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Genetically Modified Salmon

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By Josh Stiers

Table of Contents

INTRODUCTION	2
DISCUSSION	6
A. ESCAPE AND ENVIRONMENTAL IMPACT	6
B. MODIFIED FOOD IN GENERAL	11
C. REGULATION OF GENETICALLY MODIFIED FOODS	13
I. SPECIFIC FDA REGULATION OF GENETICALLY MODIFIED SALMON	17
II. EUROPEAN UNION REGULATION OF GENETICALLY MODIFIED FOOD	18
III. UNITED STATES ACCOMMODATION OF EUROPEAN UNION GUIDELINES	21
CONCLUSION	24

Introduction

Since the beginning of time, mankind has always admired salmon.¹ Salmon work hard, persevere in the face of adversity, and brave terrible peril just to complete seemingly pointless tasks. The salmon's quixotic journey back to its birthplace is both inspirational and the subject of allegory. However, mankind has also admired salmon for more than simply its inspirational story. Instead, humanity has found a much more useful quality in salmon: they are very nutritious. Families in the United States consume 284,000 metric tons of salmon annually², which is close to two pounds per capita, second only to shrimp and tuna for fish consumption.³

Unfortunately, salmon have been overfished, and their numbers in the wild have been declining rapidly.⁴ Some might say that the best way to combat this problem would be to change the way we fish, or to change our eating habits, or possibly to help the salmon reproduce in some way. But those solutions are difficult?, and often they do not yield huge success. Recently AquaBounty,⁵ an English biotechnology company, found

¹ Orin S. Kerr, *A Theory of Law*, 16 GREEN BAG 2d 111 (2012).

² University of Alaska Anchorage Institute of Social and Economic Research, *Overview of US Salmon Consumption*, http://www.iser.uaa.alaska.edu/Publications/greatsalmonrun/SalmonReport_Ch_8.pdf

³ AboutSeafood.com, *Top 10 Consumed Seafoods*, <http://www.aboutseafood.com/about/about-seafood/top-10-consumed-seafoods>

⁴ George Kimbrell, Paige Tomaselli, A "Fisheye" Lens on the Technological Dilemma: The Specter of Genetically Engineered Animals, 18 *Animal L.* 75, 77 (2011).

⁵ AquaBounty Technologies was originally incorporated in 1991 under the name A/F Protein, to pursue the commercial development of antifreeze protein-based technology under license from the University of California at Berkeley. Reorganized in 2000, it was divided into two separate entities: A/F Protein, which retained the antifreeze protein technology; and, AquaBounty Farms, which obtained the AquAdvantage® technology. This is the current organization of the company AquaBounty Technologies, *The Company*, <http://www.aquabounty.com/company/company-history-292.aspx>.

another solution to this problem. Resolving to bring “together biological sciences and molecular technology to enable an aquaculture industry capable of large-scale, efficient, and environmentally sustainable production of high quality seafood,” AquaBounty’s solution uses genetic modification to create a completely new salmon from scratch, infused with genetic abnormalities from two other fish. This newly created salmon, called the AquAdvantage Salmon (AAS), grows to over four times the size of naturally producing salmon, due to the genetic modification of AquaBounty in the zygote stage of the salmon’s development.⁶

The zygote stage of development is the earliest developmental stage of complex, or multi-celled organisms. This is an extremely critical part of the development of complex organisms, because the zygote contains all the genetic information that will define the organism for the rest of its life. Once solidified, this genetic blueprint will be copied and divided into the millions of cells that make up complex organisms, such as humans or salmon. The reason that this stage is extremely critical and highlighted in this paper is because modification of the genetic structure during this stage of development will forever change the genetic structure of the developing and adult organism. No further human intervention would be necessary, because without anything further, all genetic material would be copied and reproduced in the organism by the process of life itself. The organism would live its life as normal, without needing constant human supervision or upkeep.⁷

⁶ Matthew Morgan, *The AquAdvantage Salmon: Who Owns Escaped Genetically Modified Animals?*, 17 OCEAN & COASTAL L.J. 127, 128 (2011). How much of your paper mirrors this article??

⁷ In this specific case, scientists are modifying the zygote to add genetic material that they believe will be beneficial to salmon. Once altered, scientists do not need to do anything to accommodate the changes that they have made in the salmon (aside from those societal and environmental ones discussed in this note).

