ESSAYS

A "FISHEYE" LENS ON THE TECHNOLOGICAL DILEMMA: THE SPECTER OF GENETICALLY ENGINEERED ANIMALS

By
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One year ago, the United States Food and Drug Administration (FDA) proposed approval of the first genetically engineered (GE or transgenic) animal for food production—a salmon engineered to grow much faster than normal using genetic material from an ocean pout. Faced with concerns from scientists and the public that these "super" salmon will escape into the wild and be the final blow to wild salmon, proponents crafted a scheme that is half Michael Crichton, half Kurt Vonnegut: The engineered salmon eggs will begin life in a lab on a frozen Canadian island, then be airlifted to a guarded Panamanian fortress, where they will grow in inland tanks. After the fish reach maturity, the company will ship them back to the U.S. and sell them in grocery stores, likely without any labeling.

Unfortunately, this is not a bad science fiction novel. How did we get to this juncture, the brink of this approval? This Essay is a snapshot of GE animals through the lens of the first one proposed for commercial approval. Part I discusses AquaBounty's "AquAdvantage" GE salmon, with a focus on the environmental risks it poses. Part II looks behind the camera, explaining the philosophy that has fostered the emergence of engineered animals for industrial food production. Part III provides an overview of genetic engi-

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neering and transgenic animals. Part IV summarizes health, environmental, and animal welfare concerns. Part V explains what the lessons of agricultural biotechnology portend for animal biotechnology. Part VI discusses FDA's problematic regulatory pathway. This Essay concludes by returning to underlying principles.

I. ENGINEERING THE SALMON

As we write this, the United States Food and Drug Administration (FDA) is poised to approve the first-ever genetically engineered (GE or transgenic) animal for food production.[1] Of all species, it will most likely be a salmon, perhaps the most heroic of all creatures, which humankind has venerated since time immemorial. Here in the Pacific Northwest, salmon were the centerpiece of cultural and spiritual life for thousands of years; the region itself is defined as "wherever the salmon can get to."[2] Salmon are rightly revered for their integral roles in our ecosystems, as their sacrificial anadromous journey provides vast amounts of marine nutrients to freshwater species, including aquatic invertebrates, other fish, marine mammals, birds, and terrestrial mammals. Studies have found that trees like the Sitka spruce alongside salmon rivers grow more than three times faster than their counterparts along rivers without salmon.[3] Families up and down the West Coast still depend on healthy wild fish stocks for their livelihoods.[4] Pacific salmon fisheries, particularly in Alaska, represent some of the best remaining wild fisheries on earth.[5]

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[1] 75 Fed. Reg. 52,605, 5,2605–06 (Aug. 26, 2010).

[2] Timothy Egan, *The Good Rain: Across Time and Terrain in the Pacific Northwest* 22 (Vintage Bks. 1990).

[3] James M. Helfield & Robert J. Naiman, *Effects of Salmon-Derived Nitrogen on Riparian Forest Growth and Implications for Stream Productivity*, 82 Ecology 2403, 2406 (2001).

[4] *See* Pacific Fishery Mgt. Council, *Review of 2010 Ocean Salmon Fisheries* 85 (2011) (available at http://www.pcouncil.org/wp-content/uploads/Review_10_Final.pdf (accessed Nov. 19, 2011)) (noting that the total West Coast income impacts associated with ocean salmon fisheries for California, Oregon, and Washington were $25.4 million in 2010).

[5] *See generally* Marine Conserv. Alliance, *Sea Facts: The Seafood Industry in Alaska's Economy* (Feb. 2011) (available at http://www.marineconservationalliance.org/

Yet the incalculable worth of the species cannot be measured solely in scientific or monetary terms. Researchers still do not fully understand how salmon, after spending their adult lives traversing thousands of ocean miles, find their way home to their birth streams to complete their lifecycle.[6] A healthy salmon run is one of Nature's most awe-inspiring visions—a river teeming and leaping with life, each the Platonic ideal of fish incarnate, the embodiment of resolve. It is with good reason that the salmon is perched upon the top of many Totems.

Unfortunately, the last century's industrialization caused a precipitous decline in salmon populations, and the recent history of salmon is a story of empty promises, in which our culture has repeatedly placed other priorities above salmon survival.[7] Instead, a global industry of salmon aquaculture has risen to dominance in the last few decades, in which producers farm fish in crowded net pens on the open ocean.[8]

Like most technological fixes, industrial salmon aquaculture has created its own new adverse impacts,[9] including: release of untreated wastes and nutrients;[10] increased risk of disease and parasite transmission (such as sea lice) from farmed fish to wild fish;[11] impacts from

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wp-content/uploads/2011/02/SIAE_Feb2011a.pdf (accessed Nov. 19, 2011)) (detailing the dominance of Alaska's salmon fisheries among U.S. states and their significance in the global market); *see also* Press Release, Marine Stewardship Council, *Marine Stewardship Council Awards Sustainability Label to Alaska Salmon* (Sept. 3, 2000) (announcing Alaska salmon as the first U.S. fishery to be certified as sustainable) (available at http://www.msc.org/newsroom/news/marine-stewardship-council-awards-sustainability (accessed Nov. 19, 2011)).

[6] Matthew L. Keefer et al., *Route Selection in a Large River During the Homing Migration of Chinook Salmon (Oncorhynchus tsawytscha)*, 63 Can. J. Fisheries & Aquatic Sci. 1752, 1752–53 (2006); *see also* Richard Alleyne, The London Telegraph, *Salmon Use Magnetic Fields to Get Home to Spawn* (available at http://www.telegraph.co.uk/science/science-news/3539029/Salmon-use-magnetic-fields-to-migrate.html (Dec. 1, 2008) (accessed Nov. 19, 2011)); Marcia Barinaga, *Salmon Follow Watery Odors Home*, 286 Sci. 705, 706 (1999).

[7] *See generally* Michael C. Blumm, *Sacrificing the Salmon: A Legal and Policy History of the Decline of Columbia Basin Salmon* (BookWorld Publications & Michael C. Blumm 2002).

[8] David Boulet et al., Fisheries & Oceans Canada, *A Feasibility Study of Closed-Containment Options for the British Columbia Aquaculture Industry* 3 (Sept. 2010) (available at http://www.dfo-mpo.gc.ca/aquaculture/lib-bib/nasapi-inpasa/BC-aquaculture-CB-eng.pdf (accessed Nov. 19, 2011)).

[9] *See e.g.* Rosamond L. Naylor et al., *Nature's Subsidies to Shrimp and Salmon Farming*, 282 Sci. 883, 884 (1998) (noting that salmon farming results in discharges of nutrients, antibiotics, and pesticides into coastal waters) [hereinafter Naylor et al., *Nature's Subsidies*]; *see also* Rosamond L Naylor et al., *Effect of Aquaculture on World Fish Supplies*, 405 Nat. 1017, 1020 (2000) [hereinafter Naylor et. al., *Effect of Aquaculture*].

[10] Sena S. De Silva, *Feed Resources, Usage and Sustainability*, in *Sustainable Aquaculture: Food for the Future?* 221, 236 (Niels Svennevig et al. eds., A.A. Balkema 1999); Naylor et al., *Nature's Subsidies, supra* n. 9, at 884.

[11] Cornelia Dean, *Lice in Fish Farms Endanger Wild Salmon, Study Says*, N.Y. Times A10 (Dec. 14, 2007); Alexandra Morton et al., *Temporal Patterns of Sea Louse Infestation on Wild Pacific Salmon in Relation to the Fallowing of Atlantic Salmon Farms*, 25 N. Am. J. Fishery Mgt. 811, 819 (2005); C.D. Todd et al., *Genetic Differentia-*

the use of drugs and chemicals, such as antibiotics, pesticides, fungicides, anti-foulants, and hormones;[12] overfishing of smaller fish for salmon feed;[13] and, finally, impacts from escaped fish on wild fish and associated ecosystems.[14] Farmed salmon regularly escape from net pens, negatively impacting wild salmon stocks by increasing competition for food and breeding sites, and by reducing the fitness of wild fish through interbreeding.[15] Farmed salmon are also much less nutritious than wild salmon, containing 52% more fat and much higher levels of contaminants.[16]

Now, a Massachusetts-based company called AquaBounty Technologies (AquaBounty)[17] has developed "AquAdvantage" salmon, which is genetically engineered to produce an insulin-like growth factor hormone (IGF-1) year-round, thus reaching full size in significantly

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tion of Populations of the Copepod Sea Louse Lepeophtheirus salmonis (Króyer) Ectoparasitic on Wild and Farmed Salmonids around the Coasts of Scotland: Evidence from RAPD Markers, 210 J. Experimental Marine Biology & Ecology 251, 267–70 (1997).

12 CFS, *The Catch with Seafood*: *Human Health Impacts of Drugs & Chemicals Used by the Aquaculture Industry* (June 7, 2005) (available at http://www.centerforfoodsafety.org/pubs/Aquaculture%20report%20FINAL%206.7.2005.PDF (accessed Nov. 19, 2011)).

13 Carnivorous species such as salmon require fishmeal from wild caught fish such as mackerel, herring, menhaden, and anchovies; scientists estimate that producing a pound of farmed salmon requires more than twice the amount of wild caught fish. Pew Oceans Commn., *America's Living Oceans: Charting a Course for Sea Change* 73, 77 (May 2003) (available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Protecting_ocean_life/env_pew_oceans_final_report.pdf (accessed Nov. 19, 2011)). Aquaculture already consumes 40% of the world's fishmeal, up from 10% two decades ago, and is set to outstrip the world's fishmeal supply by 2050. Brian Halweil, *Farming Fish for the Future* 20 (Lisa Mastny ed., Worldwatch Inst. 2008).

14 Christopher A. Myrick, *Ecological Impacts of Escaped Organisms*, in *Aquaculture and the Environment in the United States* 225, 234 (J.R. Tomasso ed., U.S. Aquaculture Socy. 2002) (describing six potential negative impacts of escaped farmed organisms: genetic impacts, disease impacts, competition, predation, habitat alteration, and colonization).

15 *See* John P. Volpe et al., *Evidence of Natural Reproduction of Aquaculture-Escaped Atlantic Salmon in a Coastal British Columbia River*, 14 Conserv. Biology 899, 901–02 (2000) (noting that escaped Atlantic salmon can range significant distances from their escape sites in the Pacific and suggesting that Atlantic salmon may constitute an invasive species); *see also* Eric M. Hallerman & Anne R. Kapuscinski, *Ecological Implications of Using Transgenic Fishes in Aquaculture*, 194 ICES Marine Sci. Symp. 56, 60 (1992) (noting that even in the absence of reproduction, escaped farmed trout impact native stocks through increased competition for resources); Kjetil Hindar et al., *Genetic and Ecological Effects of Salmon Farming on Wild Salmon: Modeling from Experimental Results*, 63 ICES J. of Marine Sci. 1234, 1244 (Elsevier Ltd. 2006) (noting that interbreeding with farmed salmon tends to reduce the fitness of wild salmon populations in western Europe). On average, 15% of farmed fish escape. Hallerman & Kapuscinski, *supra* n. 15, at 59.

