UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

INSTITUTE FOR FISHERIES RESOURCES, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

Case No. 16-cv-01574-VC

ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT; GRANTING IN PART AND DENYING IN PART DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 244, 254

This case involves a challenge to a decision by the Food and Drug Administration to allow a company to create and farm genetically engineered salmon. As part of the approval process, the FDA assessed the likelihood that the engineered salmon would escape from captivity and adversely affect normal salmon—including salmon species that are endangered. The agency concluded that the engineered salmon were highly unlikely to escape from the two facilities where the company initially planned to raise them, and that even if the salmon found a way to escape they were unlikely to survive or establish themselves as a population in the wild.

The FDA did not, however, meaningfully analyze what might happen to normal salmon in the event the engineered salmon *did* survive and establish themselves in the wild. Even if this scenario was unlikely, the FDA was still required to assess the consequences of it coming to pass. This is especially true because the FDA knew that the company's salmon operations would likely grow, with additional facilities being used for farming. Obviously, as the company's operations grow, so too does the risk of engineered salmon escaping. Thus, it was particularly

important at the outset for the agency to conduct a complete assessment of the risks posed by the company's genetic engineering project, including an assessment of the consequences for normal salmon if the engineered salmon established themselves in the wild.

Indeed, we now know that the FDA has subsequently given the company permission to operate a third facility. In approving this facility, the agency relied heavily on the analysis it conducted for the first two facilities, even though that analysis had not meaningfully explained what might happen if the engineered salmon were to establish themselves in the wild. Before starting the country down a road that could well lead to commercial production of genetically engineered fish on a large scale, the FDA should have developed a full understanding—and provided a full explanation—of the potential environmental consequences. The agency is ordered to go back and complete the analysis.

I

In 2015, the FDA approved an application to create and farm genetically engineered salmon submitted by a company called AquaBounty. The salmon, which the company has named "AquAdvantage," can grow to full size in roughly half the time it takes for normal salmon to mature. In approving the application, the FDA authorized AquaBounty to produce eggs at a facility on Prince Edward Island in Canada and to grow the eggs into mature fish at a facility in Panama, with the understanding that the fish would be sold as food in the United States. The approval was conditioned on the adoption of several measures designed to minimize the risk that the AquAdvantage salmon would escape into the wild, where it might mix with normal salmon. Most prominently, the FDA specified that the salmon must be created and farmed in landlocked facilities; they may not be farmed in "net pens" that connect to the ocean.

After the approval, AquaBounty got its operations up and running in Canada and Panama. Since then, AquaBounty shut down the Panama facility and submitted a supplemental application to grow the salmon at a facility in Indiana. The FDA granted this application, again with conditions designed to minimize the risk that the genetically engineered fish would escape. In approving the supplemental application, the FDA relied on and incorporated the original

approval.

The plaintiffs in this case are a coalition of advocacy and industry groups concerned with the environmental implications of the decision to approve the AquAdvantage salmon. AquaBounty has intervened to defend the approval alongside the FDA and the other government defendants. At a high level, the plaintiffs contend: (i) the FDA's authority over "drugs" does not give it the power to regulate genetically engineered animals; and (ii) even if the FDA can regulate genetically engineered animals pursuant to its drug authority, the agency unlawfully abused that authority when it approved the AquAdvantage salmon.

The Court addressed the plaintiffs' broader contention regarding the FDA's authority in a prior ruling, and the current ruling assumes the reader is familiar with the prior one. But in a nutshell, the prior ruling held that although it might initially sound strange to hear that genetically engineered animals come within the FDA's authority to regulate "drugs," it turns out that the relevant statutory definition of a "drug" is much broader than its colloquial meaning, and the process of creating and farming genetically engineered animals indeed falls squarely within the agency's authority. The claims relating to the plaintiffs' broader attack on the FDA's authority were thus resolved in favor of the defendants as a matter of law. *Institute for Fisheries v. Hahn*, 424 F.Supp.3d 740 (N.D. Cal. 2019).

