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The AquAdvantage Salmon Controversy – A Tale of Aquaculture, Genetically Engineered Fish and Regulatory Uncertainty

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Abstract

This paper discusses the controversy around the potentially imminent commercialization of the first genetically engineered animal for human food consumption in the United States. The industrialization of commercial fishing in the wake of growing demand has led to a rapid decline in wild fish stocks. Over the last 50 years, modern aquaculture has developed into an important industry, to the point that it now supplies nearly half of all the fish humans consume. Yet modern aquaculture, including its two main commercial products, shrimp and salmon, is also associated with significant environmental problems, as well as other health, social and economic ones. Partially in response to these problems, several companies and countries have turned to genetic engineering as a possible means to improve the efficiency of fish farming. Leading this effort, AquaBounty Technologies, a Massachusetts company with operations in both Canada and Panama, is attempting to commercialize all-female infertile fish for human consumption. Using recombinant DNA (rDNA) technology, AquaBounty created an Atlantic salmon that grows twice as fast as its non-engineered counterpart. By summer 2010, AquaBounty announced that is had successfully fulfilled all the requirements necessary under the FDA's New Animal Drug Application (NADA), the agency's current framework for regulating genetically engineered animals with hereditary rDNA constructs. Yet despite what seemed to be the FDA's inclination to allow AquaBounty to commercialize the AquAdvantage salmon soon after a public hearing held in September 2010, the application continues to stir significant controversy and remains unresolved. The FDA's cautious response is perhaps unsurprising given the significance of this decision for other pending commercializations of genetically engineered animals and the criticism suggesting the unsuitability of the NADA framework to authorize such novel food.

1 Background on Fisheries and Aquaculture

1.1 The State of the World's Fisheries

1.1.1 In General

The industrialization of fishing in the 1950s and 1960s lead to a major increase in global fish catches, leading to widespread over-fishing and the collapse of many fish stocks.[1] According to the United Nations Food and Agricultural Organization's (FAO) most recent assessment of worldwide fish stocks, in 2008, over one third of worldwide fish stocks were over exploited or depleted, a nearly three fold increase over the past 35 years. Just over half of fish stocks were classified as fully exploited, meaning that they were at or close to their maximum sustainable limit of exploitation.[2] As of 2008, total world fish production was 142 million tons, of which 100 million tons were marine fish. Nearly 80 million tons of marine fish were captured, while the remaining 20 million was produced from aquaculture.[3] Out of the 142 million tons produced both from fresh water and marine sources, approximately 115 million tons was used for human food, with the remaining balance used for other products, in particular fishmeal and fish oil.[4]

The increase in fully exploited or over-exploited fish stocks parallels a slow decline of marine captures over the past decade.[5] While environmental conditions have also contributed in some cases to the decline of fish stocks, over-fishing is widely

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[1] MICHELLE ALLSOPP ET AL., STATE OF THE WORLD'S OCEANS 33 (Springer Science + Business Media B.V. 2009).
[2] FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, THE STATE OF THE WORLD FISHERIES AND AQUACULTURE 2010 35 (Food and Agriculture Organization of the United Nations 2010), *available at* http://www.fao.org/docrep/013/i1820e/i1820e.pdf.
[3] *Id.* at 3.
[4] *Id.* at 3.
[5] *Id.* at 4.

recognized as the main cause of the problem.[6] Particularly notable is the severe decline in predatory fish, including salmon. One study suggests that predatory fish stocks have declined to just 11% of the levels they were at one hundred years ago.[7] The decline in predatory fish is concerning because it is indicative of the amount of pressure that human exploitation is imposing on the ocean. The decline in the mean trophic level[8] of fishery catches[9] implies that a decline in large predatory fish at the top of the food chain is forcing fishermen to switch to fishing smaller and younger fish lower down in the food chain.[10]

Although not devoid of problems of its own, aquaculture has been increasingly viewed as a solution to the depletion of the world's fisheries. The increase in aquaculture production is such that is has offset the loss in natural fisheries production to the point that fish availability per capita has increased from 16.2 kg per person in 2004 to 17.2 kg per person in 2009.[11] Aquaculture already supplies 55 million tons out of the total 118 million tons of fish consumed annually by humans, and a further increase in aquaculture production may help reduce the pressures on wild fish stocks.[12]

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[6] ALLSOPP ET AL. *supra* note 1 at 35.
[7] Villy Christensen et al., *Hundred-year Decline of North Atlantic Predatory Fishes*, 4 FISH AND FISHERIES 1 (2003), *available at* http://www2.fisheries.com/archive/members/dpauly/journalarticles/2003/hundredyeardeclinenorthatlanticfishes.pdf.
[8] The trophic level of an animal describes the position it holds within the food web. In marine settings, the trophic level indicates how far up in the food web a particular fish relative to algae, which are situated at the bottom of the food web and are given a trophic level of 1. Zooplankton that consumes algae is thus assigned a trophic level of 2, smaller fish that consume the zooplankton are assigned a trophic level of 3, and so forth. Large predatory fish are usually assigned a trophic level of 3.5 to 4.5. *See* Daniel Pauly and Reg Watson, *Background and Interpretation of the 'Marine Trophic Index' as a Measure of Biodiversity*, 28 PHIL. TRANS. R. SOC. B 415 (2005).
[9] Ransom A. Myers & Boris Worm, *Rapid Worldwide Depletion of Predatory Fish Communities*, 423 NATURE 280 (2003).
[10] D. Pauly and R. Watson *supra* note 8.
[11] *Id*. at 3.
[12] STATE OF THE WORLD FISHERIES AND AQUACULTURE 2010 *supra* note 2 at 3.

1.1.2 Wild Salmon

Wild salmon used to be plentiful. In fact, for many years, salmon was considered a poor man's fish, and fed often enough in prisons to cause prisoner revolts in both in Europe and the New World.[13] However, after Danish and Faroe Island fishermen in the 1950s found the areas off Greenland where Atlantic salmon congregated and started fishing them in large quantities, and the Norwegians and the Swedes joined them in the 1960s, wild Atlantic salmon quickly went into permanent decline.[14] By contrast, the Pacific species of salmon found in supermarkets today are still for the most part wild.[15] However, diminished salmon runs across the Pacific coast of North America have left their viability in question.[16] For both Atlantic and Pacific salmon, excessive damming of salmon run rivers, in addition to over-fishing, are thought to be the cause of the declining wild stocks.[17] As a result, both fish are currently listed as endangered[18] and essentially all Atlantic salmon in supermarkets today is farmed.[19]

1.2 The State of Aquaculture

Aquaculture is the fastest growing animal food sector in the world.[20] Species at the low end of the food chain such as shellfish, herbivorous fish and omnivorous fish are the