AquaBounty accomplishes this genetic modification by taking a fertilized egg and adding two genes from two different fish. The first gene comes from a Chinook salmon and promotes uninhibited growth “when microinjected into fertilized, non-activated Atlantic salmon eggs.”⁸ Normally, salmon stop growing once they get to a certain size, because they have trouble swimming back upstream if they are not streamlined.⁹ But Chinook salmon spawns in deeper and larger waters than other salmon species, and they return upriver less often than other salmon species. Thus their thyroid (the growth facilitator) allows them to grow to much larger sizes.¹⁰ When the Chinook’s growth gene is inserted into an AAS salmon, that salmon’s thyroid will never inhibit the salmon from growing, thus allowing it to grow to four times its normal size.¹¹

The second gene that is added to AAS comes from the ocean pout.¹² The ocean pout has anti-freezing proteins in its blood, allowing it to live in waters close to the freezing point.¹³ This gene keeps the pout’s blood thick, and it allows more of the Chinook’s growth gene to flow through the AAS.¹⁴ Additionally, salmon naturally only grow in the spring and summer, because the waters in which they swim in the fall and winter are too cold to promote growth.¹⁵ The AAS with the pout’s anti-freezing gene does not have this problem and is able to grow throughout the cold seasons.¹⁶ This again allows the salmon to grow much faster than naturally occurring salmon are able to

⁸ US PAT 5545808, col.5 ls.8-9.

⁹ The Pacific States Marine Fisheries Commission, *Chinook Salmon*, http://www.psmfc.org/habitat/edu_chinook_facts.html

¹⁰ *Id.*

¹¹ Morgan, 17 OCEAN & COASTAL L.J. at 128.

¹² Katherine Wilinska, 21 MINN. J. INT’L L. at 148. **Not proper cite.**

¹³ James Gorman, *Dumb and Dumber: Here’s a Fish Story With Legs*, N.Y. Times, September 22, 2002.

¹⁴ Morgan, 17 OCEAN & COASTAL L.J. at 128.

¹⁵ *Id.*

¹⁶ *Id.*

grow.¹⁷ The combination of these genes allows AquaBounty's AAS to massively outgrow naturally fished and farmed salmon. AquaBounty's patent application boasts that "[a]t eight months old, the average increase of the transgenic fish was 4-fold and the largest transgenic fish was eight times bigger than the non-transgenic controls."¹⁸

All of this modification occurs at the zygote stage of the salmon's development. Thus, the salmon is allowed to develop naturally, as in nature, for the rest of its life (aside from the fact that the development itself is not natural). In essence, the AAS is almost exactly the same as a naturally occurring salmon,¹⁹ save for the beneficial meddling of scientists in its fertilized egg.

The FDA recently decided that AAS are safe for human food production,²⁰ although some critics have voiced concern over this decision. Despite the FDA's approval, some remain concerned that the salmon should not be produced for human consumption; that the consequences to the environment of the salmon escaping would be disastrous; and that allowing these salmon to be produced would seriously affect the fishing industry and their place in that industry, including the export to Europe. Aside from not allowing the salmon to be produced, these people are calling for more regulation of genetically modified food, including requiring a consumer label to be applied to all genetically modified food. Though arguably these might be valid concerns, this paper will assert that the FDA should not take a larger interest in regulating genetically

¹⁷ *Id.*

¹⁸ US PAT 5545808, col.5 ls.13-16.

¹⁹ The only difference in the salmon is the insertion of positive genetic traits. Were the salmon to be cognizant, they would not know they were different than other salmon. Nor would anyone be able to tell simply by looking at them.

²⁰ FDA, VMAAC Briefing Packet, AquAdvantage Salmon, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>

engineered salmon because, when raised for consumption, genetically engineered salmon pose no substantial threat to humans or the environment.

Discussion

A. Escape and environmental impact

The first concern voiced by AquAdvantage critics is that the impact of their AAS escaping from their tanks would be disastrous to the environment.²¹ These critics point to studies by the National Academy of Sciences and the EU, which conclude that genetically modified fish will have a higher tolerance for environmental stressors, and they will be better equipped therefore to survive in ecosystems where they previously were unable to thrive.²² They also attack the FDA's safety evaluation, asserting that the FDA was "too simplistic" in its environmental impact assessment, because "history dictates that fish held in aquaculture facilities...[inevitably] escape."²³

Usually, the risk of escape is very legitimate, because it actually does happen. Conventionally, far- raised fish are contained in an "open system".²⁴ Open systems are connected to the ocean or stream, salt or fresh water—wherever the fish need to be raised. Open systems are basically pens for the fish, constructed with nets designed to keep them from going into the open waters of the ocean or stream.²⁵ In conventional

²¹ See e.g. Kimbrell, Paige Tomaselli, *A "Fisheye" Lens on the Technological Dilemma: The Specter of Genetically Engineered Animals*, 18 ANIMAL L. 75 (2011).

