January 17, 2023

Re: Comments to 2022 Draft Amended Environmental Assessment for Production of AquAdvantage Salmon at the Bay Fortune and Rollo Bay Facilities on Prince Edward Island, Canada, Docket No. FDA-2022-N-2672

Center for Food Safety, Earthjustice, and nine organizations listed below submit these comments regarding the U.S. Food and Drug Administration (FDA)'s Draft Amended Environmental Assessment (Amended EA). 87 Fed. Reg. 69032 (Nov. 17, 2022).

Introduction

In response to the Court's order in *Institute for Fisheries Resources v. U.S. FDA,* 499 F. Supp. 3d 657 (N.D. Cal. 2020), FDA presents this Amended EA for its New Animal Drug Approval (NADA) for AquAdvantage genetically engineered (GE) salmon production by AquaBounty at its Prince Edward Island facilities. While this Amended EA improves on the previous 2015 EA, it still falls short of FDA's obligations under the National Environmental Policy Act (NEPA), as detailed below. FDA has also failed to complete consultation with the expert Services under the Endangered Species Act (ESA) and must complete said consultation prior to making any final decision on the significance of the environmental impacts from this novel and potentially disastrous GE salmon approval. FDA must also complete its duties under the Federal Food Drug and Cosmetic Act (FFDCA) to assure safety, including environmental safety, from its new animal drug approval, and explain how that is met based on the current and foreseeable future GE salmon production scheme.

Wild Atlantic salmon are critically endangered and extirpated from most of their historic habitat. Commenters hereby incorporate by reference and attach herein their 2013 comments to the draft EA. For background on the status of wild Atlantic salmon, see those 2013 comments at 4-6. As to the Gulf of Maine DPS, the latest Annual Report of the U.S. Atlantic Salmon Assessment Committee said that the "abundance remains critically low relative to interim recovery targets."[1] However, around PEI and the AquaBounty facilities, salmon are returning.[2] As FDA recognizes in the Amended EA, escaped and/or established GE salmon have the potential to severely harm the remaining wild Atlantic salmon,

[1] U.S. National Marine Fisheries Service, Northeast Fisheries Science Center (U.S.), Atlantic Salmon Commission (U.S.); North Atlantic Salmon Conservation Organization. 2021. Annual Report of the U.S Atlantic Salmon Assessment Committee, Report No. 33 – 2020 Activities. *Available at*: https://doi.org/10.25923/y1k1-xh35 (Last Accessed Jan. 13, 2023).

[2] American Salmon Foundation, Rivernotes Oct. 29, 2021, https://www.asf.ca/news-and-magazine/river-notes/asf-rivernotes-29-oct-2021 (see discussion of "Prince Edward Island"); CBC News, Atlantic salmon in 2 P.E.I. rivers may link to ancestral strain (June 25, 2015) (noting that the salmon that are returning are genetically unique at least is these rivers); Oak Meadows, Inc. *Prince Edward Island Atlantic Salmon Spawning Survey 2017,* attached and available at: https://www.salmonconservation.ca/wp-content/uploads/2019/04/Redd-Survey-Report-final.pdf (report of the increase in the number of salmon redds in a 2017 survey).

threatening the survival of the species. Breeding populations of Atlantic salmon on PEI should give FDA pause in approving GE salmon, as this will increase the potential for interaction between escaped GE salmon and wild salmon and spread of the rDNA construct into the environment.

Commenters continue to urge FDA not to approve this novel GE fish, given the admitted potential for severe harms to wild, critically endangered Atlantic salmon. At minimum, before issuing an amended NADA for the new AquaBounty GE salmon commercialization scheme (now including two facilities on PEI and no Panama grow out facility, but a new larger grow out facility in Indiana and a planned facility in Ohio), FDA must take a hard look at all of the direct, indirect, and cumulative effects of an approval in a full Environmental Impact Statement (EIS) under NEPA, complete formal ESA consultation with the expert wildlife agencies to inform its analysis, and evaluate all of this and other information from the applicant to make its separate environmental safety determination under the Federal Food Drug and Cosmetic Act (FFDCA).