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[13] PAUL GREENBERG, FOUR FISH – THE FUTURE OF THE LAST WILD FOOD 26 (The Penguin Press 2010).
[14] *Id.* at 19.
[15] *Id.*
[16] California closed its salmon fishery completely for the first time in history in 2008 and the Columbia River now hosts less than a tenth of its historical run. GREENBERG *supra* note 12 at 20.
[17] *Id.* at 18.
[18] The Chinook salmon is only partially listed as endangered or threatened in its California and Washington state ranges. *See* Species Profile, Chinook Salmon (Oncorhynchus Tshawytscha), U.S. Fish and Wildlife Service, http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=E06D (last visited May 10, 2011). Species Profile, Atlantic Salmon (Salmo Salar), U.S. Fish and Wildlife Service, http://ecos.fws.gov/speciesProfile/profile/speciesProfile.action?spcode=E07L (last visited May 10, 2011).
[19] GREENBERG *supra* note 13 at 18.
[20] ALLSOPP ET AL. *supra* note 1 at 85.

most common, but aquaculture also plays an important role in the supply of carnivorous species like shrimp and salmon.[21]

Today's aquaculture is conducted in two main settings. Freshwater aquaculture takes place in both naturally and artificially created ponds, often on agricultural land areas. Marine aquaculture takes place either in ponds built along the coast and filed with seawater, or more often in cages or net pens directly placed in coastal waters. Land-based systems can either encompass raceway systems, where water naturally flows through the fish farming operation, or re-circulating systems, in which fish are held in tanks and water is usually treated and re-circulated. Different levels of rearing intensity exist. At the most extensive level, fish are left to fend for themselves by feeding off naturally available food, while at the most intensive level, all of the required food, as well as pest and disease control drugs, are provided by the fish farmers to the fish.[22]

While growing both aquatic plants and animals has been practiced for over 4,000 years, notably in Asia,[23] modern aquaculture is a recent phenomenon. Since its modern origins in the second half of the previous century, the pace of development has been staggering. Compared to the domestication of farm animals, the domestication of fish has been described as haven taking place "overnight."[24] Equipment used to hold and rear fish has evolved significantly, as has a greater understanding of fish genetics and reproduction.[25] Both of these have led to dramatic increases in productivity. For example, to enhance growth rates and ensure that fish are larger at the time they are harvested for

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[21] *Id.*
[22] ALLSOPP ET AL. *supra* note 1 at 89.
[23] GREENBERG *supra* note 13 at 69 – 70.
[24] William Howarth, *Global Challenges in the Regulation of Aquaculture*, *in* AQUACULTURE LAW AND POLICY: TOWARDS PRINCIPLED ACCESS AND OPERATIONS 13, 15 (David L. VanderZwaag and Gloria Chao eds., Routledge 2006).
[25] Greenberg *supra* note 13 at 81 – 125 provides a detailed discussion of the origins of sea bass farming, a fish with a particularly fickle reproduction cycle that doesn't lend itself easily to domestication.

processing, modern aquaculture often resorts to making fish sterile.[26] It is also used as part of modern aquaculture containment strategies to ensure that farmed fish that escape ocean cages and pens cannot mate with wild specimens.[27] Creating sterile fish is relatively simple. To do so, farmed fish eggs are subject to heat or pressure shocks shortly after fertilization, causing them to retain an extra set of chromosomes. The resulting fish, termed "triploid," end up with three sets of chromosomes as opposed to the normal two.[28] These fish fail to develop normal sexual characteristics and the female are sterile.

In general, modern aquaculture has tended to choose the fish it raises and the production methods it uses based on consumer demands rather than on principles of sustainability. The expansion of aquaculture has been associated with a host of environmental, social, economic, health and ethical issues.[29] Aquaculture's environmental problems include the eutrophication and stimulation of unwanted algal blooms that result from the release of uneaten food pellets, dead fish and fish feces. In the case of ocean-based cage aquaculture, these releases occur directly into the surrounding ocean in which cages are located. As this waste decomposes, it releases both organic and inorganic nutrients, as well as nutrients that then stimulate algae growth. In nutrient-rich waters, as algae bloom and waste decompose, they deplete the waters' oxygen content and result in oceanic dead zones.[30] Farmed fish also carry diseases and parasites that are transferable to wild fish stocks with potentially devastating effects. Evidence shows that

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[26] *See* G. Hulata, *Genetic Manipulations in Aquaculture: A Review of Stock Improvement by Classical and Modern Technologies*, 11 GENETICA 155, 161 – 162 (2001).
[27] *Id.*
[28] *Id.*
[29] *See* David L. VanderZwaag, *Introduction – Aquaculture Law and Policy: Struggling in the Wake of the Blue Revolution*, *in* AQUACULTURE LAW AND POLICY: TOWARDS PRINCIPLED ACCESS AND OPERATIONS 1, 1 (David L. VanderZwaag and Gloria Chao eds., Routledge 2006).
[30] ALLSOPP ET AL. *supra* note 1 at 97 – 98.

the prevalence of such diseases and parasites has increased in wild stock as a result of farmed fish escaping from their holding pens and transferring them directly to wild stock. Transfer also happens when high concentrations of infested farmed fish are held in waters that also serve as wild fish habitats.[31] Finally, the escape and potentially interbreeding of farmed fish with wild ones is a major concern.[32] Social and economic issues arise from the impact aquaculture is having on traditional fisheries, how access is granted to optimal fish farming sites, the highly concentrated state of the aquaculture industry and questions about working conditions and labor practices employed in the industry.[33] Health issues arise mostly from the higher concentrations of PCBs typically found in farmed fish and the potential impacts on humans of antibiotic use in aquaculture.[34] Finally, whether or not fish should be farmed, but more significantly whether or not fish should be genetically manipulated to grow faster, are core ethical questions associated with aquaculture.[35]

1.2.1 Salmon Aquaculture

Salmon domestication started in Norway in the early 1960s. Salmon proved particularly adaptable to growth in captivity, because, contrarily to other farmed predatory fish that depend on the presence of specific microscope organisms in their first larvae phases of life, salmon hatch out of large and nutrient rich eggs off which they live for the first few weeks of their lives.[36] From there, young salmon can relatively easily be transitioned over to eating chopped-up pieces of fish. By maintaining salmon in floating ocean cages, feeding them regularly, and keeping them safe by predators, early salmon

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[31] *Id.* at 100.
[32] *Id.*
[33] VanderZwaag *supra* note 29 at 1.
[34] *Id.* at 1 – 2.
[35] *Id.* at 2.
[36] GREENBERG *supra* note 13 at 40.

farmers quickly realized that they had reversed the natural selection process that causes a 99% mortality of salmon in their early phases of life.[37] Combined with the rapidly declining availability of naturally fished salmon, there was a clear financial incentive to further improve the aquaculture process.[38]

Initial salmon farming was conducted using wild fish. Innovative Norwegians fish farmers then proceeded to cross and re-cross Atlantic salmon strains from forty different rivers to develop a fish that grew faster. In just fourteen years, or the time of seven generations of salmon, Norwegian fish farmers were able to double the growth rate of salmon.[39] This ensured dominance of the nascent fish farming industry. Expansion to other cold-water, fjord rich coastal regions of Chile,[40] Nova Scotia and British Columbia soon followed. Today, salmon is the most traded aquaculture product after shrimp. One-and-a-half million metric tons of farmed salmon are traded annually, almost all of which is Atlantic salmon.[41] In the US alone, the annual value of the salmon trade, 97% of which is imported, is worth $1.39 billion.[42] Norway remains the principal exporter, with the European Union as its main market. [43] Chile is an also an important producer, exporting mostly to Japan and the United States.[44]