²² *Id.* at 80. [Should explain EU and what its concerns are](#)

²³ *Id.*

²⁴ Morgan, 17 OCEAN & COASTAL L.J. at 133.

²⁵ Kimbrell, 18 ANIMAL L. at 77.

systems, escaping fish are an inescapable conclusion, because of natural failure of the containment, human intervention, or a host of other reasons.²⁶

There are indeed a few environmental problems with escaping farmed salmon, leading to a documented decline in the salmon population because of these escapes.²⁷ It is an obvious proposition that when humans introduce animals into the wild that have previously been farmed and fed, this negatively impacts the wild population of that animal (and may likely harm the ecosystem as a whole).

Escaped fish could first impact the wild salmon population by increasing competition for food and breeding sites.²⁸ Second, the farmed fish are not as strong or naturally fit as wild fish. When they escape and the two interbreed, the wild population loses its fitness edge and becomes a weaker fish.²⁹ Combined with more competition for resources, the weakening wild population inevitably begins to lose its competitive edge in the ecosystem, and the salmon numbers and nutritional value begin to decline.³⁰ Though inescapable, the risk of this declining wild population is considered manageable, because the escape rate of farmed salmon is only at around 1%, allowing a low enough threshold to prevent substantial collateral damage.³¹

It is possible, however, for salmon fisheries to be subject to even greater restrictions on their escape rate. Technology exists for the fisheries to create better containment systems, which is exactly what AquaBounty has done with its AAS. AquaBounty thus far has kept their fish in inland tanks to minimize the risks of their

²⁶ *Id.*

²⁷ Kimbrell, 18 ANIMAL L. at 78.

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ Wilinska, 21 MINN. J. INT'L L. at 163.

salmon escaping and releasing themselves into the wild.³² Because these tanks have no direct contact with rivers, streams, or any inlet that might lead to an ocean or wild salmon population, AquaBounty has much greater control over their salmon and the effectiveness of their controlled system.³³

AquaBounty's closed system has multiple redundant containment systems, including steel screens, additional jump fences, and lethal chemicals in the escape zones and drain areas to immediately dispose of the salmon should they happen to escape the other redundant features.³⁴ 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 disasters³⁵, human intervention³⁶, or mechanical failures.³⁷ 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.^{fn} 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.³⁸ Additionally, this geographical containment features waters in which the salmon would not be able to survive because of their extreme temperatures. They would also probably run into actual

³² *Id.*

³³ Morgan, 17 OCEAN & COASTAL L.J. at 134.

³⁴ *Id.*

³⁵ *Force Majeur*, *??e.g.* floods, tornadoes/hurricanes, earthquakes, etc.

³⁶ *E.g.* negligence, theft, sabotages.

³⁷ *Id.* Mechanical failures may include errors or disasters in shipping eggs or mishandling or improper disposal of samples. There are many points along the line aside from the containment that might be vulnerable to mistake or human error.

³⁸ *Id.* [Id.?? to what](#)

hydro-electric power plants between the salmon and the nearest wild salmon population, further compounding the salmon's ability to escape and do actual damage to the wild.³⁹

Finally, critics still suppose that should the unthinkable happen, that some of the contained salmon actually escape and insert themselves into a wild salmon population, the results would be much more devastating than when farmed salmon escape. There is no doubt that these genetically modified salmon would outcompete natural salmon for resources.⁴⁰ They would be bigger, faster, and would have a better ability to get at the natural resources.⁴¹ Additionally, they would need more resources to survive because of their size, so a single AAS would not only be replacing a single wild salmon.?? The AAS would consume? the resources of several wild salmon to sustain itself, thereby drastically reducing the numbers of wild salmon by sheer numbers and competition.⁴²

Additionally, the release of AAS into the wild would most likely cause what scientists have dubbed the "Trojan gene" effect.⁴³ AAS would have an enhanced ability to mate, because of their size and strength. However, AAS also have reduced viability as adults simply because they need so many resources to survive. Thus, when the AAS releases the Trojan gene into the wild population, each successive generation of fish would be less viable than their parent generation.⁴⁴ The salmon would become more aggressive, would have to change their breeding patterns, and ultimately would have to change their migration patterns, making them less successful and viable for all of these

³⁹ *Id.*

⁴⁰ Kimbrell, 18 Animal L. at 80.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.* at 81.

