UNITED STATES FOOD AND DRUG ADMINISTRATION

Draft Environmental Assessment and Preliminary Finding of No Significant Impact Concerning a Genetically Engineered Atlantic Salmon; Availability. 77 Fed. Reg. 76,050 (December 26, 2012)	Docket No. FDA-2011-N-0899 Submitted: April 26, 2013

Earthjustice and Center for Food Safety hereby submit these comments regarding the U.S. Food and Drug Administration (FDA)'s Draft Environmental Assessment (EA) and Preliminary Finding of No Significant Impact (FONSI) for the AquaBounty Technologies' genetically engineered (GE) salmon, AquAdvantage Salmon. 77 Fed. Reg. 76050 (Dec. 26, 2012). These comments are also endorsed and joined by Friends of the Earth.

Earthjustice is the largest nonprofit public-interest environmental law firm in the world. Through administrative advocacy and litigation, Earthjustice has helped to create a better protected and healthier environment. Since its founding 40 years ago, Earthjustice has represented more than 1,000 public-interest clients. It has been a leader in ensuring that federal agencies comply with the National Environmental Policy Act and the Endangered Species Act by carefully evaluating the environmental and species effects of proposed actions. Earthjustice has been closely involved for a number of years with efforts to ensure that genetically engineered organisms are properly studied and regulated.[1]

Center for Food Safety (CFS) is national nonprofit public interest and environmental advocacy organization working to protect human health and the environment by curbing the use of harmful food production technologies.[2] In furtherance of this mission CFS uses legal actions, groundbreaking scientific and policy reports, books and other educational materials, and grassroots campaigns, on behalf of its 300,000 members. CFS is a recognized national leader on the issue of genetically engineered organisms, and has worked on improving their regulation and addressing their impacts continuously since the organization's inception in 1997.

[1] *See generally* www.earthjustice.org
[2] *See generally* www.centerforfoodsafety.org

INTRODUCTION

FDA is proposing approval of AquaBounty's transgenic salmon as the first-ever commercial GE animal intended for human consumption. As currently constructed, this approval action would be a monumental mistake, with grave consequences. It would also be fundamentally contrary to sound science, prudent policy and applicable law.

Despite the unprecedented nature of its proposed action, FDA inexplicably did not undertake the legally-required, rigorous, and overarching analysis of the GE AquAdvantage Salmon, or the foreseeable consequences of its approval. Instead, FDA manufactured and then applied an intentionally cramped and cursory review, refusing to assess any impacts beyond those presented by AquaBounty's first two development facilities, despite being well aware that AquaBounty has specific plans to expand well beyond those facilities as quickly as possible. In an apparent attempt to further evade review and lessen the substantial controversy, the facilities are located abroad, in Panama and Canada, even though the intended initial market is the United States. Economics, logic, AquaBounty's own public statements, and government records belie this limited scope, and reveal that this machination is just the first step in a series of related actions, intentionally and artificially truncated to avoid required regulatory scrutiny and impact analysis. Producing the transgenic fish in other, unanalyzed facilities is not just intended and certain, but already in motion.

Further, FDA's review of even these two first facilities is egregiously flawed and inadequate, relying entirely on outdated scientific methodology, poor data, AquaBounty's unsupported assurances of containment, and a stubborn refusal to analyze the impacts should such containment fail. Preeminent scientists have repeatedly warned the agency that its review is deeply flawed. Government scientists with the expert wildlife agencies have also expressed alarm. Nearly 1.5 million Americans have voiced their vehement opposition. Congressional leaders have expressed their opposition in direct comments to the agency and proposed legislation. Leading environmental organizations such as the undersigned have sought comprehensive regulation and public disclosure by the government of activities related to GE salmon for more than a decade. FDA has rebuffed all of these concerns and efforts and instead has charged ahead heedlessly.

FDA's errors stem in large part from the legally unsound regulatory pathway it has chosen for transgenic animals. In 2009, FDA announced in a guidance document that it was asserting its Federal Food Drug and Cosmetic Act (FFDCA) jurisdiction over GE animals, and would regulate them as "new animal drugs." That is how the agency has proceeded here. Essentially, FDA bases review of traditional animal drugs on whether they are safe and effective, *i.e.*, whether they harm the animal to which they are given and whether they do as they claim. But GE animals are vastly different from veterinary animal drugs. They require very different kinds of risk assessments, scientific expertise, and public process.

Accordingly, first, FDA's proposed approval violates the FFDCA and the Administrative Procedure Act (APA) because it is an ultra vires and arbitrary and capricious application of the agency's authority. FDA must halt its current course and seek further authority from Congress before considering approval of any GE animals, including the AquAdvantage salmon. Absent

that, at a minimum the agency must promulgate binding FFDCA regulations specific to transgenic animals, establishing how their foreseeable environmental and socioeconomic impacts are encompassed within FDA's review standard, and issuing regulatory amendments to account for the novel risks they create, including interagency cooperation and increased transparency. Failure to so act and instead to approve the New Animal Drug Application (NADA) under the agency's current path would violate the FFDCA and APA.

Second, FDA's proposed approval violates the National Environmental Policy Act (NEPA). FDA's draft Environmental Assessment (EA) is wholly inadequate and the agency's Finding of No Significant Impact (FONSI) is arbitrary and capricious. The EA is based on incomplete and inadequate science and analyses, lacks critical data and vital risk assessments, and ignores potential consequences and uncertainties. The EA's scope is unlawfully narrow, focusing only on the two AquaBounty facilities located in Canada and Panama, thereby willfully ignoring the plainly foreseeable environmental and socioeconomic impacts of introducing GE salmon into the United States and other countries. The EA unlawfully relies on purported mitigation by AquaBounty, and on unsupported promises of future FDA analysis regarding environmental impacts of GE salmon. The EA's alternatives section is unlawfully narrow and illegally predetermined.

Instead, FDA must prepare a full Environmental Impact Statement (EIS) and a Programmatic EIS, because the agency's approval action may have significant impacts on the environment. These impacts include harm to wild salmon stocks and aquatic ecosystems from the escape of the AquaBounty salmon, as well as other environmental impacts of transgenic salmon farming, such as impacts on forage fisheries used for feed. The EIS must analyze the true scope of FDA's action, including foreseeable cumulative, connected and related future actions, such as the planned expansion, development and sale of the AquaBounty's transgenic salmon. A Programmatic EIS must analyze FDA's entire GE animal/GE fish program and the impacts of the "new animal drug" pathway FDA has created. These NEPA analyses must also include the significant intertwined socioeconomic and cultural impacts of escaped transgenic salmon on U.S. salmon fishing communities and tribes, as well as the public health questions that surround introducing a novel transgenic animal into the food supply for the first time. And the EIS must meaningfully consider and analyze all reasonable alternatives to the proposal, such as new projects and policies designed to support and expand sustainable commercial fishing practices, and protect and restore wild Atlantic salmon populations.

Third and finally, FDA's proposed approval violates the Endangered Species Act (ESA). The FDA's determination that its action will have "no effect" on threatened or protected species or their critical habitat suffers from the same fatal flaws as the agency's NEPA assessment, including relying on inadequate scientific data and an unlawful scope. Endangered species such as imperiled Atlantic salmon plainly may be affected by the approval, requiring FDA to formally consult with the expert wildlife agencies under the ESA before reaching any decision.

BACKGROUND

I. The Highly Precarious State of Wild Salmon in the United States.

A. Atlantic Salmon

Wild Atlantic salmon populations have experienced steep declines over the last centuries due to a variety of human-induced pressures including overexploitation, degradation of water quality, and damming of rivers.[3] Once inhabiting most rivers north of the Hudson River, Atlantic salmon (*Salmo salar*) in New England were severely diminished by as early as the start of the 19th century.[4] This trend has only escalated. An 1869 account of Atlantic salmon estimated that approximately 10,000 adult salmon returned to the Penobscot River alone.[5] Since 1967, the Atlantic salmon population of the entire Gulf of Maine Distinct Population Segment (GOM DPS) now rarely exceeds 5,000.[6]

Commercial fishing of wild Atlantic salmon was banned in U.S. federal waters by the New England Fishery Management Council's 1987 Fishery Management Plan.[7] In 2000, the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS) issued a final rule designating the GOM DPS as endangered under the ESA.[8] FWS and NMFS subsequently published a final rule in 2009 listing the expanded GOM DPS, updating the geographic boundaries of the freshwater range of the Atlantic salmon population to include the Androscoggin, Kennebec, and Penobscot river basins.[9] A final rule designating critical habitat for the GOM DPS was published in the Federal Register on June 19, 2009.[10]

While significant declines have occurred in all three generally recognized groups of Atlantic salmon—North American, European, and Baltic—the decline of Atlantic salmon in U.S. and Canada waters is particularly troubling. The historic range of the North American Atlantic salmon extended from northern Quebec southeast to Newfoundland, and southwest to the Long Island Sound.[11] According to the National Oceanic and Atmospheric Association's (NOAA's) Office of Protected Resources, however, "[t]he populations of Atlantic salmon present in the

---

[3] Office of Protected Resources, NOAA Fisheries, Atlantic salmon (Salmo salar). http://www.nmfs.noaa.gov/pr/species/fish/atlanticsalmon.htm (last visited Apr. 10, 2013).
[4] *Id.*
[5] Endangered and Threatened Species; Determination of Endangered Status for the Gulf of Maine Distinct Population Segment of Atlantic Salmon, Final Rule, 74 Fed. Reg. 29,344, 29,349 (June 19, 2009) (citing Fay *et al.*, 2006).
[6] *Id.*
[7] National Marine Fisheries Service and U.S. Fish and Wildlife Service (2005). Recovery Plan for the Gulf of Maine Distinct Population Segment of Atlantic Salmon (*Salmo salar*). National Marine Fisheries Service, Silver Spring, MD, 1-52. www.nmfs.noaa.gov/pr/pdfs/recovery/salmon_atlantic.pdf,
[8] Endangered and Threatened Species; Final Endangered Status for a Distinct Population Segment of Anadromous Atlantic Salmon (*Salmo salar*) in the Gulf of Maine, Final Rule, 65 Fed. Reg. 69,459 (Nov. 17, 2000).
[9] Designation of Critical Habitat for Atlantic Salmon (Salmon salar) Gulf of Maine Distinct Population Segment: Final Rule, 74 Fed. Reg. 29300 (June 19, 2009).
[10] Endangered and Threated Species; Designation of Critical Habitat for Atlantic Salmon (Salmo salar) Gulf of Maine Distinct Population Segment, Final Rule, 74 Fed. Reg. 29300 (June 19, 2009).
[11] Office of Protected Resources, NOAA Fisheries, Atlantic salmon (Salmo salar)., http://www.nmfs.noaa.gov/pr/species/fish/atlanticsalmon.htm

Gulf of Maine DPS represent the last wild populations of U.S. Atlantic salmon"[12] (emphasis added). The current dire situation is exacerbated by the fact that in this last refuge in Maine, very few rivers support wild Atlantic salmon. Specifically, of the New England rivers in which Atlantic salmon runs were historically found, only 16% currently support salmon. In these rivers, Atlantic salmon are considered to be in "critical condition."[13] A 2006 review of the status of Atlantic salmon populations estimated the probability of extinction using Population Visibility Analysis (PVA) and found that "the likelihood of extinction ranges from 19% to 75% within the next 100 years, even with the continuation of current levels of hatchery supplementation."[14]

Atlantic salmon continue to face threats that may jeopardize their environment and continued existence. Although salmon fishing is currently prohibited in the State of Maine, illegal harvest, bycatch, incidental take, and other pressures still represent significant risks to the recovery of Atlantic salmon.[15] NOAA also recognizes aquaculture practices as one of the threats facing the remaining Atlantic salmon population as they "pose ecological and genetic risks."[16] The same is true for transgenic salmon, which have been banned off the coast of Maine since 2003.[17]

B. Pacific Salmonids

Pacific salmonid populations have also faced significant declines on the west coast of the United States.[18] Pacific salmonid species are vulnerable to a number of significant natural and human threats, among them: aquaculture,[19] hydropower, agriculture, flood control, natural resource extraction, and fishing.[20]

According to NOAA's Office of Protected Resources, the majority of fish listed as endangered or threatened under the Endangered Species Act are Pacific salmonids, including certain populations of Chinook salmon (*Oncorhynchus tshawytscha*), chum salmon (*Oncorhynchus keta*), coho salmon (*Oncorhynchus kisutch*), sockeye salmon (*Oncorhynchus nerka*), and steelhead trout (*Oncorhynchus mykiss*).[21] In 2005, NMFS issued a final rule

---

[12] *Id.*
[13] U.S. Food and Drug Administration, An overview of Atlantic salmon, its natural history, aquaculture, and genetic engineering http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222635.htm (last visited Apr. 11, 2013) ("In 2004, only 60-113 individual fish were counted in the eight rivers in Maine that support Atlantic salmon.").
[14] Fay et al. (2006). Status Review for Anadromous Atlantic Salmon (Salmo salar) in the United States, 5. www.nmfs.noaa.gov/pr/pdfs/statusreviews/atlanticsalmon.pdf
[15] Fay et al. at 121-22; *see also* National Marine Fisheries Service and U.S. Fish and Wildlife Service (2005). Recovery Plan for the Gulf of Maine Distinct Population Segment of Atlantic Salmon (*Salmo salar*). National Marine Fisheries Service, Silver Spring, MD, 1-53 www.nmfs.noaa.gov/pr/pdfs/**recovery**/**salmon_atlantic**.pdf.
[16] Office of Protected Resources, NOAA Fisheries, Atlantic salmon (Salmo salar).
[17] Endangered Species Act Section 7 Consultation, Biological Opinion, Proposed modification of existing ACOE permits authorizing the installation and maintenance of aquaculture fish pens within the State of Maine ((November 19, 2003). Select pages attached as Attachment 1 hereto.
[18] Office of Protected Resources, NOAA Fisheries, Pacific Salmonids: Major Threats and Impacts http://www.nmfs.noaa.gov/pr/species/fish/salmon.htm (last visited Apr. 19, 2013).
[19] *See, e.g., Naylor*, et al. 2003. Salmon Aquaculture in the Pacific Northwest: A Global Industry. *Environment* 45(8), 18-39.
[20] *Id.*
[21] *Id.*

designating twelve Evolutionarily Significant Units (ESUs) of West Coast salmon (chum, sockeye, chinook) and steelhead under the ESA.[22]

The Pacific salmon life history usually involves one to five years of feeding in the North Pacific Ocean as juveniles and sub-adults.[23] As is the case with Atlantic salmon, Pacific salmon can cover thousands of miles during this period before their eventual return to rivers to spawn.[24]

II. FDA's Flawed and Unsuitable Regulation of GE Food Animals as New Animal Drugs, Including AquAdvantage Salmon.

In the absence of comprehensive federal law intended to address the novel impacts of transgenic organisms, FDA has attempted to define its own jurisdiction to apply pre-existing authority to regulate any new GE animals, like AquAdvantage Salmon. Although FDA had been considering the AquaBounty application for many years, FDA did not publicly announce its view of how its FFDCA authority would apply to transgenic animals until 2009, when it issued Guidance for Industry 187.[25] That guidance document formally proclaimed exclusive jurisdiction over GE animals via FDA's statutory authority to regulate new animal drugs. To justify expansion of this jurisdiction, FDA has adopted an exceedingly strained interpretation of the FFDCA's definition of "drug," which includes, among other things, "articles (other than food) intended to affect the structure of any function of the body of man or other animals," 21 U.S.C. 321(g), and "new animal drug," which is any drug that is intended for use in animals and is not generally recognized by "experts qualified by scientific training and experience" as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling, and has not been used to a material extent or for a material time. 21 U.S.C. § 321(v). According to FDA, these definitions encompass an rDNA construct in a GE animal that is intended to affect structure or function of the GE animal's body, thereby allowing the agency to regulate GE animals like AquAdvantage Salmon using existing regulations for new animal drugs. This novel effort by FDA to expand its jurisdiction has no support in the law. Moreover, FDA's new animal drug requirements do not contemplate and are not equipped to address the unique environmental and ecological issues inherent in the creation and development of GE animals.

Numerous organizations, including CFS, filed detailed comments with FDA in 2009 arguing that the framework set forth in Guidance 187 was simply unsuitable for the regulation of GE animals and GE fish. A coalition of fishing industry organizations also filed comments specific to the problems with the Guidance and the risks of GE fish. The U.S. Fish and Wildlife Service submitted comments on the Guidance, stating that "[c]omprehensive review of risks associated with genetically engineered animals requires a wide variety of expertise from multiple disciplines. The Services expertise in fish and wildlife biology, ecology and management should

[22] Endangered and Threatened Species; Designation of Critical Habitat for 12 Evolutionarily Significant Units of West Coast Salmon and Steelhead in Washington, Oregon, and Idaho, Final Rule, 70 Fed. Reg. 52,630 (Sept. 2, 2005).
[23] 70 Fed. Reg. at 52,662.
[24] *Id.*
[25] FDA Guidance for Industry 187: Regulation for Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs. Attachment 2 hereto.

be considered as policy and regulations for genetically engineered aquatic animals are developed and implemented."[26] In that letter, FWS expressly recommended that FDA "consult with the Service when reviewing New Animal Drug Applications for genetically engineered aquatic animals and when determining whether or not to exercise enforcement discretion of the NADA process for genetically engineered aquatic animals."[27] In response, FDA declared that Guidance 187 was not a rule-making and was non-binding.[28] This pending AquaBounty application for GE AquAdvantage Salmon is the first application for a transgenic animal produced for food that FDA is considering pursuant to the Guidance 187 framework. FDA's review, therefore, is both significant and precedent-setting.

III. Science-Based Controversy Surrounding FDA's Environmental Review of AquAdvantage Salmon.

FDA's current proposal is extremely controversial and its review of the potential associated environmental impacts has been severely criticized by many leading scientists with relevant expertise, including most prominently, Dr. Anne Kapuscinski, whose work on environmental risk assessment of transgenic fish has repeatedly been referenced in FDA's EA and who is regarded by government scientists as a preeminent expert in this field.

A. Comments by Experts in Environmental Risk Assessment of Transgenic Fish.

In September 2010, shortly after AquaBounty's EA[29] was made public, FDA released a Briefing Packet summarizing its evaluation of the AquAdvantage Salmon NADA.[30] At that time, FDA announced that it would be hosting a public meeting for discussion of the Briefing Packet with the Veterinary Medicine Advisory Committee (VMAC)—a panel of non-FDA experts the agency had appointed to review the agency's analysis for the AquAdvantage Salmon. Notably, only one member of the Committee—Dr. Gary Thorgaard, a fisheries biologist—had the kind of expertise necessary to properly evaluate FDA's environmental assessment.

FDA provided just 18 days between the release of its Briefing Packet and the VMAC meeting for the public to provide written comments. Noting that the period for comment was "much too short for adequate examination by the community of scientific experts on the genetics and ecology of transgenic fish and on methodologies for environmental risk assessment of transgenic fish," Drs. Kapuscinski and Fredrik Sundström —two preeminent scientists in the field—submitted detailed comments to FDA identifying significant questions and concerns

[26] U.S. Fish and Wildlife Service Comment Letter (November 18, 2008). Attachment 3 hereto.
[27] *Id*.
[28] FDA response to comments on Guidance 187, *at* http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113612.htm
[29] Environmental Assessment for AquAdvantage Salmon, AquaBounty Technologies, Inc. (August 25, 2010). Attachment 4 hereto.
[30] Briefing Packet, FDA Center for Veterinary Medicine, Veterinary Medicine Advisory Committee (Sept. 20, 2010). Attachment 5 hereto.

regarding the agency's environmental risk assessment of the AquAdvantage Salmon.[31] These comments are extremely relevant to the adequacy of FDA's draft EA and are adopted here in full and referenced throughout herein.[32]

In their 2010 comments, Kapuscinski and Sundström raised two primary concerns regarding the environmental assessment of AquAdvantage Salmon. The first questioned FDA's ability to assure and verify that the confinement measures proposed by AquaBounty are continually achieved at the PEI and Panama sites, and in future facilities, as farming of the AquAdvantage Salmon proliferates.[33] The second concern was that "[t]he scope of the Environmental Assessment is too narrow and its methods inadequate for the issues at hand." [34] They therefore urged FDA to "require a complement environmental risk assessment, as a fully transparent Environmental Impact Statement (EIS)."[35] As to the issue of the proper scope of FDA's analysis, Kapuscinski and Sundström explained:

> The current Environmental Assessment only assesses the likelihood of transgenic salmon escaping from multiple confinement at the two facilities but the proposed multiple confinement does not absolve the need for a complete environmental risk assessment, given the likely proliferation of sales of AAS eggs for growout beyond one facility in Panama. The Environmental Assessment does not provide the full information needed to predict environmental effects of AAS…It focuses on an outdated list of issues (from Kapuscinski and Hallerman 1991) and ignores the major advances in methodologies for assessing environmental risks of transgenic fish (Kapuscinski et al. 2007). These advanced methods systematically integrate information about the environment and the transgenic fish's genotype and phenotyle to identify and prioritize hazards upon which to focus the environmental risk assessment (Devlin et al. 2007, Kapuscinski et al. 2007a, Hayes et al. 2007).[36]

Kapuscinski and Sundström did not limit their comments to merely identifying these problems. Rather, they offered their directly relevant expertise in environmental risk assessment of transgenic fish, and provided FDA with specific recommendations for conducting a full and adequate science-based environmental review: (1) completion of a "quantitative failure mode analysis for each form of biological, mechanical, and geographical confinement and for the overall combination of confinement methods," and (2) completion of a "scientifically rigorous Environmental Impact Statement" that "assesses the potential genetic and ecological impacts that

---

[31] Comments on Environmental Assessment for AquAdvantage Salmon and Briefing Packet on AquAdvantage Salmon for the Veterinary Medicine Advisory Committee by Anne Kapuscinski and Fredrik Sundstöm (2010) (hereafter, "2010 Kapuscinski, Sundström Comments"). Attachment 6 hereto.

[32] Dr. Kapuscinski's and Dr. Sundström's written comments are not readily accessible on FDA's on-line administrative docket. We note that all written comment submissions made following release of the 2010 AquaBounty EA and for the VMAC must be made public and are necessarily part of the agency's administrative record for this action.

[33] 2010 Kapuscinski and Sundström Comments at 2.

[34] *Id.*

[35] *Id*.

[36] *Id.*

AquAdvantage Salmon could have on wild fish and other aspects of the environment."[37] Kapuscinski and Sundström fleshed each recommendation out fully and specifically.[38]

Kapuscinski and Sundström explained precisely the kind of failures FDA should account for in its evaluation of AquaBounty's proposed containment measures using a quantitative failure mode analysis, and recommended "doing failure mode analysis for the full range of facilities that may obtain AquAdvantage Salmon eggs in the foreseeable future, as part of a full EIS.".[39]

Kapuscinski and Sundström also explained that the EA did not provide all of the information needed to predict the environmental effects of AquAdvantage Salmon, and the need for an EIS:

> [The EA] focuses on completing only the 'exposure' step of risk assessment, and concludes there is 'extremely small' likelihood of exposure due to multiple confinement at the two facilities, thus no consequence and no need to assess the consequences. <u>As scientists, we cannot agree with this approach because it assumes 100% achievement of multiple confinement without having presented the failure mode analysis that is standard practice in technology risk assessment</u>. Even if actual exposure is very close to zero, it is still necessary to assess ecological consequences, from low to high severity consequences, and then estimate the overall risk. We also disagree with this approach because of the likely proliferation of farming AAS in numerous grow-out facilities where multiple confinement will be harder to implement and assure (Mair et al 2007).[40]

They continued to describe the information lacking in the agency's analysis, *id*. at 4, and to state that the EA did not adequately consider the growing body of research on genetic and ecological risks of transgenic fish that "shows there will be high scientific uncertainty in predicting the overall fitness and ecological effects of AAS if they enter nature because it is extremely challenging to extrapolate from experiments using semi-natural conditions (reviewed in Devlin et al. 2007, Devlin et al. 2006, Kapuscinski et al. 2007)."[41] This, they explained, "is due to key biological complexities including gene-environment interactions, background genetic effects, pleiotropic effects, tradeoffs between traits expressed across different life stages, persistent effects of the environment experienced early in lie, evolution of fertile transgenic fish after escape, ecological variability, and poorly understood ecological processes (Devlin et al. 2004b, 2007, Kapuscinski et al. 2007, Neregard et al. 2008, Pennington and Kapuscinski in press, Sundström et al. 2007b, 2009).[42] They continued:

> Overall, this research indicates it could be very misleading to base an environmental risk assessment on data for only a few traits that do not span the whole life-cycle and measured under a limited range of environmental conditions.