Improved farming techniques ensure that fresh salmon is now available year round, as opposed to seasonal wild catches. Farming has also resulted in a significant

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[37] *Id.*
[38] *Id.*
[39] *Id.* at 39.
[40] Interestingly enough, before the expansion of salmon farming industry to Chile, there was no salmon south of the equator since it acts as a thermal barrier that wild salmon, which require cold water, cannot cross. *Id.* at 43.
[41] Jeffrey L. Fox, *Transgenic Salmon Inches Toward Finish Line*, 29 NATURE 1141, 1141 (2010).
[42] Molly Peterson, *This Genetically Altered Salmon is No Fish Story*, 4197 BLOOMBERG BUSINESSWEEK 21 (2010.)
[43] Ted L. McDorman and Torsten Strom, *Aquaculture and the Multilateral Trade Regime: Issues of Seafood Safety, Labeling and the Environment, in* AQUACULTURE LAW AND POLICY: TOWARDS PRINCIPLED ACCESS AND OPERATIONS 355, 355 (David L. VanderZwaag and Gloria Chao eds., Routledge 2006).
[44] *Id.*

drop in the relative price of salmon, to a point that it is a relatively common offering in many developed country diets. The increase in salmon demand is also driven by consumer awareness about the health benefits of consuming omega-3 fatty acids. Omega-3 fatty acids are commonly found in cold-water fish like salmon as they allow these fish to maintain pliable cell membranes in frigid waters. These fatty acids have the same effect on human vascular tissue when consumed by humans.[45] A study by Harvard Medical School even suggests that the benefits of farmed salmon-derived omega-3 acids offsets the increased exposure to PCB poisoning that is also commonly said to be associated with eating farmed salmon.[46]

However, salmon farming is also the source of many concerns. First, over a million domesticated salmon escape into the wild annually. Opponents of salmon farming fear that tamed salmon risk displacing wild fish because they feed more aggressively and thus out-compete wild stocks[47] only to be later unable to reproduce as a result of having lost the traits essential to successfully spawn upriver in the wild.[48] Alternatively, there is the risk that farmed salmon, genetically modified or simply selectively bred, may actually breed with wild salmon and disrupt the natural gene pool. This so-called "Trojan gene" effect is driven by the ability of farmed salmon to reproduce much more effectively as a result of more aggressive feeding behaviors, but with the subsequent detrimental effect of

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[45] GREENBERG *supra* note 13 at 54.
[46] *See* Dariush Mozaffarian and Eric B. Rimm, *Fish Intake, Contaminants, and Human Health: Evaluating the Risks and the Benefits*, 296 J. OF AM. MED. ASS'N 1885 (2006).
[47] Several studies have shown that growth-enhanced tilapia and coho salmon eat nearly three times as much as their natural counterparts under laboratory conditions. Whether or not this would hold true in the wild is unclear. Studies by AquaBounty technologies suggest that the genetically engineered salmon are less likely to be careful about avoiding predators in their attempts to forage large amounts of food, and also exhibit poorer camouflage, suggesting that their ability to survive in the wild would be diminished. While this may suggest that escaped genetically modified salmon are less likely to successfully survive long enough to breed, should they however succeed in doing so, they could transfer unfavorable survival genes to wild salmon stocks. *See* Tony Reichhardt, *Will Souped Up Salmon Sink or Swim?*, 406 NATURE, 11, 12 (2000).
[48] GREENBERG *supra* note 13 at 44.

producing future generations of crossbred offspring that are unable to reproduce because they do not possess the essential genes to thrive in the wild and the instinct to spawn upriver.[49] A separate concern particular to farming salmon is that it requires large amounts of food, a major share of which consists of other smaller fish harvested from the wild. Although selective breeding has improved the conversion efficiency from the original six pounds of ground fish required to produce one pound of salmon to three,[50] the net loss of fish that results calls into question the sustainability of the process, particularly when the small fish in question serve as staple foods for developing nations.[51]

Despite these concerns, the salmon industry is now a multi-billion dollar business and consumer demand is unlikely to abate. Demand for seafood is expected to double over the next thirty years and aquaculture is certain to play an important role in fulfilling this demand.[52] Salmon aquaculture remains a relatively young industry and many advocate for reform of the laws and practices that govern it.[53] One approach under development in Atlantic Canada's Bay of Fundy is referred to as Integrated Multitrophic Aquaculture (IMTA). Such a farming practice combines species that require feed with both species that extract inorganic nutrients and species that extract organic particulate matter. For example, to balance the polluting effect of feed-eating salmon, seaweed and mussels[54] can be used to extract both inorganic and organic pollutants respectively.[55] Although IMTA is still in its infancy, it may provide the groundwork for the creation of a

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[49] Reichhardt *supra* note 47 at 11.
[50] GREENBERG *supra* note 13 at 44.
[51] ALLSOPP ET AL. *supra* note 1 at 105.
[52] *See* Erik Stokstad, *Engineered Fish: Friend or Foe of the Environment*, 297 SCIENCE 1798, 1798 (2002).
[53] *See generally* AQUACULTURE LAW AND POLICY: TOWARDS PRINCIPLED ACCESS AND OPERATIONS (David L. VanderZwaag and Gloria Chao eds., Routledge 2006)
[54] The presence of mussels in the waters surrounding salmon farms may also diminish the presence of infectious salmon anemia virus, an added benefit that is not overlooked by large salmon farming operations where the disease is rife. *See* GREENBERG *supra* note 13 at 72.
[55] GREENBERG *supra* note 13 at 69.

fully closed feeding system whereby some of the species that feed on the waste generated by salmon would then be used to feed smaller fish that are themselves fed to the salmon.[56] Such a system may also address the problem of diminished omega-3 acid content of farmed salmon when they are fed more grain-based diets in part to offset the higher PCB concentrations found in their wild fish feed. Because omega-3 acids can be duplicated by seaweed, in a closed feeding system, these acids would find their way into the smaller fish that feed on seaweed before being themselves fed to salmon.[57]

2 Overview of AquaBounty Technologies

AquaBounty Technologies was incorporated in 1981 and is currently based in Waltham, Massachusetts.[58] Originally founded to pursue the commercial development of antifreeze protein applications in the medical, food and cosmetic field, researchers soon realized that the ability to turn the antifreeze gene on and off could also be applied to salmon's growth hormone genes.[59] The company proceeded to create its first transgenic fish in 1989[60] and eventually acquired the license to enhanced fish growth technology from the University of Toronto and Memorial University of Newfoundland in 1996.[61] While other companies and countries pursued research to enhance farmed salmon growth characteristics using similar genetic engineering approaches, many abandoned such efforts in the late 1990s, largely in response to consumer outcry. Notable, both Otter Ferry Salmon in Scotland and New Zealand King Salmon Company considered

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[56] ALLSOPP ET AL. *supra* note 1 at 110 - 112.
[57] GREENBERG *supra* note 13 at 72 – 73.
[58] AquaBounty Technologies, The Company, http://aquabounty.com/company/company-history-292.aspx (last visited April 25, 2011).
[59] Greenberg *supra* note 13 at 66.
[60] Fox *supra* note 41 at 1141.
[61] *Id.*

developing the growth hormone technology after licensing it from A/F Protein, AquaBounty's original parent company. However, as of 2000, both companies decided to abandon their research in the wake of controversy surrounding genetically engineered foods.[62] Authorities in both Chile and Norway rejected transgenic salmon out of fear of market loss.[63] However, despite both regulatory and public opposition, many other commercial fish farming companies have continued to conduct genetic research on roughly three dozen species of fish worldwide, including other salmonids and economically important fish such as catfish and tilapia.[64] Many hope to eventually obtain market approval for their own genetically engineered fish.