What remain are the claims by which the plaintiffs challenge the FDA's particular decision to approve the AquAdvantage salmon. Although these claims are numerous, and brought under different statutes, they are all based on the assertion that the FDA failed to adequately assess the risk that the salmon would escape and survive in the wild, and the consequences that would result for the environment if this risk materialized. Technically speaking, the plaintiffs have challenged only the FDA's approval of the original application relating to the facilities on Prince Edward Island and in Panama; they have not challenged the FDA's supplemental approval for the Indiana facility. Thus, because the Panama facility has been shut down, the primary focus of this case is the Prince Edward Island facility. Nonetheless, the FDA's approval of the supplemental application relating to the Indiana facility is relevant,

because that approval builds on the original one.

At this stage, eight claims remain. Six of those claims come under the National Environmental Policy Act ("NEPA"), which requires agencies to consider the potential effect of their actions on the environment, and the Administrative Procedures Act, which instructs federal courts to set aside the actions of federal agencies that fail to comply with statutory requirements. Most prominently, Claim 2 asserts that the FDA violated NEPA by failing to take a sufficiently "hard look" at the environmental consequences of its decision to approve the AquAdvantage application. That claim is closely related to Claim 6, which alleges that in considering the application the FDA was required to prepare a more thorough environmental impact statement, rather than stopping at the less-comprehensive environmental assessment. The other four NEPA claims are simply more specific arguments about the ways in which the FDA's NEPA analysis was inadequate: that it failed to consider connected, cumulative, and interdependent actions (Claim 3); failed to adequately evaluate cumulative effects (Claim 4); failed to adequately analyze alternatives (Claim 5); and improperly relied on mitigation measures (Claim 7).

As for the two non-NEPA claims, Claim 10 alleges that the FDA violated the Endangered Species Act by failing to properly consult with two other agencies, the National Marine Fisheries Service ("NMFS") and the Fish and Wildlife Service ("FWS"), before taking an action that "may affect" a listed or endangered species—in this case, the population of wild Atlantic Salmon that lives in the Gulf of Maine. Claim 12 alleges that, aside from the environmental statutes, the Food, Drug, and Cosmetic Act ("FDCA") itself requires the FDA to consider potential environmental impacts when determining whether a drug is "safe for use" within the meaning of that statute.

II

Before turning to the individual claims, it's worth discussing a conceptual issue that runs through many of them. The plaintiffs believe that the FDA should have rejected the new drug application based on environmental concerns. But the parties have a fundamental dispute about

the extent to which the FDA even has the authority (much less the obligation) to act on those concerns. This dispute is primarily about the scope of the FDCA, which is the statute that authorizes the FDA to exercise regulatory authority over drugs. But it's also about the interplay between that statute and NEPA.

The FDCA instructs the Secretary of Health and Human Services (whose umbrella of authority includes the FDA) to approve a new animal drug application if the drug is "safe for use." 21 U.S.C. § 360b. The statute gives the word "safe" some context by stating that it "has reference to the health of man or animal." 21 U.S.C. § 321(u). When the Secretary makes a safety determination, the FDCA requires him to consider:

> among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice.

21 U.S.C. § 360b(d)(2). This language suggests that the safety determination focuses singularly on the health of humans and animals, perhaps with a particular focus on those who will, by design, come directly into contact with the drug.

For its part, NEPA requires federal agencies undertaking any major action to first consider the impact that action will have on the environment. The statute serves two related purposes. First, it promotes public awareness of the environmental impacts of the actions being contemplated by agencies. Second—and more importantly—it forces the agencies themselves to consider the environmental impact of their actions, giving the agencies an opportunity to change course upon discovering that the impact would be significant. *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).

