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THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, *et al.*,

Plaintiffs,

v.

STEPHEN HAHN, *et al.*,

Defendants,

and

AQUABOUNTY TECHNOLOGIES, INC.

Intervenor-Defendant.

Case No. 3:16-cv-01574-VC

PLAINTIFFS' OPPOSITION TO FEDERAL DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Date: August 6, 2020
Time: 10:00 a.m.
Location: Courtroom 4
Judge: Hon. Vince Chhabria

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INTRODUCTION AND SUMMARY OF ARGUMENT

Despite the significant risks and uncertainty inherent in greenlighting the first-ever commercial genetically engineered (GE) animal, Defendant FDA did not apply the rigor and caution that both the law and common sense require and that experts warned was essential. FDA refused to complete a full Environmental Impact Statement or undergo Section 7 consultation for this precedential decision despite potential impacts that far exceed the thresholds triggering those analyses for more routine and minor agency actions. Instead, FDA took a "see no evil, hear no evil, speak no evil" approach: ignoring risk, disregarding consequences and foreseeable future actions, omitting uncertainty, and overlooking geography. FDA's failures violated NEPA and the ESA.

The substantial magnitude of FDA's violations of these core environmental protections nevertheless pales in comparison to what FDA nonchalantly announced for the first time in its opposition brief: FDA abdicates any responsibility for the environmental risks of GE salmon, or any future GE animal, or for that matter any conventional animal drugs. Despite the broad nature of its FFDCA authority, as including all factors relevant to its safety determination, and a record filled with evidence documenting environmental risks, FDA claims to have no discretion whatsoever to address environmental harms. According to FDA, its long practice of NEPA assessments for animal drugs (including the EA here) is just window dressing, because it cannot act on them to regulate approvals or enforce environmental conditions. FDA declines to defend the arbitrary nature of its treatment of environmental risks in its FFDCA decision, putting all its chips on its reveal hole card. FDA's *post hoc* rationalization is as legally bankrupt as it is irresponsible. Plaintiffs are entitled to summary judgment and the GE salmon approval must be vacated.

I. FDA FAILED TO ADEQUATELY CONSIDER ENVIRONMENTAL RISK AND NOW UNLAWFULLY DISAVOWS ANY AUTHORITY OVER ENVIRONMENTAL IMPACTS.

FDA arbitrarily failed to ensure that GE salmon will be environmentally safe under the FFDCA despite concluding that the environmental risk associated with GE salmon is a highly relevant, if not the most relevant, consideration for its FFDCA evaluation. ECF 198 at 13–14, 17–

18; ECF 225 at 6–11; ECF 254 at 33. Rather than defend its decision on the administrative record and merits, FDA argues for the first time in its penultimate brief that the FFDCA actually *prohibits* any consideration of the environment. FDA contends it has *no* discretion or authority, under any statute, to impose environmental conditions for GE salmon or any future new animal drug approvals. ECF 244 at 30–31, 34–35. In other words, after this Court determined that FDA has authority to regulate GE animals as drugs under the FFDCA, ECF 229 at 18–19, FDA now reveals that the emperor has no clothes.

FDA's sweeping new legal position conflicts with the FFDCA, is inconsistent with FDA's prior policies and rationalizations, and if upheld, would result in dire consequences for GE salmon and all future new animal drugs. According to FDA's new *post hoc* position, all that is keeping AquaBounty from growing salmon in environmentally-risky conditions is their good will. And the NEPA assessment that FDA took five years to finalize loses all meaning. If FDA has no discretion to regulate environmental risks, its EA will inform nothing, contrary to NEPA's core purpose. FDA's newly discovered position is also contrary to the record: there is no question that FDA *did* consider "environmental risk, at least to some degree, when it approved the conditions of use for the genetic engineering of the AquAdvantage salmon." *Inst. for Fisheries Res. v. Hahn*, 424 F. Supp. 3d 740, 758 (N.D. Cal. 2019); *see also* Transcript of Oral Argument (Oct. 2, 2019), excerpts attached as Exhibit 1 (hereinafter "Transcript"), at 49 ("[W]e know environmental risk was considered because look where we ended up.").

The FFDCA provides FDA sufficient discretion and authority to consider and limit its approval of GE animals based on environmental effects, and FDA arbitrarily failed to ensure that GE salmon is safe for the environment. Accordingly, if the Court rejects FDA's *post hoc* position and concludes FDA does have discretion to consider the environmental effects of GE animals, Plaintiffs are entitled to summary judgment.

A. FDA's Interpretation Conflicts with the Broad Language of the FFDCA.

The FFDCA safety language is unambiguous as to the critical question: whether FDA is

limited in the factors it considers as part of its safety determination. Its expansive terms require FDA to ensure environmental safety whenever risks to the environment are implicated. The statute defines "safe" as anything related to "the health of man or animal," and states FDA "shall" consider all "relevant factors" related to safety when evaluating a new animal drug. 21 U.S.C. §§ 321(u), 360b(d)(2). Here, the record overwhelmingly demonstrates that environmental impacts were highly relevant to the decision; indeed, FDA itself consistently treated those risks as highly relevant to its safety evaluation. *E.g.*, ECF 213 at 8–11 (citing record). Based on this record, the FFDCA required FDA to consider those highly relevant environmental risks in its evaluation.

Because the statue is unambiguous, *Chevron* does not apply. As the Supreme Court recently reminded, "before concluding that a rule is genuinely ambiguous, a court must exhaust all the 'traditional tools' of construction." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019) (citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council*, 467 U.S. 837, 843 n.9 (1984), noting it adopts the "same approach" for statutes). Only when the "legal toolkit is empty" and the "interpretative question still has no single right answer" can a court "wave the ambiguity flag." *Kisor*, 139 S. Ct at 2415. The expansive plain language of Section 360b(d)(2) does not limit the factors relevant to FDA's safety evaluation, and certainly does not exclude environmental effects. Nothing further is needed for *Chevron* to "leave[] the stage." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1630 (2018).

FDA tellingly cannot identify any FFDCA provision that expressly precludes the agency from addressing environmental harm from new animal drugs. ECF 244 at 31–34; *Nat'l Cable & Telecomms. Ass'n v. F.C.C.*, 567 F.3d 659, 663–65 (D.C. Cir. 2009) (holding "sweeping language should be given broad, sweeping application" and rejecting interpretation limiting agency action when nothing in the statute expressly and unambiguously did so). To the contrary, the statutory language is broad. 21 U.S.C. §§ 360b(d)(2) (not limiting considerations for approval); 321(u)[1]

[1] FDA contends that Section 321(u) "facially" excludes consideration of indirect effects, as defined in NEPA regulations. ECF 244 at 33 (citing 40 C.F.R. § 1508.8). The plain language of Section 321(u) does not exclude consideration of any specific effects. And, in any case, the indirect effects under NEPA, "aesthetic, historic, cultural, economic, and social effects," are not relevant to FDA's safety evaluation. *See id.*

(broadly referencing the "health of man or animal"). Congress instructed FDA to ensure that drugs are "safe and effective" in order to broadly "promote public health." 21 U.S.C. § 393(b). FDA itself recognized that public health is an expansive term that incorporates environmental health. FDA-004899 (stating "public health" is an "encompassing term" including humans, the target animal, other animals consuming food from the target animal, and "other organisms in the environment in which [the target animals] are likely to be found"). This Court has already found that the "term 'safe' is certainly capacious enough to reach environmental risks, and Congress carved out space for 'other relevant factors.'" *Inst. for Fisheries Res.*, 424 F. Supp. 3d at 757.