---

[37] *Id*. at 3-4.
[38] *Id*. 3-8.
[39] *Id.* at 3-4.
[40] *Id*. at 4 (emphasis added).
[41] *Id*.
[42] *Id*.

> We are therefore concerned about overly simplistic statements of 'poor fitness' of AAS without the kinds of scientific evidence required to support such a claim….Also, the Environmental Assessment gave an unacceptably cursory mention of uncertainty… with no application of scientific methods of uncertainty analysis (Hayes et al. 2007a).[43]

Thus Kapuscinski and Sundström urged FDA to abandon the "outdated" risk methods relied upon in the EA and Briefing Packet (methods Dr. Kapuscinski herself developed), and instead follow the current, standard, "science-driven" ecological risk assessment methodology, which allows for "direct" and "honest" consideration of the "complexity and uncertainty inherent to environmental risk assessment of transgenic fish."[44]

Following submission of their written comments, Dr. Kapuscinski presented their concerns in oral testimony at the VMAC Meeting, emphasizing that the EA "does not adequately address the major questions that should be asked about genetic and ecological risks," and that FDA must evaluate the "ecological consequences and then estimate the overall risk especially given the precedent set by this Environmental Assessment."[45]

Dr. Kapuscinski continued to express her concerns regarding FDA's environmental analysis publicly after the VMAC and while the agency deliberated over the NADA.[46] In early 2013, after the current draft EA was released for public comment, Dr. Kapuscinski publicly shared her opinion that FDA still has not addressed the risk assessment deficiencies she and Dr. Sundström identified for the agency in 2010.[47] Particularly significant points raised by Dr. Kapuscinski during this interview are noted below:

> Risk assessment normally has three steps. One, you identify what the hazard is. Two, you figure out what the consequences would be to the environment if the hazard were to be realized. And the third step is, you say, "well, can we somehow manage the risk, can we do something to prevent the consequences from happening?"
>
> What FDA has done, in both the 2010 draft and 2012 draft EA, is essentially skip to step three, the risk management step. Both versions are saying: We have so many different kinds of confinement, so we are concluding that the chances of any of these fish escaping and being able to establish a reproducing population is virtually zero.
>
> The FDA has not changed much about that, compared to the 2010 EA, except for a few details. They're still hanging their whole conclusion on risk management—that is, multiple confinement systems for the fish. But what they still haven't done is what Dr.

[43] *Id.* at 5 (internal citations omitted) (emphasis added).
[44] *Id.*
[45] Dr. Kapuscinski VMAC Meeting Comments, Attachment 7 hereto; AquAdvantage Salmon, Transcript (Sept. 19-20, 2010) (hereafter "VMAC Transcript"), at 321:12-21; 321:22-25. Attachment 8 hereto.
[46] National Public Radio, Debating Genetically Modified Salmon (Dec. 9, 2011), *available at* http://www.npr.org/2011/12/09/143453487/debating-genetically-modified-salmon. Attachment 9 hereto.
[47] A risk scientist comments on AquaBounty Salmon (updated March 11, 2013), *available at* http://www.flashinthepan.net/?p=1019. (hereafter "2013 Kapuscinski Interview"). Attachment 10 hereto.

> Sundström and I asked for, which is a quantitative failure mode analysis. If multiple confinement is what their entire conclusion really rests on, and if they are correct that the levels of confinement are so great all in combination, a quantitative failure mode analysis should actually come to that same conclusion. And it would be a much more scientifically reliable way of substantiating the conclusion. As said before in our written comments, it's a standard practice in risk assessment and risk management to do a failure mode analysis, and it should be as quantitative as possible.
>
> A key part of step two is a consequence assessment. That's where one is asking, "if the fish did escape, what would happen, could that harm the environment?" In the 2012 draft EA, the FDA changed basically nothing from what was laid out as a consequence assessment in the 2010 EA, and it's just as weak and just as scientifically unacceptable as it was in the 2010 draft. Dr. Sundström and I fully explained the scientific weaknesses in our 2010 comments. I recommend that they cut out the consequence assessment, unless they are willing to make all of the changes that Dr. Sundström and I had recommended two years ago.
> ...
>
> They [FDA] are still refusing to pay attention to the updating of ecological risk assessment science that's all pulled together in a book published by a large group of scientists in 2007. Throughout both the 2010 and 2012 EA, the text cited two important publications that I led back in the early 1990s, one of which I was lead author and the other by a working group I chaired.
>
> The FDA is hinging most of its scientific approach on the consequence assessment on those two reports. And yet I myself am now saying that they've been replaced by better methods.
>
> Back in 1991 and 1995, those two reports were the best thinking about what would be the sets of questions we should be asking and how to go about getting information for environmental risk assessment. But the science has advanced tremendously since then, so much that we felt it was important to bring together all of the key scientific advances in a book published in 2007. That book went through really rigorous peer review. It was blind peer-reviewed by reviewers from around the world. The scientifically honest way to do this consequence assessment now would be to look at the best advances and draw on the best science.[48]

Asked how she feels about the fact that "your work from the 1990s is cited 14 times in [the current draft EA], yet the FDA isn't taking your recommendations," Dr. Kapuscinski stated:

> Ph.D. students are required to write a dissertation proposal and defend it before a committee. If a student cited literature in the way it was done in this report, we would fail them.

[48] *Id*. (emphases added).

> Students would get into serious trouble if they were citing really old methods, and there had been huge advances in the methods since then and they ignored that. That would be a reason to fail them.[49]

In addition to Dr. Kapuscinski, several other scientists and many environmental advocates voiced similar concerns at the VMAC, calling on FDA to complete a comprehensive environmental review. Dr. Eric Hallerman, one of FDA's presenters at the VMAC Meeting, stated that the "development of quantitative risk assessment is presently incomplete … especially regarding the likelihood of harm given exposure to the hazard. We need more studies quantifying net fitness, especially under near-wild, or wild, conditions."[50] As Dr. Hallerman put it, "we have a lot to learn about the likelihood of genetic harm being realized due to the interbreeding of wild and transgenic aquacultured fish."[51]

Even members of FDA's VMAC realized the flaws and gaps in FDA's environmental analysis. Dr. Thorgaard—again, the only fish scientist on the panel—concluded that in light of these concerns, "considering this issue in a comprehensive way, together with other agencies through an environmental impact statement, would be the best way to proceed."[52]

B. Comments of the U.S. Fish & Wildlife Service and the National Marine Fisheries Service.

Concerns about FDA's inadequate analysis have also been voiced from within the federal government—in particular, the two agencies with expertise in fish biology and marine ecosystems: the U.S. Fish & Wildlife Service and the National Marine Fisheries Service.

Shortly after the release of the 2010 Briefing Packet for AquAdvantage Salmon, Dr. Gregory Moyer, a Regional Geneticist with FWS, sent FDA a letter outlining "several criticisms and concerns" regarding the Briefing Packet, specifically the environmental risk analysis.[53] Dr. Moyer's noted that the Briefing Packet "falls short of providing an actual risk assessment of putative environmental damages in the event of escapement."[54] He explained that the "environmental analysis should provide an overview of the general risks associated with escapement or hybridization of GE and wild type individuals" which "would provide readers with an understanding of the potential harm and the degree of harm posed by GE organisms even when the risk of escapement is low." [55] He urged FDA to "more accurately quantif[y]" both the risk of escapement and degree of harm if escapement occurs.[56] Dr. Moyer added that he was concerned with phrases like "are unlikely to survive if exposed to high salinity and low temperature" "when no data have been collected on AquAdvantage salmon to evaluate the likelihood of these scenarios."[57] He further stated that although AquaBounty currently has "in

---

[49] *Id*.
[50] VMAC Transcript (Sept. 20, 2010) at 86:1-6.
[51] *Id*. at 80:8-10.
[52] *Id*. at 383:19-23.
[53] Dr. Gregory Moyer Letter to FDA (Sept. 30 2010), Attachment 11 hereto.
[54] *Id*.
[55] *Id*.
[56] *Id*.
[57] *Id*. (emphasis added).

place various standard operating procedures to minimize escapement and test for durability of the gene construct, I fail to see any policy in place for monitoring or enforcement of these SOPs by the [FDA]."[58]

Dr. Moyer's letter to FDA was followed by a similar one a few weeks later from a coalition of FWS fish conservation geneticists comprising the Conservation Genetics Community of Practice (COP).[59] This letter added:

> [T]he biological containment at either the PEI or Panama facilities along with the possible interaction of AquAdvantage salmon with endangered wild salmon stocks is of great concern to the COP. To this regard, AquaBounty Technologies has established several physical and biological containment mechanisms to prevent the escape of AquAdvantage salmon and the [EA] indicated escapement risk and establishment risks were low. However, history dictates that fish held in aquaculture facilities, either land- or water-based—escape. In addition, the information provided by AquaBounty Technologies for the likelihood of establishment relies on the assumption that farmed Atlantic salmon have not established themselves in North America. This assumption is clearly violated because Atlantic salmon juveniles have been found in several streams in the state of Washington as well as British Columbia. While interactions of these fish with native salmon are unknown any interaction between wild and transgenic salmon must be considered a serious threat. Numerous scientific publications have documented that interactions of wild and introduced fish have led to decreased numbers of wild fish (for ESA listed Atlantic stocks this is of great concern).[60]

The COP went on to explicitly state that the EA did "not give the full information needed to predict environmental effects of AquAdvantage salmon. The interpretation of findings could be very misleading because conclusions are based on data for only a few traits that do not span the life-cycle of the organism and are measured under a limited range of environmental conditions and time frames."[61] Thus, the COP recommended that FDA incorporate three specific sets of scientific data in its next EA, including that of Dr. Sundström, and also the 2007 work by Dr. Kapuscinski *et al.* assessing how fitness of transgenic fish, when they first escape, translates into environmental risk.[62] The COP also stated their view that the EA "is overly simplistic and does not adequately capture the actual risk of environmental damages to wild Atlantic salmon or the ecosystem" and that

> [a]dditional studies will be necessary to assess this risk and include (but not limited to): interbreeding with wild salmon, gene introgression into wild salmon stocks, hybridization with brown trout; disturbance of habitat or displacement of wild stocks as a result for competition for resources, predation, or even cross-mating resulting in population impact; spread of bacteria, viruses, parasites to wild salmon and other aquatic/estuarine species; ecological impacts associated

[58] *Id.* (emphasis added).
[59] Conservation Genetics Community of Practice Letter to FDA (Oct. 6, 2010). Attachment 12 hereto.
[60] *Id.*
[61] *Id.*
[62] *Id.*

> with their degree of fitness, interaction with other organisms, role in ecological processes, and potential for dispersal and persistence.[63]

As to FDA's regulatory authority, the COP noted:

> [The] current regulatory process is ineffective at handling such a situation. Economics and development take priority over the potential impact to the species or ecosystem. Instead, agencies (FDA, NOAA, USFWS) might benefit from a tiered approach to regulatory authority where such activities are reviewed, evaluated, and if approved, move to the next level of review. The ultimate or final review should lie with the authorities who manage the potentially impacted species (in the case of Atlantic salmon, those public resources are also far beyond just U.S. jurisdiction and include Panama, Canada, the European Union, and Russia). This approach would promote a "first do no harm" strategy designed to protect public resources (i.e. the target species or ecosystem of concern).[64]

Thus, the COP concluded that "[t]here are several unknowns and uncertainties regarding possible genetic, ecological, and environmental effects of AquAdvantage salmon that must be elucidated before an environmental risk assessment can be thoroughly evaluated and approved. This, along with a situation where regulatory oversight is adequate at best, suggests that approval of AquaBounty Technologies' request for commercial rearing of AquAdvantage salmon is premature."[65]

FWS' Northeast Region—Region 5, which encompasses 13 states, including Maine, and 18 Tribes—shared the COP's concerns and recommendations, and around that same time in 2010 circulated internally detailed comments urging disapproval of the AquaBounty application, and highlighting the awkward regulatory system by which FDA, rather than the agencies with relevant expertise, had jurisdiction over AquAdvantage Salmon.[66] Notably, in developing its position, FWS Region 5 consulted with Dr. Kapuscinski, noting that she is a "leader in the field of environmental risk assessment of transgenic fish," and that FWS had previously "benefited from her knowledge on this issue by having her as a keynote speaker at the Future Challenges Workshop" in August 2004 "where she spoke about transgenic fish and the need to develop effective ecological risk assessment approaches and regulatory processes."[67] FWS Region 5 specifically urged others at FWS to consider Dr. Kapuscinski's 2007 book titled, "Environmental Risk Assessment of Genetically Modified Organisms, Vol 3: Methodologies for Transgenic Fish", CABI Publishing, UK. 304pp.[68] [This is the same 2007 risk assessment book that Dr. Kapuscinski noted above, that FDA has ignored, favoring older, outdated methodologies.]

---

[63] *Id.*
[64] *Id.* (emphasis added).
[65] *Id.*
[66] Region 5 Fisheries Program Comments on FDA approval process for Aqua Bounty Technologies, Inc. (ABT)/ AquAdvantage GMO salmon. Attachment 13 hereto.
[67] *Id.*
[68] *Id.*

FWS Region 6 offered general concerns about escapement.[69] And other FWS scientists continued to express alarm regarding the potential problems with FDA's planned action.[70] On October 29, 2010, it was reported internally at FWS that "all but one Region opposes FDA approval" of the AquAdvantage Salmon NADA.[71]

NMFS has also expressed concerns. In 2010, NMFS sent a letter to FDA raising serious questions regarding containment of fertile AquAdvantage Salmon broodstock at the PEI facility, and the future marketing of AquAdvantage Salmon eggs.[72] In particular, NMFS pointed out the inconsistency between FDA's statements that its approval would be limited to particular limitations stated in the current NADA, and the agency's discussion of AquAdvantage eyed eggs produced for commercial sale.[73] NMFS noted that "[b]ecause the egg production facility and the grow-out facility are owned by AquaBounty Technologies, Inc., there would be no reason to sell the eggs unless another aquaculture facility was involved."[74] Thus, NMFS sought clarification "as to whether commercial resale of eyed eggs should be considered as part of this action" and urged that "[i]f eggs would not be sold commercially, the FDA should state definitely that these eggs would not be sold commercially nor would they be used in the United States."[75] The letter further requested additional information concerning the fertile, adult GE male AquAdvantage Salmon maintained at the PEI facility.[76]

NMFS also questioned FDA's decision to narrowly limit the action area to Canada and Panama only, noting that "the action area as defined in the ESA (50 CFR 402.02), should be identified as all areas of potential impacts as a result of this action.[77] The topics of selling commercially and rearing fertile adult males at the Canadian production facility both potentially increase the size of the action area to include the United States."[78] NMFS' letter appears to be tied to an internal agency memorandum listing various concerns with the NADA.[79] Among other things, this NMFS memonoted that:

- To produce eggs, transgenic females and neomales are used to produce eggs [sic].
- These fish can reproduce in the wild and produce genetically engineered Atlantic salmon alevins.
- It is possible, though not likely, these fish escape.
- If they escape, they would be likely they reproduce [sic] in the wild because hatchery released fish and hatchery sterilized fish continue to behave similar to wild fish (Trested et al. 2002).
- Sterilization measures are not 100% successful (approximately 95% success).

---

[69] E-mail from Larry R. Gamble to Linda Andreasen (Sept. 29, 2010). Attachment 14 hereto.
[70] FWS series of e-mails. Attachment 15 hereto.
[71] E-mail from Linda Andreasen to Joel Bader (Oct. 29, 2010). Attachment 16 hereto.
[72] NMFS Concerns Memo and Letter from Therese Conant, NMFS Acting Division Chief, Endangered Species Division, to Larissa Rudenko (Nov. 30, 2011). Attachment 17 (received from NMFS in response to January 2013 FOIA request).
[73] *Id*.
[74] *Id*. (emphasis added).
[75] *Id*.
[76] *Id*.
[77] *Id*.
[78] *Id*. (emphasis added).
[79] NMFS Concerns Memo and Letter, Attachment 17.

- Diploid genetically engineered fish would be fully capable of spawning.
- Successfully sterilized salmon would be attractive mates for wild fish and may reduce wild population fitness.
- [Regarding barriers], Described as 3-4 levels of protections, but that is the maximum. In some cases, there is only one screen between the tank and the wild.
- The EA claims discharges go directly to saltwater, creating a chemical barrier, but in fact discharges enter a several hundred yard long creek that then flows into saltwater. This creek could provide habitat to sustain juveniles.
- The barriers reduce the probability of an escape, but do not insure no escapes could ever happen.
- Because the EA didn't address [the subject of commercial sale of eggs], it is still unclear what risk this poses. Likely, if there is a high demand for eggs, that would require more fertile adults to produce those progeny.
- While unlikely, an introduction of genetically engineered Atlantic salmon could pose catastrophic threats to wild species.
- The egg production facility may pose a threat to wild Atlantic salmon, including Gulf of Maine DPS Atlantic salmon.
- Any fish introduced along the Pacific Coast would have unknown potential for affecting Pacific salmonids through hybridization.[80]

FDA and NFMS later met to discuss these issues, but regardless of what FDA represented during those meetings, NMFS' primary concerns were never clearly addressed. In particular, NMFS's prior concerns regarding the proper scope of FDA's analysis given the potential to grow AquAdvantage salmon eggs within the U.S. seem to have been completely ignored. According to a NMFS e-mail dated October 28, 2011, upon FDA's approval of this NADA, AquaBounty can sell AquAdvantage salmon eggs to companies anywhere in the U.S. for those companies to grow out.[81] The e-mail specifically states that "[t]here have been requests from several companies to USFWS (they regulate importing salmon to the US) to import those eggs, though Aqua[Bounty] has not discussed this with FDA."[82]

IV. Environmental Groups' Repeated Calls for Comprehensive Review and Transparency.

The overarching concerns and requests presented in these comments are not new or without consideration. To the contrary, public interest groups have repeatedly called on FDA and other governmental bodies to ensure adequate, transparent environmental review from the moment the public learned of this NADA.

First, over a dozen years ago, in 2001, CFS filed a suite of legal petitions with several federal agencies on the issue of transgenic fish.[83] CFS's actions were prompted in part by the first public revelation that industry and governmental steps were being taken towards potential commercial approval of GE fish. Neither FDA nor any other agency had yet declared a precise

[80] *Id.*
[81] E-mail from Jason Kahn to Jennifer Schulz (Oct. 28, 2011). Attachment 18 hereto.
[82] *Id.*
[83] *See* http://www.centerforfoodsafety.com/issues/309/ge-fish/legal-actions.

regulatory pathway, or explained how the federal agencies should integrate their authorities to address the issue; as a consequence CFS petitioned multiple agencies that had applicable statutory authority, including FDA, the Department of the Interior, the Department of Commerce, the U.S. Army Corps of Engineers, and the Department of Agriculture. CFS's petitions raised some of the very same issues and oversight lapses now being debated, calling on FDA and other agencies where relevant to, *inter alia*, establish new animal drug regulations specific to transgenic fish; establish regulations requiring monitoring, reporting and inspection procedures for any producers; require labeling of any GE fish; prohibit any approval of GE fish until and unless FDA completed an EIS and/or Programmatic EIS, and permanently prohibit such activities should they be shown to harm the environment; and prohibit any approval until and unless FDA consult with the expert wildlife agencies pursuant to the ESA.[84]

Next came FDA's Guidance 187, issued January 2009, which for the first time spelled out how FDA proposed to oversee GE animals using its FFDCA new animal drug authority. In response to the draft guidance, public interest groups filed extensive comments pointing out the flaws in FDA's proposal and the inapposite nature of the animal drug provisions as juxtaposed against the risks of genetically engineered animals. These included comments specific to the risks of GE fish, filed by a coalition of commercial fishing organizations. FDA made clear in the Guidance that it offered only "non-binding recommendations" and did "not establish legally enforceable responsibilities." [85]

After FDA produced its Briefing Packet for the AquAdvantage Salmon based on AquaBounty's August 2010 EA, environmental groups immediately raised substantial concerns regarding the adequacy of the EA and FDA's ability to properly assess the full range of potential risks presented by AquAdvantage Salmon.[86] Similar concerns were expressed by members of Congress and state legislatures, commercial fishermen groups, and consumer groups.

Finally, in May 2011, Earthjustice, on behalf of CFS, Ocean Conservancy, Friends of the Earth, Food and Water Watch, Greenpeace, and the Center for International Environmental Law, formally petitioned FDA to refrain from approving AquaBounty's NADA without first completing an EIS and revising its regulatory framework in a manner that fully and expressly accounts for the unique environmental risks presented by GE animals.[87] FDA has not yet issued a final response to the petition.

Throughout, despite the extensive public interest surrounding the AquAdvantage Salmon NADA, FDA's review process has been extraordinarily opaque, making it impossible for the public to participate in a meaningful way. In an effort to obtain relevant information concerning the NADA, Ocean Conservancy and Friends of the Earth submitted a Freedom of Information Act request to FDA in June 2011 seeking all documents, records, and materials concerning the application, including information that is known to have been submitted to the agency by AquaBounty. To date, FDA has not released the requested information or fully explained its

[84] *Id*.
[85] Guidance for Industry 187 at 5.
[86] *See, e.g.*, Environmental Group Letter re: AquaBounty Technologies' Genetically Engineered AquAdvantage Salmon (Feb. 1. 2011). Attachment 19 hereto.
[87] Citizen Petition (May 25, 2011). Attachments 20-23 hereto.

reasons for withholding it—instead providing only preliminary, incomplete, and confused responses.[88]

In a similar effort, upon release of the draft EA in December 2012, CFS and Friends of the Earth promptly sought information pertaining to FDA's ESA determination from the U.S. Fish and Wildlife Service and National Marine Fisheries Service. Both agencies have provided some responsive records and materials, but final releases have yet to occur. In the case of the National Marine Fisheries Service, timely release of certain requested information has been interrupted by the Executive Office of the President, Office of Management and Budget.[89]

ARGUMENT

I. FDA's Decision Violates the Federal Food Drug and Cosmetic Act (FFDCA) and Administrative Procedure Act (APA).

Genetically engineered animals are not animal drugs. FDA's attempt to regulate them under the animal drug provisions of the FFDCA is an *ultra vires* application of the agency's authority. The agency's interpretation of its authority to encompass these novel organisms and their concomitant novel significant risks, is an arbitrary and capricious application of its FFDCA "animal drug" authority.

The unlawful nature of FDA's attempted extension of its authority is made plain by its extremely problematic and inapposite application to AquaBounty's transgenic salmon. As explained in detail in these comments, FDA's review of the GE salmon's impacts is legally flawed and scientifically inadequate, failing to encompass or meaningfully review the most important impacts of this unprecedented transgenic fish. FDA's problems in this regard begin with the fundamentally flawed frame it attempts to apply to these novel organisms, whose attributes and risks simply cannot be forced to fit the pre-existing statutory frame.