In this litigation, the FDA has taken the narrow position that its decision whether to approve a new animal drug application must be guided by the terms of the FDCA alone. The

agency further contends that the FDCA restricts the agency to considering the health and safety of the animal to whom the drug is being administered, the person administering the drug, and any people who might eat the animal for food. Thus, the FDA insists that although it must follow NEPA's procedural requirements for evaluating and publishing environmental risks, it must ignore the results of that evaluation while deciding whether the new animal drug is safe (and thus deciding whether to approve the application).

Even by the terms of the FDCA alone, that position is wrong. Although section 360b(d)(2) mentions factors related to the humans and animals who come into direct contact with the drug, it also requires the Secretary to consider "other relevant factors." At a minimum, the broad definition of safety given by the statute—that is, having "reference to the health of man or animal"—means that a threat to the health of *any* human or animal would be properly within the scope of the Secretary's evaluation. *Cf. Natural Resources Defense Council, Inc. v. United States Food and Drug Administration*, 760 F.3d. 151 (2d Cir. 2014) (apparently accepting without deciding that the risk posed by antibiotic-resistant bacteria to people other than those who administer antibiotics to pigs could be relevant to animal drug safety). That interpretation also squares well with the FDA's statutory purpose of "protect[ing] the public health by ensuring that" drugs "are safe and effective." 21 U.S.C. § 393(b)(2)(B). So even if the FDA is correct that environmental considerations writ large were not relevant to its decision, the agency is always required to consider the subset of environmental impacts that directly involve the health of animals or humans.

To say otherwise would seem to create absurd possibilities. Suppose, for example, that a company submitted an application for a drug that would treat a disease in livestock, but the process for manufacturing that drug would invariably contaminate the water supply near the factory in a way that would kill people in the surrounding community. Surely the FDA could deny that application to avoid killing people, even if those people are not directly administering

the drug or eating the livestock.[1]

Once NEPA enters the discussion, the FDA's narrow view of its authority becomes even less defensible. As previously noted, NEPA is largely designed to ensure that agencies take environmental concerns into account when deciding whether to take a particular action. If the FDA were precluded from acting on the concerns that NEPA requires it to consider, the purpose of the statute would be largely undermined. "When confronted with two Acts of Congress allegedly touching on the same topic," courts must "strive to give effect to both." *Epic Systems Corp. v. Lewis*, 138 S. Ct. 1612, 1624 (2018) (quoting *Morton v. Mancari*, 417 U.S. 535, 551 (1974)). Thus, to the extent that the FDCA itself is unclear on whether the FDA may impose conditions or deny a permit application based on environmental concerns, the presence of NEPA counsels in favor of a broader understanding of the agency's authority. *See Natural Resources Defense Council, Inc. v. United States Environmental Protection Agency*, 859 F.2d 156, 170 (D.C. Cir. 1988) (explaining that EPA may impose "NEPA-inspired" conditions on permits for discharge of pollutants under the Clean Water Act). Perhaps it would be different if the FDCA explicitly precluded the agency from considering environmental concerns (even environmental concerns that directly affect the health of humans and animals), but the statute does no such thing.[2]

In sum, the FDA was required to consider—and had the authority to act upon—concerns

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[1] The narrow interpretation of its own authority that the FDA has taken in this litigation does not appear to match up with the agency's prior statements and actions. For example, in its Guidance for Industry on Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs, the agency stated that "environmental risks are among the factors we intend to consider in determining whether to exercise enforcement discretion." Guidance for Industry 187. And indeed, the FDA conducted an Environmental Safety Review of AquaBounty salmon in accordance with that Guidance. *See* Dkt. No. 269 at 111–39. Nor has the FDA pointed to any other instance in which it has taken the position (much less acted on the position) that it is not permitted to make decisions or take actions based on environmental concerns created by the drugs it considers for approval. The agency's position is thus not entitled to *Chevron*-style deference. *United States v. Mead Corporation*, 533 U.S. 218, 229–31 (2001).