I. NATIONAL ENVIRONMENTAL POLICY ACT

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 and provide information sufficient for the public and decisionmakers to draw informed conclusions. *See, e.g., Sierra Club v. Bosworth*, 510 F.3d 1016, 1018 (9th Cir. 2007). While FDA has expanded the scope of the activities it is analyzing (including increased egg production at PEI based on AquaBounty's current and planned expansion of grow out facilities), and its discussion of the potential harms to the environment from GE salmon, FDA's Amended EA remains insufficient.

As NEPA requires, FDA must take a "hard look" at the direct, indirect, and cumulative impacts of the proposed project, including its entire scope (the expansion of commercial production by AquaBounty). FDA cannot make a "no significant impact" finding without this hard look and an evaluation of the significance of the proposed action. FDA's Amended EA is an improvement on the first EA, but still fails to fully account for all direct and indirect impacts, including from land-based aquaculture facilities, and socioeconomic impacts. FDA still relies on containment to prevent any harms without an adequate assessment of that containment. FDA does not take climate change into account, either in the impacts to the GE salmon facilities and wild Atlantic salmon from climate change, or the project's contribution to climate change. Nor does FDA grapple with the significance factors as required before declaring the first GE fish for human consumption non-significant. FDA again fails to evaluate a reasonable number of alternatives, including a "no action" (aka *no AquAdvantage salmon*) alternative. Finally, the adequacy of the mitigation, aka the containment measures, is once again assumed without full evaluation.

For the reasons explained below, FDA must complete an EIS before re-approving any NADA for AquAdvantage salmon production.

A. Direct, Indirect, Cumulative, & Significant Impacts

While FDA now admits there could be severe impacts to wild endangered Atlantic salmon should GE salmon escape, it maintains that there is no significant impact (and no EIS is required)

because the likelihood of escape is "negligible." Amended EA at 178 ("It was concluded that the likely impact of harms will also be negligible, regardless of their possible severity, because the risk (probability of harm) is negligible for these harms. Therefore, *significant environmental impacts are not expected* in the US environment from maximum current and planned production of ABT Salmon at the Bay Fortune or Rollo Bay (Hatchery Unit and Broodstock Unit 1) facilities."). However, FDA failed to fully evaluate the significance factors that it must consider when determining whether a major action may have significant impacts necessitating an EIS. FDA also failed to fully consider all direct, indirect, and cumulative impacts, including environmental impacts of land-based aquaculture and socioeconomic impacts, and the effects of and contribution to climate change.

1. FDA ignores factors that indicate significant impacts and the requirement for a full EIS

Where "substantial questions are raised as to whether a project ... *may* cause significant degradation of some human environmental factor," an agency *must* prepare an EIS. *Ctr. for Biological Diversity*, 538 F.3d at 1219-20 (emphasis in original). Whether an action may be significant and trigger an EIS requires consideration of several factors that implicate significance. 40 C.F.R. § 1508.27 (2019); 21 C.F.R. § 25.42(b). These factors include, as applicable here, the degree to which the effects are likely to be highly controversial; the degree to which effects are highly uncertain or involve unique or unknown risks; whether the action establishes a precedent for future actions or represents a decision in principle about a future consideration; the degree to which the action may affect endangered or threatened species; the degree to which the action may cause loss or destruction of significant scientific, cultural, or historical resources; and whether the action is related to actions with individually insignificant but cumulatively significant impacts. *Id*. While only one factor is sufficient to trigger an EIS, *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 864-65 (9th Cir. 2005), here all these factors are present.

Although FDA failed to engage in the analysis, several factors tip heavily in favor of an EIS. First, the approval could not be more "precedent-setting," for both GE animals/fish in general and for the AquAdvantage GE salmon. This is the first time in history any country has approved the commercial production of a GE animal, and the GE animal happens to be one that migrates thousands of miles through the ocean. Not only is this technology new, FDA's oversight of GE animals as "animal drugs" is a brand-new program (for which the agency did not prepare an EIS either). This NEPA assessment will set the standard for all future GE animals, including data and scientific rigor. It will also set the precedent for future "AquAdvantage" GE salmon, as FDA acknowledged when it tiered the Supplemental EA for the Indiana facility to the first EA.[3] *IFR v. FDA,* 499 F. Supp. 3d at 667 (precedential factory is implicated here, because as AquaBounty expands—as with the Indiana facility—so does the possibility of exposure, and if the harm that could result from that exposure is not "properly assessed at the outset, it may