AquaBounty describes itself as a "biotechnology company focused on improving productivity in commercial aquaculture" to meet global consumer demand for high-qualify seafood.[65] Its first targeted commercial product is the AquAdvantage salmon, which grows twice as fast as commercially raised salmon.[66] After approval by the FDA, it would expect the fish to be available in supermarkets within two to three years.[67] The fish would reach harvestable size in approximately 200 days, as opposed to the current 350 days required by the domesticated Atlantic salmon currently raised on fish farms, and the 700 days required by wild salmon.[68] Even though the AquAdvantage salmon grow faster and reach mature size earlier, they are ultimately not larger than standard salmon.[69] AquaBounty's hybrid-fish was developed using the combination of modern DNA

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[62] Reichhardt *supra* note 47 at 10.
[63] Rebecca M. Bratspies, *Farming the Genetically Modified Seas – The Perils and Promise of Transgenic Salmon*, 62 AM. FISHERIES SOC'Y SYMP. 1, 14 (2008).
[64] *Id.*
[65] AquaBounty Technologies, The Company *supra* note 58.
[66] AquaBounty Technologies, AquAdvantage® Fish, http://aquabounty.com/products/ aquadvantage-295.aspx (last visited April 25, 2011).
[67] Andrew Pollack, *Modified Salmon is Safe, F.D.A. Says*, N.Y. TIMES, Sept. 3, 2010.
[68] Fox *supra* note 41 at 1141.
[69] *Id.*

procedures, including (1) gene and protein identification and analysis, (2) regulation of gene expression, (3) receptor identification and blocking technologies and (4) transgenesis.[70] Using the same DNA technology, the company is also developing equivalent tilapia and trout versions of its fast growing fish. The AquAdvantage salmon contains a growth hormone gene from the Pacific Chinook salmon that is kept active by a genetic on-switch obtained from a different fish, the ocean pout.[71] The ocean pout uses this promoter gene to regulate activity of its antifreeze protein gene, allowing it to survive the frigid water temperatures of New England and Atlantic Canada and grow year-round. By contrast, normal salmon only produce growth hormone in the spring and summer. The addition of the pout's promoter gene to the modified AquAdvantage salmon's genome ensures that the Chinook growth hormone is produced year-round, causing the salmon to grow twice as fast as a normal Atlantic salmon.[72] Because the AquAdvantage salmon grows much faster, AquaBounty expects a 20% efficiency gain in the amount of feed needed to bring the salmon to a harvestable size.[73]

In AquaBounty's proposed approach, the shock or heat treatment techniques described previously would be combined with another technique that allows for turning female salmon into male-like progenitors. Taking fertile genetically modified females and subjecting them to male sex hormone treatments converts them to sperm-producing "reverse males." Because these fish are originally females, they are only able to produce female offspring when re-bred with the eggs of another female. The fertilized eggs are

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[70] AquaBounty Technologies, Our Technology, http://aquabounty.com/technology/ technology-296.aspx (last visited April 25, 2011)
[71] Stokstad *supra* note 52 at 1798 – 1799.
[72] Pollack, *Modified Salmon is Safe*, *supra* note 67.
[73] Stokstad *supra* note 52 at 1798.

then pressure or heat treated, resulting in infertile adult female fish.[74] AquaBounty would retain a breeding stock on Prince Edward Island to produce an entire infertile female offspring stock produced solely for food production. Eggs for the production stock would be transported and hatched at an inland facility in Panama where the resulting fish would grown and ultimately be harvested and commercialized.[75] However, shocking salmon eggs to render them infertile is not entirely perfect and some scientists are concerned by the variability of results observed between batches.[76] AquaBounty's most recent data claims that it is able to consistently achieve 99.8% infertility, with variability between batches ranging from 98.9% to 100%.[77]

AquaBounty claims that its fish improves the economics of inland fish farming operations through reduced growth cycles. The company claims that such improved economics eliminate the need for ocean pens, thereby avoiding the problems they generate.[78] Traditional ocean pens used for the commercial farming of fish are associated with environmental pollution resulting from fish dejections, and escape and interbreeding of farmed fish with wild populations. However, few commercial fish farming operations build inland systems because they generally increase the cost of raising fish by 40%.[79] The advantages of using AquAdvantage salmon would need to be sufficient to justify these additional costs, but Aqua Bounty remains undeterred. The company believes that the growing demand for seafood, the ecological damages already caused by coastal

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[74] Reichhardt *supra* note 47 at 11.
[75] Fox *supra* note 41 at 1142.
[76] Reichhardt *supra* note 47 at 11 (quoting Anne Kapuscinki, specialist in biotechnology and aquaculture at the University of Minnesota in Saint Paul).
[77] AQUA BOUNTY TECHNOLOGIES, INC., ENVIRONMENTAL ASSESSMENT FOR *AQUADVANTAGE*® SALMON 60 (2010) *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf
[78] Reichhardt *supra* note 47 at 12.
[79] Stokstad *supra* note 52 at 1799.

aquaculture, and the limited number of remaining sites for further expansion of coastal aquaculture will all push the industry inland. Given these constraints, AquaBounty believes that using the AquAdvantage salmon will allow the industry to remain competitive.[80]

3 Regulation of Transgenic Animals

3.1 Commercialization Status of Genetically Engineered Animals

There are few genetically engineered animals currently commercially sold in the United States, and none are sold for food applications. AquaBounty itself has been trying to obtain market approval for the AquAdvantage salmon for over a decade. Many other companies also seeking to commercialize genetically engineering animals for food production await with anticipation the outcome of AquaBounty's application. The decision will set an important regulatory precedent and will have major implications for the future of the United States' biotechnology sector.