FDA's previous determination that environmental risk was highly relevant to its approval belies its current litigation position. FDA mischaracterizes Plaintiffs' argument as claiming that "relevant factors" must always include environmental impacts. ECF 244 at 32. That is incorrect: whether something is a relevant factor is a case-specific determination. Just as FDA need not evaluate the effects to human safety of a drug administered to a non-food animal, FDA need not evaluate environmental risk where none exists.[2] But, as here, when FDA has *already* determined that environmental factors are *highly* relevant to the safety of the drug, and the record shows that is most certainly the case, it cannot then ignore those highly relevant factors in its approval. *E.g.*, F1-00183309 ("The primary risk issue posed by the [AquAdvantage] salmon is environmental.").[3] And if, as in this case, it is undisputed that environment is a relevant factor, then FDA *must* evaluate that factor as part of its FFDCA safety determination. 21 U.S.C. § 360b(d)(1) ("In determining whether such a drug is safe for use . . . the Secretary shall consider . . . relevant factors.").

FDA's new position creates an illogical conflict between the FFDCA, NEPA, and FDA's own implementing regulations. If the FFDCA precludes consideration of environmental effects and if FDA cannot *act* based on the outcome of the NEPA review, as FDA now argues, then the NEPA analysis and process is no more meaningful than fish wrap. Yet FDA has long-established

[2] For example, FDA's regulations categorically exclude anesthetic drugs for animals from NEPA evaluation. 21 C.F.R. § 25.33.

[3] Notably, FDA made no contrary finding, nor does it argue that this determination was incorrect.

regulations that *require* the agency to conduct NEPA evaluations for new animal drug approvals. 21 C.F.R. §§ 25.20, 25.33 (1980); 21 C.F.R. § 25.1 (explaining that the regulations implement NEPA "in a manner that is consistent with FDA's authority under" FFDCA). Those regulations require FDA to both "examine[] the environmental risks of the proposed action" and ensure that any "necessary mitigating measures [to environmental impacts] are implemented as a condition for approv[al]." 21 C.F.R. § 25.40(e). The FFDCA only grants FDA authority to condition new animal drug approvals to ensure they are safe. 21 U.S.C. § 360b(a). FDA cannot interpret its safety mandate both to preclude it from prescribing environmental conditions of use—as FDA's litigation position would have it—and to meet the requirements of NEPA and its own regulations that foster consideration of such conditions. Courts "must read the statutes to give effect to each if we can do so while preserving their sense and purpose." *Watt v. Alaska*, 451 U.S. 259, 267 (1981); *see also Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("[C]ourts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."). The Court should refrain from construing NEPA and the FFDCA in a way that creates a conflict. *Forelaws on Board v. Johnson*, 743 F.2d 677, 683 (9th Cir. 1984) ("NEPA's legislative history reflects Congress's concern that agencies might attempt to avoid any compliance with NEPA by narrowly construing other statutory directives to create a conflict with NEPA.").

Contrary to FDA's arguments, other FFDCA provisions do not conflict or indicate that Congress intended to exclude environmental considerations from FDA's animal drug regulation. ECF 244 at 33–34. FDA points to language requiring FDA to consider environmental impacts for the indexing of unapproved new animal drugs for minor use. It would make little sense for Congress to require FDA to consider environmental risks for the "minor use" of unapproved new animal drugs but ignore environmental risks for *major* uses of approved new animal drugs. 21 U.S.C. §§ 360ccc-1(c)(2)(D), (E). FDA relies on *Russello v. United States*, 464 U.S. 16, 23 (1983), but the language in Section 360b is completely different than the language in Section 360ccc-1(c)(2),

and the "*Russello* presumption that the presence of a phrase in one provision and its absence in another reveals Congress' design—grows weaker with each difference in the formulation of the provisions under inspection." *City of Columbus v. Ours Garage & Wrecker Serv., Inc.*, 536 U.S. 424, 435–36 (2002); *see also Children's Hospital Ass'n of Tx. v. Azar*, 933 F.3d 764, 771–72 (D.C. Cir. 2019). Moreover, Congress added the language for minor use in 2004, long after establishing the general requirements for all new animal drugs, P.L. 108-282, 118 Stat. 891 (2004). It is reasonable to conclude that Congress understood FDA already had authority to consider the environment for all uses of new animal drugs generally, and was merely specifying that this factor must *still* be considered for minor use indexing. Likewise, Congress would not later require FDA in 2007 to study and report on the heightened environmental risks of GE fish unless Congress believed FDA had the underlying authority to consider that report and act to protect the environment from those risks. 21 U.S.C. § 2106. The FFDCA is unambiguous in providing FDA authority to consider relevant environmental risks in its animal drug safety determination.[4]

B. FDA's New *Post Hoc* Litigation Position Deserves No Deference.

Even if there were "genuine ambiguity" in the language, the agency's reading must still be reasonable. *Kisor*, 139 S. Ct. at 2415 ("And let there be no mistake: That is a requirement an agency can fail.") (citing and quoting *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 296 (2013)). FDA's litigation position is an ocean away from the reasonableness shore; it is a *post hoc* litigation position that conflicts with its own consistently expressed position throughout the record.

There is ample record evidence demonstrating that FDA consistently interpreted its

[4] FDA seems to imply (ECF 244 at 32–33) that its food additive evaluation under Section 355, from which the new animal drug language derives, precludes consideration of relevant environmental factors, but provides no legislative history to support that reading. To the contrary, when Congress added the definition of "safe" to Section 321(u), it intended FDA to determine, without limitation, that a food additive "will protect the public health from harm." S. Rep. No. 85-2422, at 6–7 (1958). And the legislative history further supports the broad and case-by-case scope of the safety evaluation, stating that FDA is required to consider certain specified factors along with "information with regard to the specific additive in question." *Id.* Case law does not support FDA's arguments either. ECF 213 at 7–8, n.5. FDA provides no rebuttal to Plaintiffs' prior arguments on this point and Plaintiffs reassert them here.

authority broadly and considered environmental safety to be a highly relevant component of its GE salmon review under the FFDCA. *E.g.*, ECF 213 at 8–11. In its own GE animal guidance, FDA expressly stated that "environmental risks are among the factors we intend to consider in determining *whether to exercise enforcement discretion*." FDA-G187-00601 (emphasis added). And, in communications during its review process, FDA assured interested parties and state legislatures that it does have authority to consider and protect the environment. *E.g.*, F1-00065842.

In contrast, FDA's position post-approval has changed repeatedly throughout this case. FDA insisted in its Motion for Judgment on the Pleadings that it cabined its environmental review to the NEPA process because the FFDCA *does not require* it to consider the environment. ECF 206 at 20–22. During oral argument, FDA revised its position, stating that while FDA has the flexibility to consider the environment under the FFDCA, its *authority* to impose environmental limitations arises under NEPA. Transcript at 18 (FDA counsel stating that FDA "has the power" to impose conditions that would ensure an environmentally-safe manufacturing process and that power "would be from NEPA"). FDA counsel assured this Court that FDA was *not* taking the position that it is precluded from considering environmental impacts under the FFDCA. *Id.* at 49 ("[T]o say there is no room [for consideration of environmental issues under the FFDCA] is not quite right."); *id.* at 44 ("The Court: I'm just asking you does the FDA have authority to insist on a condition that is solely designed to alleviate environmental concerns?" Counsel for FDA: "It could do so, yes. It has that—that authority."). FDA counsel acknowledged some of the conditions FDA imposed (including net pen restrictions) were based solely on environmental concerns. *Id.* at 33–34 ("The ocean net pens? I believe that was focused on environmental concerns."); *id.* at 36 ("That scenario deals with the environment.").

Now, FDA for the first time presents a completely new position, after it "further considered" the issue. ECF 244 at 30.[5] FDA asserts that the FFDCA actually "*precludes*

[5] Despite regulating new animals drugs for over half a century (and applying its NEPA regulations to its reviews) and working on its GE animal guidance (which states FDA will consider

consideration of environmental impacts," *id.* at 34, and that FDA "does *not* have authority under the FDCA *or* NEPA to require conditions designed to protect the environment," *id.* at 36 (emphasis added). *See also id.* at 30 ("FDA does *not* have discretion to consider purely environmental risks in determining the safety of new animal drugs."). FDA apparently now agrees that NEPA cannot by itself authorize FDA to condition approval of a new drug on the mitigation of environmental risk, but seeks to eviscerate environmental protection altogether rather than simply admit that the FFDCA provides that authority. And FDA fails to explain why it undertakes NEPA analyses if they are a meaningless charade. Rather, FDA throws up its hands and speculates that Congress might step in to fill the void created by its abdication. This is a quintessential *post hoc* rationalization, a shifting litigation position that deserves no deference whatsoever. *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 212–13 (1988) ("Deference to what appears to be nothing more than an agency's convenient litigating position would be entirely inappropriate.").