[3] Environmental Assessment, Supplement to NADA 141-454 to allow the grow-out of AquAdvantage Salmon at AquaBounty Technologies, Inc.'s Indiana Facility (April 20, 2018), https://animaldrugsatfda.fda.gov/adafda/app/search/public/document/downloadEA/862 (this EA "relies extensively on the previous EA prepared by FDA for the AquAdvantage Salmon NADA approved in November, 2015.").

never be."). Avoiding the "thoughtless setting in motion of a 'chain of bureaucratic commitment that will become progressively harder to undo the longer it continues'" is exactly why agencies must assess the precedential nature of actions when determining whether to complete an EIS. *Presidio Golf Club v. Nat'l Park Serv.*, 155 F.3d 1153, 1162-63 (9th Cir. 1998).

Further, there are unknown/uncertain risks here, as FDA's Amended EA makes clear. *E.g.,* Amended EA at 109 ("It is impossible to accurately predict any of these factors due to the many unknowns, and these factors could vary substantially depending on the pathogen/parasite and disease, compounding the uncertainty."); 140-142 (Uncertainties section). *National Parks & Conservation Ass'n v. Babbitt,* 241 F.3d 722, 732-33 (9th 2001) (highly uncertain or unknown risks mandate EIS, including uncertain mitigation). Some of this uncertainty is due to FDA failing to require the NADA applicant AquaBounty to conduct testing, like a quantitative failure mode analysis for containment measures, a fitness test for GE salmon, their reproductive success, and more. If AquaBounty wants to profit off its genetically engineered salmon, it must prove their safety. And FDA must evaluate the risks in a full EIS.

Impacts to wild Atlantic salmon, which are ESA-listed and a cultural resource, weigh in favor of a full EIS.[4] Because FDA has not yet completed consultation with the expert wildlife Services to get the most up-to-date information about the status of wild Atlantic salmon in the Maine population, and to assess the full range of risks and mitigation needed to protect these populations from GE salmon, it cannot assert that impacts will not be significant.

2. Direct, Indirect, and Cumulative Impacts to Wild Salmon

FDA has gone further in analyzing the second half of its own risk assessment equation (the effects if GE salmon were to escape confinement) in this Amended EA, albeit after vigorously defending its unlawful previous 2015 EA for five years in court. The Amended EA explains the potential—and significant—harms to wild Atlantic salmon (and other fish populations) should GE salmon escape and establish in U.S. waters. Amended EA at 129-166.

FDA concludes that the risks of this harm coming to pass should GE salmon escape/establish is "high" for harm from reproduction with wild relatives, and competition for food and habitat, and moderate for pathogen/parasite transfer. *Id.* at 165-66. For example, FDA stated "assuming exposure occurs, the likelihood of harms due AAFB and diploid AAS competing for mates and reproducing with wild and feral Atlantic salmon is considered to be *high*." *Id.* at 153 (emphasis added). Further, FDA acknowledges that: "the weight of evidence suggests that if ABT Salmon were present in the Maine environment at a high enough abundance for a sufficiently long duration, or at a high frequency, they could potentially cause *moderate to severe harms* to the Maine environment by depleting food

[4] *See e.g., U.S. EPA "*Working with Tribal Partners to Restore Fisheries in Northern Maine"

(March 23, 2021; Updated January 3, 2022), *https://www.epa.gov/sciencematters/working-tribal-partners-restore-fisheries-northern-maine.* In addition, numerous tribes across the nation also have recognized Treaty rights to harvest salmon and significant cultural connections that may be harmed by the approval of GE salmon. *See, e.g.,* https://critfc.org/about-us/critfcs-founding/.

resources used by endangered Atlantic salmon and disrupting the biotic environment through increased consumption of prey and potentially feeding on different types of prey (including endangered Atlantic salmon)." *Id.* at 157 (emphasis added). And GE salmon escapes could significantly disrupt the breeding sites for wild Atlantic salmon: "based on the vulnerability of endangered Atlantic salmon and their need for the limited spawning and nursery habitats in Maine, the likelihood of harm occurring due to competition for habitat is ranked as *high* for AAFB and diploid AAS," *id.* at 160 (emphasis added). In sum, FDA has now admitted the "high" harm side of the risk assessment scale, based on the likelihood of harms to wild Atlantic salmon (should GE salmon escape) from GE salmon reproduction with wild salmon, competition for food, and competition for habitat, resulting in harms like disruption of wild salmon reproduction, genetic changes that decrease fitness, and even the survival of wild Atlantic salmon in the Gulf of Maine DPS. *Id.* at 165-66.