Accordingly, FDA must halt this process, and instead request further authority from Congress before addressing these risks. At a minimum, it must replace non-binding Guidance 187 with binding regulations implementing FFDCA in a manner that can adequately oversee the substantial risks and impacts novel GE animals create. This will necessarily include oversight by other agencies, such as the Services, with the relevant expertise in evaluating impacts to protected species and habitats.[90]

First, the FFDCA defines the term "drug" as including, among other things, "articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . ." 21 U.S.C. § 321(g)(1)(C). "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

[88] In March 2012, Earthjustice filed an administrative appeal with the United States Department of Health and Human Services (DHHS) regarding FDA's failure to respond to the FOIA request. In March 2013, DHHS directed FDA to take action on the request. In response, FDA provided a status update explaining that the agency was continuing to search for releasable information and noting that that FDA's regulations prohibit the release of records contained within a pending New Animal Drug Application (citing 21 C.F.R. § 514.11).

[89] E-mail from Gary Jackson, NMFS FOIA Coordinator (April 15, 2013). Attachment 24 hereto.

[90] Commenters note that they previously raised this fundamental problem in their 2011 petition and called on the agency to fix it then before moving ahead with the AquaBounty application. FDA has failed to so act.

qualified by scientific training and experience" as safe and effective for use under the conditions prescribed, but which is intended for use in animals. *Id*. at § 321(v).

It is undisputed that genetically engineered animals, such as AquaBounty's transgenic salmon, are vastly different from veterinary animal drugs, the subject matter FDA regulates under the relevant provisions of the FFDCA. As mentioned above, in order to assert statutory authority over GE animals and bring them within the agency's purview, FDA has interpreted these FFDCA drug definitions to encompass the rDNA transgenic construct inside a transgenic animal, because the transgenic construct by design affects the "structure or function" of the body of the GE animal (in this case, purportedly making the salmon grow faster). FDA set forth this interpretation in Guidance 187, and applies it in the AquaBounty EA.[91]

However, FDA has not asserted authority over merely the transgenic construct; it has asserted authority over the entire GE organism(s), and purported to analyze the effects of the transgenic organism more broadly. Yet in neither Guidance 187 nor the AquaBounty EA does FDA explain how the entire transgenic animal, or here, the AquaBounty salmon, fits within its statutory animal drug authority. It is wholly unclear from FDA's EA what the agency believes to be the proper scope of the relevant statutory definition, and why. If limited to the transgenic construct, the indirect and cumulative impacts on the environment from the transgenic animal—as opposed to the impacts on the engineered animal from the construct—appear from the plain language of the statute to be beyond FDA's authority. FDA's interpretation of its authority to encompass the entire transgenic animal is thus ultra vires and/or arbitrary and capricious. It is a cardinal principle of administrative law that an agency may act only pursuant to authority delegated to it by Congress. *See Lyng v. Payne*, 476 U.S. 926, 937 (1986) ("[A]n agency's power is no greater than that delegated to it by Congress.").

Moreover, the FFDCA definition of "drug" expressly excludes "food." 21 U.S.C. § 321(g)(1)(C) (defining the term "drug" as including, among other things, "articles (other than food) intended to affect the structure or any function of the body of man or other animals . . . .") (emphasis added). The terms are mutually exclusive. The AquaBounty AquAdvantage transgenic salmon is intended to be used for "food." EA at 5. The entire (misguided) point of engineering the salmon is purportedly to grow transgenic salmon faster for human consumption.[92] Thus, by the statute's plain language it appears FDA lacks authority to regulate transgenic salmon as a "drug." An agency cannot force a statute to bear an untenable meaning. *See, e.g., Aid Ass'n for Lutherans v. U.S. Postal Service*, 321 F.3d 1166, 1177-78 (D.C. Cir. 2003) ("In this case, the Postal Service has transgressed the bounds of any delegation to fill alleged gaps in the statute, because the statute simply cannot bear the meaning that the Postal Service seeks to give it.").

---

[91] Guidance 187 at 5-6; Draft EA at 8. Because FDA is asserting a new, unprecedented extension of its statutory jurisdiction to encompass GE animals, FDA's interpretation is not entitled to any deference. Nor has FDA promulgated its interpretation in binding regulations. Rather, FDA put forth the misguided interpretation it applies here in Guidance 187, on which every page is marked "CONTAINS NON-BINDING RECOMMENDATIONS" in the header and in which FDA makes clear that it does "not establish legally enforceable responsibilities." It further indicates that it merely describes the agency's "current thinking" on the topic, illustrating that FDA could alter this interpretation of its authority at a later time. Guidance 187 at 5. This potential fluctuation underscores the uncertainty involved in the broader ramifications of any approval and hence why FDA must analyze further actions now. *See supra*.

[92] EA at 6-7.

Second, FDA's application of its authority here is arbitrary and capricious and ultra vires because the agency's authority does not encompass the myriad environmental risks of AquaBounty's GE salmon, and instead is limited to assessing whether an applicant has a legitimate "claim" for safe and effective use (*e.g.*, whether AquAdvantage's genetic engineering will generate faster-growing fish). The basic standard by which the FFDCA mandates that FDA will consider a new animal drug is whether it is "safe and effective" for the intended use, *see* 21 U.S.C. § 360b(a)(1) (describing circumstances in which a new animal drug is unsafe), with "safe" referring only to "the health of man or animal," *id*. at § 321(u). In plain English, this means that in the normal and proper animal drug context, FDA reviews the animal drug to determine whether it is safe for the animal that will be treated with it, and whether it is effective—whether it will work.[93]

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. Yet 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. *See* Natl. Research Council (NRC), Animal Biotechnology: Science-Based Concerns 61-92, at 9 (Natl. Acads. Press 2002). As these comments explain in great detail, the significant environmental impacts are of paramount concern with regards to the AquaBounty transgenic salmon. *See infra*.

Although FDA has promised that it will include environmental impacts in its GE animal assessment and purported to consider them in the draft EA (albeit in a wholly unlawful and insufficient manner), the statute and regulations neither require consideration of such factors nor set forth any minimum requirements for environmental protection.[94] Presumably FDA's interpretation is that a determination of "safety" can be read to encompass the transgenic animals' environmental impacts, and that FDA may limit such approvals to avoid or mitigate them. However, the agency has nowhere explained how or why the FFDCA's safety determination can be so applied. Guidance 187 has only two paragraphs on "environmental safety" and does not discuss how it is encompassed by the statute, Guidance 187 at 25, nor does the draft EA. The agency's interpretation is contrary to all prior practice of the agency with regard to conventional animal drugs, which instead turns on a determination of the animal's safety from the veterinary drug to be used on it.[95]

FDA appears to want it both ways in the EA, because the "no action" alternative in the EA's alternatives section states that, in the context of considering no action (denying the application), "FDA is required to approve an application for a new animal drug product when it is found to meet the FD&C Act approval standard, including that is safe and effective for its

[93] *See* Guidance 187 at 13 ("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....).").

[94] NEPA is of course a procedural statute and cannot expand an agency's substantive authority.

[95] FDA's role otherwise in overseeing the products of biotechnology is limited to food safety for transgenic ingredients, which the agency undertakes under a different section of the FFDCA, the food additive provisions. 21 U.S.C. § 348. In that context, such FDA analyses focus on food safety, and as such do not raise the same problems. Tellingly, in that context, the environmental impacts of transgenic plants are concurrently overseen by other agencies, namely USDA and EPA, not FDA.

intended use."[96] Further, in response to widespread critique of Guidance 187, on this point FDA did not affirmatively state its authority, but instead seemingly relied on the industry's good will to mitigate these impacts on its own:

> FDA recognizes that certain uses of some GE animals could pose environmental risks, and is aware of its obligations under NEPA to assess such risks. It is true that NEPA is a procedural requirement and does not give FDA new authority, such as to prohibit an activity solely because it would harm the quality of the environment. However, it has been our experience that developers of new animal drugs will choose to mitigate potential environmental impacts so that FDA can come to a finding of no significant impact on the environment for an NADA approval. They prefer such mitigation to waiting for FDA to complete an environmental impact statement for a product whose approval will have a significant environmental impact.[97]

Third, the inappropriateness of FDA's attempted purview extension to cover these issues is further illustrated by the agency's gross lack of expertise in the relevant scientific areas, such as fisheries biology. The result is the fundamentally flawed and scientifically inadequate review in the draft EA. *See infra*. Tellingly, as noted, the expert panel that FDA convened during its 2010 September VMAC hearings included only one fisheries biologist, and he called on the agency to consult with other agencies and to prepare a full EIS under NEPA. The preeminent scientists in the field have repeatedly criticized the agency's scientific assessment, concluding,among other problems, that it failed to include actual analysis and data, improperly relied on outdated and now-rejected scientific methods, failed to properly assess consequences of its action and uncertainties, and failed to include essential aspects of a scientifically rigorous risk analysis. *See Infra*. Scientists at the agencies that have the expertise to analyze these issues, NOAA and FWS, have likewise raised important questions regarding potential risks. *See infra*.

Fourth, and finally, FDA's ultra vires extension of its FFDCA animal drug authority to transgenic animals is illustrated by the poor fit between its oversight frame with regard to transparency and meaningful, timely public participation. 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. Rather, FDA can avoid disclosing basic information until the NADA has been approved. *See, e.g.*, 21 C.F.R. § 514.11(b)-(c); 21 C.F.R. § 25.50(b). This is borne out in this process, since FDA has not included in the draft EA vital scientific data and actual analyses required to assess fully the adequacy of the agency's conclusions. *See infra*. And while FDA has held a public meeting and public comment for the AquaBounty NADA and draft EA, there is no statutory requirement that it do so; the regulations provide that public review will only occur in a "limited number of actions." 21 C.F.R. § 25.51(b)(3). With regard to later supplemental approvals, the opportunities for public participation appear even murkier. *See infra*. Accordingly, while this framework may be appropriate for traditional drug approvals, the

---

[96] Draft EA at 23 (emphasis added)

[97] FDA response to public comments on Guidance 187, *available at* http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113612.htm

agency's as-applied use of such measures here is arbitrary and capricious given the broad, public impacts of transgenic animals, and the need for analysis and public review to prevent irreparable environmental harms.

Such belated and constricted disclosure also fundamentally undermines NEPA. Timing is a touchstone of NEPA. 40 C.F.R. §§ 1500.1(b), 1501.2. So is public scrutiny of agencies' proposed decisions. The statute's procedural purpose—to require consideration of impacts and alternatives prior to agency action—is completely dependent upon timely compliance and meaningful public participation. *See, e.g.*, *Marsh v. Or. Nat. Resources Council*, 490 U.S. 360, 371 (1989) (holding that 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."). FDA's interpretation and application of its FFDCA authority to transgenic animals contradicts NEPA's basic goals.

Accordingly, FDA must halt its current course and request further authority from Congress before considering approval of any GE animals, including the AquAdvantage salmon. Absent that, the agency must at a minimum promulgate binding regulations establishing that environmental impacts are encompassed with FDA's new animal drug review standard as applied to GE animals and making regulatory amendments to account for the novel risks they create, including interagency cooperation and increased transparency. Failure to so act and instead to approve the NADA under the agency's current path would violate the FFDCA and APA as ultra vires and arbitrary and capricious agency action.

II. FDA's Decision Violates the National Environmental Policy Act (NEPA) and the Administrative Procedure Act (APA).

A. FDA's EA is Patently Illegal and Inadequate.

NEPA is our national charter for protection of the environment. 40 C.F.R. § 1500.1(a). It is designed to ensure that federal agencies take a hard look at the environmental consequences of their actions. *See, e.g.*, *Sierra Club v. Bosworth*, 510 F.3d 1016, 1018 (9th Cir. 2007). For the many reasons discussed in this section, FDA's draft EA is woefully inadequate: FDA has failed to take the requisite "hard look at the environmental consequences" of its proposed decision to approve the AquaBounty application, *see, e.g.*, *Friends of the Payette v. Horseshoe Bend Hydroelectric Co.*, 989, 993 (9th Cir. 1993); *Overton Park v. Volpe*, 401 U.S. 402, 416 (1971), and failed to provide a "convincing case" in support of its FONSI. Overall, FDA's extremely deficient analysis flouts NEPA's fundamental tenets of ensuring comprehensive, timely, and transparent environmental review of agency actions.

1. The Scope of the EA is Unlawfully Narrow.

The litany of FDA's NEPA errors begins with its decision to consider this application in complete isolation from other related actions regarding the production and commercialization of AquAdvantage Salmon outside of the PEI and Panama areas, and its refusal to consider the associated broader, foreseeable impacts on the environment. The extremely narrow scope

adopted by FDA contravenes—and in many instances wholly ignores—NEPA and applicable Council on Environmental Quality (CEQ) regulations. In many ways, the FDA approach underscores that the agency has not internalized the central purposes of NEPA: to require detailed environmental analysis and to fully inform the public. Indeed, FDA's highly restrictive approach is reminiscent of the failed effort by another federal agency to limit NEPA's effect in the first years following enactment of the Act. *See Calvert Cliffs' Coordinating Committee v. Atomic Energy Commission*, 449 F.2d 1109 (D.C. Cir. 1971) ("the agency's crabbed interpretation makes a mockery of the Act").

As a fundamental matter, federal agencies cannot segment or manipulate the scope of their actions in order to avoid a finding of significance and evade the full environmental impact study NEPA demands. *See, e.g., Coalition on Sensible Transportation v. Dole*, 826 F.2d 60, 68 (D.C. Cir. 1987); 40 C.F.R. 1508.27(b)(7) ("Significance cannot be avoided by … breaking [an action] down into small component parts."). Yet this is precisely what FDA has done here, by drawing an artificially confined action area and insisting that any effort to change or expand the production of AquAdvantage Salmon, including ones already under consideration, will be analyzed separately later, if at all. This piecemeal approach is unlawful.

The CEQ's implementing regulations,[98] which are entitled to "substantial deference," *see, e.g., Andrus v. Sierra Club*, 442 U.S. 347, 358 (1979), provide that when determining the scope of its environmental review under NEPA, FDA must consider "connected, cumulative, and similar actions" together to prevent an agency from "dividing a project into multiple 'actions,' each of which individually has an insignificant environmental impact, but which collectively have a substantial impact." 40 C.F.R. § 1508.25*; see Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1305 (9th Cir. 2003), *citing Thomas v. Peterson*, 753 F.2d 754, 758 (9th Cir. 1985); *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 893-94 (9th Cir. 2002). These requirements apply to EAs and EISs alike. *See, e.g., Klamath-Siskiyou Wildlands Center v. Bureau of Land Management*, 387 F.3d 989, 998 (9th Cir. 2004).

In general, this requirement demands that FDA consider, as part of AquaBounty's current application, all known and foreseeable scenarios in which AquAdvantage Salmon may be produced, raised, and released after this initial action is approved. This requires FDA's environmental analysis to look beyond the geographic confines of this application, to review any likely future actions that may alter the conditions assumed in the current NADA, and expand the production of AquAdvantage Salmon to sites within the U.S. and around the world. Yet the draft EA does not include any express discussion of "connected, cumulative, and similar actions." Instead, FDA erroneously claims that it cannot consider any related actions along with this application because they are unknown or hypothetical.[99] This claim is flatly contrary to law and reality, given the unequivocal evidence to the contrary regarding current efforts to expand production and allow importation of AquAdvantage Salmon, and plans to develop other, similar GE fish products. Indeed, the record contains copious evidence of such plans:

[98] "The provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law." 40 C.F.R. § 1500.3. While CEQ's implementation of NEPA is due substantial deference, other agency's (such as FDA's) interpretations of CEQ regulations and NEPA are due no deference. *See, e.g., Grand Canyon Trust v. F.A.A.*, 290 F.3d 339, 342 (D.C. Cir. 2002).

[99] *See e.g.*, FDA EA at 97.

First, since the 2010 EA was released, AquaBounty's CEO Dr. Ron Stotish has repeatedly expressed AquaBounty's intention to increase production of AquAdvantage Salmon throughout the U.S. and around the world: "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...".[100] At the September 2010 VMAC, Dr. Stotish referred to the Panama site as merely "an initial production facility," explaining that 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 populations centers."[101]

AquaBounty's financial reports confirm these plans to increase production following FDA's approval of this initial application:

> In anticipation of approval, AquaBounty has developed relationships with authorities and producers in several countries that have appropriate production resources and are interested in testing the AAS [AquAdvantage Salmon] product. The Company has received a number of enquiries from developers, within the USA and elsewhere, that are enthusiastic about the economic prospects of growing AAS. Plans to expand capacity for the production of eggs for sale are in place and will be implemented as soon as approval is granted.[102]

> Two prospective customers within the U.S. have made applications to begin preliminary trials on an R&D basis of AAS [AquAdvantage Salmon] and are awaiting approval from the requisite regulatory authorities to be able to proceed. Once AAS is approved for sale, the Company will immediately begin field trials with prospective customers in the U.S. and abroad who have registered their interest.[103]

Just two months ago, in its latest shareholder meeting, AquaBounty proclaimed:

> Once [FDA] approval has been obtained, the Company plans to begin the process of preparing for and implementing customer field trials. If FDA approval is received before the end of 2013, the Company believes eggs could be supplied to field trials in January 2014. If the outcome of these trials is successful, the Company expects that sales and shipments of eggs could increase over the next two years. After FDA approval is received, the Company expects to focus on those significant fish farming markets where it believes it will have greater success in gaining approval and consumer acceptance. Currently, the company expects to market AAS in five countries after receipt of FDA approval: the US, Canada, Argentina, Chile, and China.
>
> …

[100] VMAC Meeting Transcript at 114:19-21
[101] *Id*. at 113:1-2 (emphases added).
[102] AquAdvantage Technologies, Inc., Preliminary Results for the year ended 31 December 2010, at 3 (May 3, 2011) (emphasis added). Attachment 25 hereto.
[103] AquaBounty Technologies, Inc., Interim Results for the Six Months Ended 30 June 2011 (September 23, 2011) (emphasis added). Attachment 26 hereto.

> The Company is also exploring the potential of expanding vertically into the grow-out of AAS or other developed fish, which it believes could provide an opportunity to enhance t he margin of the product and provide access to a potentially sizable market. The Company is also reviewing establishment of a second brookstock hatchery to reduce operating risk and increase its capacity. The Company believes the cost of constructing and equipping a second hatchery would be approximately $4 million. [104]

Second, recent documents obtained from the U.S. Fish and Wildlife Service and the U.S. National Marine Fisheries Service through Freedom of Information Act requests provide even greater specificity about AquaBounty's next steps and plans with respect to AquAdvantage Salmon. In particular, on July 15, 2011, AquaBounty submitted paperwork to FWS requesting permission to import AquAdvantage Salmon into the United States for purposes of testing at the University of South Dakota.[105] A January 4, 2013 FWS e-mail confirms that AquaBounty's request is still before that agency: "our nexus in this whole discussion is that we are expecting a request by the AquaBounty company to import live fish under our agency's Title 50 authority. We know this will happen because they (AquaBounty) has [sic] already issued us papers, which we could not even act upon until FDA makes their ruling."[106]

NMFS confirmed the existence of these requests in an internal e-mail from October 2011 explaining that AquaBounty can sell eggs they produce to companies anywhere in the country for those companies to grow out. That e-mail notes that "there have been requests from several companies to USFWS (they regulate importing salmon to the US) to import those eggs, though Aqua[Bounty] has not yet discussed this with FDA."[107]

Additional government correspondence reveals that a former AquaBounty executive contacted individuals from the Maine Department of Environmental Protection, NOAA, and FWS to discuss raising AquAdvantage Salmon in a hatchery, rearing, and processing facility in Maine that would discharge final waste waters into the marine environment.[108] Specifically, an October 6, 2010 e-mail from the Maine Department of Environmental Protection to NOAA and FWS explains that Joe McGonigle, a former AquaBounty Vice President, had discussed with Maine DEP the possibility of bringing GE salmon to Maine and expressed particular interest in the former Great Eastern Mussel property in St. George. *Id*. The waters of the State of Maine, of course, are home to endangered Atlantic Salmon. More recently, AquaBounty appears to have talked with an aquaculture farm in West Virginia to import AquAdvantage Salmon eggs.[109]

---

[104] AquaBounty Technologies, Inc., Proposed Fundraising and Collaborative Agreement (Feb. 15, 2013) (emphasis added). Attachment 27 hereto.
[105] E-mails involving Stuart Leon, Joel Bader, Joe Moran re: AquaBounty Title 50 Request (July 27, 2011). Attachment 28 hereto.
[106] E-mail from Joel Bader to Leslie Pokladnik re. AquaBounty Title 50 Paperwork (Jan. 4, 2013). Attachment 29 hereto.
[107] *See* J. Kahn Nov. 28, 2011 E-mail, *supra* (emphasis added).
[108] E-mail from Robert D. Stratton, Maine DEP, to individuals at NOAA and FWS (Oct. 6, 2010). Attachment 30 hereto.
[109] E-mail from Bret Preston (Feb. 7, 2011). Attachment 31 hereto.

Additional evidence that the expansion of AquAdvantage Salmon is "reasonably foreseeable" is demonstrated by FDA's entire regulatory program for GE animals and GE fish. Despite its representations, FDA's action on this application is neither isolated nor discrete; it is just one of a major federal regulatory program for commercialization of GE animals and, in this case, GE fish.[110] FDA has been setting the stage for this program for years, through regulatory interpretation and various Guidance for Industry papers. In light of these broader plans, FDA cannot lawfully proceed with its final decision on this application until it has completed both a site-specific EIS and a programmatic EIS that accounts for these broader implications.

Pursuant to 40 C.F.R. § 1508.25 actions are "connected" if they: (1) "automatically trigger other actions which may require environmental impact statements"; (2) "cannot or will not proceed unless other actions are taken previously or simultaneously"; or (3) "are interdependent parts of a larger action and depend on the larger action for their justification." *see also* 40 C.F.R. § 1502.4(a) ("Proposals or parts of proposals which are related to each other closely enough to be, in effect, a single course of action shall be evaluated in a single impact statement."). "Similar actions" are those "which when viewed with other reasonably foreseeable or proposed agency actions, have similarities that provide a basis for evaluating their environmental consequences together, such as common timing or geography." 40 C.F.R. § 1508.25(a)(3). "Cumulative actions" are those "which when viewed with other proposed actions have cumulatively significant impacts." 40 C.F.R. 1508.25(a)(2). Under 40 C.F.R. § 1508.25, FDA must recognize that even if the environmental impacts associated with this application were to be deemed insignificant, those impacts, when combined with those associated with other actions, may be collectively significant. These definitions unequivocally encompasses all existing requests to FWS or any other agency, state or federal, for importation of AquAdvantage Salmon eggs, as well as any reasonably foreseeable plans for expansion of AquaBounty's operations in other parts of the U.S. or the world.[111]

AquaBounty's plans to grow its genetically engineered AquAdvantage salmon at the Panama and Prince Edward Island facilities are connected, related, and cumulative with, *inter alia*: 1) the company's publicly stated plans to grow and sell the GE fish more broadly, at other facilities; and 2) its plans to sell the GE fish eggs to be grown by other companies at other facilities, companies, some of which have already inquired about and sought permission to import AquaBounty eggs to grow, once this NADA is approved. *See supra*. FDA's attempt to limit review here to just the two segmented facilities would allow it to crack open the regulatory door in the most narrow way, and delay—or potentially avoid altogether—broader review. *Thomas*, 753 F.2d at 758 ("Not to require [prior, comprehensive assessment of the impacts of connected actions] would permit dividing a project into multiple actions, each of which individually has an insignificant environmental impact, but which collectively have a substantial impact.").

[110] *See, e.g.,* Kevin Amos, NOAA, to Joel Bader FWS (Sept. 24, 2011) (discussing development of guidance on aquatic genetically engineered organisms to be cultured in US waters). Attachment 32 hereto.