C. FDA's Interpretation Has Dangerous Consequences for All New Animal Drug Approvals.

As this Court noted at oral argument, it makes no common sense for FDA to assert that it lacks the authority to consider the environmental consequences of a drug it is approving: "Go tell that to ten people on the street and see how they react." Transcript at 67; *see also id.* at 25 ("How could it be that the FDA doesn't have the ability to impose a condition of approval that . . . is designed to ensure that the manufacturing process doesn't destroy the environment; right?"). Yet FDA now insists on flouting common sense and—despite all of its previous assurances to the contrary—asserting that it is powerless to protect the environment from its GE animal approvals. ECF 244 at 30–37. Nor is that the logical end-point of FDA's argument: it would mean FDA could not impose or enforce environmental conditions on *all* animal drugs, GE animal or not. FDA's eleventh hour decision to abandon the field has profound negative consequences.

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environmental safety) for two decades, FDA claims it never had occasion to "flesh out" whether it can regulate environmental risks. ECF 244 at n.28. The sheer incredulity of this claim defies belief.

Without any authority to condition the GE salmon approval with environmental mitigation measures, there is no way for FDA to ensure that GE salmon will not harm the environment. FDA admits as much, stating, "FDA is not authorized by the [FFDCA] to . . . impose conditions 'to protect sensitive marine and freshwater areas'" or otherwise protect the environment. ECF 244 at 21. The FFDCA prohibits the introduction of adulterated drugs into commerce, 21 U.S.C. § 331, and "adulterated" new animal drugs are those that are deemed unsafe under Section 360b. 21 U.S.C. § 351(a)(5). In other words, enforcement to ensure the continued safety of the drug is predicated on the enforceability of any conditions imposed as part of the safety determination: If FDA does not have authority to adopt environmental conditions of use under the safety provisions of Section 360b as it now claims, then FDA has no authority to enforce the prohibitions against adulterated or unsafe new animal drugs when those conditions are violated. *See* Transcript at 23 (The Court: "[I]f your argument is that unsafe does not include environmental consequences, then how does the FDA have the authority to impose conditions that are designed to protect against adverse environmental consequences?"). That result undermines *any* protection from environmental harm associated with the production of GE salmon. For example, while FDA admits that it imposed conditions to prohibit GE salmon from being raised in ocean net pens because of environmental concerns, nothing prevents AquaBounty—or any future purchaser of GE salmon eggs—from ignoring those conditions and raising GE salmon in net pens in the heart of wild salmon habitats.[6] And, of course, FDA would have no power to condition future GE animal approvals (or enforce those conditions) in order to prevent environmental harm.

Contrary to FDA's assertions, there are no other adequate means to address these concerns. FDA points to "voluntary measures" that an applicant can take if they are "motivated to

[6] FDA implemented limitations on the use of net pens and other environmental conditions of approval explicitly under its authority in Section 360b. 80 Fed. Reg. 73,104 (Nov. 24, 2015) (citing Section 360b as authority to limit the grow-out and production of eyed-eggs to physically-contained, freshwater facilities); FDA-023113 (stating that deviations from the conditions of approval will result in the animal being unsafe and adulterated under Section 360b and Section 351 of the FFDCA). Those regulations and conditions are extra-statutory and invalid under FDA's new interpretation.

address environmental impacts" for a number of vague "economic, business, [and] public relations" reasons. ECF 244 at 35–36. FDA contends that any voluntary conditions could "become part of the approval," which then would require that a drug manufacturer must "conform to those conditions established in the approved application or face potential enforcement action from FDA." ECF 244 at 36. FDA provides no statutory or even common sense support for this magical thinking. If FDA does *not* have authority to condition a drug approval to prevent environmental harm, then FDA likewise does *not* have authority to enforce such environmental limitations.

Other existing authorities are not by themselves adequate to protect the environment. Although other federal agencies, including the wildlife Services, have separate environmental authority, FDA has disavowed any meaningful participation from those critical agencies as part of the NEPA and ESA processes, as described below. *See infra* at Section III. Moreover, the logical extension of FDA's position is that because it has no authority to address risks, it has no duty to review impacts under NEPA at all for GE salmon or any future approvals. *See* ECF 198 at 19–20; ECF 225 at 11–12 (citing cases explaining that NEPA review predicated on underlying agency authority). Nor does the possibility of future Congressional or state action provide assurance that the environmental impacts of GE salmon or future GE animals will ever be adequately addressed—neither governmental body has a duty to act.

FDA argues that a contrary interpretation would be difficult to implement, claiming "there is no framework for judicial review of agency determinations of this nature," ECF 244 at 35, but Plaintiffs have already shown that the APA provides the necessary framework for judicial review and courts have used the APA framework to evaluate other components of FDA's safety evaluation. ECF 235 at 32. Tellingly, there are also no "guideposts" for FDA's safety evaluation overall nor any of the explicit safety factors that FDA agrees it must consider under the FFDCA. 21 U.S.C. § 360b(d)(2)(A)–(D) (probable consumption, cumulative effect, other safety factors, and whether the conditions are reasonably certain to be followed in practice). But that has not interfered with the agency's evaluation, or the courts' APA review of these other safety factors. *Am.*

Cyanamid Co. v. Young, 770 F.2d 1213, 1214, 1220 (D.C. Cir. 1985) (using APA's arbitrary and capricious standard to determine whether FDA's conclusions about safety and effectiveness of a new animal drug was supported by substantial evidence). The same is true for the environmental safety component of FDA's considerations.

FDA also posits that its discretion to consider environmental harm as part of drug approvals would lead to vague "illogical and unintended effects," like the consideration of animal drug excretions.[7] ECF 244 at 34–35. It is unclear why FDA's consideration of animal drug uses, including the excretion of drugs, would be improper. And FDA cannot have it both ways: The agency argued that it has the ability to regulate the GE salmon animal because it has wide discretion to impose conditions on the use of a drug (since the GE salmon themselves are not drugs), *see Inst. for Fisheries Res.*, 424 F. Supp. 3d at 754–55, but now contends that its authority is actually restricted to only certain factors. FDA cannot now present a narrowed view of its authority in order to escape judicial review of the conditions it chose to impose.

State preemption concerns are also not an issue. ECF 244 at 35 (citing ECF 229 at 21). FDA has not issued regulations claiming preemption of state law for environmental review like the agency did in *Wyeth v. Levine*, 555 U.S. 555, 580–81 (2009). Regardless, the *Wyeth* court determined that FDA's review of safety (that presumably includes relevant environmental factors) would not automatically preempt state law under the FFDCA unless and until FDA took action to issue such regulations, and even then, such potential regulations would likely be invalid. *See id.*

* * *

This Court should hold that FDA's GE salmon approval was arbitrary because FDA ignored the hazards of the potential release or escape of GE salmon, and failed to condition the approval to address those risks by, for example, requiring development of a response plan to

[7] FDA's comparison to human drug regulation is a red herring. ECF 244 at 35 n.30. The separate human drug provisions are not at issue. Further, the approval of human drugs and new animal drugs are markedly different. The FFDCA only allows FDA to approve or deny an application for a new human drug, but FDA can conditionally approve an application for a new animal drug. *See Am. Pharm.*, 377 F. Supp. at 829 n.9.

address any release of GE salmon or eggs. *See id.* ECF 254 at 33; ECF 198 at 13–14. FDA has not argued the merits of its safety determination, and any such merits argument is now waived. *Graves v. Arpaio*, 623 F.3d 1043, 1048 (9th Cir. 2010). Accordingly, if the Court finds FDA has discretion to consider and regulate environmental risks, Plaintiffs are entitled to summary judgment.