16 Press Release, Envtl. Working Group, *First-Ever U.S. Tests of Farmed Salmon Show High Levels of Cancer-Causing PCBs* (July 30, 2003) (available at http://www.ewg.org/release/first-ever-us-tests-farmed-salmon-show-high-levels-cancer-causing-pcbs (accessed Nov. 19, 2011)).

17 AquaBounty Techs., *Company and History*, http://www.aquabounty.com/company/company-history-292.aspx (2011) (accessed Nov. 19, 2011).

less time than conventional farmed salmon.[18] The engineered genetic construct combines a growth hormone protein from the unrelated Pacific Chinook salmon (*Oncorhynchus tshawytscha*) with regulatory sequences from an antifreeze protein gene derived from an ocean pout (*Macrozoarces americanus*, also known as an eelpout), which AquaBounty inserts into the genome of Atlantic salmon.[19] The ocean pout promoter acts like a switch, keeping the growth hormone protein from turning off, which allows for continued growth of the fish. The purpose of the GE fish is to significantly decrease the time from birth to market and "improv[e] the economics of land-based production."[20]

In its proposal for FDA approval, AquaBounty stated its initial plan to produce the eggs at Prince Edward Island, Canada, transport the eggs to inland facilities in Panama, raise the AquAdvantage salmon to market size, and then harvest and ship the fish back to U.S. markets.[21] According to AquaBounty, the risk of escape is "extremely small" due to "redundant containment measures," the choice of two production sites that are "inhospitable" to salmon survival, and "biological containment" through the production of primarily all-female triploid fish.[22]

Despite claims that genetically engineering fish will be fiscally successful, the commercial viability of AquaBounty's plan is questionable. Currently, all production-scale salmon aquaculture is done in open-ocean net pen facilities.[23] More likely, this initial approval would simply crack open the regulatory door, after which AquaBounty could more easily employ broader commercialization plans.[24] Along these

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[18] *See* Veterinary Med. Advisory Comm., *Briefing Packet: AquaAdvantage Salmon* 110, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224762.pdf (Sept. 20, 2010) (accessed Nov. 19, 2011) [hereinafter VMAC Briefing Packet] (describing AquAdvantage salmon as possessing a "rapid growth phenotype"); *see also* AquaBounty Techs., *Environmental Assessment for AquAdvantage Salmon* 13, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM224760.pdf (Aug. 25, 2010) (accessed Nov. 19, 2011) [hereinafter AquaBounty, *EA for AquAdvantage*] (noting that AquAdvantage salmon have an "enhanced growth rate compared to non-transgenic Atlantic salmon").

[19] AquaBounty, *EA for AquAdvantage*, *supra* n. 18, at 12.

[20] *Id.*

[21] *Id.* at 15.

[22] *Id.* at 10; *but see* VMAC Briefing Packet, *supra* n. 18, at 115 (noting that the company's claims of sterility are "potentially misleading" because "sterility has not been explicitly verified in these fish and up to 5% of the eggs sold for grow-out may be non-triploid and still within release specifications"); Ltr. from Conserv. Genetics Community of Practice, Fish & Wildlife Serv., to FDA, *Concerns Re: VMAC Briefing Packet* 1 (Oct. 6, 2010) (copy on file with *Animal Law*) [hereinafter FWS Ltr. to FDA] (concluding that the FDA assessment "falls short of providing an actual risk assessment of putative environmental damages in the event of escapement").

[23] Boulet et al., *supra* n. 8, at 3.

[24] *See* FDA, *Veterinary Med. Advisory Comm. Meeting AquAdvantage Salmon Transcr.* 113:1–23, http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/UCM230471.pdf (Sept. 20, 2010) (accessed Nov. 19, 2011) [hereinafter VMAC Meeting Transcr.] (referring to the

lines, the company has simultaneously announced plans to expand its operations in the U.S. and around the world.[25] Notwithstanding these announcements from AquaBounty, FDA has limited the scope of its risk assessment to only the initial production sites.[26]

The environmental risks of transgenic salmon are both very real and potentially disastrous.[27] In 2002, the National Academy of Sciences issued a seminal report in which it concluded that GE fish could cause significant environmental and food safety problems.[28] More recently, a study commissioned by the European Union revealed that GE fish may have a higher tolerance for environmental stressors, enabling them to survive in ecosystems in which they were previously unable to colonize.[29] Scientists with the U.S. Fish and Wildlife Service (FWS) (which, unlike FDA, has expertise in fish biology and ecology)[30] found FDA's risk assessment "overly simplistic," failing to "adequately capture the actual risk of environmental damages" to wild salmon in the event of escape.[31] FWS warned "history dictates that fish held in aquaculture facilities, either land- or water-based, escape."[32]

When GE salmon do escape, studies have shown that they may out-compete wild salmon for resources, especially when food is scarce.[33] Additionally, transgenic salmon's over-production of IGF-1

Panama site as "an initial production facility" and explaining that the AquAdvantage salmon is "not only an economic development opportunity for a lot of countries, including the United States, but that this fish can now be grown closer to those population centers . . . .").

[25] *Id.* at 114:19–21 ("The kinds of facilities that we are thinking will be constructed in the United States and other locations are perhaps on the order of 2,000 tons . . . .").

[26] *Id.* at 125–26:15–25 (FDA's Dr. Larisa Rudenco directing committee not to consider AquaBounty's future business plans).

[27] *See generally* I. G. Cowx et al., European Food Safety Auth., *Defining Environmental Risk Assessment Criteria for Genetically Modified Fishes to Be Placed on the EU Market*, http://www.efsa.europa.eu/en/supporting/doc/69e.pdf (2010) (accessed Nov. 19, 2011).

[28] Natl. Research Council (NRC), *Animal Biotechnology: Science-Based Concerns* 61–92 (Natl. Acads. Press 2002).

[29] Cowx et al., *supra* n. 27, at 27.

[30] *See generally* FDA, *About FDA: What We Do*, http://www.fda.gov/aboutfda/whatwedo/default.htm (last updated Nov. 18, 2010) (accessed Nov. 19, 2011); FWS, *About the U.S. Fish and Wildlife Service*, http://www.fws.gov/help/about_us.html (last updated Apr. 20, 2010) (accessed Nov. 19, 2011).

[31] FWS Ltr. to FDA, *supra* n. 22, at 2.

[32] *Id.*

[33] *See e.g.* Robert H. Devlin et al., *Population Effects of Growth Hormone Transgenic Coho Salmon Depend on Food Availability and Genotype by Environment Interactions*, 101 P. Natl. Acad. Sci. 9303, 9305 (2004) (discussing experimental results showing that transgenic fish achieved a higher weight than their non-transgenic cohorts); Ming Duan et al., *Behavioral Alterations in GH Transgenic Common Carp May Explain Enhanced Competitive Feeding Ability*, 317 Aquaculture 175, 180 (2011) [hereinafter Duan et al., *Behavioral Alternations*] (discussing experimental results which indicate that increased competitive feeding ability among transgenic carp is correlated with their dominance in aggressive interactions); Ming Duan et al., *Elevated Ability to Compete for Limited Food Resources by 'All Fish' Growth Hormone Transgenic Common Carp Cyprinus carpio*, 75 J. Fish Biology 1459, 1460 (2009) (concluding that the increase in growth rate observed

leads to behavioral changes, such as increased aggressiveness[34] and altered breeding and migration patterns.[35] These traits ultimately make GE salmon less viable in the wild, although not necessarily less successful at breeding.[36]

Worse, these changes together may create what biologists have dubbed the "Trojan gene" effect, reminiscent of Homer's Trojan Horse:[37] the introduction of transgenic fish with enhanced mating success but reduced adult viability into a wild population may result in a rapid decline of the wild population.[38] The mating advantage of the larger GE fish spreads the Trojan gene throughout the wild population, until each successive generation suffers from reduced viability rates, eating away at the size of the salmon population as a whole.[39] It is survival of the "unfittest": larger, engineered salmon are more attractive to mates during reproduction, but because of unexpected physiological havoc caused by the new genes, their offspring die more often. One study concluded that the release of only sixty of these genetically engineered salmon into the environment could result in the extinction of 60,000 native salmon in less than forty salmon generations.[40]

Once engineered organisms escape or are released into the environment, it is impossible to recall or eliminate them. Unlike chemical pollution, transgenic contamination is a living pollution that can propagate itself over space and time via gene flow. As one federal court

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after growth hormone treatment comes from elevated food intake and foraging ability, leading to higher competitive ability in salmon populations); L. Fredrik Sundström et al., *Migration Growth Potential of Coho Salmon Smolts: Implications for Ecological Impacts from Growth-Enhanced Fish*, 20 Ecological Applications 1372, 1381 (2010) (discussing experimental results in which hatchery-reared transgenic fish utilized a greater proportion of stream resources than hatchery-reared wild-type fish).

[34] *See e.g.* Duan et al., *Behavioral Alterations*, *supra* n. 33, at 179 (noting that growth hormone injections increase aggressive behavior in rainbow trout).

[35] *See e.g.* Darek T. R. Moreau et al., *Reproductive Performance of Alternative Male Phenotypes of Growth Hormone Transgenic Atlantic Salmon (Salmo salar)*, 4 Evolutionary Applications 1, 6–7 (2011) (discussing the breeding performance of GH transgenic Atlantic Salmon males); *see also* Sundström et al., *supra* n. 33, at 1377–78 (comparing the migration of transgenic salmon and non-transgenic salmon).

[36] L. Sundt-Hansen et al., *Genetically Enhanced Growth Causes Increased Mortality in Hypoxic Conditions*, 3 Biology Ltrs. 165, 166–67 (2007).

[37] *See generally* Virgil, *The Aeneid of Virgil (The Aeneid)* (Joseph Trapp trans., London 1718); *see also* Moreau et al., *supra* n. 35, at 1 (describing how the Trojan gene may lead to the eventual extinction of salmon populations).

[38] Moreau et al., *supra* n. 35, at 1; *see also* William Martin Muir & Richard Duncan Howard, *Characterization of Environmental Risk of Genetically Engineered (GE) Organisms and Their Potential to Control Exotic Invasive Species*, 66 Aquatic Sci. 414, 416 (2004) (noting that the low viability of transgenic offspring will cause wild populations to decline).

[39] Pew Initiative on Food & Biotechnology, *Future Fish: Issues in Science and Regulation of Transgenic Fish* 22, http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_011403.pdf (2003) (accessed Nov. 19, 2011).