The genetically engineered animals currently sold in the United States are mostly laboratory animals used for medical research as well as the aquarium zebra fish sold under the trademark name GloFish. The GloFish went on sale in the United States on January 5, 2004 and is genetically engineered to glow in the dark,[81] but the FDA declined to exercise jurisdiction on the basis that "[b]ecause tropical aquarium fish are not used for food purposes, they pose no threat to the food supply."[82] Research in genetically

[80] Reichhardt *supra* note 47 at 12.
[81] Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation,* 6 MINN. J. L. SCI. & TECH. 457, 457 (2005).
[82] FDA Statement Regarding Glofish, U.S. Food & Drug Admin. (Dec. 9, 2003), *available at* http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngi

engineered animals is active in many different countries and is focused on efforts to improve the environmental footprints of husbandry animals, improve the production efficiency of animal-derived food and the quality of animal-derived food, and produce human pharmaceuticals using animals. The FDA expects many of these products to reach markets within the coming decade.[83] Among others, these include the University of Guelph's yet to be commercialized Enviropig, a pig engineered to digest phytic acid and thereby reduce both the need for phosphorus supplements in the animal's diet and the amount of unabsorbed phosphorus in the pig's manure, a common source of pig farming pollution.[84] New Zealand researchers are using rDNA technology to improve the cheese-making quality of milk by increasing the amount of casein protein found in milk produced by genetically engineered dairy cows.[85] The Roslin Institute in Scotland is developing genetically engineered chickens that produce pharmaceuticals in their eggs[86] as well as others that do not transmit bird flu to other chickens and thereby prevent the outbreak of bird flu within domestic poultry stocks.[87, 88]

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neeredAnimals/ucm161437.htm. For a detailed analysis of why the FDA chose not to regulate GloFish *see* Bratspies *supra* note 81.

[83] Genetically Engineered Animals, General Q&A , U.S. Food & Drug Admin. (1 Jul. 2009), *available at* http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm.

[84] University of Guelph, Enviropig, http://www.uoguelph.ca/enviropig/ (last visited May 10, 2011). Most cereal grains, including common pig feed ingredients corn and soybean, contain 50 to 75% of their phosphorus in the form of phytic acid, which cannot be digested by normal pigs.

[85] BBC News, *GM Cheese from Cow Clones*, BBC, Jan. 27, 2003, *available at* http://news.bbc.co.uk/2/hi/sci/tech/2696725.stm.

[86] Genetically Engineered Animals, General Q&A *supra* note 83.

[87] Roslin Institute, GM Chickens, http://www.roslin.ed.ac.uk/public-interest/gm-chickens/ (last visited May 10, 2011).

[88] For a more detailed list of specific applications of genetically engineered animals, *see* Genetically Engineered Animals, General Q&A *supra* note 83.

3.2 Regulation under the Federal Food, Drug and Cosmetic Act

3.2.1 General Requirements

Genetically engineered animals are regulated by the Center for Veterinary Medicine[89] under the Federal Food Drug and Cosmetic Act (FFDCA). The FDA clarified and asserted its jurisdiction over genetically engineered animals in its Guidance for Industry 187.[90] The FDA asserted jurisdiction over genetically engineered animals under the New Animal Drug provisions of the FFDCA on the grounds that the genetic modification of such animals affects their "structure and function" in a way that is analogous to how veterinary drugs affects them.[91] Under this interpretation, given that it modifies the traits of the genetically engineering animal, the FDA considers the rDNA construct, the genetic material that is inserted into the DNA of the original animal, to qualify as a "drug." The FDA extends its jurisdiction to the entire lineage of genetically engineered animals that contain the DNA modification, and includes animals that inherit the rDNA construct as a result of breeding genetically engineered animals with non-genetically engineered animals.[92] The FDA has chosen to regulate genetically engineered animals differently than genetically engineered plants on the basis that it believes that unlike plants, animals can much more easily transmit diseases to humans, a phenomenon

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[89] For detailed information on the Veterinary Medicine Advisory Committee *see* U.S. Food and Drug Administration, Veterinary Medicine Advisory Committee, http://www.fda.gov/AdvisoryCommittees/.CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/default.htm (last visited May 7, 2011).

[90] Guidance for Industry 187 – Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, U.S. Food & Drug Admin. 4 - 5 (2009), *available at* http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf (The FDA clarifies that the Guidance is meant to address only those genetically engineered animals that contain a heritable rDNA construct, and not those that contain non-heritable rDNA constructs, even though such constructs also meet the definition of new drugs. The FDA states its intent to develop a separate guidance for non-heritable DNA constructs.).

[91] 21 U.S.C. 321(g)(1)(C).

[92] Guidance 187 *supra* note 90 at 2, 6.

known scientifically as zoonotic disease transmission. Animals can also be the source of novel viral diseases that eventually affect humans. As a result, the FDA is concerned that genetic engineering of animals might enhance these risks of disease formation and transmission.[93]

Guidance 187 recommends that sponsors of genetically engineering animals provide seven core types of data to meet the information requirements of a NADA. This includes (1) the product definition, a broad characterization of the genetically engineered animal and associated claims about its properties; (2) the molecular characterization of the construct, a description of the rDNA construct and how it is assembled; (3) the molecular characterization of the genetically engineered animal lineage, a description of the rDNA construct genetic insertion method as well as an analysis of its stability over time; (4) phenotypic characterization of the genetically engineered animal, a comprehensive data set on the health and characteristics of the genetically engineered animal;[94] (5) durability plan, an explanation on how the sponsor plans to demonstrate that the genetic modification will remain stable between animal generations and continue to have the same effect; (6) environmental and food / feed safety, an assessment of any environmental impacts, and for any animals intended to be used as food for humans or other animals, an assessment of whether or not such genetically engineered animals will

[93] Genetically Engineered Animals, General Q&A *supra* note 83.
[94] To determine the potential adverse health affects of the rDNA construct on genetically engineered animals, the FDA recommends that sponsors provide veterinary and treatment records, and data on growth rates, reproductive function, and behavior. Physiological data recommendations include clinical chemistry, hematology, histopathology, and post-mortem results. Finally, sponsors are recommended to submit data indicated whether the rDNA construct or its expression products cause any direct or indirect toxicity to the animals. *See* Genetically Engineered Animals, General Q&A *supra* note 83.

be safe to eat; and (7) claim validation, a demonstration that the genetically engineered animal does actually fulfill the claims made by the sponsor.[95]

As most methods to introduce new rDNA constructs into the genetic material of an animal cannot control the exact site where the construct will be inserted, the FDA considers each animal lineage derived from separate insertions as meriting its own NADA.[96] The FDA's position is based on the fact that the location of an inserted rDNA construct can affect both the health of the animal and the level of expression of the construct.[97] Because genetically engineered animals used for commercial purposes are likely to be the descendants of the initial genetically engineered animals used for the approval, the FDA also requires that sponsors demonstrate that "the construct and / or phenotype are stability maintained in a representative sample of animals" involving multiple generations.[98]

The FDA clearly states that Guidance 187 represents the agency's "current thinking" on the topic and "does not create or confer any rights for or on any person and does not operate to bind the FDA or the public" and envisions the possibility of alternative approaches to assessing the risks and characteristics of a genetically modified animal.[99] Guidance 187 does not diminish the fact that because genetically engineered fish are akin to a new animal drug, statutes and regulation require them to have met any and all New Animal Drug Application (NADA) requirements prior to marketing. No new requirements are imposed, and the Guidance is meant to help sponsors provide the