⁴⁴ *Id.*

things.⁴⁵ The less viable wild salmon population would therefore not be able to live up to the survival of the fittest, and would be eventually completely destroyed.⁴⁶ Some scientists estimate that salmon could be extinct in less than 40 generations, should the AAS allow the Trojan gene to run rampant in wild salmon populations.⁴⁷ This “Trojan gene” scenario is not the only, but is the worst scenario? that the CABI or any scientific study has been able to postulate, and it is only a theoretical “high risk scenario” in which the GM fish outcompetes the wild fish for reproductive opportunities, only to have far weaker post-reproduction survival skills-leading to a collapse of entire wild stocks.”⁴⁸

AquaBounty has introduced an additional redundant layer of containment into their AAS 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.⁴⁹ 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.⁵⁰ 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.⁵¹ Analysis has confirmed that less than 1% of all AAS are sterile, and 100% are female.⁵²

⁴⁵ Kimbrell, 18 Animal L. at 82. [Should use supra & proper citations.](#)

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ Morgan, 17 Ocean & Coastal L.J. at 161.

⁴⁹ *Id.* at 134.

⁵⁰ *Id.*

⁵¹ Michael Bennett Homer, *Frankenfish It's What's for Dinner: The FDA, Genetically Engineered Salmon, and the Flawed Regulation of Biotechnology*, 45 COLUM. J.L. & Soc. Probs. 83, 116 (2011).

⁵² Morgan, 17 OCEAN & COASTAL L.J. at 161. [Should use supra citation instead of repeating title.](#)

Because AquaBounty has created a closed system, there is an infinitesimal chance that the AAS will escape their containment. Because of the geographic containment feature of containment, there is also an infinitesimal chance that if the AAS somehow escape their facility containment they would be able to even come close to another, wild population of salmon. Finally, because of the triploid biologic features of the fish, there is less than a 2% chance that the fish will be sterile, and there is a 100% chance that the fish will all be female. Combining all these probabilities, the chance of escape and survival to endanger a natural salmon population is effectively zero, and there should be no reason to fear any disastrous effects of what would happen if the AAS were able to escape their containment.

B. Modified Food In General

In 2000, the Department of Agriculture did a study on all of the genetically modified foods present in America. Their findings among other things, were that 25% of all corn, 54% of all soybeans, and 61% of all cotton planted in the United States had been modified in some way or another.⁵³ However, these findings proved premature if taken to be completely indicative of the extent? of genetically modified food sold in the United States. The very next year, these percentages increased to 88%, 94%, and 90%, respectively.⁵⁴ Of course, this only reflects the numbers of corn, soybeans, and cotton. Other recent estimates show that close to 75% of all processed foods that consumers purchased in supermarkets contains genetically engineered ingredients.⁵⁵ Generally, there is no significant difference between these genetically modified products and the

⁵³ Homer, 45 COLUM. J.L. & SOC. PROBS. at 83.

⁵⁴ *Id.*

⁵⁵ *Id.*

originals?, and only about one in three Americans realize the fact that most of the food they eat has already been genetically modified.⁵⁶ Genetic engineering helps to enhance agricultural efficiency, increase the amount and ability of crops to survive and that will survive, reduce the amount of food needed to be grown and the space that it will need to grow, as well as many other helpful things.⁵⁷ {Do we know for sure that there are no long term effects? Doesn't it depend to some degree about what methods and ingredients are used to create the modification. What is put into soybeans is not the same as used to genetically alter salmon.]

However, not everyone sees these modifications as unequivocally good things. Some critics worry about the technological uncertainties of genetic engineering and the effects that the foods will have not only on humans who consume them, but also the environment in which they are grown.⁵⁸ Critics fear a loss of biodiversity by extinction of species. These arguments are much the same as arguments from those worried about the wild salmon population being destroyed. Why are they the same? Because you think they are groundless? They are not as forceful, however, because no one really seems to care as much about plants as animals, and humankind has been genetically modifying plants since we discovered that we were able to graft plants together. These critics have asked the federal government for more regulation and oversight in the production of genetically modified foods.⁵⁹

Up to now, this kind of oversight and regulation has not been the United States' preferred method of dealing with genetically modified foods. Consumers have been

⁵⁶ Wilinska, 21 Minn. J. Int'l L. at 151.

⁵⁷ See e.g. Homer, 45 COLUM. J.L. & SOC. PROBS. [Improper footnotes](#)

⁵⁸ *Id.*

⁵⁹ *Id.*

traditionally more tolerant of genetic modification, assumedly for the reasons espoused above.⁶⁰ Genetically modified foods have been subjected to a lenient regulatory framework within the United States, perhaps? because of the general approach that these foods should not be assumed harmful until evidence is presented to the contrary.⁶¹

This approach has been referred to as “The Equivalence Principle”.⁶² The United States policy regarding most new products has always had a mind toward risk. Essentially, in US jurisprudence, [this is not jurisprudence!!] this principle assumes that if a genetically enhanced product is essentially or substantially equivalent to its underlying, natural product, there should be no significant adverse effect on its production or consumption.⁶³ The FDA’s statement of its own position reflects this: Transgenic foods are “generally recognized as safe,” until proven otherwise.⁶⁴ As scholars point out, this more or less means that the introduction of genetically modified products into consumer markets is controlled by free market principles.⁶⁵ This allows quicker and more exact scientific progress, and ultimately allows for better products to reach consumer markets faster.