[40] William Muir & Richard D. Howard, *Possible Ecological Risks of Transgenic Organism Release When Transgenes Affect Mating Success: Sexual Selection and the Trojan Gene Hypothesis*, 96 P. Natl. Acad. Sci. 13853, 13854–55 (1999).

found in the context of transgenic plants, "[o]nce the gene transmission occurs and a farmer's seed crop is contaminated with the [engineered] gene, there is no way for the farmer to remove the gene from the crop or control its further spread."[41] The altered salmon, once in rivers or the ocean, will reproduce, mutate, and disseminate. Their polluting power will continue, and may even increase, over time.

This type of contamination is cropping up more and more with GE plants. In the summer of 2010, two scientists from the University of Arkansas sampled feral canola plants growing along the roadside in North Dakota. They found that 80% of the plants they tested turned out to be genetically engineered, illustrating widespread gene flow from cultivated GE canola fields and the establishment of these GE plants in the wild.[42] Similarly, in November of 2010, farmers in Oregon discovered that wild populations of an experimental engineered grass, developed by Scotts Company and Monsanto, had escaped an old test site, thriving in the wild undiscovered for many years.[43] Public interest organizations challenged the legality of the field trials, arguing that the U.S. Department of Agriculture (USDA) had failed to comply with the National Environmental Policy Act (NEPA) in approving them.[44] During that litigation, Environmental Protection Agency (EPA) scientists found that the GE grass had escaped the trial, cross-pollinated with wild varieties, and contaminated a protected national grassland over twelve miles away.[45] USDA fined Scotts $500,000[46] in 2007 and presumed the issue resolved, until the discovery over five years later of new populations again growing in the wild.[47] USDA did not announce this news; instead, it came to light during the cross-ex-

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[41] *Geertson Seed Farms v. Johanns*, 2007 WL 518624, *5 (N.D. Cal. 2007).

[42] Meredith Schafer et al., Presentation of Results, *Evidence for the Establishment and Persistence of Genetically Modified Canola Populations in the U.S.* (Pitt., Pa. Aug. 6, 2010) (summary available at http://eco.confex.com/eco/2010/techprogram/P27199.HTM) (accessed Nov. 19, 2011)); Meredith Schafer et al., *Evidence for the Establishment and Persistence of Genetically Modified Canola Populations in the U.S.*, 6 Pub. Lib. Sci. ONE 1, 2 (Oct. 5, 2011) (available at http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0025736) (accessed Nov. 19, 2011); Andrew Pollack, N.Y. Times, *Canola, Pushed by Genetics, Moves into Uncharted Territories*, (available at http://www.nytimes.com/2010/08/10/science/10canola.html (Aug. 9, 2010) (accessed Nov. 19, 2011)).

[43] Mitch Lies, Capital Press, *GMO Bentgrass Found in Eastern Oregon*, http://www.capitalpress.com/oregon/ml-gmo-bentgrass-111210 (Nov. 9, 2010) (accessed Nov. 19, 2011).

[44] *Intl. Ctr. for Tech. Assessment v. Johanns*, 473 F. Supp. 2d 9, 28 (D.D.C. 2007).

[45] Jay R. Reichman et al., *Establishment of Transgenic Herbicide-Resistant Creeping Bentgrass (Agrostis solonifera L.) in Nonagronomic Habitats*, 15 Molecular Ecology 4243, 4245 (2006).

[46] Christopher Doering, Reuters, *Scotts to Pay $500,000 Fine over Biotech Bentgrass*, http://www.reuters.com/article/2007/11/27/us-scotts-usda-idUSN2643698720071127 (Nov. 26, 2007) (accessed Nov. 19, 2011).

[47] Mitch Lies, Capital Press, *Coba Presses Scotts for Bentgrass Plan*, http://www.capitalpress.com/oregon/ml-coba-letter-021111 (Feb. 10, 2011) (accessed Nov. 19, 2011).

amination of a USDA official in other GE crop litigation in late 2010.[48] In 2010, FWS concluded that this GE plant's commercialization would likely cause the extinction of two endangered plants in Oregon by spreading the GE herbicide resistance to wild relatives, which would then take over the species' critical habitat and be impossible to eradicate.[49]

FDA hearings on AquAdvantage salmon in September of 2010 also considered concerns about food safety.[50] Finally, FDA is simultaneously debating whether it will require any labeling if it approves the transgenic fish. The agency has indicated that it plans to carry over its GE plant foods labeling policy, under which there is no requirement that GE foods be labeled unless the FDA finds their change to be "material."[51]

II. THE TECHNOLOGICAL DILEMMA

> *We are most likely stuck with factory farms, given that they produce most of the beef and pork Americans consume. But it is still possible to reduce the animals' discomfort—through neuroscience. Recent advances suggest it may soon be possible to genetically engineer livestock so that they suffer much less.*[52]

How did we get to the point of engineering salmon? We live in what philosopher Jacques Ellul called the age of technology,[53] an age in which self-interest, greater productivity, greater consumption, the laws of supply and demand, and the commoditization of the world are the main drivers of technological innovation. Unfortunately, the current dominant economic systems and their intertwined technological systems are not only at odds with the ecological cycles of the natural world, but are also actively, rapidly, and severely harming the planet. We are exponentially reducing the earth's capacities in every natural realm—land, air, water, and everything in between—through ozone

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[48] Mitch Lies, Capital Press, *Feds Mum on GMO Spread*, http://www.capitalpress.com/content/ml-bentgrass-111910 (Nov. 18, 2010) (accessed Nov. 19, 2011); *see also CFS v. Vilsack*, 734 F. Supp. 2d. 948 (N.D. Cal. 2010).

[49] Ltr. from FWS to Michael C. Gregoire, Dep. Administr. of Animal & Plant Health Inspection Serv., *Draft Biological Opinion: Deregulation of Agrostis stolonifera* 2 (Feb. 2010) (copy on file with *Animal Law*) (finding the proposed action is likely to jeopardize the continued existence of the Willamette daisy (*Erigeron decumbens var decumbens*) and Bradshaw's lomatium *(Lomatium bradshawi*) and would likely adversely modify designated critical habitat of the Willamette daisy and Fender's blue butterfly (*Icaricia icarioides fenderi*)).

[50] These included allergenicity issues. *See* VMAC Briefing Packet, *supra* n. 18, at 21, 26–27, 31, 33, 104 (noting that biased culling procedures likely excluded many deformed GE salmon from analysis and stating that "the technical flaws in . . . [AquaBounty's allergy] study so limit its interpretation that we cannot rely on its results").

[51] 75 Fed. Reg. 52602; 58 Fed. Reg. 25837, 25838 (Apr. 28, 1993).

[52] Adam Shriver, *Not Grass-Fed, But at Least Pain-Free*, N.Y. Times A27 (Feb. 18, 2010).

[53] *See generally* Jacques Ellul, *The Technological Society* (John Wilkinson trans., Alfred A. Knopf, Inc. 1964).

depletion, water depletion, species extinction, deforestation, and desertification. By commodifying nature to match our own systems, we are threatening the existence of most ecosystems, and consequently our own species' survival. Anthropogenic climate change illustrates this conclusion well: Our industrial technologies have created the first man-made global environmental crisis in history. Thus the technological dilemma—the "developed" portion of the world's population has become dependent on the current technological environment. Yet the same technologies that support life for the richest part of the human population are threatening the planet's very ability to support life for much of its population, human and non-human alike.

These are not new revelations. Forty years ago, writers and leaders began urging that we institute appropriate technologies in sync with the cycles of nature, rather than the industrial technological systems causing planetary and human peril.[54] Attorneys and policymakers succeeded in passing and utilizing laws, such as the Endangered Species Act (ESA), to limit the impacts of industrial systems. Scientists began to develop more holistic visions of their vocations. This holistic approach is a step toward addressing development within the context of, rather than at the expense of, our environment.

Others, too, have come to the conclusion that our current technology is not compatible with the natural world. They have foreseen the growing conflict between globalization, mass consumption, and the laws of nature. However, their solution to the dilemma is very different. Rather than change our technological systems to better comport with the needs of living things, corporations and governments began to change life so that it fits technology. In these actors' solutions, which ignore the constraints of the natural world, living systems are to be remade and engineered at the genetic and molecular level to further the necessities of the technological age. Thus, they see genetic engineering as the tool by which we can alter life at the genetic level to better fit industrial production systems and become a technological commodity. Cloning is seen as the tool by which we can emulate the factory model of identical production for life forms. Rather than redesigning industrial agriculture to fit the animal's natural behavior, we are redesigning the animal to fit industrial agriculture. Because patent control spurs production, we must now patent genes and cells from plants, animals, and humans. Nanotechnology is a means by which we can control and manipulate matter at the atomic and molecular level to enhance industrial processes. And most recently, synthetic biology permits us to combine several of these tools to create and design entirely new life forms to perform industrial tasks.

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[54] *See generally* E.F. Schumacher, *Small Is Beautiful* (Harper & Row 1973).

III. OVERVIEW OF GENETIC ENGINEERING AND TRANSGENIC ANIMALS

Scientists commonly define biotechnology as a set of techniques that alter living organisms for the benefit of humans,[55] while genetic engineering refers to modern biotechnological processes that allow scientists to modify or manipulate genetic material to introduce new traits or characteristics into an organism.[56] Genetic engineering is fundamentally different from conventional or traditional breeding. The latter process involves identifying similar, related species with useful traits and crossing or breeding these species to produce offspring with the desired characteristics of both parents. Genetic engineering, on the other hand, cannot occur naturally. It uses recombinant DNA (rDNA) techniques to create pieces of one organism's DNA and then to insert these DNA pieces into another organism.[57] The process allows scientists to combine genetic material from vastly dissimilar and unrelated organisms—bacteria genes with animal genes, fish genes with tomato genes, or, in the case of the AquaBounty, a salmon and an ocean pout—producing unique combinations of genetic material and traits beyond the genetic potential of any traditionally bred organism.[58]

Animal biotechnology experimentation produced the first transgenic mice in 1974 by inserting foreign DNA into early-stage mouse embryos.[59] Subsequent experiments proved that the inserted DNA passed down to the animals' progeny.[60] Unlike agricultural biotechnology, the overwhelming majority of GE animals produced today are still experimental mice and rats.[61]

There are six classes of GE animals currently in development. Proponents claim these animals are capable of producing a variety of new traits that will revolutionize animal agriculture by: (1) improving animal health (e.g., disease resistance); (2) enhancing production through altered food quality traits (e.g., faster growing fish); (3) creating pharmaceuticals (e.g., animals that produce pharmaceutical products for transplantation, commonly known as "biopharm" animals); (4) enriching or enhancing animal interactions with humans (e.g., hypoal-

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55 NRC, *supra* n. 28, at 4.