However, just like in the flawed 2015 EA, FDA concludes that there is no significant impact because it concludes that the risk of containment failure is "negligible" and therefore all potential harms, no matter how likely or how severe (i.e., the extinction of a species), are insignificant. *Id.* at 167-176. But even where the likelihood of a consequence may be low, the severity of the potential impact equates to significance. *San Luis Obispo Mothers for Peace v. Nuclear Regulatory Com'n*, 449 F.3d 1016, 1028-31 (9th Cir. 2006) (possibility of intentional attack on facility was not so remote or unquantifiable to excuse the need to take a hard look at its effects). FDA did not take that hard look here. While the agency adds many pages of description of the risk equations it claims to use, e.g. Amended EA at 147, it fails to *actually* show work on the equations themselves. *See* Amended EA at 152 (concluding without explanation that, according to equation, the probability of gene flow is "negligible"). These conclusory statements do not satisfy NEPA's hard look requirement.

Further, FDA must take a "hard look" at the containment measures it claims result in a "negligible" risk of exposure of GE salmon or their pathogens/parasites to wild fish. For example, a recently published report shows the establishment of Glofish, the first commercial GE fish, in the wild.[5] This and other such information should be included in FDA's assessment of the adequacy of containment measures for this GE fish that will be grown by the *tons*, rather than in a few aquariums. As detailed in Section C below, FDA failed in this task in several critical respects. First, it still includes no quantitative failure mode analysis, despite experts urging FDA to conduct one (or more accurately, direct AquaBounty to conduct one) for decades. Second, FDA claims only that it requires this containment in a NADA approval letter, but fails to explain how it will enforce these measures to ensure their continuous efficacy. Third, evidence from the Indiana facility should give FDA grave concern about

[5] Magalhães, A.L.B., Brito, M.F.G. and Silva, L.G.M., 2022. The fluorescent introduction has begun in the southern hemisphere: presence and life-history strategies of the transgenic zebrafish Danio rerio (Cypriniformes: Danionidae) in Brazil. *Studies on Neotropical Fauna and Environment*, pp.1-13.

AquaBounty's ability to adhere to these strict containment measures, especially given that it is on the brink of financial disaster.[6]

3. FDA fails to assess the impacts of aquaculture facilities on the surrounding environment

In a footnote, FDA says that environmental considerations relating to the grow out facility in Albany, Indiana are not included in this Amended EA because they were not subject to the Court's 2020 order, and they were considered in that supplemental EA. Amended EA at 7, n.25. However, this Amended EA acknowledges, as the Court did, that AquaBounty intends to continue its expansion of commercial grow out facilities for AquAdvantage salmon in the US. Therefore, FDA should evaluate the environmental impacts of such land-based aquaculture facilities as a basis for the later site-specific supplemental EAs that will tier to this EA. These impacts to water quantity and quality of the local environment can be significant. *See* AquaBounty Exposed Report (Oct. 25, 2022), https://docs.google.com/document/d/1FysnUssU4IvPQljNl3nWnWEVkN4Yj1CYQgu3f9YXIAo/edit?usp=sharing. This includes land-based facilities' discharge of water pollution to local waterways, especially coastal facilities near historic or current salmon runs. This wastewater could include pollutants such as nitrates, phosphorus, pesticides, and drugs like antibiotics, and FDA should evaluate impacts to both wild salmon and humans, should the discharge go into water bodies that supply drinking water.

4. Climate Impacts

Not only must FDA consider the impacts of the climate crisis *on* the PEI facilities and how that changes the likelihood of escape of eggs, fish, and/or pathogens or parasites, as well as the cumulative impact of climate change and other stressors to wild Atlantic salmon, but it also must consider the climate *emissions* of this project. *See* CEQ, National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions and Climate Change, CEQ–2022–0005, https://public-inspection.federalregister.gov/2023-00158.pdf ("when conducting climate change analyses in NEPA reviews, agencies should consider: (1) the potential effects of a proposed action on climate change, including by assessing both GHG emissions and reductions from the proposed action; and (2) the effects of climate change on a proposed action and its environmental impacts."). For example, the NADA contemplates AquaBounty shipping eggs from Canada via airplane to its grow out facilities in the U.S., and such regular air shipping will have climate implications. As noted below, FDA and AquaBounty failed to provide any alternatives to the PEI-Indiana scheme, such as AquaBounty growing the eggs and fish in the *same* facilities, far inland from any historic or current wild salmon runs. This type of alternative would have alleviated the need for extensive air cargo shipping. FDA must evaluate the likely GHG emissions from its preferred alternative (as well as other alternatives that it must develop).