C. Regulation of Genetically Modified Foods

Approximately 25 percent of all consumer products marketed in the United States are overseen and approved by the FDA.⁶⁶ Congress, in enacting legislation delegating oversight power to the FDA, has created statutorily defined classes of products that the

⁶⁰ Wilinska, 21 MINN. J. INT’L L. at 163 (2012)

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ George Kimbrell, Paige Tomaselli, A "Fisheye" Lens on the Technological Dilemma: The Specter of Genetically Engineered Animals, 18 Animal L. 75, 97 (2011).

⁶⁵ See *e.g.* Wilinska, 21 MINN. J. INT’L L. at 163.

⁶⁶ FDA, Advancing Regulatory Science at FDA: A Strategic Plan (2011), *available at* <http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm>.

FDA can regulate. Because of this approach of categorizing every consumer product class, the legal and regulatory framework in which the FDA analyzes each new product varies according to which statutory category that a new product will fit into.⁶⁷ This means that rather than taking oversight over the *processes* by which food and drugs are allowed to enter into the market, the FDA really only takes control of the actual *products* themselves. While this may have been a good approach to organizing the FDA's authority when the Food, Drug, and Cosmetic Act (FDCA)⁶⁸ was enacted, it makes it increasingly difficult for FDA regulations to keep up with emerging technologies and scientific progress when it comes to new products.⁶⁹

Many commentators have expressed concern with how this affects the amount of regulation that the FDA actually has over the entrance of technologically.⁷⁰ Regardless of how valid or invalid these criticisms may be regarding this (arguably) inflexible statutory framework, the FDA has asserted authority over genetically modified animals under interpretation of several statutes codified from the FDCA.⁷¹ Additionally, the FDA has provided explanation their own internal documents concerning administrative procedure and authority.⁷² Unclear??

The FDA first has authority to regulate genetically modified animal products, because it already regulates “new animal drugs”, whether or not these animals are used

⁶⁷ Jordan Paradise & Ethan Fitzpatrick, *Synthetic Biology: Does Re-Writing Nature Require Re-Writing Regulation?*, 117 PENN ST. L. REV. 53, 63 (2012).

⁶⁸ See generally 21 U.S.C. § 301 *et seq.*

⁶⁹ *Supra* Paradise, n.67. not proper cite

⁷⁰ See e.g. Susan B. Foote & Robert J. Berlin, *Can Regulation Be as Innovative as Science and Technology? The FDA's Regulation of Combination Products*, 6 MINN. J. L. SCI. & TECH. 619, 623 (2005).

⁷¹ ⁷¹ See generally 21 U.S.C. § 301 *et seq.*

⁷² See generally e.g. FDA, Genetically Engineered Animals, <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/default.htm>; See also A Strategic Plan, *supra* n.65.

for human consumption.⁷³ As defined by federal statute, new animal drugs include “any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed.”⁷⁴ Though recombinant DNA (rDNA) might not seem like a drug to a layperson, the process is applied to animals in the same way as a conventional drug might be, and the FDA considers the two effectively the same.⁷⁵ Unclear

Last year, the FDA released guidance regarding this position, and in the most relevant part stated, “an rDNA construct is in a GE animal and is intended to affect the animal's structure or function *meets the definition of an animal drug*, whether the animal is intended for food, or used to produce another substance.”⁷⁶ Because the application of rDNA is intended to affect the animal in the same way as a conventional drug, the FDA is in charge of its regulation. The authority to regulate new animal drugs is the most important part of the FDA’s analysis of new foods, because it allows the FDA to oversee every part of the *construction* of the food, as opposed only being able to regulate the consumer product as a whole right before it hits the market. This is very technical and not very clear to a layperson. Footnotes could help explain it.

However, this is not the only way that the FDA can assert authority over genetically modified animals as food. The FDA additionally has authority to regulate genetically modified animals as human consumption because rDNA might be considered

⁷³ 21 U.S.C. § 321.

⁷⁴ *Id.*

⁷⁵ FDA, Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant Constructs 4, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf>.