56 FDA, *Animal & Veterinary: General Q&A*, http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm (last updated May 23, 2011) (accessed Nov. 19, 2011).

57 *Id.*

58 *See e.g.* Stanley Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 P. Natl. Acad. Sci. 3240, 3240–44 (1973).

59 GTC Biotherapuetics, Inc., *Blood Products Advisory Committee Meeting: Briefing Document Re: ATryn* 14, http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/UCM226514.pdf (Dec. 3, 2009) (accessed Nov. 19, 2011).

60 *Id.*

61 Nina Mak, *Animal Welfare for Sale: Genetic Engineering, Animal Welfare, Ethics and Regulation* 6, 18, http://www.aavs.org/atf/cf/%7B8989C292-EF46-4EEC-94D8-43EAA9D98B7B%7D/GE-Animals-Report.pdf (Nov. 18, 2008) (accessed Nov. 19, 2011).

lergenic pets); (5) developing animal models for human disease (e.g., pigs as models for cardiovascular disease); and (6) producing consumer products (e.g., fibers for multiple uses).[62]

The largest investments in transgenic animals thus far are from pharmaceutical companies interested in producing enzymes, clotting factors, and other bioactive proteins in milk.[63] In 2008, FDA approved ATryn, a transgenically produced anticoagulant derived from the milk of GE goats used for the prevention of blood clots in patients with a rare disease known as hereditary antithrombin (AT) deficiency.[64] The ATryn goat remains the only GE animal approved in the U.S. to produce a drug.[65]

The only GE animal currently on the U.S. commercial market is the luminescent "GloFish," a novelty fish for the home aquarium. The GloFish first came to market in 2004,[66] five years before FDA established the regulatory pathway for transgenic animals discussed *infra*. Public interest organizations challenged FDA's decision, but the court held that the agency had acted within its discretion in declining to assess or regulate the fish.[67]

Although FDA has yet to approve a single GE animal for human consumption, several are in development in addition to the AquAdvantage salmon. For example, the so-called "EnviroPig" is genetically engineered to produce less phosphorus in its manure and thus purportedly reduces the environmental impact of commercial pig

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[62] FDA, *Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant Constructs* 4, http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm113903.pdf (last updated May 17, 2011) (accessed Nov. 19, 2011) [hereinafter FDA, *Guidance*].

[63] NRC, *supra* n. 28, at 17.

[64] Jon F. Scheid, *FDA Approves First GE Animal, Human Health Product*, 23 FDA Veterinarian (newsltr. of the Ctr. for Veterinary Med.) 3–4 (No. 5, 2008).

[65] *Id.*; GTC Biotherapeutics, *GTC Biotherapeutics Inc., a LFB Group Co., Granted Protection until 2027 on Broad Transgenic Protein Production Patent, and Is Also Granted New Patent on Recombinant Anti-Thrombin Produced Transgenically*, http://www.gtc-bio.com/news.html (May 20, 2011) (accessed Nov. 19, 2011) (copy on file with *Animal Law*).

[66] Rebecca Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 Minn. J.L. Sci. & Tech. 457, 457 (2005) [hereinafter Bratspies, *Glowing*].

[67] *Intl. Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 4 (D.D.C. 2006). The Glofish is a genetically engineered ornamental pet fish developed by Yorktown Technologies, L.P.: a bright red, fluorescent zebra fish that contains inserted genetic constructs from a sea coral, which cause the fish to glow under certain kinds of light. Before bringing the fish to market, Yorktown consulted with FDA regarding regulatory approval, which FDA determined was not needed. *Id.* Plaintiffs filed suit against FDA arguing that the agency had erred in denying regulatory jurisdiction under the Federal Food Drug and Cosmetic Act (FFDCA), and had failed to comply with the National Environmental Policy Act (NEPA) and Endangered Species Act. The court interpreted FDA's decision as exercising enforcement action committed to agency discretion, rather than a regulatory action, and consequently dismissed the case. *Id.* at 6–10; *but see* Bratspies, *Glowing*, *supra* n. 66, at 473–83 (arguing that FDA erred and failed to comply with several statutory mandates, including the FFDCA and NEPA).

production.[68] Other pigs are being engineered to contain more Omega-3 fatty acids in their meat, thereby theoretically increasing the health benefits of eating pork.[69] Cows are being genetically engineered to be disease resistant to mastitis, a painful udder infection, and to bovine spongiform encephalopathy, commonly known as mad cow disease.[70] Researchers have experimented with engineering turkey hens—which are often unable to brood over their eggs in factory farm battery cages—to "silence" their "mothering gene" and thus remove that instinct.[71] In addition to salmon, researchers are also developing several other fish with various growth-enhancement and disease-resistance traits.[72]

IV. THE HEALTH, ENVIRONMENTAL, AND ANIMAL WELFARE IMPACTS OF TRANSGENIC ANIMALS

Juxtaposed against the promised future benefits of transgenic animals are abundant risks associated with their production. First, as a general matter, genetic engineering is unpredictable, often creating unintended effects. The gene product may not be appropriately expressed; the engineering can have undesired effects on the animal; or the vector used for gene transfer can escape and unintentionally enter the gene sequence of another organism.[73] Of significant concern is the possibility of pathogenic viruses, which might be generated by combining the vector used to introduce a transgene with related but nonpathogenic viruses that might already be present in an animal.[74]

The human health risks posed by the introduction of GE animals into commerce are also largely unknown. GE "biopharm" animals producing pharmaceuticals or other medical and non-medical products could accidently enter the food chain, exposing other animals and humans to the transgenes they carry.[75] Engineering with antibiotic-resistant "markers" (intended to help producers confirm that new genetic material has been transferred to the host), which may then enter the food supply, could make antibiotics less effective in fighting disease.[76] Further, proteins present in food can exert effects beyond nu-

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[68] Mak, *supra* n. 61, at 11.

[69] *Id.*

[70] *Id.* at 12. In light of the philosophical underpinnings discussed above, it should be noted that similar outcomes could be achieved by other means in many cases. Reduction of phosphorous, for example, is possible through supplementing pigs' feed with phytase at a cost of $1.14 per pig. *Id.* at 11. Mastitis results from forcing cows to produce unnaturally high quantities of milk—simply reducing milk production to a more natural level can greatly reduce mastitis. *Id.* at 12.

[71] Jaydee Hanson, *Genetically Engineered Farm Animals*, in *The CAFO Reader*, 273, 275 (Daniel Imhoff ed., Found. for Deep Ecology 2010).

[72] William M. Muir, *The Threats and Benefits of GM Fish*, 5 Eur. Molecular Biology Org. Rpts. 654, 654 (2004).

[73] NRC, *supra* n. 28, at 44.

[74] *Id.* at 52.

[75] *Id.* at 7.

[76] Hanson, *supra* n. 71, at 278.

trition, including allergenicity, bioactivity, and toxicity.[77] The expression of new proteins in GE animals can cause unknown allergic reactions and immune responses in sensitive subjects. Changes in the nutritional values of foods—increased fatty acids or decreased cholesterol—can modify nutritional quality. Unlabeled, these various changes are unknown to consumers, who may be sensitive to certain foods, have medical conditions, or have other reasons to avoid certain traits.[78]

The National Research Council (NRC) considers environmental impacts to be the greatest potential concern associated with animal biotechnology, due to the uncertainty in identifying environmental problems and the difficulty remediating identified problems.[79] As discussed *supra* in the context of GE salmon, transgenic animals may escape into the natural environment, breed with a wild population, spread the transgene throughout the wild population, and harm the balance of an ecosystem.[80] A more "fit" population of GE animals could eventually replace a wild or natural population.[81] Similarly, GE animals could displace or crowd out local populations, disturbing the natural environment by, among other things, disrupting the survival of predatory species and subsequently increasing prey populations.[82] In this way, the harm most resembles that of invasive species.

The practice of engineering animals raises a host of animal welfare concerns as well. Animals engineered to possess traits beyond their natural genetic potential may experience numerous deleterious injuries, side effects, diseases, and abnormalities.[83] Genetic engineering is a volatile process and can result in unintended effects to the modified animal. The complications are often unpredictable and can vary depending on where and how the transgene is inserted or expressed and the host animal's genetic background.[84] First, the microinjection of DNA can lead to the integration of that foreign DNA within or close to an endogenous gene, resulting in an insertional mutation.[85] Some researchers estimate that 7% to 20% of engineered mice suffer from these mutations.[86]

Further, many GE animal models "fail in one or more of the conditions conferring proper transgene expression."[87] In one example,

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77 NRC, *supra* n. 28, at 7.

78 *Id.* at 8.

79 *Id.* at 9.

80 *Id.*; Muir, *supra* n. 72, at 655.

81 Muir, *supra* n. 72, at 655.

82 NRC *supra* n. 28, at 10.

83 C. G. Van Reenen et al., *Transgenesis May Affect Farm Animal Welfare: A Case for Systematic Risk Assessment*, 79 J. Animal Sci. 1763, 1765–66 (2001) (identifying three sets of factors that may affect the welfare of transgenic farm animals: insertional mutations, transgene expression, and in vitro reproductive biotechnologies).

84 Mak, *supra* n. 61, at 7.

85 Van Reenen et al., *supra* n. 83, at 1765.

86 *Id.*

87 *Id.*

transgenes containing milk protein promoter sequences and designed to express in the mammary gland instead exhibited expression in inappropriate tissues, including the brain, heart, spleen, kidney, and salivary gland.[88] In another example, GE pigs and sheep engineered to harbor biologically active growth-promoting factors suffered from "a range of serious, often lethal, pathological conditions."[89] Finally, in vitro reproductive biotechnologies can result in additional side effects, such as the Large Offspring Syndrome.[90] When experiments do not result in a marketable product, the project may be abandoned, and any testing was done in vain.[91]

Researchers use some engineered animals as disease models, designed to "successfully" manifest diseases, meaning that the animals develop conditions similar to those seen in humans.[92] Conditions such as Alzheimer's disease, amyotrophic lateral sclerosis, and Parkinson's disease are subjects of intense research efforts.[93]

Finally, choosing to engineer animals to better fit industrial food production has broader ramifications: it simply further ingrains the dominant industrial agriculture (and aquaculture) production paradigm, continuing its other concomitant harmful impacts.[94] Engineering chickens to reduce the pain caused by life in factory farm cages is a "techno-fix" band-aid that treats one symptom but avoids curing the illness: our unsustainable system.

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[88] *Id.*

[89] *Id.*

[90] *Id.* at 1766.

[91] *See e.g.* Sara Webb, Reuters, *Pharming's U.S. Rhucin Setback Sends Shares Down*, http://www.reuters.com/assets/print?aid=USLDE71R05320110228 (Feb. 28, 2011) (accessed Nov. 19, 2011).