[2] Indeed, the presence of NEPA suggests that perhaps the FDA may take account of environmental effects writ large, rather than merely effects that directly impact humans and animals, when deciding whether to approve a drug. But that question is not presented here, because the only environmental effects at issue in the case relate to the effect of the AquAdvantage salmon on normal salmon.

regarding the effect of the AquAdvantage salmon on normal salmon. The remaining sections discuss whether the agency complied with its legal obligations in this regard.

III

In Claims 2 and 6, the plaintiffs assert that the FDA violated NEPA by concluding that approval of the new drug application would not have a significant impact on the environment—specifically, on wild salmon. The plaintiffs contend that AquaBounty's operations on Prince Edward Island will likely have a significant impact on wild salmon, and that the agency was therefore required under the statute to prepare an environmental impact statement before deciding whether to approve the application.

NEPA requires the FDA and other federal agencies to prepare a detailed environmental impact statement for any major action "significantly affecting the quality of the human environment." 42 U.S.C. § 4332(2)(C). As a preliminary step, an agency may choose to prepare a more concise "environmental assessment" that simply analyzes whether the proposed project would have a "significant" environmental impact, and thus whether the agency must prepare a full-blown environmental impact statement or may instead issue a "finding of no significant impact." *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998); 40 § C.F.R. 1508.9.

The conclusion the agency reaches in the environmental assessment (that is, whether to prepare an environmental impact statement or issue a finding of no significant impact) is subject to judicial review under the Administrative Procedures Act. The decision may be reversed only if it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Under this rule, a court reverses the determination if the agency has failed to take a sufficiently "hard look" at the question. *Blue Mountains*, 161 F.3d at 1211. An agency's decision not to prepare an environmental impact statement is considered arbitrary and capricious if the agency "fails to supply a convincing statement of reasons why potential effects are insignificant." *Id*. (quoting *Save the Yaak Committee v. Block*, 840 F.2d 714, 717 (9th

Cir. 1988)). Plaintiffs challenging the agency's decision will succeed in their claim if "substantial questions are raised" as to whether the proposed project will have significant environmental impacts. *Blue Mountains*, 161 F.3d at 1212 (quoting *Idaho Sporting Congress v. Thomas*, 137 F.3d 1146, 1149 (9th Cir. 1998)).

Here, the FDA did not adequately explain in its environmental assessment why the potential impacts of the production and growth of engineered salmon will be insignificant. The central problem is that the document failed to conduct the very inquiry it stated was necessary. In the section describing the "approach to assessment," the environmental assessment stated that an analysis of environmental risk would need to consider two probabilities: the probability of "exposure," or a bad event, and the probability of harm that could occur given exposure. Environmental Assessment § 3.1. The document thoroughly analyzed the probability of exposure, concluding that it was low. But it failed to assess and explain the potential consequences of that low probability being realized.

For the engineered salmon project, there are several steps in the chain of an "exposure." First, the engineered salmon may escape from their physical confinement. Second, they may survive in the wild. Third, they may directly interact with wild salmon, such as by mating or simply by competing for resources. Fourth, the engineered salmon may "establish," meaning that they could breed and produce a stable population that persists outside of captivity indefinitely. The "probability of exposure" therefore considers the likelihood that all these steps may occur. The FDA did a careful job on this step of the equation. It marshalled a great deal of evidence to show that the probability of engineered salmon escaping, surviving, and establishing a population is quite low. *See* Environmental Assessment § 7.5. And in the course of assessing the probability of exposure, the FDA did evaluate the risk of harm resulting from each of those intermediate steps in the exposure chain. Effectively, the agency found that the harm given escape is low because the engineered salmon are unlikely to survive long enough to do any damage; the harm given survival is low because the engineered salmon are unlikely to interact with wild salmon; and even the harm given interaction is low because the engineered salmon are

not likely to establish a population.