II. FDA VIOLATED NEPA.

The primary purpose of an EA is to inform whether significant impacts warrant the preparation of an EIS. 40 C.F.R. § 1508.9. Because FDA failed to take a "hard look"—much less the most minor glance—at the risks and consequences of GE salmon's potential interactions with wild salmon, its determination of non-significance is arbitrary and capricious. Given the unprecedented, uncertain, and far-reaching impacts of the novel GE fish approval, NEPA required a thorough EIS, not the cabined, piecemeal review that FDA did here. The Court should grant Plaintiffs summary judgment and require FDA to prepare a full EIS.

A. FDA Failed to Take a Hard Look.

FDA did not meet NEPA's hard look requirement because it completely ignored the potentially catastrophic direct and indirect effects on the environment if GE salmon escape into waters near the PEI facility. ECF 254 at 3–6; *Id.* at 11–15. First, FDA's most fundamental hard look violation was its failure to undertake the entire risk assessment equation, relying on AquaBounty's physical, biological, and geographic containment measures (exposure), but failing to assess what the consequences will be when and if they fail, and GE salmon interact with and contaminate wild salmon populations (hazard or consequences). *Id.* at 12. Experts repeatedly detailed why this was contrary to sound science. *Id.* at 3–6, 12 (and citations therein). FDA's response mantra is that those problems were only in the *draft* EA, and the final 2015 EA fixed the problems. *E.g.*, ECF 244 at 11–12.

However, the final EA did *not* consider the consequences from escape. Rather the EA's "analysis" of PEI facility consequences focuses on how "unlikely" FDA believes it is that GE salmon will break geographic and biological containment, rather than what happens if and when

they do. FDA-022433—441, FDA-022435—437; van Saun Decl., Exhibit A. In fact, there is only one paragraph in the entire EA on potential effects on the endangered Atlantic salmon in Maine waters. FDA-022441. The final EA relies solely on containment and simply concludes that there are no possible negative effects. It never actually grapples with what happens if FDA is *wrong*.

FDA cites three pages in the 200-page EA that it claims took a "hard look" at hazard, aka "what would happen if GE salmon were to be released into the environment." ECF 244 at 12–13 (citing FDA-022348–50). Yet two and a half of the three pages focus on FDA's belief that escape and establishment are unlikely, disclosing the essence of its actual approach along the way: "In other words, if there is no environmental exposure, there is also no environmental risk." FDA-022349. FDA discussed actual "likely consequences" in only three short paragraphs (FDA-022350) and only in the most general terms of GE animals broadly, comparing them to invasive species and listing five types of possible harms, without assessing them. There is no analysis of the environmental effect of AquaBounty salmon (or even GE fish) if released into the wild.[8]

FDA did not address comments from experts about the likelihood or consequences of escape, or the half-a-loaf aspects of its risk assessment approach, as it now contends. *See* ECF 244 at 12. A simple redline comparison of the draft and final EA shows that FDA did *not* fundamentally change its approach, or correct the core flaws that the scientists raised; in fact it shows very little change in substance, and did not include the fulsome approach the experts told FDA it was missing. *See* van Saun Decl., Ex. B. The final EA did not, for example, add a new section on hazards. The draft and final "environmental consequences" section discussed above and on which FDA purports to rely, FDA-022433–443, which should have included such hazards, actually shows *very little change in substance*. van Saun Decl., Ex. A (redline of Section 7.5). There is no risk

[8] FDA provides a string of record citations it claims are responsive to the experts' concerns about escape (ECF 244 at 12), but those are *2011 documents*, well before the comment period. (*e.g.*, FDA-017218). If anything, these documents show the significant concerns of experts from the wildlife agencies about the facility. *E.g.* FDA-017250-51 (NMFS biologist finding multiple flaws in containment, concluding "I have reason for concern that a GMO product could in fact escape and survive in the wild.").

assessment or hazard discussion changes hiding elsewhere. van Saun Decl., Exh. B. And the three pages that FDA specifically names (FDA-022348–50) are virtually unchanged from draft to final and did nothing to address the scientists' critiques. van Saun Decl., Ex. B at 40–44. FDA simply did not make the wholesale shifts in risk assessment, data analysis, and scope the experts urged. Consequently, FDA did not address the experts' harsh critiques of FDA's work as having "major scientific inadequacies," setting "an unacceptably low bar," and ignoring "major advances in methodologies for assessing environmental risks from transgenic fish," as FDA claims. ECF 254 at 3–4 (and citations therein).[9]

Further, FDA offers no response to the NEPA cases also requiring just what the experts told FDA the science required: that agencies must assess *both* the probability of a harm and the consequences if it does occur. ECF 254 at 13 (and cases therein). FDA's treatment of this critical impact is a far cry from the hard look NEPA requires.

Second, despite gambling everything on 100% efficacy of the containment measures, FDA failed to substantiate their reliability, including through a quantitative failure analysis. Such an assessment is especially important for a facility with up to half a million fertile GE eggs, plus fertile broodstock, near waters that support endangered Atlantic salmon. ECF 254 at 5, 13–14. FDA protests that NEPA does not specifically require failure analysis, ECF 244 at 13. 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.

[9] Contrary to FDA's representations, the final EA does not apply the newer risk assessment methods the experts urged FDA to follow. With regard to Dr. Kapuscinski specifically, the final EA has two passing, general citations to her seminal 2007 work, *see* van Saun Decl., Ex. B at 43, 180; the others are mostly to her outdated 1990s work, *id.*; reliance on which, she explained, would earn a student a failing grade in one of her classes. ECF 254 at 12. FDA certainly did not come close or even attempt to make the fundamental risk assessment changes necessary for the hazard assessment recommended by Dr. Kapuscinski in the final EA. van Saun Decl., Ex. A

FDA also appeals for deference when experts have "conflicting views." ECF 244 at 13. Here, the Court has nothing to defer to—FDA simply did not do the containment homework that the experts said it should have done. FDA instead defers to AquaBounty as its "expert," but Intervenor is entitled to zero deference—it is FDA's responsibility to evaluate impacts. ECF 244 at 13 (citing FDA-023060 and explaining, "the sponsor did not choose" to do a failure analysis).

In response to expert critiques about its failure to assess escape risks from accidents, storms, and human error, *see e.g.* FDA-029458-9; FDA-016668; FDA-019813–4; F1-00047503, FDA only points to a one-page discussion dismissing these dangers (ECF 244 at 12 (citing FDA-022435), 99 percent unchanged from draft to final)) that is predicated on the misplaced assumption that the number of broodstock would be limited. FDA-022435 ("Regardless of the scenario, the number of adult broodstock in the PEI facility will be limited" and thus "mass release" could "not occur"). At the time, FDA knew that AquaBounty intended to expand operations and broodstock. ECF 254 at 7–8. And FDA did not in fact place limits on the broodstock at the PEI facility and has now approved expanded operations to include far greater numbers than originally anticipated. *See* FDA-023113–122.

Third, NEPA also requires agencies to address and account for scientific uncertainty, 40 C.F.R. §§ 1508.27(b)(5), 1502.22. Dr. Kapuscinski and other experts told FDA the EA failed to address the large uncertainty involved, considering the unprecedented action FDA was taking. ECF 254 at 3, 6–7, 14. FDA admits it failed to undertake a "formal" uncertainty analysis, but claims what it did "mirrors" one. ECF 244 at 14. Yet the single page (FDA-022346) FDA cites says not a word about uncertainty. van Saun Decl., Ex. B at 25 (unchanged in final). And there is no evidence that FDA in fact applied the better methods detailed in Kapuscinski (2007) in the final EA. FDA again failed to consider a critical aspect of the issue. *State Farm*, 463 U.S. at 43.