[92] Marilyn J. Brown & Kathleen A. Murray, *Phenotyping of Genetically Engineered Mice: Humane, Ethical, Environmental, and Husbandry Issues*, 47 Inst. Laboratory Animal Research (ILAR) J. 118, 118 (2006); Melvin B. Dennis, *Welfare Issues of Genetically Modified Animals*, 43 ILAR J. 100, 101 (2002).

[93] Dennis, *supra* n. 92, at 101.

[94] *See e.g.* Hope M. Babcock, *Grotius, Ocean Fish Ranching, and the Public Trust Doctrine: Ride 'Em Charlie Tuna*, 26 Stan. Envtl. L.J. 3, 17–25 (2007) (discussing negative environmental, health, and socioeconomic impacts of aquaculture); Dana Cole et al., *Concentrated Swine Feeding Operations and Public Health: A Review of Occupational and Community Health Effects*, 108 Envtl. Health Persp. 685, 694 (2000) (describing health impacts); Robin Kundis Craig, *The Other Side of Sustainable Aquaculture: Mariculture and Nonpoint Source Pollution*, 9 Wash. U. J.L. & Policy 163, 171–73 (2002) (describing negative environmental, health, and socioeconomic impacts); William S. Eubanks, *The Sustainable Farm Bill: A Proposal for Permanent Environmental Change*, 39 Envtl. L. Rep. 10493, 10498–504 (2009) (detailing the myriad impacts of modern industrial agriculture on air, water, soil, and wildlife); Doug Gurian-Sherman, *CAFOs Uncovered: The Untold Costs of Confined Animal Feeding Operations* 60–61 (Union of Concerned Scientists 2008) (describing health impacts); George Wuerthner, *Assault on Nature: CAFOs and Biodiversity Loss*, in *The CAFO Reader: Tragedy of Industrial Animal Factories* 182, 184–85 (Daniel Imhoff ed., Found. for Deep Ecology 2010) (describing the environmental impacts of CAFOs).

V. SEPARATING HYPE AND MYTH FROM REALITY

What's past is prologue.[95]

It is always a challenge with new technologies to separate hype from reality. But there is good reason to be dubious that animal biotechnology will do any more than further entrench industrial agriculture's unsustainable paradigm. We need not look any further than its closest parallel, transgenic crops.

Despite a quarter century of boundless hype and promises and fifteen years of commercialization, agricultural biotechnology has failed to make any progress toward reducing world hunger, ameliorating global malnutrition, combating global warming, or creating miracle drugs through GE plant "biofactories." Instead, biotechnology firms have delivered a handful of GE commodity crops that either produce pesticides or withstand direct application of herbicides. Approximately 62% of global biotech crop acreage is herbicide-resistant, which lends crops the ability to survive direct, repeated, and indiscriminate dousing of a broad-spectrum herbicide to kill nearby weeds.[96] Monsanto Company, now the world's largest seed company,[97] has used genetic engineering primarily to create patented "Roundup Ready" crops for use in tandem with its Roundup herbicide.[98] In the U.S., the vast majority of soybeans, corn, and cotton are now glyphosate-resistant, with glyphosate being the active ingredient in Monsanto's Roundup.[99] Roundup is now sold by other companies under its generic name.[100] This broad availability has made glyphosate the most heavily used chemical pesticide in history, with 180 to 185 million pounds applied in U.S. agriculture in 2007 alone.[101] As a consequence, transgenic crop adoption increased the overall pesticide usage in the U.S. by 318.4 million pounds from 1996 to 2008.[102]

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[95] William Shakespeare, *The Tempest* 140 (Stephen Orgel ed., Oxford U. Press 1987).

[96] *Monsanto v. David*, 516 F.3d 1009, 1011 (Fed. Cir. 2008); Clive James, Intl. Serv. for the Acquisition of Agri-Biotech Applications, *Executive Summary, Brief 41: Global Status of Commercialized Biotech/GM Crops* 11–12, http://www.isaaa.org/resources/publications/briefs/41/executivesummary/pdf/Brief%2041%20-%20Executive%20Summary%20-%20English.pdf (2009) (accessed Nov. 19, 2011).

[97] Chittur Subramanian Srinivasan, *Concentration in Ownership of Plant Variety Rights: Some Implications for Developing Countries*, 28 Food Policy 519, 527 (2003).

[98] *Monsanto*, 516 F.3d at 1011.

[99] *Id.*; *see also* William Neuman & Andrew Pollack, N.Y. Times, *Farmers Cope with Roundup-Resistant Weeds*, http://www.nytimes.com/2010/05/04/business/energy-environment/04weed.html?pagewanted=all (May 3, 2010) (accessed Nov. 19, 2011) (noting that Roundup Ready crops account for approximately 90% of soybeans and 70% of corn and cotton grown in the U.S.).

[100] Neuman & Pollack, *supra* n. 99.

[101] Arthur Grube et al., EPA, *Pesticides Industry Sales and Usage: 2006 and 2007 Market Estimates* 14, http://www.epa.gov/pesticides/pestsales/07pestsales/market_estimates2007.pdf (Feb. 2011) (accessed Nov. 19, 2011).

[102] Charles Benbrook, The Organic Ctr., *Impacts of Genetically Engineered Crops on Pesticide Use in the United States: The First Thirteen Years* 47, http://www.organic-

Although the industry claims that these herbicide-resistant crops increase yields, the only independent study of their results (by the Union of Concerned Scientists) concluded that they have not—while at the same time, successes in traditional breeding have increased yields.[103] To date, not a single GE crop has been approved by USDA for climate-ready traits claimed by the industry. Currently, there are no commercially approved GE crops with higher yield potential, nutritional enhancement, or drought or salt tolerance.[104]

Weighed against these disproven "benefits" is growing evidence that these crops carry with them significant adverse environmental and intertwined socioeconomic impacts. One is the dramatic cumulative increase in pesticidal loads into our environment noted *supra*. Another is that "Roundup Ready" crops have fostered an ongoing epidemic of glyphosate-resistant "superweeds" now regarded by agronomists as one of the most serious challenges facing American agriculture.[105] The superweeds evolve when farmers grow "Roundup Ready" crops year after year; like bacteria exposed to antibiotics, some weeds naturally resistant to glyphosate survive exposure and then reproduce and flourish. Since the year 2000, glyphosate-resistant weeds have evolved in an epidemic manner,[106] infesting over 11 million acres of cropland.[107] These superweeds cause farmers to use more Roundup, more toxic herbicide cocktails, more soil-eroding tillage operations to physically remove weeds, and massive deployment of weeding crews to manually remove weeds—all of which can dramatically increase weed-control costs.[108] This has set the stage for rapid adoption of the next generation of transgenic crops, which are engineered for resistance to older, more toxic herbicides like 2,4-D, dicamba, and imidazolinones, often in combination.[109] As yet another example of the dominant cultural mindset discussed above, these multiple herbicide-resistant,

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center.org/science.pest.php?action=view&report_id=159 (Nov. 2009) (accessed Nov. 19, 2011).

103 Doug Gurian-Sherman, *Failure to Yield: Evaluating the Performance of Genetically Engineered Crops* 1 (Union of Concerned Scientists 2009) [hereinafter Gurian-Sherman, *Failure to Yield*] (noting that this was the first report to "evaluate in detail the overall, or aggregate, yield effect" of genetically engineered crops and concluding that "GE soybeans have not increased yields and GE corn has increased yield only marginally on a crop-wide basis").

104 *Id.* at 24.

105 Neuman & Pollack, *supra* n. 99; Stephen B. Powles, *Gene Amplification Delivers Glyphosate-Resistant Weed Evolution*, 107 P. Natl. Acad. Sci. 955, 955 (2010).

106 Robert F. Service, *A Growing Threat Down on the Farm*, 316 Sci. 1114, 1115 (2007).

107 Jerry Adler, *The Growing Menace from Superweeds*, 304 Sci. Am. 74, 74–79 (May 2011).

108 Georgina Gustin, St. Louis Post-Dispatch, *Resistant Weeds Leave Farmers Desperate*, http://www.stltoday.com/business/local/article_f01139be-ace0-502b-944a-0c534b70511c.html (July 17, 2011) (accessed Nov. 19, 2011).

109 *See id.* (reporting that Monsanto is working on developing dicamba-resistant soybeans and cotton); *see also* Benbrook, *supra* n. 102, at 57 (noting that the industry is "investing heavily" in the development of crops with resistance to multiple herbicides).

"stacked" crops are the pesticide/biotech industry's "solution" to glyphosate-resistant weeds—even though they will in turn foster multiple herbicide-resistant weeds and a toxic spiral of increased herbicide use in response.[110]

GE crops have also caused widespread transgenic contamination—gene flow from GE crops to related conventional or organic cultivars or wild species.[111] In the crop context, contamination is a multifaceted harm that causes significant and widespread economic harm,[112] a fundamental loss of choice for farmers and consumers,[113] and irreparable contamination of wild species.[114] Notably, FDA's and AquaBounty's hollow assurances—that the transgenic plantings would be "confined" and never escape—are typical of many crop contamination incidents. For example, in many of the crop contamination inci-

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[110] *See* William Freese, CFS, *Response to Questions from Congressional Committee Investigating Herbicide-Resistant Weeds* 10, (Sept. 30, 2010) (available at http://www.centerforfoodsafety.org/wp-content/uploads/2011/03/Oversight-hearing-Freese-Response-to-Questions-corrected.pdf (2010) (accessed Nov. 19, 2011)) (noting that the more frequently an herbicide is used, the more rapidly resistance will develop).

[111] *See e.g.* Rex Dalton, *Modified Genes Spread to Local Maize*, 456 Nat. 149, 149 (2008) (stating that transgenes from GE corn have been discovered in Mexico's traditional "landrace" maize); Lyle F. Friesen et al., *Evidence of Contamination of Pedigreed Canola (Brassica napus) Seedlots in Western Canada with Genetically Engineered Herbicide Resistance Traits*, 95 Agronomy J. 1342, 1342–47 (2003) (reporting results from a survey of twenty-seven commercial seedlots); Andrew Pollack, *Can Biotech Crops Be Good Neighbors?* N.Y. Times WK12 (Sept. 26, 2004) (discussing U.S. responses to GE contamination); Elisabeth Rosenthal, *Questions on Biotech Crops with No Clear Answers*, N.Y. Times C4 (June 6, 2006) (discussing global GE contamination).