⁷⁶ *Id.* (emphasis added).

an adulteration to the product.⁷⁷ Adulteration is defined in many ways in the statute, but most generally, a food is considered adulterated if it “bears or contains any poisonous or deleterious substance which may render it injurious to [public] health.”⁷⁸ Foods are not presumed adulterated so long as they comply with the conditions and guidelines of the FDA.⁷⁹ In the same report, the FDA added harsher compliance requirements for foods modified with rDNA, requiring that “developers of these animals must demonstrate that the construct and any new products expressed from the inserted construct are safe for the health of the [genetically engineered] animal and, if they are food animals, for food consumption.”⁸⁰ The FDA’s authority over whether a food is adulterated allows the FDA to regulate not only what composes or makes up the food, but also if the food will be harmful on a higher level, as a food for general human consumption.

Once the FDA has determined that an animal applied with changed rDNA and grown for human consumption is safe for human consumption, it must amend the applicable regulations to reflect the specific product approved.⁸¹ Though the FDA is very close to approving genetically modified salmon and adding regulation to that effect, the only applicable example of this process resulting in created regulation in current law has to do with goat milk.⁸² Many scholars have surmised that the next genetically modified animal product that will be explicitly regulated will be the AquAdvantage Salmon, and

⁷⁷ 21 U.S.C. § 360b.

⁷⁸ 21 U.S.C. § 342.

⁷⁹ Paradise, *supra* n.66 at 69.

⁸⁰ Guidance for Industry, *supra* n.74.

⁸¹ Paradise, *supra* n.66 at 70.

⁸² 21 C.F.R. § 528.1070

after a 17 year process, the FDA's own briefing packets suggest this statement will be true.⁸³

i. Specific FDA Regulation of Genetically Modified Salmon

The FDA's specific approach to deciding whether AAS should be allowed focuses on three different criteria: "The safety of the transgenic construct for the animal; safety of the food from the animal; environmental impact."⁸⁴ This paper has already discussed the environmental impact of the AAS, and the FDA reached the same conclusion about the environmental impact as that reached above. [you said earlier that it has not yet completed its investigation]The safety of the transgenic construct is not an issue in this case, because there is obviously no danger to the AAS itself. The salmon develops and lives out its life (relatively) normally in captivity, able to do everything that a naturally occurring, wild salmon would.?? Is it really the same? Additionally, even if the safety of the transgenic construct used in creating AAS *were* at issue, the FDA has already asserted its regulatory authority over the product and determined it completely safe.⁸⁵

Then the only remaining issue is for the FDA to determine the safety of the food gained from the animal. The equivalency principle lends itself very well to this analysis.⁸⁶ AquaBounty does meddle in the genetic process of the salmon. However, the scientific interference with the salmon's natural processes does not last for longer than the zygote stage of its development. After that stage, AquaBounty's only contact with their salmon

⁸³ See FDA, VMAC Briefing Packet, AquAdvantage Salmon, <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf>

⁸⁴ *Id.*

⁸⁵ As discussed *supra* in the preceding paragraphs

⁸⁶ *Contra* Kimbrell, 18 ANIMAL L. at 97.

is generally to feed it and make sure that they remain captive and do not interfere with any population of wild salmon. AAS feed normally, and they do everything that other salmon do naturally in the wild, aside from reproduce. While this somewhat destroys the salmon's majestic story, it does nothing to detrimentally impact their nutritional value. In fact, it only enhances the good nutritional qualities of naturally occurring salmon, without enhancing any of the drawbacks. This obviously passes the FDA's second concern in its test, and after assuring that there is no adverse environmental impact, the FDA has no reason to block or otherwise restrict this kind of salmon production.

The FDA's approval method and general attitude towards this type of production in the United States can be contrasted with the European Union's approach to genetically modified products in the marketplace. Historically, the European public has not been as accepting of genetically modified foods, sparking huge debate and resistance.⁸⁷ European consumers do not believe that genetically modified foods will be safe; and, even if they are safe, the consumers do not believe that their government can adequately control or oversee genetic modification or production.⁸⁸

ii. European Union Regulation of Genetically Modified Food

This public concern⁸⁹ has led to a different kind of principle governing European legislation: The Precautionary Principle.⁸⁹ This is the complete opposite of the United States' stance. Using the precautionary principle, genetically modified food is considered unsafe until it can be effectively proven that there are no risks involved.⁹⁰ Any applicant

⁸⁷ Wilinska, 21 MINN. J. INT'L L. at 163.

⁸⁸ Valery Federici, *Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws*, 35 BROOK. J. INT'L L. 515, 538 (2010).

⁸⁹ Wilinska, 21 MINN. J. INT'L L., at 163.