Finally, FDA improperly refused to consider any intertwined socioeconomic impacts of GE salmon's escape and interaction with wild salmon stocks, despite concerns raised by Tribes and fishing communities. ECF 254 at 14–15. FDA's position—an agency *never* has an obligation to

consider intertwined socioeconomic effects unless it is in an EIS—is not the law; if it was, EAs would never discuss these impacts.[10] Rather, the caselaw and NEPA regulations instruct only that such impacts *alone* do not trigger an EIS. 40 C.F.R. § 1508.14 ("[E]conomic or social effects are not intended *by themselves* to require [an EIS]."") (emphasis added). That does not mean FDA can completely disregard them in an EA, as FDA argues; it means that, like all other cognizable NEPA effects–40 C.F.R. § 1508.8(b) ("ecological . . . aesthetic, historic, cultural, economic, social, or health"), they factor into the EIS threshold determination, so long as they are interrelated with the environmental harm in question, *id.* § 1508.14. Here the socioeconomic impacts are plainly interrelated to the environmental harm: they are predicated on the escape and interaction of the GE fish with wild stocks. *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010) (transgenic contamination from a genetically engineered organism to a conventional one is cognizable NEPA injury and has "an environmental as well as an economic component").

FDA mischaracterizes *Center for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227 (N.D. Cal. Sept. 21, 2009) (and completely ignores *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Cal. Feb. 13, 2007)). In those GE crop cases, Judges White and Breyer found significant effects requiring EISs based on environmental *and* intertwined socioeconomic risks, rejecting the same argument FDA makes here. *Geertson Seed Farms*, 2007 WL 518624, at *8 ("Here, the *economic effects* on the organic and conventional farmers of the government's deregulation decision are interrelated with, and, indeed, a direct result of, the effect on the physical environment [from GE crop contamination]. . . . *APHIS was required to consider those effects in assessing whether the impact of its proposed action is 'significant.'*") (emphases added); *Ctr. for Food Safety*, 2009 WL 3047227, at *8–9 (same holding).[11] The same is true here with the risk to

[10] *See, e.g.*, *Ctr. for Envt'l Law & Policy v. BLM*, 655 F.3d 1000, 1012 (9th Cir. 2011) (EA properly refused alternative because of "concerns about the impact to local economics from the transfer of the needed volumes of water"); *Mont. Envt'l Info.Ctr. v. Office of Surface Mining*, 274 F. Supp. 3d 1074, 1096 (D. Mont. 2017) (discussing EA's "socioeconomic analysis" of a coal lease); *Hells Canyon Alliance v. U.S. Forest Serv.*, 227 F.3d 1170, 1174, 1185–86 (9th Cir. 2000) (discussing EA to "focus on economic impacts to commercial outfitters" of a public lands proposal).

[11] FDA cites *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934 (9th Cir. 2005) (addressing the here

wild salmon and the communities who depend on them.

B. FDA Should Have Completed an Environmental Impact Statement.

1. The Intensity Factors Showed Significant Effects.

FDA utterly failed to consider the intensity factors as part of its NEPA evaluation and any attempt to address them now is *post hoc* rationalization. FDA incorrectly claims that it addressed the significance intensity factors by merely citing the entire EA and FONSI, without pinpointing *where* it supposedly did so. ECF 244 at 15–16 (citing cover pages FDA-022313, FDA-022514). FDA failed to consider these factors; any attempt to do so now is *post hoc* rationalization. Any one factor alone mandates an EIS: the precedent-setting nature of this first GE food animal approval; the novel and unique risks posed by escape; the controversy around the risks of escape and of increased GE salmon production beyond the two facilities; or the precarious status of wild salmon and those that rely on them. ECF 254 at 16–17.[12]

While FDA is correct that not *every* project requires an EIS, the first approval of a GE food animal that can migrate thousands of miles and interbreed with critically endangered wild relatives is hardly just "any project." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 864–65, 868–71 (9th Cir. 2005) (requiring EIS based on intensity of cumulative impacts from increasing tanker traffic (and increased risk of catastrophic oil spill) along with other projects and their impacts to the ecosystem, and uncertainty as to how much tanker traffic would increase). Several intensity factors indicate significance.

FDA summarily dismisses uncertainty or unique risks (factor 5), ECF 244 at 15. In doing so, FDA ignores the unique and unknown risk of potentially introducing a new organism into the ecosystem. ECF 254 at 4–5. The proper question is not whether the risk to the environment is absolutely zero (as FDA asserts), ECF 244 at 15 n.15, it is "the degree to which effects are highly

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unchallenged premise that economic injury alone does not confer prudential NEPA standing) but it fully supports Plaintiffs: *Geertson* and *Ctr. for Food Safety* rely on *Ashley Creek*.

[12] Plaintiffs identified six factors at issue here, not four. *See* ECF 244 at 16; ECF 254 at 15.

uncertain or involve unique or unknown risks." 40 C.F.R. § 1508.27(b)(5). Here risks are highly uncertain (what will happen should fish escape?), unique, and unknown (this is the first migratory GE fish to be commercially produced).

FDA offers no rational explanation for how the first-ever GE animal approved for human consumption is not precedential (factor 6). This factor does not depend on the existence of a GE salmon "program," ECF 244 at 16, but rather depends on whether this action establishes a precedent of any kind. This is the first approval of any GE fish or any commercial GE animal for food consumption. And there is no indication that FDA intends to stop approving GE animals in this fashion. None of its current "rules and regulations" specifically address GE animal approvals, and there are no rules that FDA can point to that "set any standard." *See* ECF 244 at 16. With no programmatic or other EIS to guide GE animal approvals, the NEPA analysis for GE salmon is precedential for future GE food animals. *E.g.*, F1-00167786. The Court should give no weight to the fact that the Indiana facility's EA was "supplemental" rather than a new NEPA process; FDA and future GE animal developers will still look to this first process as an example. And if an animal that migrates thousands of miles and has highly endangered native relatives does not have potentially significant impacts triggering an EIS, they will ask what GE animal ever would.

FDA dismisses the significant controversy (factor 4) concerns as merely "related to early drafts" and earlier containment measures. ECF 244 at 17 n.20. FDA presumably again relies on its final EA, but offers no specifics about how the containment measures ultimately approved "succeeded" in "resolv[ing] the controversy" about the potential environmental impacts. *Nat'l Parks Conservation Ass'n. v. Semonite*, 916 F.3d 1075, 1086 (D.C. Cir. 2019) (power lines over historic river; EIS required because of (as here) controversy related to effects' scope and subject matter experts' criticism). In reality, as the redline shows, the final EA fixed nothing from the draft and ended no controversies over its inadequacies. *See supra* at 13–14; ECF 254 at 3–6. FDA failed to address the controversy or conduct an EIS that examined all aspects of the approval, in violation of NEPA. *Bark v. U.S. Forest Serv.*, No. 19-35665, 2020 WL 1656447, at *2–4 (9th Cir. Apr. 3, 2020)

(failure to prepare EIS arbitrary based on uncertainty and controversy over effects of forest thinning, ignoring expert evidence in comments); *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, No. 16-1534 (JEB), 2020 WL 1441923, at *8–16 (D.D.C. Mar. 25, 2020) (EIS required for pipeline where agency failed to resolve controversy about effects, including worst-case spill analysis).

Finally, FDA does not address its failure to consider cumulative impacts (factor 7) to already-imperiled wild salmon, effects to an ESA-protected species (factor 9), which is a significant cultural resource (factor 8). These intensity factors show that here, like in *Ocean Advocates, Bark*, *Semonite*, and *Standing Rock*, an EIS was required.

2. FDA Improperly Relied on a Mitigated FONSI.

FDA also improperly relied on mitigation to avoid an EIS. ECF 254 at 17–18. First, contrary to FDA's semantic characterizations that its approval does not include mitigation, mitigation measures are not only "after-the-fact measures." ECF 244 at 17 (lacking any citation). Rather mitigation is defined to include "[a]voiding an impact by not taking a certain action or parts of an action" and "[m]inimizing an impact by limiting the degree or magnitude of the action and its implementation." 76 Fed. Reg. at 3843, 3847 (Jan. 21, 2011). The containment measures are plainly forms of mitigation. *Id.* at 3847–48 (discussing "Mitigation Incorporated Into Project Design"). FDA *itself* refers to them as mitigation. FDA-022333 (approval conditions are "required by FDA to mitigate potential risks"). Second, FDA did not adequately analyze the mitigation measures upon which they rely so heavily. FDA failed to undertake any failure mode analysis of containment reliability, a crucial and standard part of proper risk assessment.