[112] *See e.g.* Andrew Harris & David Beasley, Bloomberg News, *Bayer Agrees to Pay $750 Million to End Lawsuits over Gene-Modified Rice*, http://www.bloomberg.com/news/2011-07-01/bayer-to-pay-750-million-to-end-lawsuits-over-genetically-modified-rice.html (July 1, 2011) (accessed Nov. 19, 2011) (reporting that the multinational chemical company Bayer AG will pay $750 million to approximately 11,000 U.S. rice farmers whose rice harvests were contaminated by a Bayer-developed experimental GE rice in 2006); K.L. Hewett & GSE Azeez, *The Economic Impacts of GM Contamination Incidents on the Organic Sector*, http://orgprints.org/12027/1/The_Economic_Impacts_of_GM_Contamination_Incidents_on_the_Organic_Sector.pdf (June 20, 2008) (accessed Nov. 19, 2011) (examining the implications of global transgenic contamination for organic farmers); U.S. Govt. Accountability Off., *Genetically Engineering Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring* 3, http://www.gao.gov/new.items/d0960.pdf (Nov. 2008) (accessed Nov. 19, 2011) (analyzing several major transgenic contamination incidents from the past decade and concluding that "the ease with which genetic material from crops can be spread makes future releases likely").

[113] *Geertson Seed Farms*, 65 ERC 1023, 1029 (N.D. Cal. 2007) (holding that a threat to "a farmer's choice to grow non-genetically engineered crops, or a consumers' choice to eat non-genetically engineered food" constitutes a legally cognizable impact and noting that "[f]or those farmers who choose to grow non-genetically engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop").

[114] Doug Gurian-Sherman, CFS, *Contaminating the Wild?: Gene Flow from Experimental Field Trials of Genetically Engineered Crops to Related Wild Plants* 1, http://www.centerforfoodsafety.org/pubs/Contaminating_the_Wild_Report.pdf (2006) (accessed Nov. 19, 2011).

dents the regulating agency and industry had similarly claimed the transgenic plantings were "confined" and would never escape.[115]

Finally, the greatest myth of all is that we need to engineer our food in order to "feed the world."[116] Even setting aside that the science shows that GE crops do not increase yields,[117] this rationale fundamentally misconceives the problem. As the United Nations General Comment on the Right to Food concluded: "The roots of the problem of hunger and malnutrition are not lack of food but lack of access to available food . . . ."[118] Hunger today results from institutional, not biological constraints. Rather than further consolidating and entrenching control of our food supply through patents, engineering, and contracts, food availability and accessibility begin with equitable and fair access to land and vital natural resources. The path toward reducing hunger includes economic reforms, redistribution of land to the landless, and sustainable and affordable farm inputs and practices. Growing food to feed local communities is a more reliable, stable food system than relying on global markets and import/export models.

AquaBounty's parroting of this general myth in support of its engineered salmon fares no better.[119] Simply put, AquaBounty's fast-growing salmon will exacerbate the unsustainability of salmon aquaculture, not solve it. Carnivorous farmed fish, like salmon, must be fed wild fish as feed.[120] In 2006, the aquaculture sector alone consumed approximately 57% of total global fishmeal production, 87% of total global fish oil production, and 55% of total other nonfood small pelagic forage fish.[121] People, particularly in food insecure areas, depend on these prey fish (like anchovies, herring, and sardines) as a rich source of nutrients and a primary protein source, as well as a means of

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115 *E.g. id.* at 22; Natl. Acad. of Sci., *Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation* 134–35 (Natl. Acad. Press 2002).

116 *See e.g.* Monsanto, *Producing More*, http://www.monsanto.com/ourcommitments/Pages/sustainable-agriculture-producing-more.aspx (accessed Nov. 19, 2011) ("To meet the demand of population growth and dietary shifts, farmers must produce more food in the next few decades than they have in the past 10,000 years combined. How will yields double? A combination of advanced plant breeding, biotechnology and improved farm-management practices."); *see also* AquaBounty Techs., *Aquaculture Market*, http://www.aquabounty.com/company/aquaculture-293.aspx (accessed Nov. 19, 2011) ("Aquaculture provides a means of partially meeting this demand, but we cannot expect to feed a burgeoning global population without employing every tool at our disposal, including enhancing aquaculture productivity through genetic engineering.").

117 Gurian-Sherman, *Failure to Yield*, *supra* n. 103, at 1.

118 U.N. Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 12: The Right to Adequate Food (Art. 11)* ¶ 5, http://www.unhcr.org/refworld/docid/4538838c11.html (May 12, 1999) (accessed Nov. 19, 2011).

119 AquaBounty Techs., *supra* n. 116.

120 *See generally* Albert G.J. Tacon et al., U.N. Food & Agric. Org., *Use of Fishery Resources as Feed Inputs to Aquaculture Development: Trends and Policy Implications* iii, ftp://ftp.fao.org/docrep/fao/009/a0604e/a0604e00.pdf (2006) (accessed Nov. 19, 2011) (discussing the aquaculture industry's heavy reliance on marine capture fisheries to sustain carnivorous farmed fish).

121 Albert G.J. Tacon & Marc Metian, *Fishing for Feed or Fishing for Food: Increasing Global Competition for Small Pelagic Forage Fish*, 38 Ambio 294, 299 (2009).

employment.[122] Prey fish make up over 25% of the total animal protein supply for approximately 1 billion people in fifty-eight countries.[123] Exporting these local prey fish from their traditional fisheries into far-off industrial aquaculture facilities in "developed" countries is a bad trade-off for the world's hungry.[124] Genetically engineered salmon that grow year-round in order to be brought to market in less time will require even more prey fish inputs, decreasing the availability of small fish as a dietary staple to people around the world. Further, degradation of aquatic ecosystems and wild stocks from escapees[125] also will counteract any food increase from faster salmon farming.

VI. FLAWED OVERSIGHT: TRANSGENIC ANIMALS AS ANIMAL DRUGS

In the U.S. there is no single overarching law or federal agency that oversees biotechnology. Rather, the U.S. government oversees its products using a "mosaic" of pre-existing laws, implemented by several agencies, known as the Coordinated Framework for the Regulation of Biotechnology (Framework).[126] Rather than advocating for new legislation to meet the novel challenges of biotechnology, the Framework concluded that existing laws and processes would suffice to evaluate biotechnology products.[127] As a result, various federal agencies divide regulatory responsibility based on each agency's historical role under pre-existing statutes.[128] Thus, FDA, EPA, and USDA share responsibility for regulating products of biotechnology: FDA oversees food safety issues; EPA oversees transgenic microbes and crops which are engineered with a pesticidal substance; and USDA regulates all other transgenic plants, overseeing experimental field trials and commercialization.[129]

The Framework policy called for these agencies to stretch the boundaries of their various existing statutes by using existing definitions and authorities to promulgate agency regulations and to oversee

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122 *See e.g.* Shakuntala Haraksingh Thilsted et al., *The Role of Small Indigenous Fish Species in Food and Nutrition Security in Bangladesh*, Naga 82, 83 (July–Dec. 1997) (noting that the majority of fish consumed by the rural poor comes from small indigenous fish species).

123 Albert G. J. Tacon, *Increasing the Contribution of Aquaculture for Food Security and Poverty Alleviation*, in *Aquaculture in the Third Millenium* 63, 69 (Rohana P. Subasinghe et al. eds., Food & Agric. Org. of the U. N. 2001) (available at http://www.fao.org/DOCREP/003/AB412E/ab412e30.htm (accessed Nov. 21, 2011)).

124 *See* U.S. Commn. on Ocean Policy, *An Ocean Blueprint for the 21st Century* 331, http://www.oceancommission.gov/documents/full_color_rpt/welcome.html (2004) (accessed Nov. 19, 2011) ("Obtaining fishmeal from traditional wild harvest practices may increase the pressure on fisheries that are fully exploited.").

125 *See supra* pt. I (describing the risks of GE salmon for wild populations).

126 51 Fed. Reg. 23302, 23302–03 (June 26, 1986).

127 *Id.* at 23303.

128 *Id.* at 23302–08, 23309, 23313–14.

129 *Id.* at 23304.

transgenic products.[130] Thus, transgenic ingredients are intended to be classified as "food additives" by FDA.[131] Transgenic plants were to be regulated by USDA as "plant pests" under the former Plant Pest Act.[132] Transgenic plants engineered with pesticidal-proteins were to be regulated under Federal Insecticide, Fungicide, and Rodenticide Act as "pesticides" by EPA, based on that term's broad definition.[133] Transgenic microorganisms would be classified as "toxic chemicals" under the Toxic Substances Control Act.[134] Transgenic animals are regulated by FDA as "new animal drugs."[135] This overarching policy decision has caused numerous structural barriers to adequate oversight, and there is a rich academic history analyzing and critiquing the Framework.[136]

FDA oversees transgenic foods by applying its authority under the Federal Food, Drug, and Cosmetics Act (FFDCA), although there are

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130 *Id.* at 23307.

131 *See* 21 U.S.C. § 321(s) (defining "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . .").

132 7 C.F.R. § 340.1 (2011); 58 Fed. Reg. 17044, 17056 (Mar. 31, 1993).

133 40 C.F.R. § 174.25 (2011); 66 Fed. Reg. 37855, 37856 (July 19, 2001).

134 *See* Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology under the Federal Coordinated Framework*, 12 Drake J. Agric. L. 439, 455 (2007) (noting that EPA regulations define any new microbe developed with biotechnology as a new chemical product under the Toxic Substances Control Act).

135 VMAC Briefing Packet, *supra* n. 18, at 1.

136 *See e.g.* Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 Wake Forest L. Rev. 93, 134 (2007) (criticizing the lack of pre-market notification, and arguing that protecting the public health requires evaluating the risks from new GE foods); Keith Aoki, *Food Forethought: Intergenerational Equity and Global Food Supply—Past, Present, and Future*, 2011 Wis. L. Rev. 399, 463 (2011) (noting that the Framework's patchwork of shared responsibility has left many holes in oversight, resulting in "piecemeal and all together ineffective regulation"); Rebecca Bratspies, *Some Thoughts on the American Approach to Regulating Genetically Modified Organisms*, 16 Kan. J.L. & Pub. Policy 393, 406 (Spring 2007) (noting that a major problem with the Framework is that it permits agencies to act simultaneously as regulators and promoters for this new technology); Margaret R. Grossman, *Biotechnology, Property Rights and the Environment*, 50 Am. J. Comp. L. 215, 226 (2002) (noting that the Framework created "sizeable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment"); John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. Cal. L. Rev. 807, 823 (2001) (noting that environmental risks posed by genetically engineered organisms are not addressed in a "coherent manner" in part because "there is no single federal statute that governs the subject matter"); Douglas A. Kysar, *Preferences for Processes: The Process/Product Distinction and the Regulation of Consumer Choice*, 118 Harv. L. Rev. 525, 559 (2004) (arguing that "the responsible agencies have diluted . . . statutory powers in practice"); Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2216, 2243 (2004) (noting that as a result of the Framework's flawed paradigm, there have been "multiple failures on the part of regulatory agencies to recognize that genetically modified products sometimes do create new and different issues than those raised by the conventional products they routinely regulate").

no specific regulations and the agency's oversight is limited at best.[137] Transgenic ingredients are classified as food additives, and, as such, seemingly should have to undergo extensive pre-market safety testing, including long-term animal studies.[138] However, in 1992 FDA issued a policy statement on transgenic foods,[139] determining that they are presumptively "generally recognized as safe" (GRAS), an exemption from the food additive requirements. The manufacturer, not FDA, determines whether a transgenic ingredient is GRAS; any consultation with FDA on that decision is voluntary.[140] Accordingly, FDA does not "approve" transgenic foods, nor undertake any independent analysis of their safety.[141] Instead, FDA has a voluntary consultation with industry on the industry's GRAS determination: it reviews summaries of the data the industry chooses to present,[142] which results in the agency issuing a "no questions" letter conveying the developer's assurances.[143] A court upheld this 1992 policy in spite of a legal challenge from public interest organizations.[144]

FDA also has authority over transgenic animals pursuant to its statutory authority to regulate new animal drugs under FFDCA;[145] in 2009, FDA issued a guidance explaining how the agency intended to apply that authority to GE animals.[146] FFDCA defines the term "drug" as including, among other things, "articles (other than food) intended

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137 Mandel, *supra* n. 136, at 2218.