[6] Paul Molyneaux, AquaBounty shares tumble, National Fisherman (Nov. 8, 2022), https://www.nationalfisherman.com/national-international/aquabounty-shares-tumble.

5. Socioeconomic Impacts

NEPA analyses must include intertwined socioeconomic impacts in determining significance. *Center for Food Safety v. Vilsack,* 2009 WL 3047227 (N.D. Cal. 2009) (ordering EIS, holding economic effects are relevant and must be addressed in the environmental review "when they are 'interrelated' with 'natural or physical environmental effects.'"); *Geertson Seed Farms v. Johanns,* 2007 WL 518624, at *8 (N.D. Cal. 2007) (USDA required to consider socioeconomic effects in assessing whether action is significant). FDA fails to assess the impacts of bringing tens of thousands of tons of "fast growing" Atlantic salmon to the market on wild-caught fisheries and the communities that rely on them. FDA must also evaluate the significant intertwined socioeconomic and cultural impacts of escaped GE salmon on U.S. salmon fishing communities and tribes, as well as the public health impacts on food consumption and potential market displacement from introducing GE salmon into the food supply. To the extent the purpose and need for approving the GE salmon is to produce additional food supply, an 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.

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 2022 was approximately $720.4 million.[7] 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 and must be corrected in an EIS.

B. Alternatives

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). The latest CEQ NEPA regulations also make it clear that EAs must include a discussion of "alternatives." 40 C.F.R. § 1501.5. Courts have found EAs insufficient when they do not include reasonable alternatives to the preferred action. *See e.g., W. Watersheds Project v. Abbey,* 719 F.3d 1035, 1050-53 (9th Cir. 2013) (EA on grazing inadequate for lack of reasonable range of alternatives, all three action alternatives had same level of grazing).

Here, FDA does not even include a "no action" alternative, much less any other alternatives to its "preferred" alternative of the original NADA. Because FDA already approved AquBounty's NADA for GE salmon egg production at the first PEI facility and grow out in Panama, FDA says it is not considering a "no action" alternative here and continues to consider its original approval the "preferred alternative."

[7] https://www.adfg.alaska.gov/index.cfm?adfg=pressreleases.pr&release=2022_11_10.

Amended EA at 14. However, that original NADA contemplated a different scheme than AquaBounty's current set up, which now includes additional facilities in PEI and grow out facilities in Indiana and possibly Ohio that are much larger than the Panama facility. With the new information in the Amended EA, FDA must consider a "no action" (*i.e.*, a no NADA) alternative, as well as a reasonable range of other alternatives. These might include limits on the quantity of GE salmon eggs produced/fish grown out, limits on where facilities can be located (*i.e.*, not feet from marine waters that support wild salmon), limits prohibiting transport of the fish between locations, and other alternatives outlined in Commenters' 2013 comments at 35-36.

C. Adequacy of Containment Measures

FDA continues to hang its FONSI determination on the success of containment measures to prevent escapes of GE salmon into the environment. Despite gambling everything (including the now-admitted severe impacts to wild Atlantic salmon) on the success of AquaBounty's containment measures, FDA fails to substantiate their reliability. This does not equate to a "hard look" at the impacts of the action, nor is FDA able to rely on this mitigation to lawfully find no significant impact under NEPA.