Finally, FDA's newly minted position that it lacks underlying authority to impose or enforce any environmental mitigation conflicts with its argument that FDA's oversight is sufficient to ensure this mitigation occurs. 76 Fed. Reg. at 3847 ("Agencies should not commit to mitigation, however, unless they have sufficient legal authorities . . . ."); *id.* at 3844 (requiring "basis for the agency to commit to perform or require the performance of particular mitigation"). FDA does not

explain how its assurances about "regular inspections" and other enforcement authority, ECF 244 at 17, squares with its disavowal of that authority. *Jones v. Gordon*, 792 F.2d 821, 829 (9th Cir. 1986) (permit conditions are mitigation, but their "effectiveness depends on how they are applied and enforced").

C. FDA Applied an Unlawfully Narrow Scope.

FDA also violated NEPA by restricting its analysis to omit past, present, and reasonably foreseeable future impacts, including AquaBounty's expansion plans, and a reasonable range of alternatives. ECF 254 at 18–24.

1. FDA Improperly Segmented its Analysis.

Despite AquaBounty's well-publicized expansion plans and public statements (including to FDA), FDA limited its review to the PEI and Panama facilities. AquaBounty subsequently closed the Panama facility and opened a new bigger facility in Indiana. And, it dramatically expanded the PEI facility to produce over ten million eggs. ECF 254 at 5 n.3, 7. FDA drafted a separate EA (but still not an EIS) for the Indiana facility, and for the PEI expansion, heavily relying on the original EA. For the PEI expansion, FDA did not allow public comment, publicize the EA, or even tell this Court or the parties about it. So there are now three separate EAs (and counting) for reasonably foreseeable actions all related to the original approval. This is literally the opposite of the analysis NEPA requires: segmented into pieces, instead of comprehensive; applied after GE salmon had pried open the regulatory door, rather than before it. ECF 254 at 18–21.

First, while FDA contends in its brief that it is mere "speculation" that GE salmon approval would be the "gateway for future approvals," ECF 244 at 19, the record reveals that this was the plan from the start. In 2006, FDA suggested AquaBounty follow a piecemeal "strategy in which the first New Animal Drug Application (NADA) approval could be granted for a particular product definition that poses minimal environmental risks (e.g., triploid *AquAdvantage* fish), and that supplemental ADAs be used to extend the approval to other related products." FDA-004908. The Court should reject FDA's more recent claims that none of the events subsequent to the

approval was foreseeable. Moreover, the NEPA "action" is not simply what AquaBounty and FDA declare, or strategically limited the permit initially, to be. 40 C.F.R. § 1508.25 (scope). NEPA prohibits agencies from avoiding the EIS threshold "by terming an action temporary or by breaking it down into small component parts." 40 C.F.R. § 1508.27(b)(7). The scope of analysis must include "connected," "cumulative," or "similar" actions *together*. 40 C.F.R. § 1508.25.

Second, there is no factual dispute that FDA's initial approval was temporary; AquaBounty's production is very different now. So FDA's *only* defense is to paint the expansion as "hypothetical" and argue that FDA could not possibly have foreseen any of what happened shortly after its approval, given it was not "certain" to happen. That future plans were not set in stone, or part of the initial production plan, does not give FDA a get-out-of-jail-free card. "Reasonable forecasting and speculation" is "implicit in NEPA." *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1246 n.9 (9th Cir. 1984). FDA mischaracterizes Plaintiffs' argument as seeking to include what is known as of 2020, ECF 244 at 18; Plaintiffs' actual argument—and what the law requires—is that FDA had to broaden its analysis based on what was "reasonably foreseeable" in 2015. 40 C.F.R. § 1508.7. The record shows FDA knew by 2010 of AquaBounty's plans to build a facility in the U.S. like the Indiana facility; it should have included analysis about this type of expansion and potential risks.[13] As early as 2013, AquaBounty made public its intentions to start expansion immediately following the initial approval.[14] In 2014, AquaBounty declared to government officials its plans to expand its PEI facility. ECF 254 at 7; F1-00175757. And the record is replete with discussions of third parties buying AquaBounty's GE salmon eggs, importing them, and growing them at other

[13] ECF 254 at 7; FDA-015389; FDA-2011CP-013–015; FDA-021163 (AquaBounty 2010 submission to FDA stating that "[o]nce [GE salmon] is approved for sale, the Company will turn its efforts to assisting the first prospective customers to secure the necessary regulatory approval for imports to their countries of AAS eggs for the purpose of commercial scale trials").

[14] FDA-031072 ("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 the margin of the product and provide access to a potentially sizable market. The Company is also reviewing the establishment of a second broodstock hatchery to reduce operating risk and increase its capacity."); FDA-021190 ("Plans to expand capacity for the production of eggs for sale are in place and will be implemented as soon as approval is granted.").

facilities.[15] This evidence is the antithesis of merely "hypothetical." These three discrete and specific types of expansion scenarios were "reasonably foreseeable future actions." FDA could and should have included and analyzed them in its EA. *See* 40 C.F.R. § 1508.7.

Third, FDA cites the correct test for improper segmentation (the "independent utility" test) but misapplies it. ECF 244 at 18; *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1215 (9th Cir. 1998). Without the initial approval, none of AquaBounty's subsequent operations have utility; all of it is predicated on first cracking the regulatory door. 40 C.F.R. § 1508.25(a)(1) ("[C]onnected actions" that should be analyzed together include those that "cannot or will not proceed unless other actions are taken previously or simultaneously" and "interdependent parts of a larger action and dependent on the larger action for their justification."). Without the initial approval, there is nothing to expand, grow out, or import.[16] FDA is looking through the wrong lens in asking only if the initial approval would have independent utility absent the related FDA/AquaBounty actions. It is enough that they are inextricably intertwined, and that the subsequent actions have no independent utility but for the initial approval. *Thomas v. Peterson*, 753 F.2d 754, 758-59 (9th Cir. 1985) (road construction and timber sales inextricably intertwined and thus connected actions requiring single EIS). In any event, there is zero record evidence that the initial approval, without more, had any independent utility either: growing GE salmon in experimental-size facilities and transporting eggs and fillets between hemispheres was not a viable business plan. F1-00047495 (FWS: "The Canada-Panama scenario seems far-fetched as a business strategy; AquaBounty may be using it as a means of gaining FDA approval in anticipation of a wider operation."). Nor was FDA merely a passive participant in piecemealing this analysis—it appears to have been the agency's idea. *Supra* at 20-21; FDA-004908.

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[15] ECF 254 at 8 (F1-00213343 and string cite therein); FDA-033445 (AquaBounty telling FDA that two U.S. customers are awaiting approval to grow GE salmon).

[16] The "larger action" FDA ignores is the actual AquaBounty production scheme, made up of the initial PEI/Panama at step one, and at least the subsequent Indiana/PEI expansion steps.

2. FDA Ignored Cumulative Impacts.

Much like the segmentation test, FDA pays lip service to the cumulative impacts definition but ignores the impact of its proposed 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." 40 C.F.R. § 1508.7. FDA admits it ended its analysis after concluding (wrongly) there was no possibility of GE fish escape, ignoring the potential cumulative impact of adding a novel organism to the marine ecosystem, *in addition to* the other past, present, and reasonably foreseeable threats to the existence of wild salmon and other marine resources. ECF 244 at 19. FDA's assertion that it did not have to consider AquaBounty's planned expansion because it need not consider any projects or plans unless they are pending before the agency is wrong on the law. *N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1078 (9th Cir.2011) ("projects need not be finalized before they are reasonably foreseeable"). And even if it did not have to consider AquaBounty's expansion, NEPA still requires agencies to consider the *past* and *present* impacts from *any* private party or agency. *Lands Council v. Powell*, 395 F.3d 1019, 1027 (9th Cir. 2005) ("NEPA requires adequate cataloguing of relevant past projects in the area."). FDA made no effort to catalogue the existing threats to wild salmon, particularly Atlantic salmon, or to then consider whether adding the risk of GE salmon escape would cause a cumulative impact. *Bark*, 2020 WL 1656447, at *8–10 (finding NEPA violation where agency merely listed other projects in EA, but failed to provide any facts or analysis, giving only conclusory statements of no cumulative impact).[17]

3. FDA Failed to Consider a Reasonable Range of Alternatives.

NEPA's primary purpose is to ensure the agency takes a hard look at its proposed action and alternatives that reduce environmental impacts, in order to inform the underlying agency action. *Ctr. for Biological Div. v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1185, 1217–19

[17] FDA makes no attempt to explain why it failed to consider intertwined cumulative impacts on those that rely on wild salmon for social, cultural, and economic reasons. *Semonite*, 916 F.3d at 1082 (cultural, aesthetic, historic and other effects constitute an important part of NEPA).