138 *Id;* William Freese & David Schubert, *Safety Testing and Regulation of Genetically Engineered Foods*, 21 Biotechnology & Genetic Engr. Revs. 299, 304–05 (2004).

139 57 Fed. Reg. 22984–23005 (May 29, 1992); Freese & Schubert, *supra* n. 138, at 303–04.

140 57 Fed. Reg. 22989 (May 29, 1992); Freese & Schubert, *supra* n. 138, at 303–04; Gregory N. Mandel, *Toward a Rational Regulation of Genetically Modified Food*, 4 Santa Clara L. Rev. 21, 24 (2006).

141 *See* Freese & Schubert, *supra* n. 138, at 303.

142 *Id.* at 304.

143 *Id.*; *see e.g.* Ltr. from Mitchell A. Cheeseman, Acting Dir., Off. of Food Additive Safety, FDA to Craig Blewett, Reg. Leader, Dow AgroSciences LLC, *Biotechnology Consultation Agency Response Letter BNF No. 000120* (Apr. 13, 2011) (available at http://www.fda.gov/Food/Biotechnology/Submissions/ucm254643.htm (accessed Nov. 19, 2011)) (comprising a typical "no questions" letter, stating: "Based on the safety and nutritional assessment Dow has conducted, it is our understanding that Dow has concluded . . . the genetically engineered corn does not raise issues that would require premarket review or approval by FDA. Based on the information Dow has provided to FDA, we have no further questions concerning the new corn variety, DAS-40278-9 corn . . . . However, as you are aware, it is Dow's continuing responsibility to ensure that foods marketed by the firm are safe . . . .").

144 *Alliance for Bio-Integrity v. Shalala*, 116 F.Supp.2d 166 (D.D.C. 2000). Internal FDA documents produced in the litigation showed that numerous scientists at FDA raised objections to the policy and argued that potential unintended effects of the transformation process necessitated mandatory review before commercialization; they were overruled. Freese & Schubert, *supra* n. 138, at 303–04.

145 21 U.S.C. § 321(v) (defining "new animal drug" as "any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including such animal feed . . . .").

146 FDA, *Guidance*, *supra* n. 62, at 5–6; *see also* 21 U.S.C. §§ 355, 360(b); 21 C.F.R. § 25.10(c) (2011).

to affect the structure or any function of the body of man or other animals . . . ."[147] "New animal drug" in turn means any drug that has not been used to a material extent or for a material time and is not recognized by "experts qualified by scientific training and experience" as safe and effective for use under the conditions prescribed, but which is intended for use in animals.[148] FDA has interpreted these definitions to encompass the rDNA construct in a GE animal, which by design affects the structure or function of the body of the GE animal in order to bring those animals, including the AquaBounty GE salmon, within the agency's regulatory purview.[149] FFDCA's New Animal Drug Application (NADA) provisions evaluate animal drugs based on three criteria: animal safety, drug effectiveness, and human safety.[150] FDA examines animal drugs, and thus GE animals, under these criteria. As described in the guidance, FDA examines: the safety of the transgenic construct for the animal; safety of the food from the animal; environmental impact; and the extent to which the producers of GE animals have met the claims made for those GE animals (i.e., the "effectiveness" of the "drug").[151]

This oversight mechanism is at best problematic, for a number of reasons. Importantly, FDA's application of animal drug provisions to transgenic food animals is an unprecedented interpretation (and perhaps an improper extension) of the agency's authority under FFDCA. Transgenic animals are very different from veterinary animal drugs, presenting new difficulties in assessment and oversight. Such forcing of transgenic square pegs into pre-existing statutory round holes is an endemic problem of U.S. oversight under the Framework.[152]

A GE animal applicant must submit evidence establishing only that its new animal drug is both safe and effective for the intended use,[153] with "safe" referring only to "the health of man or animal."[154] Hence, environmental risks resulting from the production, transport, and use of GE food animals like the AquAdvantage salmon are nowhere contemplated under FDA's statutory process. FDA's review is inadequate to comprehensively address issues of food and environmental safety because the agency's primary objective and scope is only to

147 21 U.S.C. § 321(g)(1)(C).

148 *Id.* at § 321(v).

149 AquaBounty, *EA for AquAdvantage*, *supra* n. 18, at 15.

150 FDA, *Guidance*, *supra* n. 62, at 18.

151 *Id.* at 13–20.

152 *See generally supra* nn. 136, 134 (describing academic criticism of the framework); *see also* Bratspies, *Glowing*, *supra* n. 66, at 503–04 ("The Coordinated Framework must also be reconsidered, either by the President and the Executive Branch itself or through legislative action. In particular, it is time to rethink the decision to make FDA lead agency for regulating transgenic fish and other animals. Because many of the most critical issues with regard to transgenic fish are environmental, they do not naturally fall within FDA's scope of authority.").

153 *See e.g.* 21 U.S.C. § 360b(a)(1) (describing circumstances in which a new animal drug is unsafe).

154 *Id*. at § 321(u).

assess whether an applicant has a legitimate "claim" for safe and effective use (e.g., whether AquAdvantage's genetic engineering will generate faster-growing fish).[155] Although FDA has stated that it will include environmental impacts in its assessments, the statute and regulations neither require consideration of such factors nor set forth any minimum requirements for safety. Moreover, the scope of FDA's authority under the NADA risk assessment as applied to GE animals is unclear: The "drug" may be limited to the rDNA construct or may include the entire GE animal. If limited to the former, indirect and cumulative impacts on the environment from the animal (as opposed to the impacts on the animal from the construct) might escape regulatory review.

The lack of any requirement to consider broader environmental impacts raises another question: Even if FDA were required to analyze these impacts, should that agency be the one doing it? FDA regulates food and drug safety and efficacy, and it is this authority that it applies under the Framework to oversee transgenic food safety. However, in the case of GE food animals like AquAdvantage salmon, other agencies would seem a much better fit. EPA and USDA regulate transgenic organisms' potential impacts beyond food safety, including their environmental impacts. And FWS and the National Marine Fisheries Service are the experts in fisheries issues more broadly.[156] Tellingly, the expert panel that FDA convened during its 2010 September hearings on the AquAdvantage salmon included only one fisheries biologist (who called on the agency to consult with other agencies and to prepare a full Environmental Impact Statement under NEPA).[157] Despite this glaring mismatch, it is unclear whether FDA will consult with the expert agencies during its GE-animal approval process.

Yet another weakness is a severe lack of transparency and meaningful, timely public participation, as noted by NRC.[158] Because FDA's review is a drug approval process, the FFDCA mandates strict confidentiality; the agency may not even acknowledge which NADAs are currently pending, let alone allow for public participation early in the process.[159] The 2009 FDA guidance promises but does not require "public advisory meetings."[160] Very likely, the public will have neither

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155 FDA, *Guidance*, *supra* n. 62, at 12 ("We will evaluate the NADA to determine whether you have demonstrated that the new animal drug is safe and effective for its intended use . . . . To demonstrate effectiveness of an article intended to alter a characteristic of the resulting GE animal, in general you would have to show that the GE animal had the claimed altered characteristic (e.g., that its rate of growth was as claimed . . . .).").

156 FWS, *supra* n. 30, at "Functions"; Natl. Marine Fisheries Serv., *New Priorities for the 21st Century: Strategic Plan*, http://www.nmfs.noaa.gov/mb/strategic/NMFSstrategicplan200510.pdf (2005) (accessed Nov. 19, 2011).

157 VMAC Meeting Transcr., *supra* n. 24, at 383:16–23.

158 NRC, *supra* n. 28, at 111.

159 Pew Initiative on Food & Biotechnology, *supra* n. 39, at 54.

160 *Id.* at 13.

adequate notice of the commercialization of GE animals nor an opportunity to comment.

In the context of NEPA, new-animal-drug applicants must submit an Environmental Assessment (EA) as part of their application.[161] However, NADA regulations suggests that FDA make the EA available for public review before final action is taken only for a "limited number of actions," such as when the proposed action is one "without precedent."[162] Similarly, the regulations state that a completed EIS "will become available only at the time of the approval of the product."[163] Presumably FDA concluded the AquaBounty EA was "without precedent" because the agency disclosed it before its final decision.[164] But there is no guarantee that the agency will disclose the next GE animal even a day before final approval.[165] By that time, it may be too late to prevent irreparable harm, let alone to raise concerns about potential impacts before a final decision.

Timing is a touchstone of NEPA.[166] The statute's procedural purpose—to require consideration of impacts and alternatives prior to agency action—is completely dependent upon timely compliance. Another fundamental purpose of NEPA is public scrutiny of agencies' proposed decisions that may significantly impact the environment.[167] The "broad dissemination of information mandated by NEPA" is intended to allow "the public and other government agencies to react to the effect of the proposed action at a meaningful time."[168] Belated and constricted disclosure of FDA's review fundamentally undermines NEPA.

Finally, although AquaBounty's application is limited to their current small facilities in Canada and Panama, the company has publicly stated its plans to expand to new sites in the U.S. and throughout the world.[169] FDA should analyze and consider these potential impacts in its initial approval, because once approval is granted, the agency's sub-

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161 21 C.F.R. § 514.1(b)(14); FDA, *Guidance*, *supra* n. 62, at 19 (noting that "Section 514.1(b)(14) requires that an NADA include either a claim for categorical exclusion or an environmental assessment (EA)").