1. Quantitative Failure Mode Analysis

Given the current/projected capacity of the PEI facilities to produce GE salmon eggs for all AquaBounty's current and planned grow out facilities, a quantitative failure mode analysis is even more important. Based on FDA's estimates, the facilities could produce 1,820,000 eggs that are diploid/capable of reproduction (including worst-case 5% of the AAS eggs failing to be triploid). Amended EA at 19-20. This is more than *three* times the fertile eggs FDA originally assessed in the 2015 EA where it evaluated the efficacy of the containment measures. No significant changes to that analysis were completed in this 2022 Amended EA, because FDA expressly responded only to the Court's order to complete its risk assessment and failed to do any additional assessment of the containment measures. FDA cites only the Canadian *qualitative* failure mode analysis but admits that the agency did not even provide specifics of the results. Amended EA at 77-78. As Drs. Kapuscinski and Sundström stated, FDA cannot rely 100% on the containment without presenting a failure mode analysis that is "standard practice in technology risk assessment."[8] Such an analysis is even more important where weather events are becoming increasingly severe and frequent due to climate change. Amended EA at 54 (noting tropical storm Fiona just this past September); 56 (noting climate change impacts to Atlantic Canada). As the recent IPCC Report stated: "It is an established fact that human-induced greenhouse gas emissions have led to an increased frequency and/or intensity of some weather and climate extremes since pre-industrial time, in particular for temperature extremes."[9] Further, it stated:

[8] Anne Kapuscinski, Comments on Environmental Assessment for AquAdvantage Salmon and Briefing Packet on AquAdvantage Salmon for the Veterinary Medicine Advisory Committee, 4 (2010) (attached).

[9] Seneviratne, S.I., X. Zhang, M. Adnan, W. Badi, C. Dereczynski, A. Di Luca, S. Ghosh, I. Iskandar, J. Kossin, S. Lewis, F. Otto, I. Pinto, M. Satoh, S.M. Vicente-Serrano, M. Wehner, and B. Zhou, 2021: Weather and Climate Extreme Events in a Changing Climate. In Climate Change 2021: The Physical

> Regional changes in the intensity and frequency of climate extremes generally scale with global warming. New evidence strengthens the conclusion from the IPCC Special Report on Global Warming of 1.5°C (SR1.5) that even relatively small incremental increases in global warming (+0.5°C) cause statistically significant changes in extremes on the global scale and for large regions (high confidence). In particular, this is the case for temperature extremes (very likely), the intensification of heavy precipitation (high confidence) including that associated with tropical cyclones (medium confidence), and the worsening of droughts in some regions (high confidence).

Id. at 1517.

While NEPA does not require specific methods, it does require FDA to ensure its analysis uses accurate scientific information of high quality, 40 C.F.R. §§ 1500.1(b), 1502.24, and to consider all important parts of the problem. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). FDA failed to verify reliability of containment using any methods, including the scientific standard of quantitative failure mode analysis. Without that assessment—including a full failure mode analysis—FDA cannot conclude that the containment is reliable, let alone sufficient to prevent the admittedly significant harm to wild salmon should GE salmon escape from the PEI facilities.

2. Inspections

Mitigation that supports a FONSI must be adequate and enforceable. 40 C.F.R. § 1501.6(c) ("The finding of no significant impact shall state the authority for any mitigation that the agency has adopted and any applicable monitoring or enforcement provisions. If the agency finds no significant impacts based on mitigation, the mitigated finding of no significant impact shall state any enforceable mitigation requirements or commitments that will be undertaken to avoid significant impacts."); § 1508.1(s) (definition of "mitigation"). 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) (EIS threshold is low); *Northern Plains Resource Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1085 (9th Cir. 2011) (mitigation is not proxy for data).

The containment measures outlined in the Amended EA are by definition mitigation measures to prevent harms (now recognized by FDA) from escaped GE salmon or pathogens/parasites. FDA claims that containment will work because the company, AquaBounty, has "Standard Operating Procedures" (SOP) and various levels of physical, chemical, and other containment that will continue to function

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Science Basis. Contribution of Working Group I to the Sixth Assessment Report of the Intergovernmental Panel on Climate Change [Masson-Delmotte, V., P. Zhai, A. Pirani, S.L. Connors, C. Péan, S. Berger, N. Caud, Y. Chen, L. Goldfarb, M.I. Gomis, M. Huang, K. Leitzell, E. Lonnoy, J.B.R. Matthews, T.K. Maycock, T. Waterfield, O. Yelekçi, R. Yu, and B. Zhou (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA, pp. 1513–1766, doi:10.1017/9781009157896.013.

properly. FDA claims that this will be confirmed by "future inspections by both FDA and Canadian authorities." Amended EA at 80. FDA provides no additional information about the frequency of these inspections, and whether they will be spontaneous or scheduled inspections (which could give AquaBounty time to fix any issues and conceal ongoing problems). Indeed, a recent whistleblower report on the conditions of the Indiana facility raises serious concerns about AquaBounty's ability to follow its SOPs and thus ensure that the containment measures FDA relies upon for its non-significance determination will be effective. FDA must outline the enforcement it intends to take to ensure these mitigation measures are working and to comply with NEPA.

