, so they can’t breed with normal fish

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” (typographical error “for are” was in the original) <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

AquAdvantage Salmon is a genetically engineered (GE) Atlantic salmon with a rapid-growth phenotype that has been developed over the past 15 years. The genetic modification comprises one copy of a salmon growth hormone transgene that is stably integrated at a specific site in the genome in a line of Atlantic salmon. Triploid AquAdvantage Salmon eggs for are produced in a manner that results in the culture of an all-female population of reproductively sterile fish that are otherwise substantially equivalent to farmed Atlantic salmon.

They’re all sterile and they’re all female:  they can’t breed with each other, so they can’t establish an invasive population

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://docs.lib.noaa.gov/noaa_documents/NOAA_related_docs/Fish_Wildlife/Environmental_Risks_of_Genetically_Engineered_Fish_SHrg_112_463.pdf>

The commercial deployment of all-female populations has obvious advantages in reducing risk of environmental impact and establishment of feral populations (Beardmore et al 2001, Devlin et al 2006). If all-female fish are cultivated in areas where species with which they can interbreed are absent, then establishment of feral populations is impossible. AquAdvantage Salmon will be cultivated as 100% female populations in the highlands of Panama, which support no native salmonids. This prevents the establishment of feral populations in all escape scenarios. Production of 100% female populations of Atlantic salmon is a well described process that has been practiced for almost 30 years (Johnstone and Youngson 1984; Johnstone and MacLachlan 1994).

The salmon are all female and all sterile

Joshua A. Stiers 2013. ( JD candidate, Seton Hall Law School)  1 May 2013 Genetically Modified Salmon <http://erepository.law.shu.edu/cgi/viewcontent.cgi?article=1311&context=student_scholarship> (brackets added)

AquaBounty has introduced an additional redundant layer of containment into their AAS [AquAdvantage Salmon]  for just this reason. Even if their AAS were able to escape and overcome the significant odds that they would be killed before they could even come close to a wild population, they could not reproduce, because of two reasons: All the AAS are female, and all the AAS are sterile.  All female AAS is a function of the genetic process that AquaBounty uses to create the salmon. Because of the process, all the AAS are triploid. Because all the fish have three X chromosomes, they all must be female. The third chromosome also renders them close to 100% sterile, because it is such a genetic abnormality.

Conventional aquaculture salmon don’t survive in the wild, and neither would modified salmon

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

It should be noted that intentional efforts to re-establish Atlantic salmon in their native habitats have been largely unsuccessful, inclusive of programs targeting Prince Edward Island and Lake Ontario, efforts in the latter case have been unsuccessful despite more than 100 years of attempting to do so. Moreover, farmed Atlantic salmon have not established themselves successfully in the wilds of North America (Council on Environmental Quality, 2001), despite the fact that they are reared in ocean pens on both coasts. AquAdvantage Salmon have no obvious life history advantages to suggest they would be any more invasive than conventional farmed Atlantic salmon.

No escapes:  There is only 1 approved location in the world where they can be grown, and it is well protected (and it’s on land! in the highlands of Panama)

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

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Even if a fish escaped, it would die on the way to the Pacific Ocean because the water is too warm

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

In addition to the numerous physical containment barriers in place at the Panama growout site, there also exists a powerful natural, geographic, thermal barrier that would effectively prevent AquAdvantage Salmon from migrating from the growout site to the Pacific Ocean. Stead and Laird (2002) have cited the upper lethal temperature for salmon as being 23ºC. Water temperature measurements recorded for the rivers leading from the aquaculture project to the Pacific Ocean (Table 2; Draft EA for AquAdvantage Salmon, CVM, 2010) amply demonstrate that any escaped salmon attempting to migrate downstream towards the Pacific Ocean would inevitably encounter lethal water temperatures, preventing the fish from reaching the ocean.

There are so many barriers that escape risk can be disregarded

Joshua A. Stiers 2013. ( JD candidate, Seton Hall Law School)  1 May 2013 Genetically Modified Salmon <http://erepository.law.shu.edu/cgi/viewcontent.cgi?article=1311&context=student_scholarship>

Naturally, even with multiple redundant security systems, there is still a chance of salmon escaping. But the only way that this could happen would be through natural disasters, human intervention, or mechanical failures.  Indeed, even should these containment features fail, the eggs are currently being grown thousands of miles away from the nearest salmon population, e.g. in the Panamanian highlands. Thus it appears that the probability of a single fish escaping containment and travelling thousands of nautical miles through heavily predator infested waters, mating, and spawning with enough proficiency to cause an epidemic that would decimate large populations of wild salmon seems so infinitesimal so as to be disregarded.