162 21 C.F.R. § 25.51(b)(3); 40 C.F.R. § 1506.6.

163 21 C.F.R. § 25.52(a).

164 Ctr. for Veterinary Med., FDA Veterinarian Newsltr., *FDA Holds Public Meeting on GE Salmon*, http://www.fda.gov/downloads/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/UCM236862.pdf (Dec. 15, 2010) (accessed Nov. 19, 2011).

165 21 C.F.R. §§ 25.50(b), 514.11(b)–(c).

166 *See* 40 C.F.R. §§ 1500.1(b), 1501.2 ("Agencies shall integrate the NEPA process with other planning at the earliest possible time to insure that planning and decisions reflect environmental values, to avoid delays later in the process, and to head off potential conflicts.").

167 *See e.g. Found. on Econ. Trends v. Heckler*, 756 F.2d 143, 147 (D.C. Cir. 1985) (describing NEPA as landmark legislation that requires federal agencies to consider environmental effects of major actions and as "empowering the public to scrutinize this consideration . . . ."); 40 C.F.R. § 1500.2(b).

168 *Marsh v. Or. Nat. Resources Council*, 490 U.S. 360, 371 (1989).

169 AquaBounty Techs., *Interim Results for the Six Months Ended 30 June 2011*, http://www.aquabounty.com/documents/financial/2011_Interim_Report.pdf (Sept. 23, 2011) (accessed Nov. 19, 2011).

sequent review is limited and ill-suited to review the production of transgenic animals. The holder of an approved drug application has discretion to self-determine whether a supplemental FDA approval of an animal drug is necessary before effecting certain changes in its "drug, production process, quality controls, equipment, or facilities."[170] Pre-approval is necessary only if the change has "substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug."[171] Because these provisions do not include consideration of adverse environmental effects, a transgenic-animal applicant like AquaBounty could argue that FDA approval is not needed for major changes to its facilities, containment measures, or production locations—despite the fact that such changes could pose significant new environmental risks.

The markedly different approach taken by other governments shows that it is possible for oversight of transgenic animals to be cautious, comprehensive, and specifically designed to apply to GE organisms. For example, the European Union (EU) has but one directive that specifically applies to all genetically modified organisms; the Directive recognizes that the "protection of human health and the environment requires due attention be given to controlling risks from the deliberate release into the environment of genetically modified organisms."[172] Because human health and the environment are potentially at risk, the EU takes a precautionary approach to avoid adverse effects from releasing and marketing any GE organism.[173] The Directive also requires public consultation on all proposed releases, with reasonable notice and opportunity for public comment.[174] These provisions increase transparency and allow all stakeholders, including members of the public, a chance to raise informed concerns before any approval. Moreover, considering effects on animal welfare, ethical concerns, and environmental impacts are all part of the assessment process.[175]

Finally, many governments require the labeling of GE foods for human consumption. For example, in 2004, the EU enacted regulations mandating labeling for all food products making direct use of genetically modified organisms at any point in their production.[176] Australia and New Zealand jointly require labeling for GE foods with

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170 21 C.F.R. § 514.8(b)(2).

171 *Id.*

172 Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, OJ L 106/5 (2001).

173 *Id.* at 8.

174 *Id.* at 10.

175 E. F. Einsiedel, *Public Perceptions of Transgenic Animals*, 24 Rev. Sci. Tech. 149, 154 (2005).

176 Commn. Reg. 641/2004/EC on genetically modified food and feed, OJ L 102/1 (2004); Reg. 1829/2003/EC on genetically modified food and feed, OJ L 268/6–7 (2003); Reg. 1830/2003/EC concerning the traceability and labeling of genetically modified organisms, OJ L 268/24–25 (2003).

novel DNA or novel proteins present in the final food,[177] as do Thailand,[178] Taiwan,[179] South Korea,[180] and Russia under certain circumstances.[181] Brazil requires that all GE foods display an easily understood symbol: a yellow triangle with a "T" for transgenic.[182]

VII. STOPPING THE BLEEDING, SHIFTING THE CONSCIOUSNESS

> *Our knowledge and control of the environment is not absolute knowledge or absolute control. It is a cooperative understanding and response to forces that will bring about a proper unfolding of the earth process if we do not ourselves obstruct or distort these forces that seek their proper expression. I suggest that this is the ultimate lesson in physics, biology and all the sciences, as it is the ultimate wisdom of tribal peoples and the fundamental teaching of the great civilizations. If this has been obscured by the adolescent aspect of our earlier scientific and technological development, it is now becoming clear to us on an extensive scale. If responded to properly with our new knowledge and new competencies, these forces will find their integral expression in the spontaneities of the new ecological age. To assist in bringing this about is the present task of the human community.*[183]

The proposed approval of transgenic salmon has created substantial controversy in the U.S. and worldwide.[184] In June 2011, the U.S. House of Representatives, led by a bipartisan alliance of Representa-

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177 *Austrl. N.Z. Food Stands. Code* – Stand. 1.5.2 (2011) (available at http://www.comlaw.gov.au/Details/F2011C00118 (accessed Nov. 19, 2011)).

178 Ruud Valyasevi et al., Natl. Ctr. for Genetic Engg. & Biotechnology, *Current Status of Biosafety of Genetically Modified Foods in Thailand*, http://home.biotec.or.th/newscenter/Uploads/WE_pic/radF9579.pdf (Sept. 2003) (accessed Nov. 19, 2011).

179 USDA Foreign Agric. Serv. (FAS), *Global Agriculture Information Network Report: Taiwan Biotechnology Safety Assessment Guidelines for Biotech Foods* 1, http://www.fas.usda.gov/gainfiles/200112/135683042.pdf (Dec. 19, 2001) (accessed Nov. 19, 2011).

180 USDA FAS, *Global Agriculture Information Network Report: A Summary of Korean Regulations on Agro-Biotechnology Products* 1–2, http://www.fas.usda.gov/gainfiles/200207/145783456.pdf (July 31, 2002) (accessed Nov. 19, 2011).

181 USDA FAS, *Global Agriculture Information Network Report: Russian Federation Annual Agricultural Biotechnology Report* 9, http://www.fas.usda.gov/gainfiles/200508/146130616.pdf (July 15, 2005) (accessed Nov. 19, 2011).

182 Braz. L. No. 11.105 of 24 Mar. 2005; Ordin. 2658/03 of the Ministry of Just. (available at http://anfalpet.org.br/portal/images/stories/Portaria_2658.pdf (accessed Nov. 19, 2011)).

183 Thomas Berry, *The Dream of the Earth* 48–49 (Sierra Club Bks. 1988).

184 S. 230, 112th Cong. (Jan. 31, 2011); H.R. 521, 112th Cong. (Feb. 8, 2011): S. 229, 112th Cong. (Jan. 31, 2011); H.R. 520, 112th Cong. (Feb. 8, 2011); Cal. Assembly 88, 2011–2012 Reg. Sess. (Mar. 21, 2011); Can. H. of Commons M-648, 40th Parliament 3rd Sess. (Mar. 1, 2011); Ltr. from Mark Begich et al., U.S. Sen., to Margaret Hamburg, Commr., FDA, *Concern over Approval of GE Fish* (Sept. 28, 2010) (copy on file with *Animal Law*); Ltr. from Peter A. DeFazio et al., U.S. Cong., to Margaret Hamburg, Commr., FDA, *Concern over Approval of GE Fish* (Sept. 29, 2010) (copy on file with *Animal Law*); Ltr. from Jared Huffmann et al., Cal. Legis., to Margaret Hamburg, Commr., FDA, *Concern over Approval of GE Fish* (Sept. 16, 2010) (copy on file with *Animal Law*).

tives from key salmon states, passed an amendment to FDA's appropriations bill that would prevent any funds from being used for GE salmon's approval.[185] However, if and when FDA does approve the transgenic salmon—without, at a minimum, first complying with environmental laws such as NEPA and the ESA, adjusting its regulatory framework under FFDCA to better assess and regulate the specific risks of transgenic animals and to allow for more transparency, and to require labeling—Center for Food Safety (CFS) and several other environmental, fisheries, and consumer public interest organizations have vowed to file suit challenging the decision. Further, on September 28, 2011, CFS filed a petition with FDA arguing that it must require labeling for all transgenic foods, including GE salmon, if approved.[186]

We have a saying at CFS: our work is to both "stop the bleeding and shift the consciousness." Most of our days are taken up with the former. Concrete actions such as administrative petitions, litigation, and state and local legislation are components. But these actions will not be sufficient in and of themselves. Fostering a shift in consciousness requires recognizing and addressing the underlying philosophy that drives and controls technological innovation. An order of magnitude in change is required, a paradigm shift to a system of governance and life that is based on coexistence with and benefit to natural systems. Human technologies should function within an integral relationship with earth technologies, not in a despotic manner. As Thomas Berry explains in *The Dream of the Earth*, we must move from the technological age to the ecological age.[187] This requires treating ourselves and the natural world as part of an interconnected web; to stop thinking in straight lines and start thinking, like the salmon, in circles. Without question, this is an idealized vision, but still considerably less naïve than the world vision that claims we can sustain our current industrial food system.

Furthermore, the issue of animal biotechnology is a microcosm of a larger U.S. oversight failing: over forty years have passed since the enactment of our major environmental laws. Rethinking transgenic organism oversight is an opportunity to ameliorate long-festering problems with U.S. oversight structures. Animal biotechnology developments highlight the outdated nature of our current regulatory vehicles and how ill equipped they are to deal with the issues of the

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185 H.R. Amend. 449, 112th Cong. (June 15, 2011) (amendment to H.R. 2112); Jeff Young, *House Gives Transgenic Salmon the Hook*, http://www.loe.org/blog/blogs.html?seriesID=1&blogID=9 (June 17, 2011) (accessed Nov. 19, 2011).

186 CFS, *Coalition of Consumer, Environmental, Farm Groups, and Food Companies Demand FDA Issue New Regulations on GE Foods*, http://www.centerforfoodsafety.org/2011/10/04/groups-file-legal-petition-with-fda-demanding-labeling-of-genetically-engineered-foods/ (Oct. 4, 2011) (accessed Nov. 19, 2011); *see also* CFS, *Citizen Petition before the U.S. Food and Drug Administration*, http://gmolabeling.files.wordpress.com/2011/10/ge-labeling-petition-10-11-2011-final.pdf (Oct., 11, 2011) (accessed Nov. 19, 2011).

187 Berry, *supra* n. 183, at 36–50 (describing the "ecological age").

twenty-first century. Lacking a new generation of laws more in line with the ecological and technological realities of this century, those entrusted with protecting public health and the environment can only continue to try and squeeze blood from the existing statutory stones. The animal biotechnology dialogue provides the challenge and the opportunity to rethink this social contract.