3. Whistleblower Report

As FDA will see in the attached AquaBounty Exposed Report,[10] there is reason to be seriously concerned about AquaBounty's ability to conform to its own SOPs and ensure that containment of GE fish is working. It also raises serious concerns about the environmental impacts of fish farms that FDA needs to also consider in the direct/indirect impacts analysis in a full EIS (which is completely missing from the Amended EA). The report explains how AquaBounty would stage the facility for site visits, but that this was "very different" from the typical day. *Id.* at 7-8. The report states that numerous violations were concealed from FDA, including serious violations like infrastructure degradation. *Id.* at 8. In addition to many disturbing revelations, the report most importantly discusses breaches to containment. *Id.* at 11 ("Photos show many instances of containment breaches and fish escaping from tanks as well as use of water flow and drainage practices in violation of FDA containment regulation."). Disposal of dead and dying fish in an unsecure dumpster frequented by raccoons and other wildlife show how simple it would be for wild animals to move GE salmon to waterways. *Id.* The report further describes a particular disturbing event: "during a fish transfer from one building to another, a major spill occurred that landed many GE fish on the ground within 20 feet of the effluent for the entire facility's property risking the escape of these novel GE fish into the local waterway." *Id.* Further, "images also show fish that were able to jump out of their tanks, even though there are supposed to be nets over the tanks to keep the fish safe and to prevent any potential for them to escape." *Id.*

This report and the photos and other evidence linked therein underscore that FDA must be far more rigorous in its inspection and enforcement and far more transparent in its EA/EIS as to how and why it believes that the containment measures for PEI (which will only expand as additional grow-out facilities emerge) will be reliable. FDA must not only ensure that it adequately supports its mitigation measures/takes a hard look at impacts for NEPA, but it also must consider whether continued approval of GE salmon is safe, warranted, and in the public interest under the FFDCA in light of these documented and systemic failures.

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[10] AquaBounty Exposed Report (Oct. 25, 2022), https://docs.google.com/document/d/1FysnUssU4IvPQljNl3nWnWEVkN4Yj1CYQgu3f9YXIAo/edit?usp=sharing. Jennifer Marston, BREAKING: AquaBounty in murky water after accusations of safety violations at GM salmon plant, AgFunder News (Oct. 25, 2022), https://agfundernews.com/aquabounty-in-murky-water-after-evidence-shows-safety-violations-at-ge-salmon-plant.

II. ENDANGERED SPECIES ACT

The ESA prohibits any federal action that "may affect" listed species unless the federal agency *insures*, through completion of the consultation process, that the action is not likely to jeopardize the continued existence of threatened or endangered species. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.14, 402.13. The "may affect" threshold for triggering this precautionary regulatory scheme is an extremely low bar: "[A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (emphasis added); *id*. (consultation triggered by "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character.") (emphasis added and quotations omitted). The low threshold reflects the ESA's overall "institutionalized caution" mandate, ensuring that all federal actions that could have any effect on species on the brink of extinction are scrutinized by the expert wildlife agencies – the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS). *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015). And it "reflects Congress's awareness that expert agencies … are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species." *City of Tacoma v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006).

In its original approval of GE salmon, FDA refused to undergo Section 7 consultation because it arbitrarily concluded its decision would have "no effect" on endangered salmon or their critical habitat. The Court in *Institute for Fisheries Resources,* 499 F.Supp.3d at 668, held that FDA's no effect conclusion was arbitrary and capricious and ordered the agency to reconsider that determination on remand along with its revised NEPA analysis. The Court suggested that FDA should "initiate consultation with NMFS and FWS about whether AquaBounty's application would have an effect on endangered salmon, so that the conclusions the FDA ultimately reaches in its environmental assessment are supported by the guidance of the expert agencies." *Id*. FDA appears to have taken the first steps in this process by conferring with the wildlife agencies and concluding that the GE salmon approval "may affect" listed endangered salmon. Draft EA at 179. As FDA is aware, this conclusion triggers the consultation process—a process the agency must complete before it takes any action based on this EA (including any decision whether to issue a FONSI).