[111] To determine which similar actions are "reasonably foreseeable," FDA must work closely with other agencies and AquaBounty and ensure that all relevant information pertaining to such actions are disclosed to the agency and the public.

If approved, the further foreseeable facilities to grow transgenic salmon are not limited to in-land systems. It is reasonably foreseeable that industry will seek to grow these fish in net pens, because commercial salmon farming is done almost exclusively in coastal net pens; that method of aquaculture is currently the only economically viable way to farm salmon. In-land systems are much costlier to operate and are energy and water intensive, have higher costs of feed, labor, operations and energy.[112] Net pens are a highly intensive and inherently unsustainable form of aquaculture that bring with them a host of harmful environmental impacts. Most relevant here, experience with net pens has proven that escapes are unavoidable, with millions of farmed salmon escaping each year.[113] Similarly, foreseeable and in some cases already planned, actions to expand grow-out of AquAdvantage Salmon to other sites depend on FDA's approval here for their justification. As the record shows, pending import requests to FWS to import AquaBounty's GE salmon eggs will only be considered if/when FDA grants this NADA.[114] Further, even if this evidence were not so clear, any lack of certainty as to future actions in no way negates the agency's duty to consider them. "It must be remembered that the basic thrust of an agency's responsibilities under NEPA is to predict the environmental effects of a proposed action before the action is taken and those effects fully known. Reasonable forecasting and speculation is thus implicit in NEPA and we must reject any attempt by agencies to shirk their responsibilities under NEPA by labeling any and all discussion of future environmental effects a 'crystal ball inquiry.'" *Scientists' Inst. for Public Info. v. Atomic Energy Comm'n*, 481 F.2d 1079, 1091-92 (D.C. Cir. 1973); *see also Conner v. Burford*, 848 F.2d 1441, 1450-51 (9th Cir. 1988) ("Appellants' suggestion that we approve now and ask questions later is precisely the type of environmentally blind decision-making NEPA was designed to avoid.").

FDA cannot, as it has to date, ignore all of the proof of AquaBounty's plans to expand the production and grow-out of AquAdvantage Salmon, and instead cabin its review to one piecemeal aspect. Rather, the agency must investigate, identify, and analyze within this application those and as well as any other foreseeable efforts that may collectively have a substantial impact on the natural environment. Such analysis and review necessarily must include, *inter alia*: actions advanced to import AquAdvantage Salmon eggs or live fish into the U.S. or other nations; and actions to grow and/or produce AquAdvantage Salmon at any facilities, within the U.S. or elsewhere, other than the PEI and Panama facilities considered in this application. Indeed, had FDA considered these actions as part of its assessment here, it necessarily would have properly determined that approval of this application "may significantly affect the quality of the human environment," and that preparation of an EIS is required.

In sum, to comply with NEPA and 40 C.F.R. § 1508.25, FDA must abandon the extremely narrow scope of its current draft EA, and consider all "connected, cumulative, and similar actions" within an EIS. Arbitrarily-limited reviews like FDA's here are inadequate and

---

[112] Klinger & Naylor, *Searching for solutions in aquaculture: charting a sustainable course*, 37 ANNUAL REVIEW OF ENVIRONMENT AND RESOURCES 247-276 (2012) *available at* http://woods.stanford.edu/sites/default/files/files/searching%20for%20solutions%20in%20aquaculture.pdf

[113] CFS Chart re: Annual Escapes, Attachment 33.

[114] *See supra* Jan. 4, 2013 FWS E-mail (FWS official speaking of U.S. imports live AquaBounty fish, "We know this will happen because they (AquaBounty) has [sic] already issued us papers, which we could not even act upon until FDA makes their ruling."); July 27, 2011 FWS e-mail (explaining that AquaBounty's Title 50 import request was "temporarily stopped at my desk pending a FDA decision on their GMO Atlantic Salmon".).

illegal where the agency's action triggers the large-scale creation of highly mobile animals that could literally swim outside the boundaries of the agency's overly narrow scope of review.

Moreover, the scope of FDA's analysis is further flawed because it completely excludes consideration and evaluation of the possible effects of AquAdvantage salmon on the local environments of Canada and Panama. This exclusion is premised on FDA's improper and unlawful position that "NEPA does not require an analysis of environmental effects in foreign sovereign countries."[115] NEPA has no such limitation. This assertion by FDA is arbitrary and capricious as a matter of law. Because NEPA is a procedural statute governing environmental planning that takes place within the United States, it applies without regard to whether the conduct being analyzed has potential effects *outside* of the United States. *See, e.g.*, *Environmental Defense Fund v. Massey*, 986 F.2d 528 (D.C. Cir. 1994) (rejecting argument that presumption against extraterritoriality bars NEPA's application to agency decisions with impacts outside the U.S.). The principle is that "NEPA is designed to control the decision-making process of U.S. federal agencies," *Id.* at 530, and thus NEPA requires federal agencies to consider the impacts of their decisions, regardless of whether those impacts will occur in other nations. *Id.*[116] The fact that Canada and Panama have systems in place for regulation of GE organisms does not excuse FDA from analyzing the effects in those countries of its decision to approve this application. Requiring this analysis as part of the current NADA is particularly imperative in light of the aforementioned stated plans to expand production of AquAdvantge Salmon into other parts of the world. FDA must establish the appropriate legal standard now, so that it is properly incorporated into any future actions AquaBounty may take abroad.

FDA's own regulations require the Agency to consider the overseas effects that would be triggered by approval of this application. In particular, FDA has implemented Executive Order 12,114 as part of the Agency's regulations, and explicitly acknowledged that it is required to consider possible effects of actions abroad.[117] Executive Order 12,114 titled, *Environmental Effects Abroad of Major Federal Actions*, 44 Fed. Reg. 1957 (Jan. 4, 1979), expressly seeks to ensure that federal agencies consider the impacts of major U.S. federal actions on the environment of foreign nations. The Executive Order reflects the U.S. Government's determination that it is vital for "Federal agencies to further the purpose of the National Environmental Policy Act with respect to the environment outside the United States, its territories, and possessions."[118] FDA's failure to comply with this requirement is arbitrary, capricious, and contrary to law.

---

[115] FDA EA at 10.

[116] *See also* CEQ, *Council On Environmental Quality Guidance On NEPA Analyses For Transboundary Impacts* ("NEPA requires agencies to include analysis of reasonably foreseeable transboundary effects of proposed actions in their analysis of proposed actions in the United States.").

[117] *See* 21 C.F.R. § 25.60, "Environmental Effects Abroad of Major Agency Actions"; *see also National Environmental Policy Act; Revision of Policies and Procedures*, 62 Fed. Reg. 40,570, 40,590 (July 29, 1997) ("FDA requirements include the consideration of potential environmental effects of an action on a foreign sovereign…. In the event the agency action would have a significant effect on the foreign nation, the agency official will require additional environmental documentation…") (emphasis added).

[118] Id.

2. The EA Fails to Consider Cumulative Impacts, including Intertwined Socioeconomic Impacts.

FDA acknowledges that 40 C.F.R. § 1508.7 requires the agency to consider the cumulative impacts of its proposed action.[119] Cumulative impacts are "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions regardless of what agency (federal or non-federal) or person undertakes such other actions. Cumulative impacts can result from individually minor but collectively significant actions taking place over a period time." 40 C.F.R. § 1508.7. A thorough consideration of cumulative impacts is required in the preparation of an EA. *See, e.g., Kern v. Bureau of Land Management*, 284 F.3d 1062, 1075 (9th Cir. 2002). Specifically, an EA must provide a quantified assessment of project's environmental impacts when combined with other projects. *Great Basin Mine Watch v. Hankins*, 456 F.3d 955, 972 (9th Cir. 2006). Notably, courts and the CEQ emphasize that a detailed cumulative impacts analysis is especially important in an EA, because there is a much higher risk of cumulative impacts resulting from many smaller decisions for which EAs are prepared. *See, e.g., Native Ecosystems Council v. Dombeck*, 304 F.3d 886 (9th Cir. 2002); *Kern*, 284 F.3d. at 1076 & 1078 (emphasis in original) (quoting CEQ, Considering Cumulative Effects Under the National Environmental Policy Act at 4, January 1997) ("Given that so many more EAs are prepared than EISs, adequate consideration of cumulative effects requires that EAs address them fully." "Without such individually minor, but cumulatively significant effects, "it would be easy to underestimate the cumulative impacts" of the action…, and "of other reasonably foreseeable future actions, on the [environment].").

FDA denies cumulative impacts exist. It states: "CVM has preliminarily concluded that approval of an NADA for AquAdvantage Salmon would not have any significant environmental impacts. According to FDA, the absence of environmental impacts means that there would be no 'incremental impact'; because this is the first approval for AquAdvantage Salmon, there would be no cumulative impacts."[120] FDA goes on to claim that any further consideration of cumulative impacts would be premature, given that it is looking only at the specific conditions presented in this application and "the agency does not speculate about any future business expansion by the sponsor because any such speculation would be hypothetical."[121] FDA's position with regard to the approval not having any potentially significant environmental impacts is fundamentally flawed, given, among other things, the lack a scientific basis for its FONSI, as discussed *infra*.

However, even assuming, without conceding, that FDA's FONSI for this NADA is valid, the agency's circular cumulative impacts analysis is unlawful. It is well-established that "a cumulative impacts analysis must include 'some quantified or detailed information' since without such information it is not possible for the court or the public to be sure that the agency provided the hard look that is required of its review.'" *Soda Mountain Wilderness Council v. Norton*, 424 F. Supp. 2d 1241 (E.D. Cal. 2006). In a cumulative impact analysis, "general statements about possible effects and some risk do not constitute a hard look….The cumulative

[119] FDA EA at 97.
[120] *Id*.
[121] *Id*.

impact analysis must be more than perfunctory; it must provide a 'useful analysis of the cumulative impacts of past, present, and future projects." *Muckleshoot Indian Tribe v. U.S. Forest Serv*, 177 F.3d 800, 810 (9th Cir. 1999). Moreover, a cumulative impact analysis must be timely; "it is not appropriate to defer consideration of cumulative impacts to a future date when meaningful consideration can be given now." *Neighbors of Cuddy Mountain*. "If the agency did not present this detailed information and analysis it will be found to have violated NEPA unless it provides a convincing justification as to why more information could not be provided.'" *Id.* (citing *Ocean Advocates v. Army Corps of Engineers*, 402 F.3d 846, 868 (9th Cir. 1998)).[122]

FDA's draft EA does not contain a defensible analysis of cumulative impacts, much less any "quantified or detailed information" on the matter. Instead, FDA attempts to completely circumvent this requirement, suggesting that it is absolved from the analysis because it has found that this application would not have any significant impacts. But this is not how NEPA's cumulative impacts requirement works. The cumulative impacts analysis requires FDA to consider that approval of this particular application may have indirect significant consequences on the marine environment and resources when considered in combination with related future actions concerning AquAdvantage Salmon and other GE fish. If those consequences are cumulatively significant, an EA and FONSI are simply not sufficient. An example from the Ninth Circuit is especially instructive: "[T]he addition of a small amount of sediment to a creek may have only a limited impact on salmon survival, or perhaps no impact at all. But the addition of a small amount here, a small amount there, and still more at another point could add up to something with a much greater impact, until there comes a point where even a marginal increase will mean that no salmon will survive." *Klamath-Siskiyou*, 387 F.3d at 994 (emphasis in original); *see also Ctr. for Biological Diversity*, 538 F.3d at 1216 (cumulative impacts analysis inadequate because it failed to analyze "incremental impact" of emissions on "climate change or the environment more generally in light of other past, present and reasonably foreseeable actions" with emissions).

In order to address the cumulative impact requirement, FDA must examine and evaluate the cumulative impacts of reasonably foreseeable actions concerning the proliferation of AquAdvantage Salmon actions both within the currently defined action area as well as in the greater area in which these fish may be produced following initial NADA approval. *See Kern*, 284 F.3d at 1075. The discussion must assess whether the approval of AquaBounty's current NADA, when combined with other scenarios in which the AquAdvantage Salmon or other GE fish may be produced, grown, and released, might have a cumulatively significant effect on potentially receiving marine ecosystems and wild fish populations. Because it will be impossible to ensure 100% compliance with the containment offered in this application and any future facilities, FDA must, at a minimum, fully evaluate the potential risks to endangered fish populations, including Atlantic salmon and Pacific salmonids.

The cumulative impact analysis must also include an assessment of potential aesthetic, historic, cultural, economic, social, and health impacts. 40 C.F.R. 1508.8; *see e.g., Wyoming v.*

[122] The cumulative impact analysis is wholly distinct from the scope requirements and analysis discussed above. *See Earth Island Inst. v. U.S. Forest Serv.*, 351 F.3d 1291, 1306 (9th Cir. 2003) ("Even if a single, comprehensive EIS is not required, the agency must still adequately analyze the cumulative effects of the projects within each individual EIS.").

U.S. Dept. of Agric., 661 F.3d 1209, 1251 (10th Cir. 2011) (explaining that a cumulative impacts analysis must consider all of the effects listed at 40 C.F.R. 1508.8); 40 C.F.R. § 1508.14 (when "economic or social and natural or physical environmental are interrelated," then the NEPA analysis must discuss "all of these effects on the human environment.

As indicated in the record and public comments, the potential significant socioeconomic, cultural and other foreseeable impacts on commercial fisheries will be considerable. The socioeconomic analysis FDA must perform should include an analysis of both the economic and cultural importance of Atlantic salmon, the demographics of the communities that would be impacted, an analysis of potential impacts to commercial fisheries, potential impacts to recreational fishing, potential harm to fishery dependent communities, and an analysis of the market impacts of this product's commercialization. This would also necessarily include an evaluation of how the production and potential release of AquAdvantage Salmon could affect tribal communities that depend on wild salmon for subsistence and livelihood. It is difficult to overstate the cultural and economic significance of salmon. According to the Alaska Department of Fish and Game, the value of Alaska's commercial salmon harvest in 2012 was over half a billion dollars.[123] Transgenic contamination, abundant GE salmon driving down salmon prices, or international market rejection of salmon due to concerns about transgenic contamination would have a massive impact both on the economy and the communities that rely on this industry. FDA's refusal to consider such indirect effects in this EA is unlawful, arbitrary and capricious.[124]

Also, because 40 C.F.R. § 1508.7 requires analysis of present, and reasonably foreseeable actions regardless of what agency (federal or non-Federal) or person undertakes such other actions, FDA must broaden its assessment far beyond its preferred narrow, isolated scope and look at related actions involving other governmental bodies, and the aquaculture industry. At a minimum, FDA is required to work with FWS, NMFS, the United States Environmental Protection Agency (EPA), the United States Department of Agriculture (USDA), state agencies, and AquaBounty to identify any efforts regarding the importation or production of AquAdvantage eggs or fish at sites other than those discussed in the current NADA. As noted above, this would include actions to import AquAdvantage Salmon eggs to specific sites within the U.S via permits obtained through the FWS. Hence FDA must evaluate the full range of potential cumulative impacts associated with all of these scenarios in relation to the current NADA action.[125]

---

[123] *See* http://www.adfg.alaska.gov/index.cfm?adfg=CommercialByFisherySalmon.exvesselquery

[124] FDA EA at 10

[125] We are providing relevant evidence of related current and future actions that we have obtained from other agencies through FOIA requests. Because this "drug approval" regulatory process occurs behind closed doors, the public cannot be expected to identify all "reasonably foreseeable" actions that would fall within this requirement's purview. This transparency problem underscores the arbitrary nature of FDA's use of its animal veterinary drug provisions to regulate and approve a GE animal, *see supra*. Moreover, it is FDA's absolute obligation to seek out this information by communicating with other federal agencies, state agencies, AquaBounty, and the aquaculture industry. Again, NEPA does not allow FDA to put its head in the sand, and ignore public information showing that other actions are already in the works. The legal duty to ensure adequate NEPA review rests with FDA, not the public.

Within the cumulative impact analysis, FDA must also consider how this approval will affect efforts by the FWS, NMFS, EPA, state agencies, tribes, commercial fishermen, and foreign nations to protect wild fish populations, including already imperiled Atlantic and Pacific salmonids, and promote sustainable fishing practices. Production of GE AquAdvantage salmon could cripple those efforts, causing major environmental, ecological, and economic harm.[126]

FDA wrongly dismisses even the possibility of considering related foreseeable actions by claiming they are too speculative or hypothetical.[127] An analysis of future actions in this case is anything but speculative: The federal government has hard evidence of existing requests to bring AquAdvantage Salmon eggs into the U.S., and of "reasonably foreseeable" expansion of AquaBounty's operations, as stated repeatedly by AquaBounty itself. Indeed, there can be no question that under the existing regulatory framework, FDA's approval of this GE salmon application is precedent-setting, in that it will prompt and influence future NADAs, supplemental NADAs, or permits regarding production of AquAdvantage Salmon and other GE fish (including GE tilapia and GE trout) in the United States and all around the world. FDA's failure to take such actions into account for this NADA review is quintessentially arbitrary and capricious.

3. The EA Unlawfully Relies on AquaBounty's Mitigation and Uncertain Future FDA Actions.

FDA improperly relies on AquaBounty's measures to mitigate environmental risks in order to avoid a conclusion of significance and the EIS requirement. *See* EA at 14 ("FDA determined that this application for AquAdvantage Salmon should mitigate environmental risks by the appropriate use of biological, physical, and geographic/geophysical means of containment."). CEQ defines "mitigation" to include

> (a) Avoiding the impact altogether by not taking a certain action or parts of an action.
> (b) Minimizing impacts by limiting the degree or magnitude of the action and its implementation.
> (c) Rectifying the impact by repairing, rehabilitating, or restoring the affected environment.
> (d) Reducing or eliminating the impact over time by preservation and maintenance operations during the life of the action.
> (e) Compensating for the impact by replacing or providing substitute resources or environments.

40 C.F.R. § 1508.20. Courts examine mitigated FONSIs to see whether such measures keep impacts below the EIS threshold, which is the "low standard" of whether a project "may have a significant effect." *See, e.g., Klamath Siskiyou Wildlands Center v. Boody*, 468 F.3d 549, 562 (9th Cir. 2006). FDA's reliance here does not comply with NEPA.

Mitigation must be enforceable, which includes the duty of on-going monitoring to ensure compliance. CEQ, Appropriate Use of Mitigation and Monitoring and Clarifying the

[126] *See, e.g., supra*, 2003 NMFS Biological Opinion (ban on the use of transgenic fish in aquaculture off the coast of Maine); *see also* Atlantic Salmon Federation, "A Conservation Strategy for Atlantic Salmon in Prince Edward Island," *available at* http://atlanticsalmonfederation.org/pei/2009peireport.html.
[127] FDA EA at 97.

Appropriate Use of Mitigated Findings of No Significant Impact 7 n.18 (2011);[128] *id.* at 2 (explaining that when agencies do not "monitor mitigation commitments to determine if mitigation was implemented or effective, the use of mitigation may fail to advance NEPA's purpose of ensuring informed and transparent environmental decisionmaking"). "Monitoring is essential in those important cases where the mitigation is necessary to support a FONSI and thus is part of the justification for the agency's determination not to prepare an EIS." CEQ at 10. The draft EA fails to adequately explain or analyze how FDA will monitor compliance with the AquaBounty mitigation measures upon which it depends, at either the Panama or PEI facility.

Development of mitigation measures also necessarily depends on agency expertise in its field. Any outside experts that help to develop mitigation "should be neutral parties without a financial interest in implementing the mitigation and monitoring plans." *Id.* at 5 (citing 40 C.F.R. § 1506.5). Here, FDA has no expertise in fishery biology NOAA and FWS. Those agencies, as well as preeminent scientists in the field, questioned the measures' efficacy to ensure 100% confinement of AquAdvantage Salmon. Further, the mitigation measures were developed by AquaBounty, whose financial future depends entirely upon FDA approval, precisely the party that, according to CEQ, should not be allowed to develop mitigation.

Mitigation measures cannot substitute for actually analyzing environmental impacts. *See, e.g.*, *Northern Plains Resource Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1085-86 (9th Cir. 2011). This is precisely what FDA has improperly done here, relying solely on AquaBounty's containment measures and failing to analyze the potential impacts should/when any or all of those measures fail. *See infra*. FDA has not even conducted a failure mode analysis to test the reliability of these containment measures. Nor has the agency provided any true assurance that a full environmental consequences analysis for future changes regarding the production or grow-out of AquAdvantage Salmon at other sites will be prepared and made available for public review. As Kapuscinski and Sundström have emphasized, "the proposed confinement does not absolve the need for a complete environmental risk assessment given the likely proliferation of sales of AAS for grow-out beyond one facility in Panama." 2010 Written Comments."

To justify its FONSI and evade the analyses required by 40 C.F.R. § 1508.7 and 40 C.F.R. § 1508.25, FDA also repeatedly relies on the assertion that future actions concerning production of AquAdvantage Salmon that could significantly affect the environment will be subject to additional NEPA analyses pursuant to the agency's supplemental NADA process set forth at 40 C.F.R. § 514.8. *See, e.g.*, EA at 97. There is significant question, however, as to whether that process requires the kind of review FDA claims. FDA's regulations, as well as related statutory requirements and interpreting Guidance for Industry documents, do not clearly provide assurance that the agency would conduct additional environmental analysis for future changes to this NADA, including changes that could adversely affect the environment, or that FDA would make any such analysis public. Under these circumstances, FDA must carefully explain precisely how its regulations, 21 C.F.R. 514.8, require such analysis. In addition, FDA must explain how it intends to assure this review when FWS has the authority to permit the

[128] Council on Environmental Quality, Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact 7 n.18 (2011), *available at* http://ceq.hss.doe.gov/current_developments/docs/Mitigation_and_Monitoring_Guidance_14Jan2011.pdf

importation of the GE AquAdvantage Salmon eggs into the U.S. Absent such complete explanation, FDA's invocation of its regulations in this manner is arbitrary, capricious, and unlawful.

4. The EA's Alternatives Analysis is Unlawfully Narrow and Predetermined.

FDA has failed to take the required hard look at possible alternatives to approval of AquaBounty's application. Section 102(2)(E) of NEPA requires all agencies to "[s]tudy, develop, and describe appropriate alternatives to recommended courses of action in any proposal which involves unresolved conflicts concerning alternative uses of available resources." 42 U.S.C. § 4331(2)(E). Regardless of whether an EA or EIS is prepared, NEPA "requires that alternatives be given full and meaningful consideration." *Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1229 (9th Cir. 1988). In fact, the alternatives section is considered the heart of an environmental analysis. 40 C.F.R. § 1502.14. "[I]t should present the environmental impacts of the proposal and the alternatives in comparative form, thus sharply defining the issues and providing a clear basis for choice among options by the decisionmaker and the public." *Id*. Agencies must therefore rigorously explore and objectively evaluate all reasonable alternatives, including the no action alternative. *Id*.

First, despite the rigor required by NEPA, FDA's EA presents no serious analysis of potential alternatives. Instead, FDA merely provides a cursory review of just two options it purports to have "evaluated" to satisfy this requirement: the proposed NADA approval action and the "no action" NADA disapproval action. EA at 22-24. It is a classic NEPA violation to limit the consideration of alternatives simply to (1) action or (2) no action. *See, e.g.*, *American Oceans Campaign v. Daley*, 183 F. Supp. 2d 1, 17-21 (D.D.C. 2000); *Muckleshoot Indian Tribe v. U.S. Forest Serv*, 177 F.3d 800, 813-14 (9th Cir. 1999) (consideration of only unqualified deregulation and the no action alternative is presumptively too limited to comply with NEPA). The discussion provided, and FDA's failure to consider other options, is thus unlawful and arbitrary.