“Human Health effects” / “Allergies” - Responses:

GE Salmon Safe to eat

EMILY ANTHES. New York Times 2013. ( Anthes has a master’s degree in science writing from MIT and a bachelor’s degree in the history of science and medicine from Yale.) “Don’t be afraid of Genetic Modification” 10 March 2010 <http://www.nytimes.com/2013/03/10/opinion/sunday/dont-be-afraid-of-genetic-modification.html?pagewanted=1>

If the modified fish is approved, which could still happen later this year, it will be the first transgenic animal to officially enter the human food supply. Appropriately, it has been subjected to rigorous reviews, with scientists all over the country weighing in on whether it is fit for human consumption and what might happen if it was to make its way into the wild. Some environmentalists fear that the modified salmon might wriggle free from fish farms, start reproducing, and ultimately drive wild salmon populations to extinction. But scientists, including the F.D.A.’s experts, have concluded that the fish is just as safe to eat as conventional salmon and that, raised in isolated tanks, it poses little risk to wild populations.

No allergy problem:  Other fish currently on the market have a lot more allergens than GE salmon

Purdue University News Service 2011.  5 Aug 2011 Scientist urges government ruling on genetically engineered salmon <http://www.purdue.edu/newsroom/research/2011/110805MuirSalmon.html> (brackets added)

Regarding human health concerns, AA salmon were said to have more allergens than non-genetically engineered salmon. This raised concerns that consuming the genetically engineered versions could harm people. But the data did not support this assertion. [Purdue University animal science professor William] Muir said there is no baseline for the amount of allergens a fish may contain before it is unsafe for consumption and that many fish consumed regularly, such as herring, have significantly more allergens than AA salmon. "There is as much as a hundredfold difference in the allergenicity among fish," Muir said. "At what level should it trigger concern?"

No scientific consensus on what level of allergens would be a risk.  And people who are allergic will simply… not eat it.

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

Current regulatory guidelines require an assessment of the expression of endogenous allergens due to expression of the transgene. According to the AquAdvantage® data package, such studies are intended to determine “whether the edible tissue from GE salmon is more allergenic than the non-GE comparator,” even though it is recognized that: ,“there is no consensus in the scientific and medical communities regarding the magnitude of increase in endogenous allergens in an allergenic food that would present an additional risk to public health (Goodman et al., 2008), especially considering that individuals who are allergic to a particular food would likely avoid that food.” Current regulatory guidelines do not set limits on acceptable variation of allergens in GE foods. This resulted in an experiment submitted by the applicant that was criticized by both the FDA and the VMAC for poor sample size and lack of power. However, proper experimental design is predicated on first defining a meaningful biological difference to detect. This difference, along with known variation in the metric, is used to determine sample size needed to detect a difference of that magnitude or greater with high probability, if one exists. In the case of endogenous allergens, it is not possible to define a meaningful biological difference, so any experiment conducted to detect such is neither over- nor under-powered, nor does one have any idea how to interpret the results.

The allergy risk of NON-Genetically Modified fish has never been studied, so no way to know if GM salmon have “more” allergy risk.

**Analysis:  Since  GE salmon have received MORE allergy study than non-GE fish, if “allergy risk” is a voting issue,  it would be more responsible to ban all other fish and ONLY allow GE salmon.  At the very least, we should encourage allergy-conscious customers to buy the salmon that have been studied (the GE) and avoid the ones that haven’t been studied (all other fish).**

Alison L Van Eenennaam & William M Muir 2011. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University.) Transgenic salmon: a final leap to the grocery shelf?  NATURE BIOTECHNOLOGY Aug 2011    
<https://www.researchgate.net/publication/51552701_Transgenic_salmon_A_final_leap_to_the_grocery_shelf>

The major allergens responsible for crossreactivity among distinct species of fish and amphibians are parvalbumins. These proteins control calcium flow in the muscular sarcoplasm of the white meat, and parvalbumin is known to be the major allergen in the white muscle of Atlantic salmon. The parvalbumin content of most commonly consumed fish species varies considerably and is also influenced by cooking method. In raw fish, parvalbumin levels vary significantly, with herring parvalbumin levels exceeding tuna levels by 100-fold. This natural variation brings into question the scientific justification for performing experiments  to determine whether GE fish have higher levels of endogenous allergens than their non-GE counterparts when we do not have, or require, analogous information on the fish we currently consume. In the absence of data on variation in non-GE Atlantic salmon populations and a validated approach to address the question of what level of change would be unacceptable, there is no way to evaluate whether biologically relevant differences exist in the levels of endogenous allergens in GE, or non-GE, fish.

FDA Study:  modified salmon are not dangerous to humans

Associated Press 2012. “FDA says fast-growing salmon would not harm nature” 21 Dec 2012 <http://www.komonews.com/news/consumer/FDA-says-fast-growing-salmon-would-not-harm-nature-184446781.html>

Federal health regulators say a genetically engineered salmon that grows twice as fast as normal is unlikely to harm the environment, clearing the way for the first approval of a genetically engineered animal for human consumption. The Food and Drug Administration on Friday released its environmental assessment of the AquaAdvantage salmon, a faster-growing fish which has been subject to a contentious, years long debate at the agency. The document concludes that the fish "will not have any significant impacts on the quality of the human environment of the United States."