In a short discussion, FDA concludes that its GE salmon approval is "not likely to adversely affect" endangered salmon—based, again, largely on its assumptions about the efficacy of containment measures. Given what we know about the dangers posed to wild salmon from escapes (discussed above and in the Amended EA), this conclusion is both premature and incorrect. FDA offers almost no information explaining the basis for its conclusion and does not include a Biological Assessment for the public to comment on or evaluate. As it moves forward with the consultation process, FDA must provide both the wildlife agencies and the public with its full analysis of the potential effects to wild salmon and other listed species. Moreover, FWS and NMFS biologists documented extensive concerns in their preliminary evaluations of GE salmon before the 2015 NADA approval; but because FDA refused to

consult, those scientists did not have the opportunity to fully evaluate the risks.[11] Given the documented risks posed by GE salmon (including risks to wild Atlantic salmon from GE fish escapes and the impacts to wild fish and humans from land-based aquaculture facilities in terms of water use and water pollution), and the fact that this is the first time the wildlife agencies will be involved through the consultation process, FDA must abandon its preliminary "not likely to adversely affect" determination and engage in formal Section 7 consultation with the wildlife agencies. It is critical that FWS and NMFS biologists conduct a full and independent analysis of the information in any BA and carefully scrutinize the risks posed to wild salmon from FDA's approval to ensure that GE salmon do not jeopardize the existence of wild Atlantic salmon, or any other threatened or endangered species.

III. FEDERAL FOOD DRUG AND COSMETIC ACT

In addition to its NEPA and ESA obligations, FDA has an independent duty to evaluate and "act upon—concerns regarding the effect of the AquAdvantage salmon on normal salmon." *Inst. for Fisheries Resources*, 499 F. Supp. 3d at 664–65. Indeed, FDAs own GE animal guidance requires it to evaluate the environmental safety of a new animal drug. As the Court previously determined, FDA must "deny a permit application if it concludes that adverse impacts on humans and animals render the drug unsafe. And again, the core environmental concern with respect to the engineered salmon is that they might escape and ultimately impact the health of wild salmon and fish populations." *Id.* at 665. While its NEPA analysis may partially inform this determination, NEPA analysis alone is insufficient to satisfy this independent duty. Rather as the Court held, FDA has an independent duty under the FFDCA to ensure the safety of this animal drug, including environmental safety and to explain how and why it is so concluding that its approval assures such safety. Particularly in light of the new evidence of AquaBounty's safety record at the Indiana facility discussed above, FDA must determine, based on all of the relevant factors, whether GE salmon is "safe" for the environment.

Conclusion

FDA has done a decent job of outlining the many harms to wild salmon from the potential release/escape of GE salmon, but it still has a way to go before it can justify its decision to unleash GE salmon on the world without a full Environmental Impact Statement, as informed by a formal ESA consultation, and a separate FFDCA finding of environmental safety. As FDA knows, AquaBounty keeps growing its commercial-scale GE salmon production, and future GE animals are on the horizon. That makes this NEPA/ESA/FFDCA assessment crucially important, not just to future AquAdvantage salmon expansion, but to FDA's oversight of GE animals and their potential to drastically change our environment and even lead to the extinction of our sensitive wild species. Given the ever-increasing impacts of the climate crisis on our food production and wild places, FDA must use a precautionary

[11] These expert concerns are detailed further in the briefing and administrative record in the *Inst. for Fisheries Resources* litigation and are incorporate here by reference. *See, e.g.*, ECF Nos. 254; 255 and Exhibits (255-1 to 255-35).

approach here, and put a pause on the expansion of GE salmon until it can fully assess the potential impacts, including the likelihood of escapes into the wild.

Sincerely,

CENTER FOR FOOD SAFETY

EARTHJUSTICE

FOOD & WATER WATCH

FRIENDS OF THE EARTH

FRIENDS OF MERRYMEETING BAY

NORTHWEST ATLANTIC MARINE ALLIANCE

ECOLOGY ACTION CENTRE

PACIFIC COAST FEDERATION OF FISHERMEN'S ASSOCIATIONS

INSTITUTE FOR FISHERIES RESOURCES

GLOBAL JUSTICE

AMERICAN ANTI-VIVISECTION SOCIETY