Second, FDA's alternatives analysis is also fundamentally flawed because it is—like the rest of the EA—far too limited in scope. An agency's alternatives analysis should be a function of the "purpose and need" of the action under review. *See* 40 C.F.R. § 1502.13 (agency must "specify the underlying purpose and need to which the agency is responding in proposing the alternatives…."); *City of Carmel-By-The-Sea v. U.S. Dep't of Transp*., 123 F.3d 1142, 1155 (9th Cir. 1995) ("The stated goal of a project necessarily dictates the range of 'reasonable' alternatives and an agency cannot define its objectives in unreasonably narrow terms.") (citation omitted). In the "Purpose and Need" section of the draft EA, FDA very broadly describes the world-wide overfishing crisis and the attendant decline in wild fish stocks, including Atlantic Salmon populations, as the basis for potentially approving AquaBounty's AquAdvantage Salmon NADA. EA at 5-8. Although this problem is a massive and complicated one, with numerous potential solutions, FDA then inexplicably assumes that AquAdvantage Salmon is the only viable solution for purposes of its NEPA alternatives analysis. In so assuming, FDA improperly restricts itself from considering any other options that could feasibly, effectively, and safely relieve the world's overstressed fisheries and meet the growing demand for fish protein without the potentially significant environmental risks posed by GE AquAdvantage Salmon. *Id*. at 6. The alternatives considered must include a "range of reasonable actions which might meet the

goals of the agency by using different approaches which may reduce the environmental impacts of the agency's action." *See, e.g., Soda Mountain Wilderness Council v. Norton*, 424 F. Supp. 2d 1241, 1265 (E.D. Cal. 2006).

Third, as a consequence of the overly narrow design of FDA's alternatives discussion, the commercialization of AquAdvantage Salmon becomes a foregone conclusion. Indeed, FDA did not consider a single alternative that does not involve the production of AquAdvantage Salmon. EA at 24. "An agency may not define the objectives of its actions in such unreasonably narrow terms as to make consideration of alternatives a mere formality." *Citizens Against Burlington, Inc. v. Busey*, 938 F.2d 190, 196 (D.C. Cir. 1991).

The overly narrow scope of FDA's alternatives discussion is in part a result of the agency's improper segmentation, and refusal to analyze reasonably foreseeable cumulative impacts. *See supra*. The agency must analyze now the environmental and intertwined socioeconomic impacts broader farming of AquaBounty's transgenic salmon, given that the record shows that such related, connected, and cumulative impacts will occur. *Id.* The agency must necessarily consider reasonable alternatives to the connected actions, not just the unlawfully segmented portion the draft EA only addresses.

Fourth, such a tunnel-vision focus also impermissibly accepts AquaBounty's own biased representation of its product, ignoring that "NEPA requires an agency to 'exercise a degree of skepticism in dealing with self-serving statements from a prime beneficiary of the project and to look at the general goal of the project rather than only those alternatives by which a particular applicant can reach its own specific goals." *Envtl. Law & Policy Ctr. v. United States Nuclear Regulatory Comm'n*, 470 F.3d 676, 683 (7th Cir. 2006).[129]

Fifth, particularly given the breadth of the global fishing problem FDA cites as the Purpose and Need for this AquAdvantage Salmon NADA, NEPA requires FDA to consider and evaluate a wide range of alternatives capable of addressing the same problem. 40 C.F.R. § 1502.13; *see, e.g., City of Carmel-By-The-Sea v. U.S. Dep't of Transp*., 123 F.3d at 1155. This necessarily includes, among other things, the development of new projects and policies designed to support and expand sustainable commercial fishing practices, and protect and restore native Atlantic salmon populations. FDA should also consider alternative regulatory options that would provide additional confidence in the adequacy of the agency's environmental review and oversight for this approval as well as any other potential GE animal approvals. For instance, FDA could introduce, as a condition for final action, a regulatory requirement for independent review and approval by other agencies with relevant expertise in fish biology such as NMFS, FWS, or EPA. *See, e.g.*, 40 C.F.R. 1502.14(c) (alternatives discussion shall "include reasonable alternatives not within the jurisdiction of the lead agency"). Moreover, to the extent that FDA is only interested in exploring the option of allegedly fast-growing Salmon (still an unjustified limitation), the agency must compare and evaluate non-GE methods like that which has been

[129] *Forty Most Asked Questions Concerning CEQ's NEPA Regulations,* 48 Fed. Reg. 18,026 (Mar. 23, 1981) ("In determining the scope of alternatives to be considered, the emphasis is on what is 'reasonable' rather than on whether the proponent or applicant likes or is itself capable of carrying out the particular alternative. Reasonable alternatives include those that are practical or feasible from a technical and economic standpoint and using common sense, rather than simply desirable from the standpoint of the applicant.").

developed by SalmoBreed in Norway.[130] The agency must also consider the option of waiting to consider or approve GE animals until the risk science has fully developed to ensure absolute certainty that these animals do not pose a threat to the natural environment. Courts have "repeatedly recognized that if the agency fails to consider a viable or reasonable alternative, the [NEPA analysis] is inadequate." *See Alaska Conservation Council v. Fed. Highway Admin*., 649 F.3d 1050, 1056 (9th Cir. 2011).

Sixth, the only alternative to NADA approval that FDA has actually "evaluated" is that of no action, *i.e.* disapproval of the AquaBounty NADA. Yet even this analysis is defective. In dismissing the no action option, FDA states that it is bound by the FFDCA to approve AquaBounty's NADA so long as the AquAdvantage Salmon animal drug is found to be "safe and effective" for its intended use.[131] As an initial matter, such a conclusion again illustrates that the regulatory vehicle FDA is using for GE animals is misguided and inapposite. Moreover, AquAdvantage Salmon has not been proven safe and effective, particularly as those terms relate to the protection of the environment and natural ecosystems. More significantly, FDA is bound also by NEPA to refrain from approving this NADA—regardless of the agency's findings under the FFDCA—until the agency has completed the requisite comprehensive environmental analysis of all potentially significant environmental and ecological risks presented by AquAdvantage Salmon. *See, e.g., Save Our Cumberland Mts. v. Kempthorne*, 453 F.3d 334, 343 (6th Cir. 2006).

Seventh, FDA's purported reliance on its separate FFDCA determination underscores that in FDA's view the entire NEPA process is a predetermined façade, because the agency is making/has made a separate decision, pursuant to which the agency's hands are otherwise purportedly tied.[132] Under this reasoning, presumably FDA would then have no authority to restrict or deny approval of the AquAdvantage Salmon, even if the agency's NEPA analysis concluded it would cause the extinction of wild salmon populations or other severe environmental effects. Yet this would turn the NEPA review process into a charade, and subvert the requirement that "[e]nvironmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made." 40 C.F.R. § 1502.02(g); 40 C.F.R. § 1500.1(c) ("NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action"). FDA would violate the statute's fundamental goal if it erroneously concluded that it need not or could not take into account what its NEPA analysis reveals.

Further, it is nonsensical for FDA to suggest that it complied with NEPA's mandate to take a "hard look" at the consequences of its action while simultaneously insisting it is precluded from allowing its NADA decision to be influenced its NEPA analysis. FDA has the NEPA analysis process precisely backwards: the NEPA analysis must inform the agency's decision-making process, not the other way around. *Western Watersheds Project*, 632 F.3d at 491 ("The 'hard look' must be taken objectively and in good faith, not as an exercise in form over substance, and not as a subterfuge to rationalize a decision already made") (internal citations and

[130] *See* SalmoBreed Report at http://www.salmobreed.no/newsletters/en/newsletter_5_2011.pdf
[131] FDA EA at 23.
[132] *Id*. ("FDA is required to approve an application for a new animal drug product when it is found to meet the FD&C Act approval standard, including that it is safe and effective for its intended use.").

quotation marks omitted). NEPA requires that environmental considerations be factored into government decision-making "early enough so that it can serve practically as an important contribution to the decisionmaking process and will not be used to rationalize or justify decisions already made." *Metcalf v. Daley*, 214 F.3d 1135, 1142 (9th Cir. 2000).

Finally, as another basis for rejecting the no action option, FDA asserts that should it disapprove the NADA, AquaBounty will raise AquAdvantage Salmon outside the U.S. in nations and locations that could allow for more risky production scenarios, including areas where native Atlantic Salmon are present and where Atlantic salmon is commercially farmed in net pens and lakes and/or raceways or in recirculating systems.[133] But even if it were true, this prediction would only serve to underscore the vital importance of detailed environmental analysis of the AquaBounty application and of alternatives. It by no means justifies FDA's disposal of the no action alternative. AquaBounty has made public statements touting its plans for worldwide expansion and proliferation of AquAdvantage Salmon in international markets. If these statements are given credence, FDA's disapproval of the NADA will not stymie AquaBounty's efforts; to the contrary, its hasty, unprecedented approval could expedite them by creating the first major market for AquAdvantage Salmon and potentially making it more appealing for other nations to follow suit using a regulatory approval process as lax as FDA's current one. Once this happens, it will become exceedingly difficult, if not impossible, for FDA to keep track of how and where the AquAdvantage Salmon are produced (especially given the flaws in the agency's supplemental NADA process, as discussed above). FDA must engage in a comprehensive analysis of the potential risks now, before triggering AquaBounty's planned expansion. In sum, the mere fact that upon disapproval, AquaBounty could move on to produce AquAdvanatge Salmon in other nations using less restrictive containment measures than those proposed here is speculative and contrary to logic, nor a lawful reason for FDA to rush to approve this NADA without the proper environmental review.

5. The EA Contains an Incomplete and Inadequate Scientific Analysis.

The detailed background section above catalogs the evidence of the extensive scientific controversy and uncertainty surrounding FDA's environmental analysis of AquAdvantage Salmon. This section expands on those and related deficiencies tainting the draft EA, and explains how they act to render FDA's FONSI, and decision to not complete a comprehensive EIS, arbitrary, capricious, and contrary to NEPA. Underlying this discussion is the basic principle that NEPA—at its core—contemplates high-quality information and accurate scientific analysis. 40 C.F.R. § 1500.1(b). Under these circumstances, it is particularly telling that leading scientific experts are highly critical of the EA, including in particular Dr. Kapuscinski, whom the EA relies upon heavily when it so chooses, and those in the FWS.

.

(a). Failure to Provide Actual Analysis & Real Data

Public scrutiny is essential to implementing NEPA. 40 C.F.R. §1500.1. The draft EA is inadequate because it does not contain actual analysis or real data supporting FDA's FONSI; it merely contains narratives of AquaBounty's studies and studies, many of which are quite dated,

[133] FDA EA at 3-4; 23-24

involving other types of fish. Since at least 2010, numerous efforts have been made to obtain these data, but the agency has repeatedly refused to release the relevant information. *See supra*. As Drs. Kapuscinski and Sundström previously explained:

> Where the Environmental Assessment and Briefing Packet do present some quantitative data related to environmental risk, they omit information required to scientifically verify the stated conclusions. Frequently missing information includes: sample sizes (or the given sample sizes are too small to reliably assess the scientific value of the experimental outcome), standard errors, statistical power, or description of statistical tests used to reach the stated conclusion….[there are] similar omissions in the Briefing Packet's presentation of data for other scientific issues. Such incomplete analysis and presentation of data does not meet commonly accepted scientific standards.[134]

Environmental information must be available to the public before decisions are made. 40 C.F.R. §1500.1. One major goal of NEPA is to "guarantee that the relevant information will be made available to the larger audience that may also play a role in both the decision-making process and the implementation of that decision." *Robertson v. Methow Valley Citizens*, 490 U.S. 332, 349 (1989); 40 C.F.R. §1501.2(b). Without this information, it is extremely difficult, if not impossible for the public, including scientists with the proper expertise, to provide meaningful opinions. This deficiency defeats a primary purpose of NEPA.

(b) Failure to Conduct Adequate Risk Assessment and Evaluate the Potential Environmental and Ecological Consequences of AquAdvantage Salmon.

According to prominent transgenic fish experts, there are major deficiencies in FDA's assessment of environmental and ecological risks associated with approval of the NADA and AquAdvantage Salmon. Drs. Kapuscinski and Dr. Sundström have repeatedly explained that FDA's assessment lacks crucial pieces of a defensible risk analysis, including, *inter alia*, a quantitative failure mode analysis, a thorough assessment of consequences, and a formal uncertainty analysis. FWS has similar concerns.[135] Nonetheless, FDA has chosen to ignore their expert recommendations, and instead accept outdated risk assessments approaches and methodologies and incomplete analyses.

i. Improper Reliance on Outdated Scientific Methods

Notably, the risk approach and method FDA has adopted in the EA are based on two publications led by Dr. Kapuscinski from the early 1990s, which she herself now says are no longer representative of the best available science and therefore should not be used by FDA.[136] After the release of the current draft EA, in January 2013, Dr. Kapuscinski stated as follows:

---

[134] 2010 Kapuscinski and Sundström VMAC Comments.

[135] FWS Region 5 Comments, *supra*.

[136] Kapuscinski and Sundström VMAC Comments at 2 ("The [EA] does not provide the full information needed to predict environmental effects of AAS…It focuses on an outdated list of issues (from Kapuscinski and Hallerman 1991) and ignores the major advances in methodologies for assessing environmental risks of transgenic fish (Kapuscinski et al. 2007). These advanced methods systematically integrate information about the environment and

> [E]verything that is in this EA that looks at possible consequences of a fish escape is unacceptable to me. It's very poorly done in terms of basic scientific standards in multiple ways. And if they just don't want to do the work for a more scientifically acceptable consequence assessment, then I would recommend that the FDA simply deletes all of that from this environmental assessment…
>
> They [FDA] are still refusing to pay attention to the updating of ecological risk assessment science that's all pulled together in a book published by a large group of scientists in 2007. Throughout both the 2010 and 2012 EA, the text cited two important publications that I led back in the early 1990s, one of which I was lead author and the other by a working group I chaired.
>
> The FDA is hinging most of its scientific approach on the consequence assessment on those two reports. <u>And yet I myself am now saying that they've been replaced by better methods</u>.
>
> Back in 1991 and 1995, those two reports were the best thinking about what would be the sets of questions we should be asking and how to go about getting information for environmental risk assessment. But the science has advanced tremendously since then, so much that we felt it was important to bring together all of the key scientific advances in a book published in 2007. That book went through really rigorous peer review. It was blind peer-reviewed by reviewers from around the world. The scientifically honest way to do this consequence assessment now would be to look at the best advances and draw on the best science.[137]

Dr. Kapuscinski was then asked how she feels about the fact that her "work from the 1990s is cited 14 times in [the current draft EA], yet the FDA isn't taking your recommendations." Her response is telling:

> Ph.D. students are required to write a dissertation proposal and defend it before a committee. <u>If a student cited literature in the way it was done in this report, we would fail them</u>.[138]

Such an approach is likewise unacceptable under the law as it is arbitrary, capricious, and an abuse of agency discretion to rely on outdated, disavowed science, from over 20 years ago, when the agency has been alerted by its very author, and given a blueprint of the more recent methods.

These shortcomings are particularly significant because this is a precedent-setting process. Assuming FDA approves this application, other sponsors seeking to produce AquAdvantage Salmon or approval of a new GE animal NADA, will likely mimic the same conditions and analysis of risk accepted here and cite them as established and lawful precedent

---

the transgenic fish's genotype and phenotype to identify and prioritize hazardous upon which to focus the environmental risk assessment (Devlin et al. 2007).").

[137] 2013 Kapuscinski Interview.

[138] *Id*.

for future environmental reviews. Dr. Kapuscinski recently explained that "If FDA approves these fish, the final environmental assessment is going to be the standard, it's going to set the precedent for future approvals. So it absolutely has to have the best scientific reliability and quality, especially given that future applications may not be shared with the public."[139] FWS has also recognized this problem, stating that the "current EA under review was released publicly because it sets a crucial precedent regarding human consumption of a transgenic vertebrate (fish). This is why the scientific quality of this first EA sets such a crucial precedent."[140]

ii. Lack of Quantitative Failure Mode Analysis

A specific and fatal flaw repeatedly discussed by expert scientists is that FDA's FONSI relies on the assumption that AquaBounty's proposed confinement measures, which include layers of biological, geographic, and physical containment for the PEI and Panama facilities, will be 100% successful in keeping AquAdvantage Salmon out of the natural environment.[141] Despite the requirements of current risk science, *see* above, FDA has failed to undertake a quantitative failure mode analysis for these confinement methods to assess the reliability of any and all of these proposed containment measures.[142]

Dr. Kapuscinski has confirmed that the current draft EA has not changed at all from the 2010 AquaBounty version in this regard, explaining that FDA is "still hanging their whole conclusion on risk management—that is, multiple confinement systems for the fish…They still haven't done what Dr. Sundström and I asked for, which is a quantitative failure mode analysis…As said before in our written comments, it's a standard practice in risk assessment and risk management to do a failure mode analysis, and it should be as quantitative as possible."[143]

Significantly, without a quantitative failure mode analysis, FDA can offer no assurance that the various containment measures presented in AquaBounty's application are sufficient—even in combination—to eliminate the threat of potential significant environmental effects associated with released or escaped AquAdvantage Salmon and justify the agency's FONSI determination. This lack of analysis is especially significant as it relates to the proposed biological containment of the AquAdvantage Salmon, which it claimed renders the GE fish sterile through a process of triploidy. In their 2010 VMAC comments, Sundström and Kapuscinski urged FDA to conduct a quantitative failure mode analysis that "quantifies the variability in percent triploids across treated batches of eggs and the frequency of 'exceptional diploids.'"[144] ("exceptional diploids" being those AquAdvantage Salmon that do not become triploid in the process). In support of this analysis, Drs. Kapuscinski and Sundström cited a study by Dr. Devlin (et al.) in which 97% - 99.8% of 10,000 to 19,000 treated transgenic coho salmon eggs were successfully treated with triploidy, but 1.1% exceptional diploids were detected among the treated group.[145] Dr. Devlin, who has studied transgenic salmon since 1989, has noted that these sterility rates, which are comparable to those attained by AquaBounty, are

[139] 2013 Kapuscinski Interview.
[140] FWS Region 5 Comments, *supra*.
[141] See FDA Finding of No Significant Impact, at 4.
[142] *See supra* 2010 Kapuscinski and Sundström VMAC Comments at 3; 2011 Kapuscinski NPR Transcript.
[143] 2013 Kapuscinski Interview.
[144] 2010 Kapuscinski and Sundstöm VMAC Comments.
[145] *Id*.

"not quite high enough for biological containment yet."[146] Kapuscinski and Sundström explained that exceptional diploid individuals can contain the transgene but their fertility and ability to transmit the transgene to offspring is not yet known." Thus, they asked, "[d]o exceptional diploids occur among treated [AquAdvantage Salmon]? If yes, it is necessary to determine their fertility or devise a proven way to eliminate them from eggs destined for growout.[147]" Rather than conducting the proper failure analysis, FDA merely notes that "[t]he acceptance criterion for releasing a batch of eyed-eggs for grow-out would be such that the probability would be less than 0.05 that these eggs are not at least 95% triploid."[148] *Id*. This specification still allows for the grow-out of significant numbers of potential sterile female AquAdvantage Salmon, just one of which, if released, could "initiate a process of ecological impacts."[149] *See* Devlin 2006 et al (explaining that although "induction of triploidy is currently highly effective (up to 99.8% in laboratory experiments, R.H. Devlin, unpublished data)…"further research is required to improve this technique as a sterilization method," and noting that "the escape from aquaculture facilities can involve large numbers of animals (greater than 500,000 in some cases), which based on the previous estimate, could result in the release of ~1000 diploid transgenic animals.").

The lack of a failure mode analysis is problematic not only for this NADA, but for future foreseeable, related actions. As Dr. Kapuscinski noted: "Future farming of this fish is probably not going to happen in facilities that are as confined as the one in Panama. And even if future farmers try to have lots of confinement, it gets harder and harder to make that work when you have larger-scale fish farms and tens or hundreds of fish farms around the world…[T]hat's why having a method of failure mode analysis in this precedent-setting document is so important."[150] Kapuscinski and Sundström have further noted that assuring continual implementation of multiple confinement will be difficult at just the two sites in this NADA because the "actual achievement of multiple confinement depends on many human actions, and the rigor of audit and regulatory oversight" and that "[a]n even greater challenge is how to assure multiple confinement at many, larger facilities in different environmsnts and nations as commercial production of these fish proliferates."[151] Likewise, FWS has noted that failure mode analysis is necessary given how difficult it will be for FDA to "assure, monitor, and verify that multiple

---

[146] Sarah Schmidt, *Canadian scientist's work front and centre in GE fish debate*, Postmedia News, Feb. 23, 2011, *available at* http://www.canada.com/technology/Canadian+scientist+work+front+centre+fish+debate/4334542/story.html#ixzz1Fse0GpD5.

[147] Kapuscinski and Sundström VMAC Comments; *see also* FWS Region 5 comments, supra.

[148] *Id*.

[149] EA at 40-41. FDA's position that it would be unrealistic to prove 100% efficiency of the tripoid process, and its acceptance of the fact that 5% of the fish taken to Panama may not sterile (EA at 41, fn. 20), is specific to the triploidy process proposed by AquaBounty here; it does not consider (or even mention) a NEPA alternative requiring AquaBounty to use a more effective process to induce sterility in its fish. Even Aquabounty knows its sterility process needs improvement: in 2011, AquaBounty sought $500,000 in federal funding from the United States Department of Agriculture to further study a more effective sterilization process in fish. In its grant proposal, AquaBounty acknowledged that existing technologies to control fertility are "logistically demanding, negatively impact culture performance, or do not result in 100% sterility," and it therefore had "developed a new approach termed Maternal Sterile Technology (MST) and designed for efficient, large-scale production of sterile finfish." Attachment 34 hereto.

[150] 2013 Kapuscinski Interview.

[151] 2010 Kapuscinski and Sundström VMAC Comments at 2.

confinement is continually achieved at the two facilities and in future facilities as farming of these fish proliferates."[152] Kapuscinski and Sundström have thus urged FDA to conduct a failure analysis for "the full range of facilities that may obtain AquAdvantage Salmon in the foreseeable future."[153] This analysis is needed now as FDA has already left the door open for different facilities with different forms of confinement by broadly describing the Product Definition, specifically the Limitations of Use.[154] In light of this and the fact that the agency's regulations do not expressly require additional environmental review for the implementation of such changes, *see infra*, it would be arbitrary, capricious, and unlawful for FDA to proceed without conducting analysis the quantitative science-based analysis Sundström, Kapuscinski and FWS scientists have repeatedly called for.

Kapuscinski and Sundström also highlighted the importance of failure mode analysis for physical and chemical confinement, noting that these "measures are especially prone to equipment failures, power failures, operational wear, and human error (Mair et al. 2007)."[155] They noted that while they "commend the applicant's proposed 'integrated confinement system' plan that aims to reduce these sources of failure, [] this does not remove the need for quantitative failure assessment."[156]

iii. Failure to Properly Assess Consequences and Uncertainties

FDA has not come close to adequately assessing the possible consequences and identifying the potential uncertainties associated with the accidental or deliberate release of AquAdvantage Salmon in <u>any</u> environment, including even the waters outside PEI and Panama, or areas these fish may enter upon proliferation. Instead, FDA abruptly ended its analysis with the conclusive assumption that AquaBounty's multiple confinement measures will not fail (even though it has not done a proper failure mode analysis), and provided an extraordinarily limited and misleading representation of the potential risks associated with released or escaped AquAdvantage Salmon. Drs. Kapuscinski and Sundström detailed this deficiency in 2010, yet FDA has still done nothing to correct it.[157]

> [The EA] focuses only the 'exposure' step of risk assessment, and concludes there is 'extremely small' likelihood of exposure due to multiple confinement at the two facilities, thus no consequence and no need to assess the consequences. As scientists, we cannot agree with this approach because it assumes 100% achievement of multiple confinement without having presented the failure mode analysis that is standard practice in technology risk assessment. <u>Even if actual exposure is very close to zero, it is still necessary to assess ecological consequences, from low to high severity consequences,</u>

[152] FWS Region 5 Comments.
[153] Kapuscinski and Sundström VMAC Comments at 3.
[154] FDA EA at 22- 23 ("Although no modifications are expected for the product identity or claim, depending on the outcome of the agency's final determination, the limitations of use may be modified if there is an approval."). The Limitations of Use are described generally as "AquAdvantage Salmon are produced as eyed-eggs and grown-out only in physically-contained freshwater culture facilities specified in an FDA-approved application."
[155] Kapuscinski and Sundström VMAC Comments.
[156] *Id*.
[157] See 2013 Kapuscinski Interview (explaining that FDA made did not address any of Sundström's and Kapuscinski's 2010 comments on the environmental consequence assessment).