[95] Guidance 187 *supra* note 90. *See also* Genetically Engineered Animals, General Q&A *supra* note 83.
[96] Guidance 187 *supra* note 90 at 5.
[97] *Id.*
[98] *Id.* at 6.
[99] *Id.* at 2.

necessary NADA information in order for the FDA to find that their product is safe and effective.[100]

Guidance 187 was developed in response to the lack of dedicated laws for the development of novel foods and drugs derived from genetically engineered animals, and the regulatory uncertainty this created for many biotechnology companies and investors.[101] When Guidance 187 was originally drafted, few of the public comments were critical of the agency's interpretation of its statutory authority or the recommendations for data submission.[102] However, many commentators were critical of the FDA's choice of the NADA process because, as most drug applications are confidential, there is limited opportunity for public comment and participation, and not all data is disclosed.[103] In addition, many believe that the NADA framework is inadequate and that a dedicated novel food application process is necessary,[104] with some people suggesting that it is like "jamming a square peg in a round hole."[105]

Given the novelty of genetically engineered animals for human consumption, the relative lack of regulatory experience, and the high level of public interest in the use of genetically modified animals, the FDA modified Guidance 187 to include an intent, but no formal commitment, to hold public advisory meetings prior to approving any

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[100] Genetically Engineered Animals, General Q&A *supra* note 83.
[101] Andrew Pollack, *Without U.S. Rules, Biotech Food Lacks Investors*, N.Y. TIMES, Jul. 30, 2007.
[102] Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon, U.S. Food & Drug Admin. (8 Aug. 2010), *available at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm.
[103] Andrew Pollack, *Without U.S. Rules*, *supra* note 101.
[104] Madison Smith, *Who Owns Your Dinner? A Discussion of America's Patented Genetically Engineered Food Sources, and Why Reform is Necessary*, 23 LOY. CONSUMER L. REV. 182, 195 (2010).
[105] David A. Taylor, *Genetically Engineered Salmon the FDA's Table,* 118 ENV. HEATH PERSPECTIVES 384, 384 (2010) (citing Greg Jaffe, biotechnology project director at the Center for Science in the Public Interest).

genetically engineered animal.[106] In the case of AquAdvantage salmon, the decision to hold a public hearing was the result of Aquabounty's agreement to do so. The FDA's Center for Veterinary Medicine also deemed it necessary to add additional Committee members on an *ad hoc* basis to provide missing expertise in "molecular biology and the production of genetically engineered animals," as well as "issues associated with Atlantic salmon, and salmonids in general."[107]

3.2.2 Health and Safety Issues Surrounding the AquAdvantage Salmon

In the summer of 2010, the FDA announced that after over a decade of attempting to obtain the authorization to market its AquAdvantage salmon, AquaBounty had now provided sufficient information to the agency for it to make a decision. In documents released for the public hearing held by the Veterinary Medicine Advisory Committee on September 19 – 20, 2010, the FDA stated that the AquAdvantage salmon did indeed grow faster and resulted in food that is "as safe as food from conventional Atlantic salmon."[108] Critics however pointed out that the study set a precedent with a low bar for other genetically engineered animals and focused on the fact that the data provided did not fully comply with NADA requirements.[109]

One concern was the fact that the engineered salmon had slightly higher levels of insulinlike growth factor 1 (IGF1). Studies suggest that high blood levels of this hormone may be associated with greater cancer risk, but the role of IGF1 content in food on these

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[106] Guidance 187 *supra* note 90 at 12.
[107] Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon *supra* note 102.
[108] Briefing Packet, U.S. Food & Drug Admin 62 (Sept. 20, 2010), *available at* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf.
[109] *Fox* supra note 41 at 1142.

levels remains unclear.[110] However, after a careful study, the FDA concluded that even if people consumed large volumes of AquAdvantage salmon, this would be unlikely to have an effect on their IGF1 levels.[111] There were however concerns surrounding the adequacy of the data used to conduct allergen studies, with several critics pointing out that the study was based on samples taken from only twelve fish in total.[112]

The FDA study concluded by requiring that AquaBounty develop a post-approval monitoring plan in line with what is suggested in Guidance 187. The FDA notably requested that a durability plan be set up and maintained to monitor the genetic make-up and characteristics of the genetically engineered fish, in part in response to concerns over malformations on the jaws of some fish and under-counting of deformed fish through normal culling procedures conducted during fish farming.[113]

There has been growing opposition from Congressional representatives to the approval of the AquAdvantage salmon and the FDA has yet to make a final decision on AquaBounty's NADA. The FDA has also clearly stated that it will not weigh in on the debate over ethical issues surrounding biotechnology. While it does consider the impact of new drugs, and thus rDNA constructs, on the health of animals, it does not consider its role to be to decide whether or not genetic engineering of animals for food should be allowed as a matter of policy.[114]

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[110] Pollack, *Modified Salmon is Safe*, *supra* note 67. *See also* Stokstad *supra* note 52 at 1799.
[111] Briefing Packet *supra* note 108 at 69 – 77.
[112] Smith *supra* note 104 at 204 – 205; Pollack, *Modified Salmon is Safe*, *supra* note 67.
[113] Briefing Packet *supra* note 108 at 48 – 61.
[114] Genetically Engineered Animals, General Q&A *supra* note 83.

3.2.3 Labeling Requirements

Section 514.1(b)(3) of Code of Federal Regulations requires that a NADA include three copies of each label that will be used for the new animal drug. However, this is different from labeling requirements for the actual food derived from the genetically engineered animal. The FDA has so far indicated its intent to apply the same labeling requirements to food derived from genetically engineered animals that it applies to food derived from non-genetically engineered animals and genetically engineered plants. Under its interpretation of §403(j) of the FFDCA, unless there is material information pertinent to the food derived from genetically engineered animals, there will be no specific labeling requirements.[115] In other words, if the food derived from a genetically engineered animal is no different than food derived from its non-genetically modified counterparty, the principle of equivalency prevails and no further labeling is required. If however food derived from a genetically engineered animal has different nutritional or other properties that may affect the structure and function of a consumer of such food, then labeling is required.[116]

Given the unprecedented nature of the first application to commercialize a genetically engineered animal for human consumption and the considerable public interest in the matter, the FDA chose to hold a public hearing on the labeling of genetically engineered foods the day after it held a public hearing on AquaBounty's NADA.[117] While the FDA decided to hold a public hearing "to educate the public about

[115] Guidance 187 *supra* 90 at 14.
[116] *Id.*
[117] The FDA noted that under the Notice and Comment period under Guidance 187, a substantial portion of comments focused on the issue of labeling. Comments ranged from strongly in favor of labeling to strongly

[its] food labeling principles and how they apply to foods derived from [genetically engineered] animals," it also sought comments on its current approach to the labeling of food derived from AquAdvantage salmon.[118] It specifically sought comments on whether there were "any material differences – including differences in the composition of the food or its nutritional, function or organoleptic properties – that justif[ied] naming or labeling food from [the AquAdvantage salmon] differently from food from its conventional counterparts."[119] This further suggests that the FDA intends to apply the same approach used for foods derived from genetically engineered plants, namely that the use of recombinant DNA techniques is not considered material information under §201(n) of the FFDCA. Similarly to its approach to genetically engineered plants, the FDA likely considers that the genetic manipulation of animal DNA is simply an extension of the natural selective crossbreeding processes that humans have used for many years.[120] It is however noteworthy to contrast how the FDA considers genetically engineered animals potentially more dangerous to humans than genetically engineered plants when justifying its jurisdiction and extension of NADA requirements to sponsors, but retains a stronger notion of equivalency when it comes to labeling foods once they have passed threshold requirements of safety for both human and animal consumption.