⁹⁰ See generally PARL. EUR. DOC. (Reg. 1829/2003).

seeking to produce genetically modified food must convince the European Union that the product will be safe before it can even be marketed, based on part by an independent assessment from a third party of the food's possible risks and rewards.⁹¹ This third party would be whatever "national competent authority" that each country might recognize as their own administrative body (comparable to the US's FDA).⁹² Any producer trying to sell its genetically modified products in the European Union must not only comply with EU regulations. Additionally, producers must comply with their own national standards, which might even be harsher than EU regulation. EU regulation of the application itself is extensive, applying a heavy burden on the producer to show that its product is safe.⁹³ The applicant must not only provide convincing details as to how the genetically modified food was created, stored, raised, etc.; but, also, details as to other possible concerns, such as inclusion of a "reasoned statement that the food does not give rise to ethical or religious concerns."⁹⁴ This provision alone would seem to be an extremely high hurdle for genetically modified food to jump, as many religions are highly skeptical of genetic modification in the first place. How do you know this? Naturally, the European Union's stricter approach mandates much slower growth and innovation in the marketplace, and ultimately such stricter regulation makes it much harder for the modified food industry to flourish.⁹⁵

⁹¹ See 2001 O.J. L. 106 17.04; see also 2004 O.J. L. 102 07.04.

⁹² PARL. EUR. DOC. (Reg. 1829/2003) Art.4, Sec2(a)(i) *et seq.*

⁹³ *Id.*

⁹⁴ *Id.* Art.4, Sec. 3(g).

⁹⁵ The instant subject of this entire paper may be a good example of the veracity of this statement, as a European biotech company has invested a huge amount of time and money only into developing the product for a US marketplace. [GOOD. Who is it? More could/should be said about it.](#)

The main difference between US and EU legislation has to do with the labeling of genetically modified foods.⁹⁶ The United States does not impose labeling requirements on any distributor of genetically modified foods.⁹⁷ The FDA has released *voluntary* guidelines, however,; but there is no reason for any food distributor to worry? about following these guidelines, save for consumer expectation.⁹⁸ Taken with the fact that only 1/3 of the population even knows about genetic modification of foods such as corn, there is really no need for companies to develop marketing plans to deal with consumer expectation or disapproval. This undoubtedly applies to AAS as well, as it is a genetically modified food. As discussed above, the FDA has assumed sole responsibility of regulating genetically modified animal food, and has green-lighted AAS for human consumption without a need for labeling.⁹⁹ The European Union has much stricter labeling restrictions, requiring mandatory product labeling and ultimate transparency to the consumer, as well as government monitoring and public disclosure of the growing process.¹⁰⁰ These stricter restrictions apply to any foods imported to the EU as well.¹⁰¹ In fact, the vast bulk of the EU regulations regarding genetically modified foods speak of labeling in some way or another, as most provisions include the phrase: “or a proposal for labeling [sic] the food in accordance with Article...”¹⁰² [Is there some evidence that EU consumers care more about possible safety issues? Has anyone tried to explain why the EU is so cautious?]

⁹⁶ Federici, *supra* n.90.

⁹⁷ Wilinska, 21 MINN. J. INT'L L. at 163.

⁹⁸ *Id.*

⁹⁹ Homer, 45 COLUM. J.L. & SOC. PROBS. at 83.

¹⁰⁰ Wilinska, 21 MINN. J. INT'L L. at 163.

¹⁰¹ *Id.*

¹⁰² See *e.g.* PARL. EUR. DOC. (Reg. 1829/2003) Art.4, Sec 3(f), (g), etc.

iii. United States Accommodation of European Union Guidelines

The discrepancy between labeling may very well affect the import/export salmon market in the EU. Currently, 23% of the US's salmon production is exported to the EU.¹⁰³ Should AAS begin to take over a significant portion of the salmon market, the EU may stop buying US salmon, due to its fear of receiving a product that it deems as unsafe because of failure to follow its labeling guidelines. [US companies can follow EU guidelines if they want to]The EU has already indicated that it would be very strict in its application of its regulations of international? movement of genetically modified organisms.¹⁰⁴ For various reasons,¹⁰⁵ including fear of human safety and the continued threat of a loss of biodiversity, the EU has implemented an expansive regulation regarding the import and export of genetically modified organisms. This has purportedly been done in an attempt to satisfy the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.¹⁰⁶ Not surprisingly, the United States is not a party to this Convention.

However, because of the fear of losing market viability, several senators have criticized the FDA's process of approving genetically modified foods and have tried to change the way that the process is completed, calling for stricter guidelines and labeling requirements.¹⁰⁷ Scholars have also asserted that the gap between the US and EU concept

¹⁰³ Wilinska, 21 MINN. J. INT'L L. at 163.

¹⁰⁴ See 2003 O.J. L. 287.