> and then estimate the overall risk. We also disagree with this approach because of the likely proliferation of farming AAS in numerous grow-out facilities where multiple confinement will be harder to implement and assure (Mair et al 2007).[158]

They specifically explained that "the EA did not adequately consider the growing body of research on genetic and ecological risks of transgenic fish that "shows there will be high scientific uncertainty in predicting the overall fitness and ecological effects of AAS if they enter nature because it is extremely challenging to extrapolate from experiments using semi-natural conditions (reviewed in Devlin et al 2007, Devlin et al. 2006, Kapuscinski et al. 2007)."[159] This, they explained, "is due to key biological complexities including gene-environment interactions, background genetic effects, pleiotropic effects, tradeoffs between traits expressed across different life stages, persistent effects of the environment experienced early in lie, evolution of fertile transgenic fish after escape, ecological variability, and poorly understood ecological processes (Devlin et al. 2004b, 2007, Kapuscinski et al. 2007, Neregard et al. 2008, Pennington and Kapuscinski in press, Sundström et al 2007b, 2009)."[160] Moreover, Kapuscinski and Sundström explained:

> Overall, this research indicates it could be very misleading to base an environmental risk assessment on data for only a few traits that do not span the whole life-cycle and measured under a limited range of environmental conditions. We are therefore concerned about overly simplistic statements of 'poor fitness' of AAS without the kinds of scientific evidence required to support such a claim…Also, the Environmental Assessment gave an unacceptably cursory mention of uncertainty with no application of scientific methods of uncertainty analysis.[161]

All in all, they concluded that FDA must require a "scientifically rigorous environmental impact statement before making a decision on the AAS application."[162]

In response to these concerns, FDA added an "environmental consequences" section to the current EA. The problem, according to Kapuscinski and Sundström, *supra*, is that FDA's "analysis" of potential consequences is extraordinarily inadequate in light of current scientific standards for risk assessments. It is so poorly done and indefensible that Kapuscinski has urged FDA to delete it from the EA before the agency sets a lasting scientifically unacceptable, low standard for risk assessment of all future GE fish.[163]

In addition to Kapuscinski's and Sundström's specific concerns, one need not look beyond the face of the draft EA to realize that FDA's attempt to address potential environmental and ecological consequences is incomplete, highly uncertain, riddled with unknowns, and misleading. This alone is grounds for the preparation of an EIS, as discussed below, and is also

[158] Kapuscinski and Sundström VMAC Comments.
[159] *Id*.
[160] *Id*.
[161] 2010 Kapuscinski and Sundström Comments at 4.
[162] *Id*.
[163] 2013 Kapuscinski Interview.

sufficient to support the conclusion that FDA's FONSI is entirely arbitrary, capricious, and contrary to law.

One astonishing example of the highly uncertain, incomplete, and misleading nature of FDA's environmental analysis is that the fact that neither FDA nor AquaBounty has studied the potential biological fitness of the AquAdvantage Salmon that is the subject of this NADA. FDA reveals that "[f]itness (*e.g.*, oxygen requirements, swimming speed, metabolic scope, etc.) was not explicitly evaluated in the studies submitted to the agency in support of animal safety."[164] Yet instead of obtaining this information, which is obviously crucial for determining whether AquAdvantage Salmon can survive, reproduce, and significantly impact the natural environment, FDA relies on "reports on [] fitness characteristics from peer-reviewed journals on GH transgenic Atlantic salmon" that are distinct from the AquAdvantage Salmon currently before the agency.[165] FDA asserts that these reports "indicate that changes in the observed phenotype consistent with the presence of the EO-1α construct appear to result in decreased fitness," and that this observed decreased fitness "would be expected to reduce the chances for survival and establishment should AquAdvantage Salmon escape from commercial production facilities."[166] But earlier in the EA FDA explains that "[t]he extent to which [these same reports'] results may be applicable to Atlantic salmon in general, and to AquAdvantage salmon, in particular, are unclear."[167] FDA's acceptance of these unrelated, and in many instances outdated, findings in discussing the potential environmental consequences of AquAdvantage Salmon is inexplicable. Given the lack of this data, FDA's entire discussion of survivability and potential environmental consequences is flawed, misleading, and unlawful must be redone in an EIS, with relevant studies on the specific "animal drug" FDA seeks to approve here. These studies must follow the risk analysis recommendations of Kapuscinski and Sundström to fully assess the risks and consequences associated with the specific AquAdvantage salmon product in the full range of potential receiving environments. In addition, an EIS should analyze the risks to the waters in which endangered Atlantic salmon live, breed, and migrate.

Additional evidence of the inadequacy of FDA's analysis is found in the EA's discussion of the presence of Infectious Salmon Anemia Virus (ISAV) in AquaBounty's Prince Edwards Island facility. ISAV was found at the facility in 2009, yet was not mentioned or discussed in AquaBounty's August 2010 EA, or FDA's September 2010 Briefing Packet or the VMAC.[168] The current draft EA acknowledges the ISAV outbreak and explains that ISAV has not since been reported at the facility. However, nowhere does the EA attempt to explain how the virus entered the facility in the first place and what could happen if an infected AquAdvantage Salmon were to escape into natural environments. FDA's general statements that AquAdvantage Salmon is not believed to be any more or less resistant to diseases than wild Atlantic Salmon does not address this concern, as wild Atlantic Salmon is already known to be highly susceptible to ISAV. Likewise, FDA's cursory statement that AquaAdvantage salmon "would not carry disease from

[164] FDA EA at 77.
[165] *Id*.
[166] *Id*.
[167] FDA EA at 27.
[168] See Living Oceans Society, ISA Virus Confirmed in Aquabounty's genetically-engineered salmon, Press Release (Dec. 16, 2011), Attachment 35 hereto; E-mail from Stephen Stephen to Brian Evans, "Positive Finding of Infections Salmon Anaemia Virus (ISAV), Attachment 36 hereto.

the broodstock facility" and affect endangered Atlantic salmon populations,[169] again improperly assumes 100% successful containment, and wholly ignores consideration of what might happen if an ISAV-infected AquAdvantage Salmon did find its way into the waters, particularly those outside PEI. FDA's failure to fully analyze this particular ISAV occurrence and study the associated environmental and ecological impacts is arbitrary and capricious. In addition, the absence of this information from prior FDA documents raises the question whether the agency has adequate oversight of the PEI facility and therefore cannot establish that the conditions of this NADA are consistently being met.

Moreover, as mentioned above, the EA does not provide sufficient assessment to support the presumed sterility of the AquAdvantage Salmon. FDA acknowledges that up to five percent of the AquaAdvantage salmon produced at PEI may not be sterile following induction of triploidy.[170] FDA further states that "there are no specific data demonstrating that triploid AquAdvantage Salmon are indeed sterile, that is incapable of producing viable offspring."[171] Nonetheless, FDA assumes for purposes of its environmental analysis and FONSI that all of the fish will be functionally sterile as a result of triploidy, and thus FDA does not provide any analysis in its EA of possible risks presented by sterile AquAdvantage salmon. Instead, FDA simply refers to decades old scientific studies on triploid fish to conclude that "triploidy would insure functional sterility and reproductive incompetence in the sponsor's proposed all-female populations of AquAdvantage Salmon."[172] Significantly, in all of studies cited at least some triploid females were fertile and capable of producing eggs.[173] FDA assumes, based on these studies, that the fertilized eggs from a triploid female AquAdvantage salmon would not survive. However, as James Geiger, assistant regional director for fisheries in FWS's Northeast region recently explained:

> Although AquaBounty claims their fish are sterile, that sterilization process is not 100 percent. There is the possibility that some of these fish could escape and reproductively interact with wild native salmon… Any potential offspring could reduce the biological and ecological fitness of the native wild salmon… Any potential escape, no matter how little, has the potential to harm endangered wild salmon populations.[174]

Along with the assumption on sterility, FDA neglects to fully analyze the risk associated with fertile AquAdvantage Salmon broodstock, including males.[175] The EA notes that approximately one half of the AquAdvantage Salmon at PEI are males that are capable of breeding.[176] This failure is especially alarming because upon receiving FDA approval,

---

[169] *Id*. at 104.
[170] *See* Briefing Packet at 126, 115; FDA EA at 40-41, 82 ("The acceptance criterion for releasing a batch of eyed-eggs for grow-out would be such that the probability would be less than 0.05 that these eggs are not at least 95% triploid.").
[171] *Id*. at 83.
[172] *Id*.
[173] *Id*.
[174] See http://bostonherald.com/business/business_markets/2013/01/fishing_compliance/; January 2, 2013 FWS E-mail (stating that Dr. Geiger's comment is "in line with some of the thinking within the service"), Attachment 37 hereto.
[175] FDA EA at 87 (("Biological containment of broodstock would be counterproductive to commercialization").
[176] *Id*. at 89-92.

AquaBounty may be producing millions of eggs for commercialization, hundreds of thousands of which, according to AquaBounty's own specifications may be fertile. As warned by FWS Region 5 in 2010, "[t]he diploid GMO salmon that are produced in this process are fertile, and the modified gene is passed from one generation to the next. The triploids are supposed to be sterile. The concern is twofold: escape by the diploids or their reproductive products and successful reproduction in the wild, and incomplete induction of triploidy allowing reproduction of individuals thought to be non-reproductive and therefore potentially kept under less secure conditions which could allow an escape event."[177]

Even if any escaped or released AquAdvantage Salmon are sterile, it does not necessarily follow that that they cannot disrupt ecosystems. These fish could still live in the receiving ecosystems and interact with other organisms, including endangered fish, and FDA must evaluate those potential risks as part of this NADA's NEPA assessment for the full range of scenarios in which AquAdvantage Salmon could be reared, produced, or released.

Finally, the attached comments by Dr. Jonathan Rosenfield (Attachment 38 hereto) further establish that there is indeed substantial science refuting the generic unsubstantiated assertions included in the EA and suggesting that transgenic AquAdvantage Salmon may present serious risks to wild fish populations and the natural environment.

FDA must consider this evidence and other related studies, and complete a proper risk assessment pursuant to the recommendation of expert scientists and FWS in order to adequately analyze the potential environmental effects associated with this NADA. "In the absence of such fundamental information, it would seem that any alleged 'finding' that the project will not significantly affect the species is the purest sophistry." *Sierra Club v. Norton*, 207 F.Supp.2d 1310, 1331 (S.D. Alabama 2002) (finding agency's FONSI arbitrary and capricious because it failed to address lack of certainty). Accepting FDA's failure to study the potential harms here "would turn NEPA on its head, making ignorance into a powerful factor in favor of immediate action where the agency lacks sufficient data to conclusively show not only that the proposed action would harm an endangered species, but that the harm would prove to be 'significant.'" *Sierra Club v. Norton*, 207 F. Supp. 2d at 1335. At the very least, FDA is required to disclose the uncertainties inherent in its FONSI, explain their relevance, and has the burden to show why the necessary information could not be obtained. 40 C.F.R. § 1502.22; *Envtl. Prot. Info. Ctr. v. Blackwell*, 389 F. Supp. 2d 1174, 1188 (N.D. Cal. 2004) (recognizing that 40 C.F.R. 1502.22 guides the court in determining "whether an agency can be charged with having failed to take a hard look" because information is incomplete or unavailable).

In sum, FDA's failure to conduct the proper analyses and account for the many potential risks and uncertainties implicit in this application is plain evidence that the agency did not take the requisite "hard look" at the environmental consequences of this application, and is overtly arbitrary, capricious, and contrary to law.

[177] FWS Region 5 Comments.

B. **FDA Must Prepare an EIS.**

An EIS "must be prepared if substantial questions are raised as to whether a project may cause significant degradation of some human environmental factor." *Klamath Siskiyou Wildlands Center v. Boody*, 468 F.3d 549 (9th Cir. 2006) (emphases added). "The plaintiff need not show that significant effects will in fact occur, but if the plaintiff raises substantial questions whether a project may have a significant effect, an EIS must be prepared." *Id.* (emphases added). "This is a low standard." *Id.* (emphasis added).

Here, as explained in full above, FDA has not even attempted to seriously consider whether AquAdvantage Salmon may adversely affect the marine environment, instead relying wholly on the unsubstantiated assumption that the fish will never escape confinement. As presented in Dr. Jonathan Rosenfield's letter (Attachment 38), and as noted by FWS scientists, history and science indicate that escapement of AquAdvantage Salmon is likely, and that the potential associated risks are great, ranging from ecological disruption to species extinction by way of increased competition for resources and mating, hybridization and genetic introgression. At a minimum, FDA must recognize that the possible environmental and ecological consequences of AquAdvantage Salmon are highly controversial and uncertain and particularly threatening to this transgenic fish's only remaining U.S. wild counterpart, the endangered Atlantic salmon population. For those reasons, and the many more set forth below, FDA must prepare an EIS.

FDA's regulations incorporate CEQ's requirements for preparing an EIS. 21 C.F.R. § 25.42(b). These applicable CEQ regulations require FDA to consider to the following ten factors when determining whether its approval of AquaBounty's NADA may significantly affect the quality of the environment:

(1) Impacts that may be both beneficial and adverse. A significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial.

(2) The degree to which the degree to which the proposed action affects public health or safety.

(3) Unique characteristics of the geographic area such as proximity to historic, or cultural resources, park lands, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

(4) The degree to which the effects on the quality of the human environment are likely to be highly controversial;

(5) The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks.

(6) The degree to which the action may establish precedent for future actions with significant effects or represents a decision in principle about a future consideration.

(7) Whether the action is related to other actions with individually insignificant but cumulatively significant impacts. Significance exists if it is reasonable to anticipate a cumulatively significant impact on the environment. Significance cannot be avoided by terming an action temporary or by breaking it down into small component parts.

(8) The degree to which the action may adversely affect districts, sites, highways, structures, or objects listed or eligible for listing in the National Register Places or may cause loss or destruction of significant scientific, cultural, or historical resources.

(9) The degree to which the action may adversely affect an endangered or threatened species or its habitat that has been determined to be critical under the Endangered Species Act of 1973.

(10) Whether the action threatens a violation of Federal, State, or local law or requirements imposed for the protection of the environment.

40 C.F.R. 1508.27 (emphases added); *see also* 40 C.F.R. 1502.3. As discussed below, these factors mandate the preparation of an EIS for the AquaBounty NADA.

1. Highly Controversial.

The "highly controversial" factor requires an agency to consider whether "a substantial dispute exists as to the size, nature or effect of the [project]." *Soc'y Hill Towers Owners' Ass'n v. Rendell*, 210 F.3d 168, 183-84 (3d Cir. 2000) (*quoting Hanly v. Kleindienst*, 471 F.2d 823, 830 (2d Cir.1972).

As presented above, there is extensive, ongoing scientific dispute of these very issues—scope, methodology and data—as to whether AquAdvantage salmon may escape confinement and adversely affect the natural environment and marine ecosystems, The preeminent transgenic fish risk experts—Drs. Kapuscinski and Sundström—have repeatedly criticized FDA's outdated, incomplete, and misleading analysis of potential environmental threats raised by this NADA. In particular, they have called into question FDA's failure to conduct an adequate risk assessment for this application, and highlighted specific deficiencies regarding the overly narrow scope of FDA's scientific analysis, the old methodology used, and the limited, unverifiable data presented by the agency.[178]

[178] 2010 Kapuscinski and Sundström VMAC Comments ("The current Environmental Assessment only assesses the likelihood of transgenic salmon escaping for multiple confinement at the two facilities but the proposed multiple confinement does not absolve the need for a complete environmental risk assessment, given the likely proliferation of sales of AAS eggs for growout beyond one facility in Panama. The Environmental Assessment does not provide the full information needed to predict environmental effects of AAS…It focuses on an outdated list of issues (from Kapuscinski and Hallerman 1991) and ignores the major advances in methodologies for assessing environmental risks of transgenic fish (Kapuscinski et al. 2007). These advanced methods systematically integrate information about the environment and the transgenic fish's genotype and phenotyle to identify and prioritize hazardous upon which to focus the environmental risk assessment (Devlin et al. 2007, Kapuscinski et al. 2007a, Hayes et al. 2007)") (emphases added); 2011 Kapuscinski NPR Interview; 2013 Kapuscinski Interview ("[E]verything that is in this EA that looks at possible consequences of a fish escape is unacceptable to me. It's very poorly done in terms of basic scientific standards in multiple ways. And if they just don't want to do the work for a more scientifically acceptable

Scientists within the FWS have echoed those same science-based concerns repeatedly, identifying numerous and specific problems with the quality of FDA's scientific review of the possible environmental and ecological risks, noting, in particular, the possibility of irreversible harm to imperiled salmon populations.[179] Notably, the experts within FWS have urged FDA to follow the updated risk assessment methods and approaches developed by Dr. Kapuscinski in 2007.[180] Yet, as Dr. Kapuscinski recently confirmed, FDA has failed to do so, and has instead relied on methods previously advanced by Dr. Kapuscinski herself in the 1990s, which she has repeatedly explained have been replaced by better methods that the agency should have used.[181]

Moreover, Dr. Jonathan Rosenfield, a scientist with expertise in the ecology and behavior of fish, particularly non-native invasive species and genetic introgression, further explains that FDA has failed to consider a large body of evidence suggesting that AquAdvantage Salmon will escape confinement and possibly cause serious and significant environmental and ecological harm.

Substantial controversy also exists as to the appropriate scope of FDA's environmental analysis. Kapuscinski and Sundström have recognized that FDA's approval of this action will prompt proliferation of sales of AquAdvantage Salmon eggs for grow-out beyond the facility in Panama.[182] NMFS likewise questioned whether it would be appropriate to consider to commercial resale of eyed eggs as part of this initial action.[183] This particular controversy is only amplified by evidence that efforts to import of AquAdvantage Salmon eggs into the U.S. are already underway.

2. Highly Uncertain, Unique, and Unknown Risks.

Preparation of an EIS is mandated where uncertainty may be resolved by further collection of data, or where uncertainty may be resolved by further collection of data, or where the collection of such data may prevent 'speculation on potential…effects. "The purpose of the EIS is to obviate the need for speculation by insuring that available data are gathered and analyzed prior to the implementation of the proposed action." *Nat'l Parks*, 241 F.3d at 732 (quoting *Sierra Club*, 843 F.2d at 1195). "Where an EA lacks certainty on one or more issues, it is the responsibility of the agency to provide a 'justification regarding why more definitive information could not be provided." *Blue Mountain,* 161 F.3d at 1213. "Lack of knowledge does not excuse the preparation of an EIS; rather it requires the [agency] to do the necessary work to obtain it." *Id.*

---

consequence assessment, then I would recommend that the FDA simply deletes all of that from this environmental assessment…..").

[179] See supra FWS Region 5 Comments and FWS 2010 COP Letter to FDA.

[180] FWS Region 5 Letter.

[181] 2013 Kapuscinski Interview ("Throughout both the 2010 and 2012 EA, the text cited two important publications that I led back in the early 1990s, one of which I was lead author and the other by a working group I chaired. The FDA is hinging most of its scientific approach on the consequence assessment on those two reports. And yet I myself am now saying that they've been replaced by better methods.") (emphasis added).

[182] 2010 Kapuscinski and Sundström VMAC Comments.

[183] November 30, 2010 NMFS E-mail to FDA, *supra*.

The sections above concerning the many deficiencies in the science underlying the FONSI explains that this NADA and the AquAdvantage Salmon new animal drug is replete with highly uncertain, unique, and unknown risks, which require the preparation of a comprehensive EIS, including a full, science-driven risk assessment that follows the current standard methodologies outlined by Kapuscinski and Sundström. The high degree of uncertainty regarding the environmental and ecological risks of transgenic fish has been confirmed repeatedly by leading scientists, including those whose studies are cited in the EA, and FWS.[184]

This uncertainty was even acknowledged by one of FDA's own VMAC presenters in 2010, Dr. who stated that "development of quantitative risk assessment is presently incomplete…especially regarding the likelihood of harm given exposure to the hazard. We need more studies quantifying net fitness, especially under near-wild, or wild, conditions."[185] As Dr. Hallerman put it, "we have a lot to learn about the likelihood of genetic harm being realized due to the interbreeding of wild and transgenic aquacultured fish."[186]

Tellingly, a 2008 publication by the National Research Council (NRC) of the National Academies of Science (NAS) summarizes a number of recognized research gaps limiting the understanding of the environmental effects of GE organisms on natural habitats and the wildlife within those habitats.[187] This study was done in response to concerns about the deficiencies in scientific research pertaining to GE animals, particularly their potential impacts on fish, wildlife, and natural habitats. With regard to GE fish specifically, NAS noted that additional research is needed on environmental impacts in the following six areas:

1. The development of large, variable-environment facilities to rear and assess transgenic fish in conditions as close to natural environments as possible.

2. Assessment of whether complicating gene-by-environment interactions and antagonistic pleiotropic efforts are pervasive for critical fitness traits. If these effects cannot be well defined, then laboratory experiments will be able to identify some of the forces at work in predicting fitness, but not accurately estimate magnitudes.

3. Integration of ecosystem models with demographic and genetic models, attempting model validation with surrogate (non-GEO) models in nature.

4. Development of methods for uncertainty analysis to facilitate predictions and regulatory decisions.

---

[184] *See, e.g.* 2010 Kapuscinski and Sundström VMAC Comments (explaining that the EA fails to consider the "growing body of research on genetic and ecological risks of transgenic fish" which "shows there will be high scientific uncertainty in predicting the overall fitness and ecological effects of AAS if they enter nature because it is extremely challenging to extrapolate from experiments using semi-natural conditions (reviewed in Devlin et al 2007, Devlin et al 2006, Kapuscinski et al. 2007)"; *see also* Devlin et al 2006 (explaining that ecological consequences of transgenic fish are highly uncertain and requires assessments of risk for as wide a range of conditions as possible); FWS Region 5 Comment Letter, FWS Dr. Moyer Letter, FWS COP Letter, supra.

[185] VMAC Meeting Transcript (September 20, 2010) at 86:1-6.

[186] *Id*. at 80:8-10.

[187] Research Gaps Memo, obtained through FOIA production from FWS, Attachment 39; see also Genetically Engineered Organisms, Wildlife, and Habitat: A Workshop Summary, National Research Council of the National Academies (2008). Select pages attached hereto as Attachment 40.

5. Assessment of background genetic effects on transgene phenotype.

6. Improvement on biological containment methods to minimize exposure of transgenic ecosystems, through a combination of layers of containment.[188]

The Summary specifically urges the development of longer-term, more collaborative studies on these impacts.[189] Nonetheless, FDA proceeded to conduct a limited assessment of the AquaBounty based on data known to be incomplete and uncertain, and without the active participation of other agencies, academics, or interested non-profit and non-governmental organizations.

FDA's failure to properly acknowledge and address the many gaps in its environmental risk analysis is in itself yet another NEPA violation. 40 C.F.R. § 1502.22 requires agencies to "always make clear" when there is "incomplete and unavailable information." *See, e.g.*, *Lands Council v. Powell*, 395 F.3d 1019, 1033 (9th Cir. 2005) (citing 40 C.F.R. 1502.22 to hold that NEPA "requires up-front disclosures of relevant shortcomings in the data or models.").