Perhaps demonstrating the limit of using the existing NADA framework for genetically engineering animals, the FDA seems to consider that until they reach

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against labeling. *See* Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage salmon *supra* note 102.

[118] Background Document: Public Hearing on the Labeling of Food Made from the AquAdvantage salmon, U.S. Food & Drug Admin. (Aug.8, 2010), *available* at http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm.

[119] *Id.*

[120] For a brief discussion suggesting that genetic engineering of fish is not unlike the selective breeding that has led to the creation of the Belgian Blue cattle breed, an "ugly but tasty cow" that has 40% more muscle than a normal cow due to a deficient myostatin gene that improperly regulates muscle growth, *see* Terry Bradley, *Dawn of the Frankenfish*, 395 THE ECONOMIST 4 – 6 (special section) (2010).

commercial growing facilities, genetically engineered salmon retain more drug-like characteristics than food-like characteristics, or at least are characterized as animals "treated" with drugs, where "drugs" are the rDNA construct that the growing stock contain. Indeed, regardless of whether or not it will decide to require labeling of the actual food derived from the AquAdvantage salmon, the FDA has stated that any approval will require a label that identifies the different types of rDNA constructs that accompany any eggs and young fish transiting from breeders to growers.[121] However, once the fish are commercialized in supermarkets, the FDA's proposed approach will consider the genetically engineered fish to have become purely "food." While perhaps the use of the NADA framework is merely a continuation of the FDA's precautionary approach to ensuring the safety of the food supply in the United States and a testament to the agency's ingenuity in using existing law in the face of rapidly evolving technology, it also suggests that a dedicated novel food regulatory approach for genetically engineered animals may be warranted.

3.3 Environmental Regulation

Applications for approval of genetically engineered animals are subject to environmental review under the National Environmental Policy Act (NEPA), through regulations implemented by the Council on Environmental Quality[122] and the FDA.[123] Under the extraordinary circumstances that would justify at least an environmental assessment for an action that would usually be categorically excluded from scrutiny, the FDA may consider the "harm to the environment to include not only toxicity to

[121] Smith *supra* note 104 at 195.
[122] 40 C.F.R. §§ 1500 - 1508.
[123] 21 C.F.R. §25.

environmental organisms but also environmental effects other than toxicity, such as lasting effects on ecological community dynamics."[124] Under Guidance 187, when the FDA exercises its enforcement discretion over a new genetically engineered animal, no additional NEPA action is required on the basis that the FDA includes NEPA requirements in its own review.[125] In its approval process, at a basic level, the FDA considers (1) whether the genetically engineered animal poses any threats to humans, animals or the environment; (2) whether, in the event of a release, the genetically engineered animal poses any more environmental threat than the non-genetically engineered equivalent; (3) whether the disposal of genetically engineered animals poses any threats to humans, animals or the environment; and (4) whether any other safety issues remain unaddressed by the sponsor.[126] At minima, a sponsor must prepare an environmental assessment (EA) to demonstrate whether or not the genetically engineered animal will have no significant impact on the environment. No further action on behalf of the sponsor is required in case of a finding of no significant impact (FONSI).[127] Critics of Guidance 187 claim that using the NADA approach does not fully account for environmental consequences of genetically engineered animals.[128] Questioning whether NADA is indeed the right approach may be particularly poignant given the fact that wild Atlantic salmon is currently listed as an endangered species.[129]

There are major concerns about the potential escape of AquaAdvantage salmon into the wild. To mitigate this risk, AquaBounty proposes that the commercially raised

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[124] Guidance for Industry - Environmental Assessment of Human Drug and Biologics Applications, U.S. Food & Drug Admin. 6 (1998), *available at* http://www.fda.gov/downloads/Drugs/Guidance ComplianceRegulatoryInformation/Guidances/ucm070561.pdf.
[125] Guidance 187 *supra* note 90 at 7.
[126] *Id.* at 8.
[127] *Id.* at 18.
[128] Andrew Pollack, *Genetically Altered Salmon Get Closer to the Table*, N.Y. TIMES, Jun. 25, 2010.
[129] Species Profile, Atlantic Salmon *supra* note 18.

salmon will be entirely female and infertile, and grown in physically contained production systems. This is actually a reversal from AquaBounty's original proposal to consider growing fish in ocean cage settings, where the potential escape into the wild is much higher.[130] Although not acknowledged publicly, it is perhaps because AquaBounty is unable to guarantee with absolute certainty that all the eggs it will produce at its Prince Edward Island facilities will be infertile that it chose to propose to grow the fish to commercial harvesting size only at its Panama inland facility. The FDA agrees with this approach, stating that it believes that the chance of ecological disruption or escape is small.[131]

AquaBounty's application and pending approval by the FDA were later mired in controversy surrounding the fact that the agency had supposedly not sufficiently consulted with the Fish and Wild Services and other expert agencies, and that a full Environmental Impact Statement was required to assess the potential impact of the AquAdvantage salmon on the endangered Atlantic salmon. In particular, there was concern that genetically engineered salmon might escape the Prince Edward Island breeding facility and could potentially make their way to the Atlantic ocean from there.[132] Critics accused the FDA of "applaud[ing] the company's choice of land-based containment as responsible [while] it never revealed that it is illegal in the U.S. to grow genetically engineered salmon in open-water net pens."[133] Under §7 of the Endangered Species Act, federal agencies are required to consult with expert agencies when an action

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[130] Stokstad *supra* note 52 at 1799.
[131] Briefing Pack *supra* note 108 at 118 – 119.
[132] *See* Nathan White, *House Letter Urges FDA to Protect Consumers and the Environment from Potential Dangers of GE Salmon*, Fed. Info. & News Dispatch, Inc. (Sept. 28, 2010).
[133] James Wright, *U.S. Group: FDA Ignored GM Salmon Warnings*, SeafoodSource.com, 28 Oct. 2010, *available at* http://www.seafoodsource.com/newsarticledetail.aspx?id=4294999857 (quoting Andrew Kimbrell, Executive Director at the Center for Food Safety).