(9th Cir. 2008) (EA insufficient for failure to consider range of alternative fuel standards with lower environmental impact). FDA incorrectly argues that it need only consider alternatives that "advance the application's purpose" and lacks any authority to create any alternatives beyond what a GE animal proponent proposes. ECF 244 at 20–21. To the contrary, NEPA requires FDA to analyze a reasonable range of alternatives, even if they are beyond an agency's authority. *Nat. Res. Def. Council, Inc. v. Morton*, 458 F.2d 827, 834 (D.C. Cir. 1972) (alternatives not "limit[ed] to measures the agency or official can adopt"). While alternatives are a function of the stated goals, that purpose must not be so narrow as to foreclose all alternatives but the preferred one, and must comport with the goals of the statute. ECF 254 at 22–23, citing *Nat'l Parks & Conservation Ass'n v. BLM*, 606 F.3d 1058, 1070 (9th Cir. 2010); *Citizens Against Burlington, Inc. v. Busey,* 938 F.2d 190, 196 (D.C. Cir. 1991). FDA's interpretation of its purpose and need as merely to approve or disapprove an application without considering conditions, is far too narrow. *See* ECF 244 at 21.

While there is no minimum number of reasonable alternatives required (beyond action and no action), the Ninth Circuit has found EAs that consider a very limited range of alternatives deficient, even when an EA looks at more than two alternatives (preferred and no action). *Ctr. for Biological Div.*, 538 F.3d at 1217–19 (agency's four fuel standard alternatives were "hardly different from the option" the agency preferred); *W. Watersheds Project v. Abbey*, 719 F.3d 1035, 1053 (9th Cir. 2013) (rejecting EA consideration of three action alternatives with same level of grazing as unreasonable range). The two alternatives FDA considered in the EA (to approve or not to approve) are similarly limited. And FDA's argument that it cannot require environmental conditions under the FFDCA, and so cannot feasibly evaluate environmental alternatives, is incorrect. *See supra* at Section I. FDA cannot hide behind its *post hoc* lack of discretion argument to cover its NEPA violations. *Ctr. for Biological Div.*, 538 F.3d at 1219 (rejecting agency's contention that it lacked discretion to evaluate more stringent fuel standard alternatives).

III. FDA'S "NO EFFECT" FINDING VIOLATED THE ESA.

It is well-established that the "may affect" threshold triggering Section 7 consultation is

purposefully low. ECF 254 at 24–25. While FDA quibbles with adjectives describing this standard, it is met if the action might have "any chance of affecting" a species with "any possible effect" "even if it is later determined that the actions are 'not likely' to do so." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012); 51 Fed. Reg. 19,926, 19,949 (June 3, 1986). This hair trigger makes sense in the context of the ESA's "institutionalized caution," which mandates that agencies give listed species the "highest of priorities" and the "benefit of the doubt." *Sierra Club v. Marsh*, 816 F.2d 1376, 1383, 1386 (9th Cir. 1987) (citations omitted). The consultation process implements these mandates by ensuring that the subject-matter experts at the wildlife agencies are involved in any close calls about an action's impact on an endangered species, not the inexpert action agency. Thus, a "may affect" finding and closer scrutiny from the Services in the consultation process is required even for actions that appear "unlikely" to affect a species or even those that are beneficial. *See* ESA Consultation Handbook at xv, 3–12 (available at https://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf). And the Services may conclude informal consultation only after finding that effects are "discountable, or insignificant, or completely beneficial." *Id.* at 3–12 ("Discountable effects are those extremely unlikely to occur.").

Rather than apply this precautionary standard, FDA failed to adequately consider the potential effects on endangered salmon if GE salmon escape, instead halting its analysis with the assumption that containment measures would prevent that from happening. ECF 254 at 3–4, 27–28. FDA failed to use the best available science from scientists both in and outside the government and failed to examine the full extent of effects, including AquaBounty's plans for expansion.

Contrary to its claim of "expertise," ECF 244 at 23, 27, FDA receives no ESA deference. As an action agency, FDA has no particular expertise in endangered species' survival and recovery. Rather the statute and regulations entrust responsibility for analyzing the effects on endangered species to the subject-matter experts in the Services. *Conservation Law Found. v. Ross*, 422 F. Supp. 3d 12, 28 (D.D.C. 2019) (rejecting claim of "technical expertise" because "it is not the action

agency that is the expert as to its duties under the ESA and its regulations") (emphasis in original); *Nat'l Wildlife Fed'n v. Brownlee*, 402 F.Supp.2d 1, 11 (D.D.C. 2005) (action agency's "interpretation of the ESA and its regulations" due no deference) (internal quotations and citations removed).[18]

A. The May Affect Standard is Easily Triggered Here.

FDA's briefing merely repeats the errors in its original determination: it applies the wrong legal standard and depends entirely on the flawed assumption that AquaBounty's containment measures obviate the need to consider the harms from escape. As the case law and the Services' guidance instruct, a "no effect" finding is only appropriate where there is *no possibility* of an effect—such as where no endangered species are present.[19] FDA cannot avoid analyzing the consequences of escape simply by insisting that escape will not occur. ECF 244 at 24–26.

FDA applies the wrong legal standard. ECF 244 at 24 (arguing it is "unlikely" GE salmon could survive and reproduce if they escaped); *see also id.* (citing FDA-015226, which asserts only that it is "unlikely" that older escaped salmon could survive a transition to salt water). A finding that effects are not "likely" does not meet the bright line test triggering Section 7 consultation. ECF 255, Ex. 27 (NMFS official highlighting that use of "not likely" and other language in FWS letter is most appropriately used *after* a "may affect" finding). FDA's word choice underscores the substantive problem with its decision: its total and unjustified reliance on the containment measures to prevent any and all effects. There is a plethora of evidence—including documents FDA highlights in defense—from expert academics and agency scientists demonstrating that escaped GE salmon pose real risks to endangered wild Atlantic salmon. *See, e.g.*, ECF 254 at 4–6, 8–10, 25–27 (and citations therein); ECF 252 at 5–15. But FDA never considered what harm may result if GE salmon escape; opting instead to assume that the containment measures would prevent that from

[18] *See* ECF 255-12 at 1 (FWS scientists commenting on "the awkward situation where an agency (FDA) whose jurisdiction is not focused on natural resources is entrusted with the authority to approve an act which poses such threat to the country's natural resources").

[19] For example, in *Defenders of Wildlife v. Flowers*, 414 F.3d 1066 (9th Cir. 2005) (cited by FDA, ECF 244 at 22), the Court upheld a no effect determination where it was undisputed that there were no endangered owls (or critical habitat) in the project area. Here, the PEI facility is adjacent to marine habitat in the migratory path of Atlantic salmon. ECF 254 at 30.

happening. ECF 254 at 3–6, 12–13.