In instances like this where "the incomplete information relevant to reasonably foreseeable significant adverse impacts is essential to a reasoned choice among alternatives and the overall costs of obtaining it are not exorbitant, the agency shall include the information" in its analysis. 40 C.F.R. 1502.22(a). For purposes of this requirement, "reasonably foreseeable" includes impacts which have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason." 40 C.F.R. § 1502.22(b)(1).

As applied here, this requirement means that FDA must plainly disclose the discrepancies in its analysis and conduct the kind of thorough and complete failure analysis and risk assessment recommended by Drs. Kapuscinski and Sundström, or at the very least, explain why doing so is cost prohibitive. 40 C.F.R. § 1502.22(b) further requires FDA to obtain studies that are necessary to understand the true environmental and ecological risks posed by the specific AquAdvantage Salmon for which approval is sought, should these GE fish escape into the full range of foreseeable receiving environments and ecosystems. FDA's cursory assertions that escapement of AquAdvantage Salmon and consequent harm is unlikely are irrelevant to this inquiry, as available, credible science indicates that reasonably foreseeable impacts could indeed be catastrophic.

Pursuant to the CEQ regulations, to the extent FDA concludes that the missing, but essential, information cannot be obtained because the overall costs of obtaining it are exorbitant or the means to obtain it are not known, FDA is required to include:

> (1) A statement that such information is incomplete or unavailable;
>
> (2) a statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse impacts on the human environment;

[188] *Id*.
[189] *Id*.

(3) a summary of existing credible scientific evidence which is relevant to evaluating the reasonably foreseeable significant adverse impacts on the human environment, and

(4) the agency's evaluation of such impacts based upon theoretical approaches or research methods generally accepted in the scientific community.

40 C.F.R. § 1502.22. Vague admissions of uncertainty and unknowns appear where FDA mentions that certain crucial studies have not yet been conducted by the agency or AquaBounty.[190] However, instead of explaining the true relevance of the missing information, how that information might affect the agency's FONSI determination, or why FDA has not sought to obtain the missing information, FDA simply brushes over the problem by citing to science regarding other types of fish in other contexts. This is precisely the kind of incomplete action 40 C.F.R. 40 C.F.R. §§1502.22(b) and 1508.27(b) were designed to protect against.

3. Precedent-Setting and Decision in Principle about Future Considerations.

40 C.F.R. 1508.27(b)(6) looks to whether a proposed action may establish a precedent for future actions with significant effects. "The purpose of that section is to avoid the thoughtless setting in motion of a 'chain of bureaucratic commitment that will become progressively harder to undo the longer it continues.'" *Presidio Golf Club v. Nat'l Park Serv*., 155 F.3d 1153, 1162-63 (9th Cir. 1998) (quoting *Sierra Club v. Marsh*, 769 F.2d 868, 879 (1st Cir. 1985)). It is clear that FDA's action on the current AquaBounty application will establish a precedent and a decision in principle about future GE animal applications.

Because AquaBounty's application is the very first of its kind to consider the development of a GE animal for human consumption, there can be no question that FDA's decision here will set the standard for all other GE NADAs that will come before the agency, as well as requests for similar GE approvals in other nations around the globe that may be awaiting FDA's decision. In particular, FDA's decision here will set the standard for the quality of science and environmental review that is necessary and sufficient to obtain government approval for the production and proliferation of GE animals. In this regard, FDA's action on this particular NADA represents a decision in principle about future considerations for all upcoming GE animal NADAs.

As to AquAdvantage salmon specifically, there is already ample evidence that requests to import AquAdvantage eggs to sites not addressed in the EA will be considered as soon as FDA makes its decision on the current NADA.[191] And, as noted above, FDA's own regulations do not clearly explain what kind of additional environmental review is necessary for supplemental NADAs and changes to this particular application. FDA's action on this first application will substantially influence what happens next. As Dr. Kapuscinski and FWS scientists have

[190] *See, e.g.*, FDA EA at 77 ("[f]itness (*e.g.*, oxygen requirements, swimming speed, metabolic scope, etc.) was not explicitly evaluated in the studies submitted to the agency in support of animal safety."); Draft EA at 83 ("there are no specific data demonstrating that triploid AquAdvantage Salmon are indeed sterile, that is, incapable of producing viable offspring").

[191] *See* FWS E-mails re: Import Requests, *supra*.

repeatedly warned, the precedent-setting nature of FDA's action is precisely way a comprehensive EIS that fully considers the full range of potential risks is necessary:

> …This application is setting the precedent for what would be expected of an applicable to show environmental safety to a reasonable degree in the future. And if this application is approved, and if the salmon farming industry decides that this is a good product for their business, then it's going to be adopted and farmed in places where there may not be as good confinement and where if the fish escape in some of those places-- like eastern Canada, the state of Maine, parts of Europe—where they can escape, interact with wild Atlantic salmon.[192]

4. Cumulative Significant Impacts.

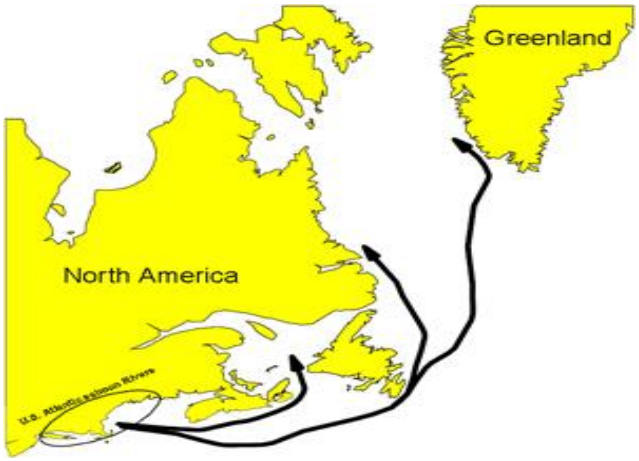
As discussed at length above, FDA's approval of this NADA will have significant cumulative impacts on the environment. This is because approval will open the doors to expanded production of AquAdvantage salmon throughout the U.S. and the world in facilities that may not have the same levels of containment measures proposed in the current NADA. Despite FDA's statements to the contrary, the agency's regulations do not clearly ensure that relevant changes to the production or manufacture of the AquAdvantage product will be subject to additional, meaningful, and public environmental review. Thus, the risks associated with those cumulative actions, many of which are already known, must be considered now, comprehensively, through an EIS.

5. Proximity to Ecologically Critical Areas & Risk to ESA Listed Species.

FDA must consider the proximity of at least the current proposed Prince Edwards Island facility to imperiled Atlantic Salmon populations. The NADA proposes to produce AquAdvantage Salmon eggs at PEI, which appears to be within the migratory range of endangered Gulf of Maine Atlantic Salmon. FDA itself has explained that anadromous Atlantic salmon are known to spend "as many as five winters at sea, thousands of miles away, and that "Atlantic salmon leave Maine rivers some time in April or May, and can be found in the waters off Labrador and Newfoundland by mid-summer. They then migrate to take advantage of available food supplies and generally spend their first winter at sea off the coast of Greenland."[193] FDA's own map shows that this migratory path includes waters off the coast of PEI:

[192] 2011 Kapuscinski NPR Interview; FWS Region 5 Comments (noting that FDA's action on this application will set a precedent and future decisions may not be subject to public review).

[193] http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222635.htm.



Atlantic Salmon demonstrate an expansive migratory pattern over their life cycle. Courtesy: N.O.A.A.

These factual statements regarding the extensive migration of Atlantic salmon directly contradict one of FDA's bases for ignoring the possible effects on populations of endangered Atlantic Salmon in Maine: "The possibility for effects to occur on endangered Atlantic salmon populations in Maine is further reduced by the great distance between PEI and the waters of Maine (as well as other areas of the north Atlantic Ocean where the Maine Atlantic salmon populations might migrate to as part of their life cycle), distances which are greater than several hundred miles by sea."[194] Contrary to FDA's dismissive, conflicting, and inaccurate statements, the PEI facility is in close proximity to endangered Atlantic salmon migratory pathways, and this fact alone demonstrates that escaped or released AquAdvantage eggs from the PEI facility could significantly affect the vulnerable wild Atlantic salmon. FDA has not evaluated these risks, however. Instead, the agency merely recites its assumptions about the proposed containment measures at the facility, and its finding that AquAdvantage Salmon would not be able to survive or reproduce in the wild (a conclusion that is not based on studies of this transgenic fish's fitness or sterility, *see* Draft EA at 77 and 83).[195] This evaluation is necessary in order to understand the possible risks and consequences of AquAdvantage Salmon, particularly fertile male and female broodstock at the PEI facility, and must be completed comprehensively in an EIS.

More generally, due to the inevitability of escapement and release, FDA must, through an EIS, specifically consider the potential risks to all endangered salmon populations, protected species, and their critical habitats.

6. ***Potential to Adversely Affect Significant Cultural Resources***.

As described herein, AquAdvantage salmon, when they escape into the natural marine environment, could have potentially significant and irreversible effects on salmon and other fish populations. Such environmental harm would immediately and adversely affect Tribes that harvest the affected fish for subsistence, livelihood, and traditional cultural practices. Salmon are a sacred food and animal for many tribes, having fished and in some cases centered their

[194] FDA EA at 94.
[195] *Id*.

entire culture around salmon since time immemorial. Numerous Tribes have recognized Treaty rights to salmon harvests that may be harmed by the approval of transgenic salmon. Thus FDA must consider whether the approval of genetically engineered salmon may result in adverse cultural or religious impacts to tribal entities. FDA should engage in government to government consultation with interested tribal entities. FDA has improperly refused to even consider this impact in the EA or elsewhere in its decisionmaking, stating that doing so is not necessary unless an EIS is required.[196] In fact, the existence of this risk mandates the preparation of an EIS.

Further, FDA has failed to meet its Federal trust responsibilities and conduct government-to-government consultation in accordance with Executive Order (EO) 13175 (Consultation and Coordination with Indian Tribal Governments). EO 13175 imposes a mandate on each agency to have "an accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications. EO 13175 § 5(a). "'Policies that have tribal implications' refers to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." *Id.* § 1(a). EO 13175 also imposes an obligation on agencies to consult with tribes early in the process. *Id.* § 5(c).

This EA constitutes a regulatory process with tribal implications because it is an action that will have substantial direct effects on one or more Indian tribes, but FDA has ignored its responsibility under EO 13175 to engage with potentially impacted tribes. The draft EA does not even mention tribes.

One potentially affected tribe is Maine's Penobscot Indian Nation. This Nation has a treaty right to subsistence fish for Atlantic salmon, yet FDA did not involve this Nation early in the process, seek its meaningful and timely input, or consult with them. The Penobscot Nation likely has an interest in this matter: it has actively engaged in various regulatory processes affecting Atlantic salmon.[197] Four tribes in Maine alone engaged in consultation with agency representatives in the aforementioned agency process.[198] This provides a strong indication that tribes have a significant interest in actions pertaining to Atlantic salmon. These potential impacts must be analyzed in an EIS.

7. Public Health & Safety.

Finally, throughout this process, public health and consumer groups have raised significant concerns regarding the adequacy of FDA's assessment of possible human health risks associated with consuming AquAdvantage Salmon. FDA improperly ignores these concerns in the draft EA; yet such impacts are cognizable NEPA impacts of significance that must be analyzed and that trigger the EIS requirement. Groups have repeatedly emphasized that FDA has yet to require or conduct any studies to assess the possible long-term health impacts of eating

[196] FDA EA at 10.
[197] *See e.g.,* 74 Fed. Reg. 117, 29358 (June 19, 2009) (Penobscot Nation's comments on rule listing Gulf of Maine Distinct Population Segment of Atlantic Salmon as Endangered).
[198] *Id.*

GE animals, has relied on AquaBounty studies using poor or insufficient data, and that, because this is a "drug" approval, what FDA has publicly released is insufficient to meaningful analyze their assessment. Groups have also noted that GE salmon presents problems for consumers who have certain allergies: the possible allergenicity with newly expressed protein(s) and endogenous allergenicity that comes from the insertion of a growth hormone construct possibly changing the level of allergenic proteins normally found in Atlantic salmon. Even the tiny sample sizes used by the company in their allergenicity tests (only 6 fish) showed that GE fish were likely to cause heightened allergic responses.

A 2009 European Union study indicated several potential food safety concerns with GE fish and their ability to grow faster and possess a higher tolerance to environmental toxins.[199] The study's authors expressed concerns that both toxins and growth hormones had a high potential to end up in consumers' bodies and called for further tests to determine safety. This demand for additional data is critical in light of FDA's 2010 data release, where results indicated that GE salmon possess 40% higher levels of the hormone called IGF-1 (insulin-like growth factor 1), which, as groups have noted, has been shown to increase the risk of certain cancers for reasons scientists do not fully understand.[200]

Finally, this proposed application of industrial aquaculture itself raises public health concerns that must be analyzed. For example, the routine use of antibiotics to control disease in factory farm operations (like the AquAdvantage salmon conditions) may adversely impact human health.[201] Human health could also be jeopardized as a result of antibiotic resistant bacteria, and exposure to certain classes of antibiotics which may cause allergic reactions.[202] And nutritionally speaking, GE salmon lack many of the beneficial qualities that salmon boast: specifically, wild salmon have 65% higher levels of beneficial omega fats than GE salmon can produce.[203]

These health issues, particularly as they relate to the insufficiency of the science underlying FDA's review, further weigh in favor of the completion of a comprehensive EIS.

C. FDA Must Prepare a Programmatic EIS.

FDA's review of the AquaBounty application marks the first potential commercial approval of a new and highly significant program pursuant to which that agency will be engaged

---

[199] Centre for Aquaculture and Environmental Research (2009) "Ecological Risk Assessment of Transgenic Salmon." Study commissioned by the European Union, the Swedish Research Council Fromas and the University of Gothenburg. Vancouver, Canada.

[200] Yu H. and T. Rohan. "Role of the Insulin-Like Growth Factor Family in Cancer Development and Progression." *Journal of the National Cancer Institute*, vol. 92, iss. 18. September 20, 2000; and Moschos, S. and C. Mantzoros. "The Role of the IGF System in Cancer: From Basic to Clinical Studies and Clinical Applications." *Oncology*, vol. 63 iss. 4. November 4, 2002.

[201] Ian Phillips et al., "Does the use of antibiotics in food animals pose a risk to human health? A critical review of published data." *Journal of Antimicrobial Chemotherapy* vol. 53, 28–52. DOI: 10.1093/jac/dkg483. December 4, 2003.

[202] Rebecca Goldberg and Tracy Triplett. "Murky Waters: The Environmental Effects of Aquaculture in the U.S." (p.44). *Environmental Defense Fund*, 1997.

[203] U.S. Food and Drug Administration (FDA) Center for Veterinary Medicine. Veterinary Medicine Advisory Committee. "Briefing Packet: AquAdvantage Salmon." September 20, 2010, at Table 28.

in efforts relating to genetically engineered organisms. Therefore, in addition to a detailed EIS for this NADA, that properly considers each of the factors above, FDA is also required to conduct a programmatic EIS (PEIS) for the federal government's broader program for the establishment and commercialization of GE animals, before proceeding with AquaBounty's application. At a minimum, FDA must prepare a PEIS for GE fish, specifically.

The purpose of a PEIS is to provide a basis for later individual specific EISs. CEQ regulation 40 C.F.R. § 1502.4(b) provides that PEISs are to be prepared "for broad Federal actions such as the adoption of new agency programs or regulations." *See also* 40 C.F.R. § 1508.18(b)(4) (definition of major federal action includes "adoption of programs, such as a group of concerted action to implement a specific policy or plan"). Moreover, an agency "program" or "proposal" that exists in fact but is not necessarily declared by the agency, also requires a PEIS. *Id* 1508.23 (defining "proposal" to include that a "proposal may exist in fact as well as by agency declaration that one exists."). These PEISs are to be "relevant to policy and [] timed to coincide with meaningful points in agency planning and decisionmaking." *Id*. at § 1502.4.

CEQ regulations at 40 C.F.R. § 1502.4 further guide agencies as to the appropriate ways to prepare programmatic EISs for broad actions and proposals. Those regulations make clear the nature of the issues that FDA must address when evaluating the AquaBounty application. In particular, they require FDA to examine the environmental effects of that application through several lenses:

> (1) geographically, including actions occurring in the same general location, such as body of water, region, or metropolitan area; (2) generically, including actions which have relevant similarities, such as common timing, impacts, alternatives, methods of implementation, media, or subject matter; (3) by stage of technological development including federal or federally assisted research, development or demonstration programs for new technologies, which if applied, could significantly affect the quality of the environment. Statements shall be prepared on such programs and shall be available before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives.

40 C.F.R. § 1502.4(c) (emphasis added).

CEQ has further explained that "the program statement has a number of advantages. It provides an occasion for a more exhaustive consideration of effects and alternatives than would be practicable in a statement on an individual action. It ensures consideration of cumulative impacts that might be slighted in a case-by-case analysis. And it avoids duplicative reconsideration of basic policy questions." *See* CEQ Memorandum to Federal Agencies on Procedures for Improving Environmental Impact Statements (May 16, 1972). "A programmatic EIS reflects the broad environmental consequences attendant upon a wide-ranging federal program. The thesis underlying programmatic EISs is that a systematic program is likely to generate disparate yet related impacts…" *Nat'l Wildlife Federation v. Appalachian Regional Comm'n*, 677 F.2d 883, 888 (D.C. Cir. 1981).

In this case, FDA has acted unlawfully and arbitrarily by producing an inadequate EA in connection with the AquaBounty application while at the same time refusing to conduct a full and far-reaching PEIS evaluation of the environmental and ecological risks attendant to the development and proliferation of GE animals or, at the very least, GE fish.

A PEIS is particularly crucial here, when FDA is acting regarding novel, transgenic organisms. When enacting NEPA, Congress expressed great concern for the "profound impact of man's activity on the interrelations of all components of the natural environment, particularly the profound influences of new and expanding technological advances . . . ". 42 U.S.C. § 4331(a). Congress was specifically wary of "[a] growing technological power which is far outstripping man's capacity to understand and ability to control its impact on the environment." S. Rep. No. 91-296, 91st Cong., 1st Sess, at 6 (1969), U.S. Code Con. & Admin. News 1969. The courts recognized from the start that "NEPA's objective of controlling the impact of technology on the environment cannot be served by all practicable means, *see* 42 U.S.C. § 4331(b), unless the statute's action forcing impact statement process is applied to ongoing federal agency programs aimed at developing new technologies, which, when applied, will affect the environment." *Scientists' Inst. for Pub. Info. v. Atomic Energy Comm'n*, 481 F.2d 1089, 1090 (D.C. Cir. 1973). "To wait until a technology attains the stage of complete commercial feasibility before considering the possible adverse environmental effects attendant upon ultimate application of the technology will undoubtedly frustrate meaningful consideration and balancing of environmental costs against economic and other benefits." *Id.*

Thus, it is well-settled that the federal government's development of a new technology with unknown environmental consequences like transgenic animals, in particular, "is the type of action in which programmatic considerations are particularly important." *Found. on Econ. Trends v. Heckler*, 756 F.2d 143, 159 (D.C. Cir. 1985) (considering the required NEPA review for NIH's approval of the release of GE organisms). This is especially so where the agency is "about to begin a process of reviewing what [would] be a stream of applications for approval" without fully understanding the risks and consequences of the new technology. *Id.; Scientists' Inst.*, 481 F.2d at 1089 (a programmatic EIS is appropriate in connection with "the development of a new program that contemplates a number of subsequent actions.").

FDA's approval of AquAdvantage Salmon is in fact the very the kind of action Congress and the courts have warned against advancing without first completing a full PEIS. Such a PEIS must consider the government's broader, underlying commitment to the mass production of GE animal for human consumption and the reasonably foreseeable environmental impacts of such a program. Not only are the ecological and environmental effects of GE animals—including AquAdvantage—highly unknown and controversial, but FDA's action on AquaBounty's unprecedented application will, as discussed throughout these comments, effectively open the regulatory door, and prompt proliferation of a GE fish industry via supplemental NADAs, FWS applications for import of AquAdvantage Salmon eggs, and new NADAs for other GE fish species, such as variations of tilapia and trout. Indeed, the government's entire regulatory scheme for approval and development of GE animals on a commercial scale without question constitutes a federal program that must be fully analyzed as soon as practicable, and certainly before FDA takes action on the current NADA.

A programmatic evaluation of GE fish specifically is necessary at this time because these are "connected actions," *see supra*, and because it can be sufficiently "forward-looking" and because "its absence will obstruct environmental review." *Found. on Econ. Trends*, 756 F.2d at 159. The PEIS is plainly "forward-looking" because it can consider the full-range of imminent and reasonably foreseeable plans for expanding the production of AquAdvantage Salmon and other similar GE fish and/or other GE animal products that are now or will soon be in development. And the absence of a programmatic EIS will preclude additional adequate environmental review, because in taking future actions on GE fish, FDA will continue to unlawfully "segment the overall program," *see, e.g.*, *National Wildlife Federation v. Appalachian Regional Commission*, 677 F.2d 883, 889 (D.C. Cir. 1981), by conducting limited environmental analysis for each individual NADA rather than evaluating the environmental impacts of the whole program as NEPA requires. "Under CEQ regulations a programmatic EIS should be prepared if actions are "connected," "cumulative," or sufficiently "similar" that a programmatic EIS is "the best way" to identify the environmental effects. *Found. On Econ. Trends*, 756 F.2d at 159 (quoting 40 C.F.R. § 1508.25).

FDA has already acknowledged its plan to pursue this kind of unlawful piecemeal approach by explaining that, even though it is aware of broader risks, it is refusing to analyze them here:

> We do case by case evaluations. We do not do programmatic assessments. We don't do a programmatic environmental assessment on what would happen if Atlantic salmon were released into the Bay of Fundy if that is outside the scope and product definition of this particular application…and that is why I cautioned you folks that you may have all the conversations that you would like with AquaBounty about their future business plans but this application considers this set of conditions of use and any other conditions of use would not be considered appropriate or lawful. [204]

Despite FDA's dogmatic insistence on a case-by-case analysis, the fact remains that the agency's action on this first NADA will set the precedent for future approval decisions regarding GE fish and commercial GE food animals. As discussed at length above, pursuant to FDA's regulations and the agency's own interpretation of the process, the environmental review accepted for the first NADA will most certainly influence future decisionmaking that could affect how and where AquAdvantage salmon are produced.

Further, the evidence shows that the current narrow agency focus is unlawful segmentation, ignoring the evidence that AquaBounty's application is already spurring

[204] Statement of Dr. Larisa Rudenko at the 2010 VMAC, Transcript, 125:15-25. The statement that a programmatic evaluation would be unlawful is incorrect given the express instruction of NEPA and CEQ's regulations. To the extent that FDA erroneously believes it has the discretion to refuse a more expansive NEPA analysis than the EA it has drafted here, it should be noted that "CEQ guidelines are entitled to substantial deference in interpreting the meaning of NEPA provisions, even when CEQ regulations are in conflict with an interpretation of NEPA adopted by one of the Federal agencies." *See, e.g.*, *Morris County Trust for Historic Preservation v. Pierce*, 714 F.2d 271, 276 (3d Cir. 1983) (citing *Andrus v. Sierra Club*, 442 U.S. 347, 358 (1979) (giving CEQ's interpretation precedence over contrary interpretation of NEPA adopted by Department of Interior).

further foreseeable development that is connected to this action. *See supra.* And because this is the very first application for a GE animal intended for human consumption, FDA's NEPA analysis here will set the standard for how future applications and requests for similar products, whether before FDA or a separate federal or state agency, will be analyzed. FDA refused to undertake a PEIS when it issued its GE animal "guidance" in 2009, although it established the regulatory pathway for GE animals, hiding behind the fact that it did not issue new regulations but instead issued a guidance. Such delay, was irresponsible then, and is unlawful now that the agency is implementing that guidance. For all of these reasons, FDA must prepare a programmatic EIS that examines the environmental impacts of GE fish before it takes final action on the AquaBounty application.