¹⁰⁵ See e.g. PARL. EUR. DOC. (Reg. 1946/2003) (4), (5), etc. ("It is important to organise the supervision and control of transboundary movements of GMOs in order to contribute to ensuring the conservation and sustainable use of biological diversity, taking also into account risks to human health, and so as to enable citizens to make a free and informed choice in regard to GMOs").

¹⁰⁶ *Id.*

¹⁰⁷ Wilinska, 21 MINN. J. INT'L L. at 163; Obviously, these senators are trying to change the guidelines to something similar to those used in EU regulation.

will widen and that the EU will ban any import of AAS into its territory.¹⁰⁸ This should not be a legitimate reason for the US to consider legislation to accommodate the European Union. First, Europeans would not be afraid to buy traditional, Alaskan fished wild or farmed salmon. Voluntary labeling from Alaskan fisheries might very well be able to recapture the 23% market share of the European Union, mitigating their declining market-share from needing to compete with AAS. Second, aside from creating a solution that would help out traditional Alaskan fisheries, continuing the policy of not requiring labeling will remain more in line with domestic consumers' expectations and the American risk assessment and efficiency model. There appears to be no reason to start a panic among consumers that might adversely affect the salmon industry, not to mention that such a panic would be started out of fear of losing more fickle or cautious foreign consumers. There is no reason to force our domestic consumers to bow to the needs of the European Union or the World Trade Organization. For obvious reasons, if Europeans are so frightened of our products that they feel obligated to ban their import, the EU should be and remains completely free to fish for their own salmon. Only in very grave circumstances should we in the US allow the European system to dictate that our government impose unneeded restrictions and sanctions on domestic consumers and producers. Again, since there is no evidence of harm by the salmon to contradict the need for no further regulation, the free market is most likely the best judge of how the European consumers and American producers should act—not the meddling of a clearly imperfect international politic.

An interesting aside that provides supplemental evidence on this point is the fact that AquaBounty is an English company, listed on the London Stock Exchange's

¹⁰⁸ *Id.*

Alternative Investment Market.¹⁰⁹ However, it is currently marketing and testing its salmon exclusively for United States consumers. Additionally, the company has applied for a US patent and is currently headquartered in Massachusetts.¹¹⁰ AquaBounty will not even attempt to market its product in the European Union, despite being listed on their stock exchange. Should the AAS turn out to be a superior product than natural salmon, this would simply be a predictable byproduct of the principle of equivalence's ability to better adapt a product to a marketplace.

¹⁰⁹ AquaBounty Technologies, *The Company*, <http://www.aquabounty.com/company/company-history-292.aspx>.

¹¹⁰ *Id.*

Conclusion

With the advent of genetic technology, new and exciting possibilities are opening up for humanity. Scholars and experts have always questioned and should always continue to question the direction that this technology is taking us. But while governmental involvement and regulation is a good thing, it should be limited to what is absolutely necessary. Unlike the current policy of the European Union, governmental intrusion should not limit the productivity or availability of products in the marketplace more than might be absolutely necessary.

AquaBounty's salmon has been genetically modified to grow bigger and stronger than naturally occurring wild or farmed salmon ever will. Plus, the AquaAdvantage salmon grow at over twice the rate of naturally occurring salmon. The FDA has extensively reviewed and recently approved the AquaAdvantage salmon as safe for human consumption, after assessing their potential impact on the environment and the safety of the salmon to be consumed. The FDA's review of the environmental impact has show that there was an infinitesimal chance that the salmon would escape into the wild and ravage natural salmon populations. Additionally, because there is no real difference between the AquaAdvantage salmon and naturally occurring salmon, the FDA has determined that there is no reason to fear its open sale on the market.

The FDA has also put forth voluntary labeling guidelines for those that wish to represent whether their salmon has or has not been genetically modified. Unless there is a huge consumer outcry against genetically modified salmon, this minimal regulation should be able to provide enough security and oversight to protect consumer choices.

There is no need for more restrictions and regulations to save consumers or to bring United States policy into line with the European Union's more cautious, draconian regulation. Because genetically modified salmon has proven safe for human consumption and has virtually no negative impact on the environment, the FDA's current regulation and approach is sufficient, and there is no need for anything additional.

Better than original. Still a little one-sided. Aren't there some scientists who may argue that we won't know the full effect on human safety until there has been some long-term studies regarding the well-being of both the salmon and human consumers.?

Have there been any examples where the US approach—allow until harm is shown—has proven disastrous? [How about some of the pills/drugs the FDA has allowed on the market. Also there is a chance that a company such as Aqua may fake/skew reported findings so as to obtain approval]

Final Grade: A-