But the analysis contained in the environmental assessment essentially stopped without assessing the possibility of harm to the natural salmon species in the unlikely event of genetically engineered salmon establishing themselves in the wild. That means that the second variable in the FDA's own risk equation, the likelihood of harm given exposure, remains unknown. Because the FDA did not fully carry out the risk analysis it prescribed for itself, the finding that approving the production and growth of these salmon will have no significant impact falls short of being a "convincing statement." *Blue Mountains*, 161 F.3d at 1211.[3]

Up to this point, a reader could not be blamed for wondering if the plaintiffs are winning their NEPA claim on little more than a technicality. If the agency did a careful job of analyzing and explaining why there is a very low risk of escape, survival, and establishment in the wild, why should it be required to go back and analyze the potential consequences of these remote risks being realized? Part of the answer is simply what the FDA itself acknowledged in the environmental assessment: a proper hazard assessment requires the equation to be completed in this fashion. But a more compelling answer lies in the NEPA regulations. In particular, agencies must evaluate the "context" and "intensity" of a proposed action by considering ten "intensity factors." 40 C.F. R. § 1508.27(b). The sixth factor, which requires the agency to consider the "degree to which the action…represents a decision in principle about a future consideration," helps show why the requirement to assess the consequences of establishment in the wild is not a mere technicality. 40 C.F.R. § 1508.27(b)(6).

The new animal drug application clearly contemplated that the engineered salmon eggs produced at the Prince Edward Island facility would be transported elsewhere to be "grown out"

[3] One scientist opined that "selection over time would be expected to simply purge the transgene from any established population, suggesting a low probability of harm resulting from exposure to AquAdvantage salmon." Environmental Assessment § 7.5.1.1 (quoting Dr. William Muir). But even if such a purge did occur, what of the impacts on wild salmon from the added competition of a new population of fish? And how would the gene be "purged" if not by interbreeding with wild salmon? The environmental assessment does not even raise these questions, let alone address them.

into fish. That implies at least a significant possibility that future applications would seek approval to build additional grow-out facilities at other locations. With every new facility built, the possibility of exposure grows. Understanding the harm that could result from that exposure—and having an explanation of it on record—will only become more important. And if that issue is not properly assessed at the outset, it may never be. The Indiana facility, for example, was approved with a "supplemental" environmental assessment based on the one created for the Prince Edward Island and Panama facilities' application. Although the adequacy of that supplemental assessment is not at issue in this litigation, the fact of its reliance on the initial assessment demonstrates the importance of ensuring that the FDA analyzed the risk thoroughly at the outset.

To be sure, the FDA is correct that it was not required to formally consider future projects that had not yet been submitted for approval. But this does not mean it would be appropriate to conduct its analysis of the proposed action without taking account of the obvious likelihood that future actions would build on it. It is not enough for the FDA to declare with respect to this initial project that the risk of exposure is so small as to justify forgoing analysis of the risk of harm given exposure. The NEPA regulations underscore that point by making possible future developments relevant to an evaluation of the environmental significance of any agency's actions.

Accordingly, on remand the FDA must complete the final step of its own risk analysis by addressing the consequences that would result from the engineered salmon successfully establishing a persistent population outside of captivity. The results of that revised analysis may show that an environmental impact statement is required, but they may also show that a finding of no significant impact is appropriate.[4]

[4] The remainder of plaintiffs' NEPA claims—Claims 3, 4, 5, and 7—are easily adjudicated in favor of the defendants. The plaintiffs have not demonstrated that there were any connected, cumulative, or interdependent actions before the FDA for consideration at the time of this environmental assessment, nor that there were cumulative impacts from prior agency actions that needed to be considered. *Compare Blue Mountains*, 161 F.3d at 1214–15 (agency was required to consider the cumulative impacts of five potential projects in the same watershed). Nor was the