II. FDA's "No Effect" Determination and its Failure to Consult with FWS and NMFS is Arbitrary, Capricious, and in Violation of the Endangered Species Act.

FDA erroneously concluded that its approval of AquaBounty's transgenic salmon would have "no effect" on protected species. FONSI at 5. That decision is arbitrary and capricious, for multiple reasons, including: (1) it is contrary to the evidence showing the potential for harm to protected species; (2) FDA entirely failed to analyze risk of harm or extent of harm to protected species or their critical habitats; (3) the agency refused to apply the proper scope of the action or consider indirect, interrelated and interdependent impacts; and (4) the agency relied on AquaBounty's mitigation assurances. Contrary to FDA's conclusion of "no effect," FDA's action on this application triggers the low threshold for consultation under ESA § 7(a)(2).

A. Statutory and Regulatory Framework

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). "The plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, whatever the cost." *Id*. at 184. Section 7 requires that every federal agency determine whether its actions "may affect" any such species or any designated critical habitat. If so, the "action" agency must consult with the "expert" wildlife agency NMFS and/or FWS to "insure" that the action is "not likely to jeopardize the continued existence" of that species, or "result in the destruction or adverse modification of habitat … determined … to be critical…." 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a); *see Citizens for Better Forestry v. United States Dep't of Agric.,* 481 F. Supp. 2d 1059, 1092 (N.D. Cal. 2007).[205] In carrying out this obligation, agencies must give the benefit of the doubt to endangered species and place the burden of risk and uncertainty on the proposed action. *See Sierra Club v. Marsh*, 816 F.2d 1376, 1386 (9th Cir. 1987) ("Congress clearly intended that [the federal agency] give the 'highest of priorities' and the 'benefit of the doubt' to preserving endangered species."). Typically, the ESA process begins when an action agency asks the Services whether any threatened/endangered species or designated critical habitat may be present in the action area. 16 § U.S.C. 1536(c)(1). If the

[205] "Jeopardize" means taking action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of that species." 50 C.F.R. § 402.02. A species' "critical habitat" includes those areas identified as "essential to the conservation of the species" and "which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

answer is affirmative, the action agency must determine whether its proposed action may affect any such species or habitat. If the action agency finds that its actions will have "no effect" on a listed species or its habitat, that is the end of the process.

In contrast, for any federal action that "may affect listed species or critical habitat," the ESA requires formal consultation culminating in a biological opinion prepared by the expert agency. 50 C.F.R. § 402.14(a). The threshold for a finding of "may affect" is extremely low. A triggering effect need not be significant; rather "any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the formal consultation requirement . . . ." 51 Fed. Reg. 19,926, 19,949 (June 3, 1986); Final ESA Section 7 Consultation Handbook at xvi (Mar. 1998) (defining "may affect" as "the appropriate conclusion when a proposed action may pose any effects on listed species . . . .") (emphasis in original).

Informal consultation may allow an action agency to avoid formal consultation, resulting in preparation of a comprehensive biological opinion, where the action agency and expert agency both find that, while an action "may affect" a listed species or critical habitat, it is "not likely to adversely affect" either of them. 50 C.F.R. § 402.13(a). Otherwise, the agency must enter formal consultation. 50 C.F.R. § 402.14(a); *Pac. Rivers Council*, 30 F.3d at 1054 n.8. An action is "likely to adversely affect" protected species, and formal consultation is required, if: "any adverse effect to listed species may occur as a direct or indirect result of the proposed action or its interrelated or interdependent actions, and the effect is not discountable, insignificant, or beneficial." *Endangered Species Consultation Handbook*, March 1998, p. xv (emphases added).

Formal consultation is complete when NMFS and/or FWS issues a "biological opinion" applying the "best scientific and commercial data available" that determines whether the action is likely to jeopardize any species or adversely modify any designated critical habitat. 50 C.F.R. § 402.14(g)(8). If so, the opinion may specify alternatives that will avoid jeopardy or adverse modification while still allowing the agency to proceed with the action. 16 U.S.C. § 1536(b)(3)(A); 50 C.F.R. § 402.14(g)(5)-(6); (h)(3); (i)(1)-(2).

B. The Agency's "No Effect" Determination is Arbitrary and Capricious.

FDA made a "no effect" determination for the NADA approval action. FONSI at 5. That conclusion suffers from several of the same fatal flaws as the FONSI and EA.

First, FDA's NEPA assessment (upon which FDA's "no effect" determination is solely based, EA at 11) falls far short of the scientific basis necessary to support an ESA finding of "no effect" on threatened and endangered species or critical habitats, for some of the same reasons the EA does not support a Finding of No Significant Impact on the environment under NEPA. *See supra*.

As discussed in greater detail above, both the PEI and Panama facilities create unstudied risks of escape and potential harm to endangered and threatened species. Expert testimony in the record belies the agency's assumptions to the contrary that rely on AquaBounty's proposed measures.[206] The transgenic salmon are capable of surviving outside either facility. In fact, both facilities are near water bodies that historically have held salmonid species. *See* EA at 59 & 63.

[206] *See* Dr. Jon Rosenfield Comments, Attachment 38.

There is a risk of escape during transport and survival.[207] In fact, notwithstanding FDA's cursory discussion of a few limited scientific studies, the GE salmon's transgenic nature makes it more likely to survive because of its more aggressive nature and enhanced growth rate.[208]

The great weight of evidence of past experiences with invasive species and escapes further supports this conclusion.[209] *See* 16 U.S.C. § 1536(a)(2) (requiring agencies to use the "best scientific and commercial data available."). When the GE salmon do escape, the impacts on the environment may be significant and irreversible, in the form of, *inter alia*, (1) ecological impacts on native species via predation and/or competition; and (2) genetic impacts via hybridization and genetic introgression.[210]

Significantly, scientists at FWS have expressed these very concerns with regard to the AquaBounty application. Commenting on the 2010 EA and Briefing Packet, FWS's Northeast Region explained:

- Transgenic fish, regardless of where they are, pose a clear and present danger to wild fish populations. Given the extremely low populations of wild Atlantic salmon in the Maine DPS, any interaction between wild and transgenic salmon must be considered a serious threat, which can disrupt redds of wild fish, compete with wild fish for available food and habitat, interbreed with wild fish, transfer disease and/or parasites, and degrade benthic habitat. The scientific literature is full of actions indicating that interactions of wild fish and aquaculture escapees (read transgenic escapees) may lead to decreased numbers of wild fish and in the worst scenario, lead to extirpation of the remaining stocks in the U.S.

- History dictates it is reasonable to assume that fish held in aquaculture facilities, either land- or water-based, will escape unless strict quarantine /water treatment/screening/ bioengineering modifications are in place and aggressively monitored. And even then, it must be assumed that escape will still occur, and protocols must be in place to deal with such a non-native organism released into the environment, and its subsequent effect on native species, habitat, and aquatic communities. Transgenic fish, whether reproductively viable or sterile, must be maintained only in biosecure (zero discharge) land-based facilities ideally positioned outside of any wild fish watersheds until appropriate laboratory and field research has been undertaken to ensure that the risk of adverse effects on wild fish has been minimized.

- ABT appears to have established several physical and biological containment mechanisms to prevent the escape of AquAdvantage salmon. However, there is still risk of escapement and we think this risk is most prevalent at the PEl facility. If the brood stock from the PEl facility were released either accidentally or with malicious intent, we do not feel enough evidence has been provided to conclude the risks to natural populations of Atlantic salmon in Canada and the U.S. are negligible. Additional

[207] *Id.*
[208] *Id.*
[209] *Id.*
[210] *Id.*

experimentation needs to be conducted to verify that any escapees from the PEl facility will not be able to tolerate the brackish water in the vicinity of the facility. Also, the lack of information on the transport procedures from PEl to Panama is troublesome. It is during this stage of the operation that malicious activities could result in these fish being lost from the direct control of ABT.

- If there is an escape event, competition from the GMO salmon would negatively impact the wild stocks. Research has shown that aquaculture-raised salmon can outcompete wild salmon, and given the already endangered status of the wild stocks, any additional threat is amplified in their impacts. References are available.

- Aside from the potential spread of the GMO growth gene if they escape and successfully reproduce, the genetic origin of the broodstock that has been developed is likely genetically distinct from Maine salmon. The concern is if escape and reproduction occurs, this could lead to a disruption of the locally adapted gene complexes of the endangered populations. In the FDA report-petition, we didn't see reference to the origin of the broodstock.[211]

FWS's Conservation Genetics Community of Practice[212] sent FDA a letter in October 2010 noting these same risks and the need for FDA to conduct a more thorough analysis:

> [T]he biological containment at either the PEI or Panama facilities along with the possible interaction of AquAdvantage salmon with endangered wild salmon stocks is of great concern to the COP. To this regard, AquaBounty Technologies has established several physical and biological containment mechanisms to prevent the escape of AquAdvantage salmon and the [EA] indicated escapement risk and establishment risks were low. However, history dictates that fish held in aquaculture facilities, either land- or water-based—escape. In addition, the information provided by AquaBounty Technologies for the likelihood of establishment relies on the assumption that farmed Atlantic salmon have not established themselves in North America. This assumption is clearly violated because Atlantic salmon juveniles have been found in several streams in the state of Washington as well as British Columbia. While interactions of these fish with native salmon are unknown any interaction between wild and transgenic salmon must be considered a serious threat. Numerous scientific publications have documented that interactions of wild and introduced fish have led to decreased numbers of wild fish (for ESA listed Atlantic stocks this is of great concern).[213]

Dr Gregory Moyer, a Regional Geneticist with FWS also FDA a letter in October 2010 outlining "several criticisms and concerns" regarding the Briefing Packet, specifically the environmental risk analysis.[214] Dr. Moyer noted that the Briefing Packet "falls short of providing an actual risk assessment of putative environmental damages in the event of

---

[211] Region 5 Comments, *supra* (emphases added).
[212] This is FWS's coalition of fish conservation genetics experts. *See* http://www.fws.gov/ConservationGeneticsCOP/index.html
[213] FWS COP Letter to FDA (October 2010), *supra*.
[214] FWS Dr. Moyer Letter to FDA (September 2010), *supra*.

escapement."[215] He explained that the "environmental analysis should provide an overview of the general risks associated with escapement or hybridization of GE and wild type individuals" which "would provide readers with an understanding of the potential harm and the degree of harm posed by GE organisms even when the risk of escapement is low."[216] He urged FDA to "more accurately quantif[y]" both the risk of escapement and degree of harm if escaped. Dr. Moyer added that he was concerned with phrases like "are unlikely to survive if exposed to high salinity and low temperature" "when no data have been collected on AquAdvantage salmon to evaluate the likelihood of these scenarios," and that although AquaBounty currently has "in place various standard operating procedures to minimize escapement and test for durability of the gene construct," he "fail[s] to see any policy in place for monitoring or enforcement of these SOPs by the [FDA]."[217]

Likewise, NMFS recognized that "[p]reventing escapes is essential to minimizing the risks to genetic deterioration of wild fish populations, especially endangered and threatened salomids whose effective populations are particularly vulnerable to the effects of interbreeding."[218] A memo from NMFS notes that while it may not be likely, it is possible that AquAdvantage Salmon will escape from the PEI and Panama facilities, and when they do, "they will likely [] reproduce in the wild because hatchery released fish and hatchery sterilized fish continue to behave similar to wild fish (Trested et al, 2002)."[219] This memo also warns that "successfully sterilized salmon would be attractive mates for wild fish and may reduce wild population fitness." It goes on to explain that, among other things:

- An introduction of genetically engineered Atlantic salmon could pose catastrophic threats to wild listed species.

- The egg production facility may pose a threat to wild Atlantic salmon, including Gulf of Maine DPS Atlantic salmon.

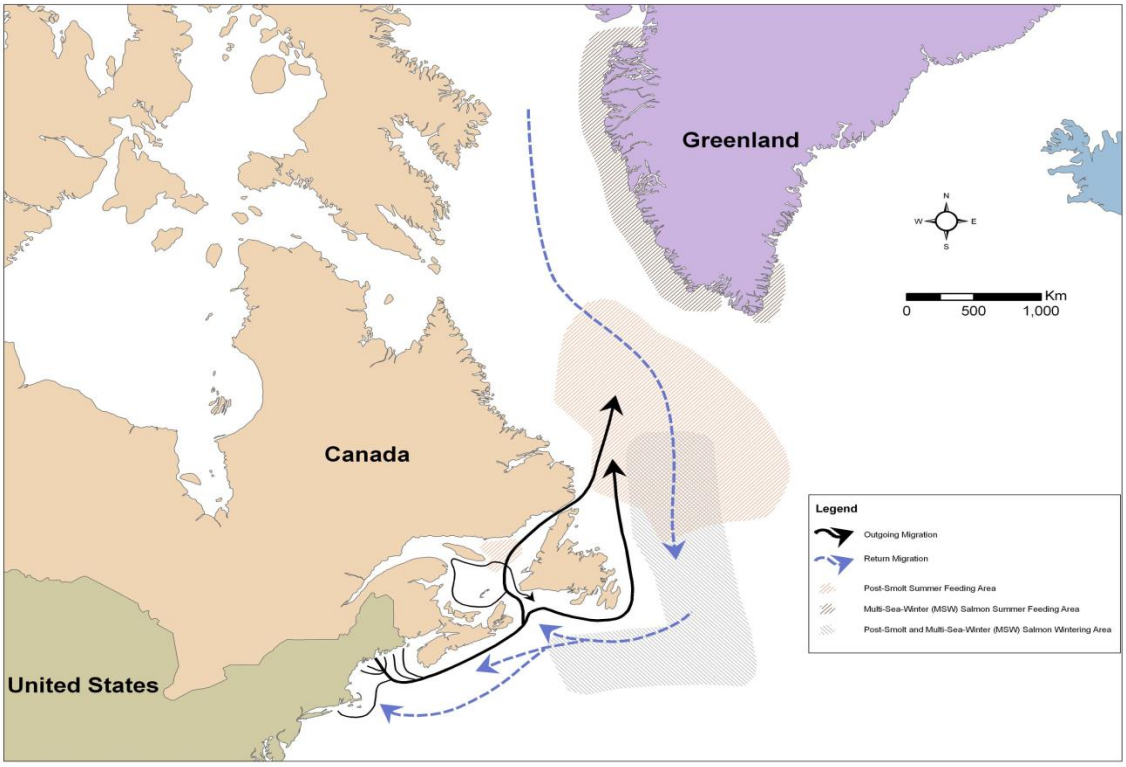
- Any fish introduced along the Pacific Coast would have the potential to affect Pacific salmoninds through hybridization.[220]

In fact, NMFS has long recognized the potential harms associated with transgenic fish. In 2003, NMFS issued an ESA Section 7 Biological Opinion (BIOp) for the Army Corp of Engineers regarding aquaculture fish pens within the State of Maine.[221] This BiOp bans the use of transgenic salmonids in aquaculture sites off the coast of Maine due to the risks they could pose to wild, endangered Atlantic salmon populations. There, NMFS expressly referenced the potential risks associated with FDA's consideration of the AquaBounty NADA and relied on studies by Dr. Kapuscinski to call for more research "to identify the impacts [] escaped

[215] *Id*.
[216] *Id*.
[217] *Id*.
[218] Therese Conant Email NOAA (Dec. 13, 2011), Attachment 41 hereto.
[219] NMFS Concerns Memo and Letter, *supra*.
[220] *Id*.
[221] 2003 BiOp, *supra*.

transgenic salmon would have on natural populations and their habitat before use for commercial aquaculture is considered."[222]

As discussed in full above, FDA did not even attempt to analyze what might happen if AquAdvantage Salmon escaped or were released from the PEI facility and did interact with endangered Gulf of Maine Atlantic Salmon, which, despite FDA's baseless representation in the EA at 94, and as shown by the following map from NOAA, migrate far north of the Maine DPS:



http://www.nefsc.noaa.gov/press_release/2008/MediaAdv/MA0807/2Saunders_MigrationRoute.jpg. Instead of analyzing this risk to these populations, FDA simply stops after concluding that such interaction was "highly unlikely" because of the various containment measures, for which FDA has not even performed a proper failure mode analysis.[223] The record evidence indicates that such an escape or release event could be significant and irreparable.[224] Indeed, FDA itself

[222] *Id*. at 74-75.
[223] 2010 Kapuscinski and Sundström VMAC Comments at 4 ("As scientists, we cannot agree with this approach because it assumes 100% achievement of multiple confinement without presenting the failure mode analysis that is standard practice in technology risk assessment. Even if actual exposure is very close to zero, it is still necessary to assess ecological consequences….").
[224] See, Dr. Jonathan Rosenfeld Comments, Attachment 38; *see also* FWS Region 5 comments, FWS COP letter, NFMS Concerns Memo and Letter.

recognized the seriousness of these potential risks when it previously acknowledged that it would formally consult with the Services if these fish were grown in net pens.[225]

The threshold for a finding of "may affect," which triggers ESA consultation, was triggered here. FDA must do far more than it has done to address the stated concerns of expert scientists and the Services to prove its approval will not jeopardize any listed species, nor adversely affect any critical habitat, and has not met that burden. *See, e.g.*, *Wash. Toxics Coalition v. Envtl. Prot. Agency*, 413 F.3d 1024, 1035 (9th Cir. 2005) ("Placing the burden on the acting agency to prove the action is non-jeopardizing is consistent with the purpose of the ESA and what we have termed its 'institutionalized caution mandate[].'").

Second, just as it did in attempting to justify its FONSI, FDA draws much too narrowly its ESA action area, to preclude consideration of any effects resulting from production of AquAdvantage Salmon anywhere but in PEI and Panama. It ignores the reasonably foreseeable direct, indirect, and cumulative impacts of its decision. It ignores the record evidence that petitions are already being submitted to grow these transgenic salmon, if approved, elsewhere. It ignores AquaBounty's public statements admitting their own plans to grow them elsewhere. It ignores that it is not economically feasible to grow these fish at just these two small facilities. It ignores that AquaBounty's current application is dependent on that future growth for its justification.

In the ESA, "'agency action' is to be construed broadly." *See Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006, 1020 (9th Cir. 2012) (en banc). "[T]he scope of the agency action is crucial because the ESA requires the biological opinion to analyze the effect of the entire agency action." *Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). Courts "interpret the term 'agency action' broadly," because "caution can only be exercised if the agency takes a look at all the possible ramifications of the agency action." *Id*. Similarly, "action area" is expressly defined as "all areas to be affected directly or indirectly by the federal action and not merely the immediate area involved in the action." 50 C.F.R. § 402.02 (emphasis added).

Similarly, "effects" of an action include not just direct, but also "indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action…." *Wild Fish Conserv. v. Salazar*, 628 F.3d 513, 525 (9th Cir. 2010) (quoting 50 C.F.R. § 402.02). "Indirect effects are those that are caused by the proposed action and are later in time, but still are reasonably certain to occur. Interrelated actions are those that are part of a larger action and depend on the larger action for their justification. Interdependent actions are those that have no independent utility apart from the action under consideration." *Id*. FDA's assessment must therefore include its action's indirect effects, and the effects of all activities "interrelated or interdependent" with that action. 50 C.F.R. § 402.02.

FDA's head-in-the-sand approach thus is directly contrary to the ESA's proper scope and mandates. FDA's approval will affect substantially more than just areas in Panama and PEI, because it will trigger the potentially unfettered proliferation of AquAdvantage Salmon in other locations, including within the United States, as reflected by pending requests for importation of

[225] 2009 FDA denial of 2001 CFS petition. Attachment 42 hereto.

AquAdvantage eggs and AquaBounty's stated plans for expansion following this initial approval decision. The action area must be considered broadly, because if AquAdvantage Salmon were to escape or be released from any foreseeable production site, they could enter any number of marine environments that are home to endangered or threatened aquatic species.[226] This later aquaculture development is plainly "reasonably certain to occur"; indeed, it is already in progress. Moreover, the ESA regulations expressly include those indirect and interrelated impacts "later in time" and "depend[ent] on the larger action for their justification." *See, e.g.*, *National Wildlife Federation v. Federal Emergency Management Agency*, 345 F. Supp. 2d 1151 (W.D. Wash. 2004) (rejecting agency argument that it could limit its scope to just the issuance of floodplain insurance and holding that the agency must also assess the impacts of later housing construction that the insurance would facilitate). Nor is it lawful for FDA to rely on the potential to consult later. Section 7(a)(2) requires consultation before an action begins, not a post mortem years later. *See, e.g.*, *Wild Fish Conservancy v. Salazar*, 628 F.3d 513, 524 (9th Cir. 2010) (intent to consult later does not cure failure to complete consultation at the outset concerning action's full extent).

Third, FDA's "no effect" determination is arbitrary because FDA did not consider impacts to threatened or endangered aquatic species and their habitats other than Atlantic salmon. As scientists have noted, the introduction of GE fish like AquAdvantage Salmon could affect entire ecosystems.[227] NMFS FDA Salmon Concerns Memo ("Any fish introduced along the Pacific Coast would have unknown potential for affecting Pacific salmonmids through hybridization."). Given, in particular, the foreseeable proliferation of AquAdvantage and the risks of escape inherent in the current application, FDA was required to consider possible effects on Pacific salmon and other salmoids, such as steelhead.[228]

Fourth, FDA violated its "rigorous" duty to "insure" against jeopardy by relying entirely on AquaBounty's third-party measures to mitigate any harm. *See, e.g.*, *Ctr. for Biological Diversity v. Rumsfeld*, 198 F. Supp. 2d 1139, 1152 (D. Ariz. 2002) (holding that mitigation measures must be "certain to occur," "subject to deadlines or otherwise-enforceable obligation," and "must address the threats to the species in a way that satisfies the jeopardy and adverse modification standards"). FDA cannot avoid consultation by relying on mitigation measures not within its control. *See Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv*., 254 F. Supp. 2d 1196, 1213-14 (D. Or. 2003) (Biological Opinion inadequate where it relied on non-federal mitigation actions not reasonably certain to occur); *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987) ("This reliance on the proposed actions of [others] does not satisfy [FDA]'s burden of insuring that its actions will not jeopardize the continued existence of the [endangered species]."). It is wholly unclear from the record how FDA would, after approval, enforce or monitor AquaBounty's purported protective measures to prevent escapes or otherwise prevent environmental harm.[229] Mitigation measures not within FDA's control are unlawfully uncertain.

---

[226] As NMFS previously indicated, because FDA's action contemplates the selling of eyed eggs commercially and rearing fertile adult males at the PEI facility, the action area must include the United States. *Supra*, NMFS Concern Memo and Letter to FDA from Therese Conant.

[227] Dr. Jonathan Rosenfeld Comments, Attachment 38.

[228] *Id.*

[229] *See 2010* Kapuscinski and Sundström VMAC Comments at 2 (questioning how FDA will oversee the facilities; "How will FDA assure and audit the company's implementation of this 'integrated confinement system'"?).

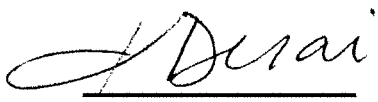
In sum, FDA's no effect finding and failure to consult is arbitrary and capricious and violates the ESA, because it fails to follow the ESA's mandated procedures, entirely fails to consider significant aspects of the issue, and offers an explanation that runs counter to the evidence before the agency.

CONCLUSION

For the foregoing reasons, FDA must suspend consideration of the AquaBounty AquAdvantage Salmon application until it has complied fully with the FFDCA, NEPA, ESA, APA, and other applicable law and regulations.

Submitted by,

George A. Kimbrell
Center for Food Safety



Khushi K. Desai
Earthjustice