In circular fashion, FDA seeks to counter Plaintiffs' argument that it erred by relying on the success of the containment measures to avoid the need to consult by pointing to examples in the record where FDA reiterated its belief in the success of the containment measures. ECF 244 at 24–26. FDA stresses that its analysis in the VMAC briefing packet contained "risk questions [that] addressed what would happen *if the salmon escape*," *id.* at 26 (citing FDA-015225–34) (emphasis in FDA brief), but the cited discussion demonstrates that this is semantics. Though each of those *questions* was phrased in terms of escape, each of the *answers* simply assumed that the containment measures will prevent salmon from escaping rather than analyzing the consequences of escape. For example, FDA answered question 4: "What are the likely consequences to the surrounding environment . . . should AquAdvantage escape?" by stating "No significant effects or risks were identified taking into consideration the containment and confinement measures currently in place for the fish and facilities." FDA-015231. *See also* FDA-015226 (answering question 2: "What is the likelihood that AquAdvantage Salmon will survive and disperse if they escape . . . ?" by asserting that the "geographical/geophysical containment" at the PEI facility make it "unlikely" that fish would survive if they escaped). Indeed, *after* reviewing this VMAC briefing packet and draft EA, FWS biologists said that "[i]f the brood stock from the PEI facility were released . . . 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." ECF 255-12 at 4.

FWS's subsequent "concurrence" does not provide the support FDA imagines. ECF 244 at 25. First, the Services' final letters are not due any special weight. *Sierra Forest Legacy v. U.S. Forest Serv.*, 598 F. Supp. 2d 1058, 1069 (N.D. Cal. 2009) (holding Services' agreements with no effect findings are not necessarily "valid, well-reasoned, or otherwise credible evidence"). Second, FWS's letter ignored or contradicted the extensive concerns and warnings documented by its own scientists, including those in its Northeast region who detailed significant concerns about the potential impacts on endangered Maine Atlantic salmon. ECF 254 at 25 (citing ECF 255-12). *See*

also ECF 252 at 8–14 (quoting from FWS scientists' concerns in ECF 255-2, 6, 11, 12, 17, 22, 23, 30). And FWS's ultimate conclusion rested on the fiction that the action was limited to importation of fillets. ECF 254 at 28 n.14 (citing ECF 255-5, 11, 30, 32, 33). Nor is NMFS's mere acknowledgement that FDA unilaterally terminated consultation supportive of the no effect finding. ECF 244 at 25. Rather, NMFS extensively documented its concerns with the risks of GE salmon, and its legal and practical concerns with FWS's letter concurring in a no-effect finding. *See* ECF 255-16, 18, 20, 21, 27, 28, 33, 34. NMFS's ultimate acknowledgment that it lacked a formal mechanism to disagree with FDA's decision is a far cry from supporting it. ECF 255-21, 28.

FDA's attempt to distinguish *Karuk Tribe* similarly fails. ECF 244 at 26. First, although the Forest Service took no position on the issue, the "no effect/may affect" standard was squarely presented and decided by the Court because the intervenor miners vigorously—though unsuccessfully—disputed that the "may affect" threshold was met. *Karuk Tribe*, 681 F.3d at 1027–1029. Second, whether FDA here used "similar language" to the Forest Service there, ECF 244 at 26, misses the point: the extensive record of scientific findings from the expert wildlife services and others about the threats and effects to endangered Atlantic salmon. ECF 254 at 4, 8–10, 25–27; ECF 252 at 8–15. That FDA dismissed those findings is a legal flaw, not a distinguishing feature. Moreover, even FDA did not go so far as to assert that the approval had *no* possible effects, instead reiterating—based solely on the presumed efficacy of containment—that harm was *unlikely*. The consultation trigger is met when there is "any possible effect" or "any chance" of affecting a species. *Karuk Tribe*, 681 F.3d at 1027. The likelihood of that effect and the magnitude of its consequences are properly the subject of the resulting consultation.

B. FDA Failed to Use the Best Available Science.

FDA misconstrues the law and record by asserting that it used the best scientific and commercial data available. ECF 244 at 27. FDA's contention that it addressed comments from Drs. Kapuscinski and Sundstrom is false. *See supra* at 13–15. Like comments from the Services, these scientists detailed not only the agency's failure to use the best available risk assessment

procedures and data (including those outlined in Dr. Kapuscinski's 2007 book), but also reiterated the vital importance that FDA conduct a quantitative failure mode analysis to evaluate the risk of failure for the containment measures. ECF 255-12 at 5, 7 (FWS biologists explaining that they consulted with Dr. Kapuscinski and agree with her comments). As highlighted by the Declaration of Dr. Anne Kapuscinski (filed concurrently),[20] FDA's indirect (and incorrect) subsequent citation to this textbook and its unexplained refusal to perform a qualitative failure mode analysis are very different from "assessing" these critical factors. Kapuscinski Dec. ¶¶ 8–9, 16.

C. FDA's Narrow Definitions of the Action and the Action Area Violated the ESA.

FDA's reliance on the four corners of AquaBounty's application to define the scope of effects it considered ignores the expansive definitions of both the effects of the action and the "action area" FDA must analyze. First, the ESA requires agencies to consider the comprehensive effects of an action, including consequences that are "caused by the proposed action and are later in time," those that stem from activities that "are part of a larger action and depend on the larger action for their justification," and those from activities "that have no independent utility apart from the action under consideration." 50 C.F.R. § 402.02 (2015). FDA's constricted analysis ignores these expansive requirements. It also ignores reality, including that AquaBounty's piecemeal expansion plan was at least in part based on FDA's suggestion. *See supra* at 20-21 (discussing FDA-004908). *See also* ECF 255-31, 5, 7, 8, 10, 13–15. Given this evidence, FDA tellingly cannot dispute that it was aware of the company's expansion plans. Instead, it insists that those future plans were in no way dependent on the initial approval. That is exactly backward. Legally, as well as economically and practically, the company's future was dependent on securing this first approval. *See supra* at 21-22, n.13–15; ECF 254 at 29–30. Like an oil company who first needs a lease to eventually drill a well, this first application was a widely-recognized foot in the

[20] In addition to this expert declaration responding directly to FDA's opposition arguments, Plaintiffs also submit several updated standing declarations, though no party has challenged Plaintiffs' standing, *see* ECF 254 at 11 n.8

regulatory door. *Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir.1988) (holding that "[p]umping oil and not 'leasing tracts'" is the purpose of the action and agency must therefore consider not just leasing but also "post-leasing activities through production and abandonment"). The "fallacy" here lies not with any confusion about cause and effect in Plaintiffs' argument, ECF 244 at 28, but rather in pretending that AquaBounty planned to perpetually fly eggs from Canada to raise in the remote mountains of Panama and then bring salmon fillets back to North American consumers. FDA's failure to realistically evaluate the obvious scope of the action violates the ESA. *Wild Fish Conservancy v. Salazar*, 628 F.3d 513, 521 (9th Cir. 2010).[21]

Second, FDA defends limiting the "action area" for effects to just the freshwater rivers near the PEI facility because salmon would have to swim far to reach Maine rivers. ECF 244 at 29–30. Of course, this misses the point that salmon escaping from the PEI facility—in the migratory pathway of endangered Atlantic salmon—are not just a threat in freshwater; they would interact with and compete with those fish in the immediate marine environment. In addition, as NMFS highlighted in its correspondence to FDA, keeping fertile broodstock at PEI and the potential for importation of eggs in the U.S. both necessitated a wider action area, including U.S. waters. ECF 255-16, 18. FDA's inexpert application is contrary to the plain language of the expert services' regulation. 50 C.F.R. § 402.02 (action area is "not merely the immediate area" of the project). FDA cannot hide behind its cramped definitions of the action and the action area to defend its no effect determination.

CONCLUSION

For all these reasons, Plaintiffs respectfully request the Court grant their summary judgment motion, declare FDA's approval violated the FFDCA, NEPA, ESA, and APA, and vacate the approval. *See* 5 U.S.C. § 706(2); *Pollinator Stewardship Council v. U.S. E.P.A.*, 806 F.3d 520, 532 (9th Cir. 2015).

[21] As the Ninth Circuit's extensive reliance on *Connor* indicates, the prohibition on piecemealing discussed in *Wild Fish* is not, as FDA argues, limited to temporal segmentation. ECF 244 at 29.

Respectfully submitted,

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