IV

Section 7 of the Endangered Species Act ("ESA") instructs agencies to determine whether a proposed action "may affect listed species or critical habitat." 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14. If so, the agency is required to consult with the National Marine Fisheries Service ("NMFS") and the Fish and Wildlife Service ("FWS") before proceeding. In a strange sequence of events: NMFS and FWS initially urged the FDA to undergo a Section 7 consultation regarding the AquaBounty operations; the FDA took the view that the production of the AquAdvantage salmon "may affect" endangered salmon, thus triggering the consultation requirement; then FWS prodded FDA to change its "may affect" determination to a "no effect" determination, the result being that formal consultation among the agencies would not be required; and thereafter the FDA issued a formal statement that approval of the engineered salmon would have no effect on the endangered species. *See Institute for Fisheries Resources v. Burwell*, No. 16-cv-01574-VC, 2016 WL 4529517, at *1 (N.D. Cal. Aug. 30, 2016). In Claim 10, the plaintiffs contend the FDA violated the ESA by failing to consult with the expert agencies, rendering the approval of AquaBounty's application arbitrary and capricious within the meaning of the APA.

It is instructive to compare the requirements under the ESA to those under NEPA. Whereas NEPA asks the agency to identify and prepare an environmental impact report for "significant" impacts on any aspect of the environment, the ESA requirements are triggered by a lower threshold, but for a narrower set of impacts. The agency must identify *any* potential effect, however small, on listed species and consult with the relevant agencies about the proposed action. *See Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006, 1027 (9th Cir.

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environmental assessment deficient in the number of alternatives it analyzed (although to the extent that its risk assessment of the proposed action was insufficient, so too was the application of that assessment to the no action alternative). *Earth Island Institute v. U.S. Forest Service*, 697 F.3d 1010, 1022 (9th Cir. 2012) (noting that NEPA's "statutory and regulatory requirements do not dictate the minimum number of alternatives that an agency must consider") (internal citations and quotations omitted). Arguments that the FDA improperly relied on mitigation strategies also fall short, because the agency did nothing but rely on the enforceable conditions of approval embedded in the application.

2012).

In this case, the NEPA and ESA review processes shared a single focus. The NEPA evaluation addressed the potential impacts of engineered salmon on wild salmon; the ESA analysis was also concerned with wild salmon, albeit more specifically the endangered Gulf of Maine Atlantic salmon. Because the FDA did not sufficiently examine whether the engineered salmon would significantly impact wild salmon under NEPA, it follows that the agency cannot defend its conclusion that the engineered salmon would have no effect at all on Gulf of Maine salmon. Indeed, the fact that the FDA apparently reached a conclusive determination that the AquaBounty salmon would have "no effect" on the Gulf of Maine Salmon in 2010, while the environmental assessment was still under active consideration and five years before the NEPA process was completed, suggests that the agency may have failed to grasp the practical relationship between the two statutes' requirements in this case. Accordingly, the plaintiffs prevail on this claim as well. On remand, the FDA must reconsider its "no effect" determination under the ESA together with its revised NEPA evaluation. Or perhaps, as it apparently tried to do early on, it 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.

V

In Claim 12, the plaintiffs contend that the FDA violated its own authorizing statute—the FDCA—when it approved AquaBounty's application. According to the plaintiffs, flaws in the agency's analysis of potential environmental harms amount not only to a violation of NEPA and the ESA, but also the FDCA, meaning that the approval was arbitrary and capricious within the meaning of the APA for that reason as well.

As already discussed in Section II, the language of the FDCA is, at a minimum, broad enough to require the FDA to consider impacts on the health of any human or animal when

reviewing safety. The agency may 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. Thus, to the extent that the FDA responds to this claim by arguing it would not be allowed to consider impacts on wild salmon as part of its "safety" analysis even if it wanted to, that argument is wrong.

But ironically, it does not follow that the FDA loses on this claim, because the FDA did take measures that prevent the genetically engineered salmon from mixing with wild salmon. Even under its narrow understanding of its authority to consider safety, the FDA agrees that it can and must consider the fate of the genetically engineered salmon over which it is exercising regulatory authority. As the agency points out, the FDCA prohibits approval of any new animal drug if "the facilities and controls used for…manufactur[ing]…such drug are inadequate to preserve its identity, strength, quality, and purity." 21 U.S.C § 360b(d)(1)(C). When the drug in question is an rDNA construct that exists in an animal, the primary threat to purity is that the animal might escape from the conditions in which it is supposed to grow, and potentially interbreed with non-engineered animals, causing the rDNA construct to exist in uncontrolled conditions.