may impact a protected species and expert agencies are required to draft a Biological Opinion on how to protect the endangered species in question in relation to the proposed action. While the FDA claimed that preliminary discussions were held with both the Fish and Wildlife Services and the National Marine Fish Services, no follow-up discussion took place. It was also alleged that as of October 2010, AquaBounty was still considering rearing fish in Atlantic waters and had approached the Fish and Wildlife Services in regards to this.[134] By contrast, in 2001, in regards to pending ocean-based fish farm permit applications, the Fish and Wildlife Services, and the National Marine Fisheries Services, issued a Biological Opinion to the Environmental Protection Agency expressing their concern that transgenic salmon would adversely affect wild Atlantic salmon. In their Opinion, both agencies banned the use of reproductively viable transgenic salmon on all ocean-based fish farms.[135] The FDA was later accused of failing to disclose the existence of this Biological Opinion at the public hearings it held in September 2010 in regards to the AquaBounty NADA.[136] In the FDA's defense, it clearly stated that the current NADA, if approved, would only be valid for exclusive rearing of the commercial fish in AquaBounty's Panama facility. Raising the fish anywhere else would require another application to the FDA, including any application by a third party to purchase fertilized eggs from the Prince Edward Island facility for growing and commercialization at any other location.[137] On the other hand, AquaBounty's official position remains unclear, and

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[134] Press Release, Troubling Emails Reveal Federal Scientists Fear FDA Approval of Genetically Engineered Salmon: "Maybe They [the FDA] Should Watch Jurassic Park.", Food and Water Watch (Nov. 15, 2010), *available at* http://www.foodandwaterwatch.org/ pressreleases/troubling-emails-reveal-federal-scientists-fear-fda-approval-of-genetically-engineered-salmon/.
[135] Biological Opinion from Fish and Wildlife Service and National Marine Fisheries Service to the Environmental Protection Agency 8 (Jan. 12, 2001), *available at* http://stopgefish.files.wordpress.com/2010/10/epa-bo.pdf
[136] Troubling Emails *supra* note 134.
[137] General Q&A *supra* note 83.

its website still suggests that the AquAvantage salmon is entirely infertile and poses no threat of interbreeding with native populations when they escape, despite its Environmental Assessment that states the contrary.[138, 139]

4 Conclusion

It is clear from the ongoing debate and regulatory approval of the AquAdvantage salmon that the choice to adopt the NADA framework to analyze the potential risks of genetically engineered animals remains questioned by several parties. Legislation is struggling to keep up with the rapid pace of innovation in the sector. Given the lack of comprehensive and dedicated legislation on the use of genetically engineered animals for food production, the FDA has been forced to use existing regulatory frameworks to the best of its capabilities. Above all, the core criticism that can be laid on the use of the NADA framework is its poor suitability to assess the idiosyncratic risks that AquAdvantage salmon pose to the already endangered Atlantic salmon. Perhaps an application by a genetically engineered animal less likely to stir environmental concerns, such as the Enviropig, may have provided for a more ordinate testing of the NADA framework. Despite some reservations about the quality of the data submitted in AquaBounty's application, the NADA at least has the merit of focusing most of its analysis on the potential human health effects of genetically engineered animals used as food. It is perhaps still too early to tell whether or not genetically engineered animals merit an entirely different approach to risk assessment given the still relative infancy of the science and its applications, but the AquAdvantage salmon case suggests that so far,

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[138] AquaBounty Technologies, AquAdvantage® Fish, http://aquabounty.com/products/ aquadvantage-295.aspx (last visited May 10, 2011).
[139] ENVIRONMENTAL ASSESSMENT *supra* note 77 at 60.

the FDA has failed to convince both the industry and the public that is has finally found the right approach to regulating genetically engineered animals used for food.

Conversely, in the midst of scientific uncertainty, it is not surprising that exactly how consumers feel about genetically engineered animals remains unclear. Even though genetically engineered plants are now found in huge numbers in the United States food supply, debate about their merits and potential risks continues. In addition, perhaps echoing the FDA's concern about more similarities between humans and animals in comparison to plants, and thus potentially higher risks of disease transmittal, consumers seem more wary about genetically engineered animals.[140] On the other hand, other polls suggest that consumers may be more willing to accept genetically engineered animals that provide environmental and nutritional benefits.[141] It is therefore not surprising that AquaBounty's application has become the focal point of debate over genetically engineered animals used for food production, and genetic engineering of animals in general.

Both the House of Representatives and the Senate have advanced bipartisan regulatory proposals to prohibit the approval of genetically engineered fish for food production by deeming them unsafe under the current FFDCA,[142] as well as a bill to separately require labeling of such foods should the FDA approve them.[143] Recently re-

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[140] Pollack, *Closer to the Table*, *supra* note 128.
[141] *Id.*
[142] Amendment to the Federal Food, Drug, and Cosmetic Act to prevent the approval of genetically-engineered fish, H.R. 6265, 111th Cong. (2010); Amendment to the Federal Food, Drug, and Cosmetic Act to prevent the approval of genetically-engineered fish, S. 3971, 111th Cong. (2010).
[143] Amendment to the Federal Food, Drug, and Cosmetic Act to require labeling of genetically-engineered fish, H.R. 6264, 111th Cong. (2010); Amendment to the Federal Food, Drug, and Cosmetic Act to require labeling of genetically-engineered fish, S. 3969, 111th Cong. (2010).

introduced in the 112th Congress,[144] the bills were originally proposed following a letter by 30 House members and 13 senators to the Obama administration questioning the FDA's review of the AquaBounty application and even asking the administration to ban the commercialization of the genetically engineered salmon.[145] No decision on the AquAdvantage application has yet to be announced, and neither AquaBounty nor the FDA have provided any further information since the September 2010 public hearings. AquaBounty has only stated its intent to continue working with the FDA and address any issues raised should the agency reject its NADA.[146] A rejection of AquaBounty's application will continue to put into question the FDA's use of the NADA framework and may push the biotechnology industry to request Congress to enact comprehensive legislation dedicated to genetically engineered animals. But on the other hand, an approval by the FDA is unlikely to silence critics of the use of the NADA framework, as well as unlikely to silence genetic engineering opponents in general. The legislative proposals put forth so far are merely stopgap measures focused on the AquaAdvantage salmon. No comprehensive legislation, with the potential to more firmly settle the issue favorably or unfavorably, has been proposed. For both consumers and the biotechnology industry, the outlook over the future of genetically engineered animals raised for food production continues to remain fraught with uncertainty.

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[144] H.R. 521, 112th Cong. (2011); S. 230, 112th Cong. (2011). H.R. 520, 112th Cong. (2011); S. 229, 112th Cong. (2011).

[145] Statement by Wenonah Hauter, Senator Introduces Common-sense Federal Bills to Address Controversial Genetically Engineered Salmon, Food & Water Watch (Nov. 18, 2010), *available at* http://www.foodandwaterwatch.org/pressreleases/senator-introduces-common-sense-federal-bills-to-address-controversial-genetically-engineered-salmon/

[146] Stuart Hirsch, *Super Salmon? AquAdvantage has Become a Lightning Road for Transgenic Critics*, SEAFOOD BUS. MAG., Dec. 1, 2010, *available at* http://www.seafoodbusiness.com/articledetail.aspx?id=4295000307.