FDA Study: Food from AquAdvantage salmon is the same as any Atlantic salmon. No risk to humans

Dr. Ronald L. Stotish 2011. (President & CEO, AquaBounty Technologies, Inc.; developers of the salmon) testimony before U.S. Senate Committee on Commerce, Science & Transportation Subcommittee on Oceans, Atmosphere, Fisheries & Coast Guard, 15 Dec 2011 “Environmental Risks of Genetically Engineered Fish” <http://www.commerce.senate.gov/public/?a=Files.Serve&File_id=c42fbd71-4d2b-48f0-8c3d-f7e7af65be20>

The FDA’s center for veterinary medicine has concluded that the AquAdvantage salmon, in addition to being indistinguishable from Atlantic salmon, is an Atlantic salmon, and that the food from AquAdvantage salmon is the same as food from any other Atlantic salmon. CVM has determined that the genetic change does not harm the fish, and is safe for the consuming public. It’s also determined that the data and the information we have provided, as well as the conditions and controls we propose to implement, that would be required upon approval of any application, provide meaningful assurance that the AquAdvantage salmon are not expected to have a significant impact on the quality of the human environment in the United States or in foreign countries.

FDA Study is good. An independent peer-reviewed scientist examined the FDA data and agrees GE salmon are safe

Purdue University News Service 2011.  5 Aug 2011 Scientist urges government ruling on genetically engineered salmon <http://www.purdue.edu/newsroom/research/2011/110805MuirSalmon.html>

A Purdue University scientist is urging federal officials to decide whether genetically engineered salmon would be allowed for U.S. consumption and arguing that not doing so may set back scientific efforts to increase food production. William Muir, a professor of animal sciences, said that based on data made available by the U.S. Food and Drug Administration, AquAdvantage (AA) salmon poses little real risk to the environment or human health. AA salmon were given a gene from Chinook salmon that speeds growth and improves feed efficiency in farm-raised fish. Developed by AquaBounty Technologies, the fish would be spawned in Canada and grown to full size in Panama, both of which are land-based, contained facilities. "We realize that any new technology can have risks, and those risks need to be assessed in a thorough and convincing manner," Muir said. "However, once the assessment has been completed and the agency concludes from the weight of evidence that risks of harm, either to the environment or to consumers, is negligible, the next step, which is to allow production and sale of the product, needs to be taken." Muir and Alison L. Van Eenennaam, an animal genomics and biotechnology Extension specialist at the University of California Davis, made the call for FDA approval in a peer-reviewed commentary in the early online version of the journal Nature Biotechnology.

“They’re not labeled as genetically modified!”

No reason they should be labeled. Turn: Labeling would be bad

Dr. David Edwards 2010. (Ph.D.; Director, Animal Biotechnology, Food & Agriculture Section, Biotechnology Innovation Organization) 19 Nov 2010 “Re: (Docket No. FDA-2010-N-0385) Food Labeling; Labeling of Food Made From AquAdvantage Salmon “ <https://www.bio.org/advocacy/letters/food-labeling-labeling-food-made-aquadvantage-salmon>

As FDA has determined previously, and the courts have upheld, the mere fact of genetic engineering as part of a product’s breeding history is not a material fact that warrants labeling. In other words, labeling is not required for the salmon meat just because genetic engineering was used in the breeding of these salmon. To require special labeling of foods that are indistinguishable based on breeding methods would mislead consumers by falsely implying material differences where none exist. The mandatory addition of immaterial product information on any product label also risks diverting consumer attention from material and important food label information, such as nutritional information.

SOURCE INDICTMENTS

Food and Water Watch - didn’t tell the whole story

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

Internal emails that Food and Water Watch obtained through a U.S. Freedom of Information Act (FOIA) request substantiate that federal agency consultations occurred. However, the group posted only selected 2010 emails from individual FWS scientists without posting other emails included in the same FOIA request from FWS scientists with contrary scientific opinions.

Environmental activists have a conflict of interest:  They raise money based on their policy position

Alison L. Van Eenennaam, Prof. William Muir & Prof. Eric Hallerman 2013. (Eenennaam - Cooperative Extension Specialist, Univ of California, Davis. Muir - Professor at Purdue University. Hallerman - Professor at Virginia Tech University)  Is Unaccountable Regulatory Delay and Political Interference Undermining the FDA and Hurting American Competitiveness?  24 July 2013  <http://www.foodnavigator-usa.com/content/download/388647/8295610/file/Food-and-Drug-Policy-Forum.pdf>

The public, and sometimes politicians, do not recognize the motivations of those making public commentary. Those with a vested interest and receiving funds, from either public or private sources, should disclose those potential conflicts of interest. During the AquAdvantage VMAC meeting, speakers who testified during the public comment period were requested “to advise the committee of any financial relationship that you may have with any company or any group that is likely to be impacted by the topic of this meeting.” Speakers from several special interest groups declared that they had no conflict of interest. However,special interest groups solicit money from their donors to influence policy. There is little transparency as to the funding sources of these organizations because donations are often listed as being from foundations or “donor advised” funds which masks the identity of the individuals or groups actually providing the money. Individuals employed by such organizations have an interest in influencing policy often by creating fear and distrust in the process. Those taking grants, or other forms of payment from all industries, including the activist industry, need to clearly declare such conflicts of interests when making public commentary**.**

Works Cited: Salmon

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