Thus, under the agency's own view of its authority, its imposition of conditions to prevent escape by genetically engineered salmon is justified by the need to protect those genetically engineered salmon from normal salmon. However strange it may sound to care about protecting genetically engineered salmon from normal salmon rather than the other way around, the upshot for purposes of this claim is that the FDA exercised authority, pursuant to the FDCA, to protect against escape by the genetically engineered salmon, which by definition protects the normal salmon. Indeed, the agency imposed conditions (like barring the use of ocean net pens), singularly focused on preventing escape. *See* Environmental Assessment Summary.[5]

[5] This finding is not inconsistent with the conclusion that the FDA's analysis was insufficient to satisfy NEPA. As explained in Section III, the environmental assessment failed to meet the

Because minimizing the risk of escape was an essential part of AquaBounty's application and the FDA's approval of that application, the agency's safety determination was not arbitrary and capricious even though it was not focusing specifically on the environmental impact of escape. As a practical matter, it's difficult to imagine how a particular focus on the broader environment during the safety evaluation would have changed the agency's analysis of whether the proposed containment measures were sufficient.

VI

Although the action is remanded for the FDA to reconsider its environmental assessment to comply with NEPA and the ESA, this is the rare case in which the agency action should not be vacated in the meantime. *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015). Vacatur of an agency action is an equitable remedy that courts can refrain from imposing when the disruptive consequences of vacatur would outweigh the seriousness of the agency's errors. *National Family Farm Coalition v. EPA*, 966 F.3d 893, 929 (9th Cir. 2020) (citing *California Communities Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012)).[6] As discussed above, the FDA's error in failing to completely analyze the risks to wild salmon in the event that engineered salmon escape and establish a population base is important in light of the significant possibility that more engineered salmon will be produced and farmed at additional facilities in the future. But because the FDA took the risk of escape seriously and imposed conditions designed to prevent escape, the short-term threat to the environment from engineered salmon at the Prince Edward Island facility (and, for that matter, the Indiana facility) is low. And to the extent other facilities are being contemplated, the FDA can conduct the analysis required

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NEPA standard because the FDA laid out a guiding principal for that analysis and then failed to carry it through—a failure that could hinder proper consideration of future actions in addition to the present one. But that failure is specific to the requirements of NEPA, and so does not necessarily imply that the safety analysis under the FDCA was also insufficient.

[6] Although *National Family Farm* did not recite the rule that remand without vacatur should be rare, it also did not repudiate that rule. Courts in the Ninth Circuit should therefore still begin with a presumption against remand without vacatur.

by this ruling before deciding whether to approve those operations. On the flip side, revoking the approval would presumably require the current stock of salmon to be destroyed, a significant loss of property and animal life that would be wasteful given the real possibility that the FDA will be able to cure the NEPA and ESA errors on remand.

VII

For the reasons stated above, the plaintiffs' motion for summary judgment is granted as to Claims 2 and 6, because the FDA did not adequately assess the risk of harm given establishment before making a finding of no significant impact. Plaintiffs' motion for summary judgment as to Claim 10 is also granted, because the agency failed to sufficiently consider whether AquAdvantage salmon may effect endangered wild salmon before deciding not to consult with NMFS and NWS as required by the ESA. The government's cross-motion for summary judgement is granted as to all other pending claims. The case is remanded to the FDA without vacatur for reconsideration of the environmental assessment under NEPA and the ESA analysis in compliance with this ruling.

IT IS SO ORDERED.

Dated: November 5, 2020

VINCE CHHABRIA